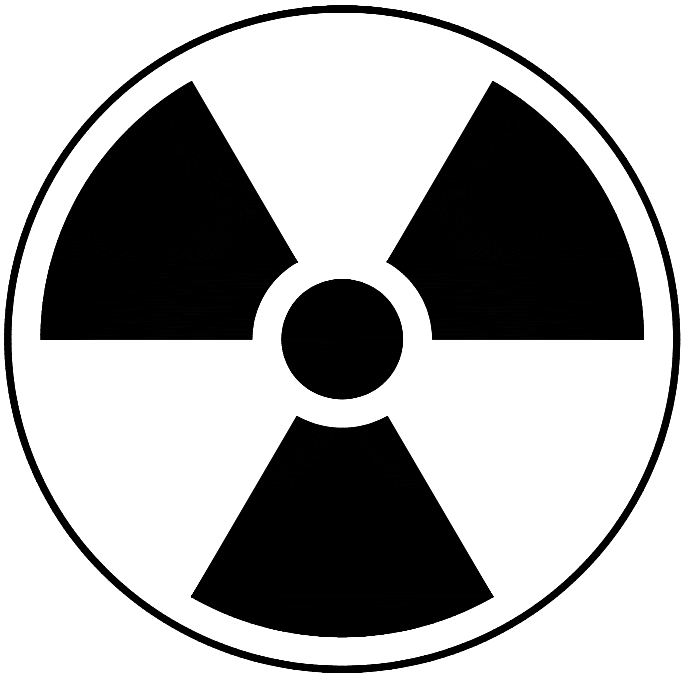
Basic Radiation
Safety Manual

Specific License



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Specific License:

Description

The United States Nuclear Regulatory Commission (US NRC) regulates most radioactive materials used in radiation gauging devices. Certain states have been authorized to act on behalf of the NRC and regulate the use of radioactive materials within their state lines. These states are said to have entered into an "agreement" with the NRC and are often referred to as Agreement States.

The NRC or any Agreement State can issue a license specific to an individual site or organization. The site or organization which receives such a license is authorized to possess and use certain types of radioactive materials. The license will specify the activities that can be performed using the radioactive materials. This license will also designate a Radiation Safety Officer (RSO) and charge this person with a variety of responsibilities whose ultimate goal is the safe handling and operation of the nuclear device.

The NRC or any Agreement State will periodically inspect the records and facilities of the licensee in order to ensure compliance with the provisions of the license.

RSO Responsibilities

Each specific licensee should carefully read their particular license to determine the exact conditions and responsibilities itemized in the license. Summarized below are some of the major requirements that are often included in a site-specific license:

- The RSO's most significant responsibilities are worker protection and record keeping.
- The RSO is responsible for the source at all times, and must make arrangements for its safe handling, storage, location, use, and disposal.
- Periodic leak testing of the device to ensure containment may be required. Ronan provides a leak testing service to assist the RSO with meeting this requirement.
- Periodic Testing of the source holder's On/Off Mechanism (if equipped) is also required.
- Loss, theft, transfer, or suspected damage to the source containment or shielding must be reported to the NRC or an Agreement State and other appropriate authorities.

Personnel Safety

Many personnel safety issues can be addressed by one basic principle – limit access to the source of radiation and thereby reduce personnel exposure levels. The primary goal is to maintain exposure levels "As Low As Reasonably Achievable" (ALARA). Four methods for achieving this goal are:

1. Limit the time spent near the source.
2. Increase the distance from the source.
3. Maintain shielding around the source.
4. Use the minimum source size that will meet the application requirements.

Regulations

The most significant and applicable regulations concerning the use of radioactive materials for industrial gauging are found in Parts 19, 20, and 30 of Title 10 of the Code of Federal Regulations (10 CFR). The licensee shall maintain a current copy of 10 CFR and/or the Agreement State equivalent.

Some of the most important and pertinent aspects of these regulations are summarized below for your reference. The 10 CFR paragraph number is shown in parentheses after each reference.

Note to licensees in Agreement States: equivalent requirements and obligations are documented in your state regulations.

Each licensee shall post the following documents, or a notice describing the documents and where they may be examined:

1. Regulations in 10 CFR Parts 19 and 20, or Agreement State Equivalent.
2. The license, license conditions or documents incorporated into the license by reference and amendments.
3. Operating procedures applicable to licensed activities (19.11).

Each licensee shall post the following documents:

1. Any notice of violation involving radiological working conditions, proposed penalties, or orders and any response from the license.
2. Current NRC Form 3 “Notice to Employees” or Agreement State equivalent (19.11).

Each licensee shall afford to the commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records (19.14; 30.52)

Each licensee shall develop, document, and implement a radiation protection program. The program shall use procedures and controls to achieve occupational doses and doses to members of the public that are As Low As Reasonably Achievable (ALARA). The radiation protection program shall be periodically reviewed (20.1101).

The licensee shall control the occupational dose to individual adults to the dose limits specified in 10 CFR 20.1201, 20.1207, 20.1208, and 20.1301.

The licensee shall make, or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the general public (20.1302).

Each licensee shall make, or cause to be made, surveys that may be necessary to comply with the regulations in 10 CFR Part 20 and are reasonable under the circumstances to evaluate:

1. The extent of radiation levels.
2. Concentrations or quantities of radioactive materials.
3. Potential radiological hazards that could be present.

Instruments used to make these measurements shall be periodically calibrated (20.1501).

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas (20.1801).

The licensee shall control and maintain constant surveillance of licensed materials that are in a controlled or unrestricted area and that are not in storage (20.1802).

The licensee shall ensure that each container of licensed material has been labeled with the radiation symbol and the words “Caution” or “Danger” and “Radioactive Material”. The label must state the type and quantity of radioactive material and assay date (20.1904).

Each licensee shall maintain records of the radiation protection program, including: the provisions of the program, audits and reviews of the programs content and implementation (20.2102).

Each licensee shall maintain records showing the results of surveys, calculations, and calibrations (20.2103).

Each licensee shall maintain records of the disposal of licensed materials made under 10 CFR 20.2002, 20.2003, 20.2004, 20.2005, 10 CFR Part 61, and disposal by burial in soil (20.2108).

Each person who receives byproduct material pursuant to a license issued under the regulations in 10 CFR Parts 30 through 36 shall keep records showing the receipt, transfer, and disposal of the byproduct material (30.51).

Each record required must be legible throughout the specified retention period. The licensee shall maintain adequate safe guards against tampering with and loss of records (20.2110).

Except for persons exempt as provided in 10 CFR Parts 30 and 150, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct materials except as authorized in a specific or general license issued pursuant to the regulations in 10 CFR Part 30 (30.3).

Radiation Safety Basics

There are three basic principles that, if followed, will limit personnel exposure to radiation and ensure safe use of the gage. These three principles are as follows:

Time:

There is a direct relationship between the amount of time spent in a given field of ionizing radiation and the absorbed dose that an individual receives.

Example:

If an individual spends one hour in a gamma field of 1 mR/hr, then they will receive a biological dose of approximately 1 mRem.

If this same individual spends two hours in the same field, he will receive a biological dose of approximately 2 mRem.

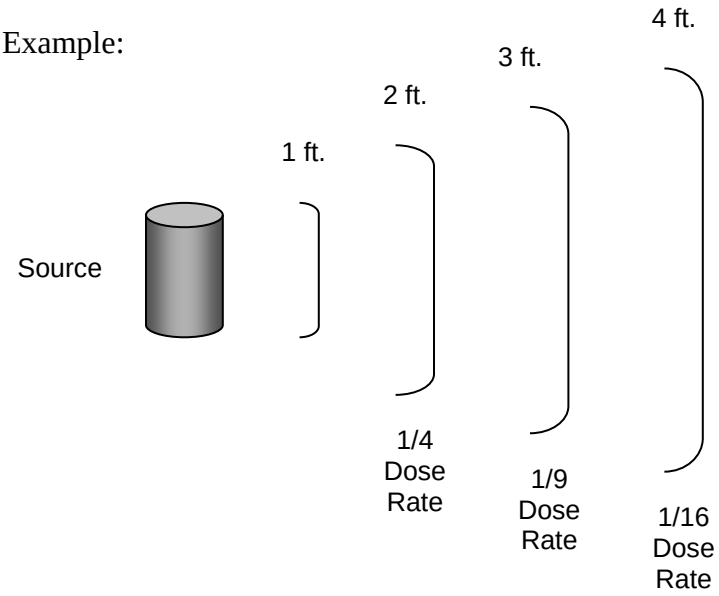
Objective:

Spend as little time in close contact with the device as possible.

Distance:

The radiation field produced by a source drops off by the inverse square of the distance from the source.

Example:



A field of 5 mR/hr will be reduced to 0.3125 mR/hr at 4 feet.

Objective:

Maintain safe distance from radioactive source.

Shielding:

Protective material can be used to reduce the radiation field in the areas surrounding a source. Half-Value Layers of materials will reduce the radiation field by half for each layer of material added.

Example:

Material	*Half-Value Thickness (broad beam)*	
	Cs-137	*Co-60*
Lead	0.25 inch	0.45 inch
Steel	0.75 inch	4 inches
Concrete	3.0 inches	1.0 inch

A field of 10 mR/hr, generated by a Cs-137 source, can be reduced to <2 mr/hr with the use of 0.75 inches of lead, per the following:

10 mR/hr / 5 mR/hr / 2.5 mR/hr / 1.25 mR/hr

Three half-value layers will reduce the field to 1.25 mR/hr. 0.25 inches of lead represents one-half-value layer, therefore 0.75 inches will reduce the field to less than 2 mR/hr.

Objective:

Ronan source holders are equipped with shielding which will reduce the fields surrounding the device to safe levels. Care should be taken to make sure that the shielding remains intact.

Dose Rates

Definitions:

RAD: (Radiation Absorbed Dose) Amount of energy imparted to matter; dose absorbed by any matter over a specified period of exposure time.

REM: (Roentgen Equivalent Man) The measure of radiation absorbed by the body; it takes into consideration the effects of an absorbed dose on human tissue; biological dose.

Calculating the intensity of the radiation field:

Formula:

$$R = \frac{k \times S}{d^2} \times 1000$$

Where:

R = Dose rate
k = Constant of radioisotope
0.5 for Cs-137
2.0 for Co-60
0.023 for Am-241
S = Source size (in mCi)
d = Distance (in inches)

To convert millirads to millirems you must multiply the absorbed dose by the quality factor (Q). The quality factor is the modifying factor used to derive dose equivalent from absorbed dose. This multiplier is required due to the fact that not all types of radiation affect the body in the same manner.

Q for gamma and beta radiation = 1

Therefore with gamma radiation:

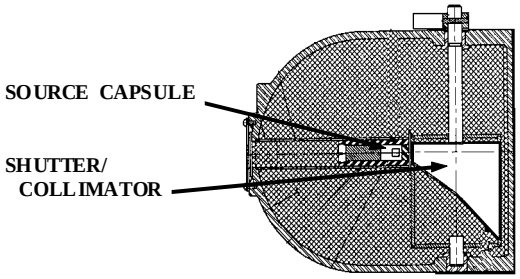
1 millirad x 1 = 1 millirem

Source holders

Ronan offers a number of different source holders designed to meet a wide variety of application needs. These can be roughly divided into *Point Source Holders, Strip or Insertion Source Holders,* and *Low Level Source Holders.* In section 2 of the manual you will find drawings that illustrate some of the most common configurations for nuclear gages using these devices. Below you will find a basic description of each device:

Point Source Holder:

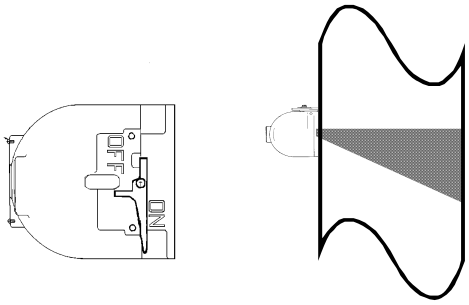
The point source holder is mounted to the external surface of the process vessel. A small slot in the lead shielding of the source holder focuses an active radiation beam through a collimated opening, into the process vessel, and toward the detector which is mounted on the opposite side of the vessel.



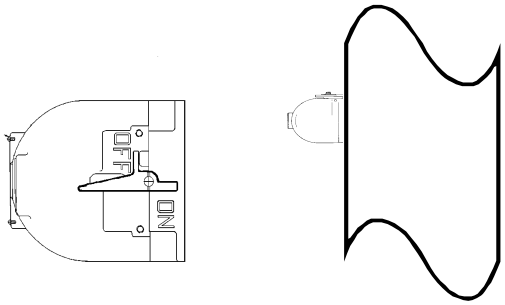
When the shutter handle is rotated to the OFF, or closed position, the shutter rotates in place to cover the small opening and shield the radiation beam. When the shutter mechanism is rotated to the ON, or open position, the collimated opening lines up with the slot in the lead shielding and a radiation beam is emitted.

When in the OFF position, the shutter handle should be padlocked to prevent unauthorized operation of the shutter.

ON

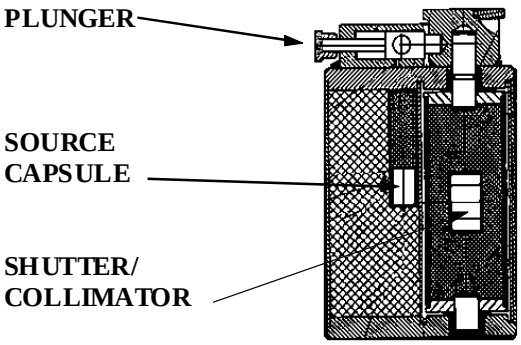


OFF



Strip Source Holders*:*

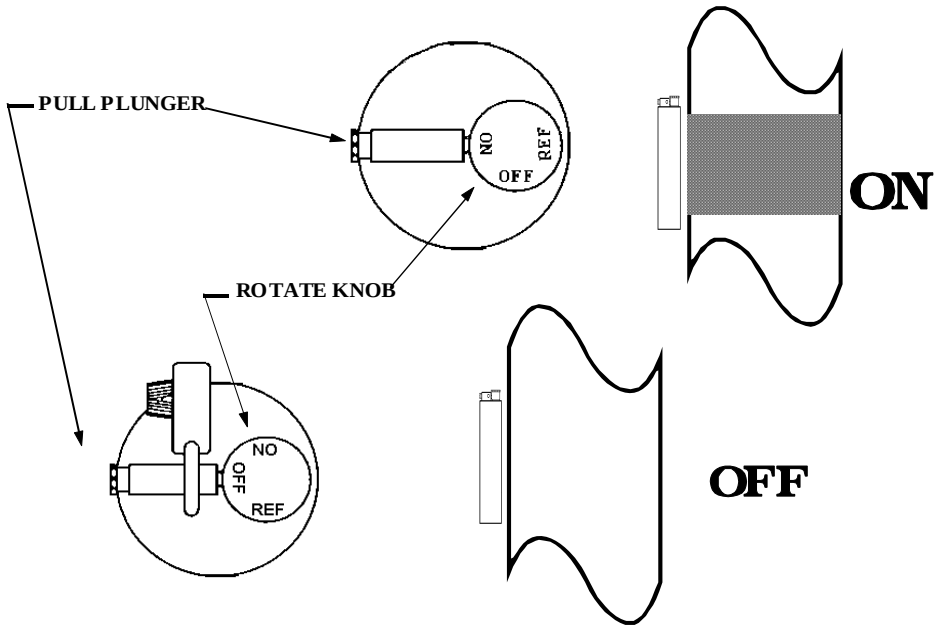
The elongated source is mounted to the external surface of the process vessel. A small slot in the lead shielding of the source holder focuses an active radiation beam through a collimated opening, into the process vessel, and toward the detector which is mounted on the opposite side of the vessel.



The source holder is equipped with a knob or handle that attaches to the internal rotary shutter. Rotating this knob will rotate the internal shutter and either activate or shut off the radiation beam.

When the source holder is equipped with a knob, a spring-tensioned plunger is used to hold the knob in place and prevent the shutter from wandering.

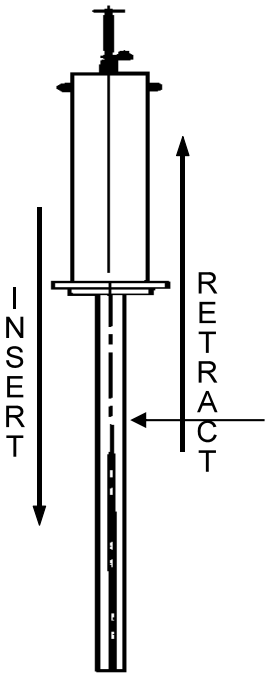
To operate the shutter knob, simply pull back the spring-tensioned plunger. This will free the knob and it should rotate easily. When in the OFF position, the plunger should be padlocked to prevent unauthorized operation of the shutter.



Insertion Source Holder:

An internal, well-type source holder is available when vessel geometry or process conditions require its use.

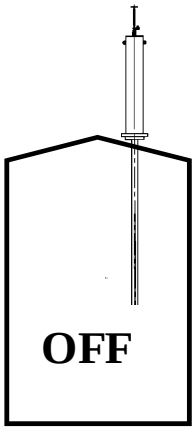
The well-type source holder is mounted so that the source can be inserted into a well or dip tube inside the process vessel. The source holder is used as shielded container for storage, handling, or shipment.

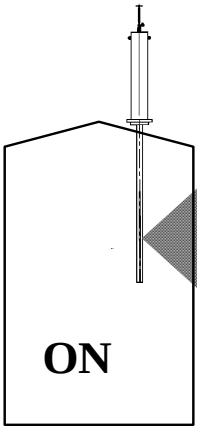


Source Capsule

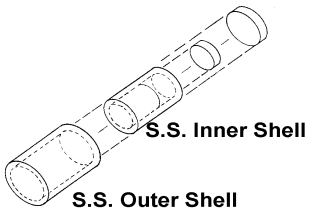
The ON/OFF mechanism, for this type of device, involves the insertion or retraction of the source into or out of the well or dip tube.

When the source is retracted into it housing (source holder), the rod can be padlocked to prevent accidental removal / extension of the source.





Source Capsule



A radioactive cesium (Cs-137) or cobalt (Co-60) source is sized to fit the needs of each application. The source material is doubly encapsulated inside a welded stainless steel cylinder and then installed in a shielded source holder.

These capsules have time-tested, high structural integrity and prevent direct exposure to the radioactive material and the spread of loose contaminant. In most cases the source holders are periodically wipe tested to verify that the capsule containment remains intact.

Cesium and cobalt sources emit gamma radiation. Gamma radiation is a high energy, electromagnetic wave or photon of energy. This type of radiation offers a number of advantages over other types of ionizing radiation:

1. Gamma radiation emitted from Cesium-137 and Cobalt-60 sources will not make the customer's process or equipment radioactive.

2. Generally, the relatively low energies emitted by cesium and cobalt sources will not change or effect materials exposed to the radiation.

3. Cesium and cobalt encapsulated sources have a high structural integrity which virtually eliminates the possibility of radioactive contamination.

Unpacking

All equipment manufactured at Ronan is carefully packaged to prevent damage during shipment. Unpack the equipment in a clean, dry area.

Examine the contents and compare them to the packing list. Immediately report any discrepancy or damage to your company's radiation safety officer (RSO), Ronan Engineering, and the carrier.

Storage

If it is necessary to store this equipment before mounting, the RSO will should assign an appropriate location. This should be somewhere that is secure from unauthorized entry and away from high traffic areas.

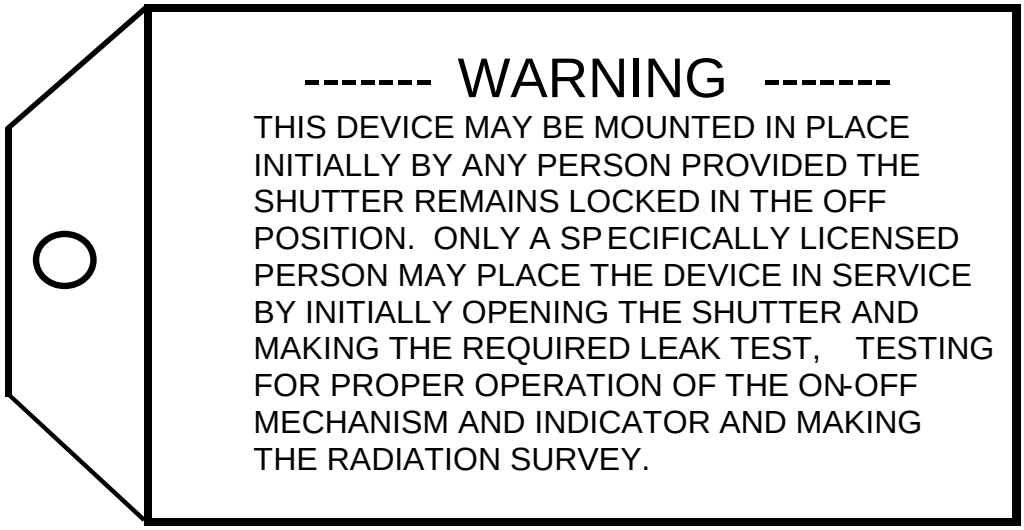
It is not necessary to post a storage area where Ronan equipment is being held as long as the field 30 cm from the surface of the source holder(s), or any surface the radiation penetrates, does not exceed 5mR/hr.

During storage avoid temperatures below freezing and areas with excessive humidity, moisture, or dirt.

Note: It is acceptable to store the source holder on its mounts, provided the device remains padlocked in the OFF or closed position.

Lock Tag

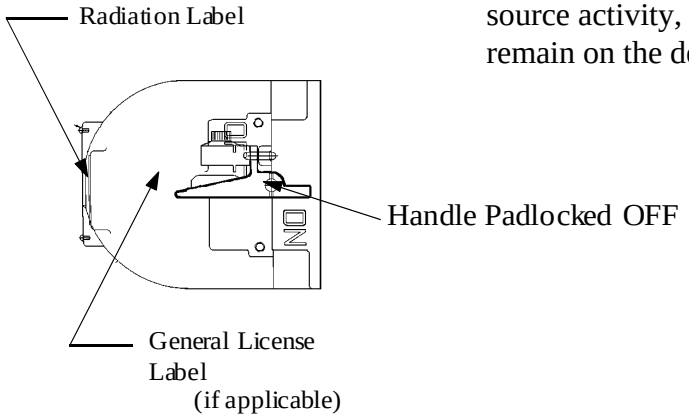
Each Ronan source holder will have a plastic tag wired to it. The tag reads as follows:

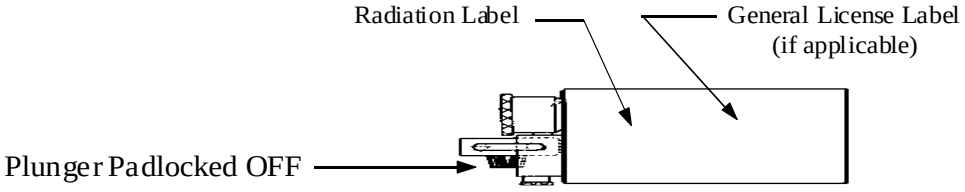


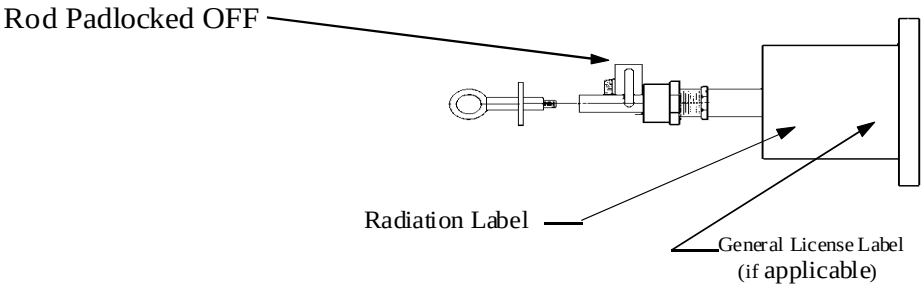
Inspection

The source holder is equipped with an ON/OFF mechanism. During shipment and storage the mechanism MUST BE SECURED in the OFF position with a padlock.

Each source holder will also have a label permanently attached to it. This label will have the radiation symbol and the words “Caution” or “Dangerous – Radioactive Materials”. This label will also include information such as source type, source activity, and serial number. This label must remain on the device, in legible condition.

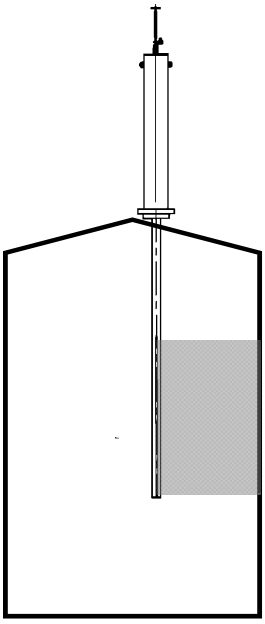




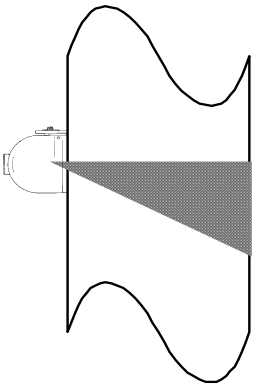


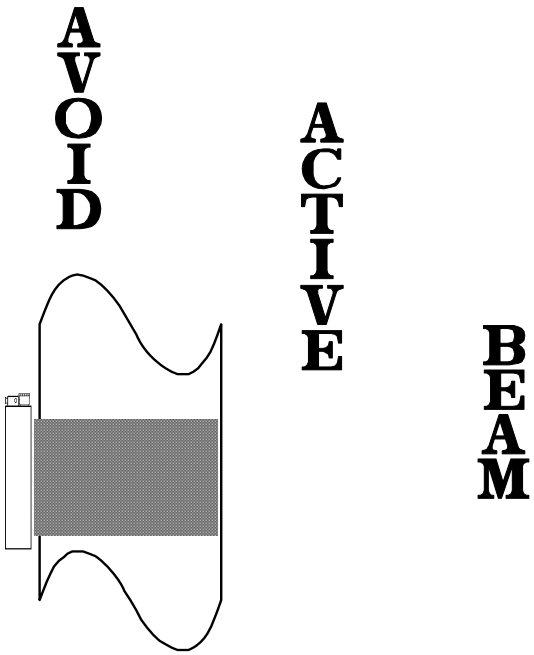
Safety Precautions

During installation the RSO will provide guidelines to assure safety. Consider the information presented in the "Regulations" section of this manual, as well as the following general guidelines:

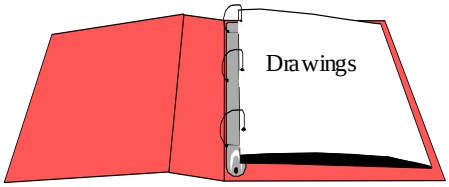


1. The source holder must remain padlocked in the OFF position until installation is complete.
2. Take all necessary precautions to assure that the source holder is not dropped or damaged.
3. **A specifically licensed individual MUST inspect the installation** prior to placing the source holder in the ON position.
4. Always turn the source holder to the OFF position when working around it, the detector, or the area between these two components.
5. When the source holder is placed in the ON position, avoid the active beam.





Mechanical Mounting



Review the configuration drawing(s) which are included in your I/O manual.

Reference the outline drawings also included in the I/O manual for the weights and dimensions of the major gage components.

Consider the following, general guidelines when mounting the sensor and detector:

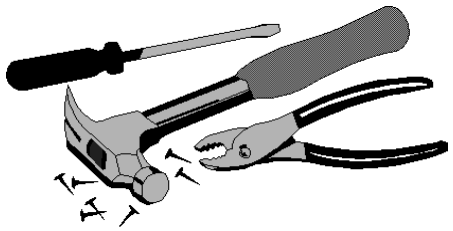
- Avoid internal vessel obstructions such as baffles, agitators, manways, and heating or cooling tubes/coils that could interfere with the transmission of the radiation beam through the vessel.

- The source and detector must be rigidly mounted so they do not move with respect to each other. Such movement will invalidate the system's calibration and/or its measurement.

- Insulation must be used at the point of installation IF:

    - The temperature of the process pipe or vessel wall exceeds 131° F (55° C), and/or…

    - The voltage transmission through the pipe or vessel wall could interfere with the signal transmission from the source to the detector.



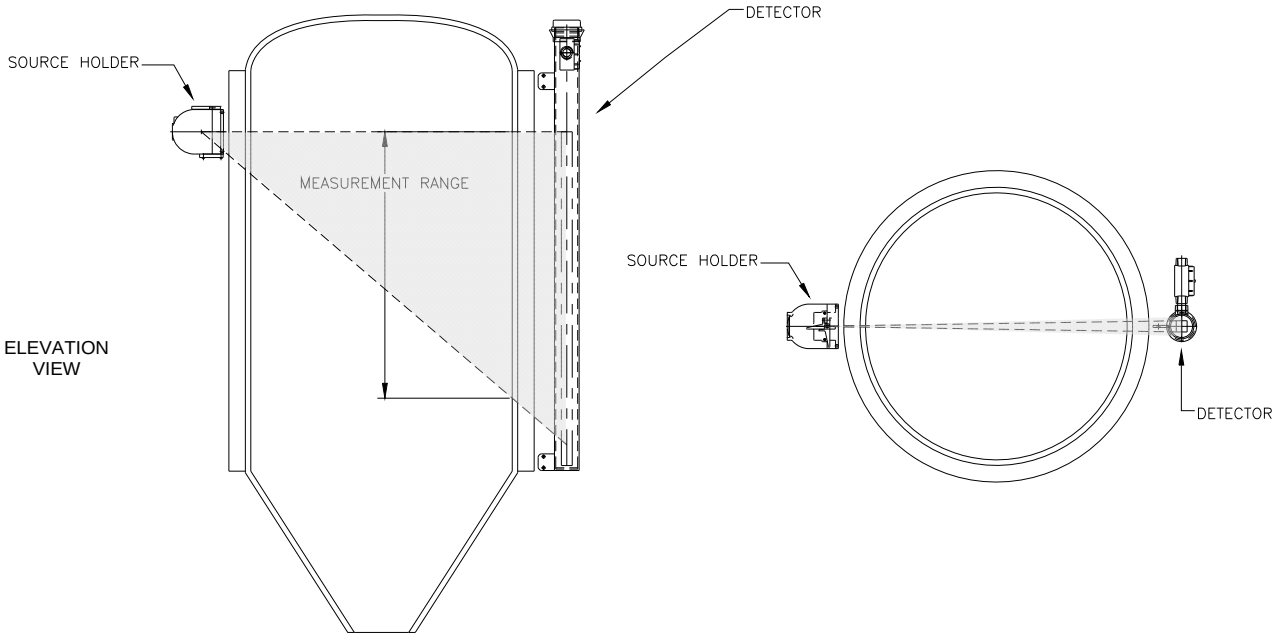
It is a good idea to have any special tools or handling equipment available when you are ready to install the gage. This will expedite the installation process and reduce the amount of time that personnel are in direct contact with the gage.

Remember to consult the installation, configuration, and outline drawings before and during installation to ensure proper location and mounting.

Mounting Basics

When mounting the gage, it is important to reference any configuration drawings or mounting instructions that are supplied. Proper mounting and alignment is critical to the operation of the gage as well as being a safety concern.

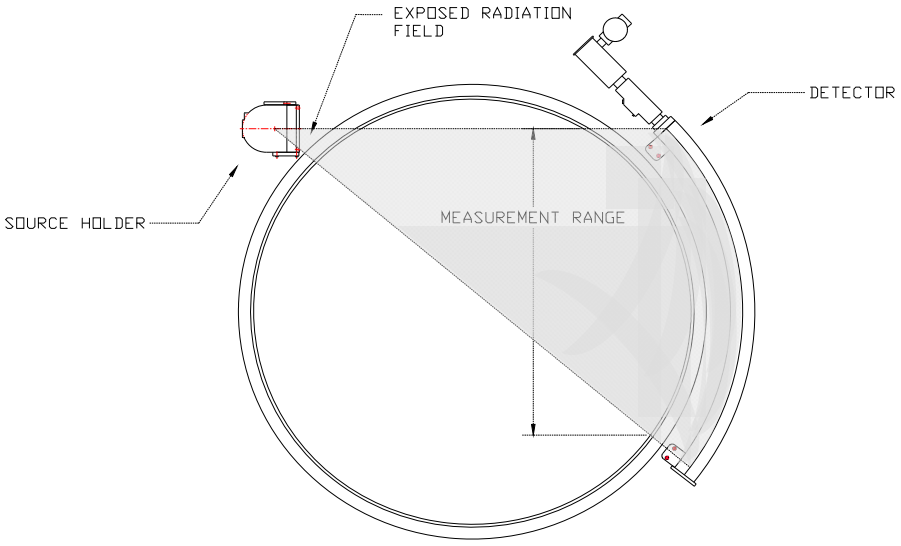
In the example below the continuous level gage is mounted to the vessel in such a way that the face of the source holder is nearly flush to the vessel wall / insulation. The gage is properly aligned so that the radiation beam is aimed directly at the detector. In addition, it would be virtually impossible for any individual to get a significant portion of their body between the face of the source holder and the vessel wall / insulation.



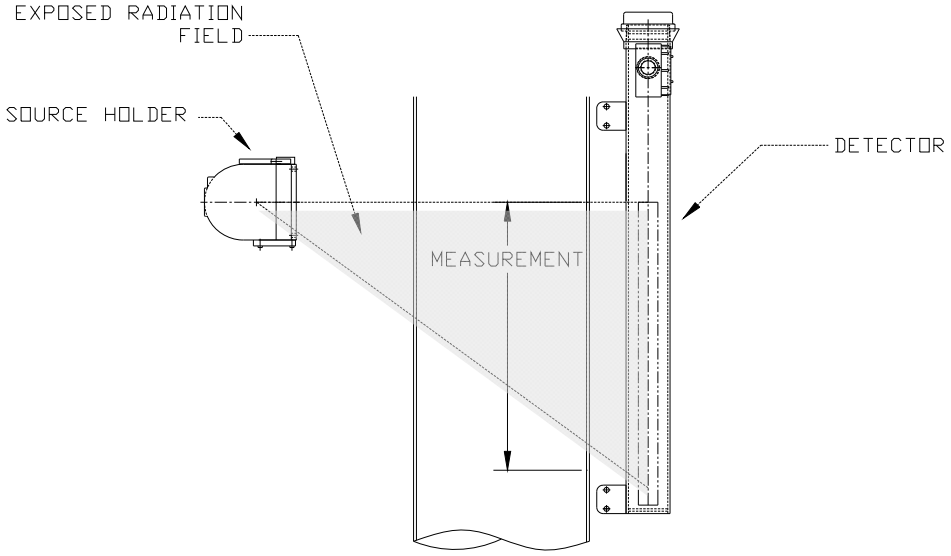
CONTINUOUS LEVEL – EXTERNAL W/SINGLE SOURCE

Note: Nearly all gages provided by Ronan are designed so that fields on the detector side of the vessel are well below the safety limits set by the NRC. If a high radiation field is detected on the detector side of the vessel shielding can be installed to reduce this field to acceptable levels.

In some circumstances it may be necessary to mount the gage in such a manner that a portion of the direct radiation beam could be accessible to personnel. In such instances, steps should be taken to prevent access to the exposed areas where the high radiation fields exist.



ELEVATION VIEW - HORIZONTAL VESSEL



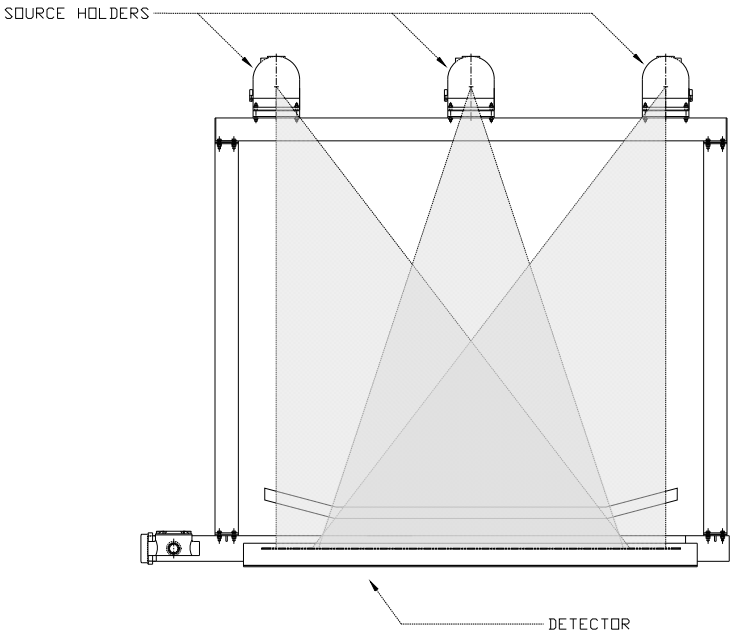
VERTICAL VESSEL - ELEVATION VIEW

Proper source holder alignment is critical to gage performance and safety.

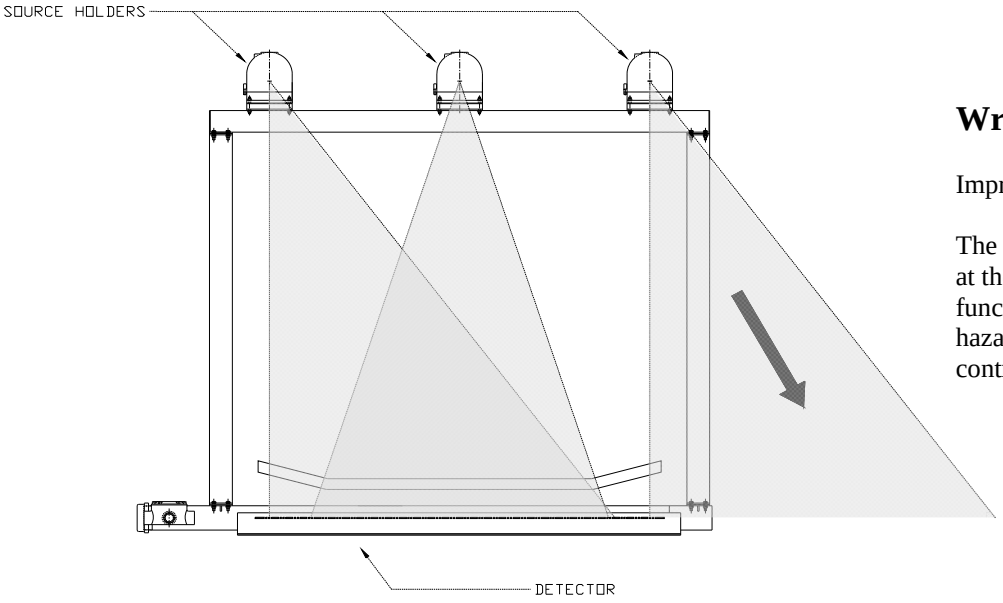
Correct!

Source holders are in proper orientation and alignment.

Radiation beams are aimed at detector and occupy the controlled area inside the weigh scale frame.



WEIGH SCALES - MULTIPLE SOURCE HOLDERS



WEIGH SCALES - MULTIPLE SOURCE HOLDERS

Wrong!

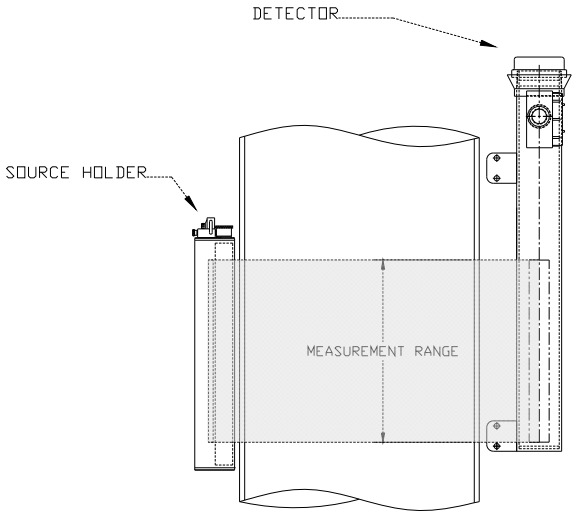
Improper alignment / orientation.

The radiation beam is not aimed at the detector. The gage will not function properly and a radiation hazard exists outside of controlled area under frame.

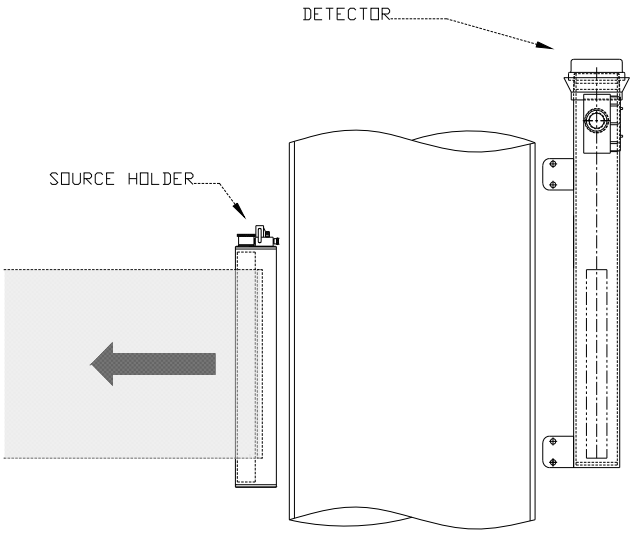
Correct!

Source holder is in proper orientation and alignment.

Radiation beam is aimed at detector and occupies the controlled area inside the vessel.



ELEVATION VIEW - LEVEL w/STRIP SOURCE



ELEVATION VIEW - LEVEL w/STRIP SOURCE

Wrong!

Improper alignment / orientation.

The radiation beam is not aimed at the detector. The gage will not function properly and a radiation hazard exists outside of controlled area / vessel.

Leak Test / Shutter Test Requirements

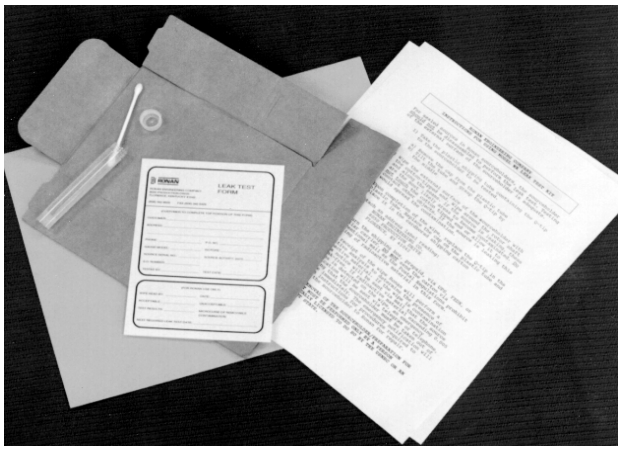
The integrity of the containment and shielding around most radioactive sources must be verified at periodic intervals specified by the NRC or an agreement state.

Testing the containment and shielding involves verifying two conditions: (1) the integrity of the source capsule and (2) the function of the ON/OFF mechanism (shutter).

Ronan provides leak test training and a leak testing service to assist in meeting these requirements. The service can be purchased on a contract basis for each individual source. After the source holder is wiped by the customer, the kit is returned to Ronan for analysis. After analysis, Ronan will issue a report and maintain a record of the results.

Leak Test Kit

The leak test procedure described here applies only to the leak test kit (WPTST-D) purchased from Ronan Engineering. As part of the service, Ronan provides a leak test kit consisting of the following items:



- A small plastic tube containing a cotton swab (Q-tip).
- A leak test form to record test information and results.
- Instructions for using the cotton swab and completing the form.
- A cardboard shipping container for returning the plastic tube, Q-tip, and leak test form to Ronan for processing.

Preparing for the Leak Test

DO NOT disassemble the sealed source assembly.

Test only the external, or exposed, portion of the source holder.

Keep the cotton swab inside the plastic tube while carrying it to the source holder.

Place the source holder shutter in the OFF or LOCKED position. See Figure 1.

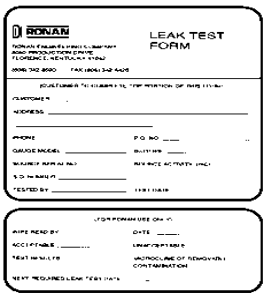
DO NOT touch the cotton swab to any surface other than the one source holder being tested.

Leak Test Procedure

Remove the cap from the plastic tube. Remove the swab from the tube.

With cotton-tipped end, wipe the external surface of the source holder. Wipe at the test points illustrated in Figure 1, covering at least 100 cm^2 (approximately 16 $inches^2$) of the surface.

Completing the Leak Test



With the cotton tip DOWN, replace the cotton swab in the plastic tube.

Replace the cap on the plastic tube.

Check the radiation label attached to the source holder and copy the information found thereon onto the top portion of the leak test form.

Place the plastic tube and the completed leak test form into the cardboard shipping container.

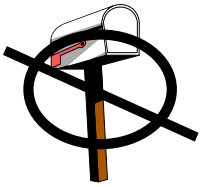
Seal the cardboard shipping container.

Returning the Leak Test

Label the cardboard shipping container as follows:

Ronan Engineering
8050 Production Drive
Florence, KY 41042 USA

DO NOT mail the completed leak test kit. U.S. Postal regulations prohibit mailing radioactive materials.

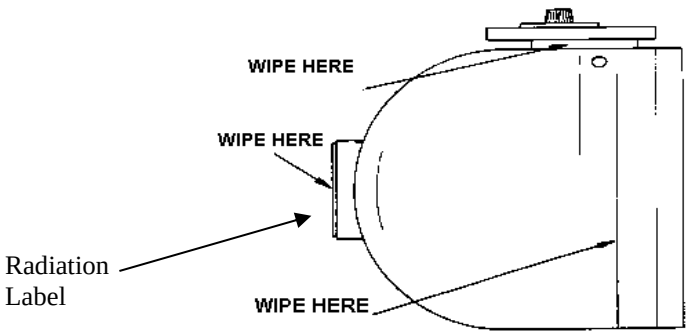


Return the leak test kit by parcel express service such as UPS, FedEx, or similar.

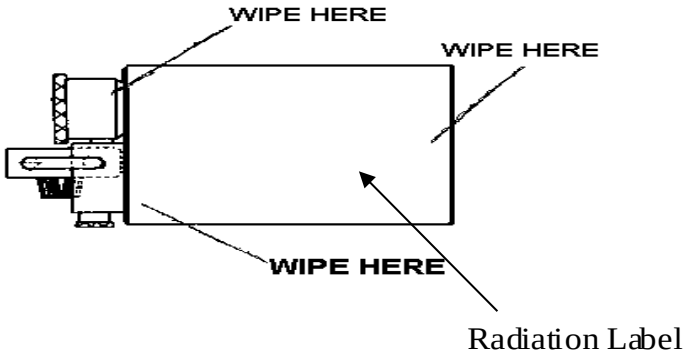
You do not need to label the package “radioactive”.

Figure 1: Wipe Test / Shutter Test

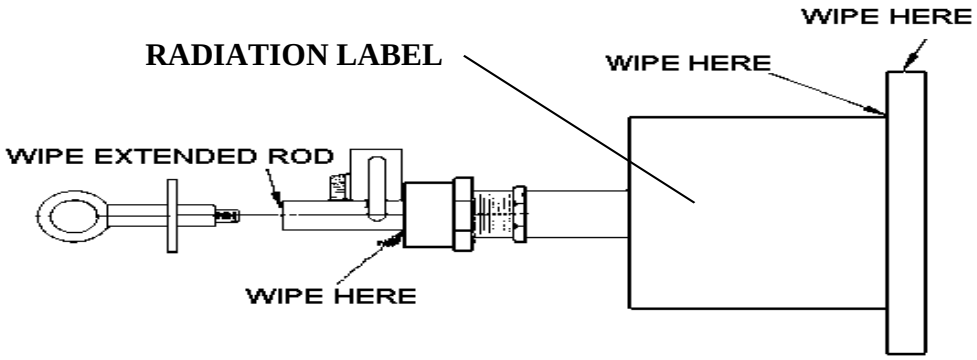
SA-1



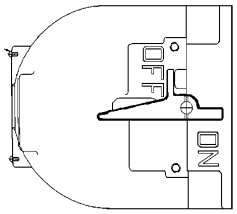
GS-300



SA-4 / SA-10 / SA-15



Shutter Checks
SA-1

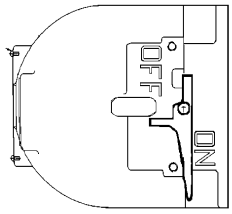


OFF

Standard, externally mounted source holders are equipped with an ON/OFF shutter. On most source holders this shutter must be checked periodically.

Test the shutter mechanism by turning the handle or rotary knob back and forth several times between the ON and OFF position. The handle or knob should rotate with only slight resistance and should not catch or stick.

DO NOT FORCE THE HANDLE!

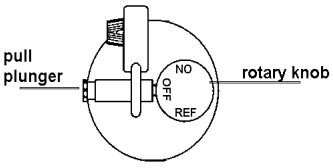


ON

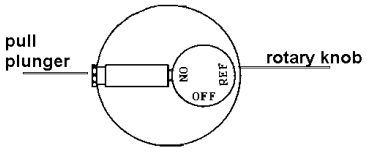
You can verify that the radiation beam is cut off when the shutter is rotated to the closed position by using a survey meter or by watching the raw detector output of the gage. You should see a significant change in counts when you close the shutter.

Note: the gage counts will not go all the way to zero.

GS-300



OFF



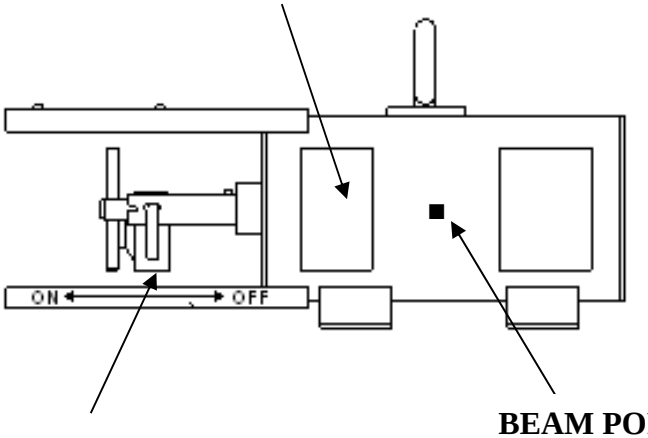
ON

GS-400 Series

This is a source holder with a moving shutter control mechanism. The **"ON/OFF"** Position label is mounted on the protection bar.

To turn the source **"ON"**, pull the actuator rod handle to engage the locating pin on top of the slot and rotate it 90° clockwise to the **"ON"** position.

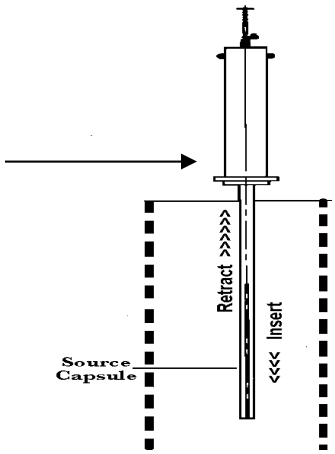
To turn the source **"OFF"**, pull the handle; rotate 90° counter-clockwise to disengage the rod to the **"OFF"** position.



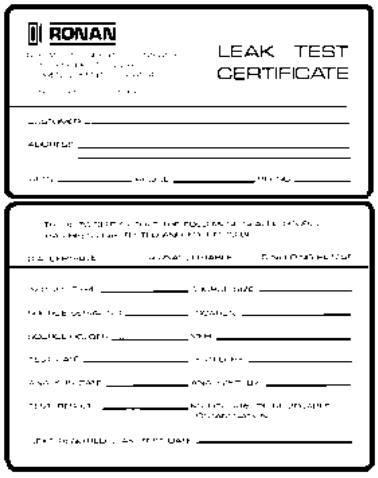
SA-4 / SA-10 / SA-15

The internally mounted, well type source holder is NOT equipped with a shutter. The source is retracted out of the well or dip tube and LOCKED into the shielded holder for temporary storage.

Verify that the source is pulled up into the source holder housing when the rod is retracted. Again, a survey meter or the gage electronics can be used to verify this.



Processing the Completed Leak Test


RONAN
LEAK TEST CERTIFICATE

Upon receipt of the leak test, Ronan will perform a sensitive analysis to determine the presence of radioactive material. If the cotton swab is contamination free, Ronan will mail a certificate to the user indicating the results of the leak test.

If radioactive material exceeding 0.005 microcuries (μCi) is detected on the cotton swab, Ronan will issue an emergency notification to the user, via telephone or fax, advising that the source holder be taken out of service immediately and shipped for disposal or repair.

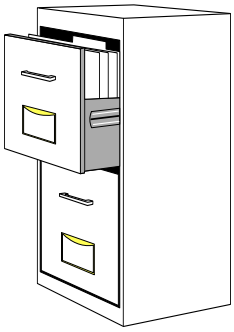
Ronan can assist, in an advisory capacity, with the removal and packaging of the device.

Record Keeping Requirements

Ronan Engineering maintains a record of each leak test analysis we perform. These records include:

- Name and address of the customer.
- Date the leak test was performed.
- Name of the person performing the test.
- Name of the person performing the analysis.
- Date the analysis was performed.
- Source serial number, radioactive isotope and mass number of the source.
- Leak test results in microcuries (μCi).

The customer is also responsible for maintaining records:

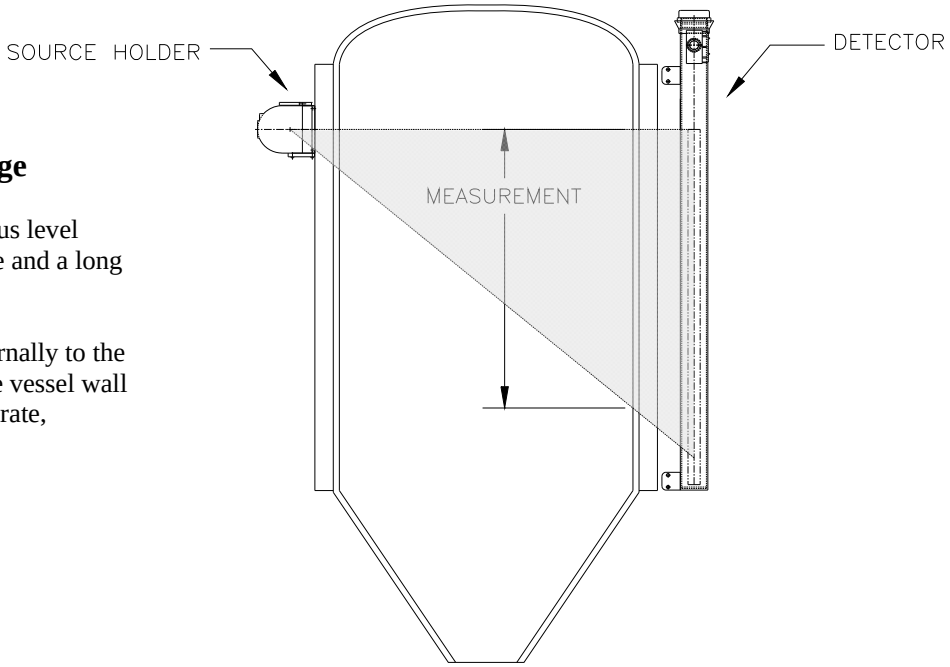


Keep Records !

- Transfer documents shipped with gage.
- Initial Radiation survey.
- Periodic leak test/shutter checks.
- Other documents as required by Federal, State, and/or local agencies.

Gage Configurations

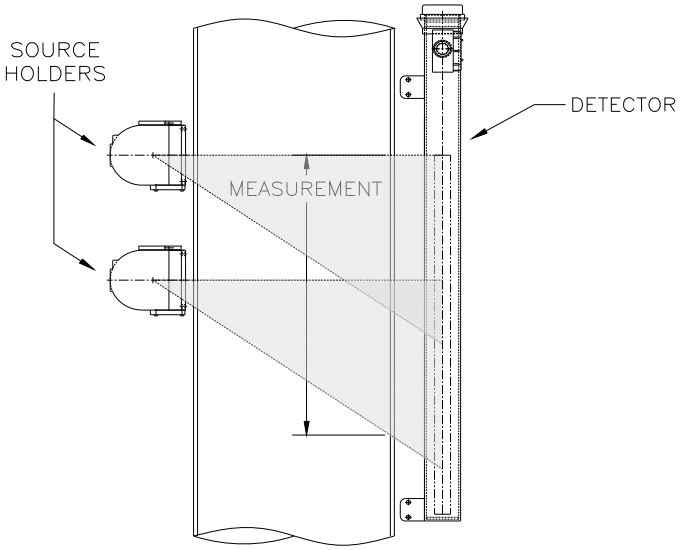
Each user's application will determine the proper configuration for the gage. On the following pages you will find some typical configurations that are commonly used in the field by specific licensees. For specific information concerning your application please reference the enclosed configuration drawings (when available).



Continuous Level Gage

Elevation view of continuous level gage using one point source and a long detector.

All equipment mounts externally to the vessel (either directly to the vessel wall via bracketing or from separate, external structures).



Continuous Level Gage

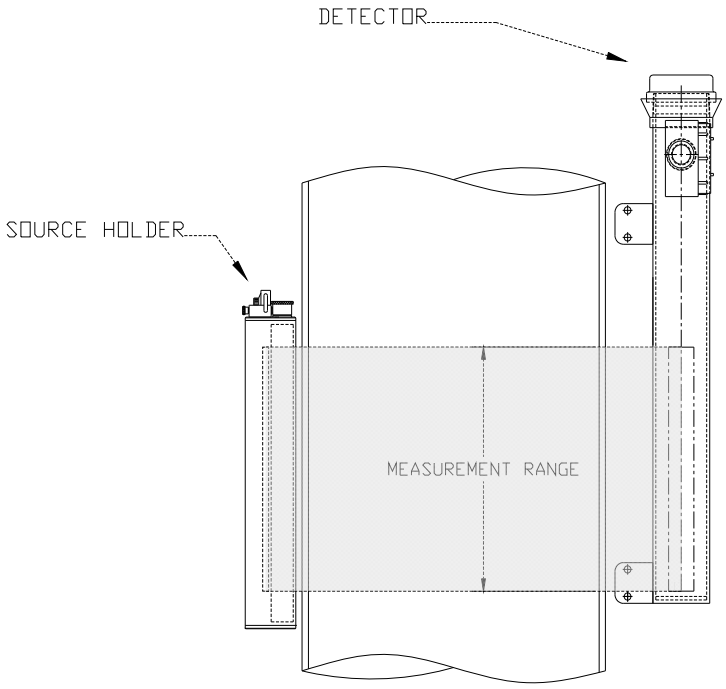
Elevation view of continuous level gage using two point sources and a single, long detector in order to cover the measurement range.

All equipment mounts externally to the vessel (either directly to the vessel wall via bracketing or from separate, external structures).

Continuous Level Gage

Elevation view of continuous level gage using a single strip source and a single, long detector in order to cover the measurement range.

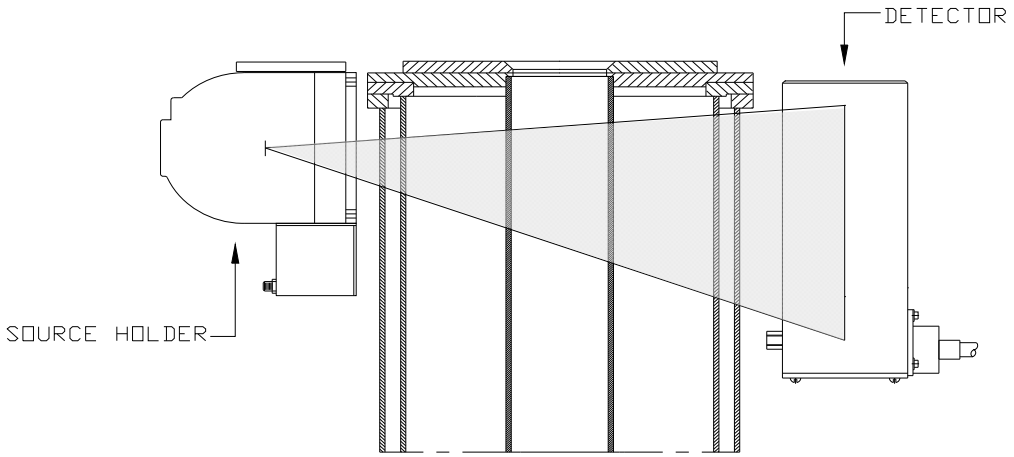
All equipment mounts externally to the vessel (either directly to the vessel wall via bracketing or from separate, external structures).



Mold Level Gage

Elevation view of mold level gage using a single point source and a long detector.

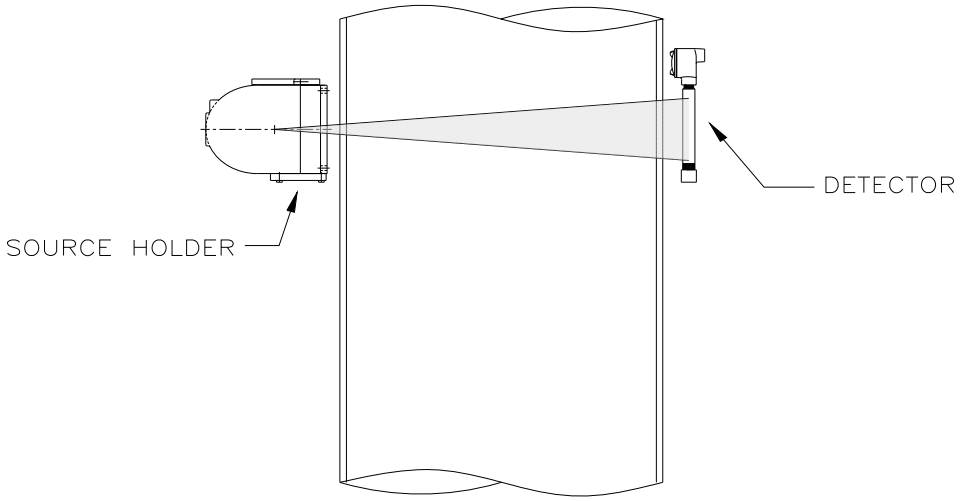
All equipment mounts externally to the mold (either directly to the mold housing, via bracketing, or from separate, external structures).



Point Level Gage

Elevation view of point level gage using a single source holder and a Geiger-Mueller detector.

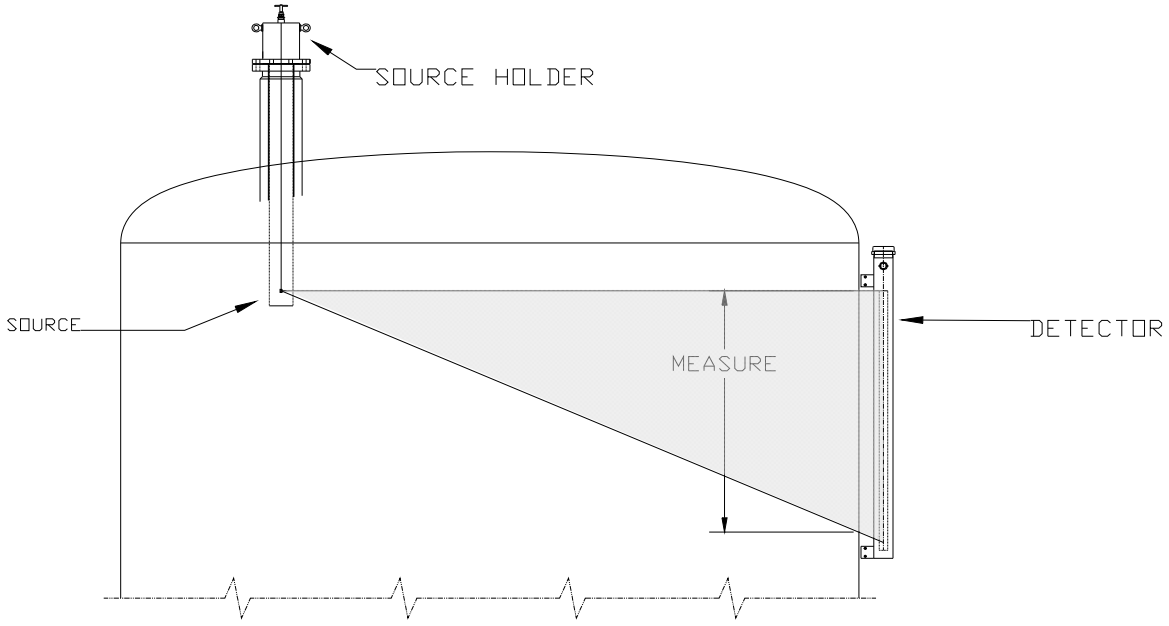
All equipment mounts externally to the vessel (either directly to the vessel wall via bracketing or from separate, external structures).



Continuous Level Gage

Elevation view of continuous level gage using an insertion style source holder and long detector.

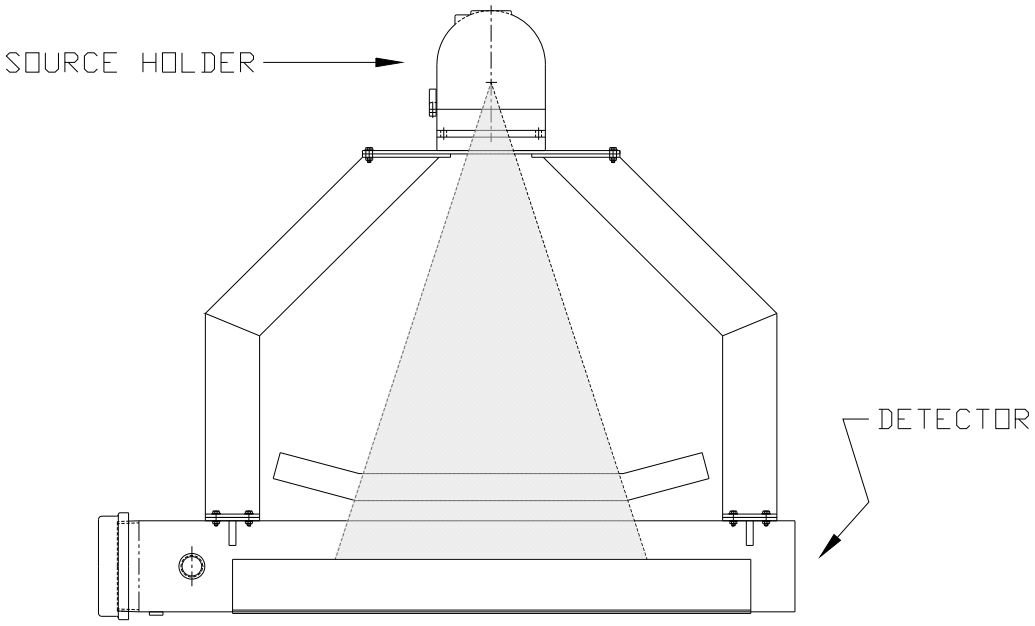
Source holder mounts to internal well and source capsule is inserted into well via an insertion rod.
The detector mounts external to the vessel (either directly to the vessel wall via bracketing or from separate, external structures.



Weigh Scale Gage

Frame mounts around conveyor system. Source holder(s) mounts to the top of the frame. A detector housing makes up the frame base and the detector mounts inside the housing.

The entire assembly can be bolted or welded to the conveyor structure.



Applicable Regulations

Listed on the following pages are annotated versions of the US NRC regulations that govern the possession and use of fixed nuclear gages. If the gage will be located in an Agreement State (see "Specific License: Description on page 1), that state will most likely have its own set of regulations with which you will need to comply.

PART 19—NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS: INSPECTION AND INVESTIGATIONS

[Top of File]

§ 19.1 Purpose.

[Top of File]

The regulations in this part establish requirements for notices, instructions, and reports by licensees and regulated entities to individuals participating in NRC-licensed and regulated activities and options available to these individuals in connection with Commission inspections of licensees and regulated entities, and to ascertain compliance with the provisions of the Atomic Energy Act of 1954, as amended, titles II and IV of the Energy Reorganization Act of 1974, and regulations, orders, and licenses thereunder. The regulations in this part also establish the rights and responsibilities of the Commission and individuals during interviews compelled by subpoena as part of agency inspections or investigations under Section 161c of the Atomic Energy Act of 1954, as amended, on any matter within the Commission's jurisdiction.

[55 FR 247, Jan. 4, 1990; 72 FR 49483, Aug. 28, 2007]

§ 19.2 Scope.

[Top of File]

(a) The regulations in this part apply to:

(1) All persons who receive, possess, use, or transfer material licensed by the NRC under the regulations in parts 30 through 36, 39, 40, 60, 61, 63, 70, or 72 of this chapter, including persons licensed to operate a production or utilization facility under parts 50 or 52 of this chapter, persons licensed to possess power reactor spent fuel in an independent spent fuel storage installation (ISFSI) under part 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter;

(2) All applicants for and holders of licenses (including construction permits and early site permits) under parts 50, 52, and 54 of this chapter;

(3) All applicants for and holders of a standard design approval under subpart E of part 52 of this chapter; and

(4) All applicants for a standard design certification under subpart B of part 52 of this chapter, and those (former) applicants whose designs have been certified under that subpart.

(b) The regulations in this part regarding interviews of individuals under subpoena apply to all investigations and inspections within the jurisdiction of the NRC other than those involving NRC employees or NRC contractors. The regulations in this part do not apply to subpoenas issued under 10 CFR 2.702.

[66 FR 55789, Nov. 2, 2001; 72 FR 49484, Aug. 28, 2007]

§ 19.3 Definitions.

[Top of File]

As used in this part:

Act means the Atomic Energy Act of 1954, (68 Stat. 919) including any amendments thereto.

Commission means the United States Nuclear Regulatory Commission.

Exclusion means the removal of counsel representing multiple interests from an interview whenever the NRC official conducting the interview has concrete evidence that the presence of the counsel would obstruct and impede the particular investigation or inspection.

License means a license issued under the regulations in parts 30 through 36,39, 40, 60, 61, 63, 70, or 72 of this chapter, including licenses to manufacture, construct and/or operate a production or utilization facility under parts 50, 52, or 54 of this chapter.

Licensee means the holder of such a license.

Regulated activities means any activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or any title of the Energy Reorganization Act of 1972, as amended.

Regulated entities means any individual, person, organization, or corporation that is subject to the regulatory jurisdiction of the NRC, including (but not limited to) an applicant for or holder of a standard design approval under subpart E of part 52 of this chapter or a standard design certification under subpart B of part 52 of this chapter.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sequestration means the separation or isolation of witnesses and their attorneys from other witnesses and their attorneys during an interview conducted as part of an investigation, inspection, or other inquiry.

Worker means an individual engaged in activities licensed or regulated by the Commission and controlled by a licensee or regulated entity, but does not include the licensee or regulated entity.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 53 FR 31680, Aug. 19, 1988; 55 FR 247, Jan. 4, 1990; 56 FR 23470, May 21, 1991; 56 FR 65948, Dec. 19, 1991; 57 FR 61785, Dec. 29, 1992; 58 FR 7736, Feb. 9, 1993; 66 FR 55789, Nov. 2, 2001; 69 FR 76600, Dec. 22, 2004; 72 FR 49484, Aug. 28, 2007]

§ 19.4 Interpretations.

[Top of File]

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 19.5 Communications.

[Top of File]

Except where otherwise specified in this part, all communications and reports concerning the regulations in this part should be addressed to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in Appendix D of part 20 of this chapter. Communications, reports, and applications may be delivered in person at the Commission's offices at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland.

[67 FR 67098, Nov. 4, 2002]

§ 19.8 Information collection requirements: OMB approval.

[Top of File]

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in the part under control number 3150-0044.

(b) The approved information collection requirements contained in this part appear in §§ 19.13 and 19.16.

[62 FR 52185, Oct. 6, 1997]

§ 19.11 Posting of notices to workers.

[Top of File]

(a) Each licensee (except for a holder of an early site permit under subpart A of part 52 of this chapter, or a holder of a manufacturing license under subpart F of part 52 of this chapter) shall post current copies of the following documents:

(1) The regulations in this part and in part 20 of this chapter;

(2) The license, license conditions, or documents incorporated into a license by reference, and amendments thereto;

(3) The operating procedures applicable to licensed activities;

(4) Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to subpart B of part 2 of this chapter, and any response from the licensee.

(b) Each applicant for and holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, each applicant for a standard design certification under subpart B of part 52 of this chapter, and each applicant for and holder of a manufacturing license under subpart F of part 52 of this chapter shall post:

(1) The regulations in this part;

(2) The operating procedures applicable to the activities regulated by the NRC which are being conducted by the applicant or holder; and

(3) Any notice of violation, proposed imposition of civil penalty, or order issued under subpart B of part 2 of this chapter, and any response from the applicant or holder.

(c) [Reserved]

(d) If posting of a document specified in paragraphs (a)(1), (2) or (3), or (b)(1) or (2) of this section is not practicable, the licensee or regulated entity may post a notice which describes the document and states where it may be examined.

(e)(1) Each licensee, each applicant for a specific license, each applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, each applicant for an early site permit under subpart A of part 52 of this chapter, and each applicant for a standard design certification under subpart B of part 52 of this chapter shall prominently post NRC Form 3, "Notice to Employees," dated August 1997. Later versions of NRC Form 3 that supersede the August 1997 version shall replace the previously posted version within 30 days of receiving the revised NRC Form 3 from the Commission.

(2) Additional copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, via email to *FORMS.Resource@nrc.gov*, or by visiting the NRC's online library at *http://www.nrc.gov/reading-rm/doc-collections/forms/*.

(f) Documents, notices, or forms posted under this section shall appear in a sufficient number of places to permit individuals engaged in NRC-licensed or regulated activities to observe them on the way to or from any particular licensed or regulated activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(g) Commission documents posted under paragraphs (a)(4) or (b)(3) of this section shall be posted within 2 working days after receipt of the documents from the Commission; the licensee's or regulated entity's response, if any, shall be posted within 2 working days after dispatch by the licensee or regulated entity. These documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 47 FR 30454, July 14, 1982; 58 FR 52408, Oct. 8, 1993; 60 FR 24551, May 9, 1995; 61 FR 6764, Feb. 22, 1996; 62 FR 48166, Sept. 15, 1997; 68 FR 58801, Oct. 10, 2003; 72 FR 49484, Aug. 28, 2007; 79 FR 66602, Nov. 10, 2014]

§ 19.12 Instruction to workers.

[Top of File]

(a) All individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem (1 mSv) shall be--

(1) Kept informed of the storage, transfer, or use of radiation and/or radioactive material;

(2) Instructed in the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

(3) Instructed in, and required to observe, to the extent within the workers control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material;

(4) Instructed of their responsibility to report promptly to the licensee any condition which may lead to or cause a violation of Commission regulations and licenses or unnecessary exposure to radiation and/or radioactive material;

(5) Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material; and

(6) Advised as to the radiation exposure reports which workers may request pursuant to § 19.13.

(b) In determining those individuals subject to the requirements of paragraph (a) of this section, licensees must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation and/or radioactive material which can reasonably be expected to occur during the life of a licensed facility. The extent of these instructions must be commensurate with potential radiological health protection problems present in the work place.

[60 FR 36043, July 13, 1995]

§ 19.13 Notifications and reports to individuals.

[Top of File]

(a) Radiation exposure data for an individual, and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual, shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Commission regulations, orders or license conditions, as shown in records maintained by the licensee pursuant to Commission regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the licensee, the name of the individual, the individual's

social security number; include the individual's exposure information; and contain the following statement:

This report is furnished to you under the provisions of the Nuclear Regulatory Commission regulation 10 CFR part 19. You should preserve this report for further reference.

(b) Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 10 CFR 20.2106. The licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if:

(1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or

(2) The individual requests his or her annual dose report.

(c)(1) At the request of a worker formerly engaged in licensed activities controlled by the licensee, each licensee shall furnish to the worker a report of the worker's exposure to radiation and/or to radioactive material:

(i) As shown in records maintained by the licensee pursuant to § 20.2106 for each year the worker was required to be monitored under the provisions of § 20.1502; and

(ii) For each year the worker was required to be monitored under the monitoring requirements in effect prior to January 1, 1994.

(2) This report must be furnished within 30 days from the time the request is made or within 30 days after the exposure of the individual has been determined by the licensee, whichever is later. This report must cover the period of time that the worker's activities involved exposure to radiation from radioactive material licensed by the Commission and must include the dates and locations of licensed activities in which the worker participated during this period.

(d) When a licensee is required by §§ 20.2202, 20.2203 or 20.2204 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Commission. This report must be transmitted no later than the transmittal to the Commission.

(e) At the request of a worker who is terminating employment with the licensee that involved exposure to radiation or radioactive materials, during the current calendar quarter or the current year, each licensee shall provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the licensee during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 44 FR 32352, June 6, 1979; 58 FR 67658, Dec. 22, 1993; 59 FR 41642, Aug. 15, 1994; 72 FR 68058, Dec. 4, 2007]

§ 19.14 Presence of representatives of licensees and regulated entities, and workers during inspections.

[Top of File]

(a) Each licensee, applicant for a license, applicant for or holder of a standard design approval under subpart E of part 52 of this chapter, applicant for an early site permit under subpart A of part 52 of this chapter, and applicant for a standard design certification under subpart B of part 52 of this chapter shall afford to the Commission at all reasonable times opportunity to inspect materials, activities, facilities, premises, and records under the regulations in this chapter.

(b) During an inspection, Commission inspectors may consult privately with workers as specified in § 19.15. The licensee, regulated entity, or the licensee's or regulated entity's representative may accompany Commission inspectors during other phases of an inspection.

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during Commission inspections, the licensee or regulated entity shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each workers' representative shall be routinely engaged in NRC-licensed or regulated activities under control of the licensee or regulated entity, and shall have received instructions as specified in § 19.12.

(e) Different representatives of licensees or regulated entities, and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the licensee or regulated entity, and the workers' representative an individual who is not routinely engaged in licensed or regulated activities under control of the license or regulated entity (for example, a consultant to the licensee, the regulated entity, or the workers' representative), shall be afforded the opportunity to accompany Commission inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, Commission inspectors are authorized to refuse to permit

accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or regulated entity to enter that area.

[72 FR 49484, Aug. 28, 2007; 76 FR 72084, Nov. 22, 2011]

§ 19.15 Consultation with workers during inspections.

[Top of File]

(a) Commission inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Commission regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the act, the regulations in this chapter, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material under the licensee's control. Any such notice in writing shall comply with the requirements of § 19.16(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to § 19.12.

§ 19.16 Requests by workers for inspections.

[Top of File]

(a) Any worker or representative of workers who believes that a violation of the Act, the regulations in this chapter, or license conditions exists or has occurred in license activities with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Administrator of the appropriate Commission Regional Office, or to Commission inspectors. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of workers. A copy shall be provided the licensee by the Regional Office Administrator, or the inspector no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Commission, except for good cause shown.

(b) If, upon receipt of such notice, the Regional Office Administrator determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 47 FR 30454, July 14, 1982; 52 FR 31610, Aug. 21, 1987]

§ 19.17 Inspections not warranted; informal review.

[Top of File]

(a) If the Administrator of the appropriate Regional Office determines, with respect to a complaint under § 19.16, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of this determination by submitting a written statement of position to the Executive Director for Operations, either by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. The Executive Director for Operations will provide the licensee with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee may submit an opposing written statement of position with the Executive Director for Operations who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Executive Director for Operations or his designee may hold an informal conference in which the complainant and the licensee may orally present their views. An informal conference may also be held at the request of the licensee, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the Executive Director for Operations shall affirm, modify, or reverse the determination of the Administrator of the appropriate Regional Office and furnish the complainant and the licensee a written notification of his decision and the reason therefor.

(b) If the Administrator of the appropriate Regional Office determines that an inspection is not warranted because the requirements of § 19.16(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of § 19.16(a).

[38 FR 22217, Aug. 17, 1973, as amended at 40 FR 8783, Mar. 3, 1975; 52 FR 31610, Aug. 21, 1987; 67 FR 77652, Dec. 19, 2002; 68 FR 58801, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 74 FR 62680, Dec. 1, 2009; 80 FR 74978, Dec. 1, 2015]

§ 19.18 Sequestration of witnesses and exclusion of counsel in interviews conducted under subpoena.

[Top of File]

(a) All witnesses compelled by subpoena to submit to agency interviews shall be sequestered unless the official conducting the interviews permits otherwise.

(b) Any witness compelled by subpoena to appear at an interview during an agency inquiry may be accompanied, represented, and advised by counsel of his or her choice. However, when the agency official conducting the inquiry determines, after consultation with the Office of the General Counsel, that the agency has concrete evidence that the presence of an attorney representing multiple interests would obstruct and impede the investigation or inspection, the agency official may prohibit that counsel from being present during the interview.

(c) The interviewing official is to provide a witness whose counsel has been excluded under paragraph (b) of this section and the witness's counsel a written statement of the reasons supporting the decision to exclude. This statement, which must be provided no later than five working days after exclusion, must explain the basis for the counsel's exclusion. This statement must also advise the witness of the witness' right to appeal the exclusion decision and obtain an automatic stay of the effectiveness of the subpoena by filing a motion to quash the subpoena with the Commission within five days of receipt of this written statement.

(d) Within five days after receipt of the written notification required in paragraph (c) of this section, a witness whose counsel has been excluded may appeal the exclusion decision by filing a motion to quash the subpoena with the Commission. The filing of the motion to quash will stay the effectiveness of the subpoena pending the Commission's decision on the motion.

(e) If a witness' counsel is excluded under paragraph (b) of this section, the interview may, at the witness' request, either proceed without counsel or be delayed for a reasonable period of time to permit the retention of new counsel. The interview may also be rescheduled to a subsequent date established by the NRC, although the interview shall not be rescheduled by the NRC to a date that precedes the expiration of the time provided under § 19.18(d) for appeal of the exclusion of counsel, unless the witness consents to an earlier date.

[55 FR 247, Jan. 4, 1990, as amended at 56 FR 65948, Dec. 19, 1991; 57 FR 61785, Dec. 29, 1992]

§ 19.20 Employee protection.

[Top of File]

Employment discrimination by a licensee, a holder of a certificate of compliance issued under part 76 of this chapter or regulated entity subject to the requirements in this part as delineated in § 19.2(a), or a contractor or subcontractor of a licensee, a holder of a certificate of compliance issued under part 76 of this chapter, or regulated entity subject to the requirements in this part as delineated in § 19.2(a), against an employee for engaging in protected activities under this part or parts 30, 40, 50, 52, 54, 60, 61, 63, 70, 72, 76, or 150 of this chapter is prohibited.

[66 FR 55789, Nov. 2, 2001; 72 FR 49485, Aug. 28, 2007]

§ 19.30 Violations.

[Top of File]

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55071, Nov. 24, 1992]

§ 19.31 Application for exemptions.

[Top of File]

The Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law, will not result in undue hazard to life and property.

[72 FR 49485, Aug. 28, 2007]

§ 19.32 Discrimination prohibited.

[Top of File]

No person shall on the grounds of sex be excluded from participation in, be denied a license, be denied the benefit of, or be subjected to discrimination under any program or activity carried on which is under the jurisdiction of the NRC under the Atomic Energy Act of 1954, as amended, or under any title of the Energy Reorganization Act of 1974, as amended. This provision will be enforced through agency provisions and regulations similar to those already established, with respect to racial and other discrimination, under Title VI of the Civil Rights Act of 1964. This remedy is not exclusive, however, and will not prejudice or cut off any other legal remedies available to a discriminatee.

[65 FR 54949, Sept. 12, 2000; 68 FR 75389, Dec. 31, 2003; 72 FR 49485, Aug. 28, 2007]

§ 19.40 Criminal penalties.

[Top of File]

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 19 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 19 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 19.1, 19.2, 19.3, 19.4, 19.5, 19.8, 19.16, 19.17, 19.18, 19.30, 19.31, and 19.40.

[57 FR 55071, Nov. 24, 1992]

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Subpart A—General Provisions

Source: 56 FR 23391, May 21, 1991, unless otherwise noted.

§ 20.1001 Purpose.

(a) The regulations in this part establish standards for protection against ionizing radiation resulting from activities conducted under licenses issued by the Nuclear Regulatory Commission. These regulations are issued under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

(b) It is the purpose of the regulations in this part to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the regulations in this part. However, nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

§ 20.1002 Scope.

The regulations in this part apply to persons licensed by the Commission to receive, possess, use, transfer, or dispose of byproduct, source, or special nuclear material or to operate a production or utilization facility under parts 30 through 36, 39, 40, 50, 52, 60, 61, 63, 70, or 72 of this chapter, and in accordance with 10 CFR 76.60 to persons required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under § 35.75, or to exposure from voluntary participation in medical research programs.

[67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002, as amended at 67 FR 77652, Dec. 19, 2002; 72 FR 49485, Aug. 28, 2007]

§ 20.1003 Definitions.

As used in this part:

Absorbed dose means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

Act means the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.), as amended.

Activity is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

Adult means an individual 18 or more years of age.

Airborne radioactive material means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations—

(1) In excess of the derived air concentrations (DACs) specified in appendix B, to §§ 20.1001-20.2401, or

(2) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

Air-purifying respirator means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

ALARA (acronym for "as low as is reasonably achievable") means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology,

the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Annual limit on intake (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 1, Columns 1 and 2, of appendix B to §§ 20.1001-20.2401).

Assigned protection factor (APF) means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

Atmosphere-supplying respirator means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Background radiation means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "*Background radiation*" does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.

Bioassay (radiobioassay) means the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

Byproduct material means—

(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

(3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(4) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Class (or *lung class* or *inhalation class*) means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y Years) of greater than 100 days.

Collective dose is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

Commission means the Nuclear Regulatory Commission or its duly authorized representatives.

Committed dose equivalent ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma W_T H_{T.50}$).

Constraint (dose constraint) means a value above which specified licensee actions are required.

Controlled area means an area, outside of a restricted area but inside the site boundary, access to which can be limited by

the licensee for any reason.

Critical Group means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Declared pregnant woman means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Deep-dose equivalent (H_d), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm^2).

Demand respirator means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Department means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c), and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat 565 at 577-578, 42 U.S.C. 7151).

Derived air concentration (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. DAC values are given in Table 1, Column 3, of appendix B to §§ 20.1001-20.2401.

Derived air concentration-hour (DAC-hour) is the product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Disposable respirator means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Distinguishable from background means that the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose or *radiation dose* is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other paragraphs of this section.

Dose equivalent (H_T) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

Dosimetry processor means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

Effective dose equivalent (H_E) is the sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma W_T H_T$).

Embryo/fetus means the developing human organism from conception until the time of birth.

Entrance or access point means any location through which an individual could gain access to radiation areas or to radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Exposure means being exposed to ionizing radiation or to radioactive material.

External dose means that portion of the dose equivalent received from radiation sources outside the body.

Extremity means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

Filtering facepiece (dust mask) means a negative pressure particulate respirator with a filter as an integral part of the

facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

Fit factor means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Generally applicable environmental radiation standards means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Government agency means any executive department, commission, independent establishment, corporation wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Gray [See § 20.1004].

Helmet means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Hood means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Individual means any human being.

Individual monitoring means—

(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;

(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

(3) The assessment of dose equivalent by the use of survey data.

Individual monitoring devices (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

Internal dose means that portion of the dose equivalent received from radioactive material taken into the body.

Lens dose equivalent (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License means a license issued under the regulations in parts 30 through 36, 39, 40, 50, 60, 61, 63, 70, or 72 of this chapter.

Licensed material means source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission.

Licensee means the holder of a license.

Limits (dose limits) means the permissible upper bounds of radiation doses.

Loose-fitting facepiece means a respiratory inlet covering that is designed to form a partial seal with the face.

Lost or missing licensed material means licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Member of the public means any individual except when that individual is receiving an occupational dose.

Minor means an individual less than 18 years of age.

Monitoring (radiation monitoring, radiation protection monitoring) means the measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E of this part. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity

equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Negative pressure respirator (tight fitting) means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nonstochastic effect means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

NRC means the Nuclear Regulatory Commission or its duly authorized representatives.

Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, "accelerator" is an equivalent term.

Person means—

(1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, Government agency other than the Commission or the Department of Energy (except that the Department shall be considered a person within the meaning of the regulations in 10 CFR chapter I to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission under section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), the Uranium Mill Tailings Radiation Control Act of 1978 (92 Stat. 3021), the Nuclear Waste Policy Act of 1982 (96 Stat. 2201), and section 3(b)(2) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (99 Stat. 1842)), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and

(2) Any legal successor, representative, agent, or agency of the foregoing.

Planned special exposure means an infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Positive pressure respirator means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator means a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Public dose means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, or from voluntary participation in medical research programs.

Qualitative fit test (QLFT) means a pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quality Factor (Q) means the modifying factor (listed in tables 1004(b).1 and 1004(b).2 of § 20.1004) that is used to derive dose equivalent from absorbed dose.

Quantitative fit test (QNFT) means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Quarter means a period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad (See § 20.1004).

Radiation (ionizing radiation) means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

Radiation area means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Reference man means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

Rem (See § 20.1004).

Residual radioactivity means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of 10 CFR part 20.

Respiratory protective device means an apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sanitary sewerage means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

Self-contained breathing apparatus (SCBA) means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow-dose equivalent (H_S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Sievert (See § 20.1004).

Site boundary means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

Source material means—

(1) Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

(2) Ores that contain, by weight, one-twentieth of 1 percent (0.05 percent), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

Special nuclear material means—

(1) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission, pursuant to the provisions of section 51 of the Act, determines to be special nuclear material, but does not include source material; or

(2) Any material artificially enriched by any of the foregoing but does not include source material.

Stochastic effects means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

Supplied-air respirator (SAR) or *airline respirator* means an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Tight-fitting facepiece means a respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Unrestricted area means an area, access to which is neither limited nor controlled by the licensee.

Uranium fuel cycle means the operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and byproduct materials from the cycle.

User seal check (fit check) means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, or isoamyl acetate check.

Very high radiation area means an area, accessible to individuals, in which radiation levels from radiation sources external to

the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in 1 hour at 1 meter from a radiation source or 1 meter from any surface that the radiation penetrates.

(Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts)).

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.

Week means 7 consecutive days starting on Sunday.

Weighting factor W_T, for an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of W_T are:

Organ Dose Weighting Factors

Organ or Tissue	W_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	[1]0.30
Whole Body	[2]1.00

[1] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[2] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T=1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Whole body means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Working level (WL) is any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in 1 liter of air that will result in the ultimate emission of $1.3x10^5$ MeV of potential alpha particle energy.

Working level month (WLM) means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year=approximately 170 hours per month).

Year means the period of time beginning in January used to determine compliance with the provisions of this part. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

[56 FR 23391, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 58 FR 7736, Feb. 9, 1993; 60 FR 36043, July 13, 1995; 60 FR 48625, Sept. 20, 1995; 61 FR 65127, Dec. 10, 1996; 62 FR 4133, Jan. 29, 1997; 62 FR 39087, July 21, 1997; 63 FR 39481, July 23, 1998; 64 FR 54556, Oct. 7, 1999; 66 FR 55789, Nov. 2, 2001; 67 FR 16304, Apr. 5, 2002; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 72 FR 55921, Oct. 1, 2007; 72 FR 68058, Dec. 4, 2007; 74 FR 62680, Dec. 1, 2009]

§ 20.1004 Units of radiation dose.

(a) Definitions. As used in this part, the units of radiation dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the

absorbed dose in rads multiplied by the quality factor (1 rem=0.01 sievert).

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv=100 rems).

(b) As used in this part, the quality factors for converting absorbed dose to dose equivalent are shown in table 1004(b).1.

Table 1004(b).1-Quality Factors and Absorbed Dose Equivalencies

Type of radiation	Quality factor (Q)	Absorbed dose equal to a unit dose equivalent[a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

(c) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in paragraph (b) of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the regulations in this part, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from table 1004(b).2 to convert a measured tissue dose in rads to dose equivalent in rems.

Table 1004(b).2.—Mean Quality Factors, Q, and Fluence Per Unit Dose Equivalent for Monoenergetic Neutrons

	Neutron energy (MeV)	Quality factor[a] (Q)	Fluence per unit dose equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermal).....	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}

	4×10^2	3.5	14×10^6

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-cm diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30-cm diameter cylinder tissue-equivalent phantom.

§ 20.1005 Units of radioactivity.

For the purposes of this part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

(a) One becquerel=1 disintegration per second (s^{-1}).

(b) One curie=3.7×10^{10} disintegrations per second=3.7×10^{10} becquerels=2.22×10^{12} disintegrations per minute.

[56 FR 23391, May 21, 1991; 56 FR 61352, Dec. 3, 1991]

§ 20.1006 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by an officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

§ 20.1007 Communications.

Unless otherwise specified, communications or reports concerning the regulations in this part should be addressed to the Executive Director for Operations (EDO), and sent either by mail to the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

[68 FR 58801, Oct. 10, 2003 as amended at 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 74 FR 62680, Dec. 1, 2009; 80 FR 74979, Dec. 1, 2015]

§ 20.1008 Implementation.

(a) [Reserved]

(b) The applicable section of §§ 20.1001-20.2402 must be used in lieu of requirements in the standards for protection against radiation in effect prior to January 1, 1994[1] that are cited in license conditions or technical specifications, except as specified in paragraphs (c), (d), and (e) of this section. If the requirements of this part are more restrictive than the existing license condition, then the licensee shall comply with this part unless exempted by paragraph (d) of this section.

(c) Any existing license condition or technical specification that is more restrictive than a requirement in §§ 20.1001-20.2402 remains in force until there is a technical specification change, license amendment, or license renewal.

(d) If a license condition or technical specification exempted a licensee from a requirement in the standards for protection against radiation in effect prior to January 1, 1994,[1] it continues to exempt a licensee from the corresponding provision of §§ 20.1001-20.2402.

(e) If a license condition cites provisions in requirements in the standards for protection against radiation in effect prior to January 1, 1994[1] and there are no corresponding provisions in §§ 20.1001-20.2402, then the license condition remains in force until there is a technical specification change, license amendment, or license renewal that modifies or removes this condition.

[59 FR 41643, Aug. 15, 1994]

[1] See §§ 20.1-20.602 codified as of January 1, 1993.

§ 20.1009 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150–0014.

(b) The approved information collection requirements contained in this part appear in §§ 20.1003, 20.1101, 20.1202, 20.1203, 20.1204, 20.1206, 20.1208, 20.1301, 20.1302, 20.1403, 20.1404, 20.1406, 20.1501, 20.1601, 20.1703, 20.1901, 20.1904, 20.1905, 20.1906, 20.2002, 20.2004, 20.2005, 20.2006, 20.2102, 20.2103, 20.2104, 20.2105, 20.2106, 20.2107, 20.2108, 20.2110, 20.2201, 20.2202, 20.2203, 20.2204, 20.2205, 20.2206, 20.2207, 20.2301, and appendix G to this part.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 20.2104, NRC Form 4 is approved under control number 3150–0005.

(2) In §§ 20.2106 and 20.2206, NRC Form 5 is approved under control number 3150–0006.

(3) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 540 and 540A is approved under control number 3150–0164.

(4) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 541 and 541A is approved under control number 3150–0166.

(5) In § 20.2006 and appendix G to 10 CFR Part 20, NRC Form 542 and 542A is approved under control number 3150–0165.

(6) In § 20.2207, NRC Form 748 is approved under control number 3150–0202.

[63 FR 50128, Sept. 21, 1998, as amended at 67 FR 67099, Nov. 4, 2002; 71 FR 65686, Nov. 8, 2006; 72 FR 55922, Oct. 1, 2007; 77 FR 39905, Jul. 6, 2012]

Subpart B--Radiation Protection Programs

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1101 Radiation protection programs.

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

[56 FR 23396, May 21, 1991, as amended at 61 FR 65127, Dec. 10, 1996; 63 FR 39482, July 23, 1998]

Subpart C--Occupational Dose Limits

Source: 56 FR 23396, May 21, 1991, unless otherwise noted.

§ 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of--

(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or

(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:

(i) A lens dose equivalent of 15 rems (0.15 Sv), and

(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see § 20.1206(e)(2)).

(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to part 20 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20).

(f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see § 20.2104(e)).

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998; 67 FR 16304, Apr. 5, 2002; 72 FR 68059, Dec. 4, 2007]

§ 20.1202 Compliance with requirements for summation of external and internal doses.

(a) If the licensee is required to monitor under both §§ 20.1502(a) and (b), the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under § 20.1502(a) or only under § 20.1502(b), then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in paragraph (b) of this section and the conditions in paragraphs (c) and (d) of this section.

(Note: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.)

(b) *Intake by inhalation*. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

(1) The sum of the fractions of the inhalation ALI for each radionuclide, or

(2) The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

(3) The sum of the calculated committed effective dose equivalents to all significantly irradiated[1] organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

(c) *Intake by oral ingestion*. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) *Intake through wounds or absorption through skin*. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption.

Note: The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be

further evaluated.

[56 FR 23396, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992]

[1] An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, (i.e., $w_T H_{T,50}$) per unit intake for any organ or tissue.

§ 20.1203 Determination of external dose from airborne radioactive material.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud (see appendix B to part 20, footnotes 1 and 2).

Note: Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

§ 20.1204 Determination of internal exposure.

(a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under § 20.1502, take suitable and timely measurements of--

(1) Concentrations of radioactive materials in air in work areas; or

(2) Quantities of radionuclides in the body; or

(3) Quantities of radionuclides excreted from the body; or

(4) Combinations of these measurements.

(b) Unless respiratory protective equipment is used, as provided in § 20.1703, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may--

(1) Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

(2) Upon prior approval of the Commission, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

(3) Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide (see appendix B to part 20) to the committed effective dose equivalent.

(d) If the licensee chooses to assess intakes of Class Y material using the measurements given in § 20.1204(a)(2) or (3), the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by §§ 20.2202 or 20.2203, in order to permit the licensee to make additional measurements basic to the assessments.

(e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either--

(1) The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from appendix B to part 20 for each radionuclide in the mixture; or

(2) The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if--

(1) The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in § 20.1201 and in

complying with the monitoring requirements in § 20.1502(b), and

(2) The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

(3) The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(h)(1) In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

(2) When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in table 1 of appendix B to part 20. In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the limit in § 20.1201(a)(1)(ii) is met.

[56 FR 23396, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.1205 [Reserved]

§ 20.1206 Planned special exposures.

A licensee may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in § 20.1201 provided that each of the following conditions is satisfied--

(a) The licensee authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

(b) The licensee (and employer if the employer is not the licensee) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(c) Before a planned special exposure, the licensee ensures that the individuals involved are--

(1) Informed of the purpose of the planned operation;

(2) Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

(3) Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(d) Prior to permitting an individual to participate in a planned special exposure, the licensee ascertains prior doses as required by § 20.2104(b) during the lifetime of the individual for each individual involved.

(e) Subject to § 20.1201(b), the licensee does not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed--

(1) The numerical values of any of the dose limits in § 20.1201(a) in any year; and

(2) Five times the annual dose limits in § 20.1201(a) during the individual's lifetime.

(f) The licensee maintains records of the conduct of a planned special exposure in accordance with § 20.2105 and submits a written report in accordance with § 20.2204.

(g) The licensee records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under § 20.1201(a) but is to be included in evaluations required by § 20.1206 (d) and (e).

[56 FR 23396, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

§ 20.1207 Occupational dose limits for minors.

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in § 20.1201.

§ 20.1208 Dose equivalent to an embryo/fetus.

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.

(c) The dose equivalent to the embryo/fetus is the sum of--

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

[56 FR 23396, May 21, 1991, as amended at 63 FR 39482, July 23, 1998]

Subpart D--Radiation Dose Limits for Individual Members of the Public

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1301 Dose limits for individual members of the public.

(a) Each licensee shall conduct operations so that -

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under § 35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if-

(1) The radiation dose received does not exceed 0.5 rem (5 mSv); and

(2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.

(d) A licensee or license applicant may apply for prior NRC authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). The licensee or license applicant shall include the following information in this application:

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section;

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

(3) The procedures to be followed to maintain the dose as low as is reasonably achievable.

(e) In addition to the requirements of this part, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190 shall comply with those standards.

(f) The Commission may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

[56 FR 23398, May 21, 1991, as amended at 60 FR 48625, Sept. 20, 1995; 62 FR 4133, Jan. 29, 1997; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002]

§ 20.1302 Compliance with dose limits for individual members of the public.

(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

(b) A licensee shall show compliance with the annual dose limit in § 20.1301 by--

(1) Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual dose limit; or

(2) Demonstrating that--

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in table 2 of appendix B to part 20; and

(ii) If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

(c) Upon approval from the Commission, the licensee may adjust the effluent concentration values in appendix B to part 20, table 2, for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

[56 FR 23398, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 60 FR 20185, Apr. 25, 1995]

Subpart E--Radiological Criteria for License Termination

Source: 62 FR 39088, July 21, 1987, unless otherwise noted.

§ 20.1401 General provisions and scope.

(a) The criteria in this subpart apply to the decommissioning of facilities licensed under parts 30, 40, 50, 52, 60, 61, 63, 70, and 72 of this chapter, and release of part of a facility or site for unrestricted use in accordance with § 50.83 of this chapter, as well as other facilities subject to the Commission's jurisdiction under the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended. For high-level and low-level waste disposal facilities (10 CFR parts 60, 61, and 63), the criteria apply only to ancillary surface facilities that support radioactive waste disposal activities. The criteria do not apply to uranium and thorium recovery facilities already subject to appendix A to 10 CFR part 40 or the uranium solution extraction facilities.

(b) The criteria in this subpart do not apply to sites which:

(1) Have been decommissioned prior to the effective date of the rule in accordance with criteria identified in the Site Decommissioning Management Plan (SDMP) Action Plan of April 16, 1992 (57 FR 13389);

(2) Have previously submitted and received Commission approval on a license termination plan (LTP) or decommissioning plan that is compatible with the SDMP Action Plan criteria; or

(3) Submit a sufficient LTP or decommissioning plan before August 20, 1998 and such LTP or decommissioning plan is approved by the Commission before August 20, 1999 and in accordance with the criteria identified in the SDMP Action Plan, except that if an EIS is required in the submittal, there will be a provision for day-for-day extension.

(c) After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, or after part of a facility or site has been released for unrestricted use in accordance with § 50.83 of this chapter and in accordance with the criteria in this subpart, the Commission will require additional cleanup only, if based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

(d) When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

[62 FR 39088, July 21, 1997, as amended at 66 FR 55789, Nov. 2, 2001; 72 FR 49485, Aug. 28, 2007]

§ 20.1402 Radiological criteria for unrestricted use.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are

as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

§ 20.1403 Criteria for license termination under restricted conditions.

A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of § 20.1402 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are--

(1) Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual 1 percent real rate of return on investment;

(2) A statement of intent in the case of Federal, State, or local Government licensees, as described in § 30.35(f)(4) of this chapter; or

(3) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Commission indicating the licensee's intent to decommission in accordance with §§ 30.36(d), 40.42(d), 50.82 (a) and (b), 70.38(d), or 72.54 of this chapter, and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

(1) Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning--

(i) Whether provisions for institutional controls proposed by the licensee;

(A) Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) TEDE per year;

(B) Will be enforceable; and

(C) Will not impose undue burdens on the local community or other affected parties.

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

(2) In seeking advice on the issues identified in § 20.1403(d)(1), the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either--

(1) 100 mrem (1 mSv) per year; or

(2) 500 mrem (5 mSv) per year provided the licensee--

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1 mSv/y) value of paragraph (e)(1) of this section are not technically achievable, would be prohibitively expensive, or would result in net

public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every 5 years to assure that the institutional controls remain in place as necessary to meet the criteria of § 20.1403(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in paragraph (c) of this section.

[76 FR 35564 Jun. 17, 2011]

§ 20.1404 Alternate criteria for license termination.

(a) The Commission may terminate a license using alternate criteria greater than the dose criterion of §§ 20.1402, 20.1403(b), and 20.1403(d)(1)(i)(A), if the licensee—

(1) Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 1 mSv/y (100 mrem/y) limit of subpart D, by submitting an analysis of possible sources of exposure;

(2) Has employed to the extent practical restrictions on site use according to the provisions of § 20.1403 in minimizing exposures at the site; and

(3) Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

(4) Has submitted a decommissioning plan or License Termination Plan (LTP) to the Commission indicating the licensee's intent to decommission in accordance with §§ 30.36(d), 40.42(d), 50.82 (a) and (b), 70.38(d), or 72.54 of this chapter, and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

(5) Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

(b) The use of alternate criteria to terminate a license requires the approval of the Commission after consideration of the NRC staff's recommendations that will address any comments provided by the Environmental Protection Agency and any public comments submitted pursuant to § 20.1405.

[76 FR 35564 Jun. 17, 2011]

§ 20.1405 Public notification and public participation.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to §§ 20.1403 or 20.1404, or whenever the Commission deems such notice to be in the public interest, the Commission shall:

(a) Notify and solicit comments from:

(1) local and State governments in the vicinity of the site and any Indian Nation or other indigenous people that have treaty or statutory rights that could be affected by the decommissioning; and

(2) the Environmental Protection Agency for cases where the licensee proposes to release a site pursuant to § 20.1404.

(b) Publish a notice in the Federal Register and in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

§ 20.1406 Minimization of contamination.

(a) Applicants for licenses, other than early site permits and manufacturing licenses under part 52 of this chapter and renewals, whose applications are submitted after August 20, 1997, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(b) Applicants for standard design certifications, standard design approvals, and manufacturing licenses under part 52 of this chapter, whose applications are submitted after August 20, 1997, shall describe in the application how facility design will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

(c) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Subpart B and radiological criteria for license termination in Subpart E of this part.

[72 FR 49485, Aug. 28, 2007; 76 FR 35564 Jun. 17, 2011]

Subpart F--Surveys and Monitoring

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1501 General.

(a) Each licensee shall make or cause to be made, surveys of areas, including the subsurface, that —

(1) May be necessary for the licensee to comply with the regulations in this part; and

(2) Are reasonable under the circumstances to evaluate--

(i) The magnitude and extent of radiation levels; and

(ii) Concentrations or quantities of residual radioactivity; and

(iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

(b) Notwithstanding § 20.2103(a) of this part, records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with §§ 30.35(g), 40.36(f), 50.75(g), 70.25(g), or 72.30(d), as applicable.

(c) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(d) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor--

(1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

(2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

[56 FR 23398, May 21, 1991, as amended at 63 FR 39482, July 23, 1998; 76 FR 35564 Jun. 17, 2011]

§ 20.1502 Conditions requiring individual monitoring of external and internal occupational dose.

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by—

(1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in §

20.1201(a),

(2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);

(3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);[2] and

(4) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor (see § 20.1204) the occupational intake of radioactive material by and assess the committed effective dose equivalent to—

(1) Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI(s) in table 1, Columns 1 and 2, of appendix B to §§ 20.1001-20.2402;

(2) Minors likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv); and

(3) Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

[56 FR 23398, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

[2] All of the occupational doses in § 20.1201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

Subpart G--Control of Exposure From External Sources in Restricted Areas

Source: 56 FR 23398, May 21, 1991, unless otherwise noted.

§ 20.1601 Control of access to high radiation areas.

(a) The licensee shall ensure that each entrance or access point to a high radiation area has one or more of the following features--

(1) A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

(2) A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

(3) Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by paragraph (a) of this section for a high radiation area, the licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) A licensee may apply to the Commission for approval of alternative methods for controlling access to high radiation areas.

(d) The licensee shall establish the controls required by paragraphs (a) and (c) of this section in a way that does not prevent individuals from leaving a high radiation area.

(e) Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that--

(1) The packages do not remain in the area longer than 3 days; and

(2) The dose rate at 1 meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

(f) Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this part and to operate within the ALARA provisions of the licensee's radiation protection program.

§ 20.1602 Control of access to very high radiation areas.

In addition to the requirements in § 20.1601, the licensee shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in 1 hour at 1 meter from a radiation source or any surface through which the radiation penetrates.

Subpart H--Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

Source: 56 FR 23400, May 21, 1991, unless otherwise noted.

§ 20.1701 Use of process or other engineering controls.

The licensee shall use, to the extent practical, process or other engineering controls (*e.g.,* containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

[64 FR 54556, Oct. 7, 1999]

§ 20.1702 Use of other controls.

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means--

(1) Control of access;

(2) Limitation of exposure times;

(3) Use of respiratory protection equipment; or

(4) Other controls.

(b) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

[64 FR 54556, Oct. 7, 1999]

§ 20.1703 Use of individual respiratory protection equipment.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material,

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this part.

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the NRC for authorized use of this equipment except as provided in this part. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

(1) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(2) Surveys and bioassays, as necessary, to evaluate actual intakes;

(3) Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(4) Written procedures regarding--

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use;

(5) Determination by a physician that the individual user is medically fit to use respiratory protection equipment:

(i) Before the initial fitting of a face sealing respirator;

(ii) Before the first field use of non-face sealing respirators, and

(iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(6) Fit testing, with fit factor $\geq$ 10 times the APF for negative pressure devices, and a fit factor $\geq$ 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the facepiece operating in the negative pressure mode.

(d) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(e) The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(g) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include--

(1) Oxygen content (v/v) of 19.5-23.5%;

(2) Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

(3) Carbon monoxide (CO) content of 10 ppm or less;

(4) Carbon dioxide content of 1,000 ppm or less; and

(5) Lack of noticable odor.

(h) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face--facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

[64 FR 54557, Oct. 7, 1999, as amended at 67 FR 77652, Dec. 19, 2002]

§ 20.1704 Further restrictions on the use of respiratory protection equipment.

The Commission may impose restrictions in addition to the provisions of §§ 20.1702, 20.1703, and Appendix A to Part 20, in

order to:

(a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

[64 FR 54557, Oct. 7, 1999]

§ 20.1705 Application for use of higher assigned protection factors.

The licensee shall obtain authorization from the Commission before using assigned protection factors in excess of those specified in Appendix A to Part 20. The Commission may authorize a licensee to use higher assigned protection factors on receipt of an application that--

(a) Describes the situation for which a need exists for higher protection factors; and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

[64 FR 54557, Oct. 7, 1999]

Subpart I--Storage and Control of Licensed Material

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

§ 20.1801 Security of stored material.

The licensee shall secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

§ 20.1802 Control of material not in storage.

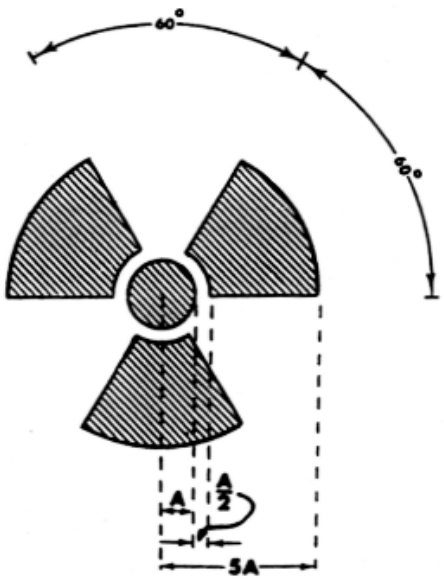
The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.

Subpart J--Precautionary Procedures

Source: 56 FR 23401, May 21, 1991, unless otherwise noted.

§ 20.1901 Caution signs.

(a) *Standard radiation symbol*. Unless otherwise authorized by the Commission, the symbol prescribed by this part shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed by this part is the three-bladed design:



RADIATION SYMBOL

(1) Cross-hatched area is to be magenta, or purple, or black, and

(2) The background is to be yellow.

(b) *Exception to color requirements for standard radiation symbol*. Notwithstanding the requirements of paragraph (a) of this section, licensees are authorized to label sources, source holders, or device components containing sources of licensed materials that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(c) *Additional information on signs and labels*. In addition to the contents of signs and labels prescribed in this part, the licensee may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

§ 20.1902 Posting requirements.

(a) *Posting of radiation areas*. The licensee shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(b) *Posting of high radiation areas*. The licensee shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(c) *Posting of very high radiation areas*. The licensee shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

(d) *Posting of airborne radioactivity areas*. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(e) *Posting of areas or rooms in which licensed material is used or stored*. The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding 10 times the quantity of such material specified in appendix C to part 20 with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

[56 FR 23401, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.1903 Exceptions to posting requirements.

(a) A licensee is not required to post caution signs in areas or rooms containing radioactive materials for periods of less than 8 hours, if each of the following conditions is met:

(1) The materials are constantly attended during these periods by an individual who takes the precautions necessary to

prevent the exposure of individuals to radiation or radioactive materials in excess of the limits established in this part; and

(2) The area or room is subject to the licensee's control.

(b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to § 20.1902 provided that the patient could be released from licensee control pursuant to § 35.75 of this chapter.

(c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the source container or housing does not exceed 0.005 rem (0.05 mSv) per hour.

(d) Rooms in hospitals or clinics that are used for teletherapy are exempt from the requirement to post caution signs under § 20.1902 if--

(1) Access to the room is controlled pursuant to 10 CFR 35.615; and

(2) Personnel in attendance take necessary precautions to prevent the inadvertent exposure of workers, other patients, and members of the public to radiation in excess of the limits established in this part.

[56 FR 23401, May 21, 1991, as amended at 57 FR 39357, Aug. 31, 1992; 62 FR 4133, Jan. 29, 1997; 63 FR 39482, July 23, 1998]

§ 20.1904 Labeling containers.

(a) The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(b) Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

§ 20.1905 Exemptions to labeling requirements.

A licensee is not required to label—

(a) Containers holding licensed material in quantities less than the quantities listed in appendix C to part 20; or

(b) Containers holding licensed material in concentrations less than those specified in table 3 of appendix B to part 20; or

(c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this part; or

(d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation,[3] or

(e) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or

(f) Installed manufacturing or process equipment, such as reactor components, piping, and tanks; or

(g) Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed under Parts 50 or 52 of this chapter, not including non-power reactors, that are within an area posted under the requirements in § 20.1902 if the containers are:

(1) Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard;

(2) Accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers; and

(3) Subject to plant procedures to ensure they are appropriately labeled, as specified at § 20.1904 before being removed from the posted area.

[56 FR 23401, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 72 FR 68059, Dec. 4, 2007]

3

Labeling of packages containing radioactive materials is required by the Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR 173.403 (m) and (w) and 173.421-424.

§ 20.1906 Procedures for receiving and opening packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in § 71.4 and appendix A to part 71 of this chapter, shall make arrangements to receive—

(1) The package when the carrier offers it for delivery; or

(2) Notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(b) Each licensee shall—

(1) Monitor the external surfaces of a labeled[3a] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4;

(2) Monitor the external surfaces of a labeled[3a] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in § 71.4 and appendix A to part 71 of this chapter; and

(3) Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

(c) The licensee shall perform the monitoring required by paragraph (b) of this section as soon as practical after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and the NRC Operations Center (301-816-5100), by telephone, when—

(1) Removable radioactive surface contamination exceeds the limits of § 71.87(i) of this chapter; or

(2) External radiation levels exceed the limits of § 71.47 of this chapter.

(e) Each licensee shall—

(1) Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

(2) Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(f) Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of paragraph (b) of this section, but are not exempt from the survey requirement in paragraph (b) of this section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

[56 FR 23401, May 21, 1991, as amended at 57 FR 39357, Aug. 31, 1992; 60 FR 20185, Apr. 25, 1995; 63 FR 39482, July 23, 1998]

[3a] Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

Subpart K--Waste Disposal

Source: 56 FR 23403, May 21, 1991, unless otherwise noted.

§ 20.2001 General requirements.

(a) A licensee shall dispose of licensed material only--

(1) By transfer to an authorized recipient as provided in § 20.2006 or in the regulations in parts 30, 40, 60, 61, 63, 70, and 72 of this chapter;

(2) By decay in storage; or

(3) By release in effluents within the limits in § 20.1301; or

(4) As authorized under §§ 20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.

(b) A person must be specifically licensed to receive waste containing licensed material from other persons for:

(1) Treatment prior to disposal; or

(2) Treatment or disposal by incineration; or

(3) Decay in storage; or

(4) Disposal at a land disposal facility licensed under part 61 of this chapter; or

(5) Disposal at a geologic repository under part 60 or part 63 of this chapter.

[56 FR 23403, May 21, 1991, as amended at 66 FR 55789, Nov. 2, 2001; 72 FR 55922, Oct. 1, 2007]

§ 20.2002 Method for obtaining approval of proposed disposal procedures.

A licensee or applicant for a license may apply to the Commission for approval of proposed procedures, not otherwise authorized in the regulations in this chapter, to dispose of licensed material generated in the licensee's activities. Each application shall include:

(a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; and

(b) An analysis and evaluation of pertinent information on the nature of the environment; and

(c) The nature and location of other potentially affected licensed and unlicensed facilities; and

(d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this part.

§ 20.2003 Disposal by release into sanitary sewerage.

(a) A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

(1) The material is readily soluble (or is readily dispersible biological material) in water; and

(2) The quantity of licensed or other radioactive material that the licensee releases into the sewer in 1 month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in table 3 of appendix B to part 20; and

(3) If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction of the limit in table 3 of appendix B to part 20 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in table 3 of appendix B to part 20; and

(ii) The sum of the fractions for each radionuclide required by paragraph (a)(3)(i) of this section does not exceed unity; and

(4) The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies (185 GBq) of hydrogen-3, 1 curie (37 GBq) of carbon-14, and 1 curie (37 GBq) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in paragraph (a) of this section.

[56 FR 23403, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995]

§ 20.2004 Treatment or disposal by incineration.

(a) A licensee may treat or dispose of licensed material by incineration only:

(1) As authorized by paragraph (b) of this section; or

(2) If the material is in a form and concentration specified in § 20.2005; or

(3) As specifically approved by the Commission pursuant to § 20.2002.

(b) (1) Waste oils (petroleum derived or synthetic oils used principally as lubricants, coolants, hydraulic or insulating fluids, or metalworking oils) that have been radioactively contaminated in the course of the operation or maintenance of a nuclear power reactor licensed under part 50 of this chapter may be incinerated on the site where generated provided that the total radioactive effluents from the facility, including the effluents from such incineration, conform to the requirements of appendix I to part 50 of this chapter and the effluent release limits contained in applicable license conditions other than effluent limits specifically related to incineration of waste oil. The licensee shall report any changes or additions to the information supplied under §§ 50.34 and 50.34a of this chapter associated with this incineration pursuant to § 50.71 of this chapter, as appropriate. The licensee shall also follow the procedures of § 50.59 of this chapter with respect to such changes to the facility or procedures.

(2) Solid residues produced in the process of incinerating waste oils must be disposed of as provided by § 20.2001.

(3) The provisions of this section authorize onsite waste oil incineration under the terms of this section and supersede any provision in an individual plant license or technical specification that may be inconsistent.

[57 FR 57656, Dec. 7, 1992]

§ 20.2005 Disposal of specific wastes.

(a) A licensee may dispose of the following licensed material as if it were not radioactive:

(1) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

(2) 0.05 microcurie (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee may not dispose of tissue under paragraph (a)(2) of this section in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records in accordance with § 20.2108.

§ 20.2006 Transfer for disposal and manifests.

(a) The requirements of this section and appendix G to 10 CFR Part 20 are designed to--

(1) Control transfers of low-level radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this part, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility (as defined in Part 61 of this chapter);

(2) Establish a manifest tracking system; and

(3) Supplement existing requirements concerning transfers and recordkeeping for those wastes.

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to 10 CFR Part 20.

(c) Each shipment manifest must include a certification by the waste generator as specified in section II of appendix G to 10 CFR Part 20.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of appendix G to 10 CFR Part 20.

(e) Any licensee shipping byproduct material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.

[63 FR 50128, Sept. 21, 1998; 72 FR 55922, Oct. 1, 2007]

§ 20.2007 Compliance with environmental and health protection regulations.

Nothing in this subpart relieves the licensee from complying with other applicable Federal, State, and local regulations

governing any other toxic or hazardous properties of materials that may be disposed of under this subpart.

§ 20.2008 Disposal of certain byproduct material.

(a) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in §20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low-level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of § 20.2006.

(b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

[72 FR 55922, Oct. 1, 2007]

Subpart L--Records

Source: 56 FR 23404, May 21, 1991, unless otherwise noted.

§ 20.2101 General provisions.

(a) Each licensee shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.

(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

(c) Not withstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in § 20.2006(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph (a) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

[56 FR 23404, May 21, 1991, as amended at 60 FR 15663, Mar. 27, 1995; 63 FR 39483, July 23, 1998]

§ 20.2102 Records of radiation protection programs.

(a) Each licensee shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

§ 20.2103 Records of surveys.

(a) Each licensee shall maintain records showing the results of surveys and calibrations required by §§ 20.1501 and 20.1906(b). The licensee shall retain these records for 3 years after the record is made.

(b) The licensee shall retain each of the following records until the Commission terminates each pertinent license requiring the record:

(1) Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents. This includes those records of results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents required under the standards for protection against radiation in effect prior to January 1, 1994; and

(2) Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose. This includes those records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose required under the standards for protection against radiation in effect prior to January 1, 1994; and

(3) Records showing the results of air sampling, surveys, and bioassays required pursuant to § 20.1703(c)(1) and (2). This includes those records showing the results of air sampling, surveys, and bioassays required under the standards for protection against radiation in effect prior to January 1, 1994; and

(4) Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment. This includes those records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20185, Apr. 25, 1995; 66 FR 64737, Dec. 14, 2001]

§ 20.2104 Determination of prior occupational dose.

(a) For each individual who is likely to receive an annual occupational dose requiring monitoring under § 20.1502, the licensee shall determine the occupational radiation dose received during the current year.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee shall determine—

(1) The internal and external doses from all previous planned special exposures; and

(2) All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

(c) In complying with the requirements of paragraphs (a) or (b) of this section, a licensee may—

(1) Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

(2) Accept, as the record of cumulative radiation dose, an up-to-date NRC Form 4, or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee); and

(3) Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee) by telephone, telegram, electronic media, or letter. The licensee shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d) The licensee shall record the exposure history of each individual, as required by paragraphs (a) or (b) of this section, on NRC Form 4, or other clear and legible record, including all of the information required by NRC Form 4.[4] The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee obtains reports, the licensee shall use the dose shown in the report in preparing the NRC Form 4. For any period in which the licensee does not obtain a report, the licensee shall place a notation on the NRC Form 4 indicating the periods of time for which data are not available.

(e) If the licensee is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee shall assume—

(1) In establishing administrative controls under § 20.1201(f) for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

(2) That the individual is not available for planned special exposures.

(f) The licensee shall retain the records on NRC Form 4 or equivalent until the Commission terminates each pertinent license requiring this record. The licensee shall retain records used in preparing NRC Form 4 for 3 years after the record is made. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 57 FR 57878, Dec. 8, 1992; 60 FR 20186, Apr. 25, 1995; 60 FR 36043, July 13, 1995; 72 FR 68059, Dec. 4, 2007]

[4] Licensees are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). Further, occupational exposure histories obtained and recorded on NRC Form 4 before January 1, 1994, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

§ 20.2105 Records of planned special exposures.

(a) For each use of the provisions of § 20.1206 for planned special exposures, the licensee shall maintain records that describe--

(1) The exceptional circumstances requiring the use of a planned special exposure; and

(2) The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

(3) What actions were necessary; and

(4) Why the actions were necessary; and

(5) How doses were maintained ALARA; and

(6) What individual and collective doses were expected to result, and the doses actually received in the planned special exposure.

(b) The licensee shall retain the records until the Commission terminates each pertinent license requiring these records.

§ 20.2106 Records of individual monitoring results.

(a) *Recordkeeping requirement*. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records[5] must include, when applicable—

(1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

(2) The estimated intake of radionuclides (see § 20.1202);

(3) The committed effective dose equivalent assigned to the intake of radionuclides;

(4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;

(5) The total effective dose equivalent when required by § 20.1202; and

(6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) *Recordkeeping frequency*. The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(c) *Recordkeeping format*. The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

(d) *Privacy protection*. The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR part 9.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(f) The licensee shall retain the required form or record until the Commission terminates each pertinent license requiring this record. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 63 FR 39483, July 23, 1998]

[5] Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this part need not be changed.

§ 20.2107 Records of dose to individual members of the public.

(a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see § 20.1301).

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.

§ 20.2108 Records of waste disposal.

(a) Each licensee shall maintain records of the disposal of licensed materials made under §§ 20.2002, 20.2003, 20.2004, 20.2005, 10 CFR part 61 and disposal by burial in soil, including burials authorized before January 28, 1981.[6]

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record. Requirements for disposition of these records, prior to license termination, are located in §§ 30.51, 40.61, 70.51, and 72.80 for activities licensed under these parts.

[56 FR 23404, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 61 FR 24673, May 16, 1996]

[6] A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization.

§ 20.2109 [Reserved]

§ 20.2110 Form of records.

Each record required by this part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Subpart M--Reports

Source: 56 FR 23406, May 21, 1991, unless otherwise noted.

§ 20.2201 Reports of theft or loss of licensed material.

(a) *Telephone reports.* (1) Each licensee shall report by telephone as follows:

(i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or

(ii) Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in appendix C to part 20 that is still missing at this time.

(2) Reports must be made as follows:

(i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter, and

(ii) All other licensees shall make reports by telephone to the NRC Operations Center (301)-816-5100.

(b) *Written reports*. (1) Each licensee required to make a report under paragraph (a) of this section shall, within 30 days after making the telephone report, make a written report setting forth the following information:

(i) A description of the licensed material involved, including kind, quantity, and chemical and physical form; and

(ii) A description of the circumstances under which the loss or theft occurred; and

(iii) A statement of disposition, or probable disposition, of the licensed material involved; and

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective

dose equivalent to persons in unrestricted areas; and

(v) Actions that have been taken, or will be taken, to recover the material; and

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(2) Reports must be made as follows:

(i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and

(ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§ 30.55(c), 37.57, 37.81, 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vii), 73.67(g)(3)(iii), 73.71, or 150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

[56 FR 23406, May 21, 1991, as amended at 58 FR 69220, Dec. 30, 1993; 60 FR 20186, Apr. 25, 1995; 66 FR 64738, Dec. 14, 2001; 67 FR 3585, Jan. 25, 2002; 78 FR 17006, Mar. 19, 2013]

§ 20.2202 Notification of incidents.

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(a) Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause any of the following conditions--

(1) An individual to receive--

(i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

(ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or

(iii) A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(b) Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:

(1) An individual to receive, in a period of 24 hours--

(i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or

(ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or

(iii) A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or

(2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(c) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who have received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with 10 CFR 50.72; and

(2) All other licensees shall make the reports required by paragraphs (a) and (b) of this section by telephone to the NRC

Operations Center (301) 816-5100.

(e) The provisions of this section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under § 20.2204.

[56 FR 23406, May 21, 1991, as amended at 56 FR 40766, Aug. 16, 1991; 57 FR 57879, Dec. 8, 1992; 59 FR 14086, Mar. 25, 1994; 63 FR 39483, July 23, 1998]

§ 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

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(a) *Reportable events*. In addition to the notification required by § 20.2202, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

(1) Any incident for which notification is required by § 20.2202; or

(2) Doses in excess of any of the following:

(i) The occupational dose limits for adults in § 20.1201; or

(ii) The occupational dose limits for a minor in § 20.1207; or

(iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or

(iv) The limits for an individual member of the public in § 20.1301; or

(v) Any applicable limit in the license; or

(vi) The ALARA constraints for air emissions established under § 20.1101(d); or

(3) Levels of radiation or concentrations of radioactive material in—

(i) A restricted area in excess of any applicable limit in the license; or

(ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in § 20.1301); or

(4) For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) *Contents of reports*. (1) Each report required by paragraph (a) of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

(2) Each report filed pursuant to paragraph (a) of this section must include for each occupationally overexposed[1] individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."

(c) For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section.

(d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

[56 FR 23406, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995; 61 FR 65127, Dec. 10, 1996; 68 FR 14309, Mar. 25, 2003; 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 72 FR 49486, Aug. 28, 2007; 74 FR 62680, Dec. 1, 2009; 80 FR 74979, Dec. 1, 2015]

[1] With respect to the limit for the embryo-fetus (§ 20.1208), the identifiers should be those of the declared pregnant woman.

§ 20.2204 Reports of planned special exposures.

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The licensee shall submit a written report to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20 within 30 days following any planned special exposure conducted in accordance with § 20.1206, informing the Commission that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by § 20.2105.

[56 FR 23406, May 21, 1991, as amended at 60 FR 20186, Apr. 25, 1995]

440.250 [Amended]

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§ 20.2205 Reports to individuals of exceeding dose limits.

When a licensee is required by §§ 20.2203 or 20.2204 to report to the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to Commission. This report must be transmitted no later than the transmittal to the Commission.

[60 FR 36043, July 13, 1995; 72 FR 68059, Dec. 4, 2007]

§ 20.2206 Reports of individual monitoring.

[Top of File]

(a) This section applies to each person licensed by the Commission to--

(1) Operate a nuclear reactor designed to produce electrical or heat energy pursuant to § 50.21(b) or § 50.22 of this chapter or a testing facility as defined in § 50.2 of this chapter; or

(2) Possess or use byproduct material for purposes of radiography pursuant to Parts 30 and 34 of this chapter; or

(3) Possess or use at any one time, for purposes of fuel processing, fabricating, or reprocessing, special nuclear material in a quantity exceeding 5,000 grams of contained uranium-235, uranium-233, or plutonium, or any combination thereof pursuant to part 70 of this chapter; or

(4) Possess high-level radioactive waste at a geologic repository operations area pursuant to part 60 or 63 of this chapter; or

(5) Possess spent fuel in an independent spent fuel storage installation (ISFSI) pursuant to part 72 of this chapter; or

(6) Receive radioactive waste from other persons for disposal under part 61 of this chapter; or

(7) Possess or use at any time, for processing or manufacturing for distribution pursuant to parts 30, 32, 33 or 35 of this chapter, byproduct material in quantities exceeding any one of the following quantities:

Radionuclide	Quantity of radionuclide[1] in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Promethium-147	10
Technetium-99m	1,000

[1] The Commission may require as a license condition, or by rule, regulation, or order pursuant to § 20.2302, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

(b) Each licensee in a category listed in paragraph (a) of this section shall submit an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by § 20.1502 during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use Form NRC 5 or electronic media containing all the information required by Form NRC 5.

(c) The licensee shall file the report required by § 20.2206(b), covering the preceding year, on or before April 30 of each year. The licensee shall submit the report to the REIRS Project Manager by an appropriate method listed in § 20.1007 or via the REIRS Web site at *http://www.reirs.com*.

[56 FR 23406, May 21, 1991, as amended at 56 FR 32072, July 15, 1991; 66 FR 5578, Nov. 2, 2001; 68 FR 58802, Oct. 10, 2003]

§ 20.2207 Reports of transactions involving nationally tracked sources.

[Top of File]

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source;

(4) The radioactive material in the source;

(5) The initial source strength in becquerels (curies) at the time of manufacture; and

(6) The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name and license number of the recipient facility and the shipping address;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The shipping date;

(9) The estimated arrival date; and

(10) For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The name, address, and license number of the person that provided the source;

(4) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(5) The radioactive material in the source;

(6) The initial or current source strength in becquerels (curies);

(7) The date for which the source strength is reported;

(8) The date of receipt; and

(9) For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the source;

(5) The initial or current source strength in becquerels (curies);

(6) The date for which the source strength is reported;

(7) The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The waste manifest number;

(4) The container identification with the nationally tracked source.

(5) The date of disposal; and

(6) The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

(1) The on-line National Source Tracking System;

(2) Electronically using a computerreadable format;

(3) By facsimile;

(4) By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

(5) By telephone with followup by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 nationally tracked sources shall report its initial inventory of Category 1 nationally tracked sources to the National Source Tracking System by January 31, 2009. Each licensee that possesses Category 2 nationally tracked sources shall report its initial inventory of Category 2 nationally tracked sources to the National Source Tracking System by January 31, 2009. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this section. The initial inventory report must include the following information:

(1) The name, address, and license number of the reporting licensee;

(2) The name of the individual preparing the report;

(3) The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

(4) The radioactive material in the sealed source;

(5) The initial or current source strength in becquerels (curies); and

(6) The date for which the source strength is reported.

[72 FR 59163, Oct. 19, 2007]

Subpart N--Exemptions and Additional Requirements

[Top of File]

Source: 56 FR 23408, May 21, 1991, unless otherwise noted.

§ 20.2301 Applications for exemptions.

The Commission may, upon application by a licensee or upon its own initiative, grant an exemption from the requirements of the regulations in this part if it determines the exemption is authorized by law and would not result in undue hazard to life or property.

§ 20.2302 Additional requirements.

[Top of File]

The Commission may, by rule, regulation, or order, impose requirements on a licensee, in addition to those established in the regulations in this part, as it deems appropriate or necessary to protect health or to minimize danger to life or property.

Subpart O—Enforcement

[Top of File]

§ 20.2401 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107 or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section; and

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

[56 FR 23408, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 55071, Nov. 24, 1992]

§ 20.2402 Criminal penalties.

[Top of File]

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in §§ 20.1001 through 20.2402 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) this section.

(b) The regulations in §§ 20.1001 through 20.2402 that are not issued under Sections 161b, 161i, or 161o for the purposes

of Section 223 are as follows: §§ 20.1001, 20.1002, 20.1003, 20.1004, 20.1005, 20.1006, 20.1007, 20.1008, 20.1009, 20.1405, 20.1704, 20.1903, 20.1905, 20.2002, 20.2007, 20.2301, 20.2302, 20.2401, and 20.2402.

[57 FR 55071, Nov. 24, 1992]

Appendix A to Part 20—Assigned Protection Factors for Respirators[a]

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	Operating mode	Assigned Protection Factors
I. Air Purifying Respirators [Particulate[b] only][c]:		
Filtering facepiece disposable[d]	Negative Pressure	([d])
Facepiece, half [e]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirators	1000
Helmet/hood	Powered air-purifying respirators	1000
Facepiece, loose-fitting	Powered air-purifying respirators	25
II. Atmosphere supplying respirators [particulate, gases and vapors[f]]:		
1. Air-line respirator:		
Facepiece, half	Demand	10
Facepiece, half	Continuous Flow	50
Facepiece, half	Pressure Demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous Flow	1000
Facepiece, full	Pressure Demand	1000
Helmet/hood	Continuous Flow	1000
Facepiece, loose-fitting	Continuous Flow	25
Suit	Continuous Flow	([g])
2. Self-contained breathing Apparatus (SCBA):		
Facepiece, full	Demand	[h]100
Facepiece, full	Pressure Demand	[i]10,000
Facepiece, full	Demand, Recirculating	[h]100
Facepiece, full	Positive Pressure Recirculating	[i]10,000
III. Combination Respirators:		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above.	

[a] These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Part. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B to Part 20 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b] Air purifying respirators with APF <100 must be equipped with particulate filters that are at least 95 percent efficient. Air

purifying respirators with APF = 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs >100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the Commission for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user seal check on this type of device. All other respiratory protection program requirements listed in § 20.1703 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e] Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of this Part are met.

[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., § 20.1703).

[h] The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

[64 FR 54558, Oct. 7, 1999; 64 FR 55524, Oct. 13, 1999]

Appendix B to Part 20—Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

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[**List of Radionuclides** - Note: Each radionuclide page contains Tables 1, 2, and 3 for that radionuclide.]

Introduction

For each radionuclide Table 1 indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 μm and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times of less than 10 days for D, for W from 10 to 100 days, and for Y greater than 100 days. The class (D, W, or Y) given in the column headed "Class" applies only to the inhalation ALIs and DACs given in Table 1, columns 2 and 3. Table 2 provides concentration limits for airborne and liquid effluents released to the general environment. Table 3 provides concentration limits for discharges to sanitary sewer systems.

Notation

The values in Tables 1, 2, and 3 are presented in the computer "E" notation. In this notation a value of 6E–02 represents a value of $6x10^{-2}$ or 0.06, 6E+2 represents $6x10^{2}$ or 600, and 6E+0 represents $6x10^{0}$ or 6.

Table 1 "Occupational Values"

Note that the columns in Table 1, of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of a given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 5 rems (stochastic ALI) or (2) a committed dose equivalent of 50 rems to an organ or

tissue (non-stochastic ALI). The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 5 rems. The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in § 20.1003. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of w_T=0.06 is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following parts of the GI tract—stomach, small intestine, upper large intestine, and lower large intestine—are to be treated as four separate organs.

Note that the dose equivalents for extremities (hands and forearms, feet and lower legs), skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone, is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. (Abbreviated organ or tissue designations are used: LLI wall = lower large intestine wall; St. wall = stomach wall; Blad wall = bladder wall; and Bone surf = bone surface.)

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 50-rem dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose to that organ (not the effective dose). For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the non-stochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity (i.e., Σ (intake (in μCi) of each radionuclide/ALI_{ns}) < 1.0). If there is an external deep dose equivalent contribution of H_d then this sum must be less than 1 – (H_d/50) instead of being < 1.0.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by: DAC=ALI(in μCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute)=[ALI/2.4x10^9] μCi/ml, where 2x10^4 ml is the volume of air breathed per minute at work by "Reference Man" under working conditions of "light work."

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. Derived air concentrations based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values relate to exposure to the single radionuclide named, but also include contributions from the in-growth of any daughter radionuclide produced in the body by the decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The value of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external radiation (see § 20.1202). When an individual is exposed to radioactive materials which fall under several of the translocation classifications (i.e., Class D, Class W, or Class Y) of the same radionuclide, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radioisotopes. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table 2 "Effluent Concentrations"

The columns in Table 2 of this appendix captioned "Effluents," "Air," and "Water," are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of § 20.1302. The concentration values given in Columns 1 and 2 of Table 2 are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.05 rem (50 millirem or 0.5 millisieverts).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table 2. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in appendix B to §§ 20.1-20.601.

The air concentration values listed in Table 2, Column 1, were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4 x 10^9ml, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 5-rem annual occupational dose limit to the 0.1-rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values (derived for adults) so that they are applicable to other age groups.

For those radionuclides for which submersion (external dose) is limiting, the occupational DAC in Table 1, Column 3, was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of "Reference Man."

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings (including occupational inhalation ALIs and DACs, air and water effluent concentrations and sewerage) require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded either from knowledge of the radionuclide composition of the source or from actual measurements.

Table 3 "Releases to Sewers"

The monthly average concentrations for release to sanitary sewers are applicable to the provisions in § 20.2003. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6(ml). The factor of 7.3×10^6(ml) is composed of a factor of 7.3×10^5(ml), the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a reference man during a year, would result in a committed effective dose equivalent of 0.5 rem.

List of Elements

Name	Atomic	
	Symbol	No.
Actinium	Ac	89
Aluminium	Al	13
Americium	Am	95
Antimony	Sb	51
Argon	Ar	18
Arsenic	As	33
Astatine	At	85
Barium	Ba	56
Berkelium	Bk	97
Beryllium	Be	4
Bismuth	Bi	83
Bromine	Br	35
Cadmium	Cd	48
Calcium	Ca	20
Californium	Cf	98
Carbon	C	6
Cerium	Ce	58
Cesium	Cs	55
Chlorine	Cl	17
Chromium	Cr	24
Cobalt	Co	27
Copper	Cu	29
Curium	Cm	96
Dysprosium	Dy	66
Einsteinium	Es	99
Erbium	Er	68
Europium	Eu	63
Femium	Fm	100

Fluorine	F	9
Francium	Fr	87
Gadolinium	Gd	64
Gallium	Ga	31
Germanium	Ge	32
Gold	Au	79
Hafniim	Hf	72
Holmium	Ho	67
Hydrogen	H	1
Indium	In	49
Iodine	I	53
Iridium	Ir	77
Iron	Fe	26
Krypton	Kr	36
Lanthanum	La	57
Lead	Pb	82
Lutetium	Lu	71
Magnesium	Mg	12
Manganese	Mn	25
Mendelevium	Md	101
Mercury	Hg	80
Molybdenum	Mo	42
Neodymium	Nd	60
Neptunium	Np	93
Nickel	Ni	28
Niobium	Nb	41
Nitrogen	N	7
Osmium	Os	76
Oxygen	O	8
Palladium	Pd	46
Phosphorus	P	15
Platinum	Pt	78
Plutonium	Pu	94
Polonium	Po	84
Potassium	K	19
Praseodymium	Pr	59
Promethium	Pm	61
Protactinium	Pa	91
Radium	Ra	88
Radon	Rn	86
Rhenium	Re	75
Rhodium	Rh	45
Rubidium	Rb	37
Ruthenium	Ru	44
Samarium	Sm	62
Scandium	Sc	21
Selenium	Se	34

Silicon	Si	14
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantaium	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Yterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30
Zirconium	Zr	40

[56 FR 23409, May 21, 1991; 56 FR 61352, Dec. 3, 1991, as amended at 57 FR 57879, Dec. 8, 1992. Redesignated at 58 FR 67659, Dec. 22, 1993; 71 FR 15007, Mar. 27, 2006; 72 FR 55922, Oct. 1, 2007; 75 FR 73938, Nov. 30, 2010]

Appendix C to Part 20—Quantities[1] of Licensed Material Requiring Labeling

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Radionuclide	Abbreviation	Quantity (μCi)
Hydrogen-3	H-3	1,000
Beryllium-7	Be-7	1,000
Beryllium-10	Be-10	1
Carbon-11	C-11	1,000
Carbon-14	C-14	100
Fluorine-18	F-18	1,000
Sodium-22	Na-22	10
Sodium-24	Na-24	100
Magnesium-28	Mg-28	100
Aluminum-26	Al-26	10
Silicon-31	Si-31	1,000
Silicon-32	Si-32	1
Phosphorus-32	P-32	10
Phosphorus-33	P-33	100
Sulfur-35	S-35	100
Chlorine-36	Cl-36	10
Chlorine-38	Cl-38	1,000
Chlorine-39	Cl-39	1,000

Argon-39	Ar-39	1,000
Argon-41	Ar-41	1,000
Potassium-40	K-40	100
Potassium-42	K-42	1,000
Potassium-43	K-43	1,000
Potassium-44	K-44	1,000
Potassium-45	K-45	1,000
Calcium-41	Ca-41	100
Calcium-45	Ca-45	100
Calcium-47	Ca-47	100
Scandium-43	Sc-43	1,000
Scandium-44m	Sc-44m	100
Scandium-44	Sc-44	100
Scandium-46	Sc-46	10
Scandium-47	Sc-47	100
Scandium-48	Sc-48	100
Scandium-49	Sc-49	1,000
Titanium-44	Ti-44	1
Titanium-45	Ti-45	1,000
Vanadium-47	V-47	1,000
Vanadium-48	V-48	100
Vanadium-49	V-49	1,000
Chromium-48	Cr-48	1,000
Chromium-49	Cr-49	1,000
Chromium-51	Cr-51	1,000
Manganese-51	Mn-51	1,000
Manganese-52m	Mn-52m	1,000
Manganese-52	Mn-52	100
Manganese-53	Mn-53	1,000
Manganese-54	Mn-54	100
Manganese-56	Mn-56	1,000
Iron-52	Fe-52	100
Iron-55	Fe-55	100
Iron-59	Fe-59	10
Iron-60	Fe-60	1
Cobalt-55	Co-55	100
Cobalt-56	Co-56	10
Cobalt-57	Co-57	100
Cobalt-58m	Co-58m	1,000
Cobalt-58	Co-58	100
Cobalt-60m	Co-60m	1,000
Cobalt-60	Co-60	1
Cobalt-61	Co-61	1,000
Cobalt-62m	Co-62m	1,000
Nickel-56	Ni-56	100
Nickel-57	Ni-57	100

Nickel-59	Ni-59	100
Nickel-63	Ni-63	100
Nickel-65	Ni-65	1,000
Nickel-66	Ni-66	10
Copper-60	Cu-60	1,000
Copper-61	Cu-61	1,000
Copper-64	Cu-64	1,000
Copper-67	Cu-67	1,000
Zinc-62	Zn-62	100
Zinc-63	Zn-63	1,000
Zinc-65	Zn-65	10
Zinc-69m	Zn-69m	100
Zinc-69	Zn-69	1,000
Zinc-71m	Zn-71m	1,000
Zinc-72	Zn-72	100
Gallium-65	Ga-65	1,000
Gallium-66	Ga-66	100
Gallium-67	Ga-67	1,000
Gallium-68	Ga-68	1,000
Gallium-70	Ga-70	1,000
Gallium-72	Ga-72	100
Gallium-73	Ga-73	1,000
Germanium-66	Ge-66	1,000
Germanium-67	Ge-67	1,000
Germanium-68	Ge-68	10
Germanium-69	Ge-69	1,000
Germanium-71	Ge-71	1,000
Germanium-75	Ge-75	1,000
Germanium-77	Ge-77	1,000
Germanium-78	Ge-78	1,000
Arsenic-69	As-69	1,000
Arsenic-70	As-70	1,000
Arsenic-71	As-71	100
Arsenic-72	As-72	100
Arsenic-73	As-73	100
Arsenic-74	As-74	100
Arsenic-76	As-76	100
Arsenic-77	As-77	100
Arsenic-78	As-78	1,000
Selenium-70	Se-70	1,000
Selenium-73m	Se-73m	1,000
Selenium-73	Se-73	100
Selenium-75	Se-75	100
Selenium-79	Se-79	100
Selenium-81m	Se-81m	1,000
Selenium-81	Se-81	1,000
Selenium-83	Se-83	1,000

Bromine-74m	Br-74m	1,000
Bromine-74	Br-74	1,000
Bromine-75	Br-75	1,000
Bromine-76	Br-76	100
Bromine-77	Br-77	1,000
Bromine-80m	Br-80m	1,000
Bromine-80	Br-80	1,000
Bromine-82	Br-82	100
Bromine-83	Br-83	1,000
Bromine-84	Br-84	1,000
Krypton-74	Kr-74	1,000
Krypton-76	Kr-76	1,000
Krypton-77	Kr-77	1,000
Krypton-79	Kr-79	1,000
Krypton-81	Kr-81	1,000
Krypton-83m	Kr-83m	1,000
Krypton-85m	Kr-85m	1,000
Krypton-85	Kr-85	1,000
Krypton-87	Kr-87	1,000
Krypton-88	Kr-88	1,000
Rubidium-79	Rb-79	1,000
Rubidium-81m	Rb-81m	1,000
Rubidium-81	Rb-81	1,000
Rubidium-82m	Rb-82m	1,000
Rubidium-83	Rb-83	100
Rubidium-84	Rb-84	100
Rubidium-86	Rb-86	100
Rubidium-87	Rb-87	100
Rubidium-88	Rb-88	1,000
Rubidium-89	Rb-89	1,000
Strontium-80	Sr-80	100
Strontium-81	Sr-81	1,000
Strontium-83	Sr-83	100
Strontium-85m	Sr-85m	1,000
Strontium-85	Sr-85	100
Strontium-87m	Sr-87m	1,000
Strontium-89	Sr-89	10
Strontium-90	Sr-90	0.1
Strontium-91	Sr-91	100
Strontium-92	Sr-92	100
Yttrium-86m	Y-86m	1,000
Yttrium-86	Y-86	100
Yttrium-87	Y-87	100
Yttrium-88	Y-88	10
Yttrium-90m	Y-90m	1,000
Yttrium-90	Y-90	10

Yttrium-91m	Y-91m	1,000
Yttrium-91	Y-91	10
Yttrium-92	Y-92	100
Yttrium-93	Y-93	100
Yttrium-94	Y-94	1,000
Yttrium-95	Y-95	1,000
Zirconium-86	Zr-86	100
Zirconium-88	Zr-88	10
Zirconium-89	Zr-89	100
Zirconium-93	Zr-93	1
Zirconium-95	Zr-95	10
Zirconium-97	Zr-97	100
Niobium-88	Nb-88	1,000
Niobium-89m (66 min)	Nb-89m	1,000
Niobium-89 (122 min)	Nb-89	1,000
Niobium-89	Nb-89	1,000
Niobium-90	Nb-90	100
Niobium-93m	Nb-93m	10
Niobium-94	Nb-94	1
Niobium-95m	Nb-95m	100
Niobium-95	Nb-95	100
Niobium-96	Nb-96	100
Niobium-97	Nb-97	1,000
Niobium-98	Nb-98	1,000
Molybdenum-90	Mo-90	100
Molybdenum-93m	Mo-93m	100
Molybdenum-93	Mo-93	10
Molybdenum-99	Mo-99	100
Molybdenum-101	Mo-101	1,000
Technetium-93m	Tc-93m	1,000
Technetium-93	Tc-93	1,000
Technetium-94m	Tc-94m	1,000
Technetium-94	Tc-94	1,000
Technetium-96m	Tc-96	1,000
Technetium-96	Tc-96	100
Technetium-97m	Tc-97m	100
Technetium-97	Tc-97	1,000
Technetium-98	Tc-98	10
Technetium-99m	Tc-99m	1,000
Technetium-99	Tc-99	100
Technetium-101	Tc-101	1,000
Technetium-104	Tc-104	1,000
Ruthenium-94	Ru-94	1,000
Ruthenium-97	Ru-97	1,000
Ruthenium-103	Ru-103	100
Ruthenium-105	Ru-105	1,000
Ruthenium-106	Ru-106	1

Rhodium-99m	Rh-99m	1,000
Rhodium-99	Rh-99	100
Rhodium-100	Rh-100	100
Rhodium-101m	Rh-101m	1,000
Rhodium-101	Rh-101	10
Rhodium-102m	Rh-102m	10
Rhodium-102	Rh-102	10
Rhodium-103m	Rh-103m	1,000
Rhodium-105	Rh-105	100
Rhodium-106m	Rh-106m	1,000
Rhodium-107	Rh-107	1,000
Palladium-100	Pd-100	100
Palladium-101	Pd-101	1,000
Palladium-103	Pd-103	100
Palladium-107	Pd-107	10
Palladium-109	Pd-109	100
Silver-102	Ag-102	1,000
Silver-103	Ag-103	1,000
Silver-104m	Ag-104m	1,000
Silver-104	Ag-104	1,000
Silver-105	Ag-105	100
Silver-106m	Ag-106m	100
Silver-106	Ag-106	1,000
Silver-108m	Ag-108m	1
Silver-110m	Ag-110m	10
Silver-111	Ag-111	100
Silver-112	Ag-112	100
Silver-115	Ag-115	1,000
Cadmium-104	Cd-104	1,000
Cadmium-107	Cd-107	1,000
Cadmium-109	Cd-109	1
Cadmium-113m	Cd-113m	0.1
Cadmium-113	Cd-113	100
Cadmium-115m	Cd-115m	10
Cadmium-115	Cd-115	100
Cadmium-117m	Cd-117m	1,000
Cadmium-117	Cd-117	1,000
Indium-109	In-109	1,000
Indium-110 (69.1 min.)	In-110	1,000
Indium-110 (4.9h)	In-110	1,000
Indium-111	In-111	100
Indium-112	In-112	1,000
Indium-113m	In-113m	1,000
Indium-114m	In-114m	10
Indium-115m	In-115m	1,000
Indium-115	In-115	100

Indium-116m	In-116m	1,000
Indium-117m	In-117m	1,000
Indium-117	In-117	1,000
Indium-119m	In-119m	1,000
Tin-110	Sn-110	100
Tin-111	Sn-111	1,000
Tin-113	Sn-113	100
Tin-117m	Sn-117m	100
Tin-119m	Sn-119m	100
Tin-121m	Sn-121m	100
Tin-121	Sn-121	1,000
Tin-123m	Sn-123m	1,000
Tin-123	Sn-123	10
Tin-125	Sn-125	10
Tin-126	Sn-126	10
Tin-127	Sn-127	1,000
Tin-128	Sn-128	1,000
Antimony-115	Sb-115	1,000
Antimony-116m	Sb-116m	1,000
Antimony-116	Sb-116	1,000
Antimony-117	Sb-117	1,000
Antimony-118m	Sb-118m	1,000
Antimony-119	Sb-119	1,000
Antimony-120 (16 min.)	Sb-120	1,000
Antimony-120 (5.76d)	Sb-120	100
Antimony-122	Sb-122	100
Antimony-124m	Sb-124m	1,000
Antimony-124	Sb-124	10
Antimony-125	Sb-125	100
Antimony-126m	Sb-126m	1,000
Antimony-126	Sb-126	100
Antimony-127	Sb-127	100
Antimony-128 (10.4 min.)	Sb-128	1,000
Antimony-128 (9.01h)	Sb-128	100
Antimony-129	Sb-129	100
Antimony-130	Sb-130	1,000
Antimony-131	Sb-131	1,000
Tellurium-116	Te-116	1,000
Tellurium-121m	Te-121m	10
Tellurium-121	Te-121	100
Tellurium-123m	Te-123m	10
Tellurium-123	Te-123	100
Tellurium-125m	Te-125m	10
Tellurium-127m	Te-127m	10
Tellurium-127	Te-127	1,000
Tellurium-129m	Te-129m	10
Tellurium-129	Te-129	1,000

Tellurium-131m	Te-131m	10
Tellurium-131	Te-131	100
Tellurium-132	Te-132	10
Tellurium-133m	Te-133m	100
Tellurium-133	Te-133	1,000
Tellurium-134	Te-134	1,000
Iodine-120m	I-120m	1,000
Iodine-120	I-120	100
Iodine-121	I-121	1,000
Iodine-123	I-123	100
Iodine-124	I-124	10
Iodine-125	I-125	1
Iodine-126	I-126	1
Iodine-128	I-128	1,000
Iodine-129	I-129	1
Iodine-130	I-130	10
Iodine-131	I-131	1
Iodine-132m	I-132m	100
Iodine-132	I-132	100
Iodine-133	I-133	10
Iodine-134	I-134	1,000
Iodine-135	I-135	100
Xenon-120	Xe-120	1,000
Xenon-121	Xe-121	1,000
Xenon-122	Xe-122	1,000
Xenon-123	Xe-123	1,000
Xenon-125	Xe-125	1,000
Xenon-127	Xe-127	1,000
Xenon-129m	Xe-129m	1,000
Xenon-131m	Xe-131m	1,000
Xenon-133m	Xe-133m	1,000
Xenon-133	Xe-133	1,000
Xenon-135m	Xe-135m	1,000
Xenon-135	Xe-135	1,000
Xenon-138	Xe-138	1,000
Cesium-125	Cs-125	1,000
Cesium-127	Cs-127	1,000
Cesium-129	Cs-129	1,000
Cesium-130	Cs-130	1,000
Cesium-131	Cs-131	1,000
Cesium-132	Cs-132	100
Cesium-134m	Cs-134m	1,000
Cesium-134	Cs-134	10
Cesium-135m	Cs-135m	1,000
Cesium-135	Cs-135	100
Cesium-136	Cs-136	10

Cesium-137	Cs-137	10
Cesium-138	Cs-138	1,000
Barium-126	Ba-126	1,000
Barium-128	B-128	100
Barium-131m	Ba-131m	1,000
Barium-131	Ba-131	100
Barium-133m	Ba-133m	100
Barium-133	Ba-133	100
Barium-135m	Ba-135m	100
Barium-139	Ba-139	1,000
Barium-140	Ba-140	100
Barium-141	Ba-141	1,000
Barium-142	Ba-142	1,000
Lanthanum-131	La-131	1,000
Lanthanum-132	La-132	100
Lanthanum-135	La-135	1,000
Lanthanum-137	La-137	10
Lanthanum-138	La-138	100
Lanthanum-140	La-140	100
Lanthanum-141	La-141	100
Lanthanum-142	La-142	1,000
Lanthanum-143	La-143	1,000
Cerium-134	Ce-134	100
Cerium-135	Ce-135	100
Cerium-137m	Ce-137m	100
Cerium-137	Ce-137	1,000
Cerium-139	Ce-139	100
Cerium-141	Ce-141	100
Cerium-143	Ce-143	100
Cerium-144	Ce-144	1
Praseodymium-136	Pr-136	1,000
Praseodymium-137	Pr-137	1,000
Praseodymium-138m	Pe-138m	1,000
Praseodymium-139	Pe-139	1,000
Praseodymium-142m	Pe-142m	1,000
Praseodymium-142	Pe-142	100
Praseodymium-143	Pe-143	100
Praseodymium-144	Pe-144	1,000
Praseodymium-145	Pe-145	100
Praseodymium-147	Pe-147	1,000
Neodymium-136	Nd-136	1,000
Neodymium-138	Nd-138	100
Neodymium-139m	Nd-139m	1,000
Neodymium-139	Nd-139	1,000
Neodymium-141	Nd-141	1,000
Neodymium-147	Nd-147	100
Neodymium-149	Nd-149	1,000

Neodymium-151	Nd-151	1,000
Promethium-141	Pm-141	1,000
Promethium-143	Pm-143	100
Promethium-144	Pm-144	10
Promethium-145	Pm-145	10
Promethium-146	Pm-146	1
Promethium-147	Pm-147	10
Promethium-148m	Pm-148m	10
Promethium-148	Pm-148	10
Promethium-149	Pm-149	100
Promethium-150	Pm-150	1,000
Promethium-151	Pm-151	100
Samarium-141m	Sm-141m	1,000
Samarium-141	Sm-141	1,000
Samarium-142	Sm-142	1,000
Samarium-145	Sm-145	100
Samarium-146	Sm-146	1
Samarium-147	Sm-147	100
Samarium-151	Sm-151	10
Samarium-153	Sm-153	100
Samarium-155	Sm-155	1,000
Samarium-156	Sm-156	1,000
Europium-145	Eu-145	100
Europium-146	Eu-146	100
Europium-147	Eu-147	100
Europium-148	Eu-148	10
Europium-149	Eu-149	100
Europium-150 (12.62h)	Eu-150	100
Europium-150 (34.2y)	Eu-150	1
Europium-152m	Eu-152m	100
Europium-152	Eu-152	1
Europium-154	Eu-154	1
Europium-155	Eu-155	10
Europium-156	Eu-156	100
Europium-157	Eu-157	100
Europium-158	Eu-158	1,000
Gadolinium-145	Gd-145	1,000
Gadolinium-146	Gd-146	10
Gadolinium-147	Gd-147	100
Gadolinium-148	Gd-148	0.001
Gadolinium-149	Gd-149	100
Gadolinium-151	Gd-151	10
Gadolinium-152	Gd-152	100
Gadolinium-153	Gd-153	10
Gadolinium-159	Gd-159	100
Terbium-147	Tb-147	1,000

Terbium-149	Tb-149	100
Terbium-150	Tb-150	1,000
Terbium-151	Tb-151	100
Terbium-153	Tb-153	1,000
Terbium-154	Tb-154	100
Terbium-155	Tb-155	1,000
Terbium-156m (5.0h)	Tb-156m	1,000
Terbium-156m (24.4h)	Tb-156m	1,000
Terbium-156	Tb-156	100
Terbium-157	Tb-157	10
Terbium-158	Tb-158	1
Terbium-160	Tb-160	10
Terbium-161	Tb-161	100
Dysprosium-155	Dy-155	1,000
Dysprosium-157	Dy-157	1,000
Dysprosium-159	Dy-159	100
Dysprosium-165	Dy-165	1,000
Dysprosium-166	Dy-166	100
Holmium-155	Ho-155	1,000
Holmium-157	Ho-157	1,000
Holmium-159	Ho-159	1,000
Holmium-161	Ho-161	1,000
Holmium-162m	Ho-162m	1,000
Holmium-162	Ho-162	1,000
Holmium-164m	Hp-164m	1,000
Holmium-164	Ho-164	1,000
Holmium-166m	Ho-166m	1
Holmium-166	Ho-166	100
Holmium-167	Ho-167	1,000
Erbium-161	Er-161	1,000
Erbium-165	Er-165	1,000
Erbium-169	Er-169	100
Erbium-171	Er-171	100
Erbium-172	Er-172	100
Thulium-162	Tm-162	1,000
Thulium-166	Tm-166	100
Thulium-167	Tm-167	100
Thulium-170	Tm-170	10
Thulium-171	Tm-171	10
Thulium-172	Tm-172	100
Thulium-173	Tm-173	100
Thulium-175	Tm-175	1,000
Ytterbium-162	Yb-162	1,000
Ytterbium-166	Yb-166	100
Ytterbium-167	Yb-167	1,000
Ytterbium-169	Yb-169	100
Ytterbium-175	Yb-175	100

Ytterbium-177	Yb-177	1,000
Ytterbium-178	Yb-178	1,000
Lutetium-169	Lu-169	100
Lutetium-170	Lu-170	100
Lutetium-171	Lu-171	100
Lutetium-172	Lu-172	100
Lutetium-173	Lu-173	10
Lutetium-174m	Lu-174m	10
Lutetium-174	Lu-174	10
Lutetium-176m	Lu-176m	1,000
Lutetium-176	Lu-176	100
Lutetium-177m	Lu-177m	10
Lutetium-177	Lu-177	100
Lutetium-178m	Lu-178m	1,000
Lutetium-178	Lu-178	1,000
Lutetium-179	Lu-179	1,000
Hafnium-170	Hf-170	100
Hafnium-172	Hf-172	1
Hafnium-173	Hf-173	1,000
Hafnium-175	Hf-175	100
Hafnium-177m	Hf-177m	1,000
Hafnium-178m	Hf-178m	0.1
Hafnium-179m	Hf-179m	10
Hafnium-180m	Hf-180m	1,000
Hafnium-181	Hf-181	10
Hafnium-182m	Hf-182m	1,000
Hafnium-182	Hf-182	0.1
Hafnium-183	Hf-183	1,000
Hafnium-184	Hf-184	100
Tantalum-172	Ta-172	1,000
Tantalum-173	Ta-173	1,000
Tantalum-174	Ta-174	1,000
Tantalum-175	Ta-175	1,000
Tantalum-176	Ta-176	100
Tantalum-177	Ta-177	1,000
Tantalum-178	Ta-178	1,000
Tantalum-179	Ta-179	100
Tantalum-180m	Ta-180m	1,000
Tantalum-180	Ta-180	100
Tantalum-182m	Ta-182m	1,000
Tantalum-182	Ta-182	10
Tantalum-183	Ta-183	100
Tantalum-184	Ta-184	100
Tantalum-185	Ta-185	1,000
Tantalum-186	Ta-186	1,000
Tungsten-176	W-176	1,000

Tungsten-177	W-177	1,000
Tungsten-178	W-178	1,000
Tungsten-179	W-179	1,000
Tungsten-181	W-181	1,000
Tungsten-185	W-185	100
Tungsten-187	W-187	100
Tungsten-188	W-188	10
Rhenium-177	Re-177	1,000
Rhenium-178	Re-178	1,000
Rhenium-181	Re-181	1,000
Rhenium-182 (12.7h)	Re-182	1,000
Rhenium-182 (64.0h)	Re-182	100
Rhenium-184m	Re-184m	10
Rhenium-184	Re-184	100
Rhenium-186m	Re-186m	10
Rhenium-186	Re-186	100
Rhenium-187	Re-187	1,000
Rhenium-188m	Re-188m	1,000
Rhenium-188	Re-188	100
Rhenium-189	Re-189	100
Osmium-180	Os-180	1,000
Osmium-181	Os-181	1,000
Osmium-182	Os-182	100
Osmium-185	Os-185	100
Osmium-189m	Os-189m	1,000
Osmium-191m	Os-191m	1,000
Osmium-191	Os-191	100
Osmium-193	Os-193	100
Osmium-194	Os-194	1
Iridium-182	Ir-182	1,000
Iridium-184	Ir-184	1,000
Iridium-185	Ir-185	1,000
Iridium-186	Ir-186	100
Iridium-187	Ir-187	1,000
Iridium-188	Ir-188	100
Iridium-189	Ir-189	100
Iridium-190m	Ir-190m	1,000
Iridium-190	Ir-190	100
Iridium-192 (73.8d)	Ir-192	1
Iridium-192m (1.4 min.)	Ir-192m	10
Iridium-194m	Ir-194m	10
Iridium-194	Ir-194	100
Iridium-195m	Ir-195m	1,000
Iridium-195	Ir-95	1,000
Platinum-186	Pt-186	1,000
Platinum-188	Pt-188	100
Platinum-189	Pt-189	1,000

Platinum-191	Pt-191	100
Platinum-193m	Pt-193m	100
Platinum-193	Pt-193	1,000
Platinum-195m	Pt-195m	100
Platinum-197m	Pt-197m	1,000
Platinum-197	Pt-197	100
Platinum-199	Pt-199	1,000
Platinum-200	Pt-200	100
Gold-193	Au-193	1,000
Gold-194	Au-194	100
Gold-195	Au-195	10
Gold-198m	Au-198m	100
Gold-198	Au-198	100
Gold-199	Au-199	100
Gold-200m	Au-200m	100
Gold-200	Au-200	1,000
Gold-201	Au-201	1,000
Mercury-193m	Hg-193m	100
Mercury-193	Hg-193	1,000
Mercury-194	Hg-194	1
Mercury-195m	Hg-195m	100
Mercury-195	Hg-195	1,000
Mercury-197m	Hg-197m	100
Mercury-197	Hg-197	1,000
Mercury-199m	Hg-199m	1,000
Mercury-203	Hg-203	100
Thallium-194m	Tl-194m	1,000
Thallium-194	Tl-194	1,000
Thallium-195	Tl-195	1,000
Thallium-197	Tl-197	1,000
Thallium-198m	Tl-198m	1,000
Thallium-198	Tl-198	1,000
Thallium-199	Tl-199	1,000
Thallium-200	Tl-200	1,000
Thallium-201	Tl-201	1,000
Thallium-202	Tl-202	100
Thallium-204	Tl-204	100
Lead-195m	Pb-195m	1,000
Lead-198	Pb-198	1,000
Lead-199	Pb-199	1,000
Lead-200	Pb-200	100
Lead-201	Pb-201	1,000
Lead-202m	Pb-202m	1,000
Lead-202	Pb-202	10
Lead-203	Pb-2023	1,000
Lead-205	Pb-205	100

Lead-209	Pb-209	1,000
Lead-210	Pb-210	0.01
Lead-211	Pb-211	100
Lead-212	Pb-212	1
Lead-214	Pb-214	100
Bismuth-200	Bi-200	1,000
Bismuth-201	Bi-201	1,000
Bismuth-202	Bi-202	1,000
Bismuth-203	Bi-203	100
Bismuth-205	Bi-205	100
Bismuth-206	Bi-206	100
Bismuth-207	Bi-207	10
Bismuth-210m	Bi-210m	0.1
Bismuth-210	Bi-210	1
Bismuth-212	Bi-212	10
Bismuth-213	Bi-213	10
Bismuth-214	Bi-214	100
Polonium-203	Po-203	1,000
Polonium-205	Po-205	1,000
Polonium-207	Po-207	1,000
Polonium-210	Po-210	0.1
Astatine-207	At-207	100
Astatine-211	At-211	10
Radon-220	Rn-220	1
Radon-222	Rn-222	1
Francium-222	Fr-222	100
Francium-223	Fr-223	100
Radium-223	Ra-223	0.1
Radium-224	Ra-224	0.1
Radium-225	Ra-225	0.1
Radium-226	Ra-226	0.1
Radium-227	Ra-227	1,000
Radium-228	Ra-228	0.1
Actinium-224	Ac-224	1
Actinium-225	Ac-225	0.01
Actinium-226	Ac-226	0.1
Actinium-227	Ac-227	0.001
Actinium-228	Ac-228	1
Thorium-226	Th-226	10
Thorium-227	Th-227	0.01
Thorium-228	Th-228	0.001
Thorium-229	Th-229	0.001
Thorium-230	Th-230	0.001
Thorium-231	Th-231	100
Thorium-232	Th-232	100
Thorium-234	Th-234	10
Thorium-natural		100

Protactinium-227	Pa-227	10
Protactinium-228	Pa-228	1
Protactinium-230	Pa-230	0.01
Protactinium-231	Pa-231	0.001
Protactinium-232	Pa-232	1
Protactinium-233	Pa-233	100
Protactinium-234	Pa-234	100
Uranium-230	U-230	0.01
Uranium-231	U-231	100
Uranium-232	U-232	0.001
Uranium-233	U-233	0.001
Uranium-234	U-234	0.001
Uranium-235	U-235	0.001
Uranium-236	U-236	0.001
Uranium-237	U-237	100
Uranium-238	U-238	100
Uranium-239	U-239	1,000
Uranium-240	U-240	100
Uranium-natural		100
Neptunium-232	Np-232	100
Neptunium-233	Np-233	1,000
Neptunium-234	Np-234	100
Neptunium-235	Np-235	100
Neptunium-236 ($1.15x10^5$y)	Np-236	0.001
Neptunium-236 (22.5h)	Np-236	1
Neptunium-237	Np-237	0.001
Neptunium-238	Np-238	10
Neptunium-239	Np-239	100
Neptunium-240	Np-240	1,000
Plutonium-234	Pu-234	10
Plutonium-235	Pu-235	1,000
Plutonium-236	Pu-236	0.001
Plutonium-237	Pu-237	100
Plutonium-238	Pu-238	0.001
Plutonium-239	Pu-239	0.001
Plutonium-240	Pu-240	0.001
Plutonium-241	Pu-241	0.01
Plutonium-242	Pu-242	0.001
Plutonium-243	Pu-243	1,000
Plutonium-244	Pu-244	0.001
Plutonium-245	Pu-245	100
Americium-237	Am-237	1,000
Americium-238	Am-238	100
Americium-239	Am-239	1,000
Americium-240	Am-240	100
Americium-241	Am-241	0.001

Americium-242m	Am-242m	0.001
Americium-242	Am-242	10
Americium-243	Am-243	0.001
Americium-244m	Am-244m	100
Americium-244	Am-244	10
Americium-245	Am-245	1,000
Americium-246m	Am-246	1,000
Americium-246	Am-246	1,000
Curium-238	Cm-238	100
Curium-240	Cm-240	0.1
Curium-241	Cm-241	1
Curium-242	Cm-242	0.01
Curium-243	Cm-243	0.001
Curium-244	Cm-244	0.001
Curium-245	Cm-245	0.001
Curium-246	Cm-246	0.001
Curium-247	Cm-247	0.001
Curium-248	Cm-248	0.001
Curium-249	Cm-249	1,000
Berkelium-245	Bk-245	100
Berkelium-246	Bk-246	100
Berkelium-247	Bk-247	0.001
Berkelium-249	Bk-249	0.1
Berkelium-250	Bk-250	10
Californium-244	Cf-244	100
Californium-246	Cf-246	1
Californium-248	Cf-248	0.01
Californium-249	Cf-249	0.001
Californium-250	Cf-250	0.001
Californium-251	Cf-251	0.001
Californium-252	Cf-252	0.001
Californium-253	Cf-253	0.1
Californium-254	Cf-254	0.001
Any alpha emitting radionuclide not listed above or mixtures or alpha emitters of unknown composition		0.001
Einsteinium-250	Es-250	100
Einsteinium-251	Es-251	100
Einsteinium-253	Es-253	0.1
Einsteinium-254m	Es-254m	1
Einsteinium-254	Es-254	0.01
Fermium-252	Fm-252	1
Fermium-253	Fm-253	1
Fermium-254	Fm-254	10
Fermium-255	Fm-255	1
Fermium-257	Fm-257	0.01
Mendelevium-257	Md-257	10
Mendelevium-258	Md-258	0.01

Any radionuclide other than alpha emitter radionuclides not listed above, or mixtures of beta emitters of unknown composition		0.01

[1] The quantities listed above were derived by taking $^{1}/_{10}$th of the most restrictive ALI listed in table 1, columns 1 and 2, of appendix B to §§ 20.1001-20.2401 of this part, rounding to the nearest factor of 10, and arbitrarily constraining the values listed between 0.001 and 1,000 μCi. Values of 100 μCi have been assigned for radionuclides having a radioactive half-life in excess of 10^9 years (except rhenium, 1000 μCi) to take into account their low specific activity.

NOTE: For purposes of §§ 20.1902(e), 20.1905(a), and 20.2201(a) where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

[56 FR 23465, May 21, 1991; 56 FR 61352, Dec. 3, 1991. Redesignated and amended at 58 FR 67659, Dec. 22, 1993; 60 FR 20186, Apr. 25, 1995]

APPENDIX D TO PART 20—UNITED STATES NUCLEAR REGULATORY COMMISSION REGIONAL OFFICES

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Region	Address	Telephone (24 hour)	E-Mail
NRC Headquarters Operations Center	USNRC, Division of Incident Response Operations, Washington, DC 20555–0001.	(301) 816–5100 (301) 951–0550 (301) 816–5151 (fax)	*H001@nrc.gov*
Region I: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406–2713.	(610) 337–5000, (800) 432–1156 TDD: (301) 415–5575	*RidsRgn1MailCenter@nrc.gov*
Region II: Alabama, Florida, Georgia, Kentucky, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands, and West Virginia.	USNRC, Region II, 245 Peachtree Center Avenue, NE., Suite 1200, Atlanta, GA 30303–1257.	(404) 997–4000, (800) 877–8510 TDD: (301) 415–5575	*RidsRgn2MailCenter@nrc.gov*
Region III: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	USNRC, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532–4352.	(630) 829–9500 (800) 522–3025 TDD: (301) 415–5575	*RidsRgn3MailCenter@nrc.gov*
Region IV: Alaska, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas, Louisiana, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wyoming, and the U.S. territories and possessions in the Pacific.	USNRC, Region IV, 1600 E. Lamar Blvd., Arlington, TX 76011–4511.	(817) 860–8100 (800) 952–9677 TDD: (301) 415–5575	*RidsRgn4MailCenter@nrc.gov*

[56 FR 23468, May 21, 1991, as amended at 56 FR 41449, Aug. 21, 1991; 58 FR 64111, Dec. 6, 1993; 59 FR 17465, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 67 FR 67099, Nov. 4, 2002; 67 FR 77652, Dec. 19, 2002; 68 FR 58802, Oct. 10, 2003; 71 FR 15007, Mar. 27, 2006; 75 FR 21980, Apr. 27, 2010; 76 FR 72084, Nov. 22, 2011; 79 FR 66602, Nov. 10, 2014]

Appendix E to Part 20--Nationally Tracked Source Thresholds

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The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

[71 FR 65686, November 8, 2006]

Appendix F to Part 20--[Reserved]

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Appendix G to Part 20--Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

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I. Manifest

A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest (OMB Control Numbers 3150-0164,-0165, and-0166) reflecting information requested on applicable NRC Forms 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, on an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by NRC to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility;

(b) LLW that is being returned to the licensee who is the "waste generator" or "generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the

uniform manifest.

NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained by writing or calling the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-5877, or by visiting the NRC's Web site at *http://www.nrc.gov* and selecting forms from the index found on the home page.

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR part 172. Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR parts 259, 261 or elsewhere, is not addressed in this section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

As used in this appendix, the following definitions apply:

Chelating agent has the same meaning as that given in § 61.2 of this chapter.

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under a Commission or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR part 263.

Generator means a licensee operating under a Commission or Agreement State license who (1) is a waste generator as defined in this part, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of § 61.56 of this chapter, and to meet Department of Transportation requirements for a Type A package.

Land disposal facility has the same meaning as that given in § 61.2 of this chapter.

NRC Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms referenced in this appendix. Licensees need not use originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the packaging requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical description means the items called for on NRC Form 541 to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means NRC Form 540 and, if required, NRC Form 540A which includes the information required by DOT in 49 CFR part 172.

Source material has the same meaning as that given in § 40.4 of this chapter.

Special nuclear material has the same meaning as that given in § 70.4 of this chapter.

Uniform Low-Level Radioactive Waste Manifest or *uniform manifest* means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity, operating under a Commission or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Waste generator means an entity, operating under a Commission or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

Waste processor means an entity, operating under a Commission or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

Information Requirements

A. General Information

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to § 61.55 of this chapter. Waste not meeting the structural stability requirements of § 61.56(b) of this chapter must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to § 61.55 of this chapter. Waste not meeting the structural stability requirements of § 61.56(b) of this chapter must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation and the Commission. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this section. A licensee shall:

1. Prepare all wastes so that the waste is classified according to § 61.55 and meets the waste characteristics requirements in § 61.56 of this chapter;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater then Class C waste, in accordance with § 61.55 of this chapter;

3. Conduct a quality assurance program to assure compliance with §§ 61.55 and 61.56 of this chapter (the program must include management evaluation of audits);

4. Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

6. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR Parts 30, 40, and 70 of this chapter; and

9. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

4. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70 of this chapter;

7. For any shipments or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph I.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to § 61.55 of this chapter and meets the waste characteristics requirements in § 61.56 of this chapter;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with §§ 61.55 and 61.57 of this chapter;

5. Conduct a quality assurance program to assure compliance with §§ 61.55 and 61.56 of this chapter (the program shall include management evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

7. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgement of the receipt of the shipment in the form of a signed copy of NRC Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgement of receipt as the record of transfer of licensed material as required by 10 CFR parts 30, 40, and 70 of this chapter;

10. For any shipment or any part of a shipment for which acknowledgement of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(l) until the Commission terminates the license; and

3. Notify the shipper and the Administrator of the nearest Commission Regional Office listed in appendix D of this part when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been cancelled.

E. Any shipment or part of a shipment for which acknowledgement is not received within the times set forth in this section must:

1. Be investigated by the shipper if the shipper has not received notification or receipt within 20 days after transfer; and

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest Commission Regional Office listed in Appendix D to this part. Each licensee who conducts a trace investigation shall file a written report with the appropriate NRC Regional Office within 2 weeks of completion of the investigation.

[60 FR 15664, Mar. 27, 1995, as amended at 60 FR 25983, May 16, 1995; 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 80 FR 74979, Dec. 1, 2015]

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

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General Provisions

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§ 30.1 Scope.

This part prescribes rules applicable to all persons in the United States governing domestic licensing of byproduct material under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and under title II of the Energy Reorganization Act of 1974 (88 Stat. 1242), and exemptions from the domestic licensing requirements permitted by Section 81 of the Act. This part also gives notice to all persons who knowingly provide to any licensee, applicant, certificate of registration holder, contractor, or subcontractor, components, equipment, materials, or other goods or services, that relate to a licensee's, applicant's or certificate of registration holder's activities subject to this part, that they may be individually subject to NRC enforcement action for violation of § 30.10.

[63 FR 1895, Jan. 13, 1998]

§ 30.2 Resolution of conflict.

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The requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In any conflict between the requirements in this part and a specific requirement in another part of the regulations in this chapter, the specific requirement governs.

[30 FR 8185, June 26, 1965]

§ 30.3 Activities requiring license.

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(a) Except as provided in paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.

(b)(1) The requirements, including provisions that are specific to licensees, in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to Government agencies or Federally recognized Indian Tribes on November 30, 2007, when conducting activities under the authority provided by paragraphs (b)(2) and (b)(3) of this section.

(2) A specifically licensed Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the licensee submits an amendment application on or before June 2, 2008.

(3) A Government agency or Federally recognized Indian Tribe that possesses and uses accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination provided that the agency or Indian Tribe submits an application for a license authorizing activities involving these materials on or before December 1, 2008.

(c)(1) The requirements, including provisions that are specific to licensees in this part and parts 19, 20, 21, and 71 of this chapter, as well as the additional requirements for specific broad scope, industrial radiography, irradiator, or well logging uses in 10 CFR parts 33, 34, 36, or 39, respectively, shall apply to all persons, other than those included in paragraph (b)(1) of this section, on August 8, 2009, or earlier as noticed by the NRC, when conducting activities under the authority provided by paragraphs (c)(2) and (c)(3) of this section.

(2) Except as provided in paragraph (b)(2) of this section, all other licensees, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a license amendment is required to authorize the activities in paragraph (a) of this section, may continue to use these materials for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits an amendment application within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(3) Except as provided in paragraph (b)(3) of this section, all other persons, who possess and use accelerator-produced radioactive material or discrete sources of radium-226 for which a specific license is required in paragraph (a) of this section, may continue to use such material for uses permitted under this part until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

(d) If a person or licensee is required to file an application for a license or amendment in accordance with paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section, but does not file for the license or amendment within the required time, the authority provided by paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section to receive or use the accelerator-produced radioactive material or discrete sources of radium-226 shall expire with respect to the person's or licensee's authority to receive and use such byproduct material. This authority shall not expire with respect to the responsibility of the person or licensee regarding the possession of such byproduct material, the decommissioning (including financial assurance) of facilities, or the disposal of such byproduct material.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6921, Feb. 17, 1978; 72 FR 55924, Oct. 1, 2007]

§ 30.4 Definitions.

[Top of File]

Accelerator-produced radioactive material means any material made radioactive by a particle accelerator.

Act means the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto;

Agreement State means any state with which the Atomic Energy Commission or the Nuclear Regulatory Commission has entered into an effective agreement under subsection 274b. of the Act. *Non-agreement State* means any other State;

Alert means events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Byproduct material means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

(2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

(ii) Any material that—

(A) Has been made radioactive by use of a particle accelerator; and

(B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

(3) Any discrete source of naturally occurring radioactive material, other than source material, that—

(i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

(ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

Commencement of construction means taking any action defined as "construction" or any other activity at the site of a facility subject to the regulations in this part that has a reasonable nexus to:

(1) Radiological health and safety; or

(2) Common defense and security.

Commission means the Nuclear Regulatory Commission and its duly authorized representatives;

Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

Construction means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

(1) Changes for temporary use of the land for public recreational purposes;

(2) Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to

establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

(3) Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

(4) Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

(5) Excavation;

(6) Erection of support buildings (*e.g.*, construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

(7) Building of service facilities (*e.g.*, paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

(8) Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

(9) Taking any other action that has no reasonable nexus to:

(i) Radiological health and safety, or

(ii) Common defense and security.

Curie means that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second;

Cyclotron means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

Decommission means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits—

(1) Release of the property for unrestricted use and termination of the license; or

(2) Release of the property under restricted conditions and termination of the license.

Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

Department and Department of Energy means the Department of Energy established by the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the Department, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104 (b), (c) and (d) of the Energy Reorganization Act of 1974 (Pub. L. 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to section 301(a) of the Department of Energy Organization Act (Pub. L. 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

Discrete source means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Effective dose equivalent means the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

Government agency means any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government;

License, except where otherwise specified means a license for by-product material issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter;

Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user as defined in 10 CFR Part 35.

Microcurie means that amount of radioactive material which disintegrates at the rate of 37 thousand atoms per second;

Millicurie means that amount of radioactive material which disintegrates at the rate of 37 million atoms per second;

Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.

Person means: (1) Any individual, corporation, partnership, firm, association, trust, estate, public or private institution,

group, Government agency other than the Commission or the Department, except that the Department shall be considered a person within the meaning of the regulations in this part to the extent that its facilities and activities are subject to the licensing and related regulatory authority of the Commission pursuant to section 202 of the Energy Reorganization Act of 1974 (88 Stat. 1244), any State or any political subdivision of or any political entity within a State, any foreign government or nation or any political subdivision of any such government or nation, or other entity; and (2) any legal successor, representative, agent, or agency of the foregoing;

Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine;

Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Production facility means production facility as defined in the regulations contained in part 50 of this chapter;

Research and development means: (1) Theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials and processes. "Research and development" as used in this part and parts 31 through 35 does not include the internal or external administration of byproduct material, or the radiation therefrom, to human beings;

Sealed source means any by product material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

Site area emergency means events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Source material means source material as defined in the regulations contained in part 40 of this chapter;

Special nuclear material means special nuclear material as defined in the regulations contained in part 70 of this chapter;

United States, when used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States;

Utilization facility means a utilization facility as defined in the regulations contained in part 50 of this chapter;

[30 FR 8185, June 26, 1965, as amended at 36 FR 1466, Jan. 30, 1971; 37 FR 5746, Mar. 21, 1972; 38 FR 29314, Oct. 24, 1973; 40 FR 8784, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 45 FR 14200, Mar. 5, 1980; 45 FR 18905, Mar. 24, 1980; 48 FR 39037, Aug. 29, 1983; 51 FR 36967, Oct. 16, 1986; 52 FR 8241, Mar. 17, 1987; 53 FR 24044, June 27, 1988; 54 FR 14059, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 36034, July 15, 1994; 59 FR 61780, Dec. 2, 1994; 62 FR 28963, May 28, 1997; 62 FR 39089, July 21, 1997; 65 FR 54950, Sept. 12, 2000; 72 FR 55924, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; 76 FR 56962, Sept. 15, 2011; 79 FR 58671, Sept. 30, 2014]

§ 30.5 Interpretations.

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Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part and parts 31 through 36 and 39 by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

§ 30.6 Communications.

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(a) Unless otherwise specified or covered under the regional licensing program as provided in paragraph (b) of this section, any communication or report concerning the regulations in parts 30 through 37 and 39 of this chapter and any application filed under these regulations may be submitted to the Commission as follows:

(1) By mail addressed: ATTN: Document Control Desk, Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

(2) By hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland.

(3) Where practicable, by electronic submission, for example, via Electronic Information Exchange, or CD–ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be

obtained by visiting the NRC 's Web site at *http://www.nrc.gov/site-help/e-submittals.html;* by e-mail to *MSHD.Resource@nrc.gov;* or by writing the Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information.

(b) The Commission has delegated to the four Regional Administrators licensing authority for selected parts of its decentralized licensing program for nuclear materials as described in paragraph (b)(1) of this section. Any communication, report, or application covered under this licensing program must be submitted to the appropriate Regional Administrator. The Administrators' jurisdictions and mailing addresses are listed in paragraph (b)(2) of this section.

(1) The delegated licensing program includes authority to issue, renew, amend, cancel, modify, suspend, or revoke licenses for nuclear materials issued pursuant to 10 CFR parts 30 through 36, 39, 40, and 70 to all persons for academic, medical, and industrial uses, with the following exceptions:

(i) Activities in the fuel cycle and special nuclear material in quantities sufficient to constitute a critical mass in any room or area. This exception does not apply to license modifications relating to termination of special nuclear material licenses that authorize possession of larger quantities when the case is referred for action from NRC's Headquarters to the Regional Administrators.

(ii) Health and safety design review of sealed sources and devices and approval, for licensing purposes, of sealed sources and devices.

(iii) Processing of source material for extracting of metallic compounds (including Zirconium, Hafnium, Tantalum, Titanium, Niobium, etc.).

(iv) Distribution of products containing radioactive material under §§ 32.11 through 32.30 and 40.52 of this chapter to persons exempt from licensing requirements.

(v) New uses or techniques for use of byproducts, source, or special nuclear material.

(2) *Submissions*. (i) *Region I*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region I non-Agreement States and the District of Columbia: Connecticut, Delaware, and Vermont. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406–2713; where email is appropriate it should be addressed to *RidsRgn1MailCenter.Resource@nrc.gov*.

(ii) *Region II*. The regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region II non-Agreement States and territories: West Virginia, Puerto Rico, and the Virgin Islands. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region I, Nuclear Material Section B, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406–2713; where email is appropriate it should be addressed to *RidsRgn1MailCenter.Resource@nrc.gov*.

(iii) *Region III*. (A) The regional licensing program for mining and milling involves all Federal facilities in the region, and non-Federal licensees in the Region III non-Agreement States of Indiana, Michigan, Missouri and the Region III Agreement States of Minnesota, Wisconsin, and Iowa. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 2443 Warrenville Road, Suite 210, Lisle, IL 60532 –4352; where e-mail is appropriate it should be addressed to *RidsRgn3MailCenter.Resource@nrc.gov*.

(B) Otherwise, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in the Region III non-Agreement States of Indiana, Michigan, and Missouri. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region III, Material Licensing Section, 2443 Warrenville Road, Suite 210, Lisle, IL 60532–4352; where e-mail is appropriate it should be addressed to *RidsRgn3MailCenter.Resource@nrc.gov*.

(iv) *Region IV*. (A) The regional licensing program for mining and milling involves all Federal facilities in the region, and non-Federal licensees in the Region IV non-Agreement States and territory of Alaska, Hawaii, Idaho, Montana, South Dakota, Wyoming and Guam and Region IV Agreement States of Oregon, California, Nevada, New Mexico, Louisiana, Mississippi, Arkansas, Oklahoma, Kansas, Nebraska, and North Dakota. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region IV, Division of Nuclear Materials Safety, 1600 E. Lamar Blvd., Arlington, TX 76011–4511; where email is appropriate, it should be addressed to *RidsRgn4MailCenter.Resource@nrc.gov*.

(B) Otherwise, the regional licensing program involves all Federal facilities in the region and non-Federal licensees in the following Region IV non-Agreement States and territory: Alaska, Hawaii, Idaho, Montana, South Dakota, Wyoming, and Guam. All mailed or hand-delivered inquiries, communications, and applications for a new license or an amendment, renewal, or termination request of an existing license specified in paragraph (b)(1) of this section must use the following address: U.S. Nuclear Regulatory Commission, Region IV, Division of Nuclear Materials Safety, 1600 E. Lamar Blvd., Arlington, TX 76011–4511; where email is appropriate, it should be addressed to *RidsRgn4MailCenter.Resource@nrc.gov*.

[48 FR 16031, Apr. 14, 1983, as amended at 49 FR 19630, May 9, 1984; 49 FR 47824, Dec. 7, 1984; 50 FR 14693, Apr. 11, 1985; 51 FR 36000, Oct. 8, 1986; 52 FR 8241, Mar. 17, 1987; 52 FR 38392, Oct. 16, 1987; 52 FR 48093, Dec. 18, 1987; 53 FR 3862, Feb. 10, 1988; 53 FR 43420, Oct. 27, 1988; 58 FR 7736, Feb. 9, 1993; 58 FR 64111, Dec. 6, 1993; 59 FR 17465, Apr. 13, 1994; 60 FR 24551, May 9, 1995; 62 FR 22880, Apr. 28, 1997; 68 FR 58803, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 71 FR 15007, Mar. 27, 2006; 72 FR 33386, Jun. 18, 2007; 73 FR 5717, Jan. 31, 2008; 74 FR 62681, Dec. 1, 2009; 75 FR 21980, Apr. 27, 2010; 75 FR 73942, Nov. 30, 2010; 76 FR 72085, Nov. 22, 2011; 77 FR 39905, Jul. 6, 2012; 77 FR 43689, Jul. 25, 2012; 78 FR 17006, Mar. 19, 2013; 78 FR 32338, May 29, 2013; 79 FR 75739, Dec. 19, 2014; 80 FR 74979, Dec. 1, 2015]

§ 30.7 Employee protection.

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(a) Discrimination by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, or privileges of employment. The protected activities are established in section 211 of the Energy Reorganization Act of 1974, as amended, and in general are related to the administration or enforcement of a requirement imposed under the Atomic Energy Act or the Energy Reorganization Act.

(1) The protected activities include but are not limited to:

(i) Providing the Commission or his or her employer information about alleged violations of either of the statutes named in paragraph (a) introductory text of this section or possible violations of requirements imposed under either of those statutes;

(ii) Refusing to engage in any practice made unlawful under either of the statutes named in paragraph (a) introductory text or under these requirements if the employee has identified the alleged illegality to the employer;

(iii) Requesting the Commission to institute action against his or her employer for the administration or enforcement of these requirements;

(iv) Testifying in any Commission proceeding, or before Congress, or at any Federal or State proceeding regarding any provision (or proposed provision) of either of the statutes named in paragraph (a) introductory text.

(v) Assisting or participating in, or is about to assist or participate in, these activities.

(2) These activities are protected even if no formal proceeding is actually initiated as a result of the employee assistance or participation.

(3) This section has no application to any employee alleging discrimination prohibited by this section who, acting without direction from his or her employer (or the employer's agent), deliberately causes a violation of any requirement of the Energy Reorganization Act of 1974, as amended, or the Atomic Energy Act of 1954, as amended.

(b) Any employee who believes that he or she has been discharged or otherwise discriminated against by any person for engaging in protected activities specified in paragraph (a)(1) of this section may seek a remedy for the discharge or discrimination through an administrative proceeding in the Department of Labor. The administrative proceeding must be initiated within 180 days after an alleged violation occurs. The employee may do this by filing a complaint alleging the violation with the Department of Labor, Employment Standards Administration, Wage and Hour Division. The Department of Labor may order reinstatement, back pay, and compensatory damages.

(c) A violation of paragraphs (a), (e), or (f) of this section by a Commission licensee, an applicant for a Commission license, or a contractor or subcontractor of a Commission licensee or applicant may be grounds for—

(1) Denial, revocation, or suspension of the license.

(2) Imposition of a civil penalty on the licensee, applicant, or a contractor or subcontractor of the licensee or applicant.

(3) Other enforcement action.

(d) Actions taken by an employer, or others, which adversely affect an employee may be predicated upon nondiscriminatory grounds. The prohibition applies when the adverse action occurs because the employee has engaged in protected activities. An employee's engagement in protected activities does not automatically render him or her immune from discharge or discipline for legitimate reasons or from adverse action dictated by nonprohibited considerations.

(e)(1) Each specific licensee, each applicant for a specific license, and each general licensee subject to part 19 shall prominently post the revision of NRC Form 3, "Notice to Employees," referenced in 10 CFR 19.11(c).

(2) The posting of NRC Form 3 must be at locations sufficient to permit employees protected by this section to observe a copy on the way to or from their place of work. Premises must be posted not later than 30 days after an application is docketed and remain posted while the application is pending before the Commission, during the term of the license, and for 30 days following license termination.

(3) Copies of NRC Form 3 may be obtained by writing to the Regional Administrator of the appropriate U.S. Nuclear Regulatory Commission Regional Office listed in appendix D to part 20 of this chapter, via email to *Forms.Resource@nrc.gov*, or by visiting the NRC's online library at *http://www.nrc.gov/reading-rm/doc-collections/forms/*.

(f) No agreement affecting the compensation, terms, conditions, or privileges of employment, including an agreement to settle a complaint filed by an employee with the Department of Labor pursuant to section 211 of the Energy Reorganization Act of 1974, as amended, may contain any provision which would prohibit, restrict, or otherwise discourage an employee from participating in protected activity as defined in paragraph (a)(1) of this section including, but not limited to, providing information to the NRC or to his or her employer on potential violations or other matters within NRC's regulatory responsibilities.

[58 FR 52408, Oct. 8, 1993, as amended at 60 FR 24551, May 9, 1995; 61 FR 6764, Feb. 22, 1996; 68 FR 58803, Oct. 10, 2003; 72 FR 63969, Nov. 14, 2007; 79 FR 66603, Nov. 10, 2014]

§ 30.8 Information collection requirements: OMB approval.

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(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0017.

(b) The approved information collection requirements contained in this part appear in §§ 30.9, 30.11, 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.41, 30.50, 30.51, 30.55, and appendices A, C, D, and E to this part.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In §§ 30.32 and 30.37, NRC Form 313 is approved under control number 3150–0120.

(2) In § 30.36, NRC Form 314 is approved under control number 3150-0028.

(3) In § 30.34, DOC/NRC Forms AP–1, AP–A, and associated forms are approved under control number 0694–0135.

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6, 1997; 62 FR 63639, Dec. 2, 1997; 63 FR 29541, June 1, 1998; 67 FR 67099, Nov. 4, 2002; 73 FR 78604, Dec. 23, 2008; 77 FR 43689, Jul. 25, 2012]

§ 30.9 Completeness and accuracy of information.

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(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

(b) Each applicant or licensee shall notify the Commission of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or common defense and security. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Commission of information that the applicant or licensee has identified as having a significant implication for public health and safety or common defense and security. Notification shall be provided to the Administrator of the appropriate Regional Office within two working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements.

[52 FR 49371, Dec. 31, 1987]

§ 30.10 Deliberate misconduct.

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(a) Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's or applicant's activities in this part, may not:

(1) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Commission; or

(2) Deliberately submit to the NRC, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be

incomplete or inaccurate in some respect material to the NRC.

(b) A person who violates paragraph (a)(1) or (a)(2) of this section may be subject to enforcement action in accordance with the procedures in 10 CFR part 2, subpart B.

(c) For the purposes of paragraph (a)(1) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a licensee, certificate of registration holder or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation, of any license issued by the Commission; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

[63 FR 1896, Jan. 13, 1998]

Exemptions

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§ 30.11 Specific exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part and parts 31 through 36 and 39 of this chapter as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any licensee's activities are exempt from the requirements of this part to the extent that its activities are licensed under the requirements of part 72 of this chapter.

(c) The Department of Energy is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 60 or 63 of this chapter.

(d) Except as specifically provided in part 61 of this chapter, any licensee is exempt from the requirements of this part to the extent that its activities are subject to the requirements of part 61 of this chapter.

[37 FR 5746, Mar. 21, 1972, as amended at 39 FR 26279, July 18, 1974; 40 FR 8784, Mar. 3, 1975; 43 FR 6921, Feb. 21, 1978; 45 FR 65530, Oct. 3, 1980; 46 FR 13979, Feb. 25, 1981; 47 FR 57480, Dec. 27, 1982; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 66 FR 51838, Oct. 11, 2001; 66 FR 55790, Nov. 2, 2001]

§ 30.12 Persons using byproduct material under certain Department of Energy and Nuclear Regulatory Commission contracts.

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Except to the extent that Department facilities or activities of the types subject to licensing pursuant to section 202 of the Energy Reorganization Act of 1974 are involved, any prime contractor of the Department is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such contractor, under his prime contract with the Department manufactures, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material for:

(a) The performance of work for the Department at a United States Government-owned or controlled site, including the transportation of byproduct material to or from such site and the performance of contract services during temporary interruptions of such transportation;

(b) Research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof; or

(c) The use or operation of nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel.

In addition to the foregoing exemptions and subject to the requirement for licensing of Department facilities and activities pursuant to section 202 of the Energy Reorganization Act of 1974, any prime contractor or subcontractor of the Department or the Commission is exempt from the requirements for a license set forth in sections 81 and 82 of the Act and from the regulations in this part to the extent that such prime contractor or subcontractor manufacturers, produces, transfers, receives, acquires, owns, possesses, or uses byproduct material under his prime contract or subcontract when the Commission determines that the exemption of the prime contractor or subcontractor is authorized by law; and that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

[40 FR 8784, Mar. 3, 1975, as amended at 43 FR 6921, Feb. 17, 1978]

§ 30.13 Carriers.

[Top of File]

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the regulations in this part and parts 31 through 37 and 39 of this chapter and the requirements for a license set forth in section 81 of the Act to the extent that they transport or store byproduct material in the regular course of carriage for another or storage incident thereto.

[37 FR 3985, Feb. 25, 1972, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 78 FR 17006, Mar. 19, 2013]

§ 30.14 Exempt concentrations

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(a) Except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in § 30.70.

(b) This section shall not be deemed to authorize the import of byproduct material or products containing byproduct material.

(c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in § 30.70 and introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 58486, Oct. 16, 2007]

§ 30.15 Certain items containing byproduct material.

[Top of File]

(a) Except for persons who apply byproduct material to, or persons who incorporate byproduct material into, the following products, or persons who initially transfer for sale or distribution the following products containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires the following products:

(1) Timepieces or hands or dials containing not more than the following specified quantities of byproduct material and not exceeding the following specified levels of radiation:

(i) 25 millicuries of tritium per timepiece,

(ii) 5 millicuries of tritium per hand,

(iii) 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial),

(iv) 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece,

(v) 20 microcuries of promethium 147 per watch hand or 40 microcuries of promethium 147 per other timepiece hand,

(vi) 60 microcuries of promethium 147 per watch dial or 120 microcuries of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial),

(vii) The levels of radiation from hands and dials containing promethium 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(A) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface,

(B) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface,

(C) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

(2)(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 μCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before October 23, 2012 for use under the general license then provided in § 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.

(3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007.

(4) [Reserved]

(5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

(6) [Reserved]

(7) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

(8) Electron tubes: *Provided*, That each tube does not contain more than one of the following specified quantities of byproduct material:

(i) 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

(ii) 1 microcurie of cobalt-60;

(iii) 5 microcuries of nickel-63;

(iv) 30 microcuries of krypton-85;

(v) 5 microcuries of cesium-137;

(vi) 30 microcuries of promethium-147;

And provided further, That the levels of radiation from each electron tube containing byproduct material do not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.[1]

(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material: *Provided*, That;

(i) Each source contains no more than one exempt quantity set forth in § 30.71, Schedule B, and

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this paragraph (a)(9), an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.

(iii) For purposes of this paragraph (a)(9), 0.05 microcurie of americium-241 is considered an exempt quantity under § 30.71, Schedule B.

(10) [Reserved]

(b) Any person who desires to apply byproduct material to, or to incorporate byproduct material into, the products exempted in paragraph (a) of this section, or who desires to initially transfer for sale or distribution such products containing byproduct material, should apply for a specific license pursuant to § 32.14 of this chapter, which license states that the product may be distributed by the licensee to persons exempt from the regulations pursuant to paragraph (a) of this section.

[31 FR 5316, Apr. 2, 1966, as amended at 31 FR 14349, Nov. 8, 1966; 32 FR 785, Jan. 24, 1967; 32 FR 6434, Apr. 26, 1967; 32 FR 13921, Oct. 6, 1967; 34 FR 6651, Apr. 18, 1969; 34 FR 19546, Dec. 11, 1969; 35 FR 6427, Apr. 22, 1970; 35 FR 8820, June 6, 1970; 43 FR 2387, Jan. 17, 1978; 43 FR 6921, Feb. 17, 1978; 46 FR 26471, May 13, 1981; 46 FR 46876, Sept. 23, 1981; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 77 FR 43689, Jul. 25, 2012]

[1] For purposes of this paragraph "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

§ 30.16 [Removed].

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[32 FR 4241, Mar. 18, 1967, as amended at 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 58486, Oct. 16, 2007]

§ 30.18 Exempt quantities.

[Top of File]

(a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does not exceed the applicable quantity set forth in § 30.71, Schedule B.

(b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct material.

(c) This section does not authorize for purposes of commercial distribution the production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution.

(d) No person may, for purposes of commercial distribution, transfer byproduct material in the individual quantities set forth in § 30.71 Schedule B, knowing or having reason to believe that such quantities of byproduct material will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.18 of this chapter, which license states that the byproduct material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of an Agreement State.

(e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007]

§ 30.19 Self-luminous products containing tritium, krypton-85, or promethium-147.

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(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147, and except as provided in paragraph (c) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 20 and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to § 32.22 of this chapter, which license authorizes the initial transfer of the product for use under this section.

(b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

(c) The exemption in paragraph (a) of this section does not apply to tritium, krypton-85, or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

[34 FR 9026, June 6, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 77 FR 43689, Jul. 25, 2012]

§ 30.20 Gas and aerosol detectors containing byproduct material

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(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.

(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or

to initially transfer such products for use under paragraph (a) of this section, should apply for a license under § 32.26 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

[34 FR 6653, Apr. 18, 1969, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6921, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 72 FR 55925, Oct. 1, 2007; 77 FR 43689, Jul. 25, 2012]

§ 30.21 Radioactive drug: Capsules containing carbon-14 urea for "in vivo" diagnostic use for humans.

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(a) Except as provided in paragraphs (b) and (c) of this section, any person is exempt from the requirements for a license set forth in Section 81 of the Act and from the regulations in this part and part 35 of this chapter provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1 μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to part 35 of this chapter.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to § 32.21 of this chapter.

(d) Nothing in this section relieves persons from complying with applicable FDA, other Federal, and State requirements governing receipt, administration, and use of drugs.

[62 FR 63640, Dec. 2, 1997]

§ 30.22 Certain industrial devices

[Top of File]

(a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

(b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.

[77 FR 43689, Jul. 25, 2012]

Licenses

[Top of File]

§ 30.31 Types of licenses.

Licenses for byproduct material are of two types: General and specific.

(a) The Commission issues a specific license to a named person who has filed an application for the license under the provisions of this part and parts 32 through 36, and 39.

(b) A general license is provided by regulation, grants authority to a person for certain activities involving byproduct material, and is effective without the filing of an application with the Commission or the issuance of a licensing document to a particular person. However, registration with the Commission may be required by the particular general license.

[65 FR 79187, Dec. 18, 2000]

§ 30.32 Application for specific licenses.

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(a) A person may file an application on NRC Form 313, "Application for Material License," in accordance with the instructions

in § 30.6 of this chapter. Information contained in previous applications, statements or reports filed with the Commission or the Atomic Energy Commission may be incorporated by reference, provided that the reference is clear and specific.

(b) The Commission may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Commission to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for license filed pursuant to the regulations in this part and parts 32 through 35 of this chapter will be considered also as an application for licenses authorizing other activities for which licenses are required by the Act, provided that the application specifies the additional activities for which licenses are requested and complies with regulations of the Commission as to applications for such licenses.

(e) Each application for a byproduct material license, other than a license exempted from part 170 of this chapter, shall be accompanied by the fee prescribed in § 170.31 of this chapter. No fee will be required to accompany an application for renewal or amendment of a license, except as provided in § 170.31 of this chapter.

(f) An application for a license to receive and possess byproduct material for the conduct of any activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by any Environmental Report required pursuant to subpart A of part 51 of this chapter.

(g)(1) Except as provided in paragraphs (g)(2), (3), and (4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either—

(i) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or

(ii) Contain the information identified in § 32.210(c) of this chapter.

(2) For sources or devices manufactured before October 23, 2012 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the application must include:

(i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and

(ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

(3) For sealed sources and devices allowed to be distributed without registration of safety information in accordance with § 32.210(g)(1) of this chapter, the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

(h) As provided by § 30.35, certain applications for specific licenses filed under this part and parts 32 through 35 of this chapter must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning. In the case of renewal applications submitted before July 27, 1990, this submittal may follow the renewal application but must be submitted on or before July 27, 1990.

(i)(1) Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in § 30.72, "Schedule C—Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

(i) An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

(ii) An emergency plan for responding to a release of radioactive material.

(2) One or more of the following factors may be used to support an evaluation submitted under paragraph (i)(1)(i) of this section:

(i) The radioactive material is physically separated so that only a portion could be involved in an accident;

(ii) All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

(iii) The release fraction in the respirable size range would be lower than the release fraction shown § 30.72 due to the chemical or physical form of the material;

(iv) The solubility of the radioactive material would reduce the dose received;

(v) Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in § 30.72;

(vi) Operating restrictions or procedures would prevent a release fraction as large as that shown in § 30.72; or

(vii) Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under paragraph (i)(1)(ii) of this section must include the following information:

(i) *Facility description.* A brief description of the licensee's facility and area near the site.

(ii) *Types of accidents.* An identification of each type of radio-active materials accident for which protective actions may be needed.

(iii) *Classification of accidents.* A classification system for classifying accidents as alerts or site area emergencies.

(iv) *Detection of accidents.* Identification of the means of detecting each type of accident in a timely manner.

(v) *Mitigation of consequences.* A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

(vi) *Assessment of releases.* A brief description of the methods and equipment to assess releases of radioactive materials.

(vii) *Responsibilities.* A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the NRC; also responsibilities for developing, maintaining, and updating the plan.

(viii) *Notification and coordination.* A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.[1]

(ix) Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the NRC.

(x) *Training.* A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

(xi) *Safe shutdown.* A brief description of the means of restoring the facility to a safe condition after an accident.

(xii) *Exercises.* Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

(xiii) *Hazardous chemicals.* A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the byproduct material.

(4) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to NRC. The licensee shall provide any comments received within the 60 days to the NRC with the emergency plan.

(j) An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include:

(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

(2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in §

32.72(a)(2) of this chapter.

(3) Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter.

(4) Information identified in § 32.72(a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.

[1] These reporting requirements do not superceed or release licensees of complying with the requirements under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499 or other state or federal reporting requirements.

[30 FR 8185, June 26, 1965, as amended at 36 FR 145, Jan. 6, 1971; 37 FR 5747, Mar. 21, 1972; 43 FR 6922, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 49 FR 27924, July 9, 1984; 52 FR 27786, July 24, 1987; 53 FR 24044, June 27, 1988; 54 FR 14060, Apr. 7, 1989; 68 FR 58804, Oct. 10, 2003; 72 FR 55925, Oct. 1, 2007; 73 FR 63570, Oct. 24, 2008; 77 FR 43689, Jul. 25, 2012; 79 FR 58671, Sept. 30, 2014]

§ 30.33 General requirements for issuance of specific licenses.

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(a) An application for a specific license will be approved if:

(1) The application is for a purpose authorized by the Act;

(2) The applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property;

(3) The applicant is qualified by training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property;

(4) The applicant satisfies any special requirements contained in parts 32 through 37 and 39 of this chapter; and

(5) In the case of an application for a license to receive and possess byproduct material for the conduct of any activity which the NRC determines will significantly affect the quality of the environment, the Director, Office of Nuclear Material Safety and Safeguards or his/her designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess byproduct material in such plant or facility. Commencement of construction as defined in § 30.4 may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

(b) Upon a determination that an application meets the requirements of the Act, and the regulations of the Commission, the Commission will issue a specific license authorizing the possession and use of byproduct material (Form NRC 374, "Byproduct Material License").

[30 FR 8185, June 26, 1965, as amended at 36 FR 12731, July 7, 1971; 37 FR 5747. Mar. 21, 1972; 39 FR 26279, July 18, 1974; 43 FR 6922, Feb. 17, 1978; 49 FR 9403, Mar. 12, 1984; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 73 FR 5717, Jan. 31, 2008; 76 FR 56962, Sep. 15, 2011; 78 FR 17006, Mar. 19, 2013; 79 FR 75739, Dec. 19, 2014]

§ 30.34 Terms and conditions of licenses

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(a) Each license issued pursuant to the regulations in this part and the regulations in parts 31 through 36 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b)(1) No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(2) An application for transfer of license must include:

(i) The identity, technical and financial qualifications of the proposed transferee; and

(ii) Financial assurance for decommissioning information required by § 30.35.

(c) Each person licensed by the Commission pursuant to the regulations in this part and parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as

otherwise provided in the license, a license issued pursuant to the regulations in this part and parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and parts 31 through 36 and 39 shall be deemed to contain the provisions set forth in section 183b.- d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any license issued pursuant to the regulations in this part and parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

(1) Promote the common defense and security;

(2) Protect health or to minimize danger to life or property;

(3) Protect restricted data;

(4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

(f) Licensees required to submit emergency plans by § 30.32(i) shall follow the emergency plan approved by the Commission. The licensee may change the approved without Commission approval only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the appropriate NRC Regional Office specified in § 30.6 and to affected offsite response organizations within six months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Commission.

(g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made.

(h)(1) Each general licensee that is required to register by § 31.5(c)(13) of this chapter and each specific licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee;

(ii) An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

(iii) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(2) This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed; and

(ii) The date of the filing of the petition.

(i) Security requirements for portable gauges.

Each portable gauge licensee shall use a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

(i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

(ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter.

(3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

(i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or

(ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter.

(4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.

(k) As required by the Additional Protocol, each specific licensee authorized to possess and use byproduct material shall file with the Commission location information described in § 75.11 of this chapter on DOC/NRC Forms AP–1 and associated forms. The licensee shall also permit verification of this information by the International Atomic Energy Agency (IAEA) and shall take other action as may be necessary to implement the US/IAEA Safeguards Agreement, as described in part 75 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 38 FR 33969, Dec. 10, 1973; 43 FR 6922, Feb. 17, 1978; 48 FR 32328, July 15, 1983; 52 FR 1295, Jan. 12, 1987; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 53 FR 23383, June 22, 1988; 54 FR 14061, Apr. 7, 1989; 58 FR 7736, Feb. 9, 1993; 59 FR 61780, Dec. 2, 1994; 65 FR 79187, Dec. 18, 2000; 70 FR 2009, Jan. 12, 2005; 72 FR 55926, Oct. 1, 2007; 73 FR 78604, Dec. 23, 2008; 74 FR 7785, Feb. 20, 2009; 76 FR 35564, Jun. 17, 2011; 77 FR 39905, Jul. 6, 2012; 79 FR 58671, Sept. 30, 2014]

§ 30.35 Financial assurance and recordkeeping for decommissioning.

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(a)(1) Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30.

(2) Each holder of, or applicant for, any specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in appendix B to part 30 (or when a combination of isotopes is involved if R, as defined in § 30.35(a)(1), divided by 10^{12} is greater than 1), shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must be submitted to NRC by December 2, 2005.

(b) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section shall either—

(1) Submit a decommissioning funding plan as described in paragraph (e) of this section; or

(2) Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by paragraph (d) of this section using one of the methods described in paragraph (f) of this section. For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but before the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section must be submitted to NRC before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to NRC, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section.

(c)(1) Each holder of a specific license issued on or after July 27, 1990, which is of a type described in paragraph (a) or (b) of this section, shall provide financial assurance for decommissioning in accordance with the criteria set forth in this section.

(2) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (a) of this section shall submit a decommissioning funding plan as described in paragraph (e) of this section or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in this section. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan, the licensee shall include a decommissioning funding plan in any application for license renewal.

(3) Each holder of a specific license issued before July 27, 1990, and of a type described in paragraph (b) of this section shall submit, on or before July 27, 1990, a decommissioning funding plan as described, in paragraph (e) of this section, or a certification of financial assurance for decommissioning in accordance with the criteria set forth in this section.

(4) Any licensee who has submitted an application before July 27, 1990, for renewal of license in accordance with § 30.37 shall provide financial assurance for decommissioning in accordance with paragraphs (a) and (b) of this section. This assurance must be submitted when this rule becomes effective November 24, 1995.

(5) Waste collectors and waste processors, as defined in 10 CFR part 20, Appendix G, must provide financial assurance in an amount based on a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the license termination criteria of 10 CFR part 20. The decommissioning funding plan must be submitted by December 2, 2005.

(6) If, in surveys made under 10 CFR 20.1501(a), residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the 10 CFR 20.1402 criteria for

unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

(d) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by December 2, 2004. Licensees required to submit the $113,000 or $225,000 amount must do so by June 2, 2005. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.)	$1,125,000
Greater than 10^3 but less than or equal to 10^4 times the applicable quantities of appendix B to part 30 in unsealed form. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.)	225,000
Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities of appendix B to part 30 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in § 30.35(a)(1), divided by 10^{10} is greater than, 1, but R divided by 10^{12} is less than or equal to 1)	113,000

(e)(1) Each decommissioning funding plan must be submitted for review and approval and must contain —

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

(A) The cost of an independent contractor to perform all decommissioning activities;

(B) The cost of meeting the 10 CFR 20.1402 criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 10 CFR 20.1403, the cost estimate may be based on meeting the 10 CFR 20.1403 criteria;

(C) The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(D) An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the DCE;

(iii) A description of the method of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility;

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (f) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

(2) At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

(ii) Waste inventory increasing above the amount previously estimated;

(iii) Waste disposal costs increasing above the amount previously estimated;

(iv) Facility modifications;

(v) Changes in authorized possession limits;

(vi) Actual remediation costs that exceed the previous cost estimate;

(vii) Onsite disposal; and

(viii) Use of a settling pond.

(f) The financial instrument must include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

(1) *Prepayment*. Prepayment is the deposit before the start of operation into an account segregated from licensee assets and

outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Commission.

(2) *A surety method, insurance, or other guarantee method*. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to this part. For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix C to this part. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix D to this part. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix E to this part. Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods used to satisfy the requirements of this section. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as five years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Commission, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Commission within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(iii) The surety method or insurance must remain in effect until the Commission has terminated the license.

(3) *An external sinking fund in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund*. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The surety, insurance, or other guarantee provisions must be as stated in paragraph (f)(2) of this section.

(4) In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in paragraph (d) of this section, and indicating that funds for decommissioning will be obtained when necessary.

(5) When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(g) Each person licensed under this part or parts 32 through 36 and 39 of this chapter shall keep records of information important to the decommissioning of a facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with § 30.34(b), licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Commission considers important to decommissioning consists of—

(1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

(2) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(3) Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or byproduct materials having only half-lives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003 (For requirements prior to January 1, 1994, see 10 CFR 20.3 as contained in the CFR edition revised as of January 1, 1993.);

(ii) All areas outside of restricted areas that require documentation under § 30.35(g)(1).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 10 CFR 20.2108; and

(iv) All areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, subpart E, or apply for approval for disposal under 10 CFR 20.2002.

(4) Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(h) In providing financial assurance under this section, each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the NRC, as follows:

(1) If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below 75 percent of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

(2) If, at any time, the fund balance falls below 75 percent of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

(3) Within 30 days of taking the actions required by paragraph (h)(1) or (h)(2) of this section, the licensee must provide a written report of such actions to the Director, Office of Nuclear Material Safety and Safeguards, and state the new balance of the fund.

[53 FR 24044, June 27, 1988, as amended at 56 FR 23471, May 21, 1991; 58 FR 39633, July 26, 1993; 58 FR 67659, Dec. 22, 1993; 58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 60 FR 38238, July 26, 1995; 61 FR 24673, May 16, 1996; 62 FR 39090, July 21, 1997; 63 FR 29541, June 1, 1998; 68 FR 57335, Oct. 3, 2003; 76 FR 35564, Jun. 17, 2011; 79 FR 75739, Dec. 19, 2014]

§ 30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

[Top of File]

(a) Each specific license expires at the end of the day on the expiration date stated in the license, unless the licensee has filed an application for renewal under § 30.37 not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of byproduct material until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall--

(1) Limit actions involving byproduct material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release in accordance with NRC requirements.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 30.6, each licensee shall provide notification to the NRC in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with NRC requirements, or submit within 12 months of notification a decommissioning plan, if required by paragraph (g)(1) of this section, and begin decommissioning upon approval of that plan if--

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements; or

(3) No principal activities under the license have been conducted for a period of 24 months; or

(4) No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with NRC requirements.

(e) Coincident with the notification required by paragraph (d) of this section, the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to § 30.35 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to paragraph (g)(4)(v) of this section.

(1) Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective November 24, 1995.

(2) Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Commission may grant a request to extend the time periods established in paragraph (d) if the Commission determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section may not commence until the Commission has made a determination on the request.

(g)(1) A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in paragraph (g)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in paragraph (i) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(h)(1) Except as provided in paragraph (i) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

(2) Except as provided in paragraph (i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(i) The Commission may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 24-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall--

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E. The licensee shall, as appropriate--

(i) Report levels of gamma radiation in units of millisieverts (microroentgen) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of megabecquerels (disintegrations per minute or microcuries) per 100 square centimeters--removable and fixed--for surfaces, megabecquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Byproduct material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 10 CFR part 20, subpart E.

(4) Records required by § 30.51 (d) and (f) have been received.

[59 FR 36034, July 15, 1994, as amended at 60 FR 38238, July 26, 1995; 61 FR 1114, Jan. 16, 1996; 61 FR 24673, May 16, 1996; 61 FR 29637, June 12, 1996; 62 FR 39090, July 21, 1997; 73 FR 42673, July 23, 2008]

§ 30.37 Application for renewal of licenses.

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Application for renewal of a specific license must be filed on NRC Form 313 and in accordance with § 30.32.

[59 FR 36035, July 15, 1994, as amended at 61 FR 1114, Jan. 16, 1996; 66 FR 64738, Dec. 14, 2001; 75 FR 73942, Nov. 30, 2010]

§ 30.38 Application for amendment of licenses and registration certificates.

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Applications for amendment of a license must be filed in accordance with § 30.32 and must specify the respects in which the licensee desires its license to be amended and the grounds for the amendment. Applications for amendment of sealed source and device registration certificates must be filed in accordance with § 32.210 of this chapter and any other applicable provisions and must specify the respects in which the certificate holder desires its certificate to be amended and the grounds for the amendment.

[49 FR 19625, May 9, 1984; 77 FR 43690, Jul. 25, 2012]

§ 30.39 Commission action on applications to renew or amend.

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In considering an application to renew or amend a license or to amend a sealed source or device registration certificate, the Commission will apply the applicable criteria set forth in § 30.33 and parts 32 through 36 and 39 of this chapter.

[30 FR 8185, June 26, 1965, as amended at 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993; 77 FR 43690, Jul. 25, 2012]

§ 30.41 Transfer of byproduct material.

[Top of File]

(a) No licensee shall transfer byproduct material except as authorized pursuant to this section.

(b) Except as otherwise provided in his license and subject to the provisions of paragraphs (c) and (d) of this section, any licensee may transfer byproduct material:

(1) To the Department;

(2) To the agency in any Agreement State which regulates radioactive material pursuant to an agreement under section 274 of the Act;

(3) To any person exempt from the licensing requirements of the Act and regulations in this part, to the extent permitted under such exemption;

(4) To any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

(5) To any person authorized to receive such byproduct material under terms of a specific license or a general license or their equivalents issued by the Atomic Energy Commission, the Commission, or an Agreement State;

(6) To a person abroad pursuant to an export license issued under part 110 of this chapter; or

(7) As otherwise authorized by the Commission in writing.

(c) Before transferring byproduct material to a specific licensee of the Commission or an Agreement State or to a general licensee who is required to register with the Commission or with an Agreement State prior to receipt of the byproduct material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred.

(d) The following methods for the verification required by paragraph (c) of this section are acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate;

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date;

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of byproduct material to be transferred, specifying the license or registration certificate number, issuing agency and expiration date: Provided, That the oral certification is confirmed in writing within 10 days;

(4) The transferor may obtain other sources of information compiled by a reporting service from official records of the Commission or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in paragraphs (d)(1) to (4) of this section are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Commission or the licensing agency of an Agreement State that the transferee is licensed to receive the byproduct material.

[38 FR 33969, Dec. 10, 1973, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6922, Feb. 17, 1978]

Records, Inspections, Tests, and Reports

[Top of File]

§ 30.50 Reporting requirements.

(a) *Immediate report*. Each licensee shall notify the NRC as soon as possible but not later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) *Twenty-four hour report*. Each licensee shall notify the NRC within 24 hours after the discovery of any of the following events involving licensed material:

(1) An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing

additional radiological controls or by prohibiting entry into the area;

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination.

(2) An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

(ii) The equipment is required to be available and operable when it is disabled or fails to function; and

(iii) No redundant equipment is available and operable to perform the required safety function.

(3) An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

(4) An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in appendix B of §§ 20.1001-20.2401 of 10 CFR part 20 for the material; and

(ii) The damage affects the integrity of the licensed material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the NRC Operations Center.[1] To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back telephone number;

(ii) A description of the event, including date and time;

(iii) The exact location of the event;

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved; and

(v) Any personnel radiation exposure data available.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the NRC using an appropriate method listed in § 30.6(a); and a copy must be sent to the appropriate NRC Regional office listed in appendix D to part 20 of this chapter. The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(ii) The exact location of the event;

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved;

(iv) Date and time of the event;

(v) Corrective actions taken or planned and the results of any evaluations or assessments; and

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(3) The provisions of § 30.50 do not apply to licensees subject to the notification requirements in § 50.72. They do apply to those part 50 licensees possessing material licensed under part 30, who are not subject to the notification requirements in § 50.72.

[56 FR 40767, Aug. 16, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 68 FR 58804, Oct. 10, 2003]

[1] The commercial telephone number for the NRC Operations Center is (301) 816-5100.

§ 30.51 Records.

[Top of File]

(a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and parts 31 through 36 of this chapter shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

(1) The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by the regulations in this part and parts 31 through 36 of this chapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c)(1) Records which must be maintained pursuant to this part and parts 31 through 36 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part and parts 31 through 36 and 39 of this chapter, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part and parts 31 through 36 and 39 of this chapter for such records shall apply unless the Commission, pursuant to § 30.11, has granted a specific exemption from the record retention requirements specified in the regulations in this part or parts 31 through 36 and 39 of this chapter.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 1981[1]), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(e) If licensed activities are transferred or assigned in accordance with § 30.34(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under §§ 20.2002 (including burials authorized before January 28, 19811), 20.2003, 20.2004, 20.2005; and

(2) Records required by § 20.2103(b)(4).

(f) Prior to license termination, each licensee shall forward the records required by § 30.35(g) to the appropriate NRC Regional Office.

[41 FR 18301, May 5, 1976, as amended at 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 53 FR 19245, May 27, 1988; 58 FR 7736, Feb. 9, 1993; 61 FR 24673, May, 16, 1996]

[1] A previous § 20.304 permitted burial of small quantities of licensed materials in soil before January 28, 1981, without specific Commission authorization. See § 20.304 contained in the 10 CFR, parts 0 to 199, edition revised as of January 1, 1981.

§ 30.52 Inspections.

[Top of File]

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

[30 FR 8185, June 26, 1965]

§ 30.53 Tests.

[Top of File]

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and parts 31 through 36 and 39 of this chapter, including tests of:

(a) Byproduct material;

(b) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

[30 FR 8185, June 26, 1965, as amended by 43 FR 6922, Feb. 17, 1978; 52 FR 8241, Mar. 17, 1987; 58 FR 7736, Feb. 9, 1993]

§ 30.55 Tritium reports

[Top of File]

(a)-(b) [Reserved]

(c) Except as specified in paragraph (d) of this section, each licensee who is authorized to possess tritium shall report promptly to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter by telephone and telegraph, mailgram, or facsimile any incident in which an attempt has been made or is believed to have been made to commit a theft or unlawful diversion of more than 10 curies of such material at any one time or more than 100 curies of such material in any one calendar year. The initial report shall be followed within a period of fifteen (15) days by a written report submitted to the appropriate NRC Regional Office which sets forth the details of the incident and its consequences. Copies of such written report shall be sent to the Director, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 30.6(a). Subsequent to the submission of the written report required by this paragraph, the licensee shall promptly inform the Office of Nuclear Material Safety and Safeguards by means of a written report of any substantive additional information, which becomes available to the licensee, concerning an attempted or apparent theft or unlawful diversion of tritium.

(d) The reports described in this section are not required for tritium possessed pursuant to a general license provided in part 31 of this chapter or for tritium contained in spent fuel.

[37 FR 9208, May 6, 1972, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 2330, Jan. 24, 1973; 41 FR 16446, Apr. 19, 1976; 43 FR 6922, Feb. 17, 1978; 46 FR 55085, Nov. 6, 1981; 49 FR 24707, June 15, 1984; 52 FR 31611, Aug. 21, 1987; 68 FR 58804, Oct. 10, 2003; 73 FR 5718, Jan. 31, 2008; 79 FR 75739, Dec. 19, 2014]

Enforcement

[Top of File]

§ 30.61 Modification and revocation of licenses and registration certificates.

(a) The terms and conditions of each license and registration certificate issued under the regulations in this part and parts 31 through 36 and 39 of this chapter shall be subject to amendment, revision, or modification by reason of amendments to the Act, or by reason of rules, regulations, and orders issued in accordance with the terms of the Act.

(b) Any license or registration certificate may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Commission to refuse to grant a license or registration certificate on an original application, or for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation, or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, no license or registration certificate shall be modified, suspended, or revoked unless, before the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee or certificate holder in writing and the licensee or certificate holder shall have been given an opportunity to demonstrate or achieve compliance with all lawful requirements.

[30 FR 8185, June 26, 1965, as amended at 35 FR 11460, July 17, 1970; 43 FR 6922, Feb. 17, 1978; 77 FR 43690, Jul. 25, 2012]

§ 30.62 Right to cause the withholding or recall of byproduct material.

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The Commission may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission, or who uses such

materials in violation of law or regulation of the Commission, or in a manner other than as disclosed in the application therefor or approved by the Commission.

[30 FR 8185, June 26, 1965, as amended at 40 FR 8785, Mar. 3, 1975]

§ 30.63 Violations.

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(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55072, Nov. 24, 1992]

§ 30.64 Criminal penalties.

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(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 30 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 30 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 30.1, 30.2, 30.4, 30.5, 30.6, 30.8, 30.11, 30.12, 30.13, 30.15, 30.31, 30.32, 30.33, 30.37, 30.38, 30.39, 30.61, 30.62, 30.63, 30.64, 30.70, 30.71, and 30.72.

[57 FR 55072, Nov. 24, 1992; 73 FR 42673, July 23, 2008]

Schedules

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§ 30.70 Schedule A--Exempt concentrations.

[See footnotes at the end of this table]

Element (atomic number)	Isotope	Col. I	Col. II
		Gas Concentration µCi/ml[1]	Liquid and Solid Concentration µCi/ml[2]
Antimony (51)	Sb 122		3×10^{-4}
	Sb 124		2×10^{-4}
	Sb 125		1×10^{-3}
Argon (18)	A 37	1×10^{-3}	
	A 41	4×10^{-7}	

Arsenic (33)	As 73		5 x 10-3
	As 74		5 x 10-4
	As 76		2 x 10-4
	As 77		8 x 10-4
Barium (56)	Ba 131		2 x 10-3
	Ba 140		3 x 10-4
Beryllium (4)	Be 7		2 x 10-2
Bismuth (83)	Bi 206		4 x 10-4
Bromine (35)	Br 82	4 x 10-7	3 x 10-3
Cadmium (48)	Cd 109		2 x 10-3
	Cd 115M		3 x 10-4
	Cd 115		3 x 10-4
Calcium (20)	Ca 45		9 x 10-5
	Ca 47		5 x 10-4
Carbon (6)	C 14	1 x 10 -6	8 x 10-3
Cerium (58)	Ce 141		9 x 10-4
	Ce 143		4 x 10-4
	Ce 144		1 x 10-4
Cesium (55)	Cs 131		2 x 10-2
	Cs 134m		6 x 10-2
	Cs 134		9 x 10-5
Chlorine (17)	Cl 38	9 x 10-7	4 x 10 -3
Chromium (24)	Cr 51		2 x 10-2
Cobalt (27)	Co 57		5 x 10 -3
	Co 58		1 x 10 -3
	Co 60		5 x 10-4
Copper (29)	Cu 64		3 x 10-3
Dysprosium (66)	Dy 165		4 x 10-3
	Dy 166		4 x 10-4
Erbium (68)	Er 169		9 x 10-4
	Er 171		1 x 10-3
Europium (63)	Eu 152 (T/2=9.2 hrs)		6 x 10-4
	Eu 155		2 x 10-3
Fluorine (9)	F 18	2 x 10-6	8 x 10-3
Gadolinium (64)	Gd 153		2 x 10-3
	Gd 159		8 x `0-4
Gallium (31)	Ga 72		4 x 10-4
Germanium (32)	Ge 71		2 x 10-2
Gold (79)	Au 196		2 x 10 -3

	Au 198		5 x 10-4
	Au 199		2 x 10 -3
Hafnium (72)	Hf 181		7 x 10-4
Hydrogen (1)	H 3	5 x 10-6	3 x 10-2
Indium (49)	In 113M		1 x 10 -2
	In 114M		2 x 10-4
Iodine (53)	I 126	3 x 10-9	2 x 10-5
	I 131	3 x 10-9	2 x 10-5
	I 132	8 x 10-8	6 x 10-4
	I 133	1 x 10-8	7 x 10-5
	I 134	2 x 10-7	1 x 10-3
Iridium (77)	Ir 190		2 x 10-3
	Ir 192		4 x 10-4
	Ir 194		3 x 10-4
Iron (26)	Fe 55		8 x 10-3
	Fe 59		6 x 10-4
Krypton (36)	Kr 85M	1 x 10-6	
	Kr 85	3 x 10 -6	
Lanthanum (57)	La 140		2 x 10-4
Lead (82)	Pb 203		4 x 10-3
Lutetium (71)	Lu 177		1 x 10-3
Manganese (25)	Mn 52		3 x 10-4
	Mn 54		1 x 10-3
	Mn 56		1 x 10-3
Mercury (80)	Hg 197M		2 x 10-3
	Hg 197		3 x 10-3
	Hg 203		2 x 10-4
Molybdenum (42)	Mo 99		2 x 10-3
Neodymium (60)	Nd 147		6 x 10-4
	Nd 149		3 x 10-3
Nickel (28)	Ni 65		1 x 10-3
Niobium (Columbium) (41)	Nb 95		1 x 10-3
	Nb 97		9 x 10-3
Osmium (76)	Os 185		7 x 10-4
	Os 191M		3 x 10-2
	Os 191		2 x 10-3
	Os 193		6 x 10-4
Palladium (46)	Pd 103		3 x 10-3
	Pd 109		9 x 10-4

Phosphorus (15)	P 32		2×10^{-4}
Platinum (78)	Pt 191		1×10^{-3}
	Pt 193M		1×10^{-2}
	Pt 197M		1×10^{-2}
	Pt 197		1×10^{-3}
Potassium (19)	K 42		3×10^{-3}
Praseodymium (59)	Pr 142		3×10^{-4}
	Pr 143		5×10^{-4}
Promethium (61)	Pm 147		2×10^{-3}
	Pm 149		4×10^{-4}
Rhenium (75)	Re 183		6×10^{-3}
	Re 186		9×10^{-4}
	Re 188		6×10^{-4}
Rhodium (45)	Rh 103M		1×10^{-1}
	Rh 105		1×10^{-3}
Rubidium (37)	Rb 86		7×10^{-4}
Ruthenium (44)	Ru 97		4×10^{-4}
	Ru 103		8×10^{-4}
	Ru 105		1×10^{-3}
	Ru 106		1×10^{-4}
Samarium (62)	Sm 153		8×10^{-4}
Scandium (21)	Sc 46		4×10^{-4}
	Sc 47		9×10^{-4}
	Sc 48		3×10^{-4}
Selenium (34)	Se 75		3×10^{-3}
Silicon (14)	Si 31		9×10^{-3}
Silver (47)	Ag 105		1×10^{-3}
	Ag 110M		3×10^{-4}
	Ag 111		4×10^{-4}
Sodium (11)	Na 24		2×10^{-3}
Strontium (38)	Sr 85		1×10^{-4}
	Sr 89		1×10^{-4}
	Sr 91		7×10^{-4}
	Sr 92		7×10^{-4}
Sulfur (16)	S 35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta 182		4×10^{-4}
Technetium (43)	Tc 96M Tc 96		1×10^{-1} 1×10^{-3}
Tellurium (52)	Te 125M		2×10^{-3}
	Te 127M		6×10^{-4}

	Te 127		3×10^{-3}
	Te 129M		3×10^{-4}
	Te 131M		6×10^{-4}
	Te 132		3×10^{-4}
Terbium (65)	Tb 160		4×10^{-4}
Thallium (81)	Tl 200 Tl 201 Tl 202 Tl 204		4×10^{-3} 3×10^{-3} 1×10^{-3} 1×10^{-3}
Thulium (69)	Tm 170 Tm 171		5×10^{-4} 5×10^{-3}
Tin (50)	Sn 113 Sn 125		9×10^{-4} 2×10^{-4}
Tungsten (Wolfram) (74)	W 181 W 187		4×10^{-3} 7×10^{-4}
Vanadium (23)	V 48		3×10^{-4}
Xenon (54)	Xe 131M	4×10^{-6}	
	Xe 133	3×10^{-6}	
	Xe 135	1×10^{-6}	
Ytterbium (70)	Yb 175		1×10^{-3}
Yttrium (39)	Y 90		2×10^{-4}
	Y 91M		3×10^{-2}
	Y 91		3×10^{-4}
	Y 92		6×10^{-4}
	Y 93		3×10^{-4}
Zinc (30)	Zn 65		1×10^{-3}
	Zn 69M		7×10^{-4}
	Zn 69		2×10^{-2}
Zirconium (40)	Zr 95		6×10^{-4}
	Zr 97		2×10^{-4}
Beta and/or gamma emitting byproduct not listed above with half-life less than three years		1×10^{-10}	1×10^{-6}

Footnotes to Schedule A

1. Values are given only for those materials normally used as gases.
2. µCi/gm for solids.

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule A, the activity stated is that of the parent isotope and takes into account the daughters.

NOTE 2: For purposes of 30.14 where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule A for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

Example:

$$\frac{\text{Concentration of Isotope A in product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

[30 FR 8185, June 26, 1965, as amended at 35 FR 3982, Mar. 3, 1970; 38 FR 29314, Oct. 24, 1973; 59 FR 5520, Feb. 7, 1994]

§ 30.71 Schedule B.

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Byproduct material	Microcuries
Antimony 122 (Sb 122)	100
Antimony 124 (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (as 77)	100
Barium 131 (Ba 131)	10
Barium 133 (Ba 133)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	10
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 129 (Cs 129)	100
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1,000
Cobalt 57 (Co 57)	100
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100

Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 9.2 h (Eu 152 9.2 h)	100
Europium 152 13 yr (Eu 152 13 yr)	1
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10
Fluorine 18 (F 18)	1,000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 67 (Ga 67)	100
Gallium 72 (Ga 72)	10
Germanium 68 (Ge 68)	10
Germanium 71 (Ge 71)	100
Gold 195 (Au 195)	10
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H3)	1,000
Indium 111 (In 111)	100
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 123 (I 123)	100
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 52 (Fe 52)	10
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100

Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10
Nickel 65 (Ni 65)	100
Niobium 93m (Nb 93m)	10
Niobium 95 (Nb 95)`	10
Niobium 97 (Nb 97)	10
Osmium 185 (Os 185)	10
Osmium 191m (Os 191)	100
Osmium 191 (Os 191)	100
Osmium 193 (Os 193)	100
Palladium 103 (Pd 103)	100
Palladium 109 (Pd 109)	100
Phosphorus 32 (P 32)	10
Platinum 191 (Pt 191)	100
Platinum 193m (Pt 193m)	100
Platinum 193 (Pt 193)	100
Platinum 197m (Pt 197m)	100
Platinum 197 (Pt 197)	100
Polonium 210 (Po 210)	0.1
Potassium 42 (K 42)	10
Potassium 43 (K 43)	10
Praseodymium 142 (Pr 142)	100
Praseodymium 143 (Pr 143)	100
Promethium 147 (Pm 147)	10
Promethium 149 (Pm 149)	10
Rhenium 186 (Re 186)	100
Rhenium 188 (Re 188)	100
Rhodium 103m (Rh 103m)	100
Rhodium 105 (Rh 105)	100
Rubidium 81 (Rb 81)	10
Rubidium 86 (Rb 86)	10
Rubidium 87 (Rb 87)	10
Ruthenium 97 (Ru 97)	100
Ruthenium 103 (Ru 103)	10
Ruthenium 105 (Ru 105)	10
Ruthenium 106 (Ru 106)	1
Samarium 151 (Sm 151)	10
Samarium 153 (Sm 153)	100
Scandium 46 (Sc 46)	10
Scandium 47 (Sc 47)	100
Scandium 48 (Sc 48)	10
Selenium 75 (Se 75)	10

Silicon 31 (Si 31)	100
Silver 105 (Ag 105)	10
Silver 110m (Ag 110m)	1
Silver 111 (Ag 111)	100
Sodium 22 (Na 22)	10
Sodium 24 (Na 24)	10
Strontium 85 (Sr 85)	10
Strontium 89 (Sr 89)	1
Strontium 90 (Sr 90)	0.1
Strontium 91 (Sr 91)	10
Strontium 92 (Sr 92)	10
Sulphur 35 (S 35)	100
Tantalum 182 (Ta 182)	10
Technetium 96 (Tc 96)	10
Technetium 97m (Tc 97m)	100
Technetium 97 (Tc 97)	100
Technetium 99m (Tc 99m)	100
Technetium 99 (Tc 99)	10
Tellurium 125 m (Te 125 m)	10
Tellurium 127m (Te 127m)	10
Tellurium 127 (Te 127)	100
Tellurium 129m (Te 129m)	10
Tellurium 129 (Te 129)	100
Tellurium 131m (Te 131m)	10
Tellurium 132 (Te 132)	10
Terbium 160 (Tb 160)	10
Thallium 200 (Tl 200)	100
Thallium 201 (Tl 201)	100
Thallium 202 (Tl 202)	100
Thallium 204 (Tl 204)	10
Thulium 170 (Tm 170)	10
Thulium 171 (Tm 171)	10
Tin 113 (Sn 113)	10
Tin 125 (Sn 125)	10
Tungsten 181 (W 181)	10
Tungsten 185 (W 185)	10
Tungsten 187 (W 187)	100
Vanadium 48 (V 48)	10
Xenon 131m (Xe 131m)	1,000
Xenon 133 (Xe 133)	100
Xenon 135 (Xe 135)	100
Ytterbium 175 (Yb 175)	100
Yttrium 87 (Y 87)	10
Yttrium 88 (Y 88)	10
Yttrium 90 (Y 90)	10
Yttrium 91 (Y91)	10

Yttrium 92 (Y92)	100
Yttrium 93 (Y93)	100
Zinc 65 (Zn 65)	10
Zinc 69m (Zn 69m)	100
Zinc 69 (Zn 69)	1,000
Zirconium 93 (Zr 93)	10
Zirconium 95 (Zr 95)	10
Zirconium 97 (Zr 97)	10
Any byproduct material not listed above other than alpha emitting byproduct materials	0.1

[35 FR 6427, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 59 FR 5519, Feb. 7, 1994; 72 FR 55926, Oct. 1, 2007]

§ 30.72 Schedule C—Quantities of radioactive materials requiring consideration of the need for an emergency plan for responding to a release.

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Radioactive material[1]	Release fraction	Quantity (curies)
Actinium-228	0.001	4,000
Americium 241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (non-carbon dioxide)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000

Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Manganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	0.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technitium-99	.01	10,000
Technitium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000

Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[4]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha[4]	.0001	20
Combinations of radioactive materials listed above[1]		

[1] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

[2] Waste packaged in Type B containers does not require an emergency plan.

[54 FR 14061, Apr. 7, 1989, as amended at 61 FR 9902, Mar. 12, 1996; 72 FR 55926, Oct. 1, 2007]

Appendix A to Part 30—Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

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I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1 or A.2 of this section. For purposes of applying the Appendix A criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site.

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to total net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

(ii) Net working capital and tangible net worth each at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $21 million; and

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current

decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

2. The parent company must have:

(i) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and –) as issued by Standard and Poor's or Aaa, Aa, A, or Baa (including adjustment of 1, 2, or 3) as issued by Moody's; and

(ii) Total net worth at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

(iii) Tangible net worth of at least $21 million; and

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used), or, for a power reactor licensee, at least six times the amount of decommissioning funds being assured by a parent company guarantee for the total of all reactor units or parts thereof.

B. The parent company's independent certified public accountant must compare the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the parent company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the parent company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of paragraph A of this section. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of paragraph A of this section, the licensee must send notice to the Commission of intent to establish alternate financial assurance as specified in the Commission's regulations. The notice must be sent by certified mail within 90 days after the end of the fiscal year for which the year end financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Parent Company Guarantee

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Commission, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Commission's regulations within 90 days after receipt by the licensee and Commission of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide alternative financial assurance that meets the provisions of the Commission's regulations in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Commission has terminated the license, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee, whose trust operations are regulated and examined by a Federal or State agency. The Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

E. The guarantor must agree that it would be subject to Commission orders to make payments under the guarantee agreement.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

1. Declare that the financial assurance guaranteed by the parent company guarantee agreement is immediately due and

payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. 1. The guarantor must agree to notify the NRC, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code, or the occurrence of any other event listed in paragraph F of this Appendix, by or against:

(i) The guarantor;

(ii) The licensee;

(iii) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(iv) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

2. This notification must include:

(i) A description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the parent company guarantee for decommissioning will be transferred to the standby trust as soon as possible;

(ii) If a petition of bankruptcy was filed, the identity of the bankruptcy court in which the petition for bankruptcy was filed; and

(iii) The date of filing of any petitions.

[53 FR 24046, June 27, 1988 as amended at 63 FR 50479, Sept. 22, 1998; 76 FR 35565 Jun. 17, 2011]

Appendix B to Part 30--Quantities[1] of Licensed Material Requiring Labeling

[Top of File]

Materials	Microcuries
Americium-241	.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cesium-131	1,000

Cesium-134m	100
Cesium-134	1
Cesium-135	10
Cesium-136	10
Cesium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 9.2h	100
Europium-152 13 yr	1
Europium-154	1
Europium-155	10
Fluorine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100

Krpton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molbdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10

Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Seleium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.10
Strontium-91	10
Strontium-92	10
Sulphur-35	100
Tantalum-182	10
Technetium-96	10
Technetium-97m	100
Technetium-97	100
Technetium-99m	100
Technetium-99	10
Tellurium-125m	10
Tellurium127m	10
Tellurium-127	100
Tellurium129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)[1]	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural)[2]	100

Uranium-233	.01
Uranium-234--Uranium-235	.01
Vandium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
Zirconium-93	10
Zirconium-95	10
Zirconium-97	10
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	.01
Any radionuclide other than alpha emitting radio-nuclides, not listed above or mixtures of beta emitters of unknown composition	.1

[1]Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[2]Based on alpha disintegration rate of U-238, U-234, and U-235.

Note: For purposes of § 20.303, where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" (i.e., "unity").

[35 FR 6425, Apr. 22, 1970, as amended at 36 FR 16898, Aug. 26, 1971; 38 FR 29314, Oct. 24, 1973; 39 FR 23991, June 28, 1974; 45 FR 71763, Oct. 30, 1980. Redesignated at 56 FR 23391, May 21, 1991, and further redesignated at 58 FR 67659, Dec. 22, 1993]

Appendix C to Part 30—Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

[Top of File]

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix C criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

(1) Tangible net worth of at least $21 million, and total net worth at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the

current amount required if certification is used).

(3) A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and –) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A of this appendix. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Commission of its intent to establish alternate financial assurance as specified in the Commission's regulations within 120 days of such notice.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Commission, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A–" and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee will notify the Commission in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poo's and Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will fund the standby trust in the amount guaranteed by the self-guarantee agreement.

G. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these regulations that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph H of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

[58 FR 68730, Dec. 29, 1993; 59 FR 1618, Jan. 12, 1994; 63 FR 50479, Sept. 22, 1998; 76 FR 35566 Jun. 17, 2011]

Appendix D to Part 30—Criteria Relating To Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have no Outstanding Rated Bonds

[Top of File]

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix D criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

(1) Tangible net worth of at least $21 million, and total net worth of at least 10 times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by total net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A of this appendix, the licensee must send notice to the NRC of intent to establish alternative financial assurance as specified in NRC regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the NRC. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the regulations within 90 days following receipt by the NRC of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will fund the standby trust in the amount of the current cost estimates for decommissioning.

E. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted. The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Commission will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

G. The guarantor must notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph F of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

[63 FR 29542, June 1, 1998; 76 FR 35567 Jun. 17, 2011]

Appendix E to Part 30—Criteria Relating to Use of Financial Tests and Self-Guarantee For Providing Reasonable Assurance of Funds For Decommissioning by Nonprofit Colleges, Universities, and Hospitals

[Top of File]

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in Paragraph II.A.(1) or the criteria in Paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or –) as issued by Standard and Poor's (S&P) or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in Paragraph II.B.(1) or the criteria in Paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or –) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

(2) For applicants or licensees that do not issue bonds, all the following tests must be met:

(a) (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

(1) The licensee's independent certified public accountant must compare the data used by the licensee in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the licensee's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the licensee's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II of this appendix. In connection with the auditing procedure, the licensee must inform the NRC within 90 days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

(2) After the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee to the Commission within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the NRC of its intent to establish alternative financial assurance as specified in NRC regulations. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that--

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, and/or return receipt requested, to the Commission. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The applicant or licensee must provide to the Commission a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Commission, the licensee will fund the standby trust in the amount of the current cost estimates for decommissioning.

E. (1) If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall notify the Commission in writing within 20 days after publication of the change by the rating service.

(2) If the licensee's most recent bond issuance ceases to be rated in any category of "A"– and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. (1) A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

(2) The trustee and trust must be acceptable to the Commission. An acceptable trustee includes an appropriate State or Federal Government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Commission has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in the part of these regulations that governs the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

G. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Commission may:

(1) Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

(2) Exercise any and all of its other rights under applicable law.

H. The guarantor must notify the NRC, in writing, immediately following the occurrence of any event listed in paragraph G of this appendix, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

[63 FR 29542, June 1, 1998; 76 FR 35568 Jun. 17, 2011]

PART 31—GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL

[Top of File]

§ 31.1 Purpose and scope.

[Top of File]

This part establishes general licenses for the possession and use of byproduct material and a general license for ownership of byproduct material. Specific provisions of 10 CFR Part 30 are applicable to general licenses established by this part. These provisions are specified in § 31.2 or in the particular general license.

[65 FR 79187, Dec. 18, 2000]

§ 31.2 Terms and conditions.

[Top of File]

The general licenses provided in this part are subject to the general provisions of Part 30 of this chapter (Secs. 30.1 through 30.10), the provisions of §§ 30.14(d), 30.34(a) to (e), 30.41, 30.50 to 30.53, 30.61 to 30.63, and Parts 19, 20, and 21, of this chapter[1] unless indicated otherwise in the specific provision of the general license.

[65 FR 79187, Dec. 18, 2000]

[1] Attention is directed particularly to the provisions of Part 20 of this chapter concerning labeling of containers.

§ 31.3 [Reserved].

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[30 FR 8189, June 26, 1965, as amended at 34 FR 6652, Apr. 18, 1969; 35 FR 3982, Mar. 3, 1970; 77 FR 43690, Jul. 25, 2012]

§ 31.4 Information collection requirements: OMB approval.

[Top of File]

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0016.

(b) The approved information collection requirements contained in this part appear in §§31.5, 31.8, 31.11, and 31.12.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 31.11, NRC Form 483 is approved under control number 3150-0038.

(2) [Reserved]

[62 FR 52186, Oct. 6, 1997, as amended at 67 FR 67099, Nov. 4, 2002; 72 FR 55926, Oct. 1, 2007]

§ 31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere[5]

[Top of File]

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b)(1) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have

been manufactured or initially transferred and labeled in accordance with the specifications contained in—

(i) A specific license issued under § 32.51 of this chapter; or

(ii) An equivalent specific license issued by an Agreement State; or

(iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter.

(2) The devices must have been received from one of the specific licensees described in paragraph (b)(1) of this section or through a transfer made under paragraph (c)(9) of this section.

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in paragraph (a) of this section:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified in the label; however:

(i) Devices containing only krypton need not be tested for leakage of radioactive material, and

(ii) Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

(3) Shall assure that the tests required by paragraph (c)(2) of this section and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(i) In accordance with the instructions provided by the labels; or

(ii) By a person holding a specific license pursuant to parts 30 and 32 of this chapter or from an Agreement State to perform such activities;

(4) Shall maintain records showing compliance with the requirements of paragraphs (c)(2) and (c)(3) of this section. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(i) Each record of a test for leakage or radioactive material required by paragraph (c)(2) of this section must be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

(ii) Each record of a test of the on-off mechanism and indicator required by paragraph (c)(2) of this section must be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

(iii) Each record that is required by paragraph (c)(3) of this section must be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 of this chapter or by an Agreement State. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the Commission. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days. Under these circumstances, the criteria set out in § 20.1402 of this chapter, "Radiological criteria for unrestricted use," may be applicable, as determined by the Commission on a case-by-case basis;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with part 110 of this chapter;

(8)(i) Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general licensee as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

(ii) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter. The report must contain—

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

(A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

(B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by paragraph (c)(1) of this section) so that the device is labeled in compliance with § 20.1904 of this chapter; however the manufacturer, model number, and serial number must be retained;

(C) Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

(D) Reports the transfer under paragraph (c)(8)(ii) of this section.

(9) Shall transfer the device to another general licensee only if—

(i) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section, a copy of § 31.2, 30.51, 20.2201, and 20.2202 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, using an appropriate method listed in § 30.6(a) of this chapter—

(A) The manufacturer's (or initial transferor's) name;

(B) The model number and the serial number of the device transferred;

(C) The transferee's name and mailing address for the location of use; and

(D) The name, title, and phone number of the responsible individual identified by the transferee in accordance with paragraph (c)(12) of this section to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20, and 21, of this chapter.

(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.

(ii) If in possession of a device meeting the criteria of paragraph (c)(13)(i) of this section, shall register these devices annually with the Commission and shall pay the fee required by Sec. 170.31 of this chapter. Registration must be done by verifying, correcting, and/or adding to the information provided in a request for registration received from the Commission. The registration information must be submitted to the NRC within 30 days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (c)(13)(i) of this section is subject to the bankruptcy notification requirement in § 30.34(h) of this chapter.

(iii) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Commission—

(A) Name and mailing address of the general licensee.

(B) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

(C) Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (c)(12) of this section.

(D) Address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage.

(E) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

(F) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(iv) Persons generally licensed by an Agreement State with respect to devices meeting the criteria in paragraph (c)(13)(i) of this section are not subject to registration requirements if the devices are used in areas subject to NRC jurisdiction for a period less than 180 days in any calendar year. The Commission will not request registration information from such licensees.

(14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(15) May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

[5] Persons possessing byproduct material in devices under a general license in § 31.5 before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of § 31.5 in effect on January 14, 1975.

[39 FR 43532, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 40 FR 14085, Mar. 28, 1975; 42 FR 25721, May 19, 1977; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 53 FR 19246, May 27, 1988; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993; 64 FR 42275, Aug. 4, 1999; 65 FR 79188, Dec. 18, 2000; 68 FR 58804, Oct. 10, 2003; 72 FR 55926, Oct. 1, 2007; 72 FR 58486, Oct. 16, 2007; 73 FR 5718, Jan. 31, 2008; 73 FR 42673, July 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 31.6 General license to install devices generally licensed in § 31.5.

[Top of File]

Any person who holds a specific license issued by an Agreement State authorizing the holder to manufacture, install, or service a device described in § 31.5 within such Agreement State is hereby granted a general license to install and service such device in any non-Agreement State and a general license to install and service such device in offshore waters, as defined in § 150.3(f) of this chapter: *Provided*, That:

(a) [Reserved]

(b) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State.

(c) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State which licensed manufacture of the device bear a statement that removal of the label is prohibited.

[30 FR 8189, June 26, 1965, as amended at 30 FR 10947, Aug. 24, 1965; 39 FR 43533, Dec. 16, 1974; 46 FR 44151, Sept. 3, 1981]

§ 31.7 Luminous safety devices for use in aircraft.

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(a) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than 10 curies of tritium or 300 millicuries of promethium-147 and that each device has been manufactured, assembled or initially transferred in accordance with a license issued under the provisions of § 32.53 of this chapter or manufactured or assembled in accordance with a specific license issued by an Agreement State which authorizes manufacture or assembly of the device for distribution to persons

generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in this section are exempt from the requirements of parts 19, 20, and 21, of this chapter, except that they shall comply with the provisions of §§ 20.2201, and 20.2202 of this chapter.

(c) This general license does not authorize the manufacture, assembly, repair or import of luminous safety devices containing tritium or promethium-147.

(d) This general license does not authorize the export of luminous safety devices containing tritium or promethium-147.

(e) This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

[30 FR 8189, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 38 FR 22220, Aug. 17, 1973; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§ 31.8 Americium-241 and radium-226 in the form of calibration or reference sources

[Top of File]

(a) A general license is issued to those persons listed in this section to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs (b) and (c) of this section, americium-241 or radium-226 in the form of calibration or reference sources:

(1) Any person in a non-Agreement State who holds a specific license issued under this chapter which authorizes receipt, possession, use, and transfer of byproduct material, source material, or special nuclear material; and

(2) Any Government agency, as defined in § 30.4 of this chapter, which holds a specific license issued under this chapter which authorizes it to receive, possess, use, and transfer byproduct material, source material, or special nuclear material.

(b) The general license in paragraph (a) of this section applies only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued under § 32.57 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the sources for distribution to persons generally licensed by the Agreement State, or in accordance with a specific license issued by a State with comparable provisions to § 32.57.

(c) The general license in paragraph (a) of this section is subject to the provisions of §§30.14(d), 30.34 (a) to (e), and 30.50 to 30.63 of this chapter, and to the provisions of parts 19, 20, and 21, of this chapter. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources under this general license:

(1) Shall not possess at any one time, at any one location of storage or use, more than 0.185 megabecquerel (5 microcuries) of americium-241 or 0.185 megabecquerel (5 microcuries) of radium-226 in such sources;

(2) Shall not receive, possess, use, or transfer a source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

> The receipt, possession, use, and transfer of this source, Model XX, Serial No. XX, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.
>
> CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM–241 [or RADIUM–226, as appropriate]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.
>
> _____
> (Name of manufacturer or initial transferor)

(3) Shall not transfer, abandon, or dispose of a source except by transfer to a person authorized by a license issued under this chapter or by an Agreement State to receive the source.

(4) Shall store a source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241 or radium-226 which might otherwise escape during storage.

(5) Shall not use a source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(d) This general license does not authorize the manufacture or import of calibration or reference sources containing americium-241 or radium-226.

(e) This general license does not authorize the export of calibration or reference sources containing americium-241 or radium-226.

[30 FR 8189, June 26, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 40767, Aug. 16, 1991; 72 FR 55927, Oct. 1, 2007]

[1] Sources generally licensed under this section before January 19, 1975, may bear labels authorized by the regulations in effect on January 1, 1975. Sources containing radium-226 generally licensed under this section and manufactured before November 30, 2007 shall be labeled in accordance with the applicable State regulations at the time of manufacture or import.

§ 31.9 General license to own byproduct material.

[Top of File]

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of this chapter, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import or export byproduct material, except as authorized in a specific license.

[30 FR 8189, June 26, 1965]

§ 31.10 General license for strontium 90 in ice detection devices.

[Top of File]

(a) A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or initially transferred in accordance with the specifications contained in a license issued pursuant to § 32.61 of this chapter or in accordance with the specifications contained in a specific license issued to the manufacturer by an Agreement State which authorizes manufacture of the ice detection devices for distribution to persons generally licensed by the Agreement State.

(b) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in paragraph (a) of this section:

(1) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license pursuant to part 30 or 32 of this chapter or from an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of § 20.2001.

(2) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

(3) Are exempt from the requirements of parts 19, 20, and 21, of this chapter except that such persons shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202 of this chapter.

(c) The general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices.

[30 FR 9905, Aug. 10, 1965, as amended at 38 FR 22220, Aug. 17, 1973; 40 FR 8785, Mar. 3, 1975; 42 FR 28896, June 6, 1977; 43 FR 6922, Feb. 17, 1978; 56 FR 23471, May 21, 1991; 56 FR 61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993]

§ 31.11 General license for use of byproduct material for certain in vitro clinical or laboratory testing.

[Top of File]

(a) A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of paragraphs (b), (c), (d), (e), and (f) of this section, the following byproduct materials in prepackaged units:

(1) Iodine-125, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(2) Iodine-131, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(3) Carbon-14, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(4) Hydrogen-3 (tritium), in units not exceeding 50 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(5) Iron-59, in units not exceeding 20 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings, or animals.

(6) Selenium-75, in units not exceeding 10 microcuries each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(7) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(8) Cobalt-57, in units not exceeding 0.37 megabecquerel (10 microcuries) each for use in in vitro clinical or laboratory tests not involving internal or external administration of byproduct material, or the radiation therefrom, to human beings or animals.

(b) A person shall not receive, acquire, possess, use, or transfer byproduct material under the general license established by paragraph (a) of this section unless that person:

(1) Has filed NRC Form 483, "Registration Certificate—In Vitro Testing with Byproduct Material Under General License," with the Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, and has received from the Commission a validated copy of NRC Form 483 with a registration number assigned; or

(2) Has a license that authorizes the medical use of byproduct material that was issued under part 35 of this chapter.

(c) A person who receives, acquires, possesses, or uses byproduct material pursuant to the general license established by paragraph (a) of this section shall comply with the following:

(1) The general licensee shall not possess at any one time, under the general license in paragraph (a) of this section, at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57 and/or iron-59 in excess of 7.4 megabecquerels (200 microcuries).

(2) The general licensee shall store the byproduct material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(3) The general licensee shall use the byproduct material only for the uses authorized by paragraph (a) of this section.

(4) The general licensee shall not transfer the byproduct material except by transfer to a person authorized to receive it by a license pursuant to this chapter or from an Agreement State, nor transfer the byproduct material in any manner other than in the unopened, labeled shipping container as received from the supplier.

(5) The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in paragraph (a)(7) of this section as required by § 20.2001.

(d) The general licensee shall not receive, acquire, possess, or use byproduct material pursuant to paragraph (a) of this section:

(1) Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued under the provisions of § 32.71 of this chapter or in accordance with the provisions of a specific license issued by an Agreement State, or before November 30, 2007, and the provisions of a specific license issued by a State with comparable provisions to § 32.71 that authorize manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed by the Agreement State or the State with comparable provisions to § 32.71.

(2) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:[1]

> This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.
>
> (Name of Manufacturer)

(e) The registrant possessing or using byproduct materials under the general license of paragraph (a) of this section shall report in writing to the Director, Office of Nuclear Material Safety and Safeguards, any changes in the information furnished by him in the "Registration Certificate—In Vitro Testing With Byproduct Material Under General License." Form NRC–483. The report shall be furnished within 30 days after the effective date of such change.

(f) Any person using byproduct material pursuant to the general license of paragraph (a) of this section is exempt from the requirements of parts 19, 20, and 21, of this chapter with respect to byproduct materials covered by that general license, except that such persons using the Mock Iodine-125 described in paragraph (a)(7) of this section shall comply with the provisions of §§ 20.2001, 20.2201, and 20.2202.

[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 1271, Jan. 11, 1973; 38 FR 34110, Dec. 11, 1973; 39 FR 26147, July 17, 1974; 40 FR 8785, Mar. 3, 1975; 41 FR 16446, Apr. 19, 1976; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 42 FR 28896, June 6, 1977; 44 FR 50325, Aug. 28, 1979; 51 FR 36967, Oct. 16, 1986; 56 FR 23471, May 21, 1991; 56 FR

61352, Dec. 3, 1991; 58 FR 67659, Dec. 22, 1993; 68 FR 58804, Oct. 10, 2003; 72 FR 55927 Oct. 1, 2007; 73 FR 5718, Jan. 31, 2008; 79 FR 75739, Dec. 19, 2014]

§ 31.12 General license for certain items and self-luminous products containing radium-226

[Top of File]

(a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to November 30, 2007.

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(3) Luminous items installed in air, marine, or land vehicles.

(4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC.

(b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and § 30.50 and 30.51 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this chapter.

(c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section:

(1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001 within 30 days.

(2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the NRC.

(3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter.

(4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC.

(5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.

(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

[53 FR 19246, May 27, 1988; 72 FR 55927 Oct. 1, 2007; 79 FR 75739, Dec. 19, 2014]

§ 31.13 [Reserved].

[Top of File]

[57 FR 55072, Nov. 24, 1992; 72 FR 55927 Oct. 1, 2007]

§ 31.14 [Reserved].

[Top of File]

[57 FR 55073, Nov. 24, 1992; 72 FR 55927 Oct. 1, 2007]

§ 31.15 [Reserved].

[Top of File]

[72 FR 55927 Oct. 1, 2007]

§ 31.16 [Reserved].

[Top of File]

[72 FR 55927 Oct. 1, 2007]

§ 31.17 [Reserved].

[Top of File]

[72 FR 55927 Oct. 1, 2007]

§ 31.18 [Reserved].

[Top of File]

[72 FR 55927 Oct. 1, 2007]

§ 31.19 [Reserved].

[Top of File]

[72 FR 55927 Oct. 1, 2007]

§ 31.20 [Reserved].

[Top of File]

[72 FR 55927 Oct. 1, 2007]

§ 31.21 Maintenance of records.

[Top of File]

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as letters, stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[72 FR 55927 Oct. 1, 2007]

§ 31.22 Violations.

[Top of File]

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of--

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of--

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[72 FR 55927 Oct. 1, 2007]

§ 31.23 Criminal penalties.

[Top of File]

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 31 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 31 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 31.1, 31.2, 31.4, 31.9, 31.22, and 31.23.

[72 FR 55927 Oct. 1, 2007; 77 FR 43690, Jul. 25, 2012]

PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL

[Top of File]

§ 32.1 Purpose and scope

[Top of File]

(a)(1) This part prescribes requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(i) Persons exempted from the licensing requirements of part 30 of this chapter, or equivalent regulations of an Agreement State, or

(ii) Persons generally licensed under part 31 of this chapter or equivalent regulations of an Agreement State.

(iii) Persons licensed under part 35 of this chapter.

(2) This part prescribes requirements for the issuance of specific licenses to persons who introduce byproduct material into a product or material owned by or in the possession of a licensee or another, and regulations governing holders of such licenses.

(3) This part prescribes certain requirements governing holders of licenses to manufacture or distribute items containing byproduct material.

(4) This part describes procedures and prescribes requirements for the issuance of certificates of registration (covering radiation safety information about a product) to manufacturers or initial transferors of sealed sources or devices containing sealed sources.

(b) The provisions and requirements of this part are in addition to, and not in substitution for, other requirements of this chapter. In particular, the provisions of part 30 of this chapter apply to applications, licenses and certificates of registration subject to this part, and the provisions of part 37 of this chapter apply to applications and licenses subject to this part.

(c)(1) The requirements in this part, including provisions that are specific tolicensees, shall apply to Government agencies and Federally recognized Indian Tribes with respect to accelerator-produced radioactive material or discrete sources of radium-226 on November 30, 2007 except that the agency or Tribe may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and radioactive drugs and sources and devices to medical use licensees, until the date of the NRC's final licensing determination, provided that the agency or Tribe submits a new license application for these activities on or before December 1, 2008 or an amendment application for these activities on or before June 2, 2008.

(2) The requirements in this part, including provisions that are specific to licensees, shall apply to all persons other than those included in paragraph (c)(1) of this section with respect to accelerator-produced radioactive material or discrete sources of radium-226 on August 8, 2009, or earlier as noticed by the NRC, except that these persons may continue to manufacture or initially transfer items containing accelerator-produced radioactive material or discrete sources of radium-226 for sale or distribution to persons exempted from the licensing requirements of part 30 of this chapter, and to persons generally licensed under part 31 of this chapter, and to sell or manufacture radioactive drugs and sources and devices to medical use licensees until the date of the NRC's final licensing determination, provided that the person submits a license application within 12 months from the waiver expiration date of August 7, 2009 or within 12 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever is earlier; or that the person submits an amendment request within 6 months from the waiver expiration date of August 7, 2009 or within 6 months from the date of an earlier termination of the waiver as noticed by the NRC, whichever date is earlier.

[30 FR 8192, June 26, 1965, as amended at 52 FR 27786, July 24, 1987; 63 FR 1896, Jan. 13, 1998; 72 FR 55928 Oct. 1, 2007; 77 FR 43690, Jul. 25, 2012; 78 FR 17006, Mar. 19, 2013; 80 FR 74979, Dec. 1, 2015]

§ 32.2 Definitions.

[Top of File]

As used in this part:

Committed dose for the purposes of this part means the radiation dose that will accumulate over time as a result of retention in the body of radioactive material. Committed dose is a generic term for internal dose and must be calculated by summing the projected dose over the 50 years after intake for all irradiated organs or tissues multiplying the doses to individual organs and tissues by applicable tissue weighting factors.

Dose commitment means the total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

Lot Tolerance Percent Defective means, expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Nationally tracked source is a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix E to part 20 of this Chapter. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control. It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both the NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

[34 FR 6653, Apr. 18, 1969, as amended at 39 FR 22129, June 20, 1974; 71 FR 65686, Nov. 8, 2006; 77 FR 43690, Jul. 25, 2012]

§ 32.3 Maintenance of records.

[Top of File]

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy of a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

[53 FR 19246, May 27, 1988]

§ 32.8 Information collection requirements: OMB approval.

[Top of File]

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0001.

(b) The approved information collection requirements contained in this part appear in §§ 32.11, 32.12, 32.14, 32.15, 32.16, 32.18, 32.19, 32.20, 32.21, 32.21a, 32.22, 32.23, 32.25, 32.26, 32.27, 32.29, 32.30, 32.31, 32.32, 32.51, 32.51a, 32.52, 32.53, 32.54, 32.55, 32.56, 32.57, 32.58, 32.61, 32.62, 32.71, 32.72, 32.74, 32.201, 32.210, and 32.211.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 32.11, NRC Form 313 is approved under control number 3150-0120.

(2) [Reserved]

[49 FR 19625, May 9, 1984, as amended at 59 FR 61780, Dec. 2, 1994; 62 FR 52186, Oct. 6 1997; 62 FR 63640, Dec. 2, 1997; 72 FR 58486, Oct. 16, 2007; 77 FR 43691, Jul. 25, 2012]

Subpart A--Exempt Concentrations and Items

[Top of File]

§ 32.11 Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license.

An application for a specific license on Form NRC-313 authorizing the introduction of byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or material containing the byproduct material will be approved if the applicant:

(a) Satisfies the general requirements specified in § 30.33 of this chapter; *provided, however*, that the requirements of § 30.33(a)(2) and (3) do not apply to an application for a license to introduce byproduct material into a product or material owned by or in the possession of the licensee or another and the transfer of ownership or possession of the product or

material containing the byproduct material, if the possession and use of the byproduct material to be introduced is authorized by a license issued by an Agreement State;

(b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

[30 FR 8192, June 26, 1965, as amended at 49 FR 19625, May 9, 1984; 72 FR 58487, Oct. 16, 2007]

§ 32.12 Same: Records and material transfer reports.

[Top of File]

(a) Each person licensed under § 32.11 shall maintain records of transfer of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the byproduct material is transferred for use under § 30.14 of this chapter or equivalent regulations of an Agreement State.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission or to an Agreement State.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.11 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 14863, Apr. 6, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58487, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 32.13 Same: Prohibition of introduction.

[Top of File]

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

[30 FR 8192, June 26, 1965; 72 FR 58487, Oct. 16, 2007]

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer

[Top of File]

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Except for electron tubes and ionization chamber smoke detectors and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) In the case of ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998; 72 FR 58487, Oct. 16, 2007; 77 FR 43691, Jul. 25, 2012]

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

[Top of File]

(a) Each person licensed under § 32.14 for products for which quality control procedures are required shall:

(1) Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions;

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in the license issued under § 32.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded; and

(3) Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material must be considered a defective unit.

(b) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria; or

(2) Any part or product contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (a)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.14; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with the procedures specified in paragraphs (a)(2) and (b)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.14.

(c) [Reserved]

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide ("americium-241" or "Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978; 72 FR 58487, Oct. 16, 2007; 73 FR 42673, July 23, 2008; 77 FR 43691, Jul. 25, 2012]

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

[Top of File]

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.14 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under § 32.14 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 23383, May 25, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58487, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 32.17 [Removed].

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[32 FR 4241, Mar. 18, 1967, as amended by 38 FR 29314, Oct. 24, 1973; 43 FR 6922, Feb. 17, 1978; 72 FR 58488, Oct. 16, 2007]

§ 32.18 Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license.

[Top of File]

An application for a specific license to manufacture, process, produce, package, repackage, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to § 30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however,* That the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

§ 32.19 Same: Conditions of licenses.

[Top of File]

Each license issued under § 32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in § 30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in § 30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.

(b) Each quantity of byproduct material set forth in § 30.71, Schedule B of this chapter shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to § 30.18 of this chapter. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(c) The immediate container of each quantity or separately packaged fractional quantity of byproduct material shall bear a durable, legible label which (1) identifies the radioisotope and the quantity of radioactivity, and (2) bears the words "Radioactive Material."

(d) In addition to the labeling information required by paragraph (c) of this section, the label affixed to the immediate container, or an accompanying brochure, shall also (1) state that the contents are exempt from NRC or Agreement State licensing requirements; (2) bear the words "Radioactive Material--Not for Human Use--Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited -- Exempt Quantities Should Not be Combined"; and (3) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

[35 FR 6428, Apr. 22, 1970]

§ 32.20 Same: Records and material transfer reports.

[Top of File]

(a) Each person licensed under § 32.18 shall maintain records of transfer of material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The licensee shall file a summary report with the Director of the Office of Nuclear Material Safety and Safeguards by an

appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.

(c) For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license.

(d)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include the total quantity of each radionuclide transferred for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution.

(e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

(f) The licensee shall maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.

[48 FR 12333, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for "in vivo" diagnostic use for humans to persons exempt from licensing; Requirements for a license.

[Top of File]

(a) An application for a specific license to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution capsules containing 37 kBq (1 μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a)(2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 μCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997, as amended at 66 FR 64738, Dec. 14, 2001]

§ 32.21a Same: Conditions of license.

[Top of File]

Each license issued under § 32.21 of this part is subject to the following conditions:

(a) The immediate container of the capsule(s) must bear a durable, legible label which:

(1) Identifies the radioisotope, the physical and chemical form, the quantity of radioactivity of each capsule at a specific date; and

(2) Bears the words "Radioactive Material."

(b) In addition to the labeling information required by paragraph (a) of this section, the label affixed to the immediate container, or an accompanying brochure also must:

(1) State that the contents are exempt from NRC or Agreement State licensing requirements; and

(2) Bears the words "Radioactive Material. For "In Vivo" Diagnostic Use Only. This Material Is Not To Be Used for Research Involving Human Subjects and Must Not Be Introduced into Foods, Beverages, Cosmetics, or Other Drugs or Medicinals, or into Products Manufactured for Commercial Distribution. This Material May Be Disposed of in Ordinary Trash."

[62 FR 63640, Dec. 2, 1997]

§ 32.22 Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer.

[Top of File]

(a) An application for a specific license to manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147, or to initially transfer such products for use pursuant to § 30.19 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, or produced pursuant to a license issued by an Agreement State.

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the self-luminous product to demonstrate that the product will meet the safety criteria set forth in § 32.23. The information should include:

(i) A description of the product and its intended use or uses.

(ii) The type and quantity of byproduct material in each unit.

(iii) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product.

(iv) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (a)(2) (iii) and (xii) of this section.

(v) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product.

(vi) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(vii) Degree of access of human beings to the product during normal handling and use.

(viii) Total quantity of byproduct material expected to be distributed in the product annually.

(ix) The expected useful life of the product.

(x) The proposed method of labeling or marking each unit with identification of the manufacturer or initial transferor of the product and the byproduct material in the product.

(xi) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product.

(xii) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(xiii) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.23 and the basis for such estimates.

(xiv) A determination that the probabilities with respect to the doses referred to in § 32.23(d) meet the criteria of that paragraph.

(xv) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.

(xvi) Any additional information, including experimental studies and tests, required by the Commission.

(3)(i) The Commission determines that the product meets the safety criteria in § 32.23; and

(ii) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.

(b) Notwithstanding the provisions of paragraph (a) of this section, the Commission may deny an application for a specific license under this section if the end uses of the product cannot be reasonably foreseen.

[34 FR 9026, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 77 FR 43691, Jul. 25, 2012]

§ 32.23 Same: Safety criteria

[Top of File]

An applicant for a license under § 32.22 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.24 of this part.

(b) In normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column II of the table in § 32.24.

(c) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(d)[1] In use and disposal of a single exempt unit, or in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.24, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

[34 FR 9027, June 6, 1969]

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

> Low—not more than one such failure per year for each 10,000 exempt units distributed.
>
> Negligible—not more than one such failure per year for each 1 million exempt units distributed.

§ 32.24 Same: Table of organ doses.

[Top of File]

Part of body	Column 1 (rem)	Column II (rem)	Column III (rem)	Column IV (rem)
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.001	0.01	0.5	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.015	0.15	7.5	200
Other organs	0.003	0.03	1.5	50

[34 FR 9329, June 13, 1969]

§ 32.25 Conditions of licenses issued under § 32.22: Quality control, labeling, and reports of transfer.

[Top of File]

Each person licensed under § 32.22 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the

quality control standards approved by the Commission;

(b) Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the product and the byproduct material in the product can be identified; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.19 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.19 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.22 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.22 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[34 FR 9027, June 6, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 48 FR 12334, Mar. 24, 1983; 68 FR 58804, Oct. 10, 2003; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, Jul. 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 32.26 Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

[Top of File]

An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter: *Provided, however*, That the requirements of § 30.33(a) (2) and (3) do not apply to an application for a license to transfer byproduct material in gas and aerosol detectors manufactured, processed or produced pursuant to a license issued by an Agreement State.

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the gas and aerosol detector to demonstrate that the product will meet the safety criteria set forth in § 32.27. The information should include:

(1) A description of the product and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the product and changes in chemical and physical form that may occur during the useful life of the product;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b) (3) and (12) of this section;

(5) Details of construction and design of the product as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the product;

(6) Maximum external radiation levels at 5 and 25 centimeters from any external surface of the product, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the product during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the product annually;

(9) The expected useful life of the product;

(10) The proposed methods of labeling or marking the detector and its point-of-sale package to satisfy the requirements of § 32.29(b);

(11) Procedures for prototype testing of the product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the product;

(12) Results of the prototype testing of the product, including any change in the form of the byproduct material contained in the product, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and dose commitments relevant to the safety criteria in § 32.27 and the basis for such estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.27(c) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

(c)(1) The Commission determines that the product meets the safety criteria in § 32.27; and

(2) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.

[34 FR 6653, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 77 FR 43691, Jul. 25, 2012]

§ 32.27 Same: Safety criteria.

[Top of File]

An applicant for a license under § 32.26 shall demonstrate that the product is designed and will be manufactured so that:

(a) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ as specified in Column I of the table in § 32.28.

(b) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

(c) In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the table in § 32.28, and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the table in § 32.28.[1]

[34 FR 6654, Apr. 18, 1969]

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used as guides in estimating compliance with the criteria:

Low--not more than one such failure per year for each 10,000 exempt units distributed.

Negligible--not more than one such failure per year for each one million exempt units distributed.

§ 32.28 Same: Table of organ doses

[Top of File]

Part of body	Column 1 (rem)	Column II (rem)	Column III (rem)
Whole body; head and trunk: active blood-forming organs; gonads; or lens of eye	0.005	0.5	15

Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.075	7.5	200
Other organs	0.015	1.5	50

[34 FR 6654, Apr. 18, 1969]

§ 32.29 Conditions of licenses issued under § 32.26: Quality control, labeling, and reports of transfer.

[Top of File]

Each person licensed under § 32.26 shall:

(a) Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each detector and its point-of-sale package so that:

(1) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide and quantity of activity; and

(iii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State.

(2) The labeling or marking specified in paragraph (b)(1) of this section is located where its will be readily visible when the detector is removed from its mounting.

(3) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.26 to transfer the detector for use pursuant to § 30.20 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement:

THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NRC SAFETY CRITERIA IN 10 CFR 32.27. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS.

(4) Each detector and point-of-sale package is provided with such other information as may be required by the Commission; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.20 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on products transferred to other persons for use under § 30.20 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each product and the model number(s);

(ii) For each radionuclide in each type of product and each model number, the total quantity of the radionuclide;

(iii) The number of units of each type of product transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.26 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.26 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the

Commission.

[34 FR 6654, Apr. 18, 1969, as amended at 43 FR 6923, Feb. 17, 1978; 45 FR 38342, June 9, 1980; 48 FR 12334, Mar. 24, 1983; 72 FR 58488, Oct. 16, 2007; 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008; 79 FR 75739, Dec. 19, 2014]

§ 32.30 Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer.

[Top of File]

An application for a specific license to manufacture, process, produce, or initially transfer for sale or distribution devices containing byproduct material for use under § 30.22 of this chapter or equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter: However, the requirements of § 30.33(a)(2) and (3) do not apply to an application for a license to transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State;

(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in § 32.31. The information should include:

(1) A description of the device and its intended use or uses;

(2) The type and quantity of byproduct material in each unit;

(3) Chemical and physical form of the byproduct material in the device and changes in chemical and physical form that may occur during the useful life of the device;

(4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b)(3) and (b)(12) of this section;

(5) Details of construction and design of the device as related to containment and shielding of the byproduct material and other safety features under normal and severe conditions of handling, storage, use, and disposal of the device;

(6) Maximum external radiation levels at 5 and 30 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement;

(7) Degree of access of human beings to the device during normal handling and use;

(8) Total quantity of byproduct material expected to be distributed in the devices annually;

(9) The expected useful life of the device;

(10) The proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of § 32.32(b);

(11) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device;

(12) Results of the prototype testing of the device, including any change in the form of the byproduct material contained in the device, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features;

(13) The estimated external radiation doses and committed doses resulting from the intake of byproduct material in any one year relevant to the safety criteria in § 32.31 and the basis for these estimates;

(14) A determination that the probabilities with respect to the doses referred to in § 32.31(a)(4) meet the criteria of that paragraph;

(15) Quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices will be required to meet; and

(16) Any additional information, including experimental studies and tests, required by the Commission.

(c)(1) The Commission determines that the device meets the safety criteria in § 32.31.

(2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment.

(3) The device has been registered in the Sealed Source and Device Registry.

[77 FR 43691, Jul. 25, 2012]

§ 32.31 Certain industrial devices containing byproduct material: Safety criteria.

[Top of File]

(a) An applicant for a license under § 32.30 shall demonstrate that the device is designed and will be manufactured so that:

(1) In normal use, handling, and storage of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, it is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the device will exceed 200 μSv (20 mrem).

(2) It is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 μSv (1 mrem).

(3) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the device from wear and abuse likely to occur in normal handling and use of the device during its useful life.

(4) In use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or committed dose in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater.[1]

(b) An applicant for a license under § 32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of 10^{-4} of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).

[77 FR 43692, Jul. 25, 2012]

[1] It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria: Low— not more than one such failure/incident per year for each 10,000 exempt units distributed. Negligible— not more than one such failure/incident per year for each one million exempt units distributed.

§ 32.32 Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer.

[Top of File]

Each person licensed under § 32.30 shall:

(a) Carry out adequate control procedures in the manufacture of the device to ensure that each production lot meets the quality control standards approved by the Commission;

(b) Label or mark each device and its point-of-sale package so that:

(1) Each item has a durable, legible, readily visible label or marking on the external surface of the device containing:

(i) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(ii) The name of the radionuclide(s) and quantity(ies) of activity;

(iii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iv) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device(documents such as operating and service manuals may be identified in the label and used to provide this information).

(2) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(i) The name of the radionuclide and quantity of activity;

(ii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and

(iii) The following or a substantially similar statement: "THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN

MANUFACTURED IN COMPLIANCE WITH U.S. NUCLEAR REGULATORY COMMISSION SAFETY CRITERIA IN 10 CFR 32.31. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(3) Each device and point-of-sale package contains such other information as may be required by the Commission; and

(c) Maintain records of all transfers and file a report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the devices are transferred for use under § 30.22 of this chapter or equivalent regulations of an Agreement State.

(3) The report must include the following information on devices transferred to other persons for use under § 30.22 or equivalent regulations of an Agreement State:

(i) A description or identification of the type of each device and the model number(s);

(ii) For each radionuclide in each type of device and each model number, the total quantity of the radionuclide; and

(iii) The number of units of each type of device transferred during the reporting period by model number.

(4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year.

(ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.30 shall file a report for the current calendar year within 30 days after ceasing distribution.

(5) If no transfers of byproduct material have been made under § 32.30 during the reporting period, the report must so indicate.

(6) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.

[77 FR 43692, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

§ 32.40 [Removed].

[Top of File]

[30 FR 8192, June 26, 1965, as amended at 31 FR 5317, Apr. 2, 1966; 43 FR 6923, Feb. 17, 1978; 72 FR 58489, Oct. 16, 2007]

Subpart B--Generally Licensed Items

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§ 32.51 Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer.

(a) An application for a specific license to manufacture, or initially transfer devices containing byproduct material to persons generally licensed under § 31.5 of this chapter or equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements of § 30.33 of this chapter;

(2) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

(i) The device can be safely operated by persons not having training in radiological protection;

(ii) Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in 1 year a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter; and

(iii) Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column IV of the table in § 32.24.

(3) Each device bears a durable, legible, clearly visible label or labels approved by the Commission which contain in a clearly identified and separate statement:

(i) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

(ii) The requirements, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

(iii) The information called for in the following statement in the same or substantially similar form:[1]

The receipt, possession, use, and transfer of this device Model_____,[2] Serial No. _____,[2] are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION--RADIOACTIVE MATERIAL

_____
(Name of manufacturer, or initial transferor)[2]

(4) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, "Caution-Radioactive Material," the radiation symbol described in § 20.1901 of this chapter, and the name of the manufacturer or initial distributor.

(5) Each device meeting the criteria of § 31.5(c)(13)(i) of this chapter, bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words, "Caution-Radioactive Material," and, if practicable, the radiation symbol described in § 20.1901 of this chapter.

(6) The device has been registered in the Sealed Source and Device Registry.

(b) In the event the applicant desires that the device be required to be tested at intervals longer than six months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in this application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices, and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Commission will consider information which includes, but is not limited to:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype tests;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under § 31.5 of this chapter, or under equivalent regulations of an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general licensee, estimated calendar quarter doses associated with such activity or activities, and the bases for these estimates. The submitted information must demonstrate that performance of this activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the annual limits specified in § 20.1201(a) of this chapter.

[39 FR 43533, Dec. 16, 1974, as amended at 40 FR 8785, Mar. 3, 1975; 42 FR 25721, May 19, 1977; 43 FR 6923, Feb. 17, 1978; 58 FR 67660, Dec. 22, 1993; 59 FR 5520, Feb. 7, 1994; 65 FR 79189, Dec. 18, 2000; 77 FR 43693, Jul. 25, 2012]

[1] Devices licensed under § 32.51 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

[2] The model, serial number, and the name of the manufacturer, or initial transferor may be omitted from this label provided

the information is elsewhere specified in labeling affixed to the device.

§ 32.51a Same: Conditions of licenses.

[Top of File]

(a) If a device containing byproduct material is to be transferred for use under the general license contained in § 31.5 of this chapter, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

(1) A copy of the general license contained in § 31.5 of this chapter; if paragraphs (c)(2) through (4) or (c)(13) of § 31.5 do not apply to the particular device, those paragraphs may be omitted.

(2) A copy of §§ 31.2, 30.51, 20.2201, and 20.2202 of this chapter;

(3) A list of the services that can only be performed by a specific licensee;

(4) Information on acceptable disposal options including estimated costs of disposal; and

(5) An indication that NRC's policy is to issue high civil penalties for improper disposal.

(b) If byproduct material is to be transferred in a device for use under an equivalent general license of an Agreement State, each person that is licensed under § 32.51 shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes--

(1) A copy of the Agreement State's regulations equivalent to §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter or a copy of §§ 31.5, 31.2, 30.51, 20.2201, and 20.2202 of this chapter. If a copy of the NRC regulations is provided to a prospective general licensee in lieu of the Agreement State's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the Agreement State; if certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

(2) A list of the services that can only be performed by a specific licensee;

(3) Information on acceptable disposal options including estimated costs of disposal; and

(4) The name or title, address, and phone number of the contact at the Agreement State regulatory agency from which additional information may be obtained.

(c) An alternative approach to informing customers may be proposed by the licensee for approval by the Commission.

(d) Each device that is transferred after February 19, 2002 must meet the labeling requirements in § 32.51(a)(3) through (5).

(e) If a notification of bankruptcy has been made under § 30.34(h) or the license is to be terminated, each person licensed under § 32.51 shall provide, upon request, to the NRC and to any appropriate Agreement State, records of final disposition required under § 32.52(c).

[65 FR 79189, Dec. 18, 2000; 65 FR 80991, Dec. 22, 2000]

§ 32.52 Same: Material transfer reports and records.

[Top of File]

Each person licensed under § 32.51 to initially transfer devices to generally licensed persons shall comply with the requirements of this section.

(a) The person shall report to the Director, Office of Nuclear Material Safety and Safeguards, ATTN: GLTS, by an appropriate method listed in § 30.6(a) of this chapter, all transfers of such devices to persons for use under the general license in § 31.5 of this chapter and all receipts of devices from persons licensed under § 31.5 of this chapter. The report must be submitted on a quarterly basis on NRC Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes—

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a § 31.5 general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a § 31.5 general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(7) If no transfers have been made to or from persons generally licensed under § 31.5 of this chapter during the reporting period, the report must so indicate.

(b) The person shall report all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.5 of this chapter and all receipts of devices from general licensees in the Agreement State's jurisdiction to the responsible Agreement State agency. The report must be submitted on Form 653—"Transfers of Industrial Devices Report" or in a clear and legible report containing all of the data required by the form.

(1) The required information for transfers to general licensees includes—

(i) The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(ii) The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

(iii) The date of transfer;

(iv) The type, model number, and serial number of the device transferred; and

(v) The quantity and type of byproduct material contained in the device.

(2) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(3) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(4) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(5) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(6) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(7) If no transfers have been made to or from a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State agency upon request of the agency.

(c) The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this section. Records required by this paragraph must be maintained for a period of 3 years following the date of the recorded event.

[65 FR 79189, Dec. 18, 2000; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008; 79 FR 75739, Dec. 19, 2014]

§ 32.53 Luminous safety devices for use in aircraft: Requirements for license to

manufacture, assemble, repair or initially transfer.

[Top of File]

An application for a specific license to manufacture, assemble, repair or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under § 31.7 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

(2) Details of construction and design;

(3) Details of the method of binding or containing the tritium or promethium-147;

(4) Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use;

(5) Quality assurance procedures to be followed that are sufficient to ensure compliance with § 32.55;

(6) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device.

(c) Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(d) The Commission determines that:

(1) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

(3) The device is so designed that it cannot easily be disassembled; and

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(ii) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(f) The device has been registered in the Sealed Source and Device Registry.

[30 FR 8192, June 26, 1965, as amended at 33 FR 6463, Apr. 27, 1968; 43 FR 6923, Feb. 17, 1978; 77 FR 43693, Jul. 25, 2012]

§ 32.54 Same: Labeling of devices.

[Top of File]

(a) A person licensed under § 32.53 to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under § 31.7 of this chapter shall, except as provided in paragraph (b) of this section, affix to each device a label containing the radiation symbol prescribed by § 20.1901 of this chapter, such other

information as may be required by the Commission including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use, and transfer of this device, Model* _____, Serial No.* ___, containing _____ (Identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL

_____
(Name of manufacturer, assembler, or initial transferor.)*

*The model, serial number, and name of manufacturer, assembler, or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

(b) If the Commission determines that it is not feasible to affix a label to the device containing all the information called for in paragraph (a) of this section, it may waive the requirements of that paragraph and require in lieu thereof that:

(1) A label be affixed to the device identifying:

(i) The manufacturer, assembler, or initial transferor; and

(ii) The type of radioactive material; and

(2) A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(i) The name of the manufacturer, assembler, or initial transferor,

(ii) The type and quantity of radioactive material,

(iii) The model number,

(iv) A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

(v) Such other information as may be required by the Commission, including disposal instructions when appropriate.

[33 FR 16331, Nov. 7, 1968, as amended at 40 FR 8785, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 63 FR 39483, July 23, 1998]

[1] Devices licensed under § 32.53 prior to January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

§ 32.55 Same: Quality assurance; prohibition of transfer.

[Top of File]

(a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

(b) Each person licensed under § 32.53 shall:

(1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (c) of this section and in the license issued under § 32.53, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(c) The licensee shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(iii) Any other criteria specified in the license issued under § 32.53.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.

[30 FR 8192, June 26, 1965, as amended at 39 FR 22129, June 20, 1974; 39 FR 26397, July 19, 1974; 77 FR 43693, Jul. 25, 2012]

§ 32.56 Same: Material transfer reports.

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(a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of Nuclear Material Safety and Safeguards, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate.

(b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the agency.

[60 FR 3737, Jan. 19, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008; 77 FR 43694, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

§ 32.57 Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer.

[Top of File]

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241 or radium-226.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and

(2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.

(e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows:

(1) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section.

(4) Source designs are rejected for which the following has been detected for any unit: Removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.

[30 FR 8192, June 26, 1965, as amended at 43 FR 6923, Feb. 17, 19781; 72 FR 55928, Oct. 1, 2007; 73 FR 42674, July 23, 2008; 77 FR 43694, Jul. 25, 2012]

§ 32.58 Same: Labeling of devices

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Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[1]

The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor

[30 FR 8192, June 26, 1965, as amended at 40 FR 8786, Mar. 3, 1975; 43 FR 6923, Feb. 17, 1978; 72 FR 55929 Oct. 1, 2007]

[1] Sources licensed under § 32.57 before January 19, 1975 may bear labels authorized by the regulations in effect on January 1, 1975.

§ 32.59 Same: Leak testing of each source

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Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter or under equivalent regulations of an Agreement State. This test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper must be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee under § 31.8 of this chapter, or equivalent regulations of an Agreement State.

[30 FR 8192, June 26, 1965; 72 FR 55929 Oct. 1, 2007; 77 FR 43694, Jul. 25, 2012]

§ 32.60 [Reserved]

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§ 32.61 Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer.

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An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under § 31.10 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of strontium-90 in the device;

(2) Details of construction and design of the source of radiation and its shielding;

(3) Radiation profile of a prototype device;

(4) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

(5) Details of quality control procedures to be followed in manufacture of the device;

(6) Description of labeling to be affixed to the device;

(7) Instructions for handling and installation of the device;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the device;

(c) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form;

(d) Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by § 20.1901(a) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices;

(e) The Commission determines that:

(1) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

(2) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use;

(3) The device is so designed that it cannot be easily disassembled;

(4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (f) of this section.

(5) Quality control procedures have been established to satisfy the requirements of § 32.62.

(f) The applicant shall subject at least five prototypes of the device to tests as follows:

(1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section.

(3) Device designs are rejected for which the following has been detected for any unit:

(i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(iii) Any other evidence of physical damage.

(g) The device has been registered in the Sealed Source and Device Registry.

[30 FR 9905, Aug. 10, 1965, as amended at 43 FR 6923, Feb. 17, 1978; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 77 FR 43694, Jul. 25, 2012]

§ 32.62 Same: Quality assurance; prohibition of transfer.

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(a) Each person licensed under § 32.61 shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(b) Each person licensed under § 32.61 shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(c) Each person licensed under § 32.61 shall:

(1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

(2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(d) Each person licensed under § 32.61 shall subject each inspection lot to:

(1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under § 32.61.

(e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter, or under an equivalent general license of an Agreement State:

(1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under § 32.61, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless:

(i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and

(ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of the license issued under § 32.61.

[30 FR 9905, Aug. 10, 1965, as amended at 39 FR 22130, June 20, 1974; 39 FR 26397, July 19, 1974; 43 FR 6923, Feb. 17, 1978; 77 FR 43694, Jul. 25, 2012]

§ 32.71 Manufacture and distribution of byproduct material for certain in vitro clinical or laboratory testing under general license

[Top of File]

An application for a specific license to manufacturer or distribute byproduct material for use under the general license of § 31.11 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter.

(b) The byproduct material is to be prepared for distribution in prepackaged units of:

(1) Iodine-125 in units not exceeding 10 microcuries each.

(2) Iodine-131 in units not exceeding 10 microcuries each.

(3) Carbon-14 in units not exceeding 10 microcuries each.

(4) Hydrogen-3 (tritium) in units not exceeding 50 microcuries each.

(5) Iron-59 in units not exceeding 20 microcuries each.

(6) Selenium-75 in units not exceeding 10 microcuries each.

(7) Mock Iodine-125 in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each.

(8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.

(c) Each prepackaged unit bears a durable, clearly visible label:

(1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and

(2) Displaying the radiation caution symbol described in § 20.1901(a) of this chapter and the words, "Caution, Radioactive Material", and "Not for Internal or External Use in Humans or Animals."

(d) The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:[1]

The radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
(Name of Manufacturer)

(e) The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such byproduct material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in § 20.2001

[33 FR 16553, Nov. 14, 1968, as amended at 38 FR 34110, Dec. 11, 1973; 39 FR 26148, July 17, 1974; 40 FR 8786, Mar. 3, 1975; 42 FR 21604, Apr. 28, 1977; 42 FR 26987, May 26, 1977; 44 FR 50325, Aug. 28, 1979; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 72 FR 55929 Oct. 1, 2007]

[1] Labels authorized by the regulations in effect on September 26, 1979, may be used until one year from September 27, 1979.

Subpart C—Specifically Licensed Items

[Top of File]

§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35

(a) An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to part 35 of this chapter will be approved if:

(1) The applicant satisfies the general requirements specified in 10 CFR 30.33;

(2) The applicant submits evidence that the applicant is at least one of the following:

(i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a);

(ii) Registered or licensed with a state agency as a drug manufacturer;

(iii) Licensed as a pharmacy by a State Board of Pharmacy;

(iv) Operating as a nuclear pharmacy within a Federal medical institution; or

(v) A Positron Emission Tomography (PET) drug production facility registered with a State agency.

(3) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(4) The applicant satisfies the following labeling requirements:

(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section:

(1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.

(2) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2,

(ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (b)(4) of this section.

(3) The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if:

(i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

(ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the NRC.

(5) Shall provide to the Commission:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or

(ii) The Commission or Agreement State license, or

(iii) Commission master materials licensee permit, or

(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and

(vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

[59 FR 61780, Dec. 2, 1994; 59 FR 65244, Dec. 19, 1994, as amended at 60 FR 324, Jan. 4, 1995; 67 FR 20370, Apr. 24, 2002; 67 FR 62872, Oct. 9, 2002; 67 FR 77652, Dec. 19, 2002; 71 FR 15007, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 72 FR 55929 Oct. 1, 2007; 77 FR 43695, Jul. 25, 2012]

§ 32.74 Manufacture and distribution of sources or devices containing byproduct material for medical use.

[Top of File]

(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if:

(1) The applicant satisfies the general requirements in § 30.33 of this chapter;

(2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(i) The byproduct material contained, its chemical and physical form, and amount;

(ii) Details of design and construction of the source or device;

(iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

(iv) For devices containing byproduct material, the radiation profile of a prototype device;

(v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

(vi) Procedures and standards for calibrating sources and devices;

(vii) Legend and methods for labeling sources and devices as to their radioactive content;

(viii) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: Provided, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§ 35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.

(4) The source or device has been registered in the Sealed Source and Device Registry.

(b)(1) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(2) In determining the acceptable interval for test of leakage of radioactive material, the Commission will consider information that includes, but is not limited to:

(i) Primary containment (source capsule);

(ii) Protection of primary containment;

(iii) Method of sealing containment;

(iv) Containment construction materials;

(v) Form of contained radioactive material;

(vi) Maximum temperature withstood during prototype tests;

(vii) Maximum pressure withstood during prototype tests;

(viii) Maximum quantity of contained radioactive material;

(ix) Radiotoxicity of contained radioactive material;

(x) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(c) If an application is filed pursuant to paragraph (a) of this section on or before October 15, 1974, for a license to manufacture and distribute a source or device that was distributed commercially on or before August 16, 1974, the applicant may continue the distribution of such source or device to group licensees until the Commission issues the license or notifies

the applicant otherwise.

[39 FR 26149, July 17, 1974, as amended at 51 FR 36967, Oct. 16, 1986; 62 FR 59276, Nov. 3, 1997; 67 FR 20370, Apr. 24, 2002; 71 FR 15008, Mar. 27, 2006; 72 FR 45150, Aug. 13, 2007; 77 FR 43695, Jul. 25, 2012]

§ 32.201 Serialization of nationally tracked sources.

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Each licensee who manufactures a nationally tracked source after February 6, 2007 shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alpha-numeric characters.

[71 FR 65686, Nov. 8, 2006; 77 FR 43695, Jul. 25, 2012]

Subpart D—Sealed Source and Device Registration

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§ 32.210 Registration of product information.

(a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.

(b) The request for review must be sent to the NRC's Office of Nuclear Material Safety and Safeguards, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter.

(c) The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

(d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Subpart A of this part includes specific criteria that apply to certain exempt products and subpart B includes specific criteria applicable to certain generally licensed devices. Subpart C includes specific provisions that apply to certain specifically licensed items.

(e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

(f) The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with—

(1) The statements and representations, including quality control program, contained in the request; and

(2) The provisions of the registration certificate.

(g) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(1) Calibration and reference sources containing no more than:

(i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or

(ii) 0.37 MBq (10 μCi), for alpha emitting radionuclides; or

(2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(i) The intended recipients are licensed under part 33 of this chapter or comparable provisions of an Agreement State; or

(ii) The recipients are authorized for research and development; or

(iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.

(h) After the certificate is issued, the Commission may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Commission will complete its evaluation in accordance with criteria specified in this section. The Commission may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

[52 FR 27786, July 24, 1987, as amended at 60 FR 24551, May 9, 1995; 68 FR 58805, Oct. 10, 2003; 73 FR 5719, Jan. 31, 2008; 77 FR 43695, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

§ 32.211 Inactivation of certificates of registration of sealed sources and devices.

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(a) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Commission shall request inactivation of the registration certificate. Such a request must be made to the NRC's Office of Nuclear Material Safety and Safeguards, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

(b) If a distribution license is to be terminated in accordance with § 30.36 of this chapter, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Commission will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

(c) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.

[77 FR 43695, Jul. 25, 2012; 79 FR 75739, Dec. 19, 2014]

Subpart E--Violations

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§ 32.301 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violations of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

[57 FR 55073, Nov. 24, 1992]

§ 32.303 Criminal penalties.

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(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 32 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in part 32 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are

as follows: §§ 32.1, 32.2, 32.8, 32.11, 32.14, 32.18, 32.21, 32.22, 32.23, 32.24, 32.26, 32.27, 32.28, 32.30, 32.31, 32.51, 32.53, 32.57, 32.61, 32.71, 32.72, 32.74, 32.301, and 32.303.

[57 FR 55073, Nov. 24, 1992, as amended at 59 FR 61781, Dec. 2, 1994; 73 FR 42674, July 23, 2008; 77 FR 43696, Jul. 25, 2012]

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