

Byproduct material	Col. I curies	Col. II curies
Iodine-135	1	.01
Iridium-192	1	.01
Iridium-194	10	.1
Iron-55	10	.1
Iron-59	1	.01
Krypton-85	100	1
Krypton-87	10	.1
Lanthanum-140	1	.01
Lutetium-177	10	.1
Manganese-52	1	.01
Manganese-54	1	.01
Manganese-56	10	.1
Mercury-197m	10	.1
Mercury-197	10	.1
Mercury-203	1	.01
Molybdenum-99	10	.1
Neodymium-147	10	.1
Neodymium-149	10	.1
Nickel-59	10	.1
Nickel-63	1	.01
Nickel-65	10	.1
Niobium-93m	1	.01
Niobium-95	1	.01
Niobium-97	100	1
Osmium-185	1	.01
Osmium-191m	100	1
Osmium-191	10	.1
Osmium-193	10	.1
Palladium-103	10	.1
Palladium-109	10	.1
Phosphorus-32	1	.01
Platinum-191	10	.1
Platinum-193m	100	1
Platinum-193	10	.1
Platinum-197m	100	1
Platinum-197	10	.1
Polonium-21001	.0001
Potassium-42	1	.01
Praseodymium-142	10	.1
Praseodymium-143	10	.1
Promethium-147	1	.01
Promethium-149	10	.1
Rhenium-186	10	.1
Rhenium-188	10	.1
Rhodium-103m	1,000	10
Rhodium-105	10	.1
Rubidium-86	1	.01
Rubidium-87	1	.01
Ruthenium-97	100	1
Ruthenium-103	1	.01
Ruthenium-105	10	.1
Ruthenium-1061	.001
Samarium-151	1	.01
Samarium-153	10	.1
Scandium-46	1	.01
Scandium-47	10	.1
Scandium-48	1	.01
Selenium-75	1	.01
Silicon-31	10	.1
Silver-105	1	.01
Silver-110m1	.001
Silver-111	10	.1
Sodium-24	1	.01
Strontium-85m	1,000	10
Strontium-85	1	.01
Strontium-89	1	.01
Strontium-9001	.0001
Strontium-91	10	.1
Strontium-92	10	.1
Sulphur-35	10	.1
Tantalum-182	1	.01
Technetium-96	10	.1
Technetium-97m	10	.1

Byproduct material	Col. I curies	Col. II curies
Technetium-97	10	.1
Technetium-99m	100	1
Technetium-99	1	.01
Tellurium-125m	1	.01
Tellurium-127m	1	.01
Tellurium-127	10	.1
Tellurium-129m	1	.01
Tellurium-129	100	1
Tellurium-131m	10	.1
Tellurium-132	1	.01
Terbium-160	1	.01
Thallium-200	10	.1
Thallium-201	10	.1
Thallium-202	10	.1
Thallium-204	1	.01
Thulium-170	1	.01
Thulium-171	1	.01
Tin-113	1	.01
Tin-125	1	.01
Tungsten-181	1	.01
Tungsten-185	1	.01
Tungsten-187	10	.1
Vanadium-48	1	.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	.1
Yttrium-90	1	.01
Yttrium-91	1	.01
Yttrium-92	10	.1
Yttrium-93	1	.01
Zinc-65	1	.01
Zinc-69m	10	.1
Zinc-69	100	1
Zirconium-93	1	.01
Zirconium-95	1	.01
Zirconium-97	1	.01
Any byproduct material other than alpha emitting byproduct material not listed above1	.001

(Sec. 201, Pub. L. 93-438; 88 Stat. 1242 (42 U.S.C. 5841))

[33 FR 14579, Sept. 28, 1968]

PART 34—LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

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APPENDIX A TO PART 34

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 34.32 also issued under sec. 206, 88 Stat. 1246 (42 U.S.C. 5846).

SOURCE: 30 FR 8198, June 26, 1965, unless otherwise noted.

§34.1 Purpose and scope.

This part prescribes requirements for the issuance of licenses for the use of sealed sources containing byproduct material and radiation safety require-

ments for persons using such sealed sources in radiography. 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 and licenses subject to this part. Nothing in this part shall apply to uses of byproduct material for medical diagnosis or therapy.

§34.2 Definitions.

As used in this part:

Permanent radiographic installation means a shielded installation or structure designed or intended for radiography and in which radiography is regularly performed.

Radiographer means any individual who performs or who, in attendance at the site where the sealed source or sources are being used, personally supervises radiographic operations and who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations and the conditions of the license;

Radiographer's assistant means any individual who under the personal supervision of a radiographer, uses radiographic exposure devices, sealed sources or related handling tools, or radiation survey instruments in radiography;

Radiographic exposure device means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure;

Radiography means the examination of the structure of materials by non-destructive methods, utilizing sealed sources of byproduct materials;

Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material;

Source changer means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources;

Storage area means any location, facility, or vehicle which is used to store,

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to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

Storage container means a device in which sealed sources are transported or stored.

[30 FR 8198, June 26, 1965, as amended at 44 FR 50807, Aug. 30, 1979; 51 FR 21740, June 16, 1986]

§34.3 Applications for specific licenses.

A person may file an application for specific license for use of sealed sources in radiography in duplicate on NRC Form 313, "Application for Material License," in accordance with the provisions of § 30.32 of this chapter.

[49 FR 27924, July 9, 1984]

§34.4 Maintenance of records.

Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original of 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; 53 FR 23383, June 22, 1988]

§34.8 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

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Act of 1980 (44 U.S.C. 3501 *et seq.*). OMB has approved the information collection requirements contained in this part under control number 3150–0007.

(b) The approved information collection requirements contained in this part appear in §§ 34.11, 34.24, 34.25, 34.26, 34.27, 34.28, 34.29, 34.31, 34.32, 34.33, and 34.43.

(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 § 34.3, Form NRC–313R is approved under control number 3150–0023.

(2) [Reserved]

[49 FR 19626, May 9, 1984]

Subpart A—Specific Licensing Requirements

§34.11 Issuance of specific licenses for use of sealed sources in radiography.

An application for a specific license for use of sealed sources in radiography will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant will have an adequate program for training radiographers and radiographers' assistants and submits to the Commission a schedule or description of such program which specifies the:

- (1) Initial training;
- (2) Periodic training;
- (3) On-the-job training;

(4) Means to be used by the licensee to determine the radiographer's knowledge and understanding of and ability to comply with Commission regulations and licensing requirements, and the operating and emergency procedures of the applicant; and

(5) In lieu of describing its initial training program for radiographers in the subjects outlined in appendix A of this part, and the description of and the means used to determine the radiographer's knowledge and understanding of these subjects, the applicant affirms that all individuals acting

as radiographers will be certified in radiation safety through the Certification Program for Industrial Radiography Radiation Safety Personnel of the American Society for Non-destructive Testing, Inc. (ASNT-IRRSP) prior to commencing duties as radiographers. From April 18, 1991, to the date of the renewal of an existing license, an approved license application is deemed to include the option, for individuals who are certified in radiation safety through the ASNT-IRRSP, to substitute ANST-IRRSP certification in lieu of the described means to determine a radiographer's knowledge and understanding of the subjects in §34.31(a)(1). (This paragraph does not affect the licensee's responsibility to assure that radiographers are properly trained in accordance with §34.31(a)).

(6) Means to be used by the licensee to determine the radiographer's assistant's knowledge and understanding of and ability to comply with the operating and emergency procedures of the applicant;

(c) The applicant has established and submits to the Commission satisfactory written operating and emergency procedures as described in §34.32;

(d) The applicant has established and submits to the Commission a description of its inspection program adequate to ensure that its radiographers and radiographers' assistants follow the Commission's regulatory requirements and the applicant's operating and emergency procedures. The inspection program must:

(1) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three months;

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than three months since the last inspection, that individual's performance must be observed and recorded the next time the individual participates in a radiographic operation; and

(3) Include the retention of inspection records on the performance of radiographers or radiographers' assistants for three years.

(e) The applicant submits a description of its over-all organizational structure pertaining to the radiography program, including specified delegations of authority and responsibility for operation of the program; and

(f) The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in leak testing sealed sources, for possible leakage and contamination and submits to the Commission a description of such procedures including:

(1) Instrumentation to be used,

(2) Method of performing test, e.g., points on equipment to be smeared and method of taking smear, and

(3) Pertinent experience of the person who will perform the test.

[30 FR 8198, June 26, 1965, as amended at 51 FR 21740, June 16, 1986; 56 FR 11509, Mar. 19, 1991]

Subpart B—Radiation Safety Requirements

EQUIPMENT CONTROL

§34.20 Performance requirements for radiography equipment.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standards Institute N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981). This publication has been approved for incorporation by reference by the Director of the FEDERAL REGISTER in accordance with 5 U.S.C. 552(a). This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Copies of the document are available for inspection at the Nuclear Regulatory Commission library, 11545 Rockville Pike, Rockville, Maryland, 20852-2738. A copy of the document is also on file at the Office of the FEDERAL REGISTER, 800 North Capitol Street NW., Suite 700, Washington, DC 20408.

Engineering analyses may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. Upon review, the Commission may find this an acceptable alternative to actual testing of the component pursuant to the referenced standard.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the—

- (i) Chemical symbol and mass number of the radionuclide in the device;
- (ii) Activity and the date on which this activity was last measured;
- (iii) Model number and serial number of the sealed source;
- (iv) Manufacturer of the sealed source; and
- (v) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR part 71.

(3) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded

position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER—RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432.

(9) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 10, 1992 must comply with the requirements of this section.

(e) All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of this section.

(f) Notwithstanding paragraphs (a), (d), and (e) of this section, equipment used in industrial radiographic operations need not comply with section 8.9.2(c) of the Endurance Test in American National Standards Institute

N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

[55 FR 852, Jan. 10, 1990; 55 FR 2281, Jan. 23, 1990, as amended at 60 FR 28325, May 31, 1995]

§ 34.21 Limits on levels of radiation for radiographic exposure devices and storage containers.

(a) Radiographic exposure devices measuring less than four (4) inches from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens per hour at six (6) inches from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four (4) inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, and ten (10) milliroentgens per hour at one meter from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

(b) Paragraph (a) of this section applies to all equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers must meet the requirements of § 34.20, and § 34.21 applies only to storage containers (source changers).

[30 FR 8198, June 26, 1965, as amended at 55 FR 853, Jan. 10, 1990; 55 FR 2281, Jan. 23, 1990]

§ 34.22 Locking of radiographic exposure devices, storage containers, and source changers.

(a) Each radiographic exposure device shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device or its container shall be kept locked when not under the direct surveillance of a radiographer or a radiographer's assistant or as otherwise may be authorized in § 34.41. In addition, during radio-

graphic operations the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers shall be kept locked when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

[44 FR 50807, Aug. 30, 1979]

§ 34.23 Storage precautions.

Locked radiographic exposure devices and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel.

§ 34.24 Radiation survey instruments.

The licensee shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part and part 20 of this chapter. Each radiation survey instrument shall be calibrated at intervals not to exceed three months and after each instrument servicing and a record shall be maintained of the results of each instrument calibration and date thereof for three years after the date of calibration. Instrumentation required by this section shall have a range such that two milliroentgens per hour through one roentgen per hour can be measured.

[30 FR 8198, June 26, 1965, as amended at 41 FR 18302, May 3, 1976; 53 FR 19246, May 27, 1988]

§ 34.25 Leak testing, repair, tagging, opening, modification and replacement of sealed sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening or any other modification of any sealed source shall be performed only by persons specifically authorized by the Commission to do so.

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(b) Each sealed source shall be tested for leakage at intervals not to exceed 6 months. In the absence of a certificate from a transferor that a test has been made within the 6 months prior to the transfer, the sealed source shall not be put into use until tested.

(c) The leak test must be capable of detecting the presence of 0.005 microcurie of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography licensee would be to test at the nearest accessible point to the sealed-source storage position, or other appropriate measuring point, by a procedure to be approved pursuant to §34.11(f). Each record of leak test results must be kept in units of microcuries [or disintegrations per minute (dpm)] and retained for inspection by the Commission for three years after it is made.

(d) Any test conducted pursuant to paragraphs (b) and (c) of this section which reveals the presence of 0.005 microcurie or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with Commission regulations. A report shall be filed, within 5 days of the test, with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 describing the equipment involved, the test results, and the corrective action taken. A copy of such report shall be sent to the Administrator of the appropriate Nuclear Regulatory Commission's Regional Office listed in appendix D of part 20 of this chapter "Standards for Protection Against Radiation."

(e) A sealed source which is not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger—Radioactive

Material—Do Not Handle—Notify Civil Authorities if Found."

[30 FR 8198, June 26, 1965, as amended at 38 FR 1271, Jan. 11, 1973; 40 FR 8786, Mar. 3, 1975; 53 FR 19246, May 27, 1988]

§34.26 Quarterly inventory.

Each licensee shall conduct a quarterly physical inventory to account for all sealed sources received and possessed under this license. The records of the inventories shall be maintained for three years from the date of the inventory for inspection by the Commission, and shall include the quantities and kinds of byproduct material, location of sealed sources, and the date of the inventory.

[41 FR 18302, May 3, 1976, as amended at 53 FR 19246, May 27, 1988]

§34.27 Utilization logs.

Each licensee shall maintain current logs, which shall be kept available for three years from the date of the recorded event, for inspection by the Commission, at the address specified in the license, showing for each sealed source the following information:

- (a) A description (or make and model number) of the radiographic exposure device or storage container in which the sealed source is located;
- (b) The identity of the radiographer to whom assigned; and
- (c) The plant or site where used and dates of use.

[30 FR 8198, June 26, 1965, as amended at 53 FR 19246, May 27, 1988]

§34.28 Inspection and maintenance of radiographic exposure devices, storage containers, and source changers.

(a) The licensee shall check for obvious defects in radiographic exposure devices, storage containers, and source changers prior to use each day the equipment is used.

(b) The licensee shall conduct a program for inspection and maintenance of radiographic exposure devices, storage containers, and source changers at intervals not to exceed three months or prior to the first use thereafter to ensure proper functioning of components important to safety. The licensee shall

retain records of these inspections and maintenance for three years.

[44 FR 50807, Aug. 30, 1979, as amended at 53 FR 19247, May 27, 1988]

§34.29 Permanent radiographic installations.

(a) Permanent radiographic installations having high radiation area entrance controls of the types described in §20.1601(a)(2), (a)(3), or (b) shall also meet the following special requirement.

(b) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation to which this section applies shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be actuated by radiation whenever the source is exposed. The audible signal shall be actuated when an attempt is made to enter the installation while the source is exposed.

(c) The alarm system must be tested at intervals not to exceed three months or prior to the first use thereafter of the source in the installation. The licensee shall retain records of these tests for three years.

[44 FR 50807, Aug. 30, 1979, as amended at 53 FR 19247, May 27, 1988; 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

REPORTING

§34.30 Reporting requirements.

(a) In addition to the reporting requirements specified in 30.50 and under other sections of this chapter, each licensee shall provide a written report to the U.S. Nuclear Regulatory Commission; Division of Industrial and Medical Nuclear Safety; Medical, Academic and Commercial Use Safety Branch; Washington, DC 20555, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable.

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position.

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function.

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section:

(1) A description of the equipment problem.

(2) Cause of each incident, if known.

(3) Manufacturer and model number of equipment involved in the incident.

(4) Place, time and date of the incident.

(5) Actions taken to establish normal operations.

(6) Corrective actions taken or planned to prevent recurrence.

(7) Qualifications of personnel involved in the incident.

(c) Reports of overexposure submitted under 10 CFR 20.405 which involve failure of safety components of radiography equipment must also include the information specified in paragraph (b) of this section.

[55 FR 853, Jan. 10, 1990, as amended at 56 FR 40768, Aug. 16, 1991]

PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANTS

§34.31 Training.

(a) The licensee shall not permit any individual to act as a radiographer until such individual:

(1) Has been instructed in the subjects outlined in appendix A of this part;

(2) Has received copies of and instruction in NRC regulations contained in this part and in the applicable sections of parts 19 and 20 of this chapter, NRC license(s) under which the radiographer will perform radiography, and the licensee's operating and emergency procedures;

(3) Has demonstrated competence to use the licensee's radiographic exposure devices, sealed sources, related handling tools, and survey instruments; and

(4) Has demonstrated understanding of the instructions in this paragraph (a) by successful completion of a written test and a field examination on the subjects covered.

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(b) The licensee shall not permit any individual to act as a radiographer's assistant until such individual:

(1) Has received copies of and instruction in the licensee's operating and emergency procedures;

(2) Has demonstrated competence to use, under the personal supervision of the radiographer, the radiographic exposure devices, sealed sources, related handling tools, and radiation survey instruments that the assistant will use; and

(3) Has demonstrated understanding of the instructions in this paragraph (b) by successfully completing a written or oral test and a field examination on the subjects covered.

(c) Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained for three years.

[44 FR 50808, Aug. 30, 1979]

§34.32 Operating and emergency procedures.

The licensee shall retain a copy of current operating and emergency procedures as a record until the Commission terminates the license that authorizes the activity for which the procedures were developed and, if superseded, retain the superseded material for three years after each change. These procedures must include instructions in at least the following:

(a) The handling and use of licensed sealed sources and radiographic exposure devices to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in part 20 of this chapter "Standards for Protection Against Radiation";

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to radiographic areas;

(d) Methods and occasions for locking and securing radiographic exposure devices, storage containers and sealed sources;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, posting

of vehicles and control of the sealed sources during transportation;

(g) Minimizing exposure of persons in the event of an accident;

(h) The procedure for notifying proper persons in the event of an accident; and

(i) Maintenance of records.

(j) The inspection and maintenance of radiographic exposure devices and storage containers.

(k) Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale.

(l) The procedure(s) for identifying and reporting defects and noncompliance, as required by part 21 of this chapter.

[30 FR 8198, June 26, 1965, as amended at 35 FR 17398, Nov. 13, 1970; 44 FR 50808, Aug. 30, 1979; 45 FR 2312, Jan. 11, 1980; 53 FR 19247, May 27, 1988]

§34.33 Personnel monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD) except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Each film badge and TLD must be assigned to and worn by only one individual.

(b) Pocket dosimeters must be read and exposures recorded daily. The licensee shall retain each record of these exposures for three years after the record is made.

(c) Pocket dosimeters shall be checked at periods not to exceed one year for correct response to radiation. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is discharged beyond its range, his film badge or TLD shall be immediately sent for processing.

(e) Reports received from the film badge or TLD processor must be retained for inspection until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(f) Each alarm ratemeter must—

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate of 500 mR/hr.;

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate.

[44 FR 50808, Aug. 30, 1979, as amended at 53 FR 19247, May 27, 1988; 55 FR 853, Jan. 10, 1990]

PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATIONS

§ 34.41 Security.

During each radiographic operation the radiographer or radiographer's assistant shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in part 20 of this chapter, except (a) where the high radiation area is equipped with a control device or an alarm system as described in § 20.1601(a)(1), (a)(2), or (a)(3) of this chapter, or (b) where the high radiation area is locked to protect against unauthorized or accidental entry.

[30 FR 8198, June 26, 1965, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993]

§ 34.42 Posting.

Notwithstanding any provisions in § 20.1903 of this chapter, areas in which radiography is being performed shall be conspicuously posted as required by § 20.1902(a) and (b) of this chapter.

[30 FR 8198, June 26, 1965, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 59 FR 1900, Jan. 13, 1994]

§ 34.43 Radiation surveys.

The licensee shall ensure that:

(a) At least one calibrated and operable radiation survey instrument is available at the location of its radiographic operations whenever radiographic operations are being performed, and at the storage area, as defined in § 34.2, whenever a radiographic exposure device, a storage container, or source is being placed in storage.

(b) A survey with a calibrated and operable radiation survey instrument is made after each exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device must be surveyed. If the radiographic exposure device has a source guide tube, the survey must include the guide tube.

(c) A survey with a calibrated and operable radiation survey instrument is made at any time a radiographic exposure device is placed in a storage area, as defined in § 34.2, to determine that the sealed source is in its shielded position. The entire circumference of the radiographic exposure device must be surveyed.

(d) A record of the storage survey required in paragraph (c) of this section is made and is retained for three years when that storage survey is the last one performed in the work day.

[51 FR 21740, June 16, 1986]

§ 34.44 Supervision of radiographers' assistants.

Whenever a radiographer's assistant uses radiographic exposure devices, uses sealed sources or related source handling tools, or conducts radiation surveys required by § 34.43(b) to determine that the sealed source has returned to the shielded position after an exposure, he shall be under the personal supervision of a radiographer. The personal supervision shall include: (a) The radiographer's personal presence at the site where the sealed sources are being used, (b) the ability of the radiographer to give immediate assistance if required, and (c) the radiographer's watching the assistant's performance of the operations referred to in this section.

[44 FR 50808, Aug. 30, 1979]

EXEMPTIONS

§ 34.51 Applications for exemptions.

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

[30 FR 8198, June 26, 1965]

VIOLATIONS

§ 34.61 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]

§ 34.63 Criminal penalties.

(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 34 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 34 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 34.1, 34.2, 34.3, 34.8, 34.11, 34.51, 34.61, and 34.63.

[57 FR 55074, Nov. 24, 1992]

APPENDIX A TO PART 34

I. FUNDAMENTALS OF RADIATION SAFETY

- A. Characteristics of gamma radiation.
- B. Units of radiation dose (mrem) and quantity of radioactivity (curie).
- C. Hazards of exposure to radiation.
- D. Levels of radiation from licensed material.
- E. Methods of controlling radiation dose:
 - 1. Working time.
 - 2. Working distances.
 - 3. Shielding.

II. RADIATION DETECTION INSTRUMENTATION TO BE USED

- A. Use of radiation survey instruments:
 - 1. Operation.
 - 2. Calibration.
 - 3. Limitations.
- B. Survey techniques.
- C. Use of personnel monitoring equipment:
 - 1. Film badges and thermoluminescent dosimeters (TLD's).
 - 2. Pocket dosimeters.
 - 3. Alarm ratemeters

III. RADIOGRAPHIC EQUIPMENT TO BE USED

- A. Remote handling equipment.
- B. Radiographic exposure devices.
- C. Storage containers.

IV. INSPECTION AND MAINTENANCE PERFORMED BY THE RADIOGRAPHERS

V. CASE HISTORIES OF RADIOGRAPHY ACCIDENTS

[44 FR 50808, Aug. 30, 1979, as amended at 55 FR 853, Jan. 10, 1990]

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

Subpart A—General Information

- Sec.
- 35.1 Purpose and scope.
- 35.2 Definitions.
- 35.5 Maintenance of records.
- 35.6 Provisions for research involving human subjects.
- 35.7 FDA, other Federal, and State requirements.