PART E

RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

Sec. E.1 - Purpose. This Part prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

Sec. E.2 - Scope. The provisions and requirements of this Part are in addition to, and not in substitution for, other requirements of these regulations. In particular, the general requirements and provisions of Parts A, B, C, D, J, T, and V of these regulations apply to applicants, licensees and registrants subject to this Part. Parts C and T of these regulations apply to licensing and transportation of radioactive material and Part B of these regulations applies to the registration of radiation machines. Except for sections which are applicable only to sealed radioactive sources, radiation machines and sealed radioactive sources are both covered by this Part. This regulation does not apply to medical uses of sources of radiation which are addressed in Parts G and X of these regulations.

Sec. E.3 - Definitions. As used in this Part, the following definitions apply:

"Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

"ANSI" means the American National Standards Institute.

"Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head)

"Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of this Part or an Agreement State meeting the requirements in Appendix A, Parts II and III of this Part.

"Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

"Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

"Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

"Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

"Drive cable" see "Control cable".

"Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.[*/]

"Field station" means a facility from which sources of radiation may be stored or used and from where equipment is dispatched.

"Guide tube" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

"Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2000 hours of hands-on experience required for a radiation safety officer in E.16a.ii. or the hands-on experience for a radiographer as required by E.17a.

"Independent certifying organization" means an independent organization that meets all of the criteria of Appendix A of this Part.

"Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

["Lay-barge radiography" (for States that authorize this activity) means industrial radiography performed on any water vessel used for laying pipe.]

["Offshore platform radiography" (for States that authorize this activity) means industrial radiography conducted from a platform over a body of water.]

"Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

"Pigtail" see "Source assembly".

"Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

"Radiation safety officer for industrial radiography" means an individual with the responsibility for the

[*/] An exposure head is also known as a source stop.

overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of E.16.

"Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency's regulations and the conditions of the license or registration.

"Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

["Radiographer's assistant" (for States who authorize this activity) means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial 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.

"Radiographic operations" means all activities associated with the presence of radioactive sources in a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

"Radiography" see "Industrial radiography."

"S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

"Shielded position" means the location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

"Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

"Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices. They may also be used for transporting and storing sealed sources.

"Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, sealed source or a storage container when it is not used for radiographic operations. Storage areas are locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

"Storage container" means a container in which sealed sources or radiation machines are secured and stored.

"Temporary jobsite" means a location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) of use authorized on the license or registration.

["Underwater radiography" (for States that authorize this activity) means industrial radiography performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.]

Sec. E.4 - Reserved.

Sec. E.5 - Licensing and Registration Requirements for Industrial Radiography Operations. The Agency will approve an application for a specific license for the use of licensed material or a registration for use of radiation machines if the applicant meets the following requirements:

a. The applicant satisfies the general requirements specified in Part B for radiation machine facilities or Part C for radioactive material, as applicable, and any special requirements contained in this Part;

b. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of E.17. The applicant need not describe the initial training and examination program for radiographers in the subjects outlined in E.17g;

c. The applicant submits procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

d. The applicant submits written operating and emergency procedures as described in E.18;

e. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer’s assistant at intervals not to exceed 6 months as described in E.17e.;

f. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility;

g. The applicant submits the qualifications of the individual(s) designated as the radiation safety officer as described in E.16a and potential designees responsible for ensuring that the licensee’s radiation safety program is implemented in accordance with approved procedures;

h. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU) shielding, the applicant must describe the procedures for performing the test. If the applicant intends to analyze its own wipe samples, the applicant must include a description of the procedures to be followed. The description must include the:

    i. Methods of collecting the samples;

ii. Qualifications of the individual who analyzes the samples;

iii. Instruments to be used; and

iv. Methods of analyzing the samples.

i. If the applicant intends to perform calibrations of survey instruments and alarming ratemeters, the applicant must describe methods to be used and the experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in E.9 and E.20g.iv.;

j. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations;

k. The applicant identifies the location(s) where all records required by this and other Parts of these regulations will be maintained;

l. [(For States that authorize this activity) If a license application includes underwater radiography/, a description of:

i. Radiation safety procedures and radiographer responsibilities unique to the performance of underwater radiography;

ii. Radiographic equipment and radiation safety equipment unique to underwater radiography; and

iii. Methods for gas-tight encapsulation of equipment; and]

m. [(For States that authorize this activity) If an application includes offshore platform and/or lay-barge radiography, a description of:

i. Transport procedures for radioactive material to be used in industrial radiographic operations;

ii. Storage facilities for radioactive material; and

iii. Methods for restricting access to radiation areas.]

Sec. E.6 - Performance Requirements for Industrial Radiography Equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

a. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standard 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 may be purchased from the American National Standards Institute, Inc., 25 West 43rd

Street, New York, New York 10036; Telephone: (212) 642–4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission Library, 11545 Rockville Pike, Rockville, Maryland 20852. A copy of the document is also on file at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

b. In addition to the requirements specified in E.6a., the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources;

i. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(1) Chemical symbol and mass number of the radionuclide in the device;

(2) Activity and the date on which this activity was last measured;

(3) Model or product code and serial number of the sealed source;

(4) Name of the manufacturer of the sealed source; and

(5) Licensee's name, address, and telephone number.

ii. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of Part T of these regulations.

iii. Modification of radiographic exposure devices, source changers, and source assemblies 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 E.6a. and E.6b., the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

i. 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.

ii. 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.

iii. 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.

iv. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER -- RADIOACTIVE"

The label may not interfere with the safe operation of the exposure device or associated equipment.

v. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

vi. Guide tubes must be used when moving the source out of the device.

vii. 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 industrial radiography operations.

viii. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

ix. Source changers must provide a system for ensuring 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 radiographic exposure devices and associated equipment must comply with the requirements of this section; and

e. As an exception to E.6a., equipment used in industrial radiographic operations need not comply with § 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 reasonably exert on the lever or crankshaft of the drive mechanism.

Sec. E.7 - Limits on External Radiation Levels From Storage Containers and Source Changers. The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

Sec. E.8 - Locking Sources of Radiation, Storage Containers and Source Changers.

a. Each radiographic exposure device must 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 and/or its container must be kept locked[**/] when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in E. 22. In addition, during radiographic operations, the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

b. Each sealed source storage container and source changer must 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 must be kept locked[***] when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

c. For x-ray machines whose design output is greater than or equal to 1MeV, the control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

Sec. E.9 - Radiation Survey Instruments.

a. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the radiation surveys required by this Part and by Part D of these regulations. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

b. The licensee or registrant shall have each radiation survey instrument required under E.9a. calibrated:

   i. At energies appropriate for use and at intervals not to exceed 6 months or after instrument servicing, except for battery changes;

   ii. At energies appropriate for use:

      (1) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale;

      (2) For logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour;

   iii. So that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

[**/] If a keyed lock, the key must be removed at all times.

c. The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with E.26.

Sec. E.10 - Leak Testing and Replacement of Sealed Sources.

a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the Nuclear Regulatory Commission, or an Agreement State.

b. The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the Nuclear Regulatory Commission, or an Agreement State.

c. Testing and recordkeeping requirements.

i. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Agency, the Nuclear Regulatory Commission, or by an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

ii. The licensee shall maintain records of the leak tests in accordance with E.27.

iii. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage and the test results received. Sealed sources that are in storage and not in use do not require leak testing, but must be tested before use or transfer to another person if the storage interval exceeds 6 months.

d. Any test conducted pursuant to E.10c. that reveals the presence of 185 becquerels (0.005microcuries) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Agency regulations. A report must be filed with the Agency within 5 days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

e. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerels (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or an Agreement State to perform the analysis. Should such

testing reveal the presence of 185 becquerel (0.005 microcuries) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with E.27.

Sec. E.11 - Quarterly Inventory.

a. Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license.

b. The licensee or registrant shall maintain records of the quarterly inventory in accordance with E.28.

Sec. E.12 - Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

a. The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

   i. The equipment is in good working condition;

   ii. The sources are adequately shielded; and

   iii. Required labeling is present.

b. Survey instrument operability must be performed using check sources or other appropriate means.

c. If equipment problems are found, the equipment must be removed from service until repaired.

d. Each licensee or registrant shall have written procedures for performance of inspection and routine maintenance of radiation machines (producing x-rays greater than or equal to 1 MeV), radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired. Replacement components shall meet design specifications.

e. The licensee's inspection and maintenance program must include written procedures for inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of

compliance or other approval.

f. Records of equipment problems and of any maintenance performed under E.12 must be made in accordance with E.30.

Sec. E.13 - Permanent Radiographic Installations.

a. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

i. An entrance control of the type described in Part D.1601 of these regulations that causes the radiation level upon entry into the area to be reduced; or

ii. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

b. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in E.13a.i.must be tested monthly. If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of E.22 and uses an alarming ratemeter. Test records for entrance controls and audible and visual alarms must be maintained in accordance with E.31.

Sec. E.14 - Labeling, Storage, and Transportation.

a. The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background, having a minimum diameter of 25 mm, and the wording:

CAUTION *
RADIOACTIVE MATERIAL
NOTIFY CIVIL AUTHORITIES [or "NAME OF COMPANY"]

* --- or "DANGER"

b. The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with regulations set out in Part T.

c. Radiographic exposure devices, source changers, storage containers, and radiation machines

machines (of greater than or equal to 1 MeV), must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

d. The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

Radiation Safety Requirements

Sec. E.15 - Conducting Industrial Radiographic Operations.

a. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of E.17c. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

b. All radiographic operations conducted at locations of use authorized on the license must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

c. [(For States who authorize this activity) a licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the Nuclear Regulatory Commission, or by an Agreement State.]

Sec. E.16 - Radiation Safety Officer. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant's program.

a. The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

   i. Completion of the training and testing requirements of E.17a.;

   ii. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

   iii. Formal training in the establishment and maintenance of a radiation protection program.

b. The Agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

c. The specific duties and authorities of the radiation safety officer include:

i. Establishing and overseeing all operating, emergency, and ALARA procedures as required by Part D of these regulations and reviewing them regularly to ensure that they conform to Agency regulations and to the license or registration conditions;

ii. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

iii. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the regulations, including any corrective measures when levels of radiation exceed established limits;

iv. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by Part D of these regulations; and

v. Ensuring that operations are conducted safely and for implementing corrective actions including stopping radiographic operations when necessary.

Sec. E.17 - Training.

a. The licensee or registrant may not permit any individual to act as a radiographer until the individual has received training in the subjects outlined in E.17g., in addition to on-the-job training consisting of hands-on experience under the supervision of a radiographer and is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this Part. The on-the-job training shall include a minimum of 2 months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material and/or 1 month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (3 months or 480 hours).

b. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

i. Has received copies of and instruction in the requirements described in the regulations contained in this Part, and applicable sections of Parts C, D, J, and T of these regulations, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

ii. Has demonstrated an understanding of items in E.17b.i. by successful completion of a written examination;.

iii. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

iv. Has demonstrated understanding of the use of the equipment described in E.17b.iii. by successful completion of a practical examination.

c. [(For States that authorize this activity), the licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

i. Has received copies of and instruction in the requirements described in the regulations contained in this Part, and applicable sections of Parts C, D, J, and T of these regulations, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

ii. Has demonstrated an understanding of items in E.17c.i. by successful completion of a written examination;

iii. Has developed competence to use, under the personal supervision of the radiographer, the radiation machines and/or radiographic exposure devices, sealed sources, associated equipment, and the radiation survey instruments that the assistant will use; and

iv. Has demonstrated understanding of the use of the equipment described in E.17c.iii. by successful completion of a practical examination.]

d. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

e. Except as provided in E.17e.iii., the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency's regulations, license or registration requirements, and operating and emergency procedures are followed.

i. The inspection program must:

(1)Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(2) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of E.17b.iii. and the radiographer's assistant must demonstrate knowledge of the training requirements of E.17c.iii. by a practical examination before these individuals can next participate in a radiographic operation.

ii. The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

iii. In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

f. The licensee or registrant shall maintain records of the above training to include certification documents, written, and practical examinations, refresher safety training and inspections of job performance in accordance with E.32.

g. The licensee or registrant shall include the following subjects required in E.17a.:

i. Fundamentals of radiation safety including:

(1) Characteristics of gamma and x-radiation;

(2) Units of radiation dose and quantity of radioactivity;

(3) Hazards of exposure to radiation;

(4) Levels of radiation from licensed and registered sources of radiation; and

(5) Methods of controlling radiation dose (time, distance, and shielding);

ii. Radiation detection instruments including:

(1) Use, operation, calibration, and limitations of radiation survey instruments;

(2) Survey techniques; and

(3) Use of personnel monitoring equipment;

iii. Equipment to be used including:

(1) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(2) Operation and control of radiation machines;

(3) Storage, control, and disposal of sources of radiation; and

(4) Inspection and maintenance of equipment.

iv. The requirements of pertinent state and federal regulations; and

v. Case histories of accidents in radiography.

Sec. E.18 - Operating and Emergency Procedures.

a. Operating and emergency procedures must include, as a minimum, instructions in the following:

i. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Part D of these regulations;

ii. Methods and occasions for conducting radiation surveys;

iii. Methods for posting and controlling access to radiographic areas;

iv. Methods and occasions for locking and securing radiographic exposure devices, transport and storage containers and sealed sources;

v. Personnel monitoring and the use of personnel monitoring equipment;

vi. Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Part T of these regulations;

vii. The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, storage containers and associated equipment;

viii. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly;

ix. The procedure(s) for identifying and reporting defects and noncompliance, as required by E.38;

x. The procedure for notifying proper persons in the event of an accident or incident;

xi. Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

xii. Source recovery procedure if licensee will perform source recoveries; and

xiii. Maintenance of records.

b. The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with E.33 and E.37.

[Sec. E.19 - (For States who authorize this activity.) Supervision of Radiographer's Assistants. The radiographer's assistant shall be under the personal supervision of a radiographer when using radiographic exposure devices, associated equipment, or a sealed source, or while conducting radiation surveys required by E.21b. to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

a. The radiographer's physical presence at the site where the sources of radiation are being used;

b. The availability of the radiographer to give immediate assistance if required; and

c. The radiographer's direct observation of the assistant's performance of the operations referred to in this section.]

Sec. E.20 - Personnel Monitoring.

a. The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a direct reading dosimeter, an alarming ratemeter, and personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using radiation machines, the use of an alarming ratemeter is not required.

   i. Pocket dosimeters must have a range from zero to 2 millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

   ii. Each personnel dosimeter must be assigned to and worn by only one individual.

   iii. Personnel dosimetry must be exchanged at periods not to exceed one month.

   iv. After replacement, each personnel dosimeter must be processed as soon as possible.

b. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with E.34.

c. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with E.34. Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

d. If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with E.34.

e. If a personnel dosimeter is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter. The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in

the records maintained in accordance with E.34.

f. Reports received from the accredited NVLAP personnel dosimeter processor must be retained in accordance with E.34.

g. Each alarming ratemeter must:

i. Be checked to ensure that the alarm functions properly (sounds) before using at the start of each shift;

ii. Be set to give an alarm signal at a preset dose rate of 5 millisieverts (500 mrem) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate;

iii. Require special means to change the preset alarm function; and

iv. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with E.34.

Sec. E.21 - Radiation Surveys. The licensee or registrant shall:

a. Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of E.9;

b. Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

c. Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in E.3, to ensure that the sealed source is in its shielded position; and

d. Maintain records in accordance with E.35.

Sec. E.22 - Surveillance. During each radiographic operation, the radiographer, or the other individual present as required by E.15, shall maintain continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Part A of these regulations, except at permanent radiographic installations where all entryways are locked and the requirements of E.13 are met.

Sec. E.23 - Posting. All areas in which industrial radiography is being performed must be conspicuously posted as required by Part D.1902 of these regulations. The exceptions listed in Part D.1903 of these regulations do not apply to industrial radiographic operations.

Recordkeeping Requirements

Sec. E.24 - Records for Industrial Radiography. Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration.

Sec. E.25 - Records of Receipt and Transfer of Sources of Radiation.

a. Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for 3 years after it is made.

b. These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Sec. E.26 - Records of Radiation Survey Instruments. Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under E.9 and retain each record for 3 years after it is made.

Sec. E.27 - Records of Leak Testing of Sealed Sources and Devices Containing DU. Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed.

Sec. E.28 - Records of Quarterly Inventory.

a. Each licensee or registrant shall maintain records of the quarterly inventory of sources of radiation, including devices containing depleted uranium as required by E.11, and retain each record for 3 years after it is made.

b. The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

Sec. E.29 - Utilization Logs.

a. Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

    i. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

    ii. The identity and signature of the radiographer to whom assigned;

iii. The location and dates of use, including the dates removed and returned to storage; and

iv. For permanent radiographic installations, the dates each radiation machine is energized.

b. The licensee or registrant shall retain the logs required by E.29a. for 3 years.

Sec. E.30 - Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

a. Each licensee or registrant shall maintain records specified in E.12 of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

b. The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

Sec. E.31 - Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations. Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by E.13 and retain each record for 3 years after it is made.

Sec. E.32 - Records of Training and Certification. Each licensee or registrant shall maintain the following records for 3 years:

a. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

b. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer.

Sec. E.33 - Copies of Operating and Emergency Procedures. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for 3 years after the change is made.

Sec. E.34 - Records of Personnel Monitoring. Each licensee or registrant shall maintain the following exposure records specified in E.20:

a. Direct reading dosimeter readings and yearly operability checks required by E.20b. and E.20c. for

3 years after the record is made;

b. Records of alarming ratemeter calibrations for 3 years after the record is made;

c. Personnel dosimeter results received from the accredited NVLAP processor until the Agency terminates the license or registration; and

d. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged personnel dosimeters, until the Agency terminates the license or registration.

Sec. E.35 - Records of Radiation Surveys. Each licensee shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in E.21c. Each record must be maintained for 3 years after it is made.

Sec. E.36 - 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 reproducing 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 or registrant shall maintain adequate safeguards against tampering with and loss of records.

Sec. E.37 - Location of Documents and Records.

a. Each licensee or registrant shall maintain copies of records required by this Part and other applicable Parts of these regulations at the location specified in E.5k.

b. Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

i. The license or registration authorizing the use of sources of radiation;

ii. A copy of Parts A, D, E & J of these regulations;

iii. Utilization logs for each source of radiation dispatched from that location as required by E.29.

iv. Records of equipment problems identified in daily checks of equipment as required by E.30a.;

v. Records of alarm system and entrance control checks required by E.31, if applicable;

vi. Records of dosimeter readings as required by E.34;

vii. Operating and emergency procedures as required by E.33;

viii. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by E.26;

ix. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by E.34;

x. Survey records as required by E.35 and Part D.2103 of these regulations as applicable, for the period of operation at the site;

xi. The shipping papers for the transportation of radioactive materials required by Part T of these regulations; and

xii. When operating under reciprocity pursuant to Part C of these regulations, a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

Notifications

Sec. E.38 - Notifications.

a. In addition to the reporting requirements specified in Part D of these regulations, each licensee or registrant shall provide a written report to the Agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

i. Unintentional disconnection of the source assembly from the control cable;

ii. Inability to retract the source assembly to its fully shielded position and secure it in this position;

iii. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

iv. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the off position, or a safety interlock fails to terminate x-ray production.

b. The licensee or registrant shall include the following information in each report submitted under E.38a., and in each report of overexposure submitted under Part D.2203 of these regulations which involves failure of safety components of radiography equipment:

i. Description of the equipment problem;

ii. Cause of each incident, if known;

iii. Name of the manufacturer and model number of equipment involved in the incident;

iv. Place, date, and time of the incident;

v. Actions taken to establish normal operations;

vi. Corrective actions taken or planned to prevent recurrence; and

vii. Names and qualifications of personnel involved in the incident.

c. Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the Agency prior to exceeding the 180 days.

Radiographer Certification

[Sec. E.39 - (For States that authorize this activity) Application and Examinations.

a. Application

i. An application for taking the examination shall be on forms prescribed and furnished by the Agency.

ii. A non-refundable fee of $XX.XX shall be submitted with the application to cover certification administrative costs, such as the examination, training documentation review, and issuance of certification.

ii. The application and the non-refundable and non-transferable application fee shall be submitted to the Agency on or before the dates specified by the Agency.

iii. Applicants who fail to appear at a scheduled exam and do not reschedule 48 hours prior to their assigned exam session shall apply for a future exam session in accordance with Section E.39.a.

iv. An individual whose certification ID card has been suspended or revoked shall obtain written approval from the Agency to apply to retake the examination.

b. Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

i. A written examination shall be held at times and places determined by the Agency. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the Agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of Parts D, E and T of these regulations.

ii. The examination will be administered by the Agency or persons authorized by the

Agency.

iii. A candidate failing an examination may apply for re-examination in accordance with E.39a. and will be re-examined. A candidate shall not retake the same version of the examination.

iv. The examination will be held at dates, times and locations designated by the Agency.

v. The examination will be in English.

vi. To take the examination, an individual shall have a picture identification card, such as a driver's license, at the time of the examination.

vii. Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.

viii. The examination will be a "closed book" examination.

ix. Any individual observed by an Agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual must wait 90 days and must resubmit a new application and an additional $XX.XX fee before taking a new examination.

x. Examination material shall be returned to the Agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.

xi. The names and scores of individuals taking the examination shall be a public record.]

[Sec. E.40 - (For States that authorize this activity) Certification Identification (ID) Card.

a. A certification ID card shall be issued to each person who successfully completes the requirements of E.17a and the examination prescribed in E.39b.

i. Each person's certification ID card shall contain their photograph. The Agency will take the photograph at the time the examination is administered.

ii. The certification ID card remains the property of the Agency and may be revoked or suspended.

iii. Any individual who wishes to replace their certification ID card shall submit to the Agency a written request for a replacement certification ID card, stating the reason a

replacement certification ID card is needed. A non-refundable fee of $XX.XX shall be paid to the Agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall maintain a copy of the request in their possession while performing industrial radiographic operations until a replacement certification ID card is received from the Agency.

b. Each certification ID card is valid for a period of five years, unless revoked or suspended in accordance with E.40d. Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.

c. Renewal of Certification ID card.

i. Applications for examination to renew a certification ID card shall be filed in accordance with E.39a.

ii. The examination for renewal of a certification ID card shall be administered in accordance with E.39b.

iii. A renewal certification ID card shall be issued in accordance with E.40a.

d. Revocation or suspension of a certification ID card.

i. Any radiographer who violates these regulations, equivalent State or Nuclear Regulatory Commission regulations, or any applicable statutory requirements may be required to show cause at a formal hearing why their certification ID card should not be revoked or suspended in accordance with E.40d.ii. of these regulations.

ii. When an Agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the Agency revokes or suspends their certification ID card, the industrial radiographer shall surrender the certification ID card to the Agency until the order is changed or the suspension expires.]

Sec. E.41 - Reciprocity.

a. All reciprocal recognition of licenses and registrations by the Agency will be granted in accordance with Part C of these regulations.

b. Reciprocal recognition by the Agency of an individual radiographer certification will be granted provided that:

i. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in E.3;

ii. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by E.17a.;

iii. The applicant presents the certification to the Agency prior to entry into the state; and

iv. No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

c. Certified individuals who are granted reciprocity by the Agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of E.17a.

Sec. E.42 - Specific Requirements for Radiographic Personnel Performing Industrial Radiography.

a. At a job site, the following shall be supplied by the licensee or registrant:

i. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

ii. A current whole body personnel dosimeter that is processed and evaluated by an accredited National Voluntary Laboratory Accreditation Program (NVLAP) processor for each person;

iii. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens assigned to each person performing radiographic operations. Each dosimeter must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters;

iv. An operable, calibrated, alarming ratemeter assigned to each person performing radiographic operations using a radiographic exposure device; and

v. The appropriate barrier ropes and signs.

b. Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

c. Industrial radiographic operations shall not be performed if any of the items in E.42a. and E.42b. are not available at the job site or are inoperable.

d. During an inspection, the Agency may terminate an operation if any of the items in E.42a. and E.42b. are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

PART E

APPENDIX A

I. Requirements for an Independent Certifying Organization.

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

2. Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs.

All certification programs must:

1. Require applicants for certification to:

   (a) Receive training in the topics set forth in E.17g. or equivalent State or Nuclear Regulatory Commission regulations, and

   (b) Satisfactorily complete a written examination covering these topics.

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

   (a) Received training in the topics set forth in E.17g. or equivalent State or Nuclear Regulatory Commission regulations;

   (b) Satisfactorily completed a minimum period of on-the-job training as specified in E.17a.; and

   (c) Received verification by a State licensee or registrant or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5. Provide a certification period of not less than 3 years nor more than 5 years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in E.17g. or equivalent State or Nuclear Regulatory Commission requirements;

2. Written in a multiple-choice format; and

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in E.17g.

PART H

RADIATION SAFETY REQUIREMENTS FOR NON-HEALING ARTS RADIATION GENERATING DEVICES (RGD)

Sec. H.1 - Purpose. This Part provides special requirements for non-healing arts radiation generating devices (RGDs) operating between 5 kiloelectron volts (keV) and 1 million electron volts (MeV). For machines operating at energies greater than 1 MeV, see Part I, (Radiation Safety Requirements for Particle Accelerators) of these regulations.

Sec. H.2 - Scope.

a. In addition to the requirements of this Part, all registrants are subject to the requirements of Parts A, B, D, and J of these regulations. This Part does not pertain to radiation safety requirements for x-ray equipment that is explicitly covered in other sections of these regulations (e.g., Diagnostic Machines [Part F], Particle Accelerators [Part I], and Radiation Safety Requirements for Industrial Radiographic Operations [Part E]).

b. Radiography that meets the definition of "cabinet radiography" (H.4) shall be regulated under this Part. This includes certified cabinet x-ray systems.

c. Radiography that occurs in a "shielded room" as defined in H.4 shall be regulated under this Part.

d. Using Radiography equipment that meets the definition of "bomb detection radiation equipment" (H.4) shall be regulated under this Part.

e. Industrial radiography that is open-beam, and not in a shielded room and not otherwise listed here, shall be regulated under Part E (Radiation Safety Requirements for Industrial Radiographic Operations) of these regulations.

Sec. H.3 - Intent. RGDs are a broad class of equipment that generate x-rays or particle radiation having energies between 5 keV and 1 MeV, and not intended for medical use on humans. If applicable, all RGDs shall comply with FDA performance standards as defined in Title 21 Code of Federal Regulations, parts 1010 thru 1050. Examples of RGDs include, but are not limited to: open and closed analytical x-ray equipment (table top and hand-held), x-ray gauges, cabinet x-ray radiography, security screening units, quality control application devices, ion implantation devices, electron beam welders, non-human use x-ray fluoroscopy, x-ray bomb detection and x-ray irradiators. The intent here is not to define safety parameters by what type of work the x-ray unit performs (analytical, gauge, radiography, etc.), but to classify by hazard (open-beam versus closed-beam) or dose rate. All other non-enclosed beam industrial radiography shall be regulated under Part E of these Regulations (Radiation Safety Requirements for Industrial Radiographic Operations).

Sec. H.4 - Definitions. As used in this Part, the following definitions apply:

"Accessible surface" means the external or outside surface of the enclosure or housing provided by the manufacturer. This includes the high-voltage generator, doors, access panels, latches, control

knobs, and other permanently mounted hardware and including the plane across the exterior edge of any opening.

"Analytical x-ray equipment" means equipment that generates (by electronic means) and uses ionizing radiation for the purpose of examining the microstructure of materials, i.e. diffraction and spectroscopy (including fluorescence).

"Baggage unit". See "Security Screening Unit".

"Beam-port" means an opening on the x-ray apparatus designed to emit a primary beam. This does not include openings on baggage units.

"Bomb detection radiographic equipment" means x-ray generating equipment used solely for the purpose of remotely detecting explosive devices. This definition does not include hand-held x-ray bomb detection equipment for the purposes of this Part.

"Cabinet radiography" means industrial radiography using radiation machines not subject to FDA performance standard for cabinet x-ray systems, in an enclosed, interlocked cabinet in which the portion of a material being irradiated is contained, and in which:

i. The radiation machine will not operate unless all openings are closed with interlocks activated;

ii. The cabinet is shielded such that every location on the exterior meets the conditions for an unrestricted area as defined in Part D of these regulations; and

iii. The cabinet is constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.

"Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not a cabinet x-ray system.

"Cathode ray tube" means any device used to accelerate electrons for demonstration or research purposes, except where such cathode ray tube is incorporated into a television or display monitor that is subject to, and has met applicable federal radiation safety performance standards in 21 CFR 1010 and 1020.10.

"Certified cabinet x-ray system" means a RGD certified by the manufacturer in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of applicable federal radiation safety performance standards 21 CFR 1010 and 1020.40.

"Certifiable cabinet x-ray system" means an existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

"Closed-beam x-ray equipment" means a system in which the beam path cannot be entered by any part of the body during normal operation.

"Cold-cathode gas discharge tube" means an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

"Collimator" means a device for restricting the useful radiation in one or more directions.

"Control panel" means a device containing means for regulation and activation of a RGD or for the preselection and indications of operating factors.

"Emergency procedure" means the written pre-planned steps to be taken in the event of actual or suspected exposure of an individual in excess of administrative or regulatory limits. This procedure shall include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring devices.

"Fail-safe design" means a design in which all realistically anticipated failures of indicators or safety components result in a condition in which individuals are safe from exposure to radiation. For example, if a light indicating "X-RAY ON" fails, the production of x-rays shall be prevented, or if a shutter status indicator fails, the shutter shall close.

"General-use system" means a personnel screening system that delivers an effective dose equal to or less than 0.25 μSv (25 μrem) per screening. Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year.

"Hand-held x-ray system" means a portable instrument that is designed to operate when held in the hand, e.g., hand-held XRF analytical devices.

"Industrial radiography" means an examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images.

"Interlock" means a device or engineered system that precludes access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

"Leakage radiation" means all radiation coming from within the source housing, except the useful beam.

"Limited-use system" means a personnel screening system that is capable of delivering an effective dose greater than 0.25 μSv (25 μrem) per screening but cannot exceed an effective dose of 10 μSv (1 mrem) per screening. Limited-use systems require additional controls and documentation to ensure that annual individual dose limits required by H.12e. are not exceeded.

"Local components" means parts of a RGD x-ray system and include areas that are struck by x-rays such as radiation source housings, beam port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

"Mobile equipment". See "Radiation generating device."

"Normal operating procedures" mean step-by-step instructions necessary to accomplish the task. These procedures may include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures, which are related to radiation safety.

"Open-beam x-ray equipment" means an open-beam x-ray system in which the beam path could be entered by any part of the body at any time.

"Personnel security screening system" means any x-ray equipment used on humans for security evaluation.

"Portable equipment". See "Radiation generating device."

"Primary beam" means the ionizing radiation coming directly from the radiation source through a beam port into the volume defined by the collimation system.

"Qualified expert" means an individual as defined in Part A of these regulations.

"Radiation generating device (or RGD)" means any system, device, subsystem, or component thereof, which may generate x-rays or particle radiation between 5 keV and 1 MeV, and not intended for healing arts use for humans or animals. A RGD may be fixed or portable, such as:

i. Mobile means RGD equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

ii. Portable means RGD equipment designed to be hand-carried;

iii. Stationary means RGD equipment that is installed or placed in a fixed location; or

iv. Transportable means RGD equipment to be installed in a vehicle or that may be readily disassembled for transport or use in a vehicle.

"Radiation Safety Officer (RSO)" means an individual as defined in Part A of these regulations.

"Radiation source (or x-ray tube) housing" means that portion of an x-ray system which contains the x-ray tube and/or secondary target. Often the housing contains radiation shielding material or inherently provides shielding.

"Radiograph" means a permanent film or digital image produced on a sensitive surface by a form of radiation other than direct visible light.

"Radiography" is the process of creating radiographic images.

"Safety device" means a device, interlock or system that prevents the entry of any portion of an individual’s body into the primary x-ray beam or that causes the beam to shut off upon entry into its path.

"Scattered radiation" means radiation that has been deviated in direction and / or energy by passing through matter.

"Security screening unit" means a non-human use open-beam or cabinet x-ray system with accessible openings designed for the detection of weapons, bombs, or contraband concealed in baggage, mail, packages or other commodities or structure.

"Shielded room" means a room housing a RGD where, with the RGD at maximum techniques, the exterior room environs meets the unrestricted area limits of 0.02 mSv (2 mrem) in any one hour and 1 mSv (100 mrem) in a year at 30 cm from the barrier. A shielded room does not include a RGD which meet the definition of cabinet x-ray systems.

"Shutter" means a moveable device used to block the useful (or primary) beam emitted from an x-ray tube assembly.

"Source" means the point of origin of the radiation, for example, the focal spot of an x-ray tube.

"Stationary equipment". See "Radiation generating device."

"Stray radiation" means the sum of leakage and scatter radiation.

"Warning device" means a visible or audible signal that warns individuals of a potential radiation hazard.

"X-ray generator" means that portion of an x-ray system which provides the accelerating high voltage and current for the x-ray tube.

"X-ray gauge" means an x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location.

Sec. H.5 - Exemptions.

a. RGDs meeting the definition of "bomb detection radiation equipment," as defined under H.4, are exempt from the requirements of H.6f. (Posting), of the General Regulatory Provisions of this Part.

b. Unless utilized in a dedicated location, hand-held RGDs are exempt from the requirements of H.6f Posting of the General Regulatory Provisions of this Part.

c. The following machines and equipment are exempt from these regulations:

    i. Domestic television receivers, providing the exposure rate at 5 centimeters from any outer surface is less than 0.005 mSv (0.5 mrem) per hour.

    ii. Cold-cathode gas discharge tubes, providing the exposure rates shall not exceed 0.1 mSv (10 mrem) per hour at a distance of thirty (30) centimeters from any point on the external surface of the tube.

iii. Other electrical equipment that produces radiation incidental to its operation for other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding not integral to the equipment is removed does not exceed 0.25 mSv (25 mrem) per year. The production testing or factory servicing for such equipment shall not be exempt.

iv. Equipment described in this subsection shall not be exempt if it is used or handled in such a manner that any individual might receive a dose of radiation in excess of the limits specified in Part D of these regulations.

Sec. H.6 - General Regulatory Provisions. Unless otherwise provided in this Part, this Section applies to all RGDs. Certified and Certifiable Cabinet X-ray Systems as defined in this Part shall also meet the requirements of 21 CFR 1020.40.

a. Warning Devices.

i. Warning devices shall be labeled so that their purpose is easily identified.

ii. An easily visible warning device light labeled with the words "X-RAY ON," or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized. This warning light shall be of a fail-safe design.

b. Labeling.

i. All RGD equipment shall be labeled with a readily visible and discernible sign or signs bearing the radiation symbol (defined in Part D.1901 of these regulations) and the words: "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube.

ii. For RGDs with designed openings, for object entries (such as baggage units), the following shall be posted at or near each opening: "CAUTION – X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED", or words having similar intent.

c. Radiation Source Housing. Each x-ray tube housing shall be subject to the following requirements:

i. Interlock. When the x-ray tube housing is the primary shielding for the x-ray tube, and is intended to be opened for normal use or maintenance, the housing shall be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened; and

ii. Radiation Emission Limit. Each x-ray tube housing shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of 5 centimeters from the x-ray tube housing surface does not exceed 0.025 mSv (2.5 mrem) per hour. This limit shall be met at the maximum tube rating. For closed-beam systems, this

requirement can be met by complying with Section H.7d. Radiation Emission Limit. For a RGD in a shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in H.9c. Radiation Emission Limit.

d. Generator Cabinet or High Voltage Source Radiation Emission Limits. Each x-ray generator or high-voltage source shall be supplied with a protective cabinet which limits leakage radiation to 2.5 μSv (0.25 mrem) per hour at a distance of 5 centimeters measured at the nearest accessible surface. For closed-beam systems, this requirement can be met by complying with Section H.7d. Radiation Emission Limit. For a RGD in a shielded room with the high-voltage generator also inside the shielded room, this limit can be met by measuring from any accessible surface outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement can be met by complying with the limits in H.9c. Radiation Emission Limit.

e. Surveys.

i. Radiation surveys of all RGDs shall be sufficient to show compliance with radiation emission requirements of this Part, and as required by Part D.1201 (Occupational Dose Limits for Adults) and Part D.1301 (Dose Limits for Individual Members of the Public) of these regulations. The radiation surveys shall be sufficient to evaluate the magnitude and extent of radiation emissions and the potential radiological hazards that could be present. At a minimum, surveys shall be performed:

(1) Upon installation of the equipment, and at least once every 12 months thereafter;

(2) Following any change in the initial arrangement, number, or type of local components in the system;

(3) Following any maintenance requiring the disassembly, removal, or repair of a local component in the system;

(4) During the performance of maintenance, calibration and other procedures if the procedures require the presence of a primary x-ray beam while any local component in the system is disassembled or removed;

(5) Post bypass of a safety device or interlock as required by H.6.h.ii;

(6) Any time a visual inspection of the local components in the system reveals an abnormal condition;

(7) Whenever a personnel monitoring device shows a significant increase over previous monitoring period or readings are approaching the limits specified in Part D.1201 (Occupational Dose Limits for Adults) of these regulations.

ii. The registrant shall have access to sufficiently calibrated, appropriate and operable radiation survey instruments to make physical radiation surveys as required by this Part. The instruments shall be capable of detecting and measuring the types and levels of radiation involved (including primary, scattered, and leakage radiation).

iii. The registrant shall assure the maintenance and calibration of all monitoring and survey instruments per Part D.1501 of these regulations.

iv. Radiation survey measurements shall not be required if a registrant can otherwise demonstrate compliance with the requirements of this Part to the satisfaction of the Agency.

f. Posting. Each area or room containing an RGD where an individual may receive 0.02 mSv (2 mrem) in any one hour or 1 mSv (100 mrem) per year shall be conspicuously posted with a sign or signs bearing the radiation symbol (as defined in Part D.1901 of these regulations) and the words "CAUTION - X-RAY EQUIPMENT," "CAUTION – RADIATION GENERATING DEVICE" or words having a similar intent.

g. Security. RGDs shall be secured in such a way as to be accessible to, or operable by, only authorized personnel when not in operation.

h. Operating Requirements.

i. Procedures. Normal operating procedures shall be written and available to all RGD workers. No individual shall be permitted to operate a RGD in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

ii. Bypassing.

(1) No individual shall bypass a safety device, interlock, or remove shielding unless such individual has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time.

(2) When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing and at the control switch.

(3) A record of any bypass of a safety device or interlock shall be maintained; the record shall contain such information as the date the alteration was made, type of alteration, length of time the unit remained in the altered condition, post bypass survey and signed by the RSO, individual who made the alteration, and the individual who restored the unit to original condition.

iii. Control Panel.

(1) The RGD can only be activated from a control panel.

(2) All indicators and controls that control the primary beam shall be identifiable and discernible through the use of labels, symbols, software displays or the equivalent.

iv. Interlocks.

(1) An interlock shall not be used to de-activate the x-ray tube or RGD, except in an emergency or during testing of the interlock system.

(2) After triggering any interlock, it shall be possible to reset the RGD to full operation only from a control panel.

(3) All interlocks shall be of a fail-safe design.

v. Multiple Sources. If more than one x-ray tube assembly(s) or focal spot can be operated sequentially or simultaneously from a control panel, visual indicators shall identify which tube assembly(s) or focal spot has been selected. The selectors shall be identified as to their function. If a letter or number is used, a reference card or table explaining the code shall be affixed to the control panel.

i. Repair or Modification of X-Ray Tube or RGD Systems. Only trained personnel or registered service provider shall be permitted to install, repair, or make modifications to the RGD. No operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main power switch with a lock-out / tag-out, rather than interlocks, shall be used for routine shutdown in preparation for repairs. It is the responsibility of the registrant to assure that qualified personnel install, repair, or make modifications to the RGD.

j. Testing of Safety Devices.

i. Tests of all safety devices, such as interlocks, shutters, warning lights, and required emergency shut-off switches shall be conducted at intervals not to exceed 6 months on all operable RGDs.

ii. If any safety device fails during testing, the RGD shall be removed from service until the safety device failure is corrected or proper temporary administrative controls established and approved in writing by the RSO.

iii. Records of safety device tests, check dates, findings and corrective actions shall be available for inspection and maintained for 5 years.

iv. Records shall include the date of the test, a list of the safety devices tested, survey instrument information, calibration date, the results of the test, the name of the person performing the tests and corrective actions taken for safety devices that fail the required test.

v. Testing of safety devices may be deferred if the unit and/or installation is clearly marked and kept out of service; units and/or installations brought back into service after exceeding the 6 month interval shall be tested prior to use.

vi. If testing of a safety device cannot be performed due to manufacturer design, the registrant shall document that the safety device will not be tested and specifically why the safety device cannot be tested.

k. Instruction and Training. The registrant shall document the scope of training required for the RGD they possess in accordance with this section. No individual shall be permitted to operate or maintain an RGD, or enter a shielded room without appropriate instruction and training. Records shall be maintained onsite of all required training and instruction, and made available for review by the Agency. Each such individual shall receive instruction in and demonstrated competence as to:

i. Types of radiation and identification of radiation hazards associated with the use of the RGD and associated equipment and precautions or measures to take to minimize radiation exposure;

ii. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

iii. Commensurate with potential hazards of use, biological effects of radiation, radiation risks, and recognition of symptoms of an acute localized exposure;

iv. Normal operating procedures for each type of RGD and associated equipment, including having received hands-on training, and procedures to prevent unauthorized use;

v. Procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation; and

vi. Performing surveys where applicable.

l. Radiation Protection Responsibility.

i. The registrant's senior management shall make the ultimate decision to use any RGD and be ultimately responsible for radiation safety.

ii. The registrant's senior management shall designate an individual responsible for radiation safety, or a RSO. This individual shall have direct access to senior management for radiation safety issues. This individual shall have training and experience commensurate with the scope of the radiation safety program to carry out the responsibilities as indicated below.

(1) Ensuring that all RGDs are operated within the limitations of the established radiation safety program and operating procedures.

(2) Instructing personnel with regard to safe working practices and ensuring all personnel are trained in radiation safety commensurate with the hazards of the job.

(3) Investigating any incident of abnormal operation or exposure or suspected overexposure of personnel to determine the cause, take remedial action, and report the incident to the proper authority.

(4) Ensuring that safety devices, interlocks, warning signals, labels, postings, and signs are functioning and located where required.

(5) Maintain all radiation safety records.

Sec. H.7 - Additional Requirements for Closed-Beam RGDs. In addition to the requirements of Section H.6, the following applies to all closed-beam x-ray RGDs:

a. System Enclosure. The radiation source, sample or object, detector, and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

b. Interlocks. All doors and panels accessing the RGDs shall be interlocked. The interlocks required by this section shall be of a fail-safe design.

c. Interlock Functions. The system enclosure, sample chamber, etc. closure shall be interlocked with the x–ray tube high voltage supply and/or a shutter in the primary beam so that no x-ray beam can enter the sample or object chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this section shall be of fail–safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.

d. Radiation Emission Limit. The radiation emission for all closed beam RGDs shall not exceed a dose rate of 0.005 mSv (0.5 mrem) in one hour at five centimeters outside any accessible surface.

e. Security Screening Units. Security screening units shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the openings and doors during generation of x-radiation.

i. During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

ii. During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

Sec. H.8 - Additional Requirements for Open Beam RGDs. In addition to the requirements in Section H.6, the following requirements apply to all open beam RGDs not otherwise addressed in this Part.

a. Safety Device.

i. The registrant shall document their justification of the use of open-beam instead of closed-beam systems.

ii. If the registrant needs to use an open-beam system, the registrant shall consider a safety device which prevents the entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path.

iii. If the registrant's use of the open-beam RGD does not permit the use of a safety device to prevent direct body exposure, the registrant shall maintain a written record of a description of the various safety devices that have been evaluated and reasons for why these devices cannot be used. These records shall be available onsite for inspection.

iv. In lieu of the safety device described in section H.8a.ii. above, the registrant shall employ alternative methods (such as policies and procedures) to minimize the possibility of unnecessary exposure. These alternative methods shall be documented. The documentation shall include information about the absence of safety devices. This documentation shall be available for inspection as long as these methods are employed, plus an additional 5 years.

v. For portable open-beam RGDs that are manufactured to be used hand-held, or potentially used as a hand-held, without such safety devices, this safety device requirement may be met by complying with all the requirements in H.9, Additional Requirements for Open-beam, Hand-held RGDs prior to use.

b. X-ray On Status. For open beam equipment, RGDs shall be provided with a readily discernible and active indication of:

i. X-ray tube "on-off" status located near the radiation source housing. The warning lights as required by H.6a.ii. can meet this requirement if the warning lights are readily discernible and viewable by anyone near the primary beam;

ii. Shutter "open-closed" status located at the control panel and near each beam port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device shall be clearly labeled as to the meaning of the status device (i.e., whether the shutter is open or closed). The status light at the control panel can meet the requirement for the status light at the beam port if the status light at the control panel is readily discernible and viewable by anyone near the primary beam; and

iii. The x-ray tube “on-off” status indicator and the shutter “open-closed” status indicators shall be of a fail-safe design.

c. Labeling. Each unit will be labeled at or near the x-ray exit beam port to identify the location of the beam with the words, "CAUTION - X-RAY BEAM", “CAUTION - HIGH INTENSITY X-RAY BEAM”, or words having a similar intent.

d. Beam Ports. Unused beam ports on radiation source housings shall be secured in the closed position in a manner which will prevent in advertent opening.

e. Shutters. On open-beam RGD configurations that are designed to accommodate interchangeable components, each beam port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling has been connected to the beam port.

f. Radiation Emission Limits. The local components of an open-beam RGD shall be located and arranged and shall include sufficient shielding or access control such that no radiation emissions exist (exclusive of the primary beam) in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits as outlined in Part D. 1301 (Dose Limits for Individual Members of the Public) of these regulations. These emissions shall be met at any specified tube rating.

g. Primary Beam Attenuation. In cases where the primary x-ray beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding or administrative procedures, to avoid exposure to any individual from the transmitted primary x-ray beam.

h. Operator Attendance. The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked or the equipment is secured to protect against unauthorized or accidental entry.

i. Control of Access. If the RGD is not in a restricted area (as defined in Part A of these regulations), the operator shall be able to control access to the RGD at all times during operation. If the RGD is not in a restricted area (as defined in Part A) and the RGD is capable of creating a radiation area or a high radiation area (as defined Part A), the operator shall be able to control access to the RGD at all times during operation, and:

i. Radiation areas shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent rate exceeds 0.05 mSv (5 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION - RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the radiation area during operation of the RGD;

ii. High radiation areas shall be conspicuously identified. The radiation source shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose equivalent rate exceeds 1 mSv (100 mrem) per hour. The area described by the temporary barricade shall be suitably posted with "CAUTION -

HIGH RADIATION AREA" signs. The operator shall ensure that no one is inside or enters the high radiation area during operation of the RGD;

iii. The operator shall perform a visual check of the controlled area to ensure it is free of all unauthorized personnel immediately prior to activating or exposing the radiation source;

iv. Surveillance of the exposure area shall be maintained during operation, either by visual or by other reliable means to ensure that no person enters the area;

v. With the exception of hand-held x-ray systems, when approaching the radiation source, following the conclusion of an exposure, the operator shall use a suitable calibrated and operable radiation detection instrument to verify that the radiation source is in its fully shielded condition or that the x-ray tube has been de-energized;

vi. A personal alarming dose rate meter may be worn to approach the work area if the device is appropriately designed and calibrated for the type of x-ray emitted (i.e., pulse or continuous), set at an appropriate level to detect the presence of the source, for example 0.02 mSv (2 mrem) per hour, and has been source-checked prior to use. The radiation in the work area must be reasonably uniform so that the device responds to radiation exposure to any part of the body. It may not be used to measure radiation levels, nor may it be used to indicate the presence of the source for potential non-uniform exposure, such as may occur during machine maintenance or work in a RGD target area;

vii. Measurement of radiation levels for a radiation survey shall be performed using an appropriate calibrated radiation survey meter (see H.6e.i. and H.6e.ii.). A radiation survey meter shall also be used when there is potential for non-uniform exposure to personnel, such as may occur during machine maintenance or work in a RGD target area;

viii. During the initial exposure, the radiation levels shall be measured around the perimeter of the controlled area. The perimeter shall be adjusted accordingly to meet the access control requirement for radiation areas or high radiation areas; and;

ix. The survey around the perimeter shall be made for each new operating condition and the perimeter adjusted accordingly. The area of operation shall be monitored periodically if radiation levels are variable.

j. Instruction and Training. In addition to the requirements in H.6k., no individual shall be permitted to operate or maintain an open-beam RGD unless such individual has received more specific and detailed instruction in and demonstrated competence as to:

i. Sources and magnitude of common radiation exposure;

ii. Units of radiation measurement;

iii. Radiation protection concepts of time, distance, shielding, and ALARA;

iv. Procedures and rights of a declared pregnancy;

v. Regulatory requirements and area postings;

vi. Worker, embryo/fetus, and public dose limits;

vii. Proper use of survey instruments and dosimetry; and

viii. The policies and procedures required by H.8a.

k. Personnel Monitoring. In addition to the requirements of Part D 1201 of these regulations (Occupational Dose Limits for Adults), extremity dosimetry shall be provided and used by:

i. Personnel working with or routinely working near and having potential for exposure to, the primary beam of an open-beam RGD; and

ii. Personnel maintaining RGDs if the maintenance procedures require the presence of a primary radiation beam when any local component in the RGD is disassembled or removed.

Sec H.9 - Additional Requirements for Open-beam, Hand-held RGDs. In addition to the requirements in Sections H.6 and H.8, the following requirements in this Section apply to open-beam, hand-held RGDs.

a. Procedures. All registrants possessing open-beam, hand-held RGDs shall have available for review to the Agency operating policies and procedures that contain measures to insure that:

i. Radiation protection is provided equivalent to that afforded in Part D. 1301 of these regulations (Dose Limits for Individual Members of the Public);

ii. Radiation protection is provided equivalent to that afforded in H.8g. (Primary Beam Attenuation);

iii. The operator will not hold the sample during operation of the RGD and that the operator's hands will not approach the primary beam;

iv. The operator will not aim the primary beam at him/herself or at any individual during operation of the RGD; and

v. Operator radiation exposure is as low as reasonably achievable (ALARA), for example, by use of ancillary equipment that will reduce exposure.

b. Training. In addition to the training requirements of H.6k. and H.8j. above, the registrant shall provide training for all users and operators on the subjects in section H.9a. Records shall be maintained of all user and operator training.

c. Radiation Emission Limit. For hand-held RGDs, the limits of H.6c.ii. (Radiation Source Housing Radiation Emission Limits) and H.6d. (Generator Cabinet or High Voltage Source Radiation Emission Limits), excluding the primary beam, shall be met if the radiation emission at any accessible surface of the RGD does not exceed 0.025 mSv (2.5 mrem) per hour at 5 cm.

d. Extremity Monitoring. For the purposes of the requirements in H.8k. (extremity monitoring), operators of hand-held RGDs shall be considered as working near the primary beam.

Sec. H.10 - Shielded Room RGDs. For RGDs that do not meet the limits of Part D. 1301 (Dose Limits to Individual Members of the Public), the RGD can be maintained inside a shielded room such that the exterior of the room meets the limits of Part D.1301 of these regulations (Dose Limits to Individual Members of the Public) when the RGD is activated. RGDs in a shielded room shall be required to meet only the requirements of H.6 (General Requirements) and the following:

a. Posting. The door to the room containing the RGD shall be posted "CAUTION – RADIATION AREA", or "CAUTION – HIGH RADIATION AREA", or "GRAVE DANGER – VERY HIGH RADIATION AREA", as required by Part D of these regulations.

b. Entrance Interlocks. All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the x-ray equipment except in an emergency or during testing.

c. Entrance Warning Devices. All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced. The warning device shall be labeled in accordance with H.6a.

d. Room Warning Lights. The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be positioned so that they can be observed from any position or orientation within the room. The lights shall be posted indicating the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.

e. Audible Room Warning Device. An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel. The registrant shall post the meaning of the warning signal and instructions on what to do; the posting shall be legible, conspicuous, and accessible to view.

f. Emergency Shut-off. If dose rates exceed the High Radiation Area limits (as defined in Part A of these regulations), emergency shut-off switches shall be located within the high radiation areas so as to be accessible to individuals therein within 10 seconds. These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut-off switches shall include a manual reset that must be reset at the switch before x-rays can again be produced from the control panel. After

an emergency shut-off switch has been activated, it shall be possible to produce x-rays again only from the control panel.

g. Separate Electrical Systems. The interlock system and the emergency shut-off system shall be separate electrical and/or mechanical systems.

h. Egress from Shielded Room. A person within the room housing a RGD shall be able to egress at all times.

i. Entry into the Shielded Room.

i. After each exposure and before entry of any personnel, a survey shall be performed upon entry to the shielded room to determine that the RGD is no longer producing radiation.

ii. Personnel devices providing an audible signal when activated by radiation will be acceptable for the survey requirement of H.10i.i.

(1) Proper operation of the audible detection device shall be checked daily and a record maintained of this check.

(2) The audible device shall be designed so as to clearly indicate entry into a 0.02 mSv (2 mrem) per hour or greater radiation field.

(3) All personnel working with the RGD shall be provided with such a device.

iii. Stationary area monitors providing an audible signal when activated by radiation will be acceptable for the survey requirement of H.10i.i.

(1) Proper operation of the stationary detection device shall be checked daily and a record maintained of this check.

(2) The stationary device shall be designed so as to clearly indicate entry into a 0.02 mSv (2 mrem) per hour or greater radiation field.

(3) Stationary area monitors shall be calibrated annually to determine that the audible signal operates at a 0.02 mSv (2 mrem) per hour radiation field.

j. Personnel Monitoring. All personnel associated with the x-ray equipment shall be provided with personnel monitoring devices that shall be calibrated for the x-ray energies being utilized. Records of personnel exposure shall be maintained.

k. Training. No registrant shall permit any individual to operate a RGD in a shielded room until such individual has received a copy of, instruction in, and demonstrated an understanding of, operating and emergency procedures for the unit and competence in its use. Records shall be maintained of all operator training.

l. Control Panel Security. The equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of radiation by the equipment.

m. Malfunctions. If a safety or warning device malfunctions, the control panel shall be locked in the "off" position. The control panel shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

Sec H.11 - Bomb Detection RGDs. In addition to the General Requirements in H.6 (not otherwise exempted under H.5a.), the following requirements in this section apply to bomb detection radiation equipment.

a. Control Panel Security. When not in use, each bomb detection radiation machine shall be locked to prevent unauthorized use. This is in addition to the requirements of H.6g. (Security).

b. Utilization Log. The registrant shall maintain for each bomb detection radiation machine a utilization log. This log shall record the description of the unit, the date removed from storage, the date returned to storage, the identity and signature of the person to whom the device is assigned, the dates of use and the site(s) of use.

c. Area Control. The registrant shall provide security to prevent entry by individuals from any point when the machine is energized during training.

Sec H.12 - RGDs Used in Personnel Security Screening or Vehicle Screening for Public Protection. In addition to the General Requirements in H.6., the following requirements in this section apply. A person requesting Agency approval for a RGD to be used in Personnel Security Screening or Vehicle Screening with intended exposure of human occupants to the primary beam for public protection shall submit in writing the following information to the Agency for evaluation and approval, and show how the dose limits noted below will be met.

a. Efficacy Evaluation. An evaluation of all known alternate methods that could achieve the goals of the security screening program, and why these methods will not be used in preference to the proposed approach utilizing ionizing radiation.

b. Equipment Evaluation. RGDs used for non-healing arts personnel security screening of humans shall be evaluated every 12 months by a qualified expert for optimization of image quality and radiation dose.

c. Dose Limits for General-Use Systems. For general-use screening systems, where system is used without regard to the number of individuals scanned or number of scans per individual in a year, an effective dose for a single complete screening shall be limited to 0.25 μSv (25 μrem).

d. Dose Limits for Limited-Use Systems. For limited-use screening systems, where equipment is capable of operation greater than 0.25 μSv (25 μrem) per screening, and is used with discretion, the effective dose per screening shall be less than or equal to 0.01 mSv (1 mrem).

e. Dose Limits for Repeat Security Screenings. Individuals subject to repeat security screening at a single venue shall not receive an effective does greater than 0.25 mSv (25 mrem) in any one year at the registrant or licensee's facility.

f. Vehicle Limitations.

i. When the procedures for operation of a mobile or fixed RGD used for security screening of vehicles includes knowingly exposing human occupants to the primary beam when screening vehicles, structures or containers, the system shall be subject to the same requirements as general-use or limited-use systems as provided in H.12a. through H.12e.

ii. If the requirements in H.12c. through H.12e. cannot be met if vehicle occupants are knowingly exposed to the primary beam of a security screening system, then there shall be means to assure the occupied portion of the vehicle is outside of the scan area while the primary beam is emitted or procedures shall be established and implemented to assure that no occupants are present in the vehicle during screening.

iii. The effective dose to an individual for a single inadvertent exposure to the primary beam shall not exceed 5 mSv (500 mrem) and should not exceed 1 mSv (100 mrem). The reliability of the procedure used to assure that there are no occupants of a vehicle to be scanned shall be commensurate with the potential severity of an inadvertent exposure. If the 5 mSv (500 mrem) limit cannot be assured, a pre-screening with a mode or system which can meet the limits in H.12c. through H.12f. shall be used to verify there are no occupants in the vehicle being examined.

Sec. H.13 - Application for Exemptions. Any RGD user or manufacturer that cannot meet the applicable requirements of the above sections in this Part shall submit to the Agency a request for an exemption to the specific regulation in question. The exemption request shall demonstrate to the Agency's satisfaction:

a. That the use of the RGD will not result in undue hazard to public health and safety or property;

b. That compliance would require replacement or substantial modification of the RGD;

c. That the registrant will achieve, through other means, radiation protection equivalent to that required by the regulation; and

d. Why the regulatory standard or requirement could not be met.