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Date: 1/19/01 2:14PM

Subject: 902 KAR 100:100

<<CABINET FOR HEALTH SERVICES.htm>>

Fred,

This should be it for a Friday afternoon. Again, if you can't open the document, call me and we will try again.

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CABINET FOR HEALTH SERVICES

Department for Public Health

Division of Public Health Protection and Safety

(Amendment)

902 KAR 100:100. Industrial radiography.

RELATES TO: KRS 211.842 to 211.852, 211.990(4), 10 CFR 34, 71, 21 CFR 1020.40

STATUTORY AUTHORITY: KRS 13B.170, 194A.050, 211.090, 211.844~~[-10 CFR 34, 71, 21 CFR 1020.40]~~

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.844 requires ~~[authorizes]~~ the Cabinet for Health Services ~~[Human Resources]~~ to provide by administrative regulation for the registration and licensing of the possession or use of sources of ionizing or electronic product radiation and the handling and disposal of radioactive waste. This administrative regulation provides radiation safety requirements for industrial radiographic operations and shall apply ~~[applies]~~ to licensees or registrants who use sources of radiation for industrial radiography.

Section 1. Specific License and Registration Requirements for Industrial Radiography. (1) An application for a specific license or registration for the use of sources of radiation in industrial radiography shall be approved if the applicant meets the following requirements:

(a) The applicant shall satisfy the general requirements specified in 902 KAR 100:040, Section 4, or 902 KAR 100:110 and 902 KAR 100:145, and any special requirements contained in this administrative regulation.

(b) The applicant shall submit an adequate program for training a radiographer and a radiographers@ assistant that meets the requirements of Section 14 of this administrative regulation.

1. After June 30, 2002, an applicant need not describe its initial training and examination program for a radiographer in the subjects outlined in Section 14 of this administrative regulation.

2. From June 30, 2000 to June 30, 2002, an applicant may affirm that an individual acting as an industrial radiographer shall be certified in radiation safety by a certifying entity, as described in 10 CFR Part 34, Appendix A, before commencing duty as a radiographer. This affirmation shall substitute for a description of its initial training and examination program for a radiographer in the subjects outlined in Section 14 of this administrative regulation.

(c) The applicant shall submit procedures for verifying and documenting the certification status of a radiographer and for ensuring that the certification of an individual acting as a radiographer remains valid.

(d) The applicant shall submit written operating and emergency procedures as described in Section 15 of this administrative regulation.

(e) The applicant shall submit a description of a program for inspections of the job performance of a radiographer and a radiographers@ assistant at intervals not to exceed six (6) months as described in Section 14 of this administrative regulation.

(f) The applicant shall submit a description of the applicant@s overall organization structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation of authority and responsibility.

(g) The applicant shall identify and list the qualifications of the individual designated as the radiation safety officer (RSO) and of the 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 shall describe the procedures for performing and the qualifications of the person authorized to do the leak testing. If the applicant intends to analyze its own wipe samples, the application shall include a description of the procedures to be followed. The description shall include:

1. Instruments to be used;

2. Methods of performing the analysis; and

3. Pertinent experience of the person analyzing the wipe samples.

(i) If the applicant intends to perform an "in-house" calibration of a survey instrument, the applicant shall describe methods to be used and the relevant experience of the person performing the calibration. A calibration shall be performed according to the procedures described and at the intervals prescribed in Section 5 of this administrative regulation.

(j) The applicant shall identify and describe the location of all field stations and permanent radiographic installations.

(k) The applicant shall identify the location where records required by this administrative regulation and other administrative regulations in 902 KAR Chapter 100 shall be maintained.

(2) A licensee shall maintain a copy of its license, documents incorporated by reference, and amendments to these items until superseded by new documents approved by the cabinet, or until the cabinet terminates the license.

Section 2. Performance Provisions for Radiography Equipment. Equipment used in industrial radiographic operations shall meet the following criteria:

(1)(a) Radiographic exposure devices, source assemblies, or sealed sources, and associated equipment shall meet the provisions specified in American National Standard Institute (ANSI) N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography", (published as NBS Handbook 136, issued January 1981).

(b) Engineering analysis shall be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. If upon review, the cabinet determines that the engineering analysis demonstrates the actual testing of the component is not necessary, the cabinet shall find the engineering analysis to be an acceptable alternative. [~~N43.9-1991, "Gamma Radiography-Specifications for Design and Testing of Apparatus" (1991).~~]

(2)(a) A radiographic exposure device shall have attached to it by the user, a durable, legible, clearly visible label bearing the ~~[following]~~:

1. Chemical symbol and mass number of the radionuclide in the device;
2. Activity and date on which this activity was last measured;
3. Model, or product code, and serial number of the sealed source;
4. Manufacturer of the sealed source; and
5. Name, address, and telephone number of the licensee or registrant.

(b) Radiographic exposure devices intended for use as Type B transport containers shall meet the applicable provisions of 10 CFR 71.

(c) Modification of exposure devices, source changers, source assemblies, or ~~[and]~~ associated equipment shall be prohibited, unless the design of a replacement component, including source holder, source assembly, controls, or guide tubes, shall not compromise the design safety features of the system.

(3) In addition to the provisions specified in subsections (1) and (2) of this section, the following provisions shall apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operation or to source changers ~~[routine operation]~~:

(a) The coupling between the source assembly and the control cable shall be designed in a manner that the source assembly cannot:

1. Become disconnected if cranked outside the guide tube; and
2. Be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(b) The device shall automatically secure the source assembly if it is cranked back into the fully shielded position within the device. The securing system shall only be released by a deliberate operation on the exposure device.

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

(d) A sealed source or source assembly shall have attached to it or engraved on it, a durable, legible, visible label with the words: "DANGER-RADIOACTIVE". The label shall not interfere with the safe operation of the exposure device or associated equipment.

(e) The guide tube shall have passed:

1. A [The] crushing test that closely approximates the crushing forces likely to be encountered during use [tests for the control tube as specified in ANSI N43.9]; and

2. A kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(f) Guide tubes shall be used if moving the source out of the device.

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

(h) The guide tube exposure head connection shall withstand the tensile test for control units specified in ANSI N432-1980 [~~N43.9~~].

(i) Source changers shall provide a system for assuring that the source cannot be accidentally withdrawn from the changer if connecting or disconnecting the drive cable to or from a source assembly.

(j) ~~[Newly manufactured radiographic exposure devices and associated equipment acquired by licensees after January 1, 1994, shall comply with the provisions of this section.]~~

~~(k)~~ Radiographic exposure devices and associated equipment in use after January 10, 1996, shall comply with the provisions of this section.

(k) Notwithstanding subsection (1)(a) of this section, equipment used in industrial radiography operations need not comply with paragraph 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 radiographic equipment can realistically exert on the lever or crankshaft of the drive mechanism.

Section 3. ~~[2:] Limits on External Levels of Radiation for Radiographic Exposure Devices and Storage Containers. The maximum exposure rate limits for storage containers and source changers shall be:~~

~~(1) 200 millirems (2 millisieverts) per hour at any exterior surface; and~~

~~(2) Ten (10) millirems (0.1 millisieverts) per hour at one (1) meter from any exterior surface with the sealed source in the shielded position. [(1) Radiographic exposure devices measuring less than four (4) inches (ten (10) centimeters) from the sealed source storage position to an exterior surface of the device shall have no radiation level in excess of fifty (50) milliroentgens per hour (mR/hr) at six (6) inches (fifteen (15) centimeters) from an exterior surface of the device.~~

~~(2) Radiographic exposure devices measuring a minimum of four (4) inches from the sealed source storage position to an exterior surface of the device, and storage containers for sealed sources or outer containers for radiographic exposure devices shall have no radiation level in excess of 200 milliroentgens per hour (mR/hr) at an exterior surface and ten (10) mR/hr at 39.4 inches (one (1) meter) from an exterior surface.~~

~~(3) The radiation levels specified shall be with the sealed source in the shielded ("off") position.~~

~~(4) Subsections (1), (2), and (3) of this section shall apply to equipment manufactured prior to January 10, 1992. After January 10, 1996, radiographic equipment other than storage containers and source changers shall meet the provisions of Section 1 of this administrative regulation, and Section 2 of this administrative regulation shall apply only to storage containers (source changers).]~~

Section 4. ~~[3:] Locking of Radiographic Exposure Devices, Storage Containers, and Source Containers. (1) A radiographic exposure device shall have [Sources of Radiation. (1) Sources of radiation shall be provided with]~~ a lock or outer locked container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source from its shielded position.

(a) An exposure device or its container shall be kept locked, and if a keyed lock, with the key removed at all times except:

1. If under the direct surveillance of a radiographer or radiographer's assistant; or
2. As authorized by Section 19 ~~[16]~~ of this administrative regulation.

(b) During radiographic operation the sealed source assembly shall be secured in the shielded position each time the source is returned to that position.

(c) A sealed source ~~[A]~~ storage container and source changer shall be:

1. Provided with a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position; and

2. Kept locked (and if a keyed lock, with the key removed at all times) if containing sealed sources, except if ~~[the container is]~~ under the direct surveillance of a radiographer or radiographer's assistant.

(2) The control panel of a radiation machine shall be:

(a) Equipped with a lock that prevents the unauthorized use of an x-ray system or the accidental production of radiation; and

(b) Kept locked and the key removed at all times, except if under the direct visual surveillance of a radiographer or radiographer's assistant. ~~[Radiographic exposure devices, source changers, and storage containers shall be locked and surveyed to assure that the sealed source is in the shielded position prior to being:-~~

~~(a) Moved from one (1) location to another; and~~

~~(b) Secured at a given location.-~~

Section 4. Storage Precautions. ~~(1) Locked radiographic exposure devices, source changers, storage containers, and other sources of radiation, including radiation machines, shall be physically secured to prevent tampering or removal by unauthorized personnel.-~~

~~(2) Radiographic exposure devices, source changers, and transport containers that contain radioactive material shall not be stored in residential locations. This provision shall not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites if:-~~

~~(a) The licensee complies with subsection (3) of this section; and~~

~~(b) The vehicle does not constitute a permanent storage location as described in subsection (4) of this section.-~~

~~(3) If a vehicle is used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels shall not exceed the limits specified in 902 KAR 100.019, Section 10(b), at the exterior surface of the vehicle.-~~

~~(4) A storage or use location shall be considered permanent if:-~~

~~(a) Radioactive material is stored at the location for more than ninety (90) days; and~~

~~(b) One (1) or more of the following applies to the location:-~~

~~1. Telephone service is established by the licensee;-~~

~~2. Industrial radiographic services are advertised for or from the location; or~~

~~3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location.]~~

Section 5. Radiation Survey Instruments. (1) A licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at a location where sources of radiation are present to make ~~[physical]~~ radiation surveys as required by this administrative regulation and 902 KAR 100:019, Section 12(1).

(2) A radiation survey instrument shall be calibrated:

(a) ~~[At energies appropriate for use;~~

~~(b)]~~ At intervals not to exceed six (6) ~~[three (3)]~~ months;

~~(b) [(c)]~~ After an [each] instrument servicing, except for battery changes; ~~[so that accuracy within plus or minus twenty (20) percent may be demonstrated;]~~

~~(c)1. [(d)]~~ At two (2) points located approximately one-third (1/3) and two-thirds (2/3) of full-scale for linear scale instruments;

2. [(e)] Midrange of each decade, and at two (2) points of at least one (1) decade for logarithmic scale instruments; ~~[and]~~

3. At three (3) points between two (2) and 1000 millirems (90.02 and ten (10) millisieverts) per hour ~~[(f) Appropriate points]~~ for digital instruments; and

(d) So that an accuracy within plus or minus twenty (20) percent of the calibration source can be demonstrated at the points checked.

(3) Records of these calibrations shall be maintained for three (3) ~~[two (2)]~~ years after the calibration date for inspection by the cabinet.

(4) Instrumentation required by this section shall have a range so that two (2) millirems (0.02 millisieverts) ~~[milliroentgens]~~ per hour through one (1) rem (0.01 sievert) ~~[roentgen]~~ per hour may be measured.

~~[(5) A radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is working properly.]~~

Section 6. Leak Testing~~[-Repairing, Tagging, Opening, Modification,]~~ and Replacement of Sealed Sources. (1) The replacement of a sealed source fastened to or contained in a radiographic exposure device, and leak testing, repairing, ~~[tagging,]~~ opening, or ~~[other]~~ modification of a sealed source shall be performed ~~[only]~~ by persons specifically authorized by the cabinet, the U.S. Nuclear Regulatory Commission, or an Agreement State.

(2) A sealed source shall be tested for leakage;

(a) At intervals not to exceed six (6) months;

(b) Using a method approved by the cabinet, the U.S. Nuclear Regulatory Commission or an agreement state; and

(c)1. By taking a wipe sample from the nearest accessible point to the sealed source where contamination might accumulate.

2. The wipe sample shall be analyzed for radioactive contamination.

3. The analysis shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample; and

4. The analysis shall be performed by a person specifically authorized by the cabinet, the U.S. Nuclear Regulatory Commission or an agreement state to perform the analysis.

(3) Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six (6) months before the transfer, it shall not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but shall be tested before use or transferring to another person if the interval of storage exceeds six (6) months.

(4) A test conducted in accordance with subsections (1) and (2) of this section which reveals the presence of 0.005 microcuries (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with 902 KAR 100:021. A report shall be filed with the Manager, Radiation Health and Toxic Agents Branch, Department of Public Health, 275 East Main Street, Frankfort, Kentucky 40621, within five (5) days of a test with results that exceed the threshold in this subsection, describing the equipment involved, the test results, and the corrective action taken.

(5) An exposure device using depleted uranium (DU) shielding and an "S" tube configuration shall be tested for DU contamination at intervals not to exceed twelve (12) months.

(a) The analysis shall be:

1. Capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample; and

2. Performed by a person specifically authorized by the cabinet, the U.S. Nuclear Regulatory Commission or an agreement state to perform the analysis.

(b) If such testing reveals the presence of 0.005 microcuries (185 Bq) or more of removable DU contamination, the exposure device shall be removed from use until an evaluation of the wear on the S-tube has been made.

(c) If the evaluation reveals that the S-tube is worn through, the device shall not be used again.

(d) 1. DU shielded devices do not have to be tested for DU contamination while in storage and not in use.

2. Before using or transferring such a device however, the device shall be tested for DU contamination if the interval of storage exceeded twelve (12) months.

(6) A licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results shall be stated in units of microcuries (becquerels). The licensee shall retain a record for three (3) years after it is made or until the source in storage is removed. [and contamination pursuant to 902 KAR 100.060. Records of leak test results shall be maintained for inspection by the cabinet.]

~~(a) For six (6) months after the next required leak test is performed; or~~

~~(b) Until the sealed source is transferred or disposed.~~

~~(3) A sealed source not fastened to or contained in a radiographic exposure device shall have permanently attached to it a durable tag at least one (1) inch square bearing:~~

~~(a) The prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background; and~~

~~(b) At least the instructions: "Danger - Radioactive Material - Do Not Handle - Notify Civil Authorities if Found."~~

Section 7. Quarterly Inventory. (1) A licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation ~~[sealed sources]~~ and ~~[radiography exposure]~~ devices containing depleted uranium received or possessed in accordance with the license ~~[by him]~~.

(2) Records of the inventories shall be maintained for three (3) ~~[two (2)]~~ years from the date of the inventory for inspection by the cabinet. The records of inventories shall include:

(a) Radionuclide;

(b) Number of curies (becquerels) or mass (for DU) in a device;

(c) ~~[Quantities and kinds of radioactive material;~~

~~(b)]~~ Location of sealed sources and devices;

(d) ~~[(c)]~~ Date of the inventory;

(e) ~~[(d)]~~ Name of the individual making the inventory; and

(f) ~~[(e)]~~ Manufacturer, model number, and serial number of sealed sources and ~~[radiography exposure]~~ devices, as appropriate.

Section 8. Utilization Logs. A licensee or registrant shall maintain utilization ~~[current]~~ logs, which shall be kept available for inspection by the cabinet for three (3) ~~[two (2)]~~ years from the date of the recorded event, at the address specified in the license or on the registration, showing for a ~~[each]~~ source of radiation the following information:

(1) A description including ~~[(or)]~~ make, ~~[and]~~ model and serial number~~}]~~ of the exposure device, radiation machine, or transport ~~[each source of radiation]~~ or storage container in which a sealed source is located;

(2) Identity and signature of the radiographer to whom assigned;

(3) Site or plant where used and dates of use; ~~[and]~~

(4) Date a ~~[each]~~ source of radiation is removed from storage and returned to storage; and

(5) For permanent radiographic installations, the dates a radiation machine is energized.

Section 9. Inspection and Maintenance of Radiographic Exposure Devices, Radiation Machines, Transport and Storage Containers, Associated Equipment, Source Changes, and Survey Instruments ~~[and other Sources of Radiation]~~. (1) A licensee or registrant shall perform:

(a) Visual and operability checks on survey meters, radiographic exposure devices, radiation machines, transport and storage containers, associated equipment, and source changers before use on a day the equipment is to be used to ensure that the:

1. Equipment is in good working condition;

2. Source is adequately shielded; and

3. Required labeling is present; and

(b) An operability check of survey instruments using check sources or other appropriate means.

(2) If an equipment problem is found, the equipment shall be removed from service until repaired.

(3) A licensee or registrant shall have written procedures for:

(a) Inspection and routine maintenance of radiographic exposure devices, radiation machines, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed three (3) months or before the first use thereafter to ensure the proper functioning of components important to safety;

(b)1. Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials.

2. Inspection and maintenance program to assure that a Type B packages is shipped and maintained in accordance with the certificate of compliance or other approval.

(4) Replacement components shall meet design specifications;

(5) If an equipment problem is found, the equipment shall be removed from service until repaired;

(6)(a) Records of equipment problems found in daily checks and quarterly inspections of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments and of any maintenance performed in accordance with subsections (1) through (3) of this section shall be kept for three (3) years for inspection by the cabinet.

(b)The record shall include:

1. The date of check or inspection;

2. Name of the inspector;

3. Equipment involved;

4. Problems found; and

5. What repair and maintenance was done. ~~[ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day of use.]~~

~~(2) A licensee or registrant shall conduct a program for inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety prior to the first use, and subsequently at intervals not to exceed three (3) months. Appropriate parts shall be maintained as specified by the manufacturer.~~

~~(3) If an inspection reveals damage to components critical to radiation safety, the device shall be:~~

~~(a) Removed from service; and~~

~~(b) Labeled as defective until repairs have been made.~~

~~(4) Records of inspection and maintenance shall be kept for two (2) years for inspection by the cabinet.~~

Section 10. Permanent Radiographic Installations. (1) Permanent radiographic installations with an entrance used for personnel access to a [having] high radiation area shall have:

(a) Entrance controls of the type described in 902 KAR 100:019, Section 14(1)(b), (c), and (2) that reduces the radiation level upon entry into the area; or [shall also meet the following provisions]:

(b) [(1) The entrance used for personnel access to the high radiation area shall have] Both visible and audible warning signals to warn of the presence of radiation.

1. [(a)] The visible signal shall be activated by radiation if the source is exposed or the machine is energized.

2. [(b)] The audible signal shall be activated if an attempt is made to enter the installation while the source is exposed or the machine is energized.

(2)(a) The [control device or] alarm system shall be tested for proper operation with a radiation source at the beginning of each day before the installation is used for radiographic operations [of equipment use].

(b) The test shall include a check of the visible and audible signals.

(c) Entrance control devices that reduce the radiation level upon entry designated in subsection (1) of this section shall be tested monthly.

(3)(a) If an entrance [a control] device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired within seven (7) calendar days [before industrial radiographic operations are resumed].

(b) The facility may continue to be used during this seven (7) day period, if the licensee implements the continuous surveillance requirements of Section 20 of this administrative regulation and uses an alarming ratemeter.

(4) Records of [these] tests for entrance control and audible and visual alarms shall be maintained for inspection by the cabinet for three (3) [two (2)] years from the date of the test.

Section 11. Labeling, Storage and Transportation. (1) A licensee shall 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 conventional colors (magenta, purple or black on a yellow background, having a minimum diameter of twenty-five (25) millimeters), and the wording

CAUTION*

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES (or "NAME OF COMPANY@)

*or "DANGER".

(2) The licensee shall not transport radioactive material unless the material is packaged, and the package is labeled, marked and accompanied with appropriate shipping papers in accordance with 10 CFR Part 71.

(3) Locked radiographic exposure devices, radiation machines, and storage containers shall be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner, which minimize danger from explosion or fire.

(4) 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 of the radioactive material from the vehicle.

Section 12. Conducting Industrial Radiographic Operations. (1)(a) If radiography is performed at a location other than a permanent radiographic installation, the radiographer shall be accompanied by at least one (1) other qualified radiographer or an individual who has at a minimum met the requirements of Section 14 of this administrative regulation. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry.

(b) Radiography shall not be performed if only one (1) qualified individual is present.

(2) Radiographic operations conducted at locations of use authorized on the license shall be conducted in a permanent radiographic installation, unless specifically authorized by the cabinet.

(3) Licensees shall have one (1) year from the effective date of this regulation, to meet the requirements for having two (2) qualified individuals present at locations other than a permanent radiographic installation as specified in subsection (1) of this section.

Section 13. Radiation Safety Officer for Industrial Radiography. The radiation safety officer (RSO) shall ensure that radiation safety is being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee@s program.

(1) The minimum qualifications, training, and experience for RSOs for industrial radiography is as follows:

(a) Completion of the training and testing requirements of Section 14 of this administrative regulation;

(b) 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

(c) Formal training in the establishment and maintenance of a radiation protection program.

(2) The cabinet may consider alternatives if the RSO has appropriate training or 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.

(3) The specific duties and authorities of the RSO shall include:

(a) Establishing and overseeing operating, emergency and ALARA procedures as required by 902 KAR 100:019, and reviewing them regularly to ensure that the procedures in use conform to current 902 KAR 100:019 procedures, conform to other requirements in 902 KAR Chapter 100 and to the license conditions.

(b) Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection is taught;

(c) Ensuring that:

1. Required radiation surveys and leak tests are performed and documented in accordance with the regulations, including corrective measures if levels of radiation exceed established limits;

2. Personnel monitoring devices are calibrated and used properly by occupationally-exposed personnel;

3. Records are kept of the monitoring results;

4. Timely notifications are made as required by 902 KAR 100:019, Section 40; and

5. Operations are conducted safely and assume control for instituting corrective actions including stopping of operations, if necessary.

(4) Licensees and registrants shall have two (2) years from the effective date of this administrative regulation, to meet the requirements of subsections (1) and (2) of this section.

Section 14. Training [~~and Testing of Radiographers and Radiographers' Assistants~~]. (1) A licensee or registrant shall not permit an individual to act as a radiographer as defined in 902 KAR 100:010 until the individual has received training in the subjects identified in subsection (8) of this section, in addition to a minimum of two (2) months of on-the-job training, and is certified through a

radiographer certification program by a certifying entity in accordance with the criteria specified in Section 1 of this administrative regulation; or

(2) A licensee or registrant may, until two (2) years from the effective date of this administrative regulation, allow an individual who has not met the requirements of this section, to act as a radiographer after the individual has received training in the subjects identified in subsection (8) of this section and demonstrated an understanding of these subjects by successful completion of a written examination that was previously submitted to and approved by the cabinet.

(3) A licensee or registrant shall not permit an individual to act as a radiographer until the individual has:

(a) ~~[Been instructed in the subjects outlined in Section 19 of this administrative regulation;~~

~~(b)] Received copies of and [;] instructions in[, and demonstrated an understanding of] the following:~~

1. Provisions contained in this administrative regulation;

2. Other applicable provisions of 902 KAR 100:019, 902 KAR 100:040, 902 KAR [100:035;] 100:070, and 902 KAR 100:165;

3. Conditions of the license or registration certificate issued by the cabinet; and

4. The licensee's or registrant's approved operating and emergency procedures;

(b) Demonstrated understanding of the licensee's license and operating and emergency procedures by successful completion of a written or oral examination covering this material;

(c) Received training in the [Demonstrated competence to] use of the licensee's [the] sources of radiation, or the registrant's radiation machine, radiation exposure devices, in the daily inspection of devices and associated equipment [related handling tools], and in the use of radiation survey instruments [which shall be employed at his assignment]; and

(d) [Successfully] Demonstrated an understanding of the use of radiographic exposure devices, sources, survey instruments and associated equipment described in paragraphs (a) and (c) of this subsection by successful completion of a practical examination covering this material.

(4) [instructions in this subsection by successful completion of a:

~~1. Written test; and~~

~~2. Field examination on the subjects covered.~~

~~(2)] A licensee or registrant shall not permit an individual to act as a radiographer's assistant as defined in 902 KAR 100:010 until the individual has:~~

(a) Received copies of, and instructions in the following:

1. Provisions contained in this administrative regulation;

2. Applicable requirements of 902 KAR 100:019, 902 KAR 100:040, 902 KAR 100:070, and 902 KAR 100:165;

3. Conditions of the license or registration certificate issued by the cabinet; and

4. The licensee's or registrant's operating and emergency procedures; [~~the licensee's or registrant's approved operating and emergency procedures;~~]

(b) Demonstrated competence to use, under the personal supervision of the radiographer, the sources of radiation, radiographic exposure devices, radiation machines, associated equipment [~~related handling tools~~], and radiation survey instruments that the assistant uses [~~which may be employed in his assignment~~]; and

(c) Demonstrated understanding of the instructions provided in paragraph (a) of this subsection by successfully completing a written test on the subjects covered and has demonstrated competence in the use of hardware described in paragraph (b) of this subsection by successful completion of a practical examination on the use of such hardware.

(5) The licensee or registrant shall provide annual refresher safety training for a radiographer and radiographer@s assistant at intervals not to exceed twelve (12) months.

(6)(a) Except, in those operations where a single individual shall serve as both radiographer and RSO and shall perform all radiography operations, the RSO or designee shall conduct an inspection program of the job performance of a radiographer and radiographer@s assistant to ensure that the cabinet@s regulations, license requirements, and the applicant@s operating and emergency procedures are followed;

(b) The inspection program shall Include observation of the performance of the radiographer and radiographer@s assistant during an actual industrial radiographic operation, at intervals not to exceed six (6) months;

(c) If a radiographer or a radiographer@s assistant has not participated in an industrial radiographic operation for more than six (6) months since the last inspection, the radiographer shall demonstrate knowledge of the training requirements of subsection (3)(c) of this section and the radiographer@s assistant shall redemonstrate knowledge of the training requirements of subsection (4)(b) of this section by a practical examination before these individuals can next participate in a radiographic operation; and

(d) The cabinet shall consider alternatives in those situations where the individual serves as both radiographer and RSO.

(7) [~~Successfully demonstrated an understanding of the instructions in this subsection by:-~~

~~1. Written or oral test; and~~

~~2. Field examination on the subjects covered.~~

~~(3) Records of the above training, specified in subsection (3) of this section, [including copies of written tests and dates of oral tests and field examinations,] shall be maintained by a licensee or registrant for inspection by the cabinet for three (3) years after the record is made [following termination of employment].~~

(a) Records shall include:

1. Radiographer certification documents;

2. Verification of certification status;

3. Copies or written tests;

4. Dates of oral tests and practical examinations;

5. Names of individuals conducting and receiving the oral and practical examinations; and

6. Documentation of annual refresher safety training and semi-annual inspections of job performance for a radiographer and a radiographer@s assistant which shall include;

a. Topics discussed during the refresher safety training;

b. Dates the annual refresher safety training was conducted; and

c. Names of the instructors and attendees.

(b) For inspections of job performance, the records shall also include a list showing the items checked and all noncompliances observed by the RSO.

(8) The licensee or registrant shall include the following subjects required in subsection (2) of this section;

(a) Fundamentals of radiation safety including;

1. Characteristics of gamma radiation;

2. Units of radiation dose and quantity of radioactivity;

3. Hazards of exposure to radiation;

4. Levels of radiation from radioactive material; and

5. Methods of controlling radiation dose by time, distance, and shielding;

(b) Radiation detection instruments including:

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

2. Survey techniques; and

3. Use of personnel monitoring equipment;

(c) 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 (pigtailed);

2. Storage, control and disposal of radioactive material;

3. Inspection and maintenance of equipment; and

4. Operation and control of radiation machines;

(d) The requirements of pertinent cabinet administrative regulations; and

(e) Case histories of accidents in radiography.

(9) Licensees and registrants shall have one (1) year from the effective date of this administrative regulation, to comply with the additional training requirements specified in subsections (3)(a) and (4)(a) of this section.

(10) Licensees and registrants shall have one (1) year from the effective date of this regulation, to comply with the certification requirements specified in subsection (1) of this section. Records of radiographer certification maintained in accordance with subsection (7) of this section shall provide appropriate affirmation of certification requirements specified in subsection (1) of this section.

Section 15. ~~[12:]~~ Operating and Emergency Procedures. (1) A licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) ~~[(1)]~~ The handling and use of sources of radiation to be employed so an ~~[that no]~~ individual is not likely to be exposed to radiation doses in excess of the limits established in 902 KAR 100:019, Section 3;

(b) ~~[(2)]~~ Methods and occasions for conducting radiation surveys;

(c) ~~[(3)]~~ Methods for controlling access to radiographic areas;

(d) [(4)] Methods and occasions for locking and securing sources of radiation, radiographic exposure devices, and transport and storage containers;

(e) [(5)] Personnel monitoring and the use of personnel monitoring equipment, including steps that shall be taken immediately by radiography personnel if a pocket dosimeter is found to be off-scale or an alarm ratemeter alarms unexpectedly;

(f) [(6)] Transportation of sources of radiation to field locations, including:

1. [(a)] Packing of radiographic exposure devices and storage containers in the [sources of radiation in] vehicles;

2. Placarding [(b) Posting] of vehicles if needed; and

3. [(c)] Control of sources of radiation during transportation;

(g) [(7)] Minimizing exposure of individuals if an accident occurs;

(h) [(8)] The procedure for notifying proper personnel if an accident occurs;

(i) [(9)] Maintenance of records; and

(j) [(10)] The inspection, [and] maintenance, and operability checks of radiographic exposure devices, radiation machines [source changers], storage containers, survey instruments, and transport containers [and other sources of radiation].

(2) The licensee or registrant shall maintain copies of current operating and emergency procedures until the cabinet terminates the license. Superseded material shall be retained for three (3) years after the change is made.

Section 16. ~~[(13)]~~ Personnel Monitoring ~~[Control]~~. (1) A licensee or registrant shall not permit an individual to act as a radiographer or radiographer's assistant unless, at all times during radiographic operations, the individual wears, on the trunk of the body, a direct reading pocket dosimeter; an operating alarm ratemeter; and a film badge or a thermoluminescent dosimeter (TLD).

(a) The wearing of an alarm ratemeter shall not be required for permanent radiography facilities in which other an appropriate alarming or a warning device is ~~[devices are]~~ in routine use or during radiographic operations using radiation machines.

(b) Pocket dosimeters shall have a range from zero to at least 200 milliroentgens (two (2) millisieverts) and be recharged daily or at the start of a shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

(c) A film badge or thermoluminescent dosimeter shall be assigned to, and worn by, only one (1) individual.

(d) Film badges shall be replaced at periods not to exceed one (1) month and TLDs shall be replaced at periods not to exceed three (3) months.

(e) After replacement, a film badge or TLD shall be processed as soon as possible.

(2) Direct reading [~~Pocket~~] dosimeters, such as pocket dosimeters or electronic personal dosimeters, shall be read and exposures recorded at the beginning and end of a shift [~~least once daily~~].

(a) If an individual's [~~a~~] pocket dosimeter is found to be off scale, or if his or her electronic personal dosimeter reads greater than 200 millirems (two (2) millisieverts), and the possibility of radiation exposure cannot be ruled out as the cause [~~discharged beyond its range~~]:

1. The film badge or thermoluminescent dosimeter shall be sent for processing within twenty-four (24) hours [~~immediately processed~~];

2. Radiographic operations by the individual shall cease; and

3. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made. This determination shall be made by the RSO or the RSO@s designee. The results of this determination shall be included in the records maintained in accordance with paragraph (b) of this subsection and subsection (4)(b) of this section.

(b) A licensee or registrant shall maintain the following exposure records:

1. Direct reading dosimeter readings and yearly operability checks for three (3) years after the record is made;

2. Reports received from the film badge or TLD processor until the cabinet terminates the license; and

3. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged film badges or TLDs, until the cabinet terminates the license.

~~[(b) Reports received from the film badge or thermoluminescent dosimeter processor and records of daily pocket dosimeter readings shall be kept for inspection until the cabinet authorizes their disposal.]~~

(3) If a film badge or thermoluminescent dosimeter is lost or damaged, the worker shall cease work immediately until:

(a) A replacement film badge or thermoluminescent dosimeter is provided; and

(b) The exposure is calculated for the time period from issuance to loss or damage of the film badge or thermoluminescent dosimeter. The results of the calculated exposure and the time period for which the film badge or TLD was lost or damaged shall be included in the records maintained in accordance with subsection (2) of this section.

(4)(a) Pocket dosimeters, or electronic personal dosimeters, shall be checked for correct response to radiation at periods not to exceed twelve (12) months [~~one (1) year~~].

(b) [~~(a)~~] Acceptable dosimeters shall read within plus or minus twenty (20) [~~thirty (30)~~] percent of the true radiation exposure.

~~[(b) Records of this check shall be maintained for inspection by the cabinet for two (2) years from the date of the check.]~~

(5)(a) An alarm ratemeter shall:

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

2. Be set to give an alarm signal at a preset dose rate of 500 mR/hr (5mSv/hr);

3. Require special means to change the preset alarm functions; [~~and~~]

4. Be calibrated at periods not to exceed twelve (12) months [~~one (1) year~~] for correct response to radiation; and [~~+~~]

5. [~~(b) Acceptable ratemeters shall~~] Alarm within plus or minus twenty (20) percent of the true radiation dose rate.

(b) Records of alarm ratemeter calibrations shall be maintained for three (3) years after the record is made.

Section 17. [~~14.~~] Documents Required at Field Stations and Temporary Job Sites. A licensee or registrant [~~conducting industrial radiography at a temporary site~~] shall have the following records available [~~at that site~~] for inspection by the cabinet at applicable field stations and all temporary job sites:

(1) A copy of the operating and emergency procedures;

(2) A current copy of the radioactive material license or registration certificate;

(3) A copy of 902 KAR 100:019, 902 KAR 100:100, and 902 KAR 100:165;

(4) Latest survey records required by Section 20 of this administrative regulation [~~and 902 KAR 100:019, Section 31, for the period of operation at the site~~];

(5) Records of direct reading dosimeters, such as pocket dosimeters or electronic personal dosimeters readings as required by Section 16 of this administrative regulation;

(6) Evidence of [~~Daily pocket dosimeter records for the period of operation at the site; and~~

~~(6)~~ The latest instrument calibration of the radiation survey instrumentation in use at the site, as required by Section 5 of this administrative regulation;

(7) Utilization records for all radiographic exposure devices dispatched from that location as required by Section 8 of this administrative regulation;

(8) Records of equipment problems identified in daily checks of equipment required by Section 9 of this administrative regulation;

(9) Records of alarm system and entrance control checks required by Section 10 of this administrative regulation, if applicable;

(10) Evidence of the latest calibrations of alarm ratemeters and operability checks of pocket dosimeters and electronic personal dosimeters as required by Section 16 of this administrative regulation;

(11) The shipping papers for the transportation of radioactive materials required by 902 KAR 100:070; and

(12) If operating in accordance with reciprocity pursuant to 902 KAR 100:065, a copy of the Agreement State or U.S. Nuclear Regulatory Commission license authorizing the use of radioactive materials. [and leak test record for specific devices in use at the site. Acceptable records include tags or labels affixed to the device or survey meter.]

Section 18. ~~[15:]~~ Specific Provisions for Radiographic Personnel Performing Industrial Radiography.

(1) At a job site, the following shall be supplied by a licensee or registrant:

(a) At least one (1) operable, calibrated survey instrument for every exposure device or radiation machine in use ;

(b) A current whole body personnel monitor (TLD or film badge) for an ~~[each]~~ individual performing radiographic operations;

(c) An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens for an ~~[each]~~ worker performing radiographic operations;

(d) Appropriate barrier ropes and signs; and

(e) An operable, calibrated, alarming ~~[alarm]~~ ratemeter for every person performing radiographic operations using a radiographic exposure device ~~[each individual]~~.

(2) A radiographer at a job site shall have on their person a valid certificate ID card issued by a certifying entity.

(3) Industrial radiographic operations shall not be performed if the items in subsections (1) and (2) [subsection (1)] of this section are not available at the job site or are inoperable.

(4) [(3)] During an inspection by the cabinet, the cabinet [inspector] may terminate an operation if items in subsections (1) and (2) [subsection (1)] of this section are not available or [and] operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

Section 19. Surveillance. [16. Security.] During a [each] radiographic operation, a radiographer or the other individual present, as required by Section 12 of this administrative regulation [radiographer's assistant] shall maintain direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, except at permanent radiographic installations where [if the high radiation area is]:

(1) Entryways are locked; and

(2) The requirements of Section 10 of this administrative regulation are met. [Equipped with a control device or an alarm system as described in 902 KAR 100:019, Section 14(1) or (2); or

(2) Locked to protect against unauthorized or accidental entry.]

Section 20. [17.] Posting. (1) An area [Except as otherwise exempt in 902 KAR 100:019, Section 25, areas] in which radiography is being performed shall be conspicuously posted as required in 902 KAR 100:019, Section 24(1) and (2).

(2) Exceptions listed in 902 KAR 100:019 do not apply to industrial radiographic operations.

Section 21. [18.] Special Provisions and Exemptions for Cabinet X-ray Systems. (1) Uses of certified and certifiable cabinet x-ray systems shall be exempt from the requirements of this administrative regulation except for the following:

(a) For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

1. A registrant shall not permit an individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit.

2. A test for proper operation of interlocks shall be conducted and recorded at intervals not to exceed six (6) months.

3. A registrant shall perform an evaluation of the radiation dose limits to determine compliance with 902 KAR 100:019, Section 10, and 21 CFR 1020.40, Cabinet X-ray Systems, 39 Federal Register 12986, April 10, 1974, at intervals not to exceed one (1) year.

4. Records shall be maintained demonstrating compliance with subsections (1)(a)1 and 2 until disposal is authorized by the cabinet.

5. Records of the evaluation required by subparagraph 3 of this paragraph shall be maintained for two (2) years after the evaluation is performed.

(b)1. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-ray Systems, 39 Federal Register 12986, April 10, 1974.

2. Modifications shall not be made to the system unless prior cabinet approval has been granted.

(2) Industrial uses of hand-held light intensified imaging devices shall be exempt from the requirements of this administrative regulation if the dose rate eighteen (18) inches from the source of radiation to any individual does not exceed two (2) millirem per hour. Devices which exceed this limit shall meet the applicable requirements of this administrative regulation and the licensing or registration requirements of 902 KAR 100:040 and 902 KAR 100:110, as applicable. [Systems for cabinet radiography designed to allow admittance of individuals shall-

(a) Comply with applicable provisions of this administrative regulation and 902 KAR 100:019, Section 10; and

(b) Be evaluated at intervals not to exceed one (1) year to assure compliance with the applicable provisions as specified in Section 15(1)(a) of this administrative regulation. Records of these evaluations shall be maintained for inspection by the cabinet for a period of two (2) years after the evaluation.

(2) If a system is a certified cabinet x-ray system, it shall comply with applicable provisions of this administrative regulation and 21 CFR 1020.40.

(3) Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet shall be exempt from the provisions of this administrative regulation, except operating personnel shall be provided with a film badge or a thermoluminescent dosimeter.

(a) A report of the results of the film badge or thermoluminescent dosimeter shall be maintained for inspection by the cabinet.

(b) A registrant shall not permit an individual to operate a cabinet x-ray system until the individual has-

1. Received a copy of, and instruction in, the operating procedures for the unit; and

2. Demonstrated competence in its use.

(c) Records which demonstrate compliance with this subsection shall be maintained for inspection by the cabinet until disposition is authorized by the cabinet.

~~(d) Tests for proper operation of high radiation area control devices or alarm systems, if applicable, shall be conducted, recorded, and maintained as described in Section 10 of this administrative regulation.~~

~~(e) A registrant shall perform an evaluation, at intervals not to exceed one (1) year, to determine compliance with 902 KAR 100:019, Section 10.~~

~~1. If a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed one (1) year to determine compliance with 21 CFR 1020.40.~~

~~2. Records of these evaluations shall be maintained for inspection by the cabinet for a period of two (2) years after the evaluation.~~

~~(4) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, unless prior approval has been granted by the cabinet under 902 KAR 100:015, Section 7.~~

~~Section 19. Minimum Training Requirements for Industrial Radiographers. Industrial radiographers shall receive minimum training in the following areas:~~

~~(1) Fundamentals of radiation safety;~~

~~(a) Characteristics of radiation;~~

~~(b) Units of radiation dose (mrem) and quantity of radioactivity (curie);~~

~~(c) Significance of radiation dose:~~

~~1. Radiation protection standards;~~

~~2. Biological effects of radiation dose;~~

~~3. Case histories of radiography accidents;~~

~~(d) Levels of radiation from sources of radiation;~~

~~(e) Methods of controlling radiation dose:~~

~~1. Working time;~~

~~2. Working distance;~~

~~3. Shielding;~~

~~(2) Radiation detection instrumentation to be used:~~

~~(a) Use of radiation survey instruments;~~

~~1. Operation;~~

~~2. Calibration;~~

~~3. Limitations;~~

~~(b) Survey techniques;~~

~~(c) Use of personnel monitoring equipment:~~

~~1. Film badges;~~

~~2. Pocket dosimeters;~~

~~3. Thermoluminescent dosimeters;~~

~~4. Alarm ratemeters;~~

~~(3) Radiographic equipment to be used:~~

~~(a) Remote handling equipment;~~

~~(b) Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtailed);~~

~~(c) Storage and transport containers and source changers;~~

~~(d) Operation and control of x-ray equipment;~~

~~(e) Collimators;~~

~~(4) Provisions of 10 CFR 34 and 902 KAR Chapter 100; and~~

~~(5) The licensee's or registrant's written operating and emergency procedures.~~

Section 22. [20.] Radiation Surveys and Survey Records. (1) A radiographic operation shall not be conducted unless calibrated and operable radiation survey instrumentation, as described in Section 5 of this administrative regulation, is available and used at a [each] location of radiographic operations.

(2) A survey with a radiation survey instrument shall be made after a [each] radiographic exposure, of the radiographic exposure device and the guide tube, if approaching the device or guide tube to determine that the sealed source has been returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment.

~~[(a) The entire circumference of the radiographic exposure device shall be surveyed.]~~

~~(b) If the radiographic exposure device has a source guide tube, the survey shall also include the guide tube.]~~

(3) A survey shall be conducted of the radiographic exposure device with a calibrated radiation survey instrument if the source is exchanged and if a radiographic exposure device is [A survey shall be made of the storage area if a radiographic exposure device is being] placed in a storage area, to ensure that the source is in its shielded position .

~~(4) [A physical radiation survey required by Section 3 of this administrative regulation shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container, or source changer in a storage area.]~~

~~(5)] A physical radiation survey shall be made after a radiographic exposure using radiographic machines to determine that the machine is "off".~~

(5) [(6)] Records shall be kept of the exposure device survey conducted before the device is placed in storage as specified in subsection (3) of this section, if that survey is the last one performed in the workday. The records shall be [surveys and] maintained for inspection by the cabinet for three (3) [two (2)] years after it is made. [completion of the survey. If the survey was used to determine an individual's exposure, the records of the survey shall be maintained until the cabinet authorizes their disposition.]

Section 21. Required Administrative Procedures for Industrial Radiography Program. (1) Licensees and registrants shall have an adequate program for training radiographers and radiographers' assistants, and submit to the cabinet a schedule or description of the program which specifies the:

~~(a) Initial training;~~

~~(b) Periodic training;~~

~~(c) On-the-job training;~~

~~(d) Means to be used by the licensee or registrant to determine the radiographer's knowledge and understanding of and ability to comply with 902 KAR Chapter 100, licensing requirements, and the licensee's or registrant's operating and emergency procedures; and~~

~~(e) Means to be used by the licensee or registrant to determine the radiographer's assistant's knowledge and understanding of, and ability to comply with, the licensee's or registrant's operating and emergency procedures.~~

~~(2) A licensee or registrant shall establish and submit to the cabinet satisfactory written operating and emergency procedures.~~

~~(3) A licensee or registrant shall submit to the cabinet a description of its inspection program adequate to ensure that license provisions, administrative regulations, and the licensee's or registrant's operating and emergency procedures shall be followed by radiographers and radiographers' assistants. The inspection program shall:~~

~~(a) Include observation of the performance of each radiographer and radiographer's assistant during an actual radiographic operation at intervals not to exceed three (3) months;~~

~~(b) Provide that, if a radiographer or a radiographer's assistant has not participated in a radiographic operation for more than three (3) months since the last inspection, the individual's performance shall be observed and recorded the next time the individual participates in a radiographic operation; and~~

~~(c) Include the retention of inspection records on the performance of radiographers or radiographers' assistants for two (2) years.~~

~~(4) A licensee or registrant shall submit to the cabinet a description of his overall organizational structure pertaining to the radiography program, including:~~

~~(a) Specified delegations of authority; and~~

~~(b) Responsibility for operation of the program.~~

~~(5) A licensee who desires to conduct his own leak tests shall establish adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination, and shall submit to the cabinet a description of the procedures including:~~

~~(a) Instrumentation to be used;~~

~~(b) Method of performing tests (for example, points on equipment to be smeared and method of taking a smear); and~~

~~(c) Pertinent experience of the person who will perform the test.]~~

Section 23. [22.] Supervision of Radiographer's Assistant. If a radiographer's assistant uses radiographic exposure devices, associated equipment, sealed sources, [~~or related source handling tools;~~] or conducts radiation surveys required by Section 22 [20] of this administrative regulation to determine that the sealed source has returned to the shielded position after an exposure or the radiation machine is off, the radiographer's assistant shall be under the personal supervision of a radiographer. The personal supervision shall include the radiographer:

(1) Being physically present at the site where a source [~~sources~~] of radiation and associated equipment is [~~are~~] being used;

(2) Watching the performance of the operations, by direct observation, referred to in this section by the radiographer's assistant; and

(3) Being in a proximity that immediate assistance shall ~~[may]~~ be given if required.

Section 24. ~~[23:]~~ Reporting Requirements. (1) In addition to the reporting requirements specified in 902 KAR 100:040, Section 18, and in accordance with other sections of this administrative regulation, a licensee or registrant shall provide a written report to the Cabinet for Health Services ~~[-Human Resources]~~, Radiation Health and Toxic Agents ~~[Control]~~ Branch within thirty (30) days of the occurrence of the following incidents involving radiographic equipment:

- (a) Unintentional disconnection of the source assembly from the control cable;
- (b) Inability to retract the source assembly to its fully shielded position and secure it in this position;
~~[or]~~
- (c) Failure of a component, critical to safe operation of the device, to properly perform its intended function; or

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

(2) The licensee or registrant shall include the following information in a report submitted in accordance with ~~[under]~~ subsection (1) of this section:

- (a) A description of the equipment problem;
- (b) Cause of an incident, if known;
- (c) Manufacturer and model number of equipment involved in the incident;
- (d) Place, time and date of the incident;
- (e) Actions taken to establish normal operations;
- (f) Corrective actions taken or planned to prevent recurrence; and
- (g) Qualifications of personnel involved in the incident.

(3) Reports of overexposures submitted under 902 KAR 100:019, Section 40, involving failure of safety components of radiography equipment shall ~~[also]~~ include the information specified in subsection (2) of this section.

(4) A licensee shall notify the cabinet if conducting radiographic operations or storing radioactive material at a location not listed on the license for a period in excess of 180 days in a calendar year.

Section 25. Incorporation [~~24. Material Incorporated~~] by Reference. (1) The American National Standard Institute (ANSI) N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography", published in NBS Handbook 136, issued January 1981 [~~N43.9-1991, "Gamma Radiography-Specifications for Design and Testing of Apparatus" (1991), is incorporated by reference~~].

(2) This material [~~A copy of the "Gamma Radiography-Specifications for Design and Testing of Apparatus"~~] may be inspected, copied, [viewed] or obtained, subject to applicable copyright law, at the Department for Public Health, Office of the Commissioner [of Health Services], 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. until 4:30 p.m. [~~Monday through Friday~~].

RICE C. LEACH, M.D., Commissioner

JIMMY D. HELTON, Secretary

APPROVED BY AGENCY: November 14, 2000

FILED WITH LRC: November 15, 2000 at 10 a.m.

PUBLIC HEARING: A public hearing on this regulation will be held December 21, 2000 at 9 a.m. in the Cabinet for Health Services Auditorium, 1st floor, Department for Health Services Building, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending shall notify this agency in writing by December 14, 2000. If no notice of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. Send written notice of intent to attend the public hearing or written comments to: Jill Lewis, Cabinet Regulation Coordinator, Cabinet for Health Services, Office of Counsel, 275 East Main Street - 4W-C, Frankfort, Kentucky 40621, Phone: (502) 564-7905, Fax: (502) 564-7573.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: John Volpe, Ph.D., 564-3700

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation provides safety requirements for the use of radioactive materials in industrial radiographic operations and for the licensees and registrants who perform industrial radiography.

(b) The necessity of this administrative regulation: This administrative regulation provides equivalent requirements for industrial radiographers to those of the U.S. Nuclear Regulatory Commission.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 211.844 requires the cabinet to provide regulations for the licensing and registration of sources of radiation.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation provides the requirements for obtaining a license or registration for performing industrial radiography.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment will require radiographers to be certified by a third party and requires a 2 person crew.

(b) The necessity of the amendment to this administrative regulation: This administrative regulation provides equivalent requirements for industrial radiographers to those of the U.S. Nuclear Regulatory Commission.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 211.844 requires the cabinet to provide regulations for the licensing and registration of sources of radiation.

(d) How the amendment will assist in the effective administration of the statutes: This regulation provides the requirements for obtaining a license or registration for performing industrial radiography.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: 11 Kentucky radioactive material licensees will be impacted by the amendment of industrial radiography. An additional 10-15 out-of-state radioactive material licensees who annually request reciprocity will also be impacted by these amendments.

(4) Provide an assessment of how the above group or groups will be impacted by either the implementation of this administrative regulation, if new, or by the change if it is an amendment: Licensees and registrants will be required to be certified through a third party and requires a two (2) person crew.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: None

(b) On a continuing basis: None

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Fees from the licensing of radioactive material users.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary to implement this amendment to the regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish any fees nor does it directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals or entities regulated by it. Disparate treatment of any person or entity subject to this administrative regulation could raise questions of arbitrary action on the part of the agency. The "equal protection" and "due process" clauses of the Fourteenth Amendment of the U.S. Constitution may be implicated as well as Sections 2 and 3 of the Kentucky Constitution.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. The Atomic Energy Act of 1954, as amended, and 10 CFR 34 and 10 CFR 71 as promulgated by the U.S. Nuclear Regulatory Commission and 21 CFR 1020.40 as promulgated by the U.S. Food and Drug Administration.

2. State compliance standards. Administrative regulation provides industrial radiographer licensees with requirements for conducting industrial radiography in Kentucky.

3. Minimum or uniform standards contained in the federal mandate. This amendment will bring about compatibility with U.S. Nuclear Regulatory Commission's requirements.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Administrative regulation provides equivalent requirements for industrial radiographer licensees to those of the U.S. Nuclear Regulatory Commission.