120.594: continued

(2) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

(a) The licensee's name;

(b) The date and time of the unauthorized departure;

(c) The projected date and time when release would have occurred;

(d) The general location address of the patient's or human research subject's home or anticipated destination following departure;

(e) The radionuclide, chemical and physical form and calculated activity at time of release;

(f) The apparent reason(s) for the departure prior to authorized release; and,

(g) A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(E) Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.

(1) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 105 CMR 120.221 as a result of the deceased's body.

(2) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 105 CMR 120.594(E)(1) has died. The written report must include:

(a) The licensee's name;

(b) The date of death;

(c) The radionuclide, chemical and physical form and calculated activity at time of death; and

(d) The names (or titles) and address(es) of known individuals who might have received exposures exceeding five mSv (500 mrem).

120.600: RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

120.601: Purpose and Scope

105 CMR 120.600 provides special requirements for analytical x-ray equipment. The requirements of 105 CMR 120.600 are in addition to, and not in substitution for, applicable requirements in other Sections of 105 CMR 120.000.

120.602: Definitions

As used in 105 CMR 120.600, the following definitions apply:

Analytical X-ray Equipment means equipment used for x-ray diffraction or fluorescence analysis.

Analytical X-ray System means a group of components utilizing x or gamma rays to determine the elemental composition or to examine the microstructure of materials.

Fail-safe Characteristics mean a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

Local Components mean part of an analytical x-ray system and include areas that are struck by x-rays such as radiation source housings, 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.

Normal Operating Procedures mean step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant (or licensee), and data recording procedures, which are related to radiation safety.

120.602: continued

Open-beam Configuration means an analytical x-ray system in which an individual could accidently place some part of his body in the primary beam path during normal operation.

Primary Beam means radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

120.603: Equipment Requirements

(A) Safety Device. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant [or licensee] may apply to the Agency for an exemption from the requirement of a safety device. Such application shall include:

(1) A description of the various safety devices that have been evaluated;

(2) The reason each of these devices cannot be used; and,

(3) A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(B) Warning Devices.

(1) Open-beam configurations shall be provided with a readily discernible indication of:

(a) X-ray tube "on-off" status located near the radiation source housing, if the primary beam is controlled in this manner; and/or,

(b) Shutter "open-closed" status located near each port on the radiation source housing, if the primary beam is controlled in this manner.

(2) Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of 105 CMR 120.600, warning devices shall have fail-safe characteristics.

(C) Ports. Unused ports on radiation source housings shall be secured in the closed position in a manner which will prevent casual opening.

(D) Labeling. All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

(1) "CAUTION - HIGH INTENSITY X-RAY BEAM", or words having a similar intent, on the x-ray source housing; and,

(2) "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED", or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or,

(3) "CAUTION - RADIOACTIVE MATERIAL", or words having a similar intent, on the source housing in accordance with 105 CMR 120.237 and 120.238 if the radiation source is a radionuclide.

(E) Shutters. On open-beam configurations installed after the effective date of 105 CMR 120.600, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

(F) Warning Lights.

(1) An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

(a) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or,

(b) In the case of a radioactive source, near any switch that opens a housing shutter and shall be illuminated only when the shutter is open.

(2) On equipment installed after the effective date of 105 CMR 120.600, warning lights shall have fail-safe characteristics.

(G) Radiation Source Housing. Each radiation source housing shall be subject to the following requirements:

120.603: continued

(1) Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.
(2) Each radioactive source housing or port cover or each x-ray tube housing shall be so constructed that, with all shutters closed, the radiation measured at a distance of five centimeters from its surface is not capable of producing a dose in excess of 2.5 millirems (0.025 mSv) in one hour. For systems utilizing x-ray tubes, this limit shall be met at any specified tube rating.

(H) Generator Cabinet. Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem (2.5 μSv) in one hour.

120.604: Area Requirements

(A) Radiation Levels. The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist 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 given in 105 CMR 120.221. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

(B) Surveys.
(1) Radiation surveys, as required by 105 CMR 120.222, of all analytical x-ray systems sufficient to show compliance with 105 CMR 120.604(A) shall be performed:
(a) Upon installation of the equipment, and at least once every 12 months thereafter;
(b) Following any change in the initial arrangement, number, or type of local components in the system;
(c) Following any maintenance requiring the disassembly or removal of a local component in the system;
(d) During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;
(e) Any time a visual inspection of the local components in the system reveals an abnormal condition; and,
(f) Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 105 CMR 120.211.
(2) Radiation survey measurements shall not be required if a registrant [or licensee] can demonstrate compliance with 105 CMR 120.604(A) to the satisfaction of the Agency.

(C) Posting. Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent in accordance with 105 CMR 120.238.

120.605: Operating Requirements

(A) Procedures. Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such individual has obtained written approval of the radiation safety officer.

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

(C) Repair or Modification of X-ray Tube Systems. Except as specified in 105 CMR 120.605(B), 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 switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

120.605: continued

(D) Radioactive Source Replacement, Testing, or Repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

120.606: Personnel Requirements

(A) Instruction. No individual shall be permitted to operate or maintain analytical x-ray equipment unless such individual has received instruction in and demonstrated competence as to:

(1) Identification of radiation hazards associated with the use of the equipment;

(2) 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;

(3) Proper operating procedures for the equipment;

(4) Recognition of symptoms of an acute localized exposure; and,

(5) Proper procedures for reporting an actual or suspected exposure.

(B) Personnel Monitoring.

(1) Finger or wrist dosimetric devices shall be provided to and shall be used by:

(a) Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and,

(b) Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

(2) Reported dose values shall not be used for the purpose of determining compliance with 105 CMR 120.200 unless evaluated by a qualified expert.

120.620: LICENSING AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

120.621: Purpose and Scope

(A) 105 CMR 120.620 contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. 105 CMR 120.620 also contains radiation safety requirements for operating irradiators. The requirements of 105 CMR 120.620 are in addition to other requirements of 105 CMR 120.000. In particular, the provisions of 105 CMR 120.001, 120.100, 120.200, 120.750 and 120.770 apply to applications and licenses subject to 105 CMR 120.620. Nothing in 105 CMR 120.620 relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(B) 105 CMR 120.620 applies to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed five grays (500 rads) per hour at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by 105 CMR 120.620.

(C) 105 CMR 120.620 does not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

120.622: Definitions

Annually means either:

(1) at intervals not to exceed one year; or

(2) once per year, at about the same time each year (plus or minus one month).