

(33) **Use of Radiopharmaceuticals for Uptake, Dilution or Excretion Studies.**

- (a) A licensee may use the following prepared radiopharmaceuticals for diagnostic studies involving the measurement of uptake, dilution, or excretion:
1. Iodine-131 as sodium iodide, iodinated human serum albumin (IHSA), labeled rose bengal, or sodium iodohippurate;
 2. Iodine-125 as sodium iodide or iodinated human serum albumin (IHSA);
 3. Cobalt-57 as labeled cyanocobalamin;
 4. Cobalt-58 as labeled cyanocobalamin;
 5. Cobalt-60 as labeled cyanocobalamin;
 6. Chromium-51 as sodium chromate or labeled human serum albumin;
 7. Iron-59 as citrate;
 8. Technetium-99m as pertechnetate;
 9. Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA) or "Product License Approval" (PLA).
- (b) A licensee using a radiopharmaceutical specified in 420-3-26-.07(33)(a) for a clinical procedure other than one specified in the product label or package insert instructions for use shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

(34) **Possession of Survey Instrument.**

A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 mrem (1.0 μ Sv) per hour to 50 mrem (500 μ Sv) per hour. The instrument shall be operable and calibrated in accordance with 420-3-26-.07(20).

Imaging and Localization

(35) **Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and**

Localization Studies.

- (a) A licensee may use the following radiopharmaceuticals, generators, and reagent kits for imaging and localization studies:
1. Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate;
 2. Technetium-99m as pertechnetate;
 3. Prepared radiopharmaceuticals and reagent kits for the preparation of the following technetium-99m labeled radiopharmaceuticals:
 - (i) Sulfur colloid,
 - (ii) Pentetate sodium,
 - (iii) Human serum albumin microspheres,
 - (iv) Polyphosphate,
 - (v) Macroaggregated human serum albumin,
 - (vi) Etidronate sodium,
 - (vii) Stannous pyrophosphate,
 - (viii) Human serum albumin,
 - (ix) Medronate sodium,
 - (x) Gluceptate sodium,
 - (xi) Oxidronate sodium,
 - (xii) Disofenin, and
 - (xiii) Succimer;
 4. Iodine-131 as sodium iodide, iodinated human serum albumin, acroaggregated iodinated human serum albumin, colloidal (microaggregated) iodinated human serum albumin, rose bengal, or sodium iodohippurate;
 5. Iodine-125 as sodium iodide or fibrinogen;

6. Chromium-51 as human serum albumin;
 7. Gold-198 in colloidal form;
 8. Mercury-197 as chlormerodrin;
 9. Selenium-75 as selenomethionine;
 10. Strontium-85 as nitrate;
 11. Ytterbium-169 as pentetate sodium;
 12. Gallium-67 as citrate;
 13. Indium-111 as chloride or DTPA;
 14. Tin-113/indium-113m generators for the elution of indium-113m as chloride;
 15. Yttrium-87/strontium-87m generators for the elution of strontium-87m;
 16. Thallium-201 as chloride;
 17. Iodine-123 as sodium iodide or iodohippurate;
 18. Any radioactive material in a diagnostic radiopharmaceutical, except aerosol or gaseous form, or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material for which the U.S. Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA) or "Product License Approval" (PLA).
- (b) A licensee using radiopharmaceuticals specified in 420-3-26-.07(35)(a) for clinical procedures shall comply with the product label or package insert regarding physical form, route of administration, and dosage range.
- (c) A licensee shall elute generators in compliance with 420-3-26-.07(36) and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.
- (d) The following radiopharmaceuticals, when used for the listed clinical procedures, are not subject to the restrictions in 420-3-26-.07(35)(b):
1. Technetium-99m pentetate as an aerosol for lung function studies.
- (e) Provided the conditions of 420-3-26-.07(37) are met a licensee shall use radioactive

aerosols or gases only if specific application is made to and approved by the Agency.

(36) Permissible Molybdenum-99 Concentration.

- (a) A licensee shall not administer a radiopharmaceutical containing more than 0.15 μCi (5.55 kBq) of molybdenum-99 per mCi (MBq) of technetium-99m.
- (b) A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each extract.
- (c) A licensee who must measure molybdenum concentration shall retain a record of each measurement for 5 years. The record shall include, for each elution or extraction of technetium-99m;
 - 1. The measured activity of the technetium expressed in mCi,
 - 2. The measured activity of the molybdenum expressed in μCi ,
 - 3. The ratio of the measures expressed as μCi of molybdenum per mCi of technetium,
 - 4. The date and time of the test, and
 - 5. The initials of the individual who performed the test.
- (d) A licensee shall report immediately to the Agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 420-3-26-.07(36)(a).

(37) Control of Aerosols and Gases.

- (a) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed by 420-3-26-.03 of these rules.
- (b) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.
- (c) A licensee shall only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.
- (d) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the

amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 420-3-26-.03 of these rules. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

- (e) A licensee shall post the time calculated in accordance with 420-3-26-.07(37)(d) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.
- (f) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 5 years.
- (g) A copy of the calculations required in 420-3-26-.07(37)(d) shall be recorded and retained for the duration of the license.

(38) Possession of Survey Instruments.

A licensee authorized to use radioactive material for imaging and localization studies shall have in its possession a portable, radiation detection survey instrument capable of detecting dose rates over the range of 0.1 mrem (1 μ Sv) per hour to 50 mrem (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(20).

Radiopharmaceuticals for Therapy

(39) Use of Radiopharmaceuticals for Therapy.

A licensee may use the following prepared radiopharmaceuticals:

- (a) Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma;
- (b) Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases;
- (c) Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;
- (d) Gold-198 as colloid for intracavitary treatment of malignant effusions;

- (e) Strontium-89 as chloride for treatment of bone pain;
- (f) Any radioactive material in a radiopharmaceutical for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA) or "Product License Approval" (PLA). The licensee shall comply with the package insert instructions regarding indications and method of administration.

(40) **Safety Instruction.**

- (a) A licensee shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed 1 year.
- (b) To satisfy 420-3-26-.07(40)(a), the instruction shall describe the licensee's procedures for:
 - 1. Patient control;
 - 2. Visitor control;
 - 3. Contamination control;
 - 4. Waste control; and
 - 5. Notification of the Radiation Safety Officer or authorized user in case of the patient's death or medical emergency.
- (c) A licensee shall retain for 5 years a record of:
 - 1. Individuals receiving instruction required by 420-3-26-.07(40)(a)
 - 2. A description of the instruction,
 - 3. The date of instruction, and
 - 4. The name of the individual who gave the instruction.

(41) **Safety Precautions.**

- (a) For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 420-3-26-.07(29), a licensee shall:

1. Provide a private room with a private sanitary facility;
2. Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room; in addition any sign shall indicate that women who think they are pregnant should contact the hospital staff;
3. Authorize visits by individuals under age 18 only on a patient-by-patient basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
4. Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 420-3-26-.03(6) of these rules, and retain for 5 years a record of each survey that includes:
 - (i) The time and date of the survey,
 - (ii) A plan of the area or list of points surveyed,
 - (iii) The measured dose rate at several points expressed in mrem per hour,
 - (iv) The instrument used to make the survey, and
 - (v) The initials of the individual who made the survey;
5. Either monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle materials and items as radioactive waste;
6. Provide the patient with radiation safety guidance that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;
7. Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute (3.33 Bq) per 100 square centimeters; and
8. Measure the thyroid burden of each individual who helped prepare or

administer a dosage of iodine-131 within 3 days after administering the dosage, and retain for the period required by 420-3-26-.03 (23)(a) of these rules a record of;

- (i) Each thyroid burden measurement,
 - (ii) Date of measurement,
 - (iii) The name of the individual whose thyroid burden was measured, and
 - (iv) The initials of the individual who made the measurements.
- (b) A licensee shall notify the Radiation Safety Officer or the authorized user immediately if the patient dies or has a medical emergency.

(42) Possession of Survey Instruments.

A licensee authorized to use radioactive material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 mrem (1 μ Sv) per hour to 50 mrem (500 μ Sv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(20).

Sealed Sources for Diagnosis

(43) Use of Sealed Sources for Diagnosis.

A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Iodine-125 as a sealed source in a device for bone mineral analysis;
- (b) Americium-241 as a sealed source in a device for bone mineral analysis;
- (c) Gadolinium-153 as a sealed source in a device for bone mineral analysis; and
- (d) Iodine-125 as a sealed source in a portable device for imaging.

(44) Availability of Survey Instrument.

A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 mrem (1 μ Sv) per hour to 50 mrem (500 μ Sv) per

hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The instrument shall be operable and calibrated in accordance with 420-3-26-.07(20).

Sources for Brachytherapy

(45) Use of Sources for Brachytherapy.

A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

- (a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
- (d) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;
- (e) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
- (f) Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;
- (g) Radon-222 as seeds for interstitial, treatment of cancer; and
- (h) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions.

(46) Safety Instruction.

- (a) The licensee shall provide oral and written radiation safety instruction to all personnel caring a patient receiving implant therapy. Refresher training shall be provided at intervals not to exceed 1 year.
- (b) To satisfy 420-3-26-.07(46)(a), the instruction shall describe:
 - 1. Size and appearance of the brachytherapy sources;
 - 2. Safe handling and shielding instructions in case of a dislodged source;

3. Procedures for patient control;
 4. Procedures for visitor control; and
 5. Procedures for notification of the Radiation Safety Officer or authorized user if the patient dies or has a medical emergency.
- (c) A licensee shall retain for 5 years a record of;
1. Individuals receiving instruction required by 420-3-26-.07(46)(a),
 2. A description of the instruction,
 3. The date of instruction, and
 4. The name of the individual who gave the instruction.
- (47) **Safety Precautions.**
- (a) For each patient receiving implant therapy, a licensee shall:
1. Not place the patient in the same room with a patient who is not receiving radiation therapy unless the licensee can demonstrate compliance with the requirement of 420-3-26-.03(14)(a) of these rules at a distance of one meter from the implant;
 2. Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or in the patient's chart where and how long visitors may stay in the patient's room; in addition any sign shall indicate that women who think they are pregnant should contact the hospital staff;
 3. Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
 4. Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 420-3-26-.03(14) of these rules, and retain for 5 years a record of each survey that includes:
 - (i) The time and date of the survey,
 - (ii) A sketch of the area or list of points surveyed,

- (iii) The measured dose rate at several points expressed in mrem (μ Sv) per hour,
 - (iv) The instrument used to make the survey, and
 - (v) The initials of the individual who made the survey; and
5. Provide the patient with radiation safety guidance that will help to keep the radiation dose to household members and the public as low as reasonably achievable before releasing the patient if the patient was administered a permanent implant.
- (b) A licensee shall notify the Radiation Safety Officer or authorized user immediately if the patient dies or has a medical emergency.

(48) Brachytherapy Sources Inventory.

- (a) Each time brachytherapy sources are returned to an area of storage from an area of use, the licensee shall immediately count the number returned to ensure that all sources taken from the storage area have been returned.
- (b) A licensee shall make a record of brachytherapy source use which includes:
- 1. The names of the individuals permitted to handle the sources;
 - 2.
 - (i) The number and activity of sources removed from storage,
 - (ii) The room number of use or patient's name,
 - (iii) The time and date they were removed from storage,
 - (iv) The number and activity of the sources in storage after the removal, and
 - (v) The initials of the individual who removed the sources from storage; and
 - 3.
 - (i) The number and activity of sources returned to storage,
 - (ii) The room number of use or patient's name,
 - (iii) The time and date they were returned to storage,
 - (iv) The number and activity of sources in storage after the return, and

- (v) The initials of the individual who returned the sources to storage.
 - (c) Immediately after implanting sources in a patient and immediately after removal of sources from a patient the licensee shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.
 - (d) A licensee shall retain the records required in 420-3-26-.07(48)(b) and (c) for 5 years.
- (49) **Release of Patients Treated With Temporary Implants.**
- (a) Immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The licensee shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.
 - (b) A licensee shall retain a record of patient surveys which demonstrate compliance with 420-3-26-.07(49)(a) for 5 years. Each record must include;
 1. The date of the survey,
 2. The name of the patient,
 3. The dose rate from the patient expressed as mrem (μSv) per hour and measured within 1 meter from the patient, and
 4. The initials of the individual who made the survey.

(50) **Possession of Survey Instruments.**

A licensee authorized to use radioactive material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting rates over the range 0.1 mrem (1 μSv) per hour to 50 mrem (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(20).

Teletherapy

(51) **Use of a Sealed Source in a Teletherapy Unit.**

A licensee shall use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

(52) Maintenance and Repair Restrictions.

Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

(53) Amendments.

In addition to the requirements specified in 420-3-26-.07 (4), a licensee shall apply for and shall receive a license amendment before:

- (a) Making any change in the treatment room shielding;
- (b) Making any change in the location of the teletherapy unit within the treatment room;
- (c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
- (d) Relocating the teletherapy unit; or
- (e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

(54) Safety Instruction.

- (a) A licensee shall post written instructions at the teletherapy unit console. To satisfy this requirement, these instructions shall inform the operator of:
 - 1. The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption; and
 - 2. The procedure to be followed if:
 - (i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and

- (ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.
 - (b) A licensee shall provide instruction in the topics identified in 420-3-26-.07(54)(a) to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed 1 year.
 - (c) A licensee shall retain for 5 years a record of;
 - 1. Individuals receiving instruction required by 420-3-26-.07(54)(b),
 - 2. A description of the instruction,
 - 3. The date of instruction, and
 - 4. The name of the individual who gave the instruction.
- (55) **Doors, Interlocks, and Warning Systems.**
- (a) A licensee shall control access to the teletherapy room by a door at each entrance.
 - (b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that shall:
 - 1. Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;
 - 2. Turn the primary beam of radiation off immediately when an entrance door is opened; and
 - 3. Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.
 - (c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.
- (56) **Possession of Survey Instrument.**
- A licensee authorized to use radioactive material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 mrem (1 μ Sv) per hour to 50 mrem (500 μ Sv) per hour, or a

portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 μ Sv) per hour to 1000 mrem (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(20).

(57) Radiation Monitoring Device.

- (a) A licensee shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.
- (b) Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.
- (c) Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.
- (d) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.
- (e) A licensee shall maintain a record of the check required by 420-3-26-.07(57)(d) for 5 years. The record shall include;
 - 1. The date of the check,
 - 2. Notation that the monitor indicates when the source is exposed, and
 - 3. The initials of the individual who performed the check.
- (f) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in 420-3-26-.07(57)(e).
- (g) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

(58) Viewing System.

A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

(59) Dosimetry Equipment.

- (a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:
1. The system shall have been calibrated by the National Bureau of Standards or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
 2. The system shall have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Science and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.
- (b) The licensee shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with 420-3-26-.07(59)(a). This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 420-3-26-.07(59)(a).
- (c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include;
1. The date,
 2. The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 420-3-26-.07(59)(a) and (b),

3. The correction factors that were deduced,
4. The names of the individuals who performed the calibration, intercomparison, or comparison, and
5. Evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM.

(60) Full Calibration Measurements.

- (a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:
 1. Before the first medical use of the unit; and
 2. Before medical use under the following conditions:
 - (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;
 - (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
 3. At intervals not exceeding 1 year.
- (b) To satisfy the requirement of 420-3-26-.07(60)(a), full calibration measurements shall include determination of:
 1. The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;
 2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
 4. Timer constancy and linearity for the range of use;

5. On-off error; and
 6. The accuracy of all distance measuring and localization devices in medical use.
- (c) A licensee shall use the dosimetry system described in 420-3-26-.07(59) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 420-3-26-.07(60)(b)(1) may then be made using a dosimetry system that indicates relative dose rates.
- (d) A licensee shall make full calibration measurements required by 420-3-26-.07(60)(a) in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p.213.
- (e) A licensee shall correct mathematically the outputs determined in 420-3-26-.07(60)(b)(1) for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding 6 months for cesium-137.
- (f) Full calibration measurements required by 420-3-26-.07(60)(a) and physical decay corrections required by 420-3-26-.07(60)(e) shall be performed by a teletherapy physicist.
- (g) A licensee shall retain a record of each calibration for the duration of the license. The record shall include;
1. The date of the calibration,
 2. The manufacturer's name, model number, and serial number for both the teletherapy unit and the source,
 3. The model numbers and serial numbers of the instruments used to calibrate the teletherapy unit.
 4. Tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy,
 5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device,
 6. An assessment of the timer linearity and constancy,

7. The calculated on-off error,
8. The estimated accuracy of each distance measuring or localization device, and
9. The signature of the teletherapy physicist.

(61) Periodic Spot-Checks.

- (a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit at intervals not to exceed one month.
- (b) To satisfy the requirement of 420-3-26-.07(61)(a), measurements shall include determination of:
 1. Timer constancy and timer linearity over the range of use;
 2. On-off error;
 3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
 4. The accuracy of all distance measuring and localization devices used for medical use;
 5. The output for one typical set of operating conditions; and
 6. The difference between the measurement made in 420-3-26-.07(61)(b)(5) and the anticipated output, expressed as a percentage of the anticipated value obtained at last full calibration corrected mathematically for physical decay.
- (c) A licensee shall use the dosimetry system described in 420-3-26-.07(59) to make the measurement required in 420-3-26-.07(61)(b)(5).
- (d) A licensee shall perform measurements required by 420-3-26-.07(61)(a) in accordance with procedures established by the teletherapy physicist. That individual does not need to actually perform the output spot-check measurements.
- (e) A licensee shall have the teletherapy physicist review the results of each output spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each output spot-check. The licensee shall keep a copy of each written notification for 5 years.
- (f) A licensee authorized to use a teletherapy unit for medical use shall perform safety

spot-checks of each teletherapy facility at intervals not to exceed 1 month.

- (g) To satisfy the requirement of 420-3-26-.07(61)(f), checks shall assure proper operation of:
1. Electrical interlocks at each teletherapy room entrance;
 2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism;
 3. Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
 4. Viewing systems;
 5. Treatment room doors from inside and outside the treatment room; and
 6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".
- (h) A licensee shall lock the control console in the "off" position if any door interlock malfunctions. No licensee shall use the unit until the interlock system is repaired unless specifically authorized by the Agency.
- (i) A licensee shall promptly repair any system identified in 420-3-26-.07(60)(g) that is not operating properly.
- (j) A licensee shall retain a record of each spot-check required by 420-3-26-.07(60)(a) and (f) for 5 years. The record shall include;
1. The date of the spot-check,
 2. The manufacturer's name, model number, and serial number for both the teletherapy unit and source,
 3. The manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit,
 4. An assessment of timer linearity and constancy,
 5. The calculated on-off error,

6. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device,
7. The measured timer accuracy for a typical treatment time,
8. The calculated on-off error,
9. The estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output,
10. Notations indicating:
 - (i) The operability of each entrance door electrical interlock,
 - (ii) Each electrical or mechanical stop,
 - (iii) Each beam condition indicator light,
 - (iv) The viewing system and doors, and
11. The signature of the individual who performed the periodic spot-check.

(62) Radiation Surveys for Teletherapy Facilities.

- (a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 420-3-26-.07(53) the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 420-3-26-.07(20) to verify that:
 1. The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 10 mrem (100 μ Sv) per hour and 2 mrem (20 μ Sv) per hour, respectively; and
 2. With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:
 - (i) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 420-3-26-.03(6) of these rules; and
 - (ii) Radiation levels in unrestricted areas do not exceed the limits specified in 420-3-26-.03(14)(a) of these rules.

- (b) If the results of the surveys required in 420-3-26-.07(62)(a) indicate any radiation levels in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the "off" position and not use the unit:
1. Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding or the treatment room shielding; or
 2. Until the licensee has received a specific exemption from the Agency.
- (c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include;
1. The date of the measurements,
 2. The reason the survey is required,
 3. The manufacturer's name, model number and serial number of the teletherapy unit,
 4. The source, and the instrument used to measure radiation levels,
 5. Each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements,
 6. A plan of the areas surrounding the treatment room that were surveyed,
 7. The measured dose rate at several points in each area expressed in mrem (μSv) per hour,
 8. The calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area, and
 9. The signature of the Radiation Safety Officer.

(63) Safety Checks for Teletherapy Facilities.

- (a) A licensee shall promptly check all systems listed in 420-3-26-.07(61), for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 420-3-26-.07(53).
- (b) If the results of the checks required in 420-3-26-.07(63)(a) indicate the malfunction of any system specified system specified in 420-3-26-.07(61), the licensee shall lock the control console in the "off" position and not use the unit except as may be neces-

sary to repair, replace, or check the malfunctioning system.

- (c) A licensee shall retain for 5 years a record of the facility checks following installation of a source. The record shall include notations indicating the operability of,
1. Each entrance door interlock,
 2. Each electrical or mechanical stop,
 3. Each beam condition indicator light,
 4. The viewing system, and doors, and
 5. The signature of the Radiation Safety Officer.

(64) Modification of Teletherapy Unit or Room Before Beginning a Treatment Program.

If the survey required by 420-3-26-.07(62) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 420-3-26-.03 (14)(a) of these rules, before beginning the treatment program the licensee shall:

- (a) Either equip the unit with stops or add additional radiation shielding to ensure compliance with 420-3-26-.03(14)(a) of these rules;
- (b) Perform the survey required by 420-3-26-.07(62) again; and
- (c) Include in the report required by 420-3-26-.07(65) the results of the initial survey, a description of the modification made to comply with 420-3-26-.07(63)(a), and the results of the second survey; or
- (d) Request and receive a license amendment under 420-3-26-.03(14)(c) of these rules that authorizes radiation levels in unrestricted areas greater than those permitted by 420-3-26-.03(14)(a) of these rules.

(65) Reports of Teletherapy Surveys, Checks, Tests, and Measurements.

A licensee shall furnish a copy of the records required in 420-3-26-.07(62), (63), and (64) and the output from the teletherapy source expressed as rem (Sv) per hour at one meter from the source as determined during the full calibration required in 420-3-26-.07(60) to the Agency within 30 days following completion of the action that initiated the record requirement.

(66) Five-Year Inspection.

- (a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
- (b) This inspection and servicing shall only be performed by persons specifically licensed to do so by the Agency, an Agreement State or the U. S. Nuclear Regulatory Commission.
- (c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record shall contain:
 - 1. The inspector's name,
 - 2. The inspector's license number,
 - 3. The date of inspection,
 - 4. The manufacturer's name and model number and serial number for both the teletherapy unit and source,
 - 5. A list of components inspected,
 - 6. A list of components serviced and the type of service,
 - 7. A list of components replaced, and
 - 8. The signature of the inspector.

Training and Experience Requirements

(67) Radiation Safety Officer.

Except as provided in 420-3-26-.07(68), an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in 420-3-26-.07(7) shall:

- (a) Be certified by:
 - 1. American Board of Health Physics in Comprehensive Health Physics; or
 - 2. American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or
 - 3. American Board of Nuclear Medicine; or

4. American Board of Science in Nuclear Medicine, or
 5. Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or
- (b) Have had 200 hours of classroom and laboratory training as follows:
1. Radiation physics and instrumentation;
 2. Radiation protection;
 3. Mathematics pertaining to the use and measurement of radioactivity;
 4. Radiation biology;
 5. Radiopharmaceutical chemistry; and
 6. 1 year of full time experience in radiation safety at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on an Agency, Agreement State, Licensing State or U. S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material; or
- (c) Be an authorized user for those radioactive material uses that come within the Radiation Safety Officer's responsibilities.

(68) Training for Experienced Radiation Safety Officer.

An individual identified as a Radiation Safety Officer on an Agency, Agreement State, Licensing State or U. S. Nuclear Regulatory Commission license on December 31, 1988, who oversees only the use of radioactive material for which the licensee was authorized on that date need not comply with the training requirements of 420-3-26-.07(67).

(69) Training for Uptake, Dilution, or Excretion Studies.

Except as provided in 420-3-26-.07(77) and (78) the licensee shall require the authorized user of a radiopharmaceutical listed in 420-3-26-.07(33) to be a physician who:

- (a) Is certified in:
1. Nuclear medicine by the American Board of Nuclear Medicine; or
 2. Diagnostic radiology by the American Board of Radiology; or
 3. Diagnostic radiology or radiology within the previous five years by the American Osteopathic Board of Radiology; or

- (b) Has completed 40 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience:
1. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry.
 2. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and shall include:
 - (i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
 - (iii) Administering dosages to patients and using syringe radiation shields;
 - (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
 - (v) Patient follow-up; or
- (c) Has successfully completed a 6 month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 420-3-26-.07(69)(b).
- (70) **Training for Imaging and Localization Studies.**

Except as provided in 420-3-26-.07(77) or (78), the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in 420-3-26-.07(35) to be a physician who:

- (a) Is certified in:
 1. Nuclear medicine by the American Board of Nuclear Medicine; or
 2. Diagnostic radiology by the American Board of Radiology; or
 3. Diagnostic radiology or radiology within the previous 5 years by the American Osteopathic Board of Radiology; or
- (b) Has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience and 500 hours of supervised clinical experience:
 1. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiopharmaceutical chemistry; and
 - (v) Radiation biology.
 2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and shall include:
 - (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - (iii) Calculating and safely preparing patient dosages;

- (iv) Using administrative controls to prevent the misadministration of radioactive material;
 - (v) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (vi) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.
3. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and shall include:
- (i) Examining patients and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;
 - (iii) Administering dosages to patients and using syringe radiation shields;
 - (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and
 - (v) Patient follow-up; or
- (c) Has successfully completed a 6 month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 420-3-26-.07(70)(b).
- (71) Training for Therapeutic Use of Radiopharmaceuticals.**

Except as provided in 420-3-26-.07(77), the licensee shall require the authorized user of a radiopharmaceutical listed in 420-3-26-.07(39) for therapy to be a physician who:

- (a) Is certified by:

1. The American Board of Nuclear Medicine; or
 2. The American Board of Radiology in radiology or therapeutic radiology; or
- (b) Has completed 80 hours of instruction in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience:
1. To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology;
 2. To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and shall include:
 - (i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;
 - (ii) Use of soluble phosphorus-32 for the treatment of ascites polycythemia vera, leukemia, or bone metastases in 3 individuals;
 - (iii) Use of iodine-131 for treatment of thyroid carcinoma in three individuals;
 - (iv) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals; and
 - (v) Use of strontium-89 chloride for treatment of bone pain in three individuals.
- (72) **Training for Therapeutic Use of Brachytherapy Sources.**

Except as provided in 420-3-26-.07(77), the licensee shall require the authorized user using

a brachytherapy source specified in 420-3-26-.07(45) for therapy to be a physician who:

- (a) Is certified in:
 1. Radiology or therapeutic radiology by the American Board of Radiology; or
 2. Radiation oncology by the American Osteopathic Board of Radiology; or
 3. Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

- (b) Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of 3 years of supervised clinical experience:
 1. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) Radiation biology.

 2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and shall include:
 - (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (ii) Checking survey meters for proper operation;
 - (iii) Preparing, implanting, and removing sealed sources;
 - (iv) Using administrative controls to prevent the misadministration of

radioactive material; and

- (v) Using emergency procedures to control radioactive material.
3. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The supervised clinical experience shall include:
- (i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
 - (ii) Selecting the proper brachytherapy sources and dose and method of administration;
 - (iii) Calculating the dose; and
 - (iv) Post-administration follow-up and review of case histories in collaboration with the authorized user.

(73) Training for Ophthalmic Use of Strontium-90.

Except as provided in 420-3-26-.07(77), the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

- (a) Is certified in radiology or therapeutic radiology by the American Board of Radiology; or
- (b) Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy:
 - 1. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (i) 6 hours of radiation physics and instrumentation;

- (ii) 6 hours of radiation protection;
 - (iii) 4 hours of mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) 8 hours of radiation biology.
2. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training must be under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and must include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:
- (i) Examination of each individual to be treated;
 - (ii) Calculation of the dose to be administered;
 - (iii) Administration of the dose; and
 - (iv) Follow-up and review of each individual's case history.

(74) Training for Use of Sealed Sources for Diagnosis.

Except as provided in 420-3-26-.07(77) the licensee shall require the authorized user using a sealed source in a device specified in 420-3-26-.07(43) to be a physician, dentist, or podiatrist who:

- (a) Is certified in:
 - 1. Radiology, diagnostic radiology with special competence in nuclear radiology, or therapeutic radiology by the American Board of Radiology; or
 - 2. Nuclear medicine by the American Board of Nuclear Medicine; or
 - 3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
- (b) Has completed 8 hours of instruction in basic radioisotope handling techniques specifically applicable to the use of the device. To satisfy the requirement for instruction, the training shall include:
 - 1. 3 hours of radiation physics, mathematics pertaining to the use and

measurement of radioactivity, and instrumentation;

2. 3 hours of radiation biology; and
3. 2 hours of radiation protection and training in the use of the device for the purposes authorized by the license.

(75) Training for Teletherapy.

Except as provided in 420-3-26-.07(77), the licensee shall require the authorized user of a sealed source specified in 420-3-26-.07(51) in a teletherapy unit to be a physician who:

(a) Is certified in:

1. Radiology or therapeutic radiology by the American Board of Radiology; or
2. Radiation oncology by the American Osteopathic Board of Radiology; or
3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(b) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience:

1. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (i) 110 hours of radiation physics and instrumentation;
 - (ii) 40 hours of radiation protection;
 - (iii) 25 hours of mathematics pertaining to the use and measurement of radioactivity; and
 - (iv) 25 hours of radiation biology.
2. To satisfy the requirement for supervised work experience, training shall be

under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State, and shall include:

- (i) Review of the full calibration measurements and periodic spot checks;
 - (ii) Preparing treatment plans and calculating treatment times;
 - (iii) Using administrative controls to prevent misadministrations;
 - (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - (v) Checking and using survey meters.
3. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in therapeutic radiology under the supervision of an authorized user at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The supervised clinical experience shall include:
- (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
 - (ii) Selecting the proper dose and how it is to be administered;
 - (iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and
 - (iv) Post-administration follow-up and review of case histories.

(76) Training for Teletherapy Physicist.

The licensee shall require the teletherapy physicist to:

- (a) Be certified by the American Board of Radiology in:
 1. Therapeutic radiological physics; or

2. Roentgen ray and gamma ray physics; or
 3. X-ray and radium physics; or
 4. Radiological physics; or
- (b) Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics from an accredited program, and have completed 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a teletherapy physicist at an authorized medical use licensee of the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. To meet this requirement, the individual shall have performed the tasks listed in 420-3-26-.07(23), (60), (61), and (62) under the supervision of a teletherapy physicist during the year of work experience.

(77) Training for Experienced Authorized Users.

Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Agency, NRC or Agreement State or Licensing State license on December 31, 1988 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of 420-3-26-.07(67) through 420-3-26-.07(79).

(78) Physician Training in a Three Month Program.

A physician who, before July 1, 1984, began a 3 month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program is exempted from the requirements of 420-3-26-.07(69) or 420-3-26-.07(70).

(79) Recentness of Training.

The training and experience specified in 420-3-26-.07(67) through 420-3-26-.07(76) must have been obtained within the 5 years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

(80) Training for Nuclear Pharmacists

The licensee shall require an authorized nuclear pharmacist to be a pharmacist who:

- (a) Is registered with the Alabama Board of Pharmacy as a pharmacist and a nuclear pharmacist, and
- (b) Has completed 200 hours of instruction in basic radioisotope handling techniques specifically applicable to the use of unsealed sources, and 500 hours of work

experience handling unsealed radioactive material under the supervision of an authorized user.

1. To satisfy the requirement for instruction, the classroom and laboratory training shall include:
 - (i) Radiation physics and instrumentation;
 - (ii) Radiation protection;
 - (iii) Mathematics pertaining to the use and measurement of radioactivity;
 - (iv) Radiation biology; and
 - (v) Radiopharmaceutical chemistry.

On-the-job training may not count toward the 200 hours of classroom and laboratory training unless it was obtained as part of a formal training course. A "formal" training course is one that incorporates the following elements:

- (i) A detailed description of the content of the course is maintained on file at the sponsoring institution and can be made available to the Agency upon request;
 - (ii) Evidence that the sponsoring institution has examined the student's knowledge of the course content is maintained on file at the institution and can be made available to the Agency upon request. This evidence of the student's overall competency in the course material should include a final grade or percentile.
 - (iii) A permanent record that the student successfully completed the course is kept at the institution.
2. To satisfy the requirement for supervised work experience, 500 hours of handling unsealed sources of radioactive material shall be under the supervision and in the physical presence of an authorized user, and shall include:
 - (i) Ordering, receiving, and unpackaging radioactive materials safely, including performing related radiation surveys;
 - (ii) Calibrating dose calibrators, scintillation detectors, and survey meters;
 - (iii) Calculating, preparing, and calibrating patient doses, including properly using radiation shields;

- (iv) Following appropriate internal control procedures to prevent mislabeling errors;
- (v) Learning emergency procedures to handle and contain spilled materials safely, including related decontamination procedures, surveys, and wipe tests;
- (vi) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and
- (vii) Performing appropriate quality control tests on prepared radiopharmaceutical kits to assure adequate radiochemical purity.

Authority: §§ 22-14-4, 22-14-6, 22-14-7, 22-14-8, and 22-14-9, Code of Alabama, 1975, as amended.

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420-3-26-.08

THE REGISTRATION OF PARTICLE ACCELERATORS

- (1) **Purpose.** This Rule 420-3-26-.08 provides for the registration of particle accelerators.
- (2) **Scope.** No person shall receive, possess, use, transfer, own, operate, or acquire a particle accelerator except as authorized in a Notice of Registration or as otherwise provided for in this Rule 420-3-26-.08.
- (3) **Definitions.** As used in this Rule 420-3-26-.08:
 - (a) "Act" means Act No. 582, Alabama Law, Regular Session, 1963, codified as 22-14-1, Code of Alabama.
 - (b) "Agency" means the State Board of Health.
 - (c) "Industrial Radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing a particle accelerator.

REGISTRATION

- (4) **Registration Procedures.** No registration shall be complete or valid until the person applying for registration has received a written Notice of Registration which shall be issued by the Agency in accordance with this Rule 420-3-26-.08, or is exempted from such requirement by this Rule 420-3-26-.08.
- (5) **Notice of Registration-Exemptions.** A Notice of Registration is not required:
 - (a) To transfer, own, receive, acquire, or possess a particle accelerator when such devices are in storage or disassembled, or otherwise incapable of intentional or accidental operation. Each person receiving such particle accelerator shall, within thirty (30) days after the receipt of the particle accelerator, notify the Agency of the type of particle accelerator and the name and address of the person supplying the particle accelerator.
 - (b) For electrical equipment that is not primarily intended to produce radiation and does not produce a radiation level greater than 0.5 mrem per hour at any readily accessible point 5 centimeters from the surface. Such equipment shall not be exempt if it is

used or handled in such a manner that any individual might receive a radiation dose exceeding the limits specified in these rules.

- (6) **Transfer of Particle Accelerators.** Any person transferring a particle accelerator shall, within thirty (30) days after the end of the calendar quarter in which any particle accelerator is transferred, notify the Agency of the type of particle accelerator and the name and address of the person to whom the particle accelerator was supplied.
- (7) **Filing of Application for Notice of Registration.**
- (a) Application for a Notice of Registration shall be filed on a form prescribed by the Agency.
 - (b) The Agency may at any time after the filing of the original application, and before the expiration of the Notice of Registration, require further statements in order to enable the Agency to determine whether the application should be granted or denied, or whether the Notice of Registration should be modified or revoked.
 - (c) Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on his behalf.
 - (d) An application for a Notice of Registration may include a request for the registration of one or more activities.
 - (e) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.
- (8) **Application for Amendments to Notices of Registration.** In addition to the requirements specified in 420-3-26-.08(14), a registrant shall apply for, and shall receive, an amendment before:
- (a) Making any change in the accelerator room shielding;
 - (b) Making any change in the location of the Particle Accelerator within the accelerator room;
 - (c) Using the Particle Accelerator in a manner that could result in increased radiation levels in areas outside the accelerator room;

- (d) Relocating the Particle Accelerator;
 - (e) Allowing an individual who is not a visiting teletherapy physicist pursuant to 420-3-26-.09(8)(f) or is not listed on the Notice of Registration to perform the duties of a teletherapy physicist; or
 - (f) Allowing any physician who is not a visiting authorized user pursuant to 420-3-26-.09(8)(i) or is not listed on the Notice of Registration to prescribe radiation treatments for humans.
- (9) **General Requirements for the Issuance of a Notice of Registration.** A registration application will be approved if the Agency determines that:
- (a) The applicant is qualified by reason of training and experience to use the particle accelerator and any associated radioactive material¹ for the purpose requested, in accordance with these rules, in such a manner as to minimize danger to public health and safety or property;
 - (b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;
 - (c) The issuance of the Notice of Registration will not be harmful to the health and safety of the public;
 - (d) The applicant has appointed a radiological safety officer who will advise and assist on radiological safety problems;
 - (e) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures; and
 - (f) The applicant satisfies any applicable special requirements in this Rule 420-3-26-.08.
- (10) **Special Requirements for Issuance of a Notice of Registration for Particle Accelerators.**
- (a) **Human Use.** In addition to the requirements set forth in 420-3-26-.08(9) above, a

¹ See Rule 420-3-26-.02 for the licensing of such radioactive material.

Notice of Registration for human use of a particle accelerator in the practice of medicine will be issued only if:

1. The applicant has access to adequate facilities for the clinical care of patients.
 2. Each physician designated on the application as an individual user has the training and experience delineated in 420-3-26-.07(75).
 3. The applicant has designated a teletherapy physicist on the application who has the training and experience delineated in 420-3-26-.07(76).
- (b) **Research and Development.** In addition to the requirements of 420-3-26-.08(9) above, a Notice of Registration for the use of a particle accelerator in research and development will be issued only if:
1. The applicant's staff has substantial experience in the use of particle accelerators for a variety of research and development uses;
 2. The applicant has established a radiation safety committee (composed of such persons as a radiological safety officer, one or more persons trained or experienced in the safe use of particle accelerators, and a representative of management or the administration) which will review and approve, in advance, proposals for such use.
- (c) **Industrial Radiography.** In addition to the requirements set forth in 420-3-26-.08(8) above, a Notice of Registration for use of a particle accelerator in industrial radiography will be issued only if:
1. The applicant has an adequate program for training radiographers and radiographer's assistants and submits to the Agency a schedule or description of such program which specifies the:
 - (i) Initial training;
 - (ii) Periodic training;
 - (iii) On-the-job training;

- (iv) Means to be used by the registrant to determine the radiographer's knowledge and understanding of and ability to comply with Agency rules and the operating and emergency procedures of the applicant; and,
 - (v) Means to be used by the registrant to determine the radiographer's knowledge and understanding of and ability to comply with Agency rules and the operating and emergency procedures of the applicant;
2. The applicant submits a completed Form ARC-20 for each person who is to perform the duties of a radiographer.
 3. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as described in 420-3-26-.04(15);
 4. The applicant has an adequate internal inspection system, or other management control, to assure that regulations, and the applicant's operating and emergency procedures are followed by radiographers and radiographers assistants; and,
 5. The applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.
- (d) **Production of Radioactive Materials.**² In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the production of multiple quantities or types of radioactive materials by a particle accelerator will be issued only if:
1. The applicant's staff has substantial experience in the use of particle accelerators to produce a variety of radioactive materials;
 2. The applicant has an adequate training program for particle accelerator operators consisting of;

² See Rule 420-3-26-.02 for the licensing requirements for the possession of such radioactive materials.

- (i) Initial training;
 - (ii) Periodic training;
 - (iii) On-the-job training; and
 - (iv) A means to be used by the applicant to determine the operator's knowledge and understanding of and ability to comply with or use:
 - I. Agency rules;
 - II. Applicant's operating and emergency procedures;
 - III. Survey instruments as required by these rules; and,
 - IV. Personnel monitoring equipment:
3. The applicant has an adequate training program for staff personnel for possession and use of radioactive materials produced by the accelerator.
- (e) **Modification of the Structure, Chemical Composition, or Bacterial Composition of Materials.** In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the modification of the structure, chemical composition, or bacterial composition of materials by a particle accelerator will be issued only if:
- 1. The applicant's staff has substantial experience in the modification of materials;
 - 2. The applicant has an adequate training program for the training of the particle accelerator operators consisting of:
 - (i) Initial training;
 - (ii) Periodic training;
 - (iii) On-the-job training;
 - (iv) A means of determining the operator's knowledge and understanding

of and ability to comply with or use:

- I. Agency rules;
- II. The applicant's operating and emergency procedures;
- III. Survey instruments as required by these rules; and,
- IV. Personnel monitoring equipment.

(10) **Issuance of a Notification of Registration.**

- (a) Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency will issue a Notice of Registration authorizing the proposed activity.
- (b) The Agency may incorporate in any Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements with respect to the registrant's particle accelerator subject to the Rule 420-3-26-.08 as it deems appropriate or necessary in order to:
 1. Minimize danger to public health and safety or property;
 2. Require the maintenance of specific records and the reporting of specific information to the Agency; and
 3. Require necessary inspections, calibrations and output checks.

(12) **Specific Terms and Conditions of the Notice of Registration.**

- (a) Each Notice of Registration issued pursuant to this Rule 420-3-26-.08 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.
- (b) Each person registered by the Agency pursuant to this Rule 420-3-26-.08 shall confine his use and possession of the particle accelerator registered to the locations and purposes authorized in the Notice of Registration.

(13) **Expiration of Registration.** Except as provided in 420-3-26-.08(14)(b), each Notice of Registration shall expire at the end of the day, in the month and year stated therein.

- (14) **Renewal of Registration.**
- (a) Applications for renewal of a Notice of Registration shall be filed in accordance with 420-3-26-.08(7).
 - (b) In any case in which a registrant, not less than thirty (30) days prior to expiration of his existing Notice of Registration, has filed an application in proper form for renewal or for a new Notice of Registration authorizing the same activities, such existing Notice of Registration shall not expire until the application has been finally determined by the Agency.
- (15) **Amendment of Notice of Registration at Request of Registrant.** Applications for amendment of a Notice of Registration shall be filed in accordance with 420-3-26-.08(7) and shall specify the respects in which the registrant desires his Notice of Registration to be amended and the grounds for such amendment.
- (16) **Agency Action on Application to Renew or Amend.** In considering an application by a registrant to renew or amend his Notice of Registration, the Agency will apply the criteria set forth in 420-3-26-.08(9), and 420-3-26-.08(10) as applicable.
- (17) **Inalienability of Notice of Registration.** No Notice of Registration issued or granted under this Rule and no right to utilize a particle accelerator granted by any Notice of Registration issued pursuant to this Rule shall be transferred, assigned, or in any manner disposed of, either voluntarily, directly, or indirectly, through transfer of control of any Notice of Registration to any persons unless the agency shall, after securing full information find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing.
- (18) **Modification, Revocation, and Termination of a Notice of Registration.**
- (a) A Notice of Registration shall be subject to amendment, revision, or modification or the Notice of Registration may be suspended or revoked by reason of amendments to the Act, or by reason of rule, regulations, or orders issued by the Agency.
 - (b) Any Notice of Registration may be revoked, suspended, modified in whole or part, for any material false statement in the application, or any statement of fact required under provisions of the Act, or because of conditions revealed by the application, or any statement of fact, or by any report, records, or inspection or other means, such

that said conditions which would warrant the Agency to refuse to grant a Notice of Registration on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the Notice of Registration, or of any rule, regulation, or order of the Agency.

- (c) Except in cases of willfulness, or those in which the public health, interest or safety requires otherwise, no Notice of Registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.
- (d) The Agency may terminate a Notice of Registration upon request submitted by the registrant to the Agency in writing.

Authority: §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, also 22-2-1, 22-2-2, 22-2-5, and 22-2-6, Code of Alabama, 1975.

Author: James L. McNees, Director, Inspection Branch, Division of Radiation Control, Bureau of Health Care Standards, Alabama Department of Public Health.

History: New 3-18-70; Repromulgated 8-21-74; Revised 1-18-78; Recodified 6-11-78; Revised and Repromulgated 10-21-81; Repromulgated effective 12-31-83. Revised and Repromulgated effective 1-31-90. Revised and Repromulgated effective 12-18-96.

420-3-26-.09

RADIATION SAFETY REQUIREMENTS FOR USERS OF PARTICLE ACCELERATORS

- (1) **Scope.** Rule 420-3-26-.03 established standards for the use of all radiation sources. The provisions of this Rule 420-3-26-.09 are in addition to, and not in substitution for, other applicable provisions of these rules.
- (2) **Definitions.**
 - (a) "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, "particle accelerator" is an equivalent term.
 - (b) "Agency" means the Alabama State Board of Health.
 - (c) "Authorized User" means a practitioner of the healing arts who is identified as an authorized user on an Agency particle accelerator registration that authorizes the medical use of a particle accelerator.
 - (d) "Beam Scatter Filter" means a filter used in order to scatter a beam of electrons.
 - (e) "Central Axis of the Beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.
 - (f) "Dose Monitoring System" means a system of devices for the detection, measurement, and display of quantities of radiation.
 - (g) "Dose Monitor Unit" means a unit response from the dose monitoring system from which the absorbed dose can be calculated.
 - (h) "Emergency Procedures" means the written preplanned steps to be taken in the event of or the potential for actual or suspected, unplanned exposure of individuals to radiation. This procedure should include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring device.

- (i) "Existing Equipment" means therapy systems subject to 420-3-26-.08 which were manufactured on or before January 1, 1985.
- (j) "Field-Flattening Filter" means a filter used to provide dose uniformity over the area of a useful beam of x-rays at a specified depth.
- (k) "Field Size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance, and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.
- (l) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.
- (m) "High Radiation Area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour at thirty (30) centimeters from the radiation source or from any surface that the radiation penetrates.
- (n) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.
- (o) "Interruption of Irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.
- (p) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.
- (q) "Misadministration" means the administration of a Therapeutic Particle Accelerator Dose:
 - 1. Involving the wrong patient or wrong treatment site;
 - 2. When the treatment consists of 3 or fewer fractions and the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 10 percent of the total prescribed dose;

3. When the calculated weekly administered dose is 30 percent or more greater than the weekly prescribed dose; or
 4. When the calculated total absorbed dose administered differs from the total absorbed dose prescribed by more than 20 percent of the total prescribed dose.
- (r) "Moving Beam Therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation. It includes arc therapy, skip therapy, and rotational therapy.
- (s) "New Equipment" means systems subject to 420-3-26-.08 which were manufactured after January 1, 1985.
- (t) "Normal Treatment Distance" means:
1. for electron irradiation, the virtual source to surface distance along the central axis of the useful beam as specified by the manufacturer of the applicator.
 2. for x-ray irradiation, the virtual source to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.
- (u) "Operating Procedures" means detailed written instructions including, but not limited to, the normal operation of movable shielding, closing of interlock circuits, manipulation of accelerator controls, radiation monitoring procedures, wearing of dosimeters, testing of interlocks, and record keeping requirements.
- (v) "Operator" means a person qualified by training and experience to assume responsibility for the safe operation of a particle accelerator.
- (w) "Personnel Monitoring Equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received such as film badges and pocket dosimeters.
- (x) "Primary Protective Barrier" means a barrier sufficient to attenuate the useful beam to the required degree.
- (y) "Protective Barrier" means a barrier of attenuating materials used to reduce radiation exposure.

- (z) "Radiation Area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirems) (0.05 mSv) in one (1) hour at 30 centimeters from the radiation source or from the surface that the radiation penetrates.
- (aa) "Radiation Head" means the structure from which the useful beam emerges.
- (bb) "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with the requirements of these rules and all conditions of the registration.
- (cc) "Scattered Radiation" means secondary radiation or radiation that, during passage through matter, has been deviated in direction.
- (dd) "Secondary Protective Barrier" means a barrier sufficient to attenuate scattered radiation to the required degree.
- (ee) "Shadow Tray" means a device attached to the radiation head to support auxiliary beam limiting material.
- (ff) "Stationary Beam Therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.
- (gg) "Target" means that part of a radiation head which, by design, intercepts a beam of accelerated particles with subsequent emission of other radiation.
- (hh) "Teletherapy Physicist" means the individual identified as the qualified teletherapy physicist on an Agency particle accelerator registration or teletherapy license.
- (ii) "Visiting Authorized Teletherapy Physicist" means a teletherapy physicist who is not identified on the registration of the registrant being visited.
- (jj) "Visiting Authorized User" means an authorized user who is not identified on the registration of the registrant being visited.
- (kk) "Virtual Source" means a point from which radiation appears to originate.

GENERAL REQUIREMENTS

- (3) **Records.** In addition to the records required elsewhere in these rules, each registrant shall maintain records of any tests or surveys required by this Rule 420-3-26-.09.

(4) **General Safety Provisions.**

- (a) The Agency may waive compliance with the specific requirements of this Part by an existing machine or installation if the registrant demonstrates, to the Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules.
- (b) **Personnel Monitoring.** Each registrant shall provide personnel monitoring devices which shall be calibrated for the appropriate radiations and energies of radiation produced by the particle accelerator and shall be used by:
1. Each individual who receives, or is likely to receive, a whole body dose in excess of 10 millirems per week; and,
 2. Each individual who enters a high radiation area.
- (c) **Shielding.** Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to assure compliance with 420-3-26-.03(6), 420-3-26-.03(12), 420-3-26-.03(13), and 420-3-26-.03(14) of these rules. All protective barriers shall be fixed except for entrance doors or beam interceptors.
- (d) **Controls and Safety Devices.**
1. Only the particle accelerator operator at the control panel located outside the shielded room shall be capable of turning on particle accelerator beams that are capable of producing exposure rates in excess of two (2) millirems per hour.
 2. All entrances into a target room, treatment room, or other high radiation areas shall be provided with safety interlocks that shut down the machine under conditions of barrier penetration.
 3. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.
 4. When any interlock is interrupted, broken, or tripped, either the particle accelerator will shut off automatically or the radiation level within the room will be reduced to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system.

5. Interlocks shall not be used to routinely shut off the particle accelerator.
6. An emergency cut-off switch shall be located in all high radiation areas. This switch shall be readily identifiable. This switch shall be capable of automatically causing the particle accelerator to either shut off or reduce the radiation level to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system. Such cut-off switch shall include a manual reset at each such switch which must be reset at the switch before the particle accelerator may be restarted by the operator at the control panel. Radiation levels produced by radioactive materials shall not be considered as the radiation levels to be reduced.
7. All locations designated as high radiation areas shall be equipped with easily observable flashing or rotating warning lights and/or audible warning devices that operate when, and only when, radiation is being produced. Each entrance to such area shall have a visual warning device, which need not be flashing or rotating, that operates when and only when radiation is being produced.
8. Each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of a high radiation area. Such warning device shall be clearly discernible in all high radiation areas.
9. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 420-3-26-.03 of these rules.
10. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.
11. The particle accelerator control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, make the particle accelerator incapable of producing any area in which the radiation exposure is in excess of two (2) millirems per hour.
12. There shall be available at each facility, appropriate portable radiation monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced by the facility. Such equipment shall be tested for proper operation daily and calibrated for the appropriate radiations at the correct interval and after each instrument servicing and repair.
13. There shall be present at the control panel a device which shall give a

continuous indication of the radiation levels being produced in the target area or areas.

14. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and on file at each accelerator facility.

(e) Operation.

1. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.
2. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency, or to test interlocks.
3. Interlocks may be prevented from operation only to test, adjust, maintain, and/or rearrange equipment provided a clear indication of such condition is made at the control panel. This subparagraph does not authorize the operation of a particle accelerator with the high radiation area warning devices incapable of proper operation.
4. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:
 - (i) authorized in writing by the radiation safety committee or the radiation safety officer;
 - (ii) recorded in a permanent log and a notice posted at the accelerator control console; and
 - (iii) terminated as soon as possible.
5. No individual shall be permitted to enter an area, the access of which is controlled by interlocks, while such interlocks are prevented from operation, to test, adjust, maintain, and/or rearrange equipment and/or parts of the particle accelerator unless such individual is utilizing appropriate personnel monitoring equipment which will give an audible indication when a dose-rate of 25 millirads per hour is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to that required elsewhere in these rules.

(5) Operator Training.

- (a) No registrant shall permit any person to act as an operator as defined in this Rule 420-3-26-.09 until such person;
 - 1. Has been instructed in the subjects outlined in Appendix A of this Rule 420-3-26-.09 and shall have demonstrated understanding thereof;
 - 2. Has received copies of and instruction in the rules contained in this Rule 420-3-26-.09 and the applicable section of Rule 420-3-26-.03, Agency Notice of Registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;
 - 3. Has demonstrated competence to use the particle accelerators, related equipment, and survey instruments which will be employed in his assignment.
 - (b) Each registrant shall maintain records that document the training of each accelerator operator as required by this rule.
- (6) **Operating and Emergency Procedures.** A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel. These operating and emergency procedures shall include instructions in at least the following:
- (a) The use of particle accelerators such that no person is likely to be exposed to radiation doses in excess of the limits established in Rule 420-3-26-.03 "Standards for Protection Against Radiation";
 - (b) Methods and occasions for conducting radiation surveys;
 - (c) Methods for controlling access to high radiation areas;
 - (d) Methods and occasions for locking the control panel of the particle accelerators;
 - (e) Personnel monitoring and the use of personnel monitoring equipment;
 - (f) Minimizing exposure of persons in the event of an accident;
 - (g) The procedures for notifying proper persons in the event of an accident; and
 - (h) Maintenance of records.
- (7) **Tests and Surveys.**

- (a) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed 3 months.
- (b) A radiation protection survey shall be performed and documented by a qualified expert, acceptable to the Agency, when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.
- (c) Any interlock which has been bypassed or otherwise prevented from operation shall be tested to determine it is functioning properly immediately upon its return to normal use.
- (d) The registrant shall retain records of the tests specified in subparagraphs (a), (b), and (c) for inspection by the Agency for two years.
- (e) A survey shall be made of each radiation area upon the initial entry by personnel into these areas following the operation of the particle accelerator. The registrant shall not be required to make a record of the survey required by this subparagraph.

(8) Therapeutic Particle Accelerator Installations.

(a) Operation.

- 1. No individual who receives occupational doses of radiation shall be in the room during irradiation unless he is the patient. No other individual shall be there except when it is clinically necessary.
- 2. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.
- 3. The operator shall have at the control panel a copy of the emergency procedures which shall include instructions for;
 - (i) Turning off the accelerator beam;
 - (ii) Removing the patient from the treatment room;
 - (iii) Securing the room against unauthorized entry; and,
 - (iv) Notifying the responsible physicians and/or radiation safety officer.
- 4. Users of particle accelerators for the treatment of humans shall not be required to have surveys made as required by 420-3-26-.09(7)(e), provided

all interlocks and warning lights are operational and functional.

(b) Equipment

1. Leakage Radiation to the Patient Area

(i) New equipment shall meet the following requirements:

- I.** For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter, or normal treatment distance, and outside the maximum useful beam size, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.
- II.** For each system, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in 420-3-26-.09(8)(b)1.(i)I for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Agency.

(ii) Existing equipment shall meet the following requirements:

- I.** For operating conditions producing maximum leakage radiation, the absorbed dose in rads (grays) due to leakage radiation, excluding neutrons, at any point in a circular plane of 2 meters radius centered on a perpendicular to the central axis of the beam 1 meter from the virtual source, and outside the maximum size useful beam, shall not exceed 0.1 percent of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular

plane. Measurements shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified.

- II. For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 420-3-26-.09(8)(b)1.(i)I. for the specified operating conditions. Records on radiation leakage shall be maintained for inspection by the Agency.

2. **Leakage Radiation Outside the Patient Area (New Equipment Only)**

- (i) The absorbed dose in rads (grays) due to leakage radiation except in the area specified in 420-3-26-.09(8)(b)1.(i)I., when measured at any point 1 meter from the path of the charged particle, before the charged particle strikes the target or window, shall not exceed 0.1 percent for x-ray leakage nor 0.05 percent for neutron leakage of the maximum absorbed dose in rads (grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in 420-3-26-.09(8)(b)1(i)I.
- (ii) The registrant shall determine or obtain from the manufacturer, the actual leakage radiation existing at the positions specified in 420-3-26-.09(8)(b)2(i) for specified operating conditions. Radiation measurements excluding neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters. Neutron measurements shall be averaged over an area up to, but not exceeding, 200 square centimeters.

3. **Beam Limiting Devices.** Adjustable or interchangeable beam limiting devices shall be provided. Such devices shall transmit no more than 5 percent of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement.

4. **Filters**

- (i) Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

- (ii) If the absorbed dose rate data required by 420-3-26-.09(8)(b)16 relates exclusively to operations with a field-flattening or beam scattering filter in place, such filter shall be removable only by the use of tools.
 - (iii) For new equipment which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering filters:
 - I. irradiation shall not be possible until a selection of a filter has been made at the treatment control panel;
 - II. an interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;
 - III. a display shall be provided at the treatment control panel showing the filter(s) in use; and
 - IV. an interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.
5. **Beam Quality.** The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

- (i) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table I. Linear interpolation shall be used for values not stated.

Table I

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

- (ii) Compliance 420-3-26-.09(8)(b)5.(i) shall be determined using:
- I. a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and perpendicular to the central axis of the beam;
 - II. the largest field size available which does not exceed 15 by 15 centimeters; and
 - III. a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.
- (iii) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table II. Linear interpolation shall be used for values not stated.

Table II

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

- (iv) Compliance with 420-3-26-.09(8)(b)5(iii) shall be determined by measurements made:
- I. within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;
 - II. using a phantom whose size and placement meet the requirements of 420-3-26-.09(8)5(ii);

- III. after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and
 - IV. using the largest field size available which does not exceed 15 by 15 centimeters.
 - (v) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding scattered neutron radiation, for specified operating conditions.
6. **Beam Monitors.** All therapy systems shall be provided with radiation detectors in the radiation head.
- (i) New equipment shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.
 - (ii) Existing equipment shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.
 - (iii) The detector and the system into which that detector is incorporated shall meet the following requirements:
 - I. Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.
 - II. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.
 - III. Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.
 - IV. For new equipment, the design of the dose monitoring systems shall assure that:
 - A. The malfunctioning of one system shall not affect the correct functioning of the second system; and
 - B. The failure of any element common to both systems which could affect the correct function of both systems shall

terminate irradiation.

- V. Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:
- A. maintain a reading until intentionally reset to zero;
 - B. have only one scale and no scale multiplying factors;
 - C. utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an over dosage of radiation, the absorbed dose may be accurately determined; and
 - D. in the event of power failure, the dose monitoring information required in 420-3-26-.09(8)(b) 6.(iii)V displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.
7. **Beam Symmetry.** In new equipment inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.
8. **Selection and Display of Dose Monitor Units,**
- (i) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.
 - (ii) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until it is reset manually for the next irradiation.
 - (iii) After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before a subsequent treatment can be initiated.

- (iv) For new equipment, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.
9. **Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.**
- (i) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.
 - (ii) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent, or 40 dose monitor units, above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 - (iii) For new equipment, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent, or 25 dose monitoring units, above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.
 - (iv) For new equipment, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.
10. **Interruption Switches.** It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.
11. **Termination Switches.** It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.
12. **Timer.**
- (i) A timer which has a display shall be provided at the treatment control

- panel. The timer shall have a preset time selector and an elapsed time indicator.
- (ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.
 - (iii) For new equipment after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.
 - (iv) The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.
13. **Selection of Radiation Type.** Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:
- (i) Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.
 - (iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - (iv) An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.
 - (v) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.
 - (vi) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.
14. **Selection of Energy.** Equipment capable of generating radiation beams of different energies shall meet the following requirements:

- (i) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - (iii) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.
 - (iv) For new equipment, an interlock system shall be provided to terminate irradiation if the energy of the electrons striking the x-ray target, or electron window, deviates by more than 20 percent, or 3 MeV, whichever is smaller, from the selected nominal energy.
15. **Selection of Stationary Beam Therapy or Moving Beam Therapy.** Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:
- (i) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.
 - (ii) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.
 - (iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.
 - (iv) The mode of operation shall be displayed at the treatment control panel.
 - (v) For new equipment, an interlock system shall be provided to terminate irradiation if:
 - I. movement of the gantry occurs during stationary beam therapy, or
 - II. movement of the gantry stops during moving beam therapy unless such stoppage is a pre-planned function.

- (vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement.
 - I. For new equipment, an interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.
 - II. For new equipment, where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.
 - (vii) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 420-3-26-.09(8)(b)9.
16. **Absorbed Dose Rate.** For new equipment, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:
- (i) The dose monitor unit rate shall be displayed at the treatment control panel.
 - (ii) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.
17. **Location of Virtual Source and Beam Orientation.** The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:
- (i) The x-ray target or the virtual source of x-rays; and

- (ii) The electron window or the virtual source of electrons if the system has electron beam capabilities.

18. **System Checking Facilities.** Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.
19. **Exemption.** Users of particle accelerators for the treatment of humans shall not be required to have portable radiation monitoring equipment as required by 420-3-26-.09(4)(d)12., provided all interlocks and warning lights are operational and functional.

(c) **Facility**

1. **Viewing Systems.** Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.
2. **Aural Communications.** Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.
3. **Exemption.** A particle accelerator used only for the treatment of humans shall not be required to have an audible warning device within the treatment room as required by 420-3-26-.09(4)(d)8.

(d) **Surveys**

1. All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, a qualified expert, as defined in 420-3-26-.01(2)(a)77. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.
2. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be transmitted by the registrant to the

Agency within 30 days of receipt of the report.

3. The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of any applicable rules.

(e) Calibrations

1. The calibration of systems subject to this rule shall be performed in accordance with the protocol published by the American Association of Physicists in Medicine, or a user submitted protocol having the prior approval of the Agency, before the system is first used for irradiation of patients and thereafter at time intervals which do not exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.
2. The calibration shall be performed under the direct supervision of a teletherapy physicist, who meets the requirements in 420-3-26-.07(74), and is named on the registration, or meets the requirements of 420-3-26-.08(8)(f), or is named on an Agency Particle Accelerator Service Registration, and who is physically present at the facility during the calibration.
3. Calibration radiation measurements required by 420-3-26-.09(8)(e) shall be performed using a dosimetry system:
 - (i) having a calibration factor for cobalt-60 gamma rays traceable to a national standard;
 - (ii) which has been calibrated within the previous 2 years and after any servicing that may have affected its calibration;
 - (iii) which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and
 - (iv) which has had constancy checks performed on the system as specified by a teletherapy physicist.
4. Calibrations shall be in sufficient detail that the absorbed dose at a reference point in soft tissue may be calculated to within an uncertainty of 5 percent.
5. The calibration of the teletherapy beam shall include but not be limited to the following determinations:

- (i) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depth.
 - (ii) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with the therapy beam.
 - (iii) The uniformity of the radiation field and any dependency upon the direction of the useful beam.
 - (iv) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.
 - (v) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.
6. Records of calibration measurements required by 420-3-26-.09(8)(e)1. and dosimetry system calibrations required by 420-3-26-.09(8)(e)3. shall be maintained for 5 years after completion of the full calibration.
 7. A copy of the latest calibration performed pursuant to 420-3-26-.09(8)(e)1 shall be available in the area of the control panel.
- (f) **Visiting Teletherapy Physicist.** A registrant may permit any visiting authorized teletherapy physicist to perform testing and calibration on the particle accelerators on a temporary basis, not to exceed 60 days in a calendar year, if:
1. The visiting teletherapy physicist has the prior written approval of the licensee's management and, if the accelerator is at an institution, the institution's Radiation Safety Committee; and
 2. The registrant has a copy of an Agency registration or Agency teletherapy license that identifies the visiting authorized teletherapy physicist by name as an approved teletherapy physicist.
- (g) **Spot Checks.** Spot checks shall be performed on all systems subject to 420-3-26-.09

that are utilized to treat humans. Such spot checks shall meet the following requirements:

1. The spot-check procedures shall be in writing and shall have been developed by a teletherapy physicist, shall have been submitted to the Agency, and shall have received Agency approval prior to implementation.
2. If a teletherapy physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a teletherapy physicist within 35 days. If any significant changes, as defined by the registrant's spot check procedures, are observed the teletherapy physicist shall be contacted immediately.
3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.
4. At intervals not to exceed 1 week, spot checks shall be made of absorbed dose measurements at a typical treatment depth in a phantom. At intervals not to exceed one month, spot checks shall be made of absorbed dose measurements at no less than two depths in a phantom.
5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.
6. The cause for a parameter exceeding a tolerance set by the teletherapy physicist shall be investigated and corrected before the system is used for patient irradiation.
7. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot-check procedures, the system shall be recalibrated as required in 420-3-26-.09(8)(e).
8. Records of spot-check measurements and of any corrective actions taken shall be maintained by the registrant for a period of 3 years after completion of the spot-check measurements.
9. Where a spot check involves a radiation measurement, such measurement shall be obtained using a measurement system satisfying the requirements of 420-3-26-.09(8)(e)3 or a measurement system which has been intercompared

within the previous year with a system meeting those requirements.

(h) **Documentation of Treatments.**

1. Each registrant shall obtain a written prescription from an authorized user for every human to be treated before using radiation to treat said human. The written prescription shall at a minimum specify the type of radiation and the radiation absorbed dose to be delivered to a specific location over a specified number of treatments.
2. For each individual being treated a treatment plan shall be made by, or under the supervision of, the authorized user or a teletherapy physicist and shall be approved by the authorized user. The treatment plan shall specify the methodology to be utilized to deliver the written prescription.
3. At the completion of each administration, the individual operator delivering the treatment shall at a minimum indicate the absorbed dose delivered and the date of treatment on the treatment plan accompanied by their initials or signature along with a notation of any abnormalities, or unusual occurrences that may have occurred.
4. Each treatment plan shall be reviewed at least once each week or after every five consecutive treatments to ensure that treatments are being delivered according to the plan.
5. All modifications or revisions to the treatment plan shall be approved by an authorized user prior to implementation. Approval of which shall be documented by the authorized user's initials or signature.

(i) **Visiting Authorized User** A registrant may permit any visiting authorized user to use the particle accelerator for medical use under the terms of the registration for 60 days each calendar year if:

1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee; and
2. The registrant has a copy of an Agency registration that identifies the visiting authorized user by name as an authorized medical user of a particle accelerator.

(j) **Records and Reports of Misadministration.**

1. When a misadministration, as defined by 420-3-26-.09 (2)(q), occurs the registrant shall notify the Agency, the affected patient's referring physician, and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications must be made within 24 hours after the registrant discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the registrant shall not delay medical care for the patient because of this.

2. Within 15 days after an initial misadministration notification to the Agency, the licensee shall report, in writing, to the Agency and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative or guardian if either was previously notified by the licensee under 420-3-26-.09(8)(j)1. The written report must include:
 - (i) The Registrant's name;
 - (ii) The referring physician's name;
 - (iii) A brief description of the event;
 - (iv) The effect on the patient;
 - (v) The action taken to prevent a recurrence;
 - (vi) Whether the registrant informed the patient or the patient's responsible relative or guardian; and
 - (vii) If not, why not.

3. Each registrant shall retain a record of each misadministration for 10 years. The record must contain;
 - (i) The names of all individuals involved in the event including the physician, allied health personnel, the patient, and the patient's referring physician,

- (ii) The patient's social security number or identification number if one has been assigned,
 - (iii) A brief description of the event,
 - (iv) The effect on the patient, and
 - (v) The action taken, if any, to prevent recurrence.
4. Aside from the notification requirement, nothing in 420-3-26-.09 (8)(j) shall affect any rights or duties of registrants, and physicians in relation to each other, patients, or responsible relatives or guardians.

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Authority: §§22-14-4, 22-14-7, and 22-14-8, Code of Alabama, 1975.

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420-3-26-.09

APPENDIX A

INSTRUCTION FOR OPERATORS

- I. Fundamentals of Radiation Safety
 - A. Characteristics of alpha, beta, gamma, neutrons, and x-radiation
 - B. Units of radiation dose (mrem) and quantity of radioactivity (curie)

- C. Biological effects of radiation
 - D. Methods of controlling radiation dose
 - 1. Working time
 - 2. Working distance
 - 3. Shielding
- II. Radiation Detection Instrumentation to be Used
- A. Use of radiation survey instruments
 - 1. Operation
 - 2. Calibration
 - 3. Limitations
 - B. Survey Techniques
 - 1. Methods of surveys
 - 2. Records which must be made and retained
 - C. Use of personnel monitoring equipment
- III. Operation and Control of Particle Accelerators
- IV. The Requirements of State Regulations
- V. The Registrant's Written Operating and Emergency Procedures

420-3-26-.10

NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS**(1) Purpose and Scope.**

This Rule 420-3-26-.10 establishes requirements for notices, instructions, and reports by licensees or registrants to individuals participating in registered or licensed activities and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and rules, orders, and licenses issued thereunder regarding radiological working conditions. The sections in this Rule 420-3-26-.10 apply to all persons who receive, possess, use, own or transfer material licensed by or registered with the Agency pursuant to the rules in Rules 420-3-26-.02, 420-3-26-.03, 420-3-26-.05, and 420-3-26-.08.

(2) Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

1. The rules in this Rule 420-3-26-.10 and Rule 420-3-26-.03;
2. The license, Notice of Registration, conditions or documents incorporated into the license by reference and amendments thereto;
3. The operating procedures applicable to work under the license or registration;
4. Any notice of violation involving radiological working conditions; or order issued pursuant to Rules 420-3-26-.02, 420-3-26-.05, or 420-3-26-.08 and any response from the licensee or registrant.

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

(c) Agency Form X "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area or is otherwise required by these rules.

- (d) Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.
 - (e) Agency documents posted pursuant to paragraph (a)4, of this section shall be posted within 2 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within 2 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 5 working days or until action correcting the violation has been completed, whichever is later.
- (3) **Instructions to Workers.** All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the unrestricted area; shall be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Agency rules and licenses for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee or registrant any conditions which may lead to or cause a violation of Agency rules and the licenses or unnecessary exposure to radiation or radioactive material; shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to 420-3-26-10(4). The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.
- (4) **Notification and Reports to Individuals.**
- (a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to Agency rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Agency rules. Each notification and report shall be in writing, include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under Chapter 420-3-26, Radiation Control, Rule 420-3-26-10. You should preserve this report for future reference."

- (b) Each licensee or registrant shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 420-3-26-.03(46).
 - (c) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formally engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to Rule 420-3-26-.03(18) of these rules. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.
 - (d) When a licensee or registrant is required pursuant to 420-3-26-.03(53) to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.
 - (e) At the request of a worker who is terminating employment during the current year with the licensee or registrant in work involving radiation dose , or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's facility in that calendar year, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at the time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.
- (5) **Presence of Representatives of Licensees or Registrants and Workers During Inspections.**

- (a) Each licensee or registrant shall afford to the Agency at all reasonable times an opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.
 - (b) During an inspection, Agency inspectors may consult privately with workers as specified in 420-3-26-.10(6). The licensee or registrant may accompany Agency inspectors during other phases of an inspection.
 - (c) If, at any time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the worker's representative an opportunity to accompany the inspectors during the inspection of physical working conditions.
 - (d) Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 420-3-26-.10(3).
 - (e) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspector.
 - (f) With approval of the licensee or registrant and the worker's representative an individual who is not routinely engaged in work under control of the licensee or registrant, for example a consultant to the licensee or registrant or to the worker's representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.
 - (g) Notwithstanding the other provisions of this rule, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the worker's representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.
- (6) **Consultation with Workers During Inspections.**
- (a) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Agency rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

- (b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, these rules, or license or registration condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 420-3-26-.10(7)(a).
- (c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to 420-3-26-.10(3).

(7) **Requests by Workers for Inspections.**

- (a) Any worker or representative of workers who believes that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.
- (b) If, upon receipt of such notice, the State Health Officer or the Director of the Division of Radiation Control determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this Section need not be limited to matters referred to in the complaint.
- (c) No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this Rule 420-3-26-.10.

(8) **Inspections Not Warranted; Informal Review.**

- (a) If the Director of the Division of Radiation Control determines, with respect to a complaint under 420-3-26-.10(7), that an inspection is not warranted because there

are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the State Health Officer who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the State Health Officer who will provide the complainant with a copy of such statements by certified mail. Upon the request of the complainant, the State Health Officer may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the State Health Officer shall affirm, modify, or reverse the determination of the Director of the Division of Radiation Control and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefore.

- (b) If the Director of the Division of Radiation Control determines that an inspection is not warranted because the requirements of 420-3-26-.10(7)(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 420-3-26-.10(7)(a).

Authority: §§ 22-14-4, 22-14-6, 22-14-7, and 22-14-8, also 22-2-2, Code of Alabama, 1975.

History: New 5-21-75; Revised 1-18-78; Recodified 6-11-78; Revised and Repromulgated 10-21-81; Repromulgated effective 12-31-83. Revised and Repromulgated effective 1-31-90. Revised and Repromulgated April 22, 1994.

Author: Kirksey E. Whatley, Director, Division of Radiation Control, Bureau of Health Care Standards, Alabama Department of Public Health.

420-3-26-.11

RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

- (1) **Purpose and Scope.** This rule 420-3-26-.11 provides special requirements for analytical x-ray equipment; provided, however, that nothing in this Rule shall apply to x-ray equipment used to detect, measure, gauge, or control the density, level, interface location, thickness of materials, or equipment used for industrial radiography as defined in Rule 420-3-26-.04, or sources of radiation used in the healing arts. The requirements of this Rule are in addition to, and not in substitution for, applicable requirements in other Rules. Note that Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.05, and 420-3-26-.10 also apply to analytical x-ray users.
- (2) **Definitions.**
 - (a) "Analytical x-ray equipment" means any device which utilizes x-rays for the purpose of examining the microstructure of materials. This includes all types of x-ray diffraction, fluorescence, and spectrographic analysis equipment.
 - (b) "Analytical x-ray system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.
 - (c) "Fail-safe characteristics" means a design feature which causes port beam shutters to close, or otherwise prevents emergence of the primary beam, upon a failure of a safety or warning device.
 - (d) "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.
 - (e) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal

operation.

- (f) "Positive visual warning light" means a warning light which has redundant lights so that a single failure will not prevent the warning light from functioning.
- (g) "Primary beam" means ionizing radiation which passes through the aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.
- (h) "Unattended operation" means any operation in which the analytical x-ray system is generating x-rays and an operator trained in accordance with 420-3-26-.11(6) of this Rule 420-3-26-.11 is not physically present in the area sufficiently near the local components to prevent any operation which could cause an individual to exceed the limits given in 420-3-26-.03(6) of these Rules.

(3) **Equipment Requirements**

- (a) **Safety Device.** A device such as a guard or interlock 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. Prior to operation a registrant may apply to the Agency for an exemption from the requirements of a safety device. Such application shall include 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. A positive visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located;
 - (i) near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; and
 - (ii) at a conspicuous location that may be visible at all local components; and

2. Open-beam configurations shall be provided with a readily discernible indication of;
 - (i) x-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or
 - (ii) shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

Warning devices shall be labeled so that their purpose is easily identified. On equipment transferred after January 1, 1977, warning devices shall have fail-safe characteristics.

- (c) **Ports.** Unused ports on radiation source housings shall be secured in the closed position in the 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 X-RAYS WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube and at a conspicuous location if the radiation source is an z-ray tube.
- (e) **Shutters.** On open-beam configurations transferred after January 1, 1977, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a shielding coupling has been connected to the port.
- (f) **Radiation Source Housing.** Each x-ray tube housing shall be constructed so that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mRem in one hour at any specified tube rating.

- (g) **Generator Cabinet.** Each x-ray generator, including high voltage rectifiers, transformers, and amplifiers, shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.
- (h) **Unattended Operation.** Each entrance to a room containing analytical x-ray equipment in unattended operations shall have a warning light with the words "X-RAY ON" or words having a similar intent. In addition, for an open-beam configuration unattended operation, there shall be a device to shut off analytical x-ray equipment upon the entrance of any person not trained in accordance with 420-3-26-.11(6) of this Rule.

(4) **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 420-3-26-.03(6) of these rules. These levels shall be met at any specified tube rating.
- (b) **Surveys.** Radiation surveys with appropriate radiation detection devices as required by 420-3-26-.03(9), of all operable analytical x-ray systems sufficient to show compliance with paragraph 420-3-2-26.11(4)(a) shall be performed quarterly and;
 - 1. Upon installation of the equipment;
 - 2. Following any change in the initial arrangement, number, or type of local components in the system;
 - 3. Following any maintenance requiring the disassembly or removal of a local component in the system;
 - 4. During the performance of maintenance and alignment procedures require the presence of the primary x-ray beam when any local component in the system is disassembled or removed;

5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and
 6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 420-3-26-.03(2).
- (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.
- (5) **Operating Requirements.**
- (a) **Procedures.** Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the individual designated to the Agency as the Radiation Safety Officer.
 - (b) **Bypassing.** No person shall bypass a safety device unless such person has obtained the approval of the designated Radiation Safety Officer. When a safety device 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.
- (6) **Personnel Requirements.**
- (a) **Instruction.** No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instructions 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 and safety devices 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. Biological effects of radiation, including symptoms of acute localized exposure; and
5. Proper procedures for reporting an actual or suspected exposure.

(b) **Personnel Monitoring.** Finger or wrist dosimetric devices shall be provided to and shall be used by:

1. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device, and
2. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of the primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

In reporting dose values, due consideration should be given to the energy of the x-ray beam and the size of the x-ray beam.

Authority: §§ 22-14-4, 22-14-7, and 22-14-8, Code of Alabama, 1975.

History: New 9-15-76; Recodified 6-11-78; Revised and Repromulgated 10-21-81; Repromulgated effective 12-31-83. Revised and Repromulgated effective 1-31-90.

420-3-26-.12

**RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS
AND SUBSURFACE TRACER STUDIES**

- (1) **Purpose.** This Rule establishes radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, subsurface tracer studies, and fishing operations. The requirements of this Rule are in addition to, and not in substitution for, the requirements of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.10, and 420-3-26-.13 of these rules.
- (2) **Scope.** This Rule applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers, or subsurface tracer studies. This Rule also applies during fishing operations that are performed to recover lost or lodged radioactive sources or devices from a well.
- (3) **Definitions.** As used in this Rule, the following definitions apply:
 - (a) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.
 - (b) "Fishing or fishing operations" means those activities associated with the recovery from downhole of a well devices or sources containing radioactive materials which has become lodged and/or disconnected from the equipment normally connecting the source or device with the surface.
 - (c) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.
 - (d) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at the well site.
 - (e) "Logging tool" means a device used subsurface to perform well-logging.
 - (f) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.
 - (g) "Personal supervision" means guidance and instruction by the supervisor who is physically present at the job

site and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

- (h) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.
 - (i) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.
 - (j) "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.
 - (k) "Temporary job site" means a location to which radioactive materials have been dispatched to perform wire-line service operations or subsurface tracer studies.
 - (l) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.
 - (m) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.
 - (n) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.
 - (o) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.
- (4) Prohibition. No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner that identifies who will assure that:

- (a) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made;
- (b) In the event a decision is made to abandon the sealed source downhole, the requirements of 420-3-26-.12(25) shall be met and implemented within 30 days,
- (c) The radiation monitoring required in 420-3-26-.12(25)(b) will be performed,
- (d) If the environment, any equipment to be used by non-licensed individuals, or personnel who are contaminated with licensed radioactive material, all are decontaminated before release from the site or released for unrestricted use, and
- (e) Persons performing fishing operations will have had at least twelve months experience in tool recovery operations. Note, this experience does not necessarily have to be with radioactive devices or sources and the fishing company will release all recovered radioactive material to the logging supervisor as soon as practicable.

Equipment Control

- (5) **Limits on Levels of Radiation.** Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Rule 420-3-26-.02 and the dose limitation requirements of Rule 420-3-26-.03 of these rules are met.
- (6) **Storage Precautions.**
 - (a) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.
 - (b) Sources of radiation shall be stored in a manner which will minimize danger from explosion and/or fire.
- (7) **Transport Precautions.** Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(8) Radiation Survey Instruments.

- (a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each temporary job site to make physical radiation surveys as required by this Rule and by 420-3-26-.03(9) of these rules. Instrumentation shall be capable of measuring 0.1 milliroentgen per hour through at least 50 milliroentgens per hour.
- (b) Each radiation survey instrument shall be calibrated:
 - 1. At intervals not to exceed 6 months and after each instrument servicing;
 - 2. At energies and radiation levels appropriate for use; and
 - 3. So that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.
- (c) Calibration records shall be maintained for a period of 2 years for inspection by the Agency.

(9) Leak Testing of Sealed Sources.

- (a) **Requirements.** Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency for 6 months after the next required leak test is performed or until transfer or disposal of the sealed source.
- (b) **Method of Testing.** Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample.
- (c) **Interval of Testing.** Each sealed source of radioactive material shall be tested at intervals not to exceed 6

months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

- (d) **Leaking or Contaminated Sources.** If the test reveals the presence of 0.005 microcurie or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these rules. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the Agency.
- (e) **Exemptions.** The following sources are exempted from the periodic leak test requirements of this section:
1. Hydrogen-3 sources;
 2. Sources of radioactive material with a half-life of 30 days or less;
 3. Sealed sources of radioactive material in gaseous form;
 4. Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less; and
 5. Sources of alpha-emitting radioactive material with an activity of 10 microcuries or less.
- (10) **Quarterly Inventory.** Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 2 years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.
- (11) **Utilization Records.** Each licensee or registrant shall maintain current records, which shall be kept available for inspection by the Agency for 2 years from the date of the recorded event, showing the following information for each source of radiation:

- (a) Make, model number, and a serial number or a description of each source of radiation used;
 - (b) The identity of the well-logging supervisor or field unit to whom assigned;
 - (c) Locations where used and dates of use; and
 - (d) In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.
- (12) Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.
- (a) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations shall be certified by the manufacturer, or other testing organization acceptable to the Agency, to meet the following minimum criteria:
 - 1. Be of doubly encapsulated construction;
 - 2. Contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical, and
 - 3. Has been prototype tested in accordance with the requirements of the U.S. Nuclear Regulatory Commission as provided in 10CFR39.41(a)(3)⁶⁹.
 - (b) For sealed sources, except those containing radioactive material in gaseous form, acquired after December 31, 1984, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of (a) above, the sealed source shall not be put into use until such determinations and testing have been performed.
 - (c) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after December 31, 1983 shall be certified by the manufacturer, or other testing organization acceptable to the Agency, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N542, "Sealed Radioactive Sources Classification" in effect on December 31, 1983.

⁶⁹See footnote 2. in 420-3-26-.01.

- (d) Certification documents shall be maintained for inspection by the Agency for a period of 2 years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the Agency authorizes disposition.

(13) Labeling.

- (a) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

**DANGER 69
RADIOACTIVE**

This labeling shall be on the smallest component transported as a separate piece of equipment.

- (b) Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

**DANGER 70
NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)**

(14) Inspection and Maintenance.

- (a) Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper label and physical conditions. Records of inspection and maintenance shall be maintained for a period of 2 years for inspection by the Agency.
- (b) If any inspection conducted pursuant to (a) above reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

70 Or CAUTION

- (c) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State.
- (14A) Use of a Sealed Source in a Well Without a Surface Casing. A licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved for each well by the Agency.

Requirements for Personnel Safety

(15) Training Requirements.

- (a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this Rule until such individual has:

1. Received, in a course recognized by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State. Instruction in the subjects outlined in Appendix A of this Rule and demonstrated an understanding thereof;
2. Read and received instruction in the rules contained in this part and the applicable sections of Rules 420-3-26-.01, 420-3-26-.03, and 420-3-26-.10, or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures, and demonstrated an understanding thereof; and
3. Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

- (c) The licensee or registrant shall maintain employee training records for inspection by the Agency for 2 years following termination of employment.

(16) Operating and Emergency Procedures. The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

- (a) Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in

Rule 420-3-26-.03 of these rules;

- (b) Methods and occasions for conducting radiation surveys;
 - (c) Methods and occasions for locking and securing sources of radiation;
 - (d) Personnel monitoring and the use of personnel monitoring equipment;
 - (e) Transportation to temporary job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;
 - (f) Minimizing exposure of individuals in the event of an accident;
 - (g) Procedure for notifying proper personnel in the event of an accident;
 - (h) Maintenance of records;
 - (i) Inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;
 - (j) Procedure to be followed in the event a sealed source is lodged downhole;
 - (k) Procedures to be used for picking up, receiving, and opening packages containing radioactive material;
 - (l) The monitoring of any well discharge line for contamination by the logging supervisor;
 - (m) Actions to be taken in the event of a ruptured sealed source to prevent the spread of contamination and to minimize the inhalation and/or ingestion of radioactive material.
- (17) Personnel Monitoring.
- (a) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual.

- (b) Personnel monitoring records shall be maintained for inspection until the Agency authorizes disposition.

**Precautionary Procedures in Logging and Subsurface
Tracer Operations**

- (18) **Security.** During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in Rule 420-3-26-.01 of these Rules.
- (19) **Handling Tools.** The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.
- (20) **Subsurface Tracer Studies.**
 - (a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.
 - (b) No licensee shall cause the injection of radioactive material for subsurface tracer studies without prior authorization from the Alabama Oil and Gas Board.
- (21) **Particle Accelerators.** No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 420-3-26-.03(2) and 420-3-26-.03(6) of these rules as applicable, are met.

Radiation Surveys and Records

- (22) **Radiation Surveys.**
 - (a) Radiation surveys and/or calculations shall be made and recorded for each area where radioactive materials are stored.
 - (b) Radiation surveys and/or calculations shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys and/or calculations shall include each source of radiation or combination of sources to be transported in the vehicle.

- (c) After removal of the sealed source from the logging tool and before departing the job site, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.
 - (d) Radiation surveys shall be made and recorded at the job site or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.
 - (e) Records required pursuant to (a) through (d) above, shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the Agency for 2 years after completion of the survey.
- (23) Documents and Records Required at Field Stations. Each licensee or registrant shall maintain, for inspection by the Agency, the following documents and records for the specific devices and sources used at the field station:
- (a) Appropriate license, certificate of registration, or equivalent document;
 - (b) Operating and emergency procedures;
 - (c) Applicable rules;
 - (d) Records of the latest survey instrument calibrations pursuant to 420-3-26-.12(8);
 - (e) Records of the latest leak test results pursuant to 420-3-26-.12(9);
 - (f) Quarterly inventories required pursuant to 420-3-26-.12(10);
 - (g) Utilization records required pursuant to 420-3-26-.12(11);
 - (h) Records of inspection and maintenance required pursuant to 420-3-26-.12(14); and
 - (i) Survey records required pursuant to 420-3-26-.12(22).

- (24) Documents and Records Required at Temporary Job Sites. Each licensee or registrant conducting operations at a temporary job site shall have the following documents and records available at that site for inspection by the Agency:
- (a) Operating and emergency procedures;
 - (b) Survey records required pursuant to 420-3-26-.12(22) for the period of operation at the site;
 - (c) Evidence of current calibration for the radiation survey instruments in use at the site; and
 - (d) When operating in the State under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s).
- (25) Notification of Incidents, Abandonment, and Lost Sources.
- (a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Rule 420-3-26-.03 of these rules.
 - (b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:
 1. Monitor at the surface for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations; and
 2. Notify the Agency immediately by telephone. Such notice shall:
 - (i) Indicate the well location,
 - (ii) Describe the experience of the fishing personnel and the procedures to be followed by the fishing personnel to assure that the radioactive material is not likely to be released, and
 - (iii) The estimated depth of the source.
 - (c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:
 1. Advise the well-operator of these rules and those

of the Alabama Oil and Gas Board, and an appropriate method of abandonment, which shall include:

- (i) The immobilization and sealing in place of the radioactive source with a concrete plug,
 - (ii) The setting of a whipstock or other deflection device, and
 - (iii) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by (d);
2. Notify the Agency by telephone, giving the circumstances of the loss, and obtain approval of the proposed abandonment procedures; and
 3. File a written report with the Agency within 30 days of the abandonment, setting forth the following information:
 - (i) Date of occurrence and a brief description of attempts to recover the source,
 - (ii) A description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form,
 - (iii) Surface location and identification of well,
 - (iv) Results of efforts to immobilize and set the source in place,
 - (v) Depth of the radioactive source,
 - (vi) Depth of the top of the cement plug,
 - (vii) Depth of the well, and
 - (viii) Information contained on the permanent identification plaque.
- (d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque⁷¹ for posting the well or well-bore.

⁷¹ An example of a suggested plaque is shown in Appendix B of this rule 420-3-26-.11.

This plaque shall:

- (i) Be constructed of long-lasting material, such as stainless steel or monel, and
- (ii) Contain the following information engraved on its face:
 - (I) The word "CAUTION",
 - (II) The radiation symbol without the conventional color requirement,
 - (III) The date of abandonment,
 - (IV) The name of the well operator or well owner,
 - (V) The well name and well identification number(s) or other designation,
 - (VI) The sealed source(s) by radionuclide and quantity of activity,
 - (VII) The source depth and the depth to the top of the plug, and
 - (VIII) An appropriate warning, depending on the specific circumstances of each abandonment.⁷²
- (e) The licensee shall immediately notify the Agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

⁷² Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "do not enlarge casing"; or (c) "do not re-enter hole", followed by the words, "before contacting the Radiological Health Branch, Alabama Department of Public Health."

Authority: §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-11,
Code of Alabama 1975.

Author: Aubrey V. Godwin, Director Division of Radiation
Control, Alabama Department of Public Health

History: Adopted effective 12-31-83. Revised and Repromul-
gated effective 1-31-90. Revised Effective 10-1-91

420-3-26-13

ADMINISTRATIVE PROCEDURES

- (1) **Purpose and Scope.** This Rule establishes the administrative procedures for the Agency as the Radiation Control Agency and describes the organization, methods of conducting business, and interpretations as required by the Alabama Administrative Procedures Act.
- (2) **Organization and Method of Conducting Business.**
 - (a) **Organization.** The State Board of Health is designated in Section 22-14-4, Code of Alabama, 1975 as the State Radiation Control Agency with the State Health Officer as Director. The Director has designated the Division of Radiation Control to implement Chapter 14 of Title 22, Code of Alabama, 1975. The State Health Officer as Director may delegate certain duties to the Division of Radiation Control and its Director. These duties are:
 1. To inspect, process applications to register x-ray facilities, and investigate accidents, incidents, and overexposures as may be required to assure the safe use of x-ray equipment as is defined in these rules.
 2. To inspect, the use of particle accelerators and radioactive material, process applications to register particle accelerators, process applications to license the use of radioactive material(s), and investigate accidents, incidents and overexposures as may be required to assure the safe use of particle accelerators or radioactive materials.
 3. To conduct environmental monitoring around nuclear facilities which have a reasonable potential for releasing radioactive material into the environment.
 4. To develop emergency plans for responding to any radiological emergency in accordance with Memoranda of Understanding and other Agencies.
 5. To respond to, and pursuant to written delegations, issue orders necessary to protect the public health and safety during radiation emergencies, incidents or accidents.
 6. To conduct limited training in the safe use of radiation.
 7. To answer public inquiries, investigate complaints, and provide limited quantities of general information to the public.
 8. To receive, process, and coordinate with other agencies requests for orders for the routing of radioactive material shipments.

9. To determine the compliance of a person's use of radiation as the result of an inspection, investigation, or review of submitted information. This is subject to review and appeal as provided for in this Rule.
10. To issue orders directing compliance with these rules, and when not contested issue orders to suspend, revoke, or modify a license or registration, or sources of radiation.
11. To develop contracts for programs compatible with the Act.
12. To issue orders relating to the routing of radioactive materials as provided for in this Rule.
13. To maintain an index and file of all decisions, opinions, and declaratory rulings issued by the Agency, by subject matter. Copies of these orders are available in the Division of Radiation Control's Office for public review and copying at 25¢ per page.
14. To maintain a file of all licenses, registrations, inspections, investigations and related correspondence for public inspection and copying at 25¢ per page. Certain files may be temporarily unavailable when being used by the Staff or pending determination of compliance or enforcement action. Further, information as determined pursuant to Section 22-14-6(d) Code of Alabama shall not be available for public review or copying.
15. To maintain a list of all forms, statements of policy, instructions, guides, and interpretations available for public review and copying.
16. To maintain copies of all memoranda of understanding or contracts between the Agency and other agencies relating to the radiation program in Alabama, for public inspection and for copying at 25¢ per page.
17. To issue orders suspending a license if the inspection fees are not paid within 45 days of billing the licensee as provided for in the Act.
18. To notify a licensee of any proposed civil penalty as may be determined in accordance to Appendix A of this Rule 420-3-26-.13. Note, the licensee may appeal or provide mitigating information for consideration before a final order is issued.

(b) Applications for Licenses, Registration, or Notice of Registration.

1. All applications for a radioactive materials license shall meet the applicable requirements of Rule 420-3-26-.02 of these rules before being approved. To

assist applicants in preparing their applications, the Agency has prepared instructions and guides which are available on request. In addition, any application for the commercial burial of low-level radioactive wastes must conform with the Agency policy statement, copies of which are available on request. Amendment requests may be submitted by letter but must otherwise meet the requirements of an application prior to approval.

2. All applications for a Notice of Registration shall meet the applicable requirements of Rule 420-3-26-.08 of these rules before being approved. Amendment requests may be submitted by letter but must otherwise meet the requirement of an application prior to approval.
3. All application to register x-ray equipment shall meet the requirements of Rule 420-3-26-.05 of these rules prior to approval. Amendment requests may be by letter but must otherwise meet the requirements for an application prior to approval.
4. Any application may be approved in part, for those proposed activities for which adequate information was supplied. Those proposed portions for which inadequate information was supplied may be approved upon receipt of additional, sufficient information without a reapplication.
5. Any person's application or amendment request which is denied may request a hearing within 30 days of the denial of the application or amendment request in accordance with the hearing procedures of this Rule.
6. Any application or amendment request will be considered abandoned, upon failure of the applicant to supply any additional reasonable information requested to determine whether the application meets the requirements of these rules within 90 days of the written request for supplemental information. This section does not apply if the applicant files for a hearing pursuant to 5 above.
7. Except for the activities listed in 420-3-26-.02(10)(q)4, if the Agency fails to respond to an application by either issuing the appropriate license, amendment, or Notice of Registration; by requesting additional supplemental information; or by denying the request within 90 days of Agency receiving the supplemental information in writing, or the application, if supplemental information was not requested; the applicant may file a petition with the Agency requiring the approval of the request. Such petition only needs to show that the Agency has received, in writing, all of the information requested from the applicant and at least 90 days has elapsed without a request for information and no action has been taken by the Agency. The petition will be granted unless the Agency can show that prior to the filing of the petition,

- (i) the Agency requested in writing sent to the last known address of the applicant, additional information which has not been received,
- (ii) the Agency denied the application, or
- (iii) the construction, testing, or technical studies have not been completed by the Agency.

(3) **Hearings.**

(a) **Rule Making.**

1. In conformance with Section 5 of the Administrative Procedures Act (Act 81-855), the Agency shall adopt its rules and regulations. Any notice regarding the adoption, repeal or amendment of such rules shall include:
 - (i) The terms or substance of the proposed action.
 - (ii) A description of the subject and issues involved if not included in (i).
 - (iii) The address where written comments or statements may be delivered and the last time and date for delivering such statements.
 - (iv) The date, time, and place for oral statements to be made and any conditions pertaining thereto.
 - (v) Who the hearing officer will be if other than the Division Director or Agency Director.
2. **Petitions for Rulemaking.**
 - (i) Any interested person may petition the Agency to issue, amend, or rescind any rule. The petition should be addressed to the Director, Division of Radiation Control, Alabama Department of Public Health, Montgomery, Al. 36130.
 - (ii) Each petition filed under this section shall:
 - (I) Set forth a general solution to the problem or the substance or text of any proposed rule, or amendment or specify the rule which is to be revoked or amended;
 - (II) State clearly and concisely the petitioner's grounds for and interest in the action requested;

- (III) Include a statement in support of the petition which shall set forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific or other data involved which is reasonable available to the petitioner, and such other pertinent information as the petitioner deems necessary to support the action sought. In support of its petition, the petitioner should note any specific cases of which the petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.
- (iii) If it is determined that the petition includes the information required by paragraph (ii) of this section and is complete and is probably needed, the Director Division of Radiation Control or his designee through the Agency Secretary will cause a notice of the petition to be published in the Alabama Administrative Monthly in accordance with the rule making provisions of this Rule, within 60 days.
- (iv) If it is determined by the Director of Division of Radiation Control that the petition does not include the information required by paragraph (ii) of this section, or is incomplete or is not needed to protect the health and safety or not authorized by law, the petitioner will be notified of that determination and the respects in which the petition is deficient and will be accorded an opportunity to submit additional data to correct any deficiency within 90 days of the notification to the petitioner of any deficiency, the petition may be returned to the petitioner without prejudice.
- (v) No hearing or rulemaking will be held on the petition unless the Director of the Division of Radiation Control determines that sufficient reason exists, he will initiate rule-making proceeding as provided in this Rule. In any other case he will deny the petition and will notify the petitioner with a simple statement of denial. The petitioner may appeal the denial pursuant to the appeal provisions of this Rule.

(b) Appeals

1. All orders, determinations, or denials of the Director, Division of Radiation Control, or of any local Health Departments are appealable to the State Health Officer. All initial determinations, orders, or denials of the State Officer as Agency Director are appealable as described in this section. In addition, this Rule provides for certain informal procedures to resolve contested cases.

2. Any request to appeal an order, determination, or denial shall be filed within 30 days of receiving written notice of such order, determination or denial. Such request should be addressed to:

State Health Officer
Alabama Department of Public Health
Montgomery, Alabama 36130-3017
- All appeals should:
 - (i) For each exception, separately numbered; state concisely, without supporting argument the single error of fact or law which is being asserted in that exception and identify with particularly the portion of the decision, determination, order or denial to which the exception is addressed. A brief in support of the exception(s) should accompany the exception(s). Within 10 days of receiving the request, the Division Staff, and any other party, shall file their response to the petition.
 - (ii) All documents filed under this section shall be accompanied by a certificate reflecting service upon all parties to the proceeding.
3. Within 5 business days of receiving the Staff's response the State Health Officer shall issue an order designating:
 - (i) The Hearing Officer and any members of a Hearing Board (such as the Radiation Advisory Board of Health);
 - (ii) The date, time, and place for the start of the hearing;
 - (iii) The issues to be resolved;
 - (iv) And other matters appropriate for such an order, such as contained in Section 12(2) of the Alabama Administrative Procedures Act.
4. The Hearing Officer, or Hearing Board, as appropriate, shall submit their recommendations to the State Health Officer, together with the record of the proceeding as described in Section 12(b) of the Alabama Administrative Procedures Act within 10 business days of the close of the hearing.
5. The State Health Officer after reviewing the record and the recommendations shall issue an order upholding, denying or modifying the matter being appealed within 5 business days of receiving the recommendations described in paragraph (4) above. This order will be the final order of the Agency unless the State Committee of Public Health, sua sponte, elects to review the order within 30 days of its issuance.

(c) Conduct of Hearings

1. All adjudicatory hearings shall be conducted in accordance with 10CFR Part 2 Sections 2.705; 2.706; 2.707; 2.711; 2.712; except (f); 2.713; 2.714; 2.715; 2.716; 2.718 except (b). (h), (i), (k), (l), and (m); 2.719; 2.730; 2.731; 2.732; 2.733; 2.740; 2.741 except (e); 2.742; 2.743; 2.750; except (c); 2.753; and 2.757 as in effect July 1, 1989. All references to the Commission, Atomic Safety and Licensing Board, and Presiding Officer, are to be replaced with the Hearing Officer.
2. Documents shall be filed with the State Health Officer or the Hearing Officer in adjudication subject to this Rule, either by (1) delivery to the office of the State Health Officer, in the RSA Tower, 201 Monroe Street, Montgomery, or (2) U. S. Mail to the State Health Officer, Alabama Department of Public Health, Montgomery, Alabama 36130-3017.
3. All documents offered for filing shall be accompanied by proof of service upon all parties to the proceeding or their attorney of record, the Hearing Officer and Hearing Board members if any.
4. Filing by U. S. Mail will be deemed to be complete as of the time of deposit in the mail with sufficient postage.
5. Parties to all adjudicatory hearing shall consist of the petitioner or appellant, the Division of Radiation Control and such others as may be admitted by the Hearing Officer.
6. Rulemaking and investigatory hearing shall be conducted in accordance with the procedures outlined in the order established in the hearing. The Hearing Officer has the authority to conduct the hearing in an orderly manner and may require the consolidation of statements and close or adjourn the hearing to another day or time in the event the hearing becomes disorderly. In these hearings the Hearing Officer, Hearing Board members, and the Division of Radiation Control may ask questions of witnesses. If appropriate, they may be placed under oath.

(4) Guidance Documents of Division of Radiation Control. From time to time the Division of Radiation Control may prepare instructions, guidance documents, suggested procedures, etc., to assist persons in complying with these rules. These documents are to provide assistance and are not binding on the Board of Health. Further, other methods may be acceptable and will be approved if the rules are otherwise met. The Board of Health's policy for minimum acceptable training, experience and equipment is to be the same as the U. S. Nuclear Regulatory Commission.

(5) The Routing of Radioactive Material Shipments.

- (a) Applications for designating a route shall contain sufficient information to make the assessment and determination required by 49 CFR 171.8 in effect July 1, 1989. Copies of this regulation and the associated U. S. Department of Transportation guide "Guidelines for Selecting preferred Highway Routes for Large Quantity Shipments of Radioactive Materials" are available from the Agency.
 - (b) Upon receiving a routing request (10 copies) with adequate information to make the necessary assessment and determination, when designated by proper delegation of the Agency Director, the Director, Division of Radiation Control shall notify the Alabama Departments of Public Safety, Highway and Emergency Management and any counties and municipalities along the proposed alternate routes of the request.
 - (c) The Agency Director or the Director, Division of Radiation Control shall also cause a notice to be published in a newspaper of general circulation near the routes under consideration. Such notice shall provide for an investigation hearing to be conducted by the Agency Director or the Director, Division of Radiation Control as the Hearing Officer. Such notice shall provide for receiving written comments and shall indicate the date which comments will be received. This date may be modified at the hearing if appropriate.
 - (d) Within 30 days of the end of the written comment period, the Agency Director or the Director, Division of Radiation Control will issue an order with his decision. This order shall briefly detail the basis for the decision. This is appealable as any other initial order by the Agency Director or order or decision of the Director, Division of Radiation Control.
- (6) **Criteria for Determining Enforcement Action.**
- (a) A major continuing goal of the Agency is to assure that ionizing radiation source facilities are constructed and operated with the necessary degree of safety and reliability. Similarly, it is the responsibility of the Agency to assure a corresponding degree of management controls and safety in the licensed materials processes and programs.

The nuclear industry generally recognizes the necessity for improvements in safety as well as the economic advantages that are derived by extending the management techniques and philosophy of safety to the operations of plants and processes. It is essential that all registrants and licensees meet these high standards.

While broad sanctions are available to the Agency in the event they are necessary, the objectives of safety and reliability should generally be achievable through augmented internal management programs.

Results of Agency inspections and investigations of licensed activities have shown that

registrants and licensees have not in all cases complied with regulatory requirements and it has been necessary to take specific enforcement actions commensurate with the violations. This document sets out the criteria for enforcement actions to be taken with respect to future violations of license conditions relating to health and safety, in accordance with the Alabama Regulations for Control of Radiation and Act 582, Regular Session 1963, Title 22, Chapter 14, Code of Alabama, 1975, as amended.

The enforcement actions available to the agency in the exercise of its regulatory responsibilities may be divided into the following four basic types which are applicable to specific enforcement situations:

1. **Non-Compliance Letters**

This is a letter describing the proposed violations and request to reply within usually thirty (30) days. In his reply, the registrant or licensee may:

- (i) Deny any or all violations
- (ii) Indicate what corrective measures have been instituted and their effect.
- (iii) Indicate proposed corrective actions and the date when compliance will be achieved.

2. **Written Notices of Violations**

Enforcement actions may be written notices to registrants or licensees, citing the proposed violations observed during investigations, inspections, or inquiries. This is a formal notice and requires at least a written response.

3. **Civil Penalties.** The Agency has authority to assess a civil penalty of radioactive material licensees in cases where the noncompliance is serious or repeated. Appendix A details how and when the civil penalties are determined and how they may be reduced.

4. **Orders to Cease and Desist; and Orders for Suspension, Modification or Revocation of a License or to Suspend the Activities of a Registrant.**

The Agency has authority to issue orders to "cease and desist," and orders to suspend, modify, or revoke licenses. Such orders are preceded by certain procedural requirements including a written notice of violation to the licensee or registrant providing him with an opportunity to respond as to the corrective measures being taken. In the event the licensee or registrant fails to respond to the notice or to demonstrate that satisfactory corrective action is being

taken, an order to show cause may be issued requiring the licensee or registrant to show why the particular order (either of revocation, or modification or suspension) should not be made effective. In those instances where the health, safety, or interest of employees or to the public so requires or willful violation of the agency's rules is involved, the notice provision may be dispensed with and, in addition, the particular order may be made immediately effective pending further order. In addition to proceeding by way of order, the Agency may also, pursuant to Section 22-14-12, request the Attorney General to obtain an injunction or other court order to enjoin licensees or registrants from violating the Act or any rules or order issued thereunder.

Authority: §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-11, 22-14-12, 22-14-13, 41-22-4, 41-22-5, 41-22-6, 41-22-7, 41-22-9, 41-22-11, 41-22-12, 41-22-13, 41-22-14, 41-22-15, 41-22-16, 41-22-17, 41-22-18, and 41-22-19, Code of Alabama, 1975.

History: Adopted effective 12-31-83. Revised and Repromulgated effective 1-31-90.

Appendix A**General Statement of Policy and Procedure
for
Enforcement Actions**

The following statement of general policy and procedure explains the enforcement policy and procedures of the Agency and its staff in initiating enforcement actions. This statement is applicable to enforcement in matters involving the public health and safety, and the environment.

- (1) **Introduction and Purpose.** The purpose of the Agency enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:
 - (a) Ensuring compliance with Agency rules and license conditions or registration commitments;
 - (b) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;
 - (c) Deterring future violations and occurrences of conditions adverse to environmental quality; and
 - (d) Encouraging improvement of licensee or registrant and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees or registrants who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the Agency expects. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees or registrants who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed or registered activities.

- (2) **Procedural Framework.** Rule 420-3-26-.13 of these rules sets forth the procedures the Agency uses in exercising its enforcement authority. This rule sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 420-3-26-.13(2). This rule provides that the Agency Director or Radiation Control Division Director initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest, in writing, the proposed imposition of a civil penalty. After evaluation of the licensee's response, the Director may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed. The procedure for issuing an order to show cause why a license should not be modified,

suspended, or revoked or why such other action should not be taken is set forth in Rule 420-3-26-.13. The mechanism for modifying a license or registration by order is set forth in the same rule. These sections provide an opportunity for a hearing to the affected licensee. However, the Agency is authorized to make orders immediately effective if the public health, safety or interest so requires.

- (3) **Severity of Violation.** Regulatory requirements¹ have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

- (a) Health Physics;
- (b) Transportation;
- (c) Radioactive Materials Operations;
- (d) Miscellaneous Matters; and
- (e) Emergency Preparedness.

Licensed or registered activities not directly covered by one of the above listed areas, e.g., reciprocity license or registered activities, will be placed in the activity area most suitable in light of the particular violation involved. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public or an individual. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern. Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in nuclear medicine is not directly comparable to that associated with Severity Level I violations in industrial radiography.

While examples are provided in Supplements I through V for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Agency places on a particular type of violation of Agency requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

¹ The term "requirement" as used in this Appendix means a legally binding requirement such as a statute, rule, regulation, license condition, technical specification, or order.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify, to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, i.e., inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (i.e., negligence not amounting to careless disregard, carelessness, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

The Agency expects licensees or registrants to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in the Supplements, the severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee or registrant will not normally be cited for a failure to report a condition or event unless the licensee or registrant was actually aware of the condition or event which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

(4) **Enforcement Conferences.** Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, the Agency will normally hold an enforcement conference with the licensee or registrant prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:

1. discuss the violations or nonconformance, the significance of each and causes, and the licensee's or registrant's corrective actions;
2. determine whether there are any aggravating or mitigating circumstances; and
3. obtain other information which will help determine the appropriate enforcement action.

In addition, during the enforcement conference, the licensee or registrant will be given an opportunity to explain to the Agency what corrective actions (if any) were taken or will be

taken following discovery of the potential violation or nonconformance. Licensees or registrants will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be announced to the public.

When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, terminating, or revoking a license or registration, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken.

- (5) **Enforcement Actions.** This section describes the enforcement sanctions available to Agency and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, the Agency will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. With very limited exceptions, whenever a violation of Agency requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, action by the Radiation Control Division Director is appropriate in the form of a Notice of Violation requiring a formal response from the recipient describing corrective actions. The relatively small number of cases involving elevated enforcement action receives substantial attention by the public, and may have significant impact on the licensee's or registrant's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending, terminating, or revoking licenses or registrations; or orders to cease and desist from designated activities.

- (a) **Notice of Violation.** A notice of violation is a written notice setting forth one or more violations of a legally, binding requirement. The notice normally requires the recipient to provide a written statement describing:

1. corrective steps which have been taken and the results achieved;
2. corrective steps which will be taken to prevent recurrence; and
3. the date when full compliance will be achieved.

The Agency may require responses to notices of violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

The Agency uses the notice of violation as the standard method for formalizing the existence of a violation. A notice of violation is normally the only enforcement action taken, except in cases where the criteria for civil penalties and orders, as set forth in

Sections (5)(b) and (5)(c) respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

Licenses or registrants are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee or registrant quality assurance measures or management controls. Generally, however, licensees or registrants are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

(b) **Civil Penalty.** A civil penalty applies only to radioactive material licensees and is a monetary penalty that may be imposed for violation of:

1. certain specified licensing provisions of the Section 22-14, Code of Alabama, 1975, as amended, or supplementary Agency rule or orders;
2. any requirement for which a license may be revoked; or

Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Civil penalties are imposed absent mitigating circumstances for Severity Level I and II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar² to previous violations for which the licensee failed to take effective corrective action.

In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

Civil penalties will normally be assessed for any willful violation of any Agency requirement including those at any severity level.

The Agency imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various fuel cycle, and materials programs. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater potential consequences to the public and licensee employees receive higher civil

² The word "similar" as used in this Rule, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action for the previous violation.

penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the Agency's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, the Agency will consider as necessary an increase or decrease on a case-by-case basis.

The Agency attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems expeditiously and effectively. To encourage licensee self-identification and correction of violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant Agency identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Agency intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of \$10,000³ per violation, per day. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

The Agency reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. After considering all relevant circumstances, adjustments to these values may be made for the factors described in the following table.

TABLE 1A. - BASE CIVIL PENALTIES¹

³ \$1,000 for qualifying small businesses and non-profit entities.

	Plant operations const., health physics and EP	Transportation Greater than type A quantity ²	Type A quantity or less ³
a. Industrial Processors ⁴	\$10,000	\$10,000	\$5,000
b. Mills and Uranium Conversion Facilities	\$10,000	\$5,000	\$2,000
c. Industrial Users of Material ⁵	\$10,000	\$5,000	\$2,000
d. Waste Disposal Licensees	\$10,000	\$5,000	\$2,000
e. Academic or Medical Institutions	\$5,000	\$2,500	\$1,000
f. Other Material Licensees	\$1,000	\$2,500	\$1,000

- ¹ For qualifying small businesses and non-profit entities use one-tenth the values listed in the table. Civil penalties only apply to radioactive material licensees.
- ² Includes high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.
- ³ Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.
- ⁴ Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.
- ⁵ Includes industrial radiographers, nuclear pharmacies, and other industrial users.

1. **Prompt Identification and Reporting.** Reduction of up to 50% of the base civil penalty may be given when a licensee identifies the violation and promptly reports the violation to the Agency. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

2. **Corrective Action to Prevent Recurrence.** Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty as much as 50% of the base value shown in Table 1. On the other hand, the civil penalty may be increased as much as 50% of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action--such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.
3. **Past Performance.** Reduction by as much as 100% of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100% for prior poor performance in the general area of concern.

In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective action for prior similar problems may result in an increase in the civil penalty.
4. **Prior Notice of Similar Events.** The base civil penalty may be increased as much as 50% for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific Agency or industry notification, and had failed to take effective preventive steps.
5. **Multiple Occurrences.** The base civil penalty may be increased as much as 50% where multiple examples of a particular violation are identified during the inspection period.

The above factors are additive. However, in no instance will a civil penalty for any one violation exceed \$10,000 per day.

The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

- (i) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and as

such subject to a separate additional civil penalty.

- (ii) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.
- (iii) Alternatively, whether or not a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, the focus is on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

TABLE 1B. - BASE CIVIL PENALTIES
 Applies only to Radioactive Material Licensees

Severity Level	Base civil penalty amount (percent of amount listed in Table 1A)
I ----- -	100%
II ----- --	80%

III----- --	50%
IV----- -	15%
V----- --	5%

- (c) **Orders.** An order is a written Agency directive to modify, suspend, terminate, or revoke a license or registration; to cease and desist from a given practice or activity; or to take such other action as may be proper (see 420-3-26-.13). Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate. Orders may be issued as set forth below.
1. License or Registration Modification Orders are issued when some change in a licensee or registrant's equipment, procedures, or management controls is necessary.
 2. Suspension Orders may be used:
 - (i) To remove a threat to the public health and safety, or the environment;
 - (ii) To stop facility construction when:
 - (I) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, or
 - (II) the licensee's or registrant's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;
 - (iii) When the licensee or registrant has not responded adequately to other enforcement action;
 - (iv) When the licensee or registrant interferes with the conduct of an inspection or investigation; or
 - (v) For any reason not mentioned above for which license revocation or registration termination is legally authorized.

Suspensions may apply to all or part of the licensed or registered activity. Ordinarily,

a licensed or registered activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

3. Revocation Orders may be used:
 - (i) When a licensee or registrant is unable or unwilling to comply with Agency requirements,
 - (ii) When a licensee or registrant refuses to correct a violation,
 - (iii) When a licensee or registrant does not respond to a notice of violation where a response was required,
 - (iv) When a licensee refuses to pay a fee or civil penalty required by Act 82-328, as amended, or
 - (v) For any other reason for which revocation is authorized under these rules (e.g., any condition which would warrant refusal of a license or registration on an original application).
4. Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by the Agency that such activity is unauthorized.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the Agency believes a basis could reasonably exist for not taking the action as proposed, the licensee or registrant will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

- (d) **Escalation of Enforcement Sanctions.** The Agency considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, the Agency will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Agency carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to the case in accordance with the criteria described in Sections (5)(b) and (5)(c) above.

Examples of enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

Normally the progression of enforcement actions for similar violations will be based on violations under a single license or registration. When more than one facility is covered by a single license or registration, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license or registration. For example, a survey violation at Unit 2 of a multiunit plant that repeats an earlier violation at Unit 1 might be considered similar.

TABLE 2. - EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA UNDER THE SAME LICENSE OR REGISTRATION

Severity of Violation	Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)		
	1st	2nd	3rd
I----- -	(^a + ^b)	(^a + ^b + ^c)	(^d)
II----- -	(^a)	(^a + ^b)	(^a + ^b + ^c)
III----- -	----- -	(^a)	(^a + ^b)

^a Civil penalty, applies only to radioactive material licensees.

^b Suspension of affected operations until the Radiological Health Branch Director is satisfied that there is reasonable assurance that the licensee or registrant can operate in compliance with the applicable requirements; or modification of the license or registration, as appropriate.

^c Show cause for modification or revocation of the license or registration, as appropriate.

^d Further action, as appropriate.

(e) **Enforcement Actions Involving Individuals.** Enforcement actions involving individuals, including licensed users or physicians or registered users, are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action will normally be taken only when there is little doubt that the individual fully understood, or should have understood, his or her responsibility: knew, or should have known, the required actions: and knowingly, or with careless disregard (i.e., with more than mere negligence), failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the

level of Severity Level III, IV or V violations will be handled by citing only the facility licensee or registrant.

More serious violations, including those involving the integrity of an individual (e.g., lying to the Agency), concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual. Action against the individual, however, will not be taken if the improper action by the individual was caused by management failures. The following examples of situations illustrate this concept:

1. Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee or registrant.
2. Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.
3. Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation unless the individual did not express his or her concern or objection to the direction.
4. Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.
5. Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Examples of situations which could result in enforcement actions against individuals include, but are not limited to, violations which involve:

1. Recognizing a violation of procedural requirements and willfully not taking corrective action.
2. Willfully performing unauthorized bypassing or required safety systems.
3. Willfully defeating alarms which have safety significance.
4. Unauthorized abandoning of controls.
5. Inattention to duty such as sleeping or being intoxicated while on duty.
6. Willfully taking actions that violate License or Technical Specification Limiting Conditions for Operation or registration commitments.

7. Falsifying records required for Agency regulations or by the facility licensee or registrant.
8. Willfully failing to take "immediate actions" of emergency procedures.
9. Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel.

Any proposed enforcement action against individuals must be done by the Radiation Control Division Director. The opportunity for an Enforcement Conference with the individual will usually be provided.

Examples of sanctions that may be appropriate against Agency licensed or registered operators are:

1. Issuance of a letter of reprimand to be placed in the operator's license file or registration file,
2. Issuance of a Notice of Violation, and
3. Suspension for a specified period, modification, or revocation of the license or registration authorization.

The sanctions are listed in escalating order of significance. ⁴ The particular sanction to be used should be determined on a case-by-case basis.

In the case of an unlicensed individual, an Order modifying the facility license to require the removal of the individual from all radioactive material related activities for a specified period of time or indefinitely may be appropriate.

(f) **Reopening Closed Enforcement Actions.** If significant new information is received or obtained by the Agency which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case basis, are expected to occur rarely, and require the specific approval of the Radiation Control Division Director.

(g) **Exercise of Discretion.**

⁴ Except for individuals subject to civil penalties because they are persons as defined by Section 22-14 et.se., Code of Alabama, 1975, as amended, and are licensed as the named licensee on the licensing document.

1. Because the Agency wants to encourage and support licensee or registrant initiative for self-identification and correction of problems, Agency will not generally issue a notice of violation for a violation that meets all of the following criteria:
 - (i) It was identified by the licensee or registrant;
 - (ii) It fits in Severity Level IV or V;
 - (iii) It was reported, if required;
 - (iv) It was or will be corrected, including to prevent recurrence, within a reasonable time; and
 - (v) It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation.

2. The Agency may also refrain from issuing a Notice of Violation or a proposed civil penalty for violations that meet all of the following criteria:
 - (i)
 - (I) The Agency has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of a licensee's or registrant's operations or the licensee or registrant is forced into an extended shutdown or work stoppage related to generally poor performance over a long period;
 - (II) The licensee or registrant has developed and is aggressively implementing during the shutdown a comprehensive program for problem identification and correction; and
 - (III) Agency concurrence is needed by the licensee or registrant prior to restart.
 - (ii) Non-willful violations are identified by the licensee or registrant (as opposed to the Agency) as the result of its comprehensive program, or the violations are identified as a result of an employee allegation to the licensee. If the Agency identifies the violation, the Agency should determine whether enforcement action is necessary to achieve remedial action.
 - (iii) The violations are based upon activities of the licensee or registrant prior to the events leading to the shutdown, and

- (iv) The non-willful violations would normally not be categorized as higher than Severity Level III violations under the Agency's Enforcement Policy.

Notwithstanding the above, a civil penalty may be proposed in a case where multiple Severity Level III violations are discovered. This action would be taken when judgment warrants it on the circumstances of the individual case.

- (h) **Related Administrative Actions.** In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, the Agency also uses administrative mechanisms, such as bulletins, information notices, generic letters, notices of deviation, notices of nonconformance and confirmatory action letters to supplement its enforcement program. The Agency expects licenses to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees or registrants to make sure that such commitments are met.
1. Bulletins, Information Notices and Generic Letters are written notifications to groups of licensees or registrants identifying specific problems and recommending specific actions.
 2. Notices of Deviation are written notices describing a licensee's or registrant's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee or registrant to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.
 3. Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, or the environment.
 4. Notices of Nonconformance are written notices describing non-licensees' or registrant's failures to meet commitments which have not been made legally binding requirements by the Agency. An example is a commitment made in a procurement contract with a licensee or registrant. Notices of Nonconformance request non-licensees or registrants to provide written explanations or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.
- (6) **Referrals to the Attorney General.** Alleged or suspected criminal violations of Section 22-14 et. seq., Code of Alabama, 1975, as amended, are referred to the Attorney General for investigation. Such referral does not preclude the Agency from taking other enforcement

action under this General Statement of Policy. However, such actions will be coordinated with the Attorney General to the extent practicable.

- (7) **Inaccurate and Incomplete Information.** A violation of the regulations on submitting incomplete and inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information or the failure to provide significant information identified by a licensee or registrant normally will be categorized based on the guidance herein in (3) of this Appendix, "Severity of Violations", and in Supplement IV.

The Agency recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Agency must be able to rely on oral communications from licensee officials concerning significant information. A licensor registrant or registrant official for purposes of application of the Enforcement Policy means a first line supervisor or above as well as a licensed individual or registered activity, radiation safety officer, or a person listed on a license or registration as an authorized user of licensed material or registered equipment or activity. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as:

- (a) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;
- (b) the opportunity and time available prior to the communication to assure the accuracy or completeness of the information;
- (c) the degree of intent or negligence, if any, involved;
- (d) the formality of the communication;
- (e) the reasonableness of Agency reliance on the information;
- (f) the importance of the information which was wrong or not provided; and
- (g) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee or registrant official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the Agency by a licensee or registrant official or others on behalf of a licensee or registrant, if a record was made of the oral informant, and provided to the licensee or registrant thereby permitting an

opportunity to correct the oral informant, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee or registrant and was not subsequently corrected in a timely manner.

When a licensee or registrant has corrected inaccurate or incomplete information, the decision to issue a citation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the case of detection of the error, the timeliness of the correction, whether the Agency or the licensee or registrant identified the problem with the communication, and whether the Agency relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee or registrant prior to reliance by the Agency, or before the Agency raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the other hand, if the misinformation is identified after the Agency relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken even if it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new information or advance in technology, a citation normally would not be appropriate if, when the new information became available, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information which the licensee or registrant does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee or registrant later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee or registrant as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's or registrant's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Agency may exercise its authority to issue orders modifying, suspending, or revoking the license or registration. The Agency recognizes that enforcement determinations must be made on a case-by-case basis taking into consideration the issues described above.

- (8) **Public Disclosure of Enforcement Actions.** In accordance with 420-3-26-.01, all enforcement actions and licensees' or registrant's responses are publicly available for inspection. In addition, press releases are generally prepared for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Levels I, II, or III, press releases are prepared at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally prepared for Notices of Violation.
- (9) **Responsibilities.** The Director, Division of Radiation Control, as the principal enforcement officer of the Agency, has been delegated the authority to issue notices of violations, civil

penalties, and orders. In recognition that the regulation of radiation related activities in many cases does not lend itself to a mechanistic treatment, the Director, Radiological Health Branch must exercise judgment and discretion in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to impose a civil penalty and the amount of such penalty, after considering the general principles of this statement of policy and the technical significance of the violations and the surrounding circumstances. The State Committee of Public Health will be provided written notification of all enforcement actions involving civil penalties or orders.

SUPPLEMENT I - SEVERITY CATEGORIES

Health Physics 420-3-26-.03⁵

- (1) **Severity I.** - Violations involving for example:
 - (a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;
 - (b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;
 - (c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 420-3-26-.03(7);
 - (d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 420-3-26-.03(18); or
 - (e) Exposure of a worker in restricted areas of ten times the limits of 420-3-26-.03(4).
- (2) **Severity II.** - Violations involving for example:
 - (a) Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;
 - (b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;
 - (c) Release of radioactive material to an unrestricted area in excess of five times the limits of 420-3-26-.03(7);

⁵ Personnel overexposures and associated violations, incurred during a life-saving effort, will be treated on a case-by-case basis.

- (d) Failure to make an immediate notification as required by 420-3-26-.03(24)(a)1. and 420-3-26-.03(24)(a)2.;
 - (e) Disposal of licensed material in quantities or concentrations in excess of five times the limits of 420-3-26-.03(18); or
 - (f) Exposure of a worker in restricted areas in excess of five times the limits of 420-3-26-.03(4).
- (3) **Severity III.** - Violations involving for example:
- (a) Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;
 - (b) A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in any seven consecutive days;
 - (c) Failure to make a 24-hour notification as required by 420-3-26-.03(24)(b) or an immediate notification required by 420-3-26-.03(24)(a);
 - (d) Substantial potential for an exposure or release in excess of Rule 420-3-26-.03 whether or not such exposure or release occurs (e.g., entry into high radiation areas in the vicinity of exposed radiographic sources, or operating x-ray equipment without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);
 - (e) Release of radioactive material to an unrestricted area in excess of the limits of 420-3-26-.03(7);
 - (f) Improper disposal of licensed material not covered in Severity Level I or II;
 - (g) Exposure of a worker in restricted areas in excess of the limits of 420-3-26-.03(4);
 - (h) Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;
 - (i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;
 - (j) Conduct of licensee or registrant's activities by a technically unqualified person; or
 - (k) Significant failure to control licensed material or a registered activity.

- (4) **Severity IV.** - Violations involving for example:
- (a) Exposures in excess of the limits of 420-3-26-.03(2) not constituting Severity Level I, II, or III violations;
 - (b) A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;
 - (c) Failure to make a 30-day notification required by 420-3-26-.03(25);
 - (d) Failure to make a follow-up written report as required by 420-3-26-.03(23)(b), and 420-3-26-.10(4); or
 - (e) Any other matter that has more than minor safety or environmental significance.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

SUPPLEMENT II - Severity Categories

Transportation ⁶

- (1) **Severity I.** - Violations of NRC transportation requirements involving for example:
- (a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or
 - (b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the U.S. Department of Transportation limits.
- (2) **Severity II.** - Violations of Agency transportation requirements involving for example:
- (a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of U. S. Department of Transportation requirements;

⁶ Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper and a carrier. When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

- (b) Surface contamination or external radiation levels in excess of five times U. S. Department of Transportation limits that did not result from a breach of package integrity; or
 - (c) Failure to make required initial notification associated with Severity Level I or II violations.
- (3) **Severity III.** - Violations of Agency transportation requirements involving for example:
- (a) Breach of package integrity;
 - (b) Surface contamination or external radiation levels in excess of, but less than a factor of five above U. S. Department of Transportation requirements, that did not result from a breach of package integrity;
 - (c) Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:
 - 1. Improper identification of the type, quantity, or form of material;
 - 2. Failure of the carrier or recipient to exercise adequate controls; or
 - 3. Substantial potential for personnel exposure or contamination, or improper transfer of material; or
 - (d) Failure to make required initial notification associated with Severity Level III violations.
- (4) **Severity IV.** - Violations of Agency transportation requirements involving for example:
- (a) Package selection or preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of U. S. Department of Transportation requirements; or
 - (b) Other violations that have more than minor safety or environmental significance.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

SUPPLEMENT III - Severity Categories

Radioactive Materials Operations

- (1) **Severity I.** - Violations involving for example:
- (a) Radiation levels, contamination levels, or releases that exceed ten times the limits

- specified in the license; or
- (b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function.
- (2) **Severity II.** - Violations involving for example:
- (a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or
 - (b) A system designed to prevent or mitigate a serious safety event being inoperable.
- (3) **Severity III.** - Violations involving for example:
- (a) Failure to control access to licensed materials or registered operations for radiation purposes as specified by Agency requirements;
 - (b) Possession or use of unauthorized equipment or materials in the conduct of licensee or registrant activities which degrades safety;
 - (c) Use of radioactive material on humans where such use is not authorized;
 - (d) Conduct licensed or registered activities by a technically unqualified person;
 - (e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or
 - (f) Medical therapeutic misadministrations.
- (4) **Severity IV.** - Violations involving for example:
- (a) Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;
 - (b) Other violations that have more than minor safety or environmental significance; or
 - (c) Failure to report medical diagnostic misadministrations.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

SUPPLEMENT IV - Severity Categories

Miscellaneous Matters

- (1) **Severity I** - Violations involving for example:
- (a) Inaccurate or incomplete information ⁷ which is provided to the Agency;
 - 1. deliberately with the knowledge of a licensee or registrant official that the information is incomplete or inaccurate, or
 - 2. if the information, had or been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety.
 - (b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;
 - 1. incomplete or inaccurate because of falsification by or with the knowledge of a licensee or registrant official, or
 - 2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations;
 - (c) Information which the licensee or registrant has identified as having significant implications for public health and safety ("significant information identified by a licensee or registrant") and which is deliberately withheld from the Agency;
 - (d) Action by senior corporate management in violation of 420-3-26-.10(7)(c) or similar rule against an employee.
- (2) **Severity II** - Violations involving for example:
- (a) Inaccurate or incomplete information which is provided to the Agency;
 - 1. by a licensee or registrant official because of careless disregard for the completeness or accuracy of the information, or
 - 2. if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position.

⁷ In applying the examples in this supplement regarding inaccurate or incomplete information and records, reference also should be made to the information in (6) of this Appendix.

- (b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;
 - 1. incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a licensee or registrant official, or
 - 2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;
 - (c) "Significant information identified by a licensee or registrant" and not provided to the Agency because of careless disregard on the part of a licensee or registrant official; or
 - (d) Action by plant management above first-line supervision in violation of 420-3-26-.10(7)(c) or similar regulations against an employee;
- (3) **Severity III.** - Violations involving for example:
- (a) Incomplete or inaccurate information which is provided to the Agency;
 - 1. because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or
 - 2. if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection of a formal request for information;
 - (b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;
 - 1. incomplete or inaccurate because of inadequate actions on the part of licensee or registrant officials but not amounting to a Severity Level I or II violation, or
 - 2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;
 - (c) Failure to provide "significant information identified by a licensee or registrant" to the Agency and not amounting to a Severity Level I or II violation", or
 - (d) Action by first-line supervision in violation of 420-3-26-.010(7)(c) or similar

regulations against an employee.

- (4) **Severity IV.** - Violations involving for example:
- (a) Incomplete or inaccurate information of more than minor significance which is provided to the Agency but not amounting to a Severity Level I, II, or III violation;
 - (b) Information which the Agency requires be kept by a licensee or registrant and which is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation; or
- (5) **Severity V.** - Violations involving for example:
- (a) Incomplete or inaccurate information which is provided to the Agency and the incompleteness or inaccuracy is of minor significance, or
 - (b) Information which the Agency requires be kept by a licensee or registrant which is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance.

SUPPLEMENT V - Severity Categories

Emergency Preparedness

- (1) **Severity I.** - Violations involving for example:
- In a general emergency, licensee failure to promptly
- (a) correctly classify the event,
 - (b) make required notifications to responsible Federal, State, and local agencies, or
 - (c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).
- (2) **Severity II.** - Violations involving for example:
- (a) In a site area emergency, licensee failure to promptly
 - 1. correctly classify the event,
 - 2. make required notifications to responsible Federal, State, and local agencies, or
 - 3. respond to the event (e.g., assess actual or potential offsite consequences,

activate emergency response facilities, and augment shift staff); or

- (b) Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.
- (3) **Severity III.** - Violations involving for example:
- (a) In an alert, licensee failure to promptly
 - 1. correctly classify the event,
 - 2. make required notifications to responsible Federal, State, and local agencies, or
 - 3. respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or
 - (b) Licensee or registrant's failure to meet or implement emergency planning standard involving assessment or notification.
- (4) **Severity IV.** - Violations involving for example:
- Licensee or registrant's failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.
- (5) **Severity V.** - Violations that have minor safety or environmental significance.

420-3-26-.14

**RADIATION SAFETY
REQUIREMENTS FOR IRRADIATORS**

- (1) **Purpose and Scope.**
- (a) This rule contains requirements for the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This rule also contains radiation safety requirements for operating irradiators. The requirements of this rule are in addition to other requirements of these rules. Nothing in this rule 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) The requirements in this rule apply 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 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this rule.
 - (c) The requirements in this rule do not apply to self-contained dry-source-storage irradiators 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 for the irradiation of materials for nondestructive testing purposes; gauging; or open-field, agricultural irradiations.
- (2) **Definitions.**
- (a) "Annually" means at intervals not to exceed one year.
 - (b) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.
 - (c) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but

does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

- (d) "Irradiator operator" means an individual who has successfully completed the training and testing described in 420-3-26-.14(17) and is authorized by the terms of the license to operate the irradiator without a supervisor present.
- (e) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in 420-3-26-.14(17).
- (f) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.
- (g) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.
- (h) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.
- (i) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.
- (k) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.
- (l) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.
- (m) "Sealed source" (see definition in 420-3-26-.01(2)(a) 95.).
- (n) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the US Geological Survey.

- (o) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.
- (3) **Start of Construction.** The applicant may not begin construction of a new irradiator prior to the submission to the Agency of both an application for a license for the irradiator and any fee required by the applicable state requirement or statute. As used in this part, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the appropriate state statute, rules, regulations, and orders issued under the appropriate state statute.
- (4) **Applications for Exemptions.** Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives from the requirements of this rule. The Agency will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.
- (5) **Request for Written Statements.** Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Agency's request, submit a written statement to enable the Agency to determine whether the license should be modified, suspended, or revoked.
- (6) **Performance Criteria for Sealed Sources.**
 - (a) Requirements for sealed sources installed in irradiators after July 1, 1996:
 1. Must have been evaluated in accordance with 10 CFR 32.210 and issued a certificate of registration.
 2. Must be doubly encapsulated;
 3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
 5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in 420-3-26-.14(6)(b) through (g).
 - (b) **Temperature.** The test source must be held at -40°C for 20 minutes, 600°C for one hour, and then be subjected to thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.
 - (c) **Pressure.** The test source must be twice subjected for at least five minutes to an absolute external pressure of 2 million newtons per square meter.
 - (d) **Impact.** A 2 kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.
 - (e) **Vibration.** The test source must be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.
 - (f) **Puncture.** A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.
 - (g) **Bend.** If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.
- (7) **Access Control.**
- (a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are

exposed must cause the sources to return promptly to the shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The control panel lock must be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers must not prevent any individual in the radiation room from leaving.

- (b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on-site of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.
- (c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in 420-3-26-.14(7)(b). The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.
- (d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.
- (e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to the fully shielded position.
- (f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.
- (g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words,

"CAUTION (or DANGER) RADIOACTIVE MATERIAL." Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA", but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

- (h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.
- (i) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators or facility management shall have access to keys that operate the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual who is not necessarily on-site but who is prepared to respond or summon assistance.

(10) **Shielding.**

- (a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour must be locked, roped off, or posted.
- (b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.
- (c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 mrem) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 mrem) per hour.

(9) **Fire Protection.**

- (a) The radiation room at a panoramic irradiator must have heat and smoke

detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

- (b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

(10) **Radiation Monitors.**

- (a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.
- (b) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

(11) **Control of Source Movement.**

- (a) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.
- (b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.
- (c) The control console of a panoramic irradiator must have a control that

promptly returns the sources to the shielded position.

- (d) Each control for a panoramic irradiator must be clearly marked as to its function.

(12) Irradiator Pools.

- (a) For licenses initially issued after July 1, 1996, irradiator pools must either:
 - 1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or
 - 2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.
- (b) For licenses initially issued after July 1, 1996, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.
- (c) A means must be provided to replenish water losses from the pool.
- (d) A visible indicator must be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.
- (e) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.
- (f) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.
- (g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (2 mrem) per hour.

- (13) **Source Rack Protection.** If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.
- (14) **Power Failures.**
- (a) If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.
 - (b) The lock on the door of the radiation room of a panoramic irradiator must remain locked in the event of a power failure.
 - (c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.
- (15) **Design Requirements.** Irradiators whose construction begins after July 1, 1996, must meet the design requirements of this section.
- (a) **Shielding.** For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 420-3-26-.14(8). If the irradiator will use more than 2×10^{17} becquerels (5 million Ci) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.
 - (b) **Foundations.** For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.
 - (c) **Pool integrity.** For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 420-3-26-.14(12)(b), and that metal components are metallurgically compatible with other components in the pool.
 - (d) **Water handling system.** For pool irradiators, the licensee shall verify that

the design of the water purification system is adequate to meet the requirements of 420-3-26-.14(12)(e). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

- (e) **Radiation monitors.** For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 420-3-26-.14(10)(a). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 420-3-26-.14(21)(b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.
- (f) **Source rack.** For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.
- (g) **Access control.** For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 420-3-26-.14(7).
- (h) **Fire protection.** For panoramic irradiators, the licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.
- (i) **Source return.** For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than ten seconds.

- (j) **Seismic.** For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.
 - (k) **Wiring.** For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.
- (16) **Construction Monitoring and Acceptance Testing.** The requirements of this section must be met for irradiators whose construction begins after July 1, 1996. The requirements must be met prior to loading sources.
- (a) **Shielding.** For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.
 - (b) **Foundations.** For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.
 - (c) **Pool integrity.** For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of 420-3-26-.14(12)(b).
 - (d) **Water handling system.** For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.
 - (e) **Radiation monitors.** For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 420-3-26-.14(10)(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet 420-3-26-.14(21)(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 420-3-26-.14(10)(b).

- (f) **Source rack.** For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 420-3-26-.14(13) are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.
 - (g) **Access control.** For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.
 - (h) **Fire protection.** For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.
 - (i) **Source return.** For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.
 - (j) **Computer systems.** For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.
 - (k) **Wiring.** For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.
- (17) **Training.**
- (a) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must be instructed in:

1. The fundamentals of radiation protection applied to irradiators. This must include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;
 2. The requirements of these rules and the applicable sections of Rule 420-3-26-.03 and Rule 420-3-26-.10 that are relevant to the irradiator;
 3. The operation of the irradiator;
 4. Those operating and emergency procedures listed in 420-3-26-.14(18) that the individual is responsible for performing; and
 5. Case histories of accidents or problems involving irradiators.
- (b) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.
- (c) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.
- (d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:
1. Changes in operating and emergency procedures since the last review, if any;

2. Changes in regulations and license conditions since the last review, if any;
 3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;
 4. Relevant results of inspections of operator safety performance;
 5. Relevant results of the facility's inspection and maintenance checks; and
 6. A drill to practice an emergency or abnormal event procedure.
- (e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.
- (f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 420-3-26-.14(18) that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.
- (g) Individuals who must be prepared to respond to alarms required by 420-3-26-.14(7)(b) and (i), 420-3-26-.14(9)(a), 420-3-26-.14(10)(a) and (b), and 420-3-26-.14(21)(b) shall be trained and tested on how to respond. Each individual shall be retested at least annually. Tests may be oral.

(18) Operating and Emergency Procedures.

- (a) The licensee shall have and follow written operating procedures for:
1. Operation of the irradiator, including entering and leaving the radiation room;
 2. Use of personnel dosimeters;
 3. Surveying the shielding of panoramic irradiators;

4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;
 5. Leak testing of sources;
 6. Inspection and maintenance checks required by 420-3-26-.14(22);
 7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and
 8. Inspection of movable shielding required by 420-3-26-.14(7)(h), if applicable.
- (b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:
1. Sources stuck in the unshielded position;
 2. Personnel overexposures;
 3. A radiation alarm from the product exit portal monitor or pool monitor;
 4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;
 5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;
 6. A prolonged loss of electrical power;
 7. A fire alarm or explosion in the radiation room;
 8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;
 9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and
 10. The jamming of automatic conveyor systems.

- (c) The licensee may revise operating and emergency procedures without Agency approval only if all of the following conditions are met:
1. The revisions do not reduce the safety of the facility;
 2. The revisions are consistent with the outline or summary of procedures submitted with the license application;
 3. The revisions have been reviewed and approved by the radiation safety officer; and
 4. The users or operators are instructed and tested on the revised procedures before they are put into use.

(19) **Personnel Monitoring.**

- (a) Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges [see 420-3-26-.03(17)(c)]. Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs must be processed at least quarterly.
- (b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of the paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within $\pm 20\%$ of the true radiation dose.

(20) **Radiation Surveys.**

- (a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of new sources or any modification

to the radiation room shielding or structure that might increase dose rates.

- (b) If the radiation levels specified in 420-3-26-.14(8) are exceeded, the facility must be modified to comply with the requirements in 420-3-26-.14(8).
- (c) Portable radiation survey meters must be calibrated at least annually to an accuracy of $\pm 20\%$ for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.
- (d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Table II, Column 2 or Table III of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage" of rule 420-3-26-.03.
- (e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

(21) Detection of Leaking Sources.

- (a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 μCi) of radioactive material and must be performed by a person approved by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State, to perform the test.
- (b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test

has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

- (c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Agency, the Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an Agency, the Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table II, Column 2, Appendix B of 420-3-26-.03. See 420-3-26-.02(29) for reporting requirements.

(22) Inspection and Maintenance.

- (a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:
1. Operability of each aspect of the access control system required by 420-3-26-.14(7).
 2. Functioning of the source position indicator required by 420-3-26-.14(11)(b).

3. Operability of the radiation monitor for radioactive contamination in pool water required by 420-3-26-.14(21)(b) using a radiation check source, if applicable.
 4. Operability of the over-pool radiation monitor at underwater irradiators as required by 420-3-26-.14(10)(b).
 5. Operability of the product exit monitor required by 420-3-26-.14(10)(a).
 6. Operability of the emergency source return control required by 420-3-26-.14(11)(c).
 7. Visual inspection of leak-tightness of systems through which pool water circulates.
 8. Operability of the heat and smoke detectors and extinguisher system required by 420-3-26-.14(9), without turning extinguishers on.
 9. Operability of the means of pool water replenishment required by 420-3-26-.14(12)(c).
 10. Operability of the indicators of high and low pool water levels required by 420-3-26-.14(12)(d).
 11. Operability of the intrusion alarm required by 420-3-26-.14(7)(i), if applicable.
 12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
 13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 420-3-26-.14(13).
 14. Amount of water added to the pool to determine if the pool is leaking.
 15. Electrical wiring on required safety systems for radiation damage.
 16. Pool water conductivity measurements and analysis as required by 420-3-26-.14(23)(b).
- (b) Malfunctions and defects found during inspection and maintenance checks

must be repaired within time frames specified in the license or license application.

(23) Pool Water Purity.

- (a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.
- (b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

(24) Attendance During Operation.

- (a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on site:
 - 1. Whenever the irradiator is operated using an automatic product conveyor system; and
 - 2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.
- (b) At a panoramic irradiator at which static irradiations with no movement of the product are occurring, a person who has received the training on how to respond to alarms described in 420-3-26-.14(17)(g) must be on site.
- (c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 420-3-26-.14(17)(f) and (g). Static irradiations may be performed without a person present at the facility.

(25) Entering and Leaving the Radiation Room.

- (a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.
 - (b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:
 - 1. Visually inspect the entire radiation room to verify that no one else is in it; and
 - 2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.
 - (c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 420-3-26-.14(10)(b) is operating with backup power.
- (26) **Irradiation of Explosive or Flammable Materials.**
- (a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.
 - (b) Irradiation of more than small quantities of flammable material with a flash point below 140°F is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.
- (27) **Records and Retention Periods.** The licensee shall maintain the following records at the irradiator for the periods specified.
- (a) A copy of the license, the license conditions, documents incorporated into the license by reference, and amendments thereto until superseded by new documents or until the Agency terminates the license for documents not

superseded.

- (b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of 420-3-26-.14(17)(a), (b), (c), (d), (f), and (g) until three years after the individual terminates work.
- (c) Records of the annual evaluations of the safety performance of irradiator operators required by 420-3-26-.14(17)(e) for three years after the evaluation.
- (d) A copy of the current operating and emergency procedures required by 420-3-26-.14(18) until superseded or the Agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 420-3-26-.14(18)(c)3. retained for three years from the date of the change.
- (e) Film badge and TLD results required by 420-3-26-.14(19) until the Agency terminates the license.
- (f) Records of radiation surveys required by 420-3-26-.14(20) for three years from the date of the survey.
- (g) Records of radiation survey meter calibrations required by 420-3-26-.14(20) and pool water conductivity meter calibrations required by 420-3-26-.14(23)(b) until three years from the date of calibration.
- (h) Records of the results of leak tests required by 420-3-26-.14(21)(a) and the results of contamination checks required by 420-3-26-.14(21)(b) for three years from the date of each test.
- (i) Records of inspection and maintenance checks required by 420-3-26-.14(22) for three years.
- (j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.
- (k) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by Rule 420-3-26-.01 and Rule 420-3-26-.03.
- (l) Records on the design checks required by 420-3-26-.14(15) and the construction control checks as required by 420-3-26-.14(16) until the license is terminated. The records must be signed and dated. The title or

qualification of the person signing must be included.

- (m) Records related to decommissioning of the irradiator as required by 420-3-26-.02(26)(i).

(28) Reports.

- (a) In addition to the reporting requirements in other parts of these rules, the licensee shall report the following events if not reported under other sections of these rules:
 1. Source stuck in an unshielded position.
 2. Any fire or explosion in a radiation room.
 3. Damage to the source racks.
 4. Failure of the cable or drive mechanism used to move the source racks.
 5. Inoperability of the access control system.
 6. Detection of radiation source by the product exit monitor.
 7. Detection of radioactive contamination attributable to licensed radioactive material.
 8. Structural damage to the pool liner or walls.
 9. Water loss or leakage from the source storage pool, greater than the irradiator pool design parameters submitted by the licensee or applicant.
 10. Pool water conductivity exceeding 100 microsiemens per centimeter.
- (b) The report must include a telephone report within 24 hours as described in 420-3-26-.02(29)(c)1. and a written report within 30 days as described in 420-3-26-.02(29)(c)2.

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- Authority: §§22-14-4-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, also 22-2-1, 22-2-2, 22-2-5, and 22-2-6, Code of Alabama, 1975.
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