STATE OF MAINE
DEPARTMENT OF HUMAN SERVICES
DIVISION OF HEALTH ENGINEERING
10 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0010

ANGUS S. KING, JR.
GOVERNOR

KEVIN W. CONCANNON
COMMISSIONER

Date: January 23, 2002
To: Paul Lohaus, Director
USNRC Office of State and Tribal Programs

From: Shawn Seeley
Maine Radiation Control Program

Re: Rulemaking: Changes to Radiation Regulations

Dear Paul:
Enclosed please find the more proposed regulations to be added to the ones sent to you office a few weeks ago. There will be a public hearing on these proposed rules on January 28, 2002 from 9:00 am – Noon at the DHS offices at 219 Capital Street, Augusta. The comment period for written comments is by the close of business on February 8, 2002. As a reminder, all comments must be submitted to this office in writing to be valid.

The RATS Id numbers affected are as follows:

1995-3, 1995-4, 1995-5, 1995-6, & 1995-7
1996-1
1997-5
1998-1, 1998-5, & 1998-6
1999-3
2000-1

If you have any questions, do not hesitate to contact this office at 207-287-5676. Thank you.

Shawn Seeley

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COMMISSIONER

January 25, 2002

To: All Maine Specific License Holders
ACR Members/Consultants/OSTP-NRC

From: Shawn Seeley, Senior Radioactive Materials Inspector
Maine Radiation Control Program

Re: 2002 Rulemaking addendum

Enclosed please find an addendum to the proposed changes to the State of Maine Rules Relating to Radiation Protection (Parts C, D, E, J, K & L). These are changes based upon comments received from the US Nuclear Regulatory Commission review of the Maine Regulations and their compatibility with the Federal regulations.

There will be a public hearing on these proposed rules on January 28, 2002 from 9:00 am – Noon at the DHS offices at 219 Capital Street, Augusta. The comment period for written comments is by the close of business on February 8, 2002. If you need additional time for submission of comments, please submit a letter to this office and we may be able to extend the comments period. As a reminder, all comments must be submitted to this office in writing to be valid.

If you have any questions, do not hesitate to contact this office at 207-287-5676. Thank you.

Sincerely,

Shawn Seeley

H. Licensing the Manufacture and Distribution of Ice Detection Devices. An application for a specific license to manufacture and distribute ice detection devices to persons generally licensed under C.6.G will be approved subject to the following conditions:

(1) the applicant satisfies the general requirements of C.8, and

(2) the criteria of Sections 32.61, 32.62, 32.103 of 10 CFR Part 32 are met.

1. Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Part G Licenses.

(1) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to Part G for the uses listed in Part G.100, 200 and 300 will be approved if:

~~(1)~~a) The applicant satisfies the general requirements specified in C.8. of this part;

~~(2)~~b) The applicant submits evidence that the applicant is at least one of the following:

~~(a)~~i) ~~the radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA~~Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug manufacturer, or

~~(ii)~~ii) Registered or licensed with a state agency as a drug manufacturer; or

(iii) Licensed as a pharmacy by a State Board of Pharmacy; or

(iv) Operating as a nuclear pharmacy within a Federal medical institution.

~~the manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;~~

~~(3)~~c) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees; and

(d) The applicant satisfies the following labeling requirements: ~~The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and~~

~~(4)~~(i) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

(ii) A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an

identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) A licensee described by paragraph (1)(b)(iii) or (iv) of this section:

(a) May prepare radioactive drugs for medical use, as defined in Part G.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (2)(b) and (2)(c) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in Part G.

(b) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(i) This individual qualifies as an authorized nuclear pharmacist as defined in Part G.2,

(ii) This individual meets the requirements specified in Part G and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist, or

(iii) This individual is designated as an authorized nuclear pharmacist in accordance with paragraph (2)(c) of this section.

(c) The actions authorized in paragraphs (2)(a) and (2)(b) of this section are permitted in spite of more restrictive language in license conditions.

(d) May designate a pharmacist (as defined in Part G.2) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the Agency under this part.

(e) Shall provide to the Agency a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)(b)(i) and (2)(b)(iii) of this section, the individual to work as an authorized nuclear pharmacist.

(3) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(a) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(b) Check each instrument for constancy and proper operation at the beginning of each day of use.

(4) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

~~(a) The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to Part G as appropriate, for the uses in G.100, 200 and 300 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or a Licensing State.~~

~~(b) The labels, leaflets or brochures required by C.11.1.(1) are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.~~

(1) minimize danger to public health and safety or property;

(2) require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) prevent loss or theft of material subject to this part.

14. Specific Terms and Conditions of License.

A. Each license issued pursuant to this part shall be subject to all provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

B. No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, now or hereafter in effect and to all valid rules, regulations and orders of the Agency and shall give its consent in writing.

C. Each person licensed by the Agency pursuant to this part shall confine his use and possession of the material licensed to the locations and purposes authorized in the license.

D. Each licensee shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(1) The licensee;

(2) An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

(4) This notification must indicate:

(a) The bankruptcy court in which the petition for bankruptcy was filed; and

(b) The date of the filing of the petition.

15. Expiration and Termination of Licenses

A. Except as provided in C.16.B and paragraph .D(3) of this section, each specific license expires at the end of the day, in the month and year stated in the license.

B. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when the licensee decides to terminate all activities involving materials authorized under the license. The notification and request for termination of the license must include the reports and information specified in paragraphs .D(1)(d) and (e) of this section. The licensee is subject to the provisions of paragraphs (D) and (E) of this section, as applicable.

C. Each licensee shall notify the Agency immediately, in writing, and request termination of the license when no principal activities under the license have been conducted for a period of 24 months, or no principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

~~C~~D. No less than 30 days before the expiration date specified in a specific license the licensee shall either:

38. Transfer for Disposal and Manifests.

A. The requirements of D.38, Appendices D and G of this Part are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low- level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and record keeping for those wastes.

B. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Section I of Appendix D.

C. Each shipment manifest shall include a certification by the waste generator as specified in Section II of Appendix D.

D. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix D.

39. Compliance with Environmental and Health Protection Regulations.

Nothing in D.33, D.34, D.35, D.36, D.37, or D.38 relieves the licensee or registrant from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to D.33, D.34, D.35, D.36, D.37, or D.38.

RECORDS

40. General Provisions.

A. Each licensee or registrant shall use the units (curie, rad, rem and roentgen) including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by Part D.

B. In the records required by this Part, the licensee may record quantities in the International System of Units (SI) in parentheses following each of the units specified in paragraph A. However, all quantities must be recorded as stated in paragraph A.

C. Not withstanding the requirements of paragraph A of this section, when recording information on shipment manifests, as required in D.38, information must be recorded in SI units or in SI units and units as specified in paragraph A above.

D. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by Part D, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, ~~eye~~ lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

41. Records of Radiation Protection Programs.

A. Each licensee or registrant shall maintain records of the radiation protection program, including:

(1) The provisions of the program; and

(2) Audits and other reviews of program content and implementation.

B. The licensee or registrant shall retain the records required by D.41.A(1) until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by D.41.A(2) for 3 years after the record is made.

57. Notifications and Reports to Individuals.

A. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in J.4 of these regulations.

B. When a licensee or registrant is required pursuant to D.53 to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of J.4.A of these regulations.

58. Reports of Leaking or Contaminated Sealed Sources. The licensee or registrant shall file a report within 5 days with the Agency if the test for leakage or contamination required pursuant to D.16. indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

ADDITIONAL REQUIREMENTS

59. Vacating Premises. Each specific licensee or registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of his activities, notify the Agency in writing of intent to vacate. When deemed necessary by the Agency, the licensee shall decontaminate the premises in such a manner as the Agency may specify.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

60. General Provisions and Scope. The criteria in this subpart apply to the decommissioning of facilities licensed under Parts C, E , G and K of these regulations.

A. The criteria in this subpart do not apply to sites, which have been decommissioned prior to the effective date of this rule.

B. After a site has been decommissioned and the license terminated in accordance with the criteria in this subpart, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of this subpart were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

C. When calculating TEDE to the average member of the critical group the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

D. Specific time limits for the completing the decommissioning process.

(1) Licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but not later than 24 months following the initiation of decommissioning.

(2) When decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but not later than 24 months following the initiation of decommissioning.

E. The Agency may approve a request for an alternative schedule for completion of the decommissioning of the site or separate building or outdoor area, and license termination is appropriate, if the Agency determines that the alternative is warranted.

22. Posting.

A. All areas in which industrial radiography is being performed must be conspicuously posted as required by D.28. Exceptions listed in D.29. do not apply to industrial radiographic operations.

B. Whenever practicable, ropes and/or barriers shall be used in addition to appropriate signs to designate areas in accordance with Part D.28. and to help prevent unauthorized entry.

C During pipeline industrial radiographic operations, sufficient radiation signs and other barriers shall be posted to prevent unmonitored individuals from entering the area in accordance with Part D.28.

D. In lieu of the requirements of E.22.A., a restricted area may be established in accordance with Part D and be posted in accordance with E.22.A., for example, both signs may be posted at the same location at the boundary of the restricted area.

23. Utilization logs.

A. Each licensee and registrant shall make and maintain current logs of the use, removal, and return to storage of each source of radiation. The information shall be recorded in the log when the source is removed from and returned to storage. The logs shall include:

(1) A ~~unique identification, for example,~~ description, including the make, model and ~~the~~ serial number, of the following:

(a) Each radiation machine;
(b) Each radiographic exposure device containing a sealed source or transport and storage container in which the sealed source is located; and
(c) Each sealed source;

(2) The name and signature of the radiographer using the source of radiation;

(3) The location(s) and date(s) where each source of radiation is used; and

(4) The date(s) each source of radiation is removed from storage and returned to storage.

B. Utilization logs shall be kept on clear, legible records containing all the information required by paragraph A. above.

C. Records of utilization logs shall be made and maintained for Agency inspection in accordance with E.26. These must be retained as specified in E.26.F.

24. Reciprocity.

A. All reciprocal recognition of licenses or certificates of registration by the Agency will be granted in accordance with Parts C & E of these regulations.

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

1. The individual holds a valid certification in the appropriate category and class issued by a certifying entity, as defined in this Part;

2. The requirements and procedures of the certifying entity issuing the certification afford the same or comparable certification standards as those afforded by this Part; and

(e) A brachytherapy radiation dose:

(I) Involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(II) Involving a sealed source that is leaking;

(III) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(IV) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(f) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:

(I) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

(II) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

(17) "**Mobile nuclear medicine service**" means the transportation and medical use of radioactive material.

(18) "**Output**" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(19) "**PET**" means Positron Emission Tomography.

(20) "**Podiatric use**" means the intentional external administration of the radiation from radioactive material to patients under the supervision of an authorized user in the practice of podiatry.

(21) "**Prescribed dosage**" means the quantity of radiopharmaceutical activity as documented:

(a) In a written directive; or

(b) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

(22) "**Prescribed dose**" means

(a) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

(b) For teletherapy, the total dose and dose per fraction as documented in the written directive; or

(c) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

(2) Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

D. A licensee shall check each survey instrument for proper operation with the dedicated check source before each use. The licensee is not required to keep records of these checks.

E. The licensee shall retain a record of each calibration required in G.18.A. for 2 years. The record shall include:

(1) A description of the calibration procedure; and

(2) A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

F. To meet the requirements of G.18.A., .B., and .C., the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to perform calibrations of survey instruments. Records of calibrations which contain information required by G.18.E. shall be maintained by the licensee.

19. Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.

A. This section does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to Parts C and G, or equivalent US Nuclear Regulatory Commission, Agreement State, or Licensing State requirements.

B. For other than unit dosages obtained pursuant to paragraph A of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:

1. Perfrom tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; AND

2. Check each instrument for constancy and proper operation at the beginning of each day of use.

~~19~~20. Assay of Radiopharmaceutical Dosages. A licensee shall:

A. Assay, within 30 minutes before medical use, the activity of each radiopharmaceutical dosage that contains more than 10 microcuries (370 kBq) of a photon-emitting radionuclide;

B. Assay, before medical use, the activity of each radiopharmaceutical dosage with a desired activity of 10 microcuries (370 kBq) or less of a photon-emitting radionuclide to verify that the dosage does not exceed 10 microcuries (370 kBq); and

C. Retain a record of the assays required by G.~~19~~20.A. and .B. for 2 years. To satisfy this requirement, the record shall contain the:

(1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;

UPTAKE, DILUTION, AND EXCRETION

100. Use of unsealed radioactive material ~~Radiopharmaceuticals~~ for Uptake, Dilution, or Excretion Studies.

A. A licensee may use ~~any~~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) ~~byproduct~~ unsealed 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),~~ prepared for medical use that is either:

1. Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent US Nuclear Regulatory Commission, Agreement State or Licensing State requirements; OR

2. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Part G, or an individual under the supervision of either as specified in Part G.

G.100.B.

B. A licensee using a radiopharmaceutical specified in G.100.A. for a clinical procedure other than one specified in the product label or package insert instructions shall comply with the product label or package insert instructions regarding physical form, route of administration and dosage range.

101. Possession of Survey Instrument. A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem (1.0 μSv) per hour to 50 millirems (500 μSv) per hour. The instrument shall be operable and calibrated in accordance with G.18.

IMAGING AND LOCALIZATION

200. Use of unsealed radioactive material ~~Radiopharmaceuticals, Generators, and Reagent Kits~~ for Imaging and Localization Studies.

A. A licensee may use for imaging and localization studies ~~the following~~ any unsealed radioactive material ~~radiopharmaceuticals, generators, and reagent kits for imaging and localization studies~~ prepared for medical use that is either:

(1). Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent US Nuclear Regulatory Commission, Agreement State or Licensing State requirements; OR

(2). Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Part G, or an individual under the supervision of either as specified in Part G.

~~(1) Molybdenum-99/technetium-99m generators for the elution or extraction of technetium-99m as pertechnetate;~~

~~(2) Technetium-99m as pertechnetate;~~

-(3) This section includes aAny 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 Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA).

B. A licensee using radiopharmaceuticals specified in G.200.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 G.201. and prepare radiopharmaceuticals from kits in accordance with the manufacturer's instructions.

D. Technetium-99m pertechnetate as an aerosol for lung function studies is not subject to the restrictions in G.200.B.:

E. Provided the conditions of G.202 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

201. Permissible Molybdenum-99 Concentration.

A. A licensee shall not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m (0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m).

B. A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration in each eluate or extract.

C. A licensee who must measure molybdenum concentration shall retain a record of each measurement for 3 years. The record shall include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries (megabecquerels), the measured activity of molybdenum expressed in microcuries (kilobecquerels), the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium (kilobecquerels of molybdenum per megabecquerel of technetium), the date of the test, and 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 G.201.A.

202. 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 D.6 and D.14 of these regulations.

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 referenced in Part D.6 of these regulations. 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 G.202.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 2 years.

G. A copy of the calculations required in G.202.D. shall be recorded and retained for the duration of the license.

203. Possession of Survey Instruments. A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem (1 μSv) per hour to 50 millirems (500 μSv) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem (10 μSv) per hour to 1000 millirems (10 mSv) per hour. The instruments shall be operable and calibrated in accordance with G.18.

RADIOPHARMACEUTICALS FOR THERAPY

300. Use of Radiopharmaceuticals for Therapy.

A. A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

(1). Obtained from a manufacturer or preparer licensed pursuant to Part C or equivalent US Nuclear Regulatory Commission, Agreement State or Licensing State requirements; OR

(2). Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Part G, or an individual under the supervision of either as specified in Part G.

~~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~~B. Any unsealed radioactive material in a radiopharmaceutical and 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). The licensee shall comply with the package insert instructions regarding indications and method of administration.

301. 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 G.301.A., the instruction shall describe the licensee's procedures for:

Facsimile Cover Sheet

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Pages Including this cover page: 14

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