Mr. Terry Frazee, Chairman
SR-6 Committee
Division of Radiation Protection
Department of Health
Airdustrial Center Building #5
P.O. Box 47827
Olympia, WA 98504-7827

FEB - 6 1997

Dear Mr. Frazee:

Mrs. Schneider discussed with you during the May 1996 Conference of Radiation Control Program Directors (CRCPD) meeting the need to revise the Rationale of Part G for the February 29, 1996 Revisions to the Suggested State Regulations for the Control of Radiation (SSRCR). Since this revision to Part G was published without the concurrence of the Nuclear Regulatory Commission, we recommend that the Rationale for Part G be specific in the sections where there are differences between Part G and 10 CFR Part 35 and the reasons the SR-6 Group choose not to follow the Federal regulation. This level of detail in the SSRCR's rationale is consistent with the January 1991 "CRCPD Policies and Procedures for Preparation and Publication of the Suggested State Regulations for Control of Radiation."

Enclosed are those sections of the Rationale for Part G which we recommend the SR-6 Group revise to clarify the differences between the SSRCR and Part 35. We believe with these changes, any State, especially one contemplating Agreement State status, which uses the SSRCR will then be aware of the difference between the SSRCR model regulations and the Federal regulations. In addition to these recommendations, other NRC staff comments were submitted to CRCPD in Enclosures 4, 5, and 6 via a letter dated December 29, 1995 and have not yet been addressed. If you have any questions, please contact Thomas O'Brien at 301-415-2308 or Kathleen Schneider at 301-415-2320.

Sincerely,

Original Signed By:
PAUL H. LOHAUS

Paul H. Lohaus, Deputy Director
Office of State Programs

Enclosure:
As stated

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Mr. Terry Frazee, Chairman
SR-6 Committee
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Department of Health
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Enclosed are those sections of the Rationale for Part G which we recommend the SR-6 Group revise to clarify the differences between the SSRCR and Part 35. We believe with these changes, any State, especially one contemplating Agreement State status, which uses the SSRCR will then be aware of the difference between the SSRCR model regulations and the Federal regulations. In addition to these recommendations, other NRC staff comments were submitted to CRCPD in Enclosures 4, 5, and 6 via a letter dated December 29, 1995 and have not yet been addressed. If you have any questions, please contact Thomas O'Brien at 301-415-2308 or Kathleen Schneider at 301-415-2320.

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NRC COMMENTS ON RATIONALE FOR PART G

Section G.2 - Definitions

SSR Excerpt

"Address of use" is defined and "area of use" is revised consistent with positron emission tomography usage. The definition of "ALARA" is deleted since it is now found in the proposed Part A. Having the term defined in more than one place is unnecessary and possibly confusing if subtle differences arise. To accommodate the Nuclear Regulatory Commission's revision of "misadministration," definitions of "diagnostic clinical procedures manual," "prescribed dosage," "prescribed dose," "recordable event," and "written directive" were added. The potentially significant dose to a patient from even "small" diagnostic quantities of I-131 as sodium iodide warrants requiring a specific "written directive" for administration of I-131 along with other therapeutic procedures. Even though I-125 as sodium iodide is not used clinically, it has been included in the definitions in order to be compatible with the Nuclear Regulatory Commission.

NRC Comment

The rationale should indicate that the definition for "Medical use" is not compatible with the NRC definition as it does not indicate the administration is performed under the supervision of an authorized user.

Section G.8 - Radiation Safety Committee

NRC Comment

Although not required for reasons of compatibility, the rationale should discuss the SR-6 Committee's decision to use the term "occupational doses" in G.8bi rather than the NRC term "individual and collective doses" specified in 10 CFR 35.22(b)(1).

Section G.13 - Quality Management Program

NRC Comment

As identified in our Enclosure 4 of our letter dated December 29, 1995 to the CRCPD Executive Secretary, there are four additions needed to this section for it to be compatible with NRC's QM rule. These items are listed below.

1. To cover existing licensees, add a new section to G.13 substantially equivalent to Section 35.32(f)(2) that would: (a) require a licensee to submit a written certification that the QMP has been implemented; and (b) require a licensee to make the QMP available for review when requested by the regulatory agency.

per SC-45 Div 3

this is not in 35.32(f)(2). what is the basis for it? Is this the reason for "substantially" above?

2. To cover existing licensees, add to section G.13e a statement substantially equivalent to Section 35.32(e) that would require licensees to make the QMP modification available for review when requested by the regulatory agency.

3. To cover new applicants, add a new section equivalent to Section 35.32(f)(1) requiring that the applicant include a copy of their QMP as a part of their application for a license.

4. Modify section G.13 such that the first sentence reads: "Each applicant or licensee .... " (See Section 35.32(a)).

If the above points are not incorporated into SSR Part G, the rationale needs to identify the specific areas of SSR Part G that are not compatible with NRC requirements.

Also, as stated in our December 29, 1995 letter, the rationale should note that the NRC has permitted increased flexibility to Agreement States in two areas: the timing of QMP submittals by licensees to Agreement State regulatory agencies, and the ability to expand Agreement State misadministration definitions to include reference to other non-Atomic Energy Act modalities. It is suggested that these ~~flexibilities~~ areas of flexibility be identified in the rationale.

Section G.17 - Possession, Use, Calibration, and Check of Dose Calibrators

SSR Excerpt

This section has been restructured to require quality control procedures recommended by the national cognizant body, the American National Standards Institute, or alternative procedures approved by the Agency. Specific procedures are updated and provided in brackets should the Agency require them. The appropriate tests can be performed by an individual other than the Radiation Safety Officer. Automatic approval of radium-226 for calibration and check source use is eliminated as part of the effort to discourage the use of radium. Only calibration sources are required to be traceable to the National Institute of Standards and Technology or other primary standards recognized by the National Institute of Standards and Technology (for instance, the French Bureau National de Metrologie). Only one of the sources used for calibration requires 5 percent precision; the other source(s) need only be known to be within 10 percent of their stated activity.

NRC Comment

The rationale should discuss the Committee's decision to require 5 percent precision for one calibration source while NRC requires this precision for two sources and justification as to why the NRC requirement for one of the sources to have a principal photon energy between 100 keV and 500 keV is not stated. The rationale should identify ~~that~~ both of the above NRC requirements need to be met for compatibility reasons.

Mr. Terry Frazee, Chairman
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Department of Health
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c/o Division of Radiation Protection
Department of Health
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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

February 6, 1997

Mr. Terry Frazee, Chairman
SR-6 Committee
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Department of Health
Airdustrial Center Building #5
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Olympia, WA 98504-7827

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Office of State Programs

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Section G.8 - Radiation Safety Committee

NRC Comment

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Section G.13 - Quality Management Program

NRC Comment

As identified in our Enclosure 4 of our letter dated December 29, 1995 to the CRCPD Executive Secretary, there are revisions needed in this section for it to be compatible with the NRC's QM rule. These items are summarized below.

1. To cover existing licensees, add a new section to G.13 that provides the flexibilities in determining the method by which a licensee is required to submit its QMP to the agency and the timing of that submittal as indicated in All Agreement States letter SP-95-184.

2. To cover new applicants, add a new section equivalent to Section 35.32(f)(1) requiring that the applicant include a copy of their QMP as a part of their application for a license.

3. Modify section G.13 such that the first sentence reads: "Each applicant or licensee .... " (See Section 35.32(a)).

If the above points are not incorporated into SSR Part G, the rationale needs to identify the specific areas of SSR Part G that are not compatible with NRC requirements.

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SSR Excerpt

This section has been restructured to require quality control procedures recommended by the national cognizant body, the American National Standards Institute, or alternative procedures approved by the Agency. Specific procedures are updated and provided in brackets should the Agency require them. The appropriate tests can be performed by an individual other than the Radiation Safety Officer. Automatic approval of radium-226 for calibration and check source use is eliminated as part of the effort to discourage the use of radium. Only calibration sources are required to be traceable to the National Institute of Standards and Technology or other primary standards recognized by the National Institute of Standards and Technology (for instance, the French Bureau National de Metrologie). Only one of the sources used for calibration requires 5 percent precision; the other source(s) need only be known to be within 10 percent of their stated activity.

NRC Comment

The rationale should discuss the Committee's decision to require 5 percent precision for one calibration source while NRC requires this precision for two sources and justification as to why the NRC requirement for one of the sources to have a principal photon energy between 100 keV and 500 keV is not stated. The rationale should identify both of the above NRC requirements, as necessary, to be met for compatibility reasons.

Section G.21 - Requirements for Possession of Sealed Sources and Brachytherapy Sources

SSR Excerpt

The full range of options for leaking sources is spelled out. The leak test may be performed by someone other than the Radiation Safety Officer.

NRC Comment

While not required for compatibility reasons, the rationale should discuss the SR-6 Committee's decision to allow repair or disposal of a leaking source in addition to NRC's storage requirement.

Section G.23 - Syringe Labels

NRC Comment

While not required for compatibility reasons, the rationale should detail the items made less prescriptive and the SR-6 Committee basis for the action.

Section G.34 - Radionuclide Contaminants

NRC Comment

The conversions from uCi to kBq in G.34ai-iii are incorrect. Additionally, the term "chloride" should be added after "Rb-82" in G.34aiii for consistency with G.34aii.

Conference of Radiation Control Program Directors, Inc.
205 Capital Avenue
Frankfort, Kentucky 40601
Phone (502) 227-4543 Facsimile (502) 227-7862

MEMO

TO: Recipients of December 1995 Amendments to the SSRCRs

FROM: Chuck Hardin

DATE: February 29, 1996

SUBJECT: Revised Parts A, B, D, F, G and J

Enclosed are revisions to the above referenced Parts of the Suggested State Regulations for the Control of Radiation (SSRCRs). These amended Parts supersede their respective former editions and should replace the older versions. The user is cautioned that since the SSRCRs are so closely interwoven, the understanding of any single Part may depend on the understanding of other appropriate parts of the SSRCRs.

Special attention should be paid to Part G. *This part was published without the concurrence of the Nuclear Regulatory Commission (NRC).* The reason stated by the NRC for not concurring with Part G is: "The revisions of Part G contain provisions which are different from the NRC Quality Management rule." ***Agreement states should be made aware this may be an area of compatibility with regard to their agreement with the NRC.*** For a more detailed discussion as to why the CRCPD published this Part without NRC concurrence, please refer to the rationale attached to the revised Part G. Should additional explanation be desired, please contact the Chairman of Part G, Terry Frazee with the Washington Division of Radiation Protection, phone # 360/753-3461.

The user of the SSRCRs should pay careful attention to cross references when new or revised parts are published. Should any inconsistencies be found in these cross references, please advise Terry Devine in the Office of Executive Director, phone # 502/227-4543.

State and local radiation control programs may obtain one free copy of these amendments on disks from the Office of Executive Director by providing the office with three formatted 3.5" floppy disks. Should additional copies be desired by a state or local radiation control program, there will be a charge of $25, in addition to the requirement of three formatted floppy disks. Copies of the SSRCRs on floppy disks are not available to individuals outside of state and local radiation control agencies and federal agencies that supported this project. Therefore, ***you are requested not to copy these regulations for entities outside your agency.***

These amended Parts have been produced using *WordPerfect 6.0, DOS version*. If you are using *WordPerfect 5.1, DOS version*, you will not be able to open a document produced with *WordPerfect 6.0*. If you desire the document in *WordPerfect 5.1*, you must specify that requirement at the time you request the disk version of the document. However, because there are some very complicated tables in some of the parts, we cannot guarantee that some loss of formatting and/or loss of proper pagination may occur when the documents are provided in *WordPerfect 5.1*. For example, Appendix C in Part D, when saved in 5.1, resulted in a significant pagination error. Likewise, although *WordPerfect for Windows* and *Word for Windows* will open a file produced by the DOS version of WordPerfect, again we cannot guarantee consistent formatting and pagination. We strongly urge the user to obtain *WordPerfect 6.0, DOS version* when using these documents.

1995
RATIONALE FOR REVISIONS

PART G
USE OF RADIONUCLIDES IN THE HEALING ARTS

Introduction

Major changes have resulted from 1) the Nuclear Regulatory Commission's revision of the definition of "misadministration" and establishment of a "quality management program" requirement; 2) attempts to recognize the practice of medicine as solely a state regulated function; and 3) incorporating provisions pertinent to the use of positron emission tomography. Early drafts of Part G had suggested modified language for the "quality management program" based on the Committee's judgment that the Nuclear Regulatory Commission's requirement was overly prescriptive especially in light of at least one state's existing (and successful) program. Other sections also had proposed language which varied from 10 CFR 35. However, in the final revision to Part G, the focus has been on providing model regulations which can be adopted by individual states without concern that Division 1 and Division 2 matters of compatibility will be raised following adoption. Therefore, the Nuclear Regulatory Commission language was adopted (with one exception as noted below) for any regulations deemed to be "matters of compatibility."

Other requirements in Part G were modified to be more performance oriented. Certain requirements potentially impinging on the practice of medicine have been modified to focus more on radiation safety. Record retention requirements were adjusted to meet the Nuclear Regulatory Commission criteria. With the addition of a new section, all sections from G.13 and above have been renumbered. Cross references internally and to other Suggested State Regulations for Control of Radiation Parts have been updated and, where used, units of measurement are given with the International System of Units first, followed by special radiation units in parentheses. Internal referencing and the use of numerals have been made to conform to current style guidelines. Minor editing was also performed without further reference below.

Specific Provisions

Sec. G.1 - Purpose and Scope. Terms appropriate for the use of positron emission tomography radiopharmaceuticals are added. By virtue of their short-half lives, positron emission tomography radiopharmaceuticals may need to be produced in an accelerator, prepared from a special radionuclide generator, and/or compounded in a form suitable for human use by the licensee.

Sec. G.2 - Definitions. "Address of use" is defined and "area of use" is revised consistent with positron emission tomography usage. The definition of "ALARA" is deleted since it is now found in the proposed Part A. Having the term defined in more than one place is unnecessary and possibly confusing if subtle differences arise. To accommodate the Nuclear Regulatory Commission's revision of "misadministration," definitions of "diagnostic clinical procedures manual," "prescribed dosage," "prescribed dose," "recordable event," and "written directive" were added. The potentially significant dose to a patient from even "small" diagnostic quantities of I-131 as sodium iodide warrants requiring a specific "written directive" for administration of I-131 along with other

therapeutic procedures. Even though I-125 as sodium iodide is not used clinically, it has been included in the definitions in order to be compatible with the Nuclear Regulatory Commission.

Sec. G.3 - License Required. Terms associated with positron emission tomography usage are included.

Sec. G.6 - ALARA Program. ALARA is now defined in Part A. Editing was done to clarify that there are two different levels requiring investigation and investigation plus action when evaluating personnel exposures.

Sec. G.7 - Radiation Safety Officer. Specific reference is made to the investigation of misadministrations as a duty of the Radiation Safety Officer.

Sec. G.10 - Supervision. It is important that an experienced and knowledgeable individual (an authorized user) be available to communicate with a supervised individual in the event a question or concern comes up during a procedure. However, requiring a physical presence does not add appreciably to the level of radiation safety and may place an unwarranted constraint on the practice of medicine. The supervising authorized user, or another authorized user, can communicate appropriate instructions to the supervised individual without interrupting care of his or her own patients unless warranted by the circumstances. For instance, it may be much more appropriate to have an experienced technologist handle a spill than to expect a physician to return to the hot lab to supervise cleanup. The regulation now allows an authorized user other than the supervising authorized user (including an authorized user under another licensee) to be consulted by a supervised individual when needed. This could be when the supervising authorized user is on vacation or when another authorized user has more experience with a given problem.

The regulation now recognizes that individuals working under the supervision of the authorized user may require a permit under state and local regulations. These supervised individuals are now explicitly instructed to follow the written radiation safety procedures and written quality management plan established by the licensee. This is important for technologists working at a facility on a part-time or temporary basis who may be more familiar with another facility's procedures.

Sec. G.12 - Mobile Nuclear Medicine Service Administrative Requirements. This section was changed to allow a licensee to use a separately licensed mobile service for off-hours and vacation backup and to provide special services such as mobile positron emission tomography which the facility would not otherwise be able to offer its patients. The regulation also makes clear the responsibility of the mobile service to inform the client facility whenever radiopharmaceuticals are being administered. Accountability of radioactive materials and waste disposal segregation should be assured through the Agency's licensing and compliance activities.

Sec. G.13 - Quality Management Program. This is a new section incorporating the major elements of the Nuclear Regulatory Commission's "quality management" rule. The focus is on assuring that radiation is administered as intended by the authorized user through policies and procedures for preparing written directives, verifying patient identity, updating clinical procedures, validating treatment plans, identifying and evaluating deviations, and conducting an annual evaluation. The licensee is allowed (by the Nuclear Regulatory Commission and therefore by this section of Part G as well) to modify its quality management program without prior approval of the Agency. However,

the Nuclear Regulatory Commission requires the licensee initially to submit a copy of the licensee's quality management program to the Nuclear Regulatory Commission along with a certification that the program has been implemented. The Committee believes this could impose a significant resource burden on the states especially where Agency required submittals must be reviewed within a time frame fixed by internal procedure or state law. The resulting peak workload could cause the Agency to forego other licensing actions and licensee inspections to the overall detriment of the radiation control program.

The Committee has requested the Nuclear Regulatory Commission allow, as an alternative to its "submittal" requirement, the Committee recommendation that the state evaluate its program resources and, if practical, require licensees (through administrative order or confirmatory letter) to submit their quality management programs to the state. States should review and comment on such submittals in a timely fashion. If review of submitted quality management programs is not practical, the state should require licensees to submit a letter stating or certifying that a quality management program has been implemented which meets the requirements of G.13. In either event, the state should adopt a license application review process that assesses (but does not tie to the license in keeping with G.13e.) the quality management program and institute an inspection procedure that reviews implementation of the quality management program.

Sec. G.14 - Records, Notifications, and Reports of Misadministrations. The section is updated to conform to the Nuclear Regulatory Commission's notification requirement and the title of the section is changed to reflect the emphasis on notifications. This and all succeeding sections have been renumbered relative to the previous edition.

Sec. G.15 - Suppliers. Language has been added recognizing the practice of pharmacy. Also, brachytherapy sources are explicitly required to come from a supplier licensed to manufacture and distribute such sources.

Sec. G.16 - Quality Control of Diagnostic Equipment. The section and title have been updated to indicate that equipment important to patient safety includes diagnostic equipment and is not limited to equipment that produces an image. The minimum quality control is clarified.

Sec. G.17 - Possession, Use, Calibration, and Check of Dose Calibrators. The section has been restructured to require quality control procedures recommended by the national cognizant body, the American National Standards Institute, or alternative procedures approved by the Agency. Specific procedures are updated and provided in brackets should the Agency require them. The appropriate tests can be performed by an individual other than the Radiation Safety Officer. Automatic approval of radium-226 for calibration and check source use is eliminated as part of the effort to discourage the use of radium. Only calibration sources are required to be traceable to the National Institute of Standards and Technology or other primary standards recognized by the National Institute of Standards and Technology (for instance, the French Bureau National de Métrologie). Only one of the sources used for calibration requires 5 percent precision; the other source(s) need only be known to be within 10 percent of their stated activity.

Sec. G.18 - Calibration and Check of Survey Instruments. Language missing from G.18c. has been restored so that a correction chart or graph need only be provided for instruments with calibration error greater than 10 percent.

Sec. G.19 - Assay of Radiopharmaceutical Dosages. This section has been modified to cover radiopharmaceuticals in which the radiation of principal interest is alpha or beta radiation.

Sec. G.21 - Requirements for Possession of Sealed Sources and Brachytherapy Sources. The full range of options for leaking sources is spelled out. The leak test may be performed by someone other than the Radiation Safety Officer.

Sec. G.22 - Syringe Shields. This section now allows syringes to be kept in shielded areas as well as in syringe shields.

Sec. G.23 - Syringe Labels. This section has been made less prescriptive.

Sec. G.28 - Mobile Nuclear Medicine Service Technical Requirements. Mobile services may be allowed to use radioactive gases only when the Agency has specifically evaluated and approved each area of use. The checks and tests of equipment being transported from place to place are clarified. The undefined term "location of use" is changed to "area of use" which is defined. A specific survey for removable contamination is now required.

Sec. G.31 - Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies. The specific listing of individual radiopharmaceuticals is eliminated since permission to use them is adequately covered under the Food and Drug Administration acceptance or approval and several listed are no longer clinically acceptable. Requiring compliance with the package insert is eliminated because it is an infringement on the practice of medicine. The practice of pharmacy is recognized.

Sec. G.33 - Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies. Same as comments for G.31. In addition, gases and aerosols are left out of the generic approval in order for the Agency to evaluate the area of use and the conditions of use to assure compliance with airborne release standards.

Sec. G.34 - Radionuclide Contaminants. This section has been updated to reflect the availability of strontium-82/rubidium-82 generators for positron emission tomography studies. Radionuclide contaminant limits are from the package insert/information submitted to United States Pharmacopeia.

Sec. G.35 - Control of Aerosols and Gases. The provision for directly venting aerosols and gases to the atmosphere has been bracketed to indicate this should be an option and no longer a prime consideration. Direct venting is not current accepted practice. Reference to Part D is corrected (proposed Part D).

Sec. G.37 - Use of Radiopharmaceuticals for Therapy. Same as comments for G.31.

Sec. G.39 - Safety Precautions. The importance of instructing the patient and the patient's family (where appropriate) is emphasized especially for therapy patients whether hospitalized or not. Where language barriers exist, the use of written as well as oral instruction will facilitate getting the message across to the patient. Also, alternatives to the required thyroid bioassay may be considered when preparing doses of stabilized I-131.

Sec. G.41 - Use of Sealed Sources for Diagnosis. The use of Gadolinium-153 in a portable device

for imaging was added.

Sec. G.43 - Use of Sources for Brachytherapy. Radium-226 sources and radon-222 seeds are deleted to discourage their use. These sources should be specifically licensed to heighten awareness of their existence.

Sec. G.45 - Safety Precautions. The importance of instructing the patient and the patient's family (where appropriate) is emphasized. Where language barriers exist, the use of written as well as oral instruction will facilitate getting the message across to the patient.

Sec. G.58 - Full Calibration Measurements. The current protocol for therapy calibrations is referenced.

Sec. G.65 - Radiation Safety Officer. The connector "or" between subsections G.65b. and G.65c. is added to make it clear that any one of the three methods may be used to qualify as the Radiation Safety Officer. Without this specific connector the section could be read to mean that the Radiation Safety Officer must also be an authorized user. The authorized user as Radiation Safety Officer is appropriate for non-institutional settings provided a minimum amount of instruction in basic radiation safety and radionuclide handling techniques can be demonstrated. Additional certifying boards are also added.

Sec. G.67 - Training for Uptake, Dilution, or Excretion Studies. An additional certifying board is included.

Sec. G.68 - Training for Imaging and Localization Studies. Same comment as G.67.

Sec. G.69 - Training for Therapeutic Use of Radiopharmaceuticals. Additional certifying boards are included. Use of strontium-89 chloride for the treatment of pain associated with bone metastases is included.

Sec. G.72 - Training for Use of Sealed Sources for Diagnosis. An additional certifying board is included.

Sec. G.74 - Training for Teletherapy Physicist. Same comment as G.72.

Matters for Future Consideration

Broad Technical Issues

1. Whether special requirements are needed for the practice of pharmacy and whether nuclear pharmacy should be regulated as a defined specialty under Part G (use of radionuclides in the healing arts is direct application of radiation to humans).

2. Whether veterinarians should be regulated as part of the medical community under Part G (use of radionuclides in the healing arts is direct application of radiation to humans).

3. Whether site specific immunotherapy (monoclonal antibodies) requires special regulations added to Part G.

4. Whether High Dose Rate Afterloaders require special regulations added to Part G.

5. Whether many of the current provisions of Part G are overly prescriptive, do not apply uniformly to large and small licensees, and are better addressed in licensing guidance.

6. Whether to incorporate the Nuclear Regulatory Commission's "Patient Release Criteria" based only on dose or to retain some aspects of the easier to use limits based on quantities of radioactive material or dose rates; and how best to address pure beta-emitters and alpha emitters.

7. Whether medical licensee management should be given broader authority to approve authorized users and visiting authorized users as long as they meet the current training and experience requirements and whether the licensee needs to do more than just document the users credentials or report when an authorized user leaves the licensee.

8. Whether the physician user should be present during radiopharmaceutical therapy procedures since potential consequences to personnel, facilities, the patient, and the public could be severe.

9. Whether the term "confinement for medical care" should be defined to mean an area under the direct control of the licensee and not the patient's home or a hotel room rather than merely "hospitalization"; and under what circumstances may non-hospitalized patients receive radiopharmaceutical therapy.

10. Whether there is a need for a separate quality assurance section for therapy.

11. Whether 200 hours of classroom and laboratory training is sufficient background for a Radiation Safety Officer and whether this training should be in a 4 year accredited college or university.

12. Whether training and experience requirements have been adequately addressed through the currently recognized certifying boards; whether additional boards should be recognized or, in some cases, whether a currently approved board should be removed from the approved list; and whether the training and experience requirements themselves need to be updated, including consideration of requirements for nuclear cardiology.

<u>Specific Technical Issues</u>

13. Whether the definition for "brachytherapy" in G.2 should include reference to solid and plated sources in addition to sealed sources being utilized to deliver a radiation dose.

14. Whether the geometry test in G.17b.iv. is needed given the current state of dose calibrator technology.

15. Whether the calibration requirements in G.18 should be updated to address instruments for area contamination surveys, probe efficiency, the emission energy spectrum of sources used for calibrations, and the use of electronic pulsers.

16. Whether the maximum amount allowed under the general license in G.20a. should be increased to accommodate the larger sources used for SPECT floods.

17. Whether there is justification to add I-125 seeds to the list of exemptions from the leak test requirement in G.21f.iv.

18. Whether the removable contamination limits in G.26 are too restrictive.

19. Whether the survey requirements in G.26 should be updated to address efficiency of portable survey instruments, and exemptions for areas where only radioactive materials with extremely short half-lives are used.

20. Whether the requirements for storage of volatiles and gases in G.29 should be updated to address the use of storage containers and shielding equivalent to the shippers' radiation shield and container, and the storage of syringes, etc. prepared for patients but not yet administered.

21. Whether the decay-in-storage requirement in G.30a.i. to hold radioactive material for a minimum of ten half lives is warranted when an appropriate survey meter cannot distinguish any readings above background even before that time is reached.

22. Whether radionuclide contaminant levels should be cited by reference to the United States Pharmacopeia rather than specified as they currently are in G.34.

23. Whether the control of aerosols and gases as specified in G.35 employs overly conservative assumptions when applied to Xe-133 (assuming uniform distribution upon release in a room; not treating a Noble gas as an external source only).

24. Whether a survey instrument is really needed for licensees using sealed sources for diagnosis (G.42).

25. Whether the teletherapy room viewing system requirement in G.56 should require aural communication as well as visual observation.

26. Whether the requirement for a calibrated dosimetry system in G.57 should be a performance standard so that groups other than the National Institute of Standards and Technology or the American Association of Physicists in Medicine can participate.

Editorial Issues

27. Whether clarification is needed for certain terms such as "compounding," "availability to communicate immediately," and "type of use."

28. Whether sections enforcing general considerations that apply equally as well to radiation

machines or to a broader segment of radioactive materials users should be moved to Part A or Part D where they would be applicable to all radiation users. Examples of such sections include: G.4 License Amendments, G.5 Notification, G.6 ALARA Program, G.7 Radiation Safety Officer, G.8 Radiation Safety Committee, G.9 Authority and Responsibilities, G.10 Supervision, G.16 Quality Control, G.18 Survey Instruments, most of G.21 Possession of Sources (leak tests), G.26 Surveys for Contamination, and G.53 Doors, Interlocks, and Warning Systems. Only specific requirements concerning radionuclides in the healing arts would remain in Part G.

29. Whether definitions applicable to more than one Part, such as "area of use," "management," and "therapy physicist," should be moved to Part A.

30. Whether redundant or repetitive sections, such as G.32, G.40, G.42, G.48 and G.54 which similarly address possession of survey instruments, and G.38, G.44 and G.52 concerning safety instruction, should be combined.

31. Whether values repeated in different units of measure should have the same number of significant digits, e.g. 15 mCi and 550 MBq (rather than 555 MBq), and whether the metric coefficient that will give numbers larger than one should be used.

Suggested State Regulations for Control of Radiation

Part G

The Conference of Radiation Control Program Directors, Inc.'s Board of Directors has endorsed and adopted amendments to Part G of the *Suggested State Regulations for Control of Radiation.* This amended Part replaces the previous version of the Part.

Part G is published with the concurrence of
the **Environmental Protection Agency.**

Part G is published without the concurrence of
the **Nuclear Regulatory Commission.**

The **Food and Drug Administration**
did not provide a response
within the 60-day time period
relating to concurrence with Part G.

December 1995

PART G

USE OF RADIONUCLIDES IN THE HEALING ARTS

Sec. G.1 - Purpose and Scope. Part G establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of Part G are in addition to, and not in substitution for, others in these regulations. The requirements and provisions of these regulations apply to applicants and licensees subject to Part G unless specifically exempted.

Sec. G.2 - Definitions. As used in Part G, the following definitions apply:

"Address of use" means the building or buildings that are identified on the license and where radioactive material may be produced, prepared, received, used, or stored.

"Area of use" means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

"Authorized user" means a practitioner of the healing arts who is identified as an authorized user on an Agency[, Agreement State, Licensing State or the Nuclear Regulatory Commission] license that authorizes the medical use of radioactive material.

"Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

"Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

"Management" means the chief executive officer or that individual's designee.

"Medical institution" means an organization in which several medical disciplines are practiced.

"Medical use" means the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.

"Misadministration" means the administration of:

(1) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131:

(a) Involving the wrong patient or wrong radiopharmaceutical; or

(b) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 megabecquerels (30 μCi);

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(a) Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

(b) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage;

(3) A gamma stereotactic radiosurgery radiation dose:

(a) Involving the wrong patient or wrong treatment site; or

(b) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(4) A teletherapy radiation dose:

(a) Involving the wrong patient, wrong mode of treatment, or wrong treatment site; or

(b) When the treatment consists of 3 or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

(c) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(d) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(5) A brachytherapy radiation dose:

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

(b) Involving a sealed source that is leaking; or

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

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

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131, both:

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

(b) When the dose to the patient exceeds 50 millisieverts (5 rem) effective dose equivalent or 500 millisieverts (50 rem) dose equivalent to any individual organ.

"Mobile nuclear medicine service" means the transportation and medical use of radioactive material.

"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.

"Prescribed dosage" means the quantity of radiopharmaceutical activity as documented:

(1) In a written directive; or

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

"Prescribed dose" means:

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

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

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

"Recordable event" means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and the difference between the administered dosage and the prescribed dosage exceeds 555 kilobecquerels (15 μCi);

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

"Teletherapy physicist" means an individual identified as the qualified teletherapy physicist on an Agency license.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

"Visiting authorized user" means an authorized user who is not identified on the license of the licensee being visited.

"Written directive" means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in (6), containing the following information:

(1) For any administration of quantities greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131: the radionuclide, and dosage; or

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; or

(3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or

(4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or

(5) For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or

(6) For all other brachytherapy,

(a) Prior to implantation: the radionuclide, number of sources, and source strengths; and

(b) After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

General Regulatory Requirements

Sec. G.3 - License Required.

a. No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to these regulations.

b. Unless prohibited by license condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in Part G under the supervision of an authorized user as provided in G.10.

Sec. G.4 - License Amendments. A licensee shall apply for and receive a license amendment:

a. Before using radioactive material for a method or type of medical use not permitted by the license issued under Part G;

b. Before permitting anyone, except a visiting authorized user described in G.11, to work as an authorized user under the license;

c. Before changing a Radiation Safety Officer or Teletherapy Physicist;

d. Before receiving radioactive material in excess of the amount authorized on the license;

e. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

f. Before changing statements, representations, and procedures which are incorporated into the license.

Sec. G.5 - Notifications. A licensee shall notify the Agency in writing within 30 days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist, permanently discontinues performance of duties under the license.

Additional Requirements

Sec. G.6 - ALARA Program.

a. Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in Part A of these regulations.

b. To satisfy the requirement of G.6a.:

   i. The management, Radiation Safety Officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or the Radiation Safety Committee; or

   ii. For licensees that are not medical institutions, management and all authorized users shall participate in the program as required by the Radiation Safety Officer.

c. The ALARA program shall include an annual review by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

d. The licensee shall retain a current written description of the ALARA program for the duration of the license. The written description shall include:

   i. A commitment by management to keep occupational doses as low as reasonably achievable;

   ii. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

   iii. Personnel exposure investigational levels as established in accordance with G.8b.viii. that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

   iv. Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

Sec. G.7 - Radiation Safety Officer.

a. A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

b. The Radiation Safety Officer shall:

i. Investigate overexposures, misadministrations, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

ii. Implement written policy and procedures for:

(1) Authorizing the purchase of radioactive material;

(2) Receiving and opening packages of radioactive material;

(3) Storing radioactive material;

(4) Keeping an inventory record of radioactive material;

(5) Using radioactive material safely;

(6) Taking emergency action if control of radioactive material is lost;

(7) Performing periodic radiation surveys;

(8) Performing checks and calibrations of survey instruments and other safety equipment;

(9) Disposing of radioactive material;

(10) Training personnel who work in or frequent areas where radioactive material is used or stored; and

(11) Keeping a copy of all records and reports required by the Agency regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations; and

iii. For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; or

iv. For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

Sec. G.8 - Radiation Safety Committee. Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of radioactive material.

a. The Committee shall meet the following administrative requirements:

i. Membership must consist of at least 3 individuals and shall include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate;

ii. The Committee shall meet at least once each calendar quarter;

iii. To establish a quorum and to conduct business, one-half of the Committee's membership shall be present, including the Radiation Safety Officer and the management's representative;

iv. The minutes of each Radiation Safety Committee meeting shall include:

(1) The date of the meeting;

(2) Members present;

(3) Members absent;

(4) Summary of deliberations and discussions;

(5) Recommended actions and the numerical results of all ballots; and

(6) Documentation of any reviews required in G.6c. and G.8b.;

v. The Committee shall provide each member with a copy of the meeting minutes, and retain one copy until the Agency authorizes its disposition.

b. To oversee the use of licensed material, the Committee shall:

i. Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

ii. Review, on the basis of safety and with regard to the training and experience standards of Part G, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal;

iii. Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

iv. Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;

v. Review quarterly, with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

vi. Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

vii. Review annually, with the assistance of the Radiation Safety Officer, the radioactive material program; and

viii. Establish a table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and/or considerations of action by the Radiation Safety Officer.

Sec. G.9 - Statement of Authorities and Responsibilities.

a. A licensee shall provide sufficient authority and organizational freedom to the Radiation Safety Officer and the Radiation Safety Committee to:

i. Identify radiation safety problems;

ii. Initiate, recommend, or provide solutions; and

iii. Verify implementation of corrective actions.

b. A licensee shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.

Sec. G.10 - Supervision.

a. A licensee who permits the receipt, possession, production, preparation, compounding, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by G.3 shall:

i. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the licensee's written quality management program;

ii. Periodically review the supervised individual's use of radioactive material, the records kept to reflect this use, and provide reinstruction as needed;

iii. Require an authorized user to be immediately available to communicate with the supervised individual; and

iv. Require that only those individuals permitted under state and local regulations and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients.

b. A licensee shall require the supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material under G.3 to:

i. Follow the instructions of the supervising authorized user;

ii. Follow the written radiation safety and quality management procedures established by the licensee; and

iii. Comply with these regulations and the license conditions with respect to the use of radioactive material.

Sec. G.11 - Visiting Authorized User.

a. A licensee may permit any visiting authorized user to use licensed material for medical use under the terms of the licensee's license for 60 days each year if:

i. The visiting authorized user has the prior written permission of the licensee's management and, if the use occurs on behalf of an institution, the institution's Radiation Safety Committee;

ii. The licensee has a copy of an Agency[, Agreement State, Licensing State or the Nuclear Regulatory Commission] license that identifies the visiting authorized user by name as an authorized user for medical use; and

iii. Only those procedures for which the visiting authorized user is specifically authorized by an Agency[, Agreement State, Licensing State or the Nuclear Regulatory Commission] license are performed by that individual.

b. A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in G.11a.

c. A licensee shall retain copies of the records specified in G.11a. [for 3 years from the date of the last visit].

Sec. G.12 - Mobile Nuclear Medicine Service Administrative Requirements.

a. The Agency shall license mobile nuclear medicine services and/or clients of such services. The mobile nuclear medicine service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be

licensed if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

b. Mobile nuclear medicine service licensees shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile nuclear medicine service.

c. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a license. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's license.

d. A mobile nuclear medicine service shall inform a responsible individual, such as a representative of management or a Registered Nurse in charge of the patient or the Registered Nurse in charge of the nursing unit, who is on site at each client's address of use at the time that radiopharmaceuticals are being administered.

Sec. G.13 - Quality Management Program.

a. Each applicant or licensee shall establish and maintain a written quality management program to provide assurance that radioactive material or radiation therefrom will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

i. That, prior to administration, a written directive is prepared for:

(1) Any teletherapy radiation dose;

(2) Any gamma stereotactic radiosurgery radiation dose;

(3) Any brachytherapy radiation dose;

(4) Any administration of quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131; or

(5) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized

user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the paitient's record and a written directive is prepared within 24 hours of the oral directive.)

ii. That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

iii. That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

iv. That each administration is in accordance with the written directive; and

v. That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

b. Each licensee shall:

i. Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

ii. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of G.13a.; and

iii. Retain records of each review, including the evaluations and findings of the review, in an auditable form for 3 years.

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c. The licensee shall evaluate and respond to each recordable event, within 30 days after discovery of the recordable event, by:

i. Assembling the relevant facts including the cause;

ii. Identifying what, if any, corrective action is required to prevent recurrence; and

iii. Retaining a record, in an auditable form, for 3 years, of the relevant facts and what corrective action, if any, was taken.

d. Each licensee shall retain:

i. Each written directive; and

ii. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in G.13a.i., in an auditable form, for 3 years after the date of administration.

e. The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. Furnish mod to State ? or NRC only when requested

Sec. G.14 - Records, Notifications, and Reports of Misadministrations.

a. For a misadministration:

i. The licensee shall notify the Agency by telephone no later than 24 hours after discovery of the misadministration;

ii. The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physicians's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient;

iii. The licensee shall notify the referring physician and also notify the patient of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the patient or that, based on medical judgement, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

iv. If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the Agency; or

(ii) A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

b. Each licensee shall retain a record of each misadministration for 5 years. The record shall contain the names of all individuals involved (including the prescribing physician, allied

health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

c. Aside from the notification requirement, nothing in G.14a. and G.14b. shall affect any rights or duties of licensees and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

Sec. G.15 - Suppliers. A licensee shall use for medical use only:

a. Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a license issued pursuant to these regulations or the equivalent regulations of another Agreement State, a Licensing State or the Nuclear Regulatory Commission; and

b. Reagent kits, radiopharmaceuticals, and/or radiobiologics that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the Food and Drug Administration; or

c. Radiopharmaceuticals compounded from a prescription in accordance with the regulations of the state Board of Pharmacy.

d. Teletherapy and brachytherapy sources manufactured and distributed in accordance with a license issued pursuant to these regulations, or the equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

Specific Requirements

[Sec. G.16 - Quality Control of Diagnostic Equipment. Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.]

Sec. G.17 - Possession, Use, Calibration, and Check of Dose Calibrators.

a. A medical use licensee authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient. In the case where the ionization type dose calibrator cannot be used effectively to verify administered activity, the licensee shall use an alternative method. Any alternative method to the use of a dose calibrator shall be approved by the Agency in writing. Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

b. Each licensee shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient. As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute in ANSI N42.13-1986 [or the licensee shall:

i. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. The check shall be done on a frequently used setting with a sealed source of not less than 1.35 megabecquerels (50 μCi) of any photon-emitting radionuclide with a half-life greater than 90 days;

ii. Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides with activities of at least 1.85 megabecquerels (50 μCi) each. The activity of one source shall be determined by the manufacturer to be within 5 percent of the stated activity. All other sources used for this test shall be within 10 percent of the stated activity. All sources used to satisfy the accuracy test shall be calibration sources traceable to the National Institute of Standards and Technology or other standards recognized as being equivalent by the National Institute of Standards and Technology;

iii. Test each dose calibrator for linearity upon installation and at intervals not to exceed 3 months thereafter over the range of use between 370 kilobecquerels (10 μCi) and the highest dosage that will be assayed; and

iv. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 370 kilobecquerels (10 μCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

d. A licensee shall also perform checks and tests required by G.17b. following adjustment or repair of the dose calibrator.

e. A licensee shall retain a record of each check and test required by G.17 for 3 years. The records required by G.17b. shall include:

i. For G.17b.i., the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

ii. For G.17b.ii., the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the individual who performed the test;

iii. For G.17b.iii., the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the individual who performed the test; and

iv. For G.17b.iv., the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the individual who performed the test].

Sec. G.18 - Calibration and Check of Survey Instruments.

a. A licensee shall ensure that the survey instruments used to show compliance with Part G have been calibrated before first use, annually, and following repair.

b. To satisfy the requirements of G.18a., the licensee shall:

i. Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;
NIST traceable

ii. For each scale that shall be calibrated, calibrate 2 readings separated by at least 50 percent of scale rating; and

iii. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

c. To satisfy the requirements of G.18b., the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and consider a point as calibrated if the indicated exposure rate differs from the calculated exposure 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.18a. for 3 years. The record shall include:

i. A description of the calibration procedure; and

ii. 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.18a., b., and c., the licensee may obtain the services of individuals licensed by the Agency, the 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.18e. shall be maintained by the licensee.

Sec. G.19 - 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 370 kilobecquerels (10 μCi) of a photon-emitting radionuclide;

b. Assay, before medical use, the activity of each radiopharmaceutical dosage emitting alpha and/or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:

   i. In unit dose form, calibrated by the supplier for individual patients; and

   ii. From a supplier which participates in a measurement quality assurance program with the National Institute of Standards and Technology, and which is designed to ensure that unit doses have a calibration traceable to a national standard;

c. Retain a record of the assays or calibrations required by G.19a. and b. for 3 years. To satisfy this requirement, the record shall contain the:

   i. radiopharmaceutical, or the radionuclide administered;

   ii. Patient's name, and identification number if one has been assigned;

   iii. Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;

   iv. Date and time of the assay or calibration and the date and time of the administration; and

   v. Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program specified in G.18b.

Sec. G.20 - Authorization for Calibration and Reference Sources. Any person authorized by G.3 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

a. Sealed sources manufactured and distributed by persons specifically licensed pursuant to Part C of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State and that do not exceed 555 megabecquerels (15 mCi) each;

b. Any radioactive material [listed in G.31 or G.33] with a half-life of 100 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

c. Any radioactive material [listed in G.31 or G.33] with a half-life greater than 100 days in individual amounts not to exceed 7.4 megabecquerels (200 μCi) each; and

d. Technetium-99m in individual amounts not to exceed 1.85 gigabecquerels (50 mCi).

Sec. G.21 - Requirements for Possession of Sealed Sources and Brachytherapy Sources.

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

b. A licensee in possession of a sealed source shall assure that:

i. The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and

ii. The source is tested for leakage at intervals not to exceed 6 months or at intervals approved by the Agency, another Agreement State, a Licensing State or the Nuclear Regulatory Commission.

c. To satisfy the leak test requirements of G.21b., the licensee shall assure that:

i. Leak tests are capable of detecting the presence of 185 becquerels (0.005 μCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 becquerels (0.001 μCi) per 24 hours;

ii. Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

iii. Test samples are taken when the device containing the source is in the "off" position.

d. A licensee shall retain leak test records for 5 years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (μCi), a description of the method used to measure each test sample, the date of the test, and the signature of the individual who performed the test.

e. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

i. Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of Part D of these regulations; and

ii. File a report with the Agency within 5 days of receiving the leak test results with the Agency describing the equipment involved, the test results, and the action taken.

f. A licensee need not perform a leak test on the following sources:

i. Sources containing only radioactive material with a half-life of less than 30 days;

ii. Sources containing only radioactive material as a gas;

iii. Sources containing 3.7 megabecquerels (100 μCi) or less of beta- or photon-emitting material or 370 kilobecquerels (10 μCi) or less of alpha-emitting material; [and]

iv. Seeds of iridium-192 encased in nylon ribbon[; and

v. Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within 6 months before the date of use or transfer].

g. A licensee in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed 3 months. The licensee shall retain each inventory record for 5 years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the individual who performed the inventory.

h. A licensee in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

i. A licensee shall retain a record of each survey required in G.21h. for 3 years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the individual who performed the survey.

Sec. G.22 - Syringe Shields.

a. A licensee shall keep syringes that contain radioactive material to be administered in an appropriate radiation shield or shielded area.

b. A licensee shall require each individual who prepares or administers radiopharmaceuticals to use an appropriate syringe radiation shield unless the use of the shield is contraindicated for that patient.

Sec. G.23 - Syringe Labels. Unless utilized immediately, a licensee shall conspicuously identify each syringe, or syringe radiation shield as to contents or intended patient.

Sec. G.24 - Vial Shields. A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

Sec. G.25 - Vial Shield Labels. A licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

Sec. G.26 - Surveys for Ambient Radiation Dose Rate and Contamination.

a. A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by G.26a. and b. so as to able to measure dose rates as low as 1 microsievert (0.1 mrem) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by G.26a. and b. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each day of use all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are stored.

f. A licensee shall conduct the surveys required by G.26e. so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).

g. A licensee shall establish removable contamination action levels for the surveys required by G.26e. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

h. A licensee shall retain a record of each survey required by G.26a., b., and e. for 3 years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

Sec. G.27 - Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

a. A licensee shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

   i. The dose rate from the patient is less than 50 μSv (5 millirems) per hour at a distance of 1 meter; or

ii. The activity in the patient is less than 1.11 GBq (30 millicuries).

b. A licensee shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 50 μSv (5 millirems) per hour at a distance of 1 meter.

Sec. G.28 - Mobile Nuclear Medicine Service Technical Requirements. A licensee providing mobile nuclear medicine service shall:

a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

b. Bring into each area of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;

d. In addition to complying with G.17 and G.18, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use;

e. Carry a survey meter calibrated in accordance with G.18 in each vehicle that is being used to transport radioactive material, and, before leaving a client area of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument, including a survey for removable contamination, to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed;

f. Retain a record of each survey required by G.28e. for 3 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour, the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey; and

g. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards.

Sec. G.29 - Storage of Volatiles and Gases.

a. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

b. A licensee shall store and use a multidose container in a properly functioning fume hood.

Sec. G.30 - Decay-In-Storage.

a. Before disposal in ordinary trash, a licensee shall hold radioactive material for decay-in-storage and is exempt from the waste disposal requirements of Part D of these regulations if the licensee:

i. Holds radioactive material for decay a minimum of 10 half-lives;

ii. Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

iii. Removes or obliterates all radiation labels; and

iv. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

b. For radioactive material disposed in accordance with G.30a., the licensee shall retain a record of each disposal for 3 years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

Specific Requirements for the Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies

Sec. G.31 - Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.

A licensee may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion:

a. Which has been granted acceptance or approval by the Food and Drug Administration; or

b. Which is prepared and compounded in accordance with the regulations of the state Board of Pharmacy.

Sec. G.32 - 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 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.18.

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Specific Requirements for the Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies

Sec. G.33 - Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies.

A licensee may use any radioactive material in a diagnostic radiopharmaceutical (except aerosol or gaseous forms) or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material:

a. Which has been granted acceptance or approval by the Food and Drug Administration; or

b. Which has been prepared and compounded in accordance with the regulations of the state Board of Pharmacy;

c. A licensee shall elute generators in compliance with G.34;

d. Provided the conditions of G.35 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

Sec. G.34 - Radionuclide Contaminants.

a. A licensee shall not administer a radiopharmaceutical containing:

i. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);

ii. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride);

iii. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

b. A licensee preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in G.34a.

c. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement for 3 years. The record shall include, for each elution or extraction tested, the measured activity of the radiopharmaceutical expressed in megabecquerels (mCi), the measured activity of contaminant expressed in kilobecquerels (μCi), the ratio of the measures expressed as kilobecquerels (μCi) of contaminant per megabecquerel (mCi) of radiopharmaceutical, 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 radionuclide contaminant concentration exceeding the limits specified in G.34a.

Sec. G.35 - 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 in Part D 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 with respect 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 Part D 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.35d. 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 3 years.

g. A copy of the calculations required in G.35d. shall be recorded and retained for the duration of the license.

Sec. G.36 - 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 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.18.

Specific Requirements for the Use of Radiopharmaceuticals for Therapy

Sec. G.37 - Use of Radiopharmaceuticals for Therapy. A licensee may use any radioactive material in a radiopharmaceutical and for a therapeutic use:

a. Which has been granted acceptance or approval by the Food and Drug Administration; or

b. Which has been prepared and compounded in accordance with the regulations of the state Board of Pharmacy.

Sec. G.38 - 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.38a., the instruction shall describe the licensee's procedures for:

i. Patient control;

ii. Visitor control;

iii. Contamination control;

iv. Waste control;

v. Notification of the Radiation Safety Officer or authorized user in case of the patient's death or medical emergency; and

vi. Training for workers as required by Part J of these regulations.

c. A licensee shall keep a record of individuals receiving instruction required by G.38a., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the Agency for 3 years.

Sec. G.39 - Safety Precautions.

a. For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with G.27, a licensee shall:

i. Provide a private room with a private sanitary facility;

ii. 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;

iii. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

iv. 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 Part D of these regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

v. 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 these materials and items as radioactive waste;

vi. Instruct the patient and, where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;

vii. 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 3.33 becquerels (200 dpm) per 100 square centimeters; and

viii. Measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 within 3 days after administering the dosage, and retain for the period required by Part D of these regulations a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Other procedures acceptable to the Agency may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.

b. For each non-hospitalized patient receiving radiopharmaceutical therapy, the licensee shall instruct the patient and, where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.

c. The Radiation Safety Officer or the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

Sec. G.40 - Possession of Survey Instruments. A licensee authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.18.

Specific Requirements for the Use of Sealed Sources for Diagnosis

Sec. G.41 - 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 or in a portable device for imaging; and

d. Iodine-125 as a sealed source in a portable device for imaging.

Sec. G.42 - 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 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instrument shall be operable and calibrated in accordance with G.18.

Specific Requirements for the Use of Sources for Brachytherapy

Sec. G.43 - 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. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

g. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

Sec. G.44 - Safety Instruction.

a. The licensee shall provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training shall be provided at intervals not to exceed 1 year.

b. To satisfy G.44a., the instruction shall describe:

   i. Size and appearance of the brachytherapy sources;

   ii. Safe handling and shielding instructions in case of a dislodged source;

iii. Procedures for patient control;

iv. Procedures for visitor control;

v. Procedures for notification of the Radiation Safety Officer or authorized user if the patient dies or has a medical emergency; and

vi. Training for workers as required by Part J of these regulations.

c. A licensee shall maintain a record of individuals receiving instruction required by G.44a., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.

Sec. G.45 - Safety Precautions.

a. For each patient receiving implant therapy a licensee shall:

i. 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 radiation dose limits for individual members of the public as specified in Part D of these regulations at a distance of 1 meter from the implant;

ii. Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's chart where and how long visitors may stay in the patient's room;

iii. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;

iv. 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 Part D of these regulations and retain for 3 years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

v. Before authorizing the release of a patient administered a permanent implant, instruct the patient, and where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help keep the radiation dose to household members and the public as low as reasonably achievable.

b. The Radiation Safety Officer or authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

Sec. G.46 - 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 or otherwise verify 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 utilization which includes:

i. The names of the individuals permitted to handle the sources;

ii. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

iii. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and 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 maintain the records required in G.46b. and c. for 3 years.

Sec. G.47 - Release of Patients Treated With Temporary Implants.

a. Immediately after removing the last temporary implant source from a patient, the licensee shall perform 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 maintain a record of patient surveys which demonstrate compliance with G.47a. for 3 years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as microsieverts (mrems) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.

Sec. G.48 - Possession of Survey Instruments. A licensee authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (mrems) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.18.

Specific Requirements for the Use of a Sealed Source in Teletherapy

Sec. G.49 - 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.

Sec. G.50 - Maintenance and Repair Restrictions. Only a person specifically licensed by the Agency, the 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.

Sec. G.51 - Amendments. In addition to the requirements specified in G.4, a licensee shall apply for and 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.

Sec. G.52 - Safety Instruction.

a. A licensee shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:

   i. 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;

   ii. The procedure to be followed if 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

   iii. 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 G.52a. 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 maintain a record of individuals receiving instruction required by G.52b., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for 3 years.

Sec. G.53 - 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:

i. Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

ii. Turn the beam of radiation "off" immediately when an entrance door is opened; and

iii. 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 conspicuously visible beam condition indicator light.

Sec. G.54 - Possession of Survey Instrument. A licensee authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.18.

Sec. G.55 - 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 shall 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 shall 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 G.55d. for 3 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and 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. 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 G.55e.

g. A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

Sec. G.56 - 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.

Sec. G.57 - 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:

   i. The system shall have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

   ii. 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 Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiation physics center accredited by the American Association of Physicists in Medicine. 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 G.57a. This comparison shall have been performed within the previous

year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in G.57a.

c. The licensee shall maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.57a. and b., the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

Sec. G.58 - Full Calibration Measurements.

a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

   i. Before the first medical use of the unit;

   ii. Before medical use under the following conditions:

      (1) 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;

      (2) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

      (3) 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

   iii. At intervals not exceeding 1 year.

b. To satisfy the requirement of G.58a., full calibration measurements shall include determination of:

   i. The output within 3 percent for the range of field sizes and for the distance or range of distances used for medical use;

   ii. The coincidence of the radiation field and the field indicated by the light beam localizing device;

   iii. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

   iv. Timer accuracy, constancy, and linearity;

v. "On-off" error; and

vi. The accuracy of all distance measuring and localization devices in medical use.

c. A licensee shall use the dosimetry system described in G.57 to measure the output for 1 set of exposure conditions. The remaining radiation measurements required in G.58b.i. may then be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by G.58a. in accordance with the measurements required for annual calibration by "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Medical Physics, Vol. 21, No. 4, 1994, pp. 581-618.

e. A licensee shall correct mathematically the outputs determined in G.58b.i. for physical decay for intervals not exceeding 1 month for cobalt-60 and intervals not exceeding 6 months for cesium-137.

f. Full calibration measurements required by G.58a. and physical decay corrections required by G.58e. shall be performed by a teletherapy physicist named on the licensee's license or authorized by a license issued by the Nuclear Regulatory Commission or an Agreement State to perform such services.

g. A licensee shall maintain a record of each calibration for the duration of the license. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

Sec. G.59 - 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 1 month.

b. To satisfy the requirement of C.59a., spot checks shall include determination of:

i. Timer constancy and timer linearity over the range of use;

ii. "On-off" error;

iii. The coincidence of the radiation field and the field indicated by the light beam localizing device;

iv. The accuracy of all distance measuring and localization devices used for medical use;

v. The output for 1 typical set of operating conditions; and

vi. The difference between the measurement made in G.59b.v. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

c. A licensee shall use the dosimetry system described in G.57 to make the spot check required in G.59b.v.

d. A licensee shall perform spot checks required by G.59a. in accordance with procedures established by the teletherapy physicist. The teletherapy physicist 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 2 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 G.59f., safety spot checks shall assure proper operation of:

i. Electrical interlocks at each teletherapy room entrance;

ii. 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;

iii. Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

iv. Viewing systems;

v. Treatment room doors from inside and outside the treatment room; and

vi. 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 G.59g. that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

j. A licensee shall maintain a record of each spot check required by G.59a. and f. for 3 years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit, and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

Sec. G.60 - 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 G.51, the licensee shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with G.18 to verify that:

i. 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 100 microsieverts (10 mrems) per hour and 20 microsieverts (2 mrems) per hour, respectively; and

ii. 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:

(1) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Part D of these regulations; and

(2) Radiation levels in unrestricted areas do not exceed the limits specified in Part D of these regulations.

b. If the results of the surveys required in G.60a. 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:

i. Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

ii. Until the licensee has received a specific exemption from the Agency.

c. A licensee shall maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation

levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrems) per hour, the calculated maximum level of radiation over a period of 1 week for each restricted and unrestricted area and the signature of the Radiation Safety Officer.

Sec. G.61 - Safety Spot Checks for Teletherapy Facilities.

a. A licensee shall promptly check all systems listed in G.59g. for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by G.51.

b. If the results of the safety spot checks required in G.61a. indicate the malfunction of any system specified in G.59, the licensee shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

c. A licensee shall maintain a record of the safety spot checks following installation of a source for 3 years. The record shall include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the Radiation Safety Officer.

Sec. G.62 - Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by G.60 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by Part D of these regulations, before beginning the treatment program the licensee shall:

a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with Part D of these regulations;

b. Perform the survey required by G.60 again; and

c. Include in the report required by G.63 the results of the initial survey, a description of the modification made to comply with G.62a., and the results of the second survey; or

d. Request and receive a license amendment under Part D of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by Part D of these regulations.

Sec. G.63 - Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A licensee shall furnish a copy of the records required in G.60, G.61, G.62 and the output from the teletherapy source expressed as grays (rads) per hour at 1 meter from the source as determined during the full calibration required in G.58 to the Agency within 30 days following completion of the action that initiated the record requirement.

Sec. G.64 - 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 Nuclear Regulatory Commission.

c. A licensee shall maintain a record of the inspection and servicing for the duration of the license. The record shall contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

Specific Requirements for Training

Sec. G.65 - Radiation Safety Officer. Except as provided in G.66, an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in G.7 shall:

a. Be certified by the:

   i. American Board of Health Physics in Comprehensive Health Physics; or

   ii. American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or

   iii. American Board of Nuclear Medicine; or

   iv. American Board of Science in Nuclear Medicine; or

   v. Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or

   vi. American Board of Medical Physics in Radiation Oncology Physics; or

   vii. Royal College of Physicians and Surgeons of Canada in Nuclear Medicine; or

   viii. American Osteopathic Board of Radiology; or

   ix. American Osteopathic Board of Nuclear Medicine; or

b. Have had 200 hours of classroom and laboratory training covering:

   i. Radiation physics and instrumentation;

   ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Radiation biology;

v. Radiopharmaceutical chemistry; and

vi. Have had 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 the 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.

Sec. G.66 - Training for Experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on an Agency, Agreement State, Licensing State, or Nuclear Regulatory Commission license on [insert effective date of rule] 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 G.65.

Sec. G.67 - Training for Uptake, Dilution, or Excretion Studies. Except as provided in G.75 and G.76, the licensee shall require the authorized user of a radiopharmaceutical listed in G.31 to be a physician who:

a. Is certified in:

i. Nuclear medicine by the American Board of Nuclear Medicine; or

ii. Diagnostic radiology by the American Board of Radiology; or

iii. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

iv. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

v. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 40 hours of instruction in basic radionuclide handling techniques applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.

i. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiation biology; and

(5) Radiopharmaceutical chemistry.

ii. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

(1) Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

(2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(3) Administering dosages to patients and using syringe radiation shields;

(4) Collaborating with the authorized user in the interpretation of radionuclide test results; and

(5) Patient followup; or

c. Has successfully completed a six-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 G.67b.

Sec. G.68 - Training for Imaging and Localization Studies. Except as provided in G.75 or G.76, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in G.33 to be a physician who:

a. Is certified in:

i. Nuclear medicine by the American Board of Nuclear Medicine; or

ii. Diagnostic radiology by the American Board of Radiology; or

iii. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

iv. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

v. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 200 hours of instruction in basic radionuclide 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.

i. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity;

(4) Radiopharmaceutical chemistry; and

(5) Radiation biology.

ii. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

(3) Calculating and safely preparing patient dosages;

(4) Using administrative controls to prevent the misadministration of radioactive material;

(5) Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(6) 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.

iii. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(1) Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

(2) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

(3) Administering dosages to patients and using syringe radiation shields;

(4) Collaborating with the authorized user in the interpretation of radionuclide test results; and

(5) Patient followup; or

c. Has successfully completed a six-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 G.68b.

Sec. G.69 - Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in G.75, the licensee shall require the authorized user of a radiopharmaceutical listed in G.37 for therapy to be a physician who:

a. Is certified in:

i. Nuclear medicine by the American Board of Nuclear Medicine; or

ii. Radiation oncology, therapeutic radiology, or radiology by the American Board of Radiology; or

iii. Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or

iv. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

i. To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology;

ii. To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(1) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in ten individuals;

(2) Use of soluble phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

(3) Use of iodine-131 for treatment of thyroid carcinoma in three individuals;

(4) Use of colloidal chromic phosphorus-32 or of colloidal gold-198 for intracavitary treatment of malignant effusions in three individuals; and

(5) Use of strontium-89 as strontium chloride for the treatment of pain associated with bone metastases in three individuals.

Sec. G.70 - Training for Therapeutic Use of Brachytherapy Sources. Except as provided in G.75, the licensee shall require the authorized user using a brachytherapy source specified in G.43 for therapy to be a physician who:

a. Is certified in:

i. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

ii. Radiation oncology by the American Osteopathic Board of Radiology; or

iii. Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

iv. 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 radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

i. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology.

ii. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

(1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(2) Checking survey meters for proper operation;

(3) Preparing, implanting, and removing sealed sources;

(4) Using administrative controls to prevent the misadministration of radioactive material; and

(5) Using emergency procedures to control radioactive material.

iii. To satisfy the requirement for a period of supervised clinical experience, training shall include one 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 two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

(2) Selecting the proper brachytherapy sources, dose, and method of administration;

(3) Calculating the dose; and

(4) Post-administration followup and review of case histories in collaboration with the authorized user.

Sec. G.71 - Training for Ophthalmic Use of Strontium-90. Except as provided in G.75, the licensee shall require the authorized user using only strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is certified in radiology, therapeutic radiology, or radiation oncology 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 radionuclide handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

i. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology.

ii. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of 5 individuals that includes:

(1) Examination of each individual to be treated;

(2) Calculation of the dose to be administered;

(3) Administration of the dose; and

(4) Followup and review of each individual's case history.

Sec. G.72 - Training for Use of Sealed Sources for Diagnosis. Except as provided in G.75, the licensee shall require the authorized user using a sealed source in a device specified in G.41 to be a physician, dentist, or podiatrist who:

a. Is certified in:

i. Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

ii. Nuclear medicine by the American Board of Nuclear Medicine; or

iii. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

iv. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

b. Has completed 8 hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

i. To satisfy the requirement for instruction, the training shall include:

(1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

(2) Radiation biology; and

(3) Radiation protection and training in the use of the device for the purposes authorized by the license.

Sec. G.73 - Training for Teletherapy. Except as provided in G.75, the licensee shall require the authorized user of a sealed source specified in G.49 in a teletherapy unit to be a physician who:

a. Is certified in:

i. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

ii. Radiation oncology by the American Osteopathic Board of Radiology; or

iii. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

iv. 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 radionuclide 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.

i. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(1) Radiation physics and instrumentation;

(2) Radiation protection;

(3) Mathematics pertaining to the use and measurement of radioactivity; and

(4) Radiation biology.

ii. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

(1) Review of the full calibration measurements and periodic spot checks;

(2) Preparing treatment plans and calculating treatment times;

(3) Using administrative controls to prevent misadministrations;

(4) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

(5) Checking and using survey meters.

iii. 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 a medical institution. The supervised clinical experience shall include:

(1) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

(2) Selecting the proper dose and how it is to be administered;

(3) 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

(4) Post-administration followup and review of case histories.

Sec. G.74 - Training for Teletherapy Physicist. The licensee shall require the teletherapy physicist to:

a. Be certified by the American Board of Radiology in:

i. Therapeutic radiological physics;

ii. Roentgen-ray and gamma-ray physics;

iii. X-ray and radium physics; or

iv. Radiological physics; or

b. Be certified by the American Board of Medical Physics in radiation oncology physics; or

c. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, 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 a medical institution. To meet this requirement, the individual shall have performed the tasks listed in G.21, G.58, G.59, and G.60 under the supervision of a teletherapy physicist during the year of work experience.

Sec. G.75 - Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an Agency[, the Nuclear Regulatory Commission or Agreement State or Licensing State] license on [insert effective date of rule] who

perform only those methods of use for which they were authorized on that date need not comply with the training requirements of G.65 through G.77.

Sec. G.76 - Physician Training in a Three-Month Program. A physician who, before July 1, 1984, began a three-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 G.67 or G.68.

Sec. G.77 - Recentness of Training. The training and experience specified in G.65 through G.74 shall 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.