




# Conference of Radiation Control Program Directors, Inc.

Office of Executive Director ♦ 205 Capital Avenue ♦ Frankfort, KY 40601  
Phone: 502/227-4543 ♦ Fax: 502/227-7862 ♦ Web Site: www.crcpd.org  
Central E-mail: staff@crcpd.org

## MEMORANDUM

**TO:** CRCPD Board of Directors,  
CRCPD Federal Liaisons

**FROM:** Ron Fraass   
Executive Director

**DATE:** October 16, 2002

**RE:** Adoption of Revised Part G (2002) into the SSRCR's

### Board of Directors

#### *Chairperson*

Cynthia C. Cardwell  
Texas

#### *Chairperson-Elect*

Richard A. Ratliff  
Texas

#### *Past Chairperson*

Paul J. Merges, Ph D  
New York

#### *Treasurer*

Terry C. Frazee  
Washington

#### *Members-at-Large*

Julia A. Schmitt  
Nebraska

Russell S. Takata  
Hawaii

Debbie B. Gilley  
Florida

### Office of Executive Director

*Executive Director*  
Ronald G. Fraass  
Kentucky

*Administrative Officer*  
Patricia C. Gorman  
Kentucky

Please find enclosed **Part G -USE OF RADIONUCLIDES IN THE HEALING ARTS** as submitted to the CRCPD board by the SR-6 working group, chaired by David Walter. In addition, I have included the 2002 Rationale for Part G, the SR-6 working group's response to peer review comments, and a review of issues by Terry Devine.

This revision of Part G represents a complete rewrite of the previous Part G (1995). This Part G (2002) reflects extensive rule revision at the federal level. As the content and organization of Part G (2002) is considerably different from the previous Part G (1995), there are no edit marks in this draft that reference the previous Part G (1995).

Should the board have any questions or concerns regarding form or format, please feel free to contact Bruce Hirschler of my staff.

**Cc:** Pat Gorman, Administrative Officer., CRCPD  
David Walter, Chair, SR-6  
Bruce Hirschler, Tech. Asst, CRCPD

SP02

## MEMORANDUM

Date: 10 October 2002  
To: CRCPD Board of Directors  
cc: David Walter, Bruce Hirschler, Pat Gorman  
From: Terry Devine, CRCPD, Ph. 502/227-4543, Fax 502/223-7026, e-mail tdevine@crcpd.org  
Re: Comments on Sept.02 Draft SSRCR Part G received 1 Oct. 2002

Pat Gorman asked me to review, for the Board, this draft of Part G and associated rationale with particular regard for the citations and as to how comments were dealt with by the committee. Ron Fraass asked me to note any requirement that doesn't make sense. Nearly all of my comments were on the previous draft and have been dealt with for this Sept. draft.

Among citations to other passages of the SSRCR, I found no error. Two are contingent upon Board approval of 2002 Part D. I did not check citations on matters of compatibility; however, NRC commented extensively.

G.39f I understood David to say that the wipe sensitivity of 2000 dpm is to conform to DOT regulations, which are soon to change. A footnote citing that passage of 49 CFR might be useful.

G.53a.ii(1) The citations are to the 1995 D.301, which is the limit on dose to the public in general. If you  
G.62a.iv approve the 2002 Part D, the citations in G should be to the new passage, D.1301, that explicitly  
G.123 addresses dose limits for persons exposed to nuclear medicine patients.

You will wish to study the comments by NRC in their 20 Sept.'02 letter to you and the responses by the committee in their rationale and personal communications.

Of the other comments on previous drafts that were reported in the committee's 'Analysis' (note that several Sec. Nr's. have changed in successive drafts) all corrections were implemented per the responses, or otherwise addressed. There are three passages of which I have trouble making sense, and suggest the following:

G.33b.i Current text, "Calibrate all required scale readings up to 10 millisieverts...with a radiation source."  
I'd suggest, "Calibrate all of the scales that are required in G.33b.ii(2), including that to 10  
millisieverts (1000 mrem) per hour, with a radiation source."

G.41e "...consistent response with a it's dedicated check source..."

G.39f Current, "...so as to be able to detect contamination on each wipe sample of 33.3 becquerels..."  
I suggest, "so as to be able to detect as little as 33 Bq (2000 dpm) on each wipe sample."

A few typos in the Sept. edition are being dealt with by David and Bruce: delete three periods in G.18c, delete a comma after 'in' in G.51c(2), add the footnote re absence of Licensing state to G.29a & G.51a, '3 years' in G.100b [b and remove a sentence break from G.20a.iv The G.12-14 gap is intended by the committee.

The rationale seemed to me exceptionally well and cleanly written. The rationale for the previous editions should be added to the '02 edition.

Correlations needed with other parts are addressed in the rationale pages 12-13. Also, "Area of use," "Address of use," "Dedicated check source," "Management," in '02 Part G might also be appropriate in Part A. Also in '02 Part G, "Sealed source" is defined in both the '95 A and the '02 draft A, and "Sealed Source and Device Registry" is defined in the '02 draft A. Might the procedure for assessing removable contamination, T.15h, also be appropriate in Part D (the committee finds it overly prescriptive for Part G).

-----

## PART G

### USE OF RADIONUCLIDES IN THE HEALING ARTS

#### General Information

**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 these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of Part G are in addition to, and not in substitution for, others in these regulations unless specifically exempted.

**Sec. G.2 - Definitions.**

["Accredited institution" means a teaching facility for nuclear medicine technology or radiation therapy technology whose standards are accepted by the United States Department of Education.]

"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 an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

"Authorized medical physicist" means an individual who:

- (1) Meets the requirements in G.26 or G.29; or
- (2) Is identified as an authorized medical physicist on a specific medical use license or equivalent permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or
- (3) Is identified as an authorized medical physicist on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific medical use license of broad scope that is authorized to permit the use of radioactive material.

"Authorized nuclear pharmacist" means a pharmacist who:

- (1) Meets the requirements in G.27 or G.29; or [and]
- (2) Is identified as an authorized nuclear pharmacist on a specific license or equivalent permit that authorizes medical use, the practice of nuclear pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or

- (3) Is identified as an authorized nuclear pharmacist on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the use of radioactive material.

"Authorized user" means a physician, dentist, or podiatrist who:

- (1) Meets the requirements in G.30 and G.46a., G.51a., G.56a., G.57a., G.58a., G.67a., G.68, G.70a., or G.88a.; or
- (2) Is identified as an authorized user on a license or equivalent permit issued by the Agency, Nuclear Regulatory Commission, Agreement State or Licensing State; or
- (3) Is identified as an authorized user on a permit issued by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State specific license of broad scope that is authorized to permit the medical use of radioactive material.

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

"Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

"Client's address" means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with G.41.

"Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

"Dentist" means an individual licensed to practice dentistry by the state in which the Agency is located.

"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, or in the case of sealed sources for diagnosis, the procedure.

"High dose-rate remote afterloader" (HDR) means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the treatment site.

"Low dose-rate remote afterloader" (LDR) means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the treatment site.

"Management" means the chief executive officer or other individual having the authority to manage,

direct, or administer the licensee's activities, or those persons' delegate or delegates.

"Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually applied or inserted.

"Misadministration" means an event that meets the criteria in G.119a.

"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 from radioactive material to patients or human research subjects under the supervision of an authorized user.

"Medium dose-rate remote afterloader" (MDR) means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the treatment site.

"Mobile medical service" means the transportation of radioactive material or its medical use at the client's address.

["Nuclear medicine technologist" means an individual who meets the requirements of G.28a. and is under the supervision of an authorized user, to prepare or administer radioactive drugs to patients or human research subjects, or perform *in vivo* or *in vitro* measurements for medical purposes.]

["Nuclear medicine technology" means the science and art of *in vivo* and *in vitro* detection and measurement of radioactivity and the administration of radioactive drugs to patients or human research subjects for diagnostic and therapeutic purposes.]

"Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

"Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

"Pharmacist" means an individual licensed by the appropriate authority to practice pharmacy in the state in which the Agency is located.

"Physician" means a doctor of medicine or doctor of osteopathy licensed by the appropriate authority to prescribe drugs in the practice of medicine in the state in which the Agency is located.

"Podiatrist" means an individual licensed by the appropriate authority to practice podiatry in the state in which the Agency is located.

"Preceptor" means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear

pharmacist, [nuclear medicine technologist, radiation therapy technologist] or a Radiation Safety Officer.

"Prescribed dosage" means the specified activity or range of activity of a radioactive drug as documented:

- (1) In a written directive as specified in G.22.; or
- (2) In accordance with the directions of the authorized user for procedures performed pursuant to G.44, G.47 and G.52.

"Prescribed dose" means:

- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive;
- (2) For teletherapy, the total dose and dose per fraction as documented in the written directive;
- (3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or
- (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

"Pulsed dose-rate remote afterloader" (PDR) means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

- (1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and
- (2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

"Radiation Safety Officer" means an individual who:

- (1) Meets the requirements in G.25 or G.29; or
- (2) Is identified as a Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the Agency for similar types and uses of radioactive material.

["Radiation therapist" means an individual who meets the requirements of G.28b. and is under the supervision of an authorized user to perform procedures and apply radiation emitted from sealed radioactive sources to human beings for therapeutic purposes.]

["Radiation therapy technology" means the science and art of applying radiation emitted from sealed

radioactive sources to patients or human research subjects for therapeutic purposes.]

"Radioactive drug" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

"Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

"Sealed Source and Device Registry" means the national registry that contains the registration certificates maintained by the Nuclear Regulatory Commission, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

"Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

"Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

"Teletherapy" as used in this Part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

"Temporary jobsite" as used in this Part, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

"Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

"Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

"Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

"Type of use" means use of radioactive material as specified under G.44, G.47, G.52, G.59, G.69, G.71 or G.89.

"Unit dosage" means a dosage that:

- (1) Is obtained or prepared in accordance with the regulations for uses described in G.44, G.47, or G.52; and
- (2) Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

"Written directive" means an authorized user's written order for the administration of radioactive

material or radiation from radioactive material to a specific patient or human research subject, as specified in G.22.

Sec. G.3 - Maintenance of Records. Each record required by Part G must be legible throughout the retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

Sec. G.4 - Provisions for Research Involving Human Subjects. A licensee may conduct research involving human subjects using radioactive material provided:

- a. That the research is conducted, funded, supported, or regulated by a Federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;
- b. The research involving human subjects authorized in G.4a. shall be conducted using radioactive material authorized for medical use in the license; and
- c. Nothing in G.4 relieves licensees from complying with the other requirements in Part G.

Sec. G.5 - U.S. Food and Drug Administration, Federal, and State Requirements. Nothing in this Part relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

Sec. G.6 - Implementation.

- a. A licensee shall implement the provisions in Part G on [insert effective date of the rule].
- b. When a requirement in Part G differs from the requirement in an existing license condition, the requirement in this Part shall govern.
- c. Any existing license condition that is not affected by a requirement in Part G remains in effect until there is a license amendment or license renewal.
- d. If a license condition exempted a licensee from a provision of Part G on [insert effective date of the rule], it will continue to exempt a licensee from the corresponding provision in Part G.
- e. If a license condition cites provisions in Part G that will be deleted on [insert effective date of



the rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

- f. Licensees shall continue to comply with any license condition that requires it to implement procedures required by G.74, G.80, G.81 and G.82 until there is a license amendment or renewal that modifies the license condition.

**Sec. G.7 - License Required.**

- a. A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, the Nuclear Regulatory Commission or an Agreement State, or as allowed in G.7b. or G.7c.
- b. 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.21, unless prohibited by license condition.
- c. An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in Part G under the supervision of an authorized nuclear pharmacist or authorized user as provided in G.21, unless prohibited by license condition.

**Sec. G.8 - Application for License, Amendment, or Renewal.**

- a. An application must be signed by the applicant's or licensee's management.
- b. An application for a license for medical use of radioactive material as described in G.44, G.47, G.52, G.59, G.69, G.71 or G.89 must be made by:
  - i. Filing an original [and one copy] of [insert Agency application form name], and
  - ii. Submitting procedures required by sections G.23, [G.31,] G.74, G.80, G.81 and G.82, as applicable.
- c. A request for a license amendment or renewal must be made by:
  - i. Submitting an original [and one copy] in letter format.
  - ii. Submitting procedures required by sections G.23, [G.31,] G.74, G.80, G.81 and G.82, as applicable.
- d. In addition to the requirements in G.8b. and G.8c., an application for a license or amendment for medical use of radioactive material as described in G.89 of this Part must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in G.1 through G.43, as well as any specific information on:
  - i. Radiation safety precautions and instructions;

- ii. Training and experience of proposed users;
  - iii. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and
  - iv. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.
- e. The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.
- f. An applicant that satisfies the requirements specified in C.27b. may apply for a Type A specific license of broad scope.

Sec. G.9 - Mobile Medical Service Administrative Requirements.

- a. The Agency shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.
- b. Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. 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 address for use by the mobile medical service.
- c. A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.
- d. A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.
- e. A licensee providing mobile medical services shall retain the letter required in G.9b. in accordance with G.101.
- f. A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:
- i. The current operating and emergency procedures;
  - ii. A copy of the license;

- iii. Copies of the letter required by G.9b.;
  - iv. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and
  - v. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.
- g. A mobile medical service licensee shall maintain all records required by Parts D and G of these regulations at a location within the Agency's jurisdiction that is:
- i. A single address of use:
    - (1) Identified as the records retention location; and
    - (2) Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or
  - ii. When no address of use is identified on the license for records retention, the mobile unit:
    - (1) Identified in the license; and
    - (2) Whose current client's address schedule and location schedule is reported to the Agency.

**Sec. G.10 - License Amendments.** A licensee shall apply for and must receive a license amendment:

- a. Before it receives, prepares or uses radioactive material for a type of use that is permitted under Part G, but that is not authorized on the licensee's current license issued pursuant to Part G;
- b. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license; except an individual who is:
  - i. For an authorized user, an individual who meets the requirements in G.30 and G.46a., G.51a., G.56a., G.57a., G.58a., G.67a., G.70a., or G.88a. or;
  - ii. For an authorized nuclear pharmacist, an individual who meets the requirements in G.27a. and G.30;
  - iii. For an authorized medical physicist, an individual who meets the requirements in G.26a. and G.30;
  - iv. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Nuclear Regulatory Commission or Agreement State license or

Licensing State or other equivalent permit or license recognized by the Agency that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or

- v. Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Nuclear Regulatory Commission or Agreement State or Licensing State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.
- c. Before it changes Radiation Safety Officers, except as provided in G.18c.;
- d. Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;
- e. Before it adds to or changes the areas of use identified in the application or on the license, except as specified in G.11b.iv.;
- f. Before it changes the address(es) of use identified in the application or on the license;
- g. Before it changes statements, representations, and procedures which are incorporated into the license; and
- h. Before it releases licensed facilities for unrestricted use.

Sec. G.11 - Notifications.

- a. A licensee shall provide to the Agency a copy of the board certification, the Nuclear Regulatory Commission, Agreement State or Licensing State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist, pursuant to G.10b.
- b. A licensee shall notify the Agency by letter no later than 30 days after:
  - i. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
  - ii. The licensee's mailing address changes;
  - iii. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in C.31b. of these regulations; or
  - iv. The licensee has added to or changed the areas where radioactive material is used in accordance with G.44 and G.47.

**Sec. G.15 - Exemptions Regarding Type A Specific Licenses of Broad Scope.** A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

- a. The provisions of G.8d. regarding the need to file an amendment to the license for medical uses of radioactive material as described in G.89;
- b. The provisions of G.10b. regarding the need to file an amendment before permitting anyone to work as an authorized user, an authorized nuclear pharmacist or an authorized medical physicist under the license;
- c. The provisions of G.10e. regarding additions to or changes in the areas of use at the addresses specified in the license;
- d. The provisions of G.11a. regarding notification to the Agency for new authorized users, new authorized nuclear pharmacists and new authorized medical physicists;
- e. The provisions of G.24a. regarding suppliers for sealed sources.

**Sec. G.16 - License Issuance.**

- a. The Agency shall issue a license for the medical use of radioactive material if:
  - i. The applicant has filed [insert proper license application form ID] in accordance with the instructions in G.8;
  - ii. The applicant has paid any applicable fee;
  - iii. The applicant meets the requirements of Part C of these regulations; and
  - iv. The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.
- b. The Agency shall issue a license for mobile services if the applicant:
  - i. Meets the requirements in G.16a.; and
  - ii. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with G.40.

**Sec. G.17 - Specific Exemptions.** The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in Part G as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

## General Administrative Requirements

### Sec. G.18 - Authority and Responsibilities for the Radiation Protection Program.

- a. In addition to the radiation protection program requirements of D.101 of these regulations, a licensee's management must approve in writing:
  - i. Requests for license application, renewal, or amendments before submittal to the Agency;
  - ii. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and
  - iii. Radiation protection program changes that do not require a license amendment and are permitted under G.19.
- b. A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.
- c. For up to sixty days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in G.18e., provided the licensee takes the actions required in G.18b.,d.,e. and h. A licensee may simultaneously appoint more than one temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.
- d. A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.
- e. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:
  - i. Identify radiation safety problems;
  - ii. Initiate, recommend, or provide corrective actions;
  - iii. Stop unsafe operations; and,
  - iv. Verify implementation of corrective actions.
- f. Licensees that are authorized for two or more different types of radioactive material use under G.52, G.59, G.71, and G.89, or two or more types of units under G.71 shall establish a

Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The Committee must 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, and may include other members as the licensee deems appropriate.

- [g. A licensee's Radiation Safety Committee shall meet as necessary, but at a minimum shall meet at intervals not to exceed 12 [6] months. The licensee shall maintain minutes of each meeting in accordance with G.90.]
- h. A licensee shall retain a record of actions taken pursuant to G.18a., G.18b. and G.18d. in accordance with G.90.

Sec. G.19 - Radiation Protection Program Changes.

- a. A licensee may revise its radiation protection program without Agency approval if:
  - i. The revision does not require an amendment under G.10;
  - ii. The revision is in compliance with the regulations and the license;
  - iii. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and
  - iv. The affected individuals are instructed on the revised program before the changes are implemented.
- b. A licensee shall retain a record of each change in accordance with G.91.

Sec. G.20 - Duties of Authorized User and Authorized Medical Physicist.

- a. A licensee shall assure that only authorized users for the type of radioactive material used:
  - i. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and
  - ii. Direct, as specified in G.21 and G.22, or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;
  - iii. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with G.7b., G.7c. and G.21;
  - [iv. Perform the final interpretation of the results of tests, studies, or treatments]
- b. A licensee shall assure that only authorized medical physicists perform, as applicable:

- i. Full calibration measurements as described in G.77, G.78, and G.79;
- ii. Periodic spot checks as described in G.80, G.81, and G.82; and
- iii. Radiation surveys as described in G.84.

Sec. G.21 - Supervision.

- a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by G.7b. shall:
  - i. In addition to the requirements in J.12 of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of Part G, and license conditions with respect to the use of radioactive material; and
  - ii. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, regulations of Part G, and license conditions with respect to the medical use of radioactive material.
- b. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by G.7c., shall:
  - i. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and
  - ii. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of Part G, and license conditions.
- [c. Unless physical presence as described in other sections of Part G is required, a licensee who permits supervised activities under G.21a. and G.21b. shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification;] and
- d. A licensee that permits supervised activities under G.21a. and G.21b. is responsible for the acts and omissions of the supervised individual.

Sec. G.22 - Written Directives.

- a. A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30  $\mu$ Ci), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.



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 as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

- b. The written directive must contain the patient or human research subject's name and the following:
  - i. For an administration of a dosage of radioactive drug containing radioactive material, the radioactive drug containing radioactive material, dosage, and route of administration;
  - ii. For gamma stereotactic radiosurgery, the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
  - iii. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;
  - iv. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
  - v. For all other brachytherapy including LDR, MDR, and PDR:
    - (1) Prior to implantation: treatment site, the radionuclide, and dose; and
    - (2) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose).
- c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.
- d. 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 as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.
- d. The licensee shall retain the written directive in accordance with G.92.

Sec. G.23 - Procedures for Administrations Requiring a Written Directive.

- a. For any administration requiring a written directive, the licensee shall develop, implement,

and maintain written procedures to provide high confidence that:

- i. The patient's or human research subject's identity is verified before each administration; and
  - ii. Each administration is in accordance with the written directive.
- b. The procedures required by G.23a. must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:
- i. Verifying the identity of the patient or human research subject;
  - ii. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;
  - iii. Checking both manual and computer-generated dose calculations; and
  - iv. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by G.71.

Sec. G.24 - Suppliers for Sealed Sources or Devices for Medical Use. For medical use, a licensee may only use:

- a. Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Part C of these regulations or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State; or
- b. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Part C of these regulations or the equivalent requirements of the Nuclear Regulatory Commission, an Agreement State or a Licensing State.

Sec. G.25 - Training for Radiation Safety Officer. Except as provided in G.29, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in G.18 to be an individual who:

- a. Is certified by a speciality board whose certification process includes all of the requirements in G.25b. and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State, or;<sup>2/</sup>
- b. i. Has completed a structured educational program consisting of both:
  - (1) 200 hours of didactic training in the following areas:
    - (a) Radiation physics and instrumentation;

---

<sup>2/</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

- (b) Radiation protection;
  - (c) Mathematics pertaining to the use and measurement of radioactivity;
  - (d) Radiation biology; and
  - (e) Radiation dosimetry; and
- (2) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Nuclear Regulatory Commission or Agreement State license that authorizes similar type(s) of use(s) of radioactive material involving the following;
- (a) Shipping, receiving, and performing related radiation surveys;
  - (b) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;
  - (c) Securing and controlling radioactive material;
  - (d) Using administrative controls to avoid mistakes in the administration of radioactive material;
  - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;
  - (f) Using emergency procedures to control radioactive material;
  - (g) Disposing of radioactive material; and
- ii. Has obtained written certification, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in G.25b.i. and has achieved a level of radiation safety knowledge sufficient to independently function as an RSO for medical uses of radioactive material; or
- c. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual has Radiation Safety Officer responsibilities.

**Sec. G.26 - Training for Authorized Medical Physicist.** The licensee shall require the authorized medical physicist to be an individual who:

- a. Is certified by a speciality board whose certification process includes all of the training and experience requirements in G.26b. and whose certification has been recognized by the

Nuclear Regulatory Commission or an Agreement State<sup>2/</sup>; or

- b. i. Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the Agency, another Agreement State or the Nuclear Regulatory Commission and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in G.36, G.64e., G.77, G.78, G.79, G.80, G.81, G.82 and G.84, as applicable; and
- ii. Has obtained written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in G.26b.i. and has achieved a level of competency sufficient to independently function as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

Sec. G.27 - Training for an Authorized Nuclear Pharmacist. The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

- a. Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in G.27b. and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State<sup>2/</sup>; or
- b. i. Has completed 700 hours in a structured educational program consisting of both:
  - (1) Didactic training in the following areas:
    - (a) Radiation physics and instrumentation;
    - (b) Radiation protection;
    - (c) Mathematics pertaining to the use and measurement of radioactivity;
    - (d) Chemistry of radioactive material for medical use; and
    - (e) Radiation biology; and
  - (2) Supervised practical experience in a nuclear pharmacy involving:
    - (a) Shipping, receiving, and performing related radiation surveys;
    - (b) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

---

<sup>2/</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

- (c) Calculating, assaying, and safely preparing dosages for patients or human research subjects;
  - (d) Using administrative controls to avoid misadministrations in the administration of radioactive material; and
  - (e) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
- ii. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in G.27b.i. and has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

[Sec. G.28 - Training and Technical Requirements for Nuclear Medicine Technologists and Radiation Therapists.]

- a. The licensee shall require a nuclear medicine technologist using radioactive materials under the supervision of an authorized user to be an individual who:
  - i. Is certified in:
    - (1) Nuclear Medicine by the Nuclear Medicine Technology Certification Board;
    - (2) Nuclear Medicine by the American Registry of Radiologic Technologists with competency in Nuclear Medicine; or,
  - ii. Be board eligible to take the CNMT or ARRT(N) examinations; or,
  - iii. Has successfully completed a training program in nuclear medicine which has resulted in a certificate, associate degree, or baccalaureate degree in a nuclear medicine technology program from an accredited institution; or,
  - iv. Has performed as a full-time nuclear medicine technologist for a minimum of two years during the past five-year period under the supervision of an authorized user who certifies the experience in writing; or,
  - v. Has completed 80 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material that includes:
    - (1) Classroom and laboratory training in the following areas:
      - (a) Radiation physics and instrumentation;
      - (b) Radiation protection;

- (c) Mathematics pertaining to the use and measurement of radioactivity;
  - (d) Chemistry of radioactive material for medical use; and
  - (e) Radiation biology; and
- (2) Work experience, under the supervision of an authorized user involving:
- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (b) Quality Control checking of instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
  - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
  - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
  - (f) Administering dosages to patients or human research subjects; and
- (3) Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of radiation safety competency sufficient to independently function as a nuclear medicine technologist.
- b. The licensee shall require a radiation therapist using radioactive materials under the supervision of an authorized user to be an individual who:
- i. Is certified in Radiation Therapy by the American Registry of Radiologic Technologists (ARRT(T)); or
  - ii. Be board eligible to take the ARRT(T) examination; or,
  - iii. Has successfully completed a training program in radiation therapy which has resulted in a certificate, associate degree, or baccalaureate degree in a radiologic technology program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology;<sup>1/</sup> or,

---

<sup>1/</sup> "Essentials and guidelines of an Accredited Educational Program for the Radiation Therapy Technologist", Joint Review Committee on Education in Radiologic Technology, 1988.

- iv. Has performed as a full-time radiation therapist for a minimum of two years during the past five-year period under the supervision of an authorized user who certifies the experience in writing; or
- v. Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material that includes:
  - (1) Classroom and laboratory training in the following areas:
    - (a) Radiation physics and instrumentation;
    - (b) Radiation protection;
    - (c) Mathematics pertaining to the use and measurement of radioactivity; and
    - (d) Radiation biology; and
  - (2) Work experience, under the supervision of an authorized user involving:
    - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - (b) Assisting the authorized user in simulating the patient for treatment;
    - (c) Preparing the patient for treatment;
    - (d) Implementing treatment plans as prescribed by the authorized user;
    - (e) Providing written documentation of treatment setup and patient treatments;
    - (f) Quality control checks to determine that devices used to deliver the radiation doses are in compliance with institutional standards and performing checks for proper operation of survey meters;
    - (g) Preparing or assisting in the preparation of sources, and implantation and removal of sealed sources;
    - (h) Delivering doses to patients or human research subjects under the supervision of the authorized user;
    - (i) Maintaining running inventories of radioactive material on hand;
    - (j) Using administrative controls to prevent a misadministration involving the use of radioactive material; and,

- (k) Properly implementing emergency procedures; and
- (3) Has obtained written certification, signed by a preceptor authorized user that the individual has satisfactorily completed the requirements of this section and has achieved a level of radiation safety competency sufficient to independently function as a radiation therapist
- c. Individuals working as nuclear medicine technologists or radiation therapists for a facility holding an Agency license prior to [insert effective date of these rules] need not comply with the training requirements of this section.
- d. The licensee shall maintain records of the above training as specified in G.104.]

Sec. G.29 - Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist.

- a. An individual identified as a Radiation Safety Officer, a medical physicist, or a nuclear pharmacist on a Nuclear Regulatory Commission, an Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, before [insert effective date of the rule] need not comply with the training requirements of G.25, G.26 and G.27, respectively.
- b. Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of radioactive material on a Nuclear Regulatory Commission or Agreement State license or on a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee that authorizes medical use or the practice of nuclear pharmacy, issued before [insert effective date of the rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of G.46, G.51, G.56, G.57, G.58, G.67, G.68, G.70 and G.88.

Sec. G.30 - Recentness of Training. The training and experience specified in Part G must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

**General Technical Requirements**

[Sec. G.31 - 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.32 - Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.

- a. For direct measurements performed in accordance with G.34, a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.
- b. A licensee shall test the instrumentation required in G.32a. in accordance with nationally recognized standards or the manufacturer's instructions.
- c. [The tests required in G.32b. shall at a minimum include tests for constancy, linearity, accuracy and geometry dependence, as appropriate to demonstrate proper operation of the instrument.
- d.] A licensee shall retain a record of each instrument test required by G.32 in accordance with G.95.

Sec. G.33 - Calibration of Survey Instruments.

- a. A licensee shall ensure that the survey instruments used to show compliance with Part G and Part D of these regulations have been calibrated before first use, annually, and following any repair that will affect the calibration.
- b. To satisfy the requirements of G.33a., the licensee shall:
  - i. Calibrate all required scale readings up to 10 millisieverts (1000 mrem) per hour with a radiation source;
  - ii. Have each radiation survey instrument calibrated:
    - (1) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;
    - (2) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and
    - (3) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.
  - iii. Conspicuously note on the instrument the date of calibration.
- c. The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

- d. [A licensee shall check each survey instrument for consistent response with a 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 survey instrument calibration in accordance with G.96.

Sec. G.34 - Determination of Dosages of Radioactive Material for Medical Use.

- a. A licensee shall determine and record the activity of each dosage prior to medical use. [For photon-emitting radioactive material, this determination shall be within 30 minutes prior to medical use. For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-life of the radioactive material.]
- b. For a unit dosage, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to Part C of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.
- c. For other than unit dosages, this determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to Part C of these regulations or equivalent provisions of the Nuclear Regulatory Commission, Agreement State or Licensing State.
- d. Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.
- e. A licensee shall retain a record of the dosage determination required by Part G in accordance with G.97.

Sec. G.35 - Authorization for Calibration, Transmission and Reference Sources. Any person authorized by G.7 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 1.11 gigabecquerels (30 mCi) each;
- b. Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);
- c. Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

- i. 7.4 megabecquerels (200  $\mu$ Ci); or
  - ii. 1000 times the quantities in Appendix B of Part C of these regulations; and
- d. Technetium-99m in amounts as needed.

**Sec. G.36 - 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.
- b. A licensee in possession of a sealed source shall:
  - i. Test the source for leakage in accordance with Part D of these regulations.
  - ii. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Agency, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.
- c. If the leak test reveals the presence of 185 becquerels (0.005  $\mu$ Ci) or more of removable contamination, the licensee shall:
  - i. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Parts C and D of these regulations;
  - ii. File a report with the Agency within 5 days of receiving the leak tests results in accordance with G.121.
- d. A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with G.98.

**Sec. G.37 - Labels.** Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

**[Sec. G.38 - Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.]

**Sec. G.39 - Surveys for Ambient Radiation Dose Rate and Contamination.**

- a. Except as provided in G.39b., a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material requiring a written directive were prepared for use or administered.

- b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.
- c. A licensee shall conduct the surveys required by G.39a. and b. so as to be 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.39a. and G.39b. 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 generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.
- f. A licensee shall conduct the surveys required by G.39e. 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.39e. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.]
- h. A licensee does not need to perform the surveys required by G.39a. in area(s) where patients or human research subjects are confined when they can not be released pursuant to G.40.
- i. A licensee shall retain a record of each survey in accordance with G.99.

Sec. G.40 - Release of Individuals Containing Radioactive Drugs or Implants.

- a. A licensee may authorize the release [from its control] of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisievert (0.5 rem).
- b. For patients administered radioactive material for which a written directive is required, a licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:<sup>2/</sup>
  - i. Guidance on the interruption or discontinuation of breast-feeding; and
  - ii. Information on the potential consequences, if any, of failure to follow the guidance.

---

<sup>2/</sup> This may have health and safety implications, see Rational for Part G 2002

- [b. A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:
  - i. Guidance on the interruption or discontinuation of breast-feeding; and
  - ii. Information on the potential consequences, if any, of failure to follow the guidance.]
- [c. Release of the patient must be approved by an individual listed as an authorized user on the Agency license, and who is approved for the type of radioactive material use for which the patient being released has received.]
- d. The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with G.100.
- e. The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with G.100.
- [f. Notwithstanding G.40a., the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.
- g. The licensee shall immediately notify the Agency in accordance with G.122 if a patient departs prior to an authorized release.
- h. The licensee shall notify the Agency in accordance with G.123:
  - i. When they are aware that a patient containing radioactive material and who has been released in accordance with G.40 dies; and,
  - ii. If it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.]

**Sec. G.41 - Mobile Medical Service Technical Requirements.** A licensee providing mobile medical service shall:

- a. Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;
- b. Bring into each client's address 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 a client's address;
- d. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more

- frequent. At a minimum, the check for proper function shall include a constancy check;
- e. Check survey instruments for consistent response with a dedicated check source before use at each client's address;
  - f. Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Part D of these regulations;
  - [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;] and,
  - h. Retain a record of each survey required by G.41 f. in accordance with G.101.

[Sec. G.42 - Storage and Control of Volatiles and Gases.]

- a. A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.
- b. A licensee shall store and use a multi-dose container in a properly functioning fume hood.
- c. 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.
- d. 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.
- e. A licensee shall check the operation of collection systems monthly. Records of these checks shall be maintained for 3 years.]

Sec. G.43 - Decay-in-Storage.

- a. A licensee may hold radioactive material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
  - i. Monitors radioactive material at the container surface before disposal 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;
  - ii. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and
  - iii. 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.43a. of this section, the licensee shall

retain a record of each disposal in accordance with G.102.

### Specific Requirements for the Use of Radioactive Material for Uptake, Dilution, or Excretion Studies

Sec. G.44 - Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for which a Written Directive is Not Required. A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

- a. Obtained from a manufacturer or preparer licensed pursuant to Part C of these regulations or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in G.46, G.51, or an individual under the supervision of either as specified in G.21; or
- c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- d. Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA for use in research.

[Sec. G.45 - 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 of 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.33.]

Sec. G.46 - Training for Uptake, Dilution, and Excretion Studies. Except as provided in G.29, the licensee shall require an authorized user of an unsealed radioactive material for the uses authorized under G.44 to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.46c. and whose certification has been recognized by the Nuclear Regulatory Commission, or an Agreement State; or
- b. Is an authorized user under G.51 or G.56, or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- c. i. Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes:

- (1) Classroom and laboratory training in the following areas:
    - (a) Radiation physics and instrumentation;
    - (b) Radiation protection;
    - (c) Mathematics pertaining to the use and measurement of radioactivity;
    - (d) Chemistry of radioactive material for medical use; and
    - (e) Radiation biology; and
  - (2) Work experience, under the supervision of an authorized user who meets the requirements in G.46, G.51 or G.56 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:
    - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - (b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
    - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
    - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
    - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
    - (f) Administering dosages to patients or human research subjects; and
- ii. Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in G.46, G.51 or G.56 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in G.46c.i. and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under G.44.<sup>2/</sup>

---

<sup>2/</sup> *Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.*



**Specific Requirements for the Use of Unsealed Radioactive Material - Written Directive Not Required**

Sec. G.47 - Use of Unsealed Radioactive Material for Imaging and Localization Studies for which a Written Directive is Not Required. A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in G.22 that is:

- a. Obtained from a manufacturer or preparer licensed pursuant to Part C of these regulations or equivalent regulations of another Agreement State, a Licensing State, or the Nuclear Regulatory Commission; or
- b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in G.51, or an individual under the supervision of either as specified in G.21; or
- c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State or Licensing State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or
- d. Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.
- e. Provided the conditions of G.42 are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

Sec. G.48 - Radionuclide Contaminants.

- a. A licensee shall not administer to humans a radioactive drug containing:
  - i. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15  $\mu$ Ci 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  $\mu$ Ci 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  $\mu$ Ci of Sr-85 per mCi of Rb-82).
- b. To demonstrate compliance with G.48a., the licensee preparing radioactive drugs from radionuclide generators shall:
  - i. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;
  - ii. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

- c. A licensee who must measure radionuclide contaminant concentration shall retain a record of each measurement in accordance with G.103.
- d. A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in G.48a.

[Sec. G.49 - Reserved.]

[Sec. G.50 - 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 of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]

Sec. G.51 - Training for Imaging and Localization Studies. Except as provided in G.29, the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under G.47 to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.51c. and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or
- b. Is an authorized user under G.56, or equivalent Agreement State, or Nuclear Regulatory Commission requirements; or
- c. i. Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies that includes, at a minimum:
  - (1) Classroom and laboratory training in the following areas:
    - (a) Radiation physics and instrumentation;
    - (b) Radiation protection;
    - (c) Mathematics pertaining to the use and measurement of radioactivity;
    - (d) Chemistry of radioactive material for medical use;
    - (e) Radiation biology; and
  - (2) Work experience, under the supervision of an authorized user, who meets the requirements in, G.51 or G.56, or equivalent Agreement State, or Nuclear Regulatory Commission requirements, involving:

- (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (b) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
  - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
  - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
  - (f) Administering radiopharmaceutical dosages to patients or human research subjects; and
  - (g) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and
- ii. Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in G.51 or G.56, or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in G.51 c.i. and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under G.47.<sup>2</sup>

**Specific Requirements for the Use of Unsealed Radioactive Material - Written Directive Required**

**Sec. G.52 - Use of Unsealed Radioactive Material for which a Written Directive is Required.** A licensee may use any unsealed radioactive material for diagnostic or therapeutic medical use for which a written directive is required that has been:

- a. Obtained from a manufacturer or preparer licensed in accordance with Part C of these regulations; or
- b. Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in G.51 or G.56, or an individual under the supervision of either as specified in G.29; or

<sup>2</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

- c. Obtained from and prepared by an Agency, Nuclear Regulatory Commission, Agreement State, or Licensing State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the FDA for use in research; or
- d. Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by FDA for use in research.

Sec. G.53 - Safety Instruction. In addition to the requirements of J.12 of these regulations:

- a. A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with G.40. The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:
  - i. Patient or human research subject control;
  - ii. Visitor control to include the following:
    - (1) Routine visitation to hospitalized individuals in accordance with Part D of these regulations;
    - (2) Contamination control;
    - (3) Waste control; and
    - (4) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.
- b. A licensee shall retain a record of individuals receiving instruction in accordance with G.105.

Sec. G.54 - Safety Precautions.

- a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with G.40, a licensee shall:
  - i. Quarter the patient or the human research subject either in:
    - (1) A private room with a private sanitary facility; or
    - (2) A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with G.40; and,
  - ii. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's

chart where and how long visitors may stay in the patient's or the human research subject's room; and

- iii. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity 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 such material and items as radioactive waste.
- b. The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Agency in accordance with G.123 if it is possible that any individual could receive exposures in excess of Part D.301 of these regulations as a result of the deceased's body.

**[Sec. G.55 - Possession of Survey Instruments.** A licensee authorized to use radioactive material for which a written directive is required 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 of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]

**Sec. G.56 - Training for Use of Unsealed Radioactive Material for which a Written Directive is Required.** Except as provided in G.29, the licensee shall require an authorized user of radioactive material for the uses authorized under G.52 to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements of G.56b. and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission;<sup>2/</sup> or
- b. i. Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive, that includes:
  - (1) Classroom and laboratory training in the following areas:
    - (a) Radiation physics and instrumentation;
    - (b) Radiation protection;
    - (c) Mathematics pertaining to the use and measurement of radioactivity;
    - (d) Chemistry of radioactive material for medical use; and

<sup>2/</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

- (e) Radiation biology; and
- (2) Work experience, under the supervision of an authorized user who meets the requirements in G.56 or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of G.56b. must have experience in administering dosages in the same dosage category or categories listed in G.56b.ii. as the individual requesting authorized user status. The work experience must involve:
  - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (b) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;
  - (c) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (d) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;
  - (e) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
  - (f) Administering dosages to patients or human research subjects; and
  - (g) Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs containing radioactive material; and
- ii. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of 3 cases in each of the following categories for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised work experience required by G.56b.i.(2):
  - (1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;
  - (2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;<sup>2/</sup>
  - (3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or
  - (4) Parenteral administration of any other radionuclide; and

---

<sup>2/</sup> Experience with at least 3 cases in category (2) also satisfies the requirement in category (1).

- iii. Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in G.56 or equivalent Agreement State, or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements G.56b.i. and G.56b.ii. and has achieved a level of competency sufficient to independently function as an authorized user for the medical uses authorized under G.56. The preceptor authorized user who meets the requirements of G.56b. must have experience in administering dosages in the same dosage category or categories listed in G.56b.ii. as the individual requesting authorized user status.

Sec. G.57 - Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.<sup>21</sup> Except as provided in G.29, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.57c. and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission;<sup>22</sup> or
- b. Is an authorized user under G.56a., G.56b., for uses listed in G.56b.ii.(1) or (2), G.58 or equivalent Agreement State or Nuclear Regulatory Commission requirements; or
- c. i. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:
  - (1) Radiation physics and instrumentation;
  - (2) Radiation protection;
  - (3) Mathematics pertaining to the use and measurement of radioactivity;
  - (4) Chemistry of radioactive material for medical use; and
  - (5) Radiation biology; and
- ii. Has work experience under the supervision of an authorized user who meets the requirements in G.56a., G.56b., G.57 or G.58, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user who meets the requirements of G.56b. must have experience in administering dosages as specified in G.56b.ii.(1) or G.56b.ii.(2); the work experience must involve:
  - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

<sup>21</sup> This rule has possible health and safety implications, please see Rationale for Part G 2002 for additional information.

<sup>22</sup> Licensing States not included because of compatibility B. States may want to recognize the Licensing States Certification for NARM.

- (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
  - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (4) Using administrative controls to prevent a misadministration involving the use of radioactive material;
  - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
  - (6) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
- iii. Has obtained written certification that the individual has satisfactorily completed the requirements in G.57c.i. and G.57c.ii., and has achieved a level of competency sufficient to independently function as an authorized user for medical uses of unsealed radioactive material using sodium iodide I-131. The written certification must be signed by a preceptor authorized user who meets the requirements of G.56a., G.56b, G.57 or G.58, or equivalent Agreement State or Nuclear Regulatory Commission requirements. The preceptor authorized user who meets the requirements of G.56b. must have experience in administering dosages as specified in G.56b.ii.(1) and/or (2).

Sec. G.58 - Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.<sup>2/</sup> Except as provided in G.29, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.57c. and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission; or
- b. Is an authorized user under G.56a., G.56b. for uses listed in G.56b.ii.(2), or equivalent Agreement State, Licensing State or Nuclear Regulatory Commission requirements; or
- c. i. Has successfully completed 80 hours classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include:
  - (1) Radiation physics and instrumentation;

---

<sup>2/</sup>This rule has possible health and safety implications, please see Rationale for Part G 2002 for more information.



- (2) Radiation protection;
  - (3) Mathematics pertaining to the use and measurement of radioactivity;
  - (4) Chemistry of radioactive material for medical use; and
  - (5) Radiation biology; and
- ii. Has work experience, under the supervision of an authorized user who meets the requirements in G.56a., G.56b., G.58, or equivalent Agreement State, or Nuclear Regulatory Commission requirements. A supervising authorized user, who meets the requirements of G.56b., must have experience in administering dosages as specified in G.56b.ii.(2). The work experience must involve:
- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
  - (2) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
  - (3) Calculating, measuring, and safely preparing patient or human research subject dosages;
  - (4) Using administrative controls to prevent a misadministration involving the use of radioactive material;
  - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;
  - (6) Administering dosages to patients or human research subjects that includes at least 3 cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and
- iii. Has obtained written certification that the individual has satisfactorily completed the requirements in G.58c.i. and G.58c.ii. and has achieved a level of competency sufficient to independently function as an authorized user for medical uses of unsealed radioactive material using sodium iodide I-131 in activities greater than 1.22 gigabecquerels (33 millicuries). The written certification must be signed by a preceptor authorized user, who meets the requirements of G.56b., G.58, or equivalent Agreement State or Nuclear Regulatory Commission requirements. A preceptor authorized user who meets the requirements of G.56b., must have experience in administering dosages as specified in G.56b.ii.(2).

#### Manual Brachytherapy

Sec. G.59 - Use of Sealed Sources for Manual Brachytherapy. A licensee shall use only

brachytherapy sources for therapeutic medical uses:

- a. As approved in the Sealed Source and Device Registry; or
- b. In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.24a. are met.

Sec. G.60 - Surveys After Source Implant and Removal.

- a. Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.
- b. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.
- c. A licensee shall retain a record of the surveys in accordance with G.106.

Sec. G. 61 - Brachytherapy Sources Inventory.

- a. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.
- b. Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.
- c. A licensee shall maintain a record of the brachytherapy source accountability in accordance with G.107.

Sec. G.62 - Safety Instruction. In addition to the requirements of J.12 of these regulations:

- a. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with G.40. Instruction must be commensurate with the duties of the personnel and shall include the following:
  - i. Size and appearance of the brachytherapy sources;
  - ii. Safe handling and shielding instructions;
  - iii. Patient or human research subject control;
  - iv. Visitor control, including both:
    - (1) Routine visitation of hospitalized individuals in accordance with D.301a.i. of these regulations; and

- (2) Visitation authorized in accordance with D.301c. of these regulations; and
- v. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Agency in accordance with G.123 if it is possible that any individual could receive exposures in excess of 5 millisievert (500 mrem) as a result of the deceased's body.
- b. A licensee shall retain a record of individuals receiving instruction in accordance with G.105.

**Sec. G.63 - Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.**

- a. For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with G.40, a licensee shall:
  - i. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;
  - ii. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.
- b. A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:
  - i. Dislodged from the patient; or
  - ii. Lodged within the patient following removal of the source applicators.
- c. The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

**Sec. G.64 - Calibration Measurements of Brachytherapy Sealed Sources.**

- a. Prior to the first medical use of a brachytherapy sealed source on or after [insert effective date of the rule], a licensee shall perform the following:
  - i. Determine the source output or activity using a dosimetry system that meets the requirements of G.76a.;
  - ii. Determine source positioning accuracy within applicators; and
  - iii. Use published protocols accepted by nationally recognized bodies to meet the requirements of G.64a.i. and G.64a.ii.

- b. A licensee may use measurements provided by the source manufacturer [or by a calibration laboratory accredited by the American Association of Physicists in Medicine] that are made in accordance with G.64a.
- c. A licensee shall mathematically correct the outputs or activities determined in G.64a. of this section for physical decay at intervals consistent with 1.0 percent physical decay.
- d. An authorized medical physicist shall perform or review the calculation measurements made pursuant to G.64a., G.64b., or G.64c.
- e. Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs G.64a., G.64b., and G.64c.
- f. A licensee shall retain a record of each calibration in accordance with G.108.
- g. A licensee shall retain a record of decay calculations required by G.64e. in accordance with G.109.

Sec. G.65 - Therapy-related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- a. The source-specific input parameters required by the dose calculation algorithm;
- b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
- c. The accuracy of isodose plots and graphic displays; and
- d. The accuracy of the software used to determine radioactive source positions from radiographic images.

[Sec. G.66 - Possession of Survey Instruments. A licensee authorized to use manual brachytherapy sources 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 of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]

Sec. G.67 - Training for Use of Manual Brachytherapy Sources. Except as provided in G.29, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under G.59 to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.67b. and whose certification has been recognized by an Agreement State

or the Nuclear Regulatory Commission;<sup>2/</sup> or

- b. i. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
  - (1) 200 hours of classroom and laboratory training in the following areas:
    - (a) Radiation physics and instrumentation;
    - (b) Radiation protection;
    - (c) Mathematics pertaining to the use and measurement of radioactivity; and
    - (d) Radiation biology; and
  - (2) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.67 or equivalent Agreement State, or Nuclear Regulatory Commission requirements at a medical institution, involving:
    - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
    - (b) Checking survey meters for proper operation;
    - (c) Preparing, implanting, and removing brachytherapy sources;
    - (d) Maintaining running inventories of material on hand;
    - (e) Using administrative controls to prevent a misadministration involving the use of radioactive material;
    - (f) Using emergency procedures to control radioactive material; and
- ii. Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.67 or equivalent Agreement State or Nuclear Regulatory Commission requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.67b.i.(2); and
- iii. Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in G.67 or equivalent Agreement State or Nuclear Regulatory

<sup>2/</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

Commission requirements, that the individual has satisfactorily completed the requirements in G.67b.i. and G.67b.ii. and has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the medical uses authorized under G.59.

Sec. G.68 - Training for ophthalmic use of strontium-90. Except as provided in G.29, the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under G.59 to be a physician who:

- a. Is an authorized user under G.67 or equivalent Agreement State or Nuclear Regulatory Commission requirements;<sup>2/</sup> or,
- b.
  - i. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:
    - (1) Radiation physics and instrumentation;
    - (2) Radiation protection;
    - (3) Mathematics pertaining to the use and measurement of radioactivity; and,
    - (4) Radiation biology; and,
  - ii. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user who meets the requirements of G.67 or G.68, and that includes the use of strontium-90 for the ophthalmic treatment of five 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) Follow-up and review of each individual's case history; and,
  - iii. Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in G.67 or G.68 or equivalent Agreement State or Nuclear Regulatory Commission requirements, that the individual has satisfactorily completed the requirements in paragraphs i. and ii. of this section and has achieved a level of competency sufficient to independently function as an authorized user of strontium-90 for ophthalmic use.

---

<sup>2/</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

## Sealed Sources For Diagnosis

**Sec. G.69 - Use of Sealed Sources for Diagnosis.** A licensee shall use only sealed sources for diagnostic medical uses:

- a. Approved in the Sealed Source and Device Registry; and,
- b. Handled in accordance with the manufacturer's radiation safety instructions.

**Sec. G.70 - Training for Use of Sealed Sources for Diagnosis.** Except as provided in G.29, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under G.69 to be a physician, dentist, or podiatrist who:

- a. Is certified by a speciality board whose certification process includes all of the requirements in G.70b. and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission;<sup>2/</sup> or
- b. Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes:
  - i. Radiation physics and instrumentation;
  - ii. Radiation protection;
  - iii. Mathematics pertaining to the use and measurement of radioactivity;
  - iv. Radiation biology; and
  - v. Training in the use of the device for the uses requested.

## Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

**Sec. G.71 - Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.** A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

- a. As approved in the Sealed Source and Device Registry; or
- b. In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of G.24a. are met.

<sup>2/</sup>Licensing State not included because of compatibility B. State may want to recognize the Licensing State certification for NARM.

Sec. G.72 - Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.

- a. Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.
- b. A licensee shall retain a record of the surveys in accordance with G.106.

Sec. G.73 - Installation, Maintenance, Adjustment, and Repair.

- a. Only a person specifically licensed by the Agency, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- b. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.
- c. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State, Licensing State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.
- d. A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with G.110.

Sec. G.74 - Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.

- a. A licensee shall:
  - i. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
  - ii. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
  - iii. Prevent dual operation of more than one radiation producing device in a treatment



room, if applicable; and

- iv. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:
  - (1) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
  - (2) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
  - (3) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- b. A copy of the procedures required by G.74a.iv. must be physically located at the unit console.
- c. A licensee shall post instructions at the unit console to inform the operator of:
  - i. The location of the procedures required by G.74a.iv.; and
  - ii. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.
- d. A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in:
  - i. The procedures identified in G.74a.iv.; and
  - ii. The operating procedures for the unit.
- e. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.
- f. A licensee shall retain a record of individuals receiving instruction required by G.74d., in accordance with G.105.

**Sec. G.75 - Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

- a. A licensee shall control access to the treatment room by a door at each entrance.
- b. A licensee shall equip each entrance to the treatment room with an electrical interlock system

that will:

- i. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
  - ii. Cause the source(s) to be shielded promptly when an entrance door is opened; and
  - iii. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
- c. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
- d. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
- e. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.
- f. In addition to the requirements specified in G.75a. through G.75e., a licensee shall:
- i. For [low dose-rate,] medium dose-rate, and pulsed dose-rate remote afterloader units, require:
    - (1) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and
    - (2) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.
  - ii. For high dose-rate remote afterloader units, require:
    - (1) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and
    - (2) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

- iii. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.
- iv. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.
- g. A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:
  - i. Remains in the unshielded position; or
  - ii. Lodges within the patient following completion of the treatment.

**Sec. G.76 - Dosimetry Equipment.**

- a. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.
  - i. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
  - ii. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.
- b. The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with G.76a. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in G.76a.

- c. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with G.111.

Sec. G.77 - Full Calibration Measurements on Teletherapy Units.

- 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; and
  - 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;
    - (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.77a., full calibration measurements must 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 and linearity over the range of use;
  - 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.76a. to measure the output for one set of exposure conditions. The remaining radiation measurements required in G77b.i. may be made using a dosimetry system that indicates relative dose rates.

- d. A licensee shall make full calibration measurements required by G.77a. in accordance with published protocols accepted by nationally recognized bodies.
- e. A licensee shall mathematically correct the outputs determined in G.77b.i. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.
- f. Full calibration measurements required by G.77a. and physical decay corrections required by G.77e. must be performed by the authorized medical physicist.
- g. A licensee shall retain a record of each calibration in accordance with G.112.

Sec. G.78 - Full Calibration Measurements on Remote Afterloader Units.

- a. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:
  - i. Before the first medical use of the unit;
  - ii. Before medical use under the following conditions:
    - (1) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
    - (2) Following any repair of the 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 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
  - iv. At intervals not exceeding 1 year for low dose-rate remote afterloader units.
- b. To satisfy the requirement of G.78a., full calibration measurements must include, as applicable, determination of:
  - i. The output within +/- 5 percent;
  - ii. Source positioning accuracy to within +/- 1 millimeter;
  - iii. Source retraction with backup battery upon power failure;
  - iv. Length of the source transfer tubes;
  - v. Timer accuracy and linearity over the typical range of use;
  - vi. Length of the applicators; and

- vii. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
- c. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in G.78b., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.
- d. A licensee shall use the dosimetry system described in G.76a. to measure the output.
- e. A licensee shall make full calibration measurements required by G.78a. of this section in accordance with published protocols accepted by nationally recognized bodies.
- f. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with G.78a. through G.78e.
- g. A licensee shall mathematically correct the outputs determined in G.78b.i. for physical decay at intervals consistent with 1 percent physical decay.
- h. Full calibration measurements required by G.78a. and physical decay corrections required by G.78g. must be performed by the authorized medical physicist.
- i. A licensee shall retain a record of each calibration in accordance with G.112.

Sec. G.79 - Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

- a. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each 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 sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
    - (3) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
  - iii. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

- b. To satisfy the requirement of G.79a., full calibration measurements must include determination of:
- i. The output within +/-3 percent;
  - ii. Relative helmet factors;
  - iii. Isocenter coincidence;
  - iv. Timer accuracy and linearity over the range of use;
  - v. On-off error;
  - vi. Trunnion centricity;
  - vii. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
  - viii. Helmet microswitches;
  - ix. Emergency timing circuits; and
  - x. Stereotactic frames and localizing devices (trunnions).
- c. A licensee shall use the dosimetry system described in G.76a. to measure the output for one set of exposure conditions. The remaining radiation measurements required in G.79b.i. may be made using a dosimetry system that indicates relative dose rates.
- d. A licensee shall make full calibration measurements required by G.79a. in accordance with published protocols accepted by nationally recognized bodies.
- e. A licensee shall mathematically correct the outputs determined in G.79b.i. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.
- f. Full calibration measurements required by G.79a. and physical decay corrections required by G.79e. must be performed by the authorized medical physicist.
- g. A licensee shall retain a record of each calibration in accordance with G.112.

Sec. G.80 - Periodic Spot-Checks for Teletherapy Units.

- a. A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

- i. Timer accuracy, 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 one typical set of operating conditions measured with the dosimetry system described in G.76b.; and
  - vi. The difference between the measurement made in G.80a.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).
- b. A licensee shall perform measurements required by G.80a. in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.
- c. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.
- d. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to 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. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
  - iv. Viewing and intercom 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.
- e. If the results of the checks required in G.80d. indicate the malfunction of any system, a 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.



- f. A licensee shall retain a record of each spot-check required by G.80a. and G.80d., in accordance with G.113.

Sec. G.81 - Periodic Spot-Checks for Remote Afterloader Units.

- a. A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:
  - i. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;
  - ii. Prior to each patient treatment with a low dose-rate remote afterloader unit; and
  - iii. After each source installation.
- b. The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in G.81a. The authorized medical physicist need not actually perform the spot-check measurements.
- c. A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.
- d. To satisfy the requirements of G.81a., spot-checks must, at a minimum, assure proper operation of:
  - i. Electrical interlocks at each remote afterloader unit room entrance;
  - ii. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
  - iii. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;
  - iv. Emergency response equipment;
  - v. Radiation monitors used to indicate the source position;
  - vi. Timer accuracy;
  - vii. Clock (date and time) in the unit's computer; and
  - viii. Decayed source(s) activity in the unit's computer.
- e. If the results of the checks required in G.81d. indicate the malfunction of any system, a 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.

f. A licensee shall retain a record of each check required by G.81d. in accordance with G.114.

Sec. G.82 - Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.

a. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

- i. Monthly;
- ii. At the beginning of each day of use; and
- iii. After each source installation.

b. The licensee shall have the authorized medical physicist:

- i. Establish written procedures for performing the spot-checks required in G.82a.; and
- ii. Review the results of each spot-check required by G.82a.i. within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot check.

c. To satisfy the requirements of G.82a.i., spot-checks must, at a minimum:

- i. Assure proper operation of:
  - (1) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
  - (2) Helmet microswitches;
  - (3) Emergency timing circuits; and
  - (4) Stereotactic frames and localizing devices (trunnions).
- ii. Determine :
  - (1) The output for one typical set of operating conditions measured with the dosimetry system described in G.76b.;
  - (2) The difference between the measurement made in G.82c.ii.(1) 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);

- (3) Source output against computer calculation;
  - (4) Timer accuracy and linearity over the range of use;
  - (5) On-off error; and
  - (6) Trunnion centricity.
- d. To satisfy the requirements of G.82a.ii. and G.82a.iii., spot-checks must assure proper operation of:
- i. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;
  - ii. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;
  - iii. Viewing and intercom systems;
  - iv. Timer termination;
  - v. Radiation monitors used to indicate room exposures; and
  - vi. Emergency off buttons.
- e. A licensee shall arrange for prompt repair of any system identified in G.82c. that is not operating properly.
- f. If the results of the checks required in G.82d. indicate the malfunction of any system, a 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.
- g. A licensee shall retain a record of each check required by G.82c. and G.82d. in accordance with G.115.

**Sec. G.83 - Additional Technical Requirements for Mobile Remote Afterloader Units.**

- a. A licensee providing mobile remote afterloader service shall:
- i. Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and
  - ii. Account for all sources before departure from a client's address of use.
- b. In addition to the periodic spot-checks required by G.81, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

- i. Electrical interlocks on treatment area access points;
  - ii. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;
  - iii. Viewing and intercom systems;
  - iv. Applicators, source transfer tubes, and transfer tube-applicator interfaces;
  - v. Radiation monitors used to indicate room exposures;
  - vi. Source positioning (accuracy); and
  - vii. Radiation monitors used to indicate whether the source has returned to a safe shielded position.
- c. In addition to the requirements for checks in G.83b., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
  - d. If the results of the checks required in G.83b. indicate the malfunction of any system, a 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.
  - e. A licensee shall retain a record of each check required by G.83b. in accordance with G.116.

Sec. G.84 - Radiation Surveys.

- a. In addition to the survey requirements in D.501 of these regulations, a person licensed pursuant to Part G shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.
- b. The licensee shall make the survey required by G.84a. at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
- c. A licensee shall retain a record of the radiation surveys required by G.84a. in accordance with G.117.

Sec. G.85 - Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units.

- a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during 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 may only be performed by persons specifically licensed to do so by the Agency, an Agreement State, a Licensing State or the Nuclear Regulatory Commission.
- c. A licensee shall keep a record of the inspection and servicing in accordance with G.118.

Sec. G.86 - Therapy-Related Computer Systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

- a. The source-specific input parameters required by the dose calculation algorithm;
- b. The accuracy of dose, dwell time, and treatment time calculations at representative points;
- c. The accuracy of isodose plots and graphic displays;
- d. The accuracy of the software used to determine radioactive source positions from radiographic images; and
- e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

[Sec. G.87 - Possession of Survey Instruments. A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units 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 of 10 microsieverts (1 mrem) per hour to 10 millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with G.33.]

Sec. G.88 - Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units. Except as provided in G.29, the licensee shall require an authorized user of a sealed source for a use authorized under G.71 to be a physician who:

- a. Is certified by a medical specialty board whose certification process includes all of the requirements in G.88b, and whose certification has been recognized by an Agreement State or the Nuclear Regulatory Commission;<sup>2/</sup> or
- b. i. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:
  - (1) 200 hours of classroom and laboratory training in the following areas:
    - (a) Radiation physics and instrumentation;

<sup>2/</sup> Licensing State not included because compatibility B. State may want to recognize the Licensing State certification for NARM.

- (b) Radiation protection;
  - (c) Mathematics pertaining to the use and measurement of radioactivity;  
and
  - (d) Radiation biology; and
- ii. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in G.88 or equivalent Agreement State or Nuclear Regulatory Commission requirements at a medical institution, involving:
- (1) Reviewing full calibration measurements and periodic spot checks;
  - (2) Preparing treatment plans and calculating treatment doses and times;
  - (3) Using administrative controls to prevent a misadministration involving the use of radioactive material;
  - (4) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;
  - (5) Checking and using survey meters; and
  - (6) Selecting the proper dose and how it is to be administered; and
- iii. Three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in G.88 or equivalent Agreement State or Nuclear Regulatory requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by G.88b.ii.; and
- iv. Has obtained written certification, signed by a preceptor authorized user, who meets the requirements in G.88, equivalent Agreement State or Nuclear Regulatory requirements, that the individual has satisfactorily completed the requirements in G.88b.i. and G.88b.ii. and has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.

### **Other Medical Uses of Radioactive Material or Radiation from Radioactive Material**

#### **Sec. G.89 - Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.**

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Part G if:

- a. The applicant or licensee has submitted the information required by G.8b., G.8c. and G.8d.; and
- b. The applicant or licensee has received written approval from the NRC, an Agreement State, or Licensing State in a license and uses the material in accordance with the regulations and specific conditions the NRC, Agreement State, or Licensing State considers necessary for the medical use of the material.

### **Records**

#### **Sec. G.90 - Records of Authority and Responsibilities for Radiation Protection Programs.**

- a. A licensee shall retain a record of actions taken by the licensee's management in accordance with G.18a. for 5 years. The record must include a summary of the actions taken and a signature of licensee management.
- b. The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by G.18d., and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by G.18b. The record must include the signature of the Radiation Safety Officer and licensee management.
- c. [The minutes of each Radiation Safety Committee meeting held in accordance with G.18g. shall include:
  - i. The date of the meeting;
  - ii. Members present;
  - iii. Members absent; and
  - iv. Summary of deliberations and discussions.]

**Sec. G.91 - Records of Radiation Protection Program Safety Changes.** A licensee shall retain a record of each radiation protection program change made in accordance with G.19a. for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

**Sec. G.92 - Records of Written Directives.** A licensee shall retain a copy of each written directive as required by G.22 for 3 years.

**Sec. G.93 - Records of Misadministrations.** A licensee shall retain a record of misadministrations reported in accordance with G.119 for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the

event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

Sec. G.94 - Record of a Dose to an Embryo/Fetus or a Nursing Child.<sup>2/</sup> A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with G.120 for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

Sec. G.95 - Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material. A licensee shall maintain a record of instrument calibrations required by G.32 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Sec. G.96 - Records of Survey Instrument Calibrations. A licensee shall maintain a record of survey instrument calibrations required by G.33 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

Sec. G.97 - Records of Dosages of Unsealed Radioactive Material for Medical Use. A licensee shall maintain a record of dosage determinations required by G.34 for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30  $\mu$ Ci); the date and time of the dosage determination; and the name of the individual who determined the dosage.

Sec. G.98 - Records of Possession of Sealed Sources and Brachytherapy Sources. A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by G.36d. for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

Sec. G.99 - Records of Surveys for Ambient Radiation Exposure Rate. A licensee shall retain a record of each survey required by G.39 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

---

<sup>2/</sup> This rule may have health and safety implications, please see Rational for Part G 2002 for more information.



**Sec. G.100 - Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.**

- a. A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release.
- b. A licensee shall retain a record, for three years after the date of release, that the instructions required by G.40b. were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 1 millisievert (0.1 rem).

[b. A licensee shall retain a record, for three years after the date of release, that the instructions required by G.40b. were provided to a breast-feeding woman.]

**Sec. G.101 - Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.**

- a. A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by G.9b., for 3 years after the last provision of service.
- b. A licensee shall retain the record of each survey required by G.41f. for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

**Sec. G.102 - Records of Decay-in-Storage.** A licensee shall maintain records of the disposal of licensed materials, as required by G.43, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

**Sec. G.103 - Records of Radionuclide Purity.** A licensee shall maintain a record of the radionuclide contaminant concentration tests required by G.48 for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicurie), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicurie), the time and date of the measurement, and the name of the individual who made the measurement.

**[Sec. G.104 - Records of Training.** A licensee shall maintain records of training required by G.28 for 3 years after the last date an individual was authorized to act as a nuclear medicine technologist or radiation therapist at the licensee's facility.]

**Sec. G.105 - Records of Safety Instruction and Training.** A licensee shall maintain a record of safety instructions and training required by G.53, G.62 and G.74 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

**Sec. G.106 - Records of Radiation Surveys of Patients and Human Research Subjects.** A licensee

shall maintain a record of the surveys required by G.60 and G.72 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

Sec. G.107 - Records of Brachytherapy Source Inventory.

- a. A licensee shall maintain a record of brachytherapy source accountability required by G.61 for 3 years.
- b. For temporary implants, the record must include:
  - i. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and
  - ii. The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.
- c. For permanent implants, the record must include:
  - i. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;
  - ii. The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and
  - iii. The number and activity of sources permanently implanted in the patient or human research subject.

Sec. G.108 - Records of Calibration Measurements on Brachytherapy Sources. A licensee shall maintain a record of the calibrations on brachytherapy sources required by G.64 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

Sec. G.109 - Records of Decay of Strontium-90 Sources for Ophthalmic Treatments. The licensee shall maintain a record of the activity of a strontium-90 source required by G.64 for the life of the source. The record must include the date and initial activity of the source as determined under G.64, and for each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

Sec. G.110 - Records of Installation, Maintenance, Adjustment, and Repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by G.73 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description

of the service, and name(s) of the individual(s) who performed the work.

Sec. G.111 - Records of Dosimetry Equipment.

- a. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with G.76 for the duration of the license.
- b. For each calibration, intercomparison, or comparison, the record must include:
  - i. The date;
  - ii. The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by G.76a. and G.76b.;
  - iii. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
  - iv. The names of the individuals who performed the calibration, intercomparison, or comparison.

Sec. G.112 - Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.

- a. A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by G.77, G.78 and G.79 for 3 years.
- b. The record must include:
  - i. The date of the calibration;
  - ii. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;
  - iii. The results and assessments of the full calibrations;
  - iv. The results of the autoradiograph required for low dose-rate remote afterloader units; and
  - v. The signature of the authorized medical physicist who performed the full calibration.

Sec. G.113 - Records of Periodic Spot-Checks for Teletherapy Units.

- a. A licensee shall retain a record of each periodic spot-check for teletherapy units required by G.80 for 3 years.
- b. The record must include:

- i. The date of the spot-check;
- ii. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
- iii. An assessment of timer linearity and constancy;
- iv. The calculated on-off error;
- v. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
- vi. The determined accuracy of each distance measuring and localization device;
- vii. The difference between the anticipated output and the measured output;
- viii. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
- ix. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

Sec. G.114 - Records of Periodic Spot-Checks for Remote Afterloader Units.

- a. A licensee shall retain a record of each spot-check for remote afterloader units required by G.81 for 3 years.
- b. The record must include, as applicable:
  - i. The date of the spot-check;
  - ii. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;
  - iii. An assessment of timer accuracy;
  - iv. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and
  - v. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

**Sec. G.115 - Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

- a. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by G.82 for 3 years.
- b. The record must include:
  - i. The date of the spot-check;
  - ii. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;
  - iii. An assessment of timer linearity and accuracy;
  - iv. The calculated on-off error;
  - v. A determination of trunnion centricity;
  - vi. The difference between the anticipated output and the measured output;
  - vii. An assessment of source output against computer calculations;
  - viii. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems; timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and
  - ix. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

**Sec. G.116 - Records of Additional Technical Requirements for Mobile Remote Afterloader Units.**

- a. A licensee shall retain a record of each check for mobile remote afterloader units required by G.83 for 3 years.
- b. The record must include:
  - i. The date of the check;
  - ii. The manufacturer's name, model number, and serial number of the remote afterloader unit;
  - iii. Notations accounting for all sources before the licensee departs from a facility;
  - iv. Notations indicating the operability of each entrance door electrical interlock,

radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

- v. The signature of the individual who performed the check.

Sec. G.117 - Records of Surveys of Therapeutic Treatment Units.

- a. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with G.84 for the duration of use of the unit.
- b. The record must include:
  - i. The date of the measurements;
  - ii. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;
  - iii. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
  - iv. The signature of the individual who performed the test.

Sec. G.118 - Records of 5-Year Inspection for Teletherapy and Gamma Stereotactic Surgery Units.

- a. A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by G.85 for the duration of use of the unit.
- b. The record must contain:
  - i. The inspector's radioactive materials license number;
  - ii. The date of inspection;
  - iii. The manufacturer's name and model number and serial number of both the treatment unit and source;
  - iv. A list of components inspected and serviced, and the type of service; and
  - v. The signature of the inspector.

**Reports**

Sec. G.119 - Reports and Notifications of Misadministrations.

- a. Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or

radiation from radioactive material results in:

- i. A dose that differs from the prescribed dose by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and either
  - (1) The total dose delivered differs from the prescribed dose by 20 percent or more;
  - (2) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
  - (3) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
- ii. A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:
  - (1) An administration of a wrong radioactive drug;
  - (2) An administration of a radioactive drug containing radioactive material by the wrong route of administration;
  - (3) An administration of a dose or dosage to the wrong individual or human research subject;
  - (4) An administration of a dose or dosage delivered by the wrong mode of treatment; or
  - (5) A leaking sealed source.
- iii. A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sievert (50 rem) to an organ or tissue and 50 percent of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).
- b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
- c. The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.
- d. The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration.

- i. The written report must include:
    - (1) The licensee's name;
    - (2) The name of the prescribing physician;
    - (3) A brief description of the event;
    - (4) Why the event occurred;
    - (5) The effect, if any, on the individual(s) who received the administration;
    - (6) Actions, if any, that have been taken, or are planned, to prevent recurrence;
    - (7) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.
  - ii. The report may not contain the individual's name or any other information that could lead to identification of the individual.
- e. The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.
- g. A licensee shall retain a record of a misadministration in accordance with G.93. A copy of the record required under G.93 shall be provided to the referring physician if other than the licensee, within 15 days after discovery of the misadministration.



Sec. G.120 - Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.<sup>2</sup>

- a. A licensee shall report any dose to an embryo/fetus that is greater than 5 millisievert (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
- b. A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast feeding individual that:
  - i. Is greater than 5 millisievert (500 mrem) total effective dose equivalent; or
  - ii. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
- c. The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.120a. or G.120b.
- d. The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in G.120a. or G.120b.
  - i. The written report must include:
    - (1) The licensee's name;
    - (2) The name of the prescribing physician;
    - (3) A brief description of the event;
    - (4) Why the event occurred;
    - (5) The effect on the embryo/fetus or the nursing child;
    - (6) What actions, if any, have been taken, or are planned, to prevent recurrence; and
    - (7) Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.
  - ii. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

<sup>2</sup> This rule may have health and safety implications, please see 2002 Rational for Part G for more information.

- e. The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under G.120a. or G.120b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.
- f. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with G.94. A copy of the record required under G.94 shall be provided to the referring physician, if other than the licensee, within 15 days after discovery of the event.

Sec. G.121 - Reports of Leaking Sources. A licensee shall file a report with the Agency within 5 days if a leakage test required by G.36 reveals the presence of 185 Becquerel (0.005  $\mu\text{Ci}$ ) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

Sec. G.122 - Reports of Patient Departure Prior to Authorized Release.

- a. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under G.40a.
- b. The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:
  - i. The licensee's name;
  - ii. The date and time of the unauthorized departure;
  - iii. The projected date and time when release would have occurred;
  - iv. The address of the patient's or human research subject's home or anticipated destination following departure;
  - v. The radionuclide, chemical and physical form and calculated activity at time of release;

- vi. The apparent reason(s) for the departure prior to authorized release; and
- vii. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

**Sec. G.123 - Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.**

- a. The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of Part D.301 of these regulations as a result of the deceased's body.
- b. The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in G.120a. has died. The written report must include:
  - i. The licensee's name;
  - ii. The date of death;
  - iii. The radionuclide, chemical and physical form and calculated activity at time of death; and,
  - iv. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisieverts (500 mrem).

## 2002 Rationale

## Part G

## Use of Radionuclides in the Healing Arts

Introduction

After numerous comment periods, which included comments and recommendations made at public meetings during 1998 and 1999, the U.S. Nuclear Regulatory Commission published the final revision of 10CFR Part 35 in the Federal Register on April 24, 2002, and its effective date is October 24, 2002.

The new Part 35 includes the following changes:

1. A move toward more "risk-informed, performance-based" regulations.
2. Dropping the requirement that a licensee submit all required written procedures for review by the Agency.
3. Addition of a rule that requires the licensee to report a dose equivalent greater than 50 millisievert (5 rem) to an embryo/fetus or nursing infant which is the result of administration of radioactive material or radiation from radioactive material to a pregnant individual or nursing mother. **Please see discussion section.**
4. Addition of rules for high-dose-rate, pulsed-dose-rate and low-dose-rate remote afterloaders, and gamma stereotactic radiosurgery imaging units.
5. Dropping the requirement that all medical institutions must have a Radiation Safety Committee.
6. More stringent training and experience requirements for authorized users of unsealed radioactive material for therapy (with the exception of oral sodium I-131 users).
7. Less restrictive training and experience requirements for authorized users of oral sodium I-131 in activities less than 33 mCi. **Please see discussion section.**
8. Addition of rules for the regulation of new medical uses of radioactive material (See G.89).
9. Inclusion of the requirement that the preceptor authorized user must submit written certification that the individual has achieved a level of competency sufficient to independently function as an authorized user for the medical uses requested. **Please see discussion section.**
10. Less reiteration of rules that are also found in other parts (such as 10CFR Part 20).

## Specific Considerations

### I. Discussion

Because of the major changes made to 10 CFR Part 35, the equivalent Part G of the Suggested State Regulations for the Control of Radiation (SSRCR) was revised in its entirety. If adopted as written, Part G will be compatible with NRC Part 35.

#### Radiation Safety Committee Requirements

The revised Part 35 no longer requires a licensee to establish a radiation safety committee unless the licensee is authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of uses under Subpart H. The rule specifies who must be represented on the committee, but nothing else.

The committee considered this rule change, and has adopted it. However, we have also included bracketed text (G.18g) which specifies the minimum number of times each year (as little as once) the committee must meet and requirements for the maintenance of minutes for each meeting (G.90). The committee recommends adoption of these bracketed sections. This rule has been designated as a compatibility category H&S, therefore an Agency may adopt the more restrictive text if they wish.

#### Training and Experience Requirements

During meetings conducted during the rule making process, members of the Advisory Committee on Medical Uses of Isotopes (ACMUI) indicated that the NRC's proposed revisions for training and experience appeared acceptable. However, the ACMUI notified the NRC during their February, 2002 meeting that the NRC's proposed training and experience requirements were inaccurate. Specifically, some of the certifying entities stated that they do not require an individual to meet the supervised clinical experience section of the NRC's proposed rules to sit for their board exams. Based on the ACMUI's statements, the NRC has established a two year transition period within which the old Subpart J (35.900) series training and experience requirements will be retained. During this two year period, the NRC will determine whether revisions to the new training and experience rules are necessary, and if so, will prepare them for implementation. The transition period will begin on the effective date of the rule. For Agreement States, the two year transition period is concurrent with the three year compatibility requirement, not consecutive. The NRC states that for purposes of compatibility, Agreement States should adopt the revised rule in its entirety, recognizing that the current training and experience requirements (the old Subpart J) are compatibility category D, and any revised training and experience requirements (which will go into effect on or before October 24, 2004) are compatibility category B.

The committee has considered these statements in revising Part G. Regarding the NRC's statements about adoption of the revised training and experience requirements, the committee believes that, for the most part, the revised criteria are appropriate. We therefore have included the revised training and experience rules in this revision of Part G.

Under these rules, new Radiation Safety Officers, authorized medical physicists, authorized nuclear pharmacists, and authorized users may be certified by a specialty board whose certification process includes all of the training, experience, and written, signed preceptor certification requirements of that section of the rules, and whose certification process has been recognized by the NRC or an

Agreement State. Specialty boards are not listed by name in the rule text so as to allow additions, deletions, and amendments in the recognized list without a rule revision. A list of recognized boards is to be maintained by the NRC on their web site. If a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist or authorized user is not certified by a recognized board, they must submit evidence that they have completed the required training and experience sections of the rule along with a written preceptor certification. The written certification, signed by an appropriate preceptor, indicates that the individual has satisfactorily completed the required didactic and supervised clinical requirements of the rules, and has achieved a level of competency or radiation safety knowledge sufficient to function independently in their requested duties.

While the committee does agree with the majority of the changes made by the NRC for training and experience requirements, we wish to discuss two sections which the NRC has added.

#### Training for Authorized Users of Oral Sodium Iodine 131.

Rules G.57 and G.58 correspond to NRC 35.392 and 35.394. These rules describe the training and experience requirements for authorized users of oral sodium I-131 only. If the route of administration or chemical form is anything other than oral sodium iodine 131, the authorized user must meet the training requirements specified in G.56. G.56 is an all new rule which requires authorized users to receive a total of 700 hours of classroom/laboratory training and work experience, as well as supervised clinical experience administering dosages of radioactive drugs in a minimum of three cases in each of the categories for which the individual is requesting authorized user status. The previous Part 35 rules required the prospective authorized user to obtain 80 hours of didactic radiation safety training, as well as supervised clinical experience (3 cases for treatment of thyroid carcinoma and 10 cases for treatment of hyperthyroidism or cardiac dysfunction).

The NRC's new 35.392 (G.57) and 35.394 (G.58) carry over the 80 hours of didactic radiation safety training, but they drop the number of cases of supervised clinical experience for the treatment of hyperthyroidism from 10 to 3.

The NRC has reclassified all revised training and experience rules from a compatibility category D to a compatibility category B. Category B classifications are for "activities that have direct and significant transboundary implications". The committee failed to see any clear transboundary implications, and requested clarification from the NRC. In their response, the NRC stated, "On balance, the Commission determined that T&E requirements represent significant transboundary issues that have direct and significant effects in multiple jurisdictions. Therefore, the Commission followed the 1997 Policy in determining that compatibility Category B is more appropriate than Category C for the T&E requirements in Part 35 to ensure consistency between NRC and the Agreement States. State action to adopt more restrictive T&E requirements could create nonuniformity and inconsistency in the provision of medical services across State boundaries and result in increased costs to the national healthcare delivery system. This is true, not just for nuclear medicine licensees, but for all authorized users of byproduct material in Part 35."

While the committee understands that any regulation of licensed material may increase the cost of business or services offered by a licensee, the increased health and safety that results from a regulation can, and should, offset the increased costs.

In the opinion of the committee, these rules do not appear to meet the NRC criteria of "risk-informed, performance-based" regulations. While an authorized user of diagnostic

radiopharmaceuticals for imaging and localization studies is required to receive at least 700 hours of didactic training and supervised clinical experience, both 35.392 (G.57) and 35.394 (G.58) only require the authorized user to receive at least 80 hours of didactic training, and supervised work experience in the form of 3 cases involving the oral administration of sodium I-131. The committee believes that the use of oral sodium I-131 carries a much higher radiation safety risk to the patient, occupationally exposed workers, ancillary personnel and the public than any diagnostic use. In fact, we feel it carries a higher risk than the use of other common therapy radiopharmaceuticals, including others containing iodine 131.

During this rulemaking process, a review of the NRC's Nuclear Material Events Database (NMED) was made. Data for medical use of unsealed radioactive material was reviewed for the time period of January 1, 1989 through May 3, 2002. During this period there were 107 events that were reportable, but did not meet the abnormal occurrence criteria. Of these, one involved I-123 (0.9%), two involved Sr-89 (1.9%), two involved unsealed I-125 (1.9%), four involved Sm-153 (3.7%), four involved unsealed P-32 (3.7%), and ninety-four involved I-131 (88%).

Of the thirty-nine reported abnormal occurrences which were the result of incorrect doses to patients (wrong patient, wrong radiopharmaceutical or wrong dose) between January 1, 1989 and May 3, 2002, one involved Sm-153 (2.5%), one involved Sr-89 (2.5%), two involved P-32 (5%), and thirty-five involved I-131 (90%).

The NRC made additional statements regarding the use of NMED data in their response to our request for clarification. In their letter, the NRC states, "We do not agree that the Abnormal Occurrence Reports (AOR) support the need for more training for authorized users of Sodium Iodide-131. It should be recognized, that based on a review of AOR data, the majority of Sodium Iodide-131 medical misadministrations occur in hospitals where physicians typically exceed minimum T&E requirements versus freestanding facilities or private offices where physicians meet minimum T&E requirements. The historic AOR data does not support, based on health and safety considerations including the low probability of such events, an increase in T&E requirements for these or any other category of authorized user. After careful consideration of this complex issue, the Commission arrived at a consensus that, in its judgment, there is a greater benefit to uniformity and consistency, nationwide, in applying compatibility Category B rather than Category C to Agreement State T&E requirements."

In the committee's opinion, the risk involved to the patient, occupationally exposed worker and the public warrants increased training and experience requirements.

Based on the high degree of risk and previous misadministration and abnormal occurrence data involving oral sodium I-131, it is the committee's opinion that users of oral sodium I-131 should also be required to receive 700 hours of classroom/laboratory training and work experience, and three supervised cases of clinical experience with oral sodium I-131. **However, in order to maintain compatibility with the NRC, you must adopt both G.57 and G.58.**

In addition, you should note that the NRC rule text for 35.390(b)(1)(ii)(G)(3) and (4) covers only supervised clinical experience gained in the parenteral administration of isotopes. Therefore, the supervised clinical experience cannot include the oral administration of any isotopes other than the sodium iodide 131 covered in 35.390(b)(1)(ii)(G)(1) and (2).

Patient Release Rule (G.40b.)

Several questions have arisen since the NRC adopted the patient release rule (35.75). For instance, why is it appropriate to allow a member of the general public to receive a 500 mrem exposure from a released patient, when they cannot receive any more than a 100 mrem exposure from any other licensed or registered activity? How do you handle individuals, such as home health nurses, nurses aides and nursing home staff, who in one year, may come into contact with numerous patients who have been released in accordance with 35.75? They might easily exceed 500 mrem TEDE during that year. What does an Agency do with recovered waste that is the result of a released patient?

There is no way of knowing with certainty if the release of a patient will result in excessive or unnecessary exposures to the public. There have been studies that show that any exposures occurring from released patients are less than 500 mrem. However, these are not blinded studies. The committee believes if a licensee uses appropriate radiation safety and health physics factors in deciding if a patient can be released, and if the patient and their family receive, and follow, adequate oral and written radiation safety instruction, radiotherapy patients can be released and result in minimal radiation exposures to the public. To assist Agencies in maintaining public exposures ALARA, the committee has a number of recommendations for this rule.

The NRC rule requires the licensee to provide additional instructions, including written instructions, to a released individual on actions recommended to maintain doses to other individuals ALARA; if the TEDE to any other individual could exceed 1 millisievert (100 mrem). The rule text in G.40b. and G.100b. is the same as that found in 35.75(b) and 35.2075(b). However, the committee believes that all patients should receive oral and written instructions when they are released. For that reason, the committee recommends that the optional, bracketed rule text in G.40b. and G.100b. be adopted.

The committee also recommends the inclusion of three additional sections to G.40 that we believe will enhance radiation safety. These sections are bracketed in the revised Part G as sections G.40c., G.40g. and G.40h.

The recommended G.40c. requires that an authorized user approve the release of the patient. The committee believes that an authorized user physician familiar with the type of radioactive material use the patient under went should give final approval for their release. This also keeps an authorized user informed of any releases, and any radiological basis for authorizing the release of the patient.

The recommended G.40g. requires the licensee to notify the Agency if a patient departs prior to an authorized release. Physicians and hospitals cannot hold a patient against their will. The committee believes that the Agency should be aware of individuals in the public domain that could result in exposures to members of the general public exceeding 500 mrem.

The recommended G.40h. requires the licensee to notify the Agency when they become aware of the death of a released patient containing radioactive material whose body might expose an individual member of the public to greater than a 500 mrem exposure.

Because only NRC 35.75(a) and (b) have been assigned a compatibility category C, and 35.2075(b) has been assigned a compatibility category D, an Agreement State can adopt the above recommended bracketed text without jeopardizing compatibility.



Besides the above described three sections that the Committee believes will improve radiation safety, the committee has also included optional, bracketed text (G.40f.) that can assist the Agency in the proper disposal of radioactive waste, traceable to the licensee as its origin, that is discovered in a solid waste stream.

#### Records of Doses to an Embryo/Fetus or a Nursing Child (G.94 and G.120)

These rules (corresponding to 35.3047) describe the record and reporting requirements for a licensee should an embryo/fetus or nursing child receive a dose equivalent greater than 50 millisievert (5 rem). The NRC included this rule to help alleviate the number of reports that a licensee must submit as the result of a nursing child exceeding the dose limits of Part 20 (5 millisieverts or 500 mrem) when a nursing individual receives a diagnostic dosage, and to include embryo/fetuses in the reporting requirements. The NRC rule text does not specifically approve 5 rem TEDE exposures to the embryo/fetus or nursing infant, and is not intended to be an exception to Part 20 dose limits. Embryos and fetuses are not considered members of the public. With the exception of declared pregnant occupationally exposed individuals, there are no exposure limits to the embryo/fetus specified in the rules. The limit for the declared pregnant individual is 5 millisieverts (500 mrem) to the embryo/fetus over the entire term of the pregnancy. But because there are no such limits for non-occupationally exposed individuals, 35.3047 has effectively set the exposure limit at the level of the reporting requirement (50 millisievert or 5000 mrem). Unfortunately, this exception to the reporting requirements also appears to give tacit approval for such exposures to nursing children. In addition, the NRC rule adds to the already confusing number of dose limit and reporting requirements of Part 20.

While the committee agrees, in part, with the intent of this rule, we believe that accidental exposures above the 500 mrem limits to the embryo/fetus and nursing child should be reported. We believe the radiosensitivity of the embryo/fetus and developing child warrant such requirements.

The NRC has assigned a compatibility category C to 35.3047, therefore Agreement States can be more restrictive than the NRC. The committee has included rules G.94 and G.120, but has lowered the reporting level to 500 mrem. Doses exceeding 500 mrem to a nursing child should not occur if the patient is properly questioned and instructed. And it should be noted that Part D rules allow a trained authorized user to knowingly approve any amount of exposure to the embryo/fetus if, through the use of their medical and radiation safety knowledge, they decide the risk is justified.

There are other areas of Part G that are more restrictive than, or in addition to, NRC Part 35 requirements. Descriptions of these rule texts follow.

There are a number of differences or additions in the definitions section. None of these differences will affect compatibility. These differences are specified below.

The committee added a definition for "Accredited institution" that is only necessary if the Agency adopts the training and experience requirements for nuclear medicine technologists and radiation therapists (G.28).

The NRC changed the term "misadministration" to "medical event". The committee has not adopted this change. The committee sees any medical action taken toward or on behalf of the patient or human research subject as being a medical event. We feel the term "misadministration" is much clearer and more appropriate.

The committee has added the words "or equal to" in the definition of "medium dose-rate remote afterloader" so that a dose equal to 12 gray (1200 rads) per hour is not excluded in the definitions.

Because the committee included minimum training and experience criteria for nuclear medicine technologists and radiation therapists, definitions of "nuclear medicine technologist", "nuclear medicine technology", "radiation therapist" and "radiation therapy technology" have been added.

The NRC has much broader definitions for "Dentist", "Pharmacist", "Physician" and "Podiatrist" because there is no national authority to license these individuals, and the NRC's jurisdiction crosses state lines. But because these individuals must be licensed to practice their chosen profession by the appropriate authority in each state, the Part G definitions reflect this.

Part G requires the licensee to submit required written procedures for review by the Agency. The NRC does not require all required written procedures to be submitted for review. They intend to review such procedures only when a problem is found during an inspection that should have been addressed by one of these required procedures. The committee believes that it is better to determine the adequacy of a written procedure before a problem occurs. Waiting until after a problem occurs to review written procedures is reactive, not pro-active, and the committee doesn't believe this is in the best radiation safety interest of patients or occupational workers. What's more, the review and discussion of a written procedure opens the lines of communication, and allows the building of a rapport between the licensee and the regulating agency. It can also increase the confidence of both parties in the resultant radiation safety program.

We have added Sec. G.9 - Mobile Medical Service Administration Requirements. Paragraphs b. and c. correspond to NRC 35.80(a)(1) and (b), respectively. The committee moved these licensing requirements to this section because we felt it made the rule easier to follow and more clear.

During formulation of the new Part G, the committee found that some states had adopted the NRC's decision to drop requirements to amend the license before allowing a new authorized user/pharmacist/physicist to begin work under the license. In this case, the licensee is only required to notify the Agency within thirty days of the licensee approving an individual to act as an authorized user/pharmacist/physicist. The new authorized user/pharmacist/physicist will then be added to the license by the Agency during the next routine amendment (refer to G.10 and G.11.).

However, there are also many states that currently still require a new authorized user/pharmacist/physicist to be amended onto the license prior to assigning permanent authorized user/pharmacist/physicist status to the individual. These states still allow visiting authorized users/pharmacists/physicists. If you prefer to continue the visiting authorized user program, the following changes to Part G must be made:

Replace G.10b. with the following text:

- b. Before permitting anyone, except a visiting authorized user described in G.12, a visiting authorized medical physicist as described in G.13, or a visiting authorized nuclear pharmacist as described in G.14, to work as an authorized user, authorized medical physicist or authorized nuclear pharmacist under the license.

Amend G.11 to read as follows:

Sec. G.11 - Notifications.

- a. A licensee shall notify the Agency by letter no later than 30 days after:
  - i. A Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change;
  - ii. The licensee's mailing address changes;
  - iii. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in C.31b. of these regulations; or
  - iv. The licensee has added to or changed the areas where radioactive material is used in accordance with G.44, G.47 G.52 and G.69.

Add sections G.12, G.13, and G.14 as follows:

Sec. G.12 - Visiting Authorized User.

- a. A licensee may permit a physician to act as a visiting authorized user and use licensed material for medical use under the terms of the licensee's license for 60 days each calendar year if:
  - i. The visiting authorized user has the prior written permission of the licensee's management and Radiation Safety Committee if one is required;
  - ii. The licensee has a copy of:
    - (1) An Agency, Agreement State, Licensing State or Nuclear Regulatory Commission license that identifies the visiting authorized user by name as an authorized user for medical use; or
    - (2) A permit issued by an Agency, NRC, Agreement State or Licensing State specific license of broad scope that identifies the authorized user by name as an authorized user for medical use; and,
  - iii. The visiting authorized user performs only those procedures:
    - (1) For which they are specifically authorized to perform on an Agency, Agreement State, Licensing State or Nuclear Regulatory Commission license; and,
    - (2) Which are specifically approved on the licensee's license.
- 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.12a.

- c. A licensee shall retain copies of the records specified in G.12a. [for 3 years from the date of the last visit].

Sec. G.13 - Visiting Authorized Medical Physicist.

- a. A licensee may permit a medical physicist to act as a visiting authorized medical physicist, and perform the duties of a medical physicist under the terms of the licensee's license for 60 days each calendar year if:
- i. The visiting authorized medical physicist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and
  - ii. The licensee has a copy of:
    - (1) An Agency, Agreement State, Licensing State or Nuclear Regulatory Commission license that identifies the individual as an authorized medical physicist; or
    - (2) A permit issued by an Agency, NRC, Agreement State or Licensing State specific license of broad scope that identifies the medical physicist by name as an authorized medical physicist.
- b. A licensee need not apply for a license amendment in order to permit a visiting authorized medical physicist to perform licensed duties as described in G.13a.
- c. A licensee shall retain copies of the records specified in G.13a. [for 3 years from the date of the last visit].

Sec. G.14 - Visiting Authorized Nuclear Pharmacist.

- a. A licensee may permit a nuclear pharmacist to act as a visiting authorized nuclear pharmacist, and to perform the duties of a nuclear pharmacist under the terms of the licensee's license for 60 days each calendar year if:
- i. The visiting authorized nuclear pharmacist has the prior written permission of the licensee's management and Radiation Safety Committee, if one is required; and
  - ii. The licensee has a copy of:
    - (1) An Agency, Agreement State, Licensing State or Nuclear Regulatory Commission license that identifies the individual as an authorized nuclear pharmacist; or
    - (2) A permit issued by an Agency, NRC, Agreement State or Licensing State specific license of broad scope that identifies the nuclear pharmacist by name as an authorized nuclear pharmacist.

- b. A licensee need not apply for a license amendment in order to permit a visiting authorized nuclear pharmacist to perform licensed duties as described in G.14a.
- c. A licensee shall retain copies of the records specified in G.14a. [for 3 years from the date of the last visit].

Add the following rule section to G.18a.:

- iv. Any individual before allowing that individual to work as a visiting authorized user, visiting authorized nuclear pharmacist or visiting authorized medical physicist.

A public meeting on the revision of Part 35 was held between the NRC and the Organization of Agreement States. During this meeting, many individuals commented that the specific duties of the authorized user should be detailed in the rules. The committee agrees, and has responded by including rule text that specifies the duties of an authorized user and authorized medical physicist (G.20). The committee also considered alternative text for G.20, but decided that a single option in the actual rule text was less confusing. However, to allow maximum flexibility, alternative G.20a. text is as follows:

Sec. G.20 - Duties of Authorized User and Authorized Medical Physicist.

- a. A licensee shall assure that only authorized users of radioactive material:
  - i. Select the patients to receive radioactive material or radiation from radioactive material;
  - ii. Prescribe the radiopharmaceutical dosage and/or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and
  - iii. Interpret the results of tests, studies, or treatments.

The committee has continued to include rule text regarding the availability of an authorized user to communicate with a supervised individual (G.21c.). The NRC does not include this text in their rule. The committee believes that communication is key to supervision, and has left this section in the revised rule as recommended, optional, bracketed text.

We have included a set of minimum training and experience criteria for nuclear medicine technologists and radiation therapists (G.28), and required training records retention (G.101). Many states already have registration, licensing or other training requirements for nuclear medicine technologists and radiation therapists. However other states have requested that the committee include some sort of minimum technologist training and experience. The training and experience requirements only refer to radiation safety training, and meeting them cannot be construed as being adequate to assure that the technologist is competent in their field. These rules are not a matter of compatibility, but are offered as optional rule text.

We have included Sec. G.31 - Quality Control of Diagnostic Equipment. The NRC proposes to not address this subject, but rather allow QC requirements to be more performance based and goals

oriented. The committee recommends that this bracketed text be included in the rule for imaging equipment such as gamma cameras. This serves to remind the licensee of their QC requirements.

We have specified the minimum quality control tests required for the licensee to perform on instruments used to measure the activity of unsealed sources in G.32c. This bracketed, optional text makes the rule more specific and less performance based. It is not required to maintain compatibility, however it makes it clear to the licensee what minimum QC the Agency will accept.

We have added bracketed text in G.33d, requiring daily checks of survey meter consistency of response. This is a reinforcement of Part D requirements that surveys be performed with an "operable" survey meter. This text is not required to maintain compatibility.

In G.34 the NRC is relying on the "standards of care" to assure that the dose is calibrated within a reasonable time before administration. The committee recommends the bracketed text in G.34a be adopted as the minimum requirement to lessen the possibility of misadministrations and to enhance ALARA.

The committee included previous rule text in the bracketed G.38, "Vial Shields". The NRC has deleted this clarifying text from the revised rule. They have decided to let Part 20 stand alone on this subject without additional reminders to the licensee. This text is not required for compatibility purposes, however the committee believes that it reinforces the Part D ALARA requirement and recommends that it be included.

For "Surveys for Ambient Radiation Dose Rate and Contamination"(G.39), the NRC only requires surveys in areas where radiopharmaceuticals that require a written directive are prepared and used. They are relying on Part 20 requirements to assure that "appropriate" surveys are performed. Since appropriate is not defined, and would require the inspector to make judgment calls at each inspection, the committee prefers setting the minimum acceptable criteria in the rules. We have added, and recommend the inclusion of, the bracketed text of paragraphs G.39b. through G.39g.

In G.42, "Storage and Control of Volatiles and Gases", the NRC is allowing Part 20 to stand alone and has deleted this rule. The committee believes this type of reminder in the rules is helpful to the licensee and ALARA, and recommends it be included.

The NRC has dropped the text of G.45; "Possession of Survey Instrument", and is relying on Part 20 requirements to assure that the licensee has proper survey capabilities. Although this text is not required for compatibility, the committee recommends adoption of it as reinforcement of Part D requirements.

In G.48, "Radionuclide Contaminants"; the committee has added requirements to the rules pertaining to the possible break through of strontium-82, and strontium-85 because of the increase in use of strontium-82/rubidium-82 generators.

The NRC has deleted the rule text found in Sec. G.50 - Possession of Survey Instruments, and is relying on Part 20 requirements to assure that the licensee has proper survey capabilities. Although this text is not required for compatibility, the committee recommends adoption of it as reinforcement of Part D requirements.

Throughout these rules, we have included Licensing State as a legal entity along with Agreement States and the U.S. Nuclear Regulatory Commission whenever possible. However, whenever a rule section has been assigned a compatibility category B or C, we have not included Licensing State to assure that the section is compatible with NRC rules. An Agency may wish to include Licensing States, but should first check with the NRC regarding compatibility.

## II. Other Corresponding Rule Changes

If Part G is adopted, there are some corresponding changes to other Parts that should be made. Below are the changes that would be required. Where appropriate, new or additional text has been underlined.

Part A should have the definition of “Sealed Source and Device Registry” added to it.

Sec. C.28j. - Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses.

Sec. C.28j. and C.28j.iv.(1) - Change references from G.30, G.32 and G.36 to G.44, G.47 and G.52.

Sec. C.28k. - Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. Change reference from G.32 to G.47 and G.52.

Sec. C.28k.v.(2) - Change reference from G.32 to G.47 and G.52.

C.28l. - Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. Change references from G.40 and G.42 to G.59 and G.69.

Sec. C.28l.iii. - Change references from G.40 and G.42 to G.59 and G.69.

Sec. D.301 - Dose Limits for Individual Members of the Public.

- a. Each licensee or registrant shall conduct operations so that:
  - i. Except as provided in D.301a.iii., the total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 millisievert (0.1 rem) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with G.40 of these regulations, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.1003; and
  - ii. The dose in any unrestricted area from external sources does not exceed 0.02 millisievert (0.002 rem) in any one hour; and
  - iii. The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed 5 millisievert (0.5 rem).

iv. Notwithstanding D.301a.i., a licensee may permit visitors to individuals who are not released in accordance with G.40 of these regulations to receive a radiation dose greater than 1 millisievert (0.1 rem) if:

- (1) The radiation dose received does not exceed 5 millisievert (0.5 rem); and,
- (2) The authorized user, as defined in Part G of these regulations, determines, before the visit, that it is appropriate.

III. Compatibility Issues

As stated in the NRC's Statements of Consideration, sections of 10 CFR Part 35 will be a matter of compatibility. There are no compatibility category A designations in the revised Part 35. The following is a list of sections (as found in the revised Part G) that have been designated a compatibility category B, C or H&S:

<u>Rule Section</u>	<u>Compatibility Designation</u>
G.2 - Definitions:	
Agreement State	B
Authorized medical physicist	B
Authorized nuclear pharmacist	B
Authorized user	B
Medical use	C
Prescribed dosage	C
Prescribed dose	C
Radiation safety officer	B
Sealed source	B
Treatment site	C
G.4 - Provisions for research involving human subjects	C
G.7 - License required	C
G.9 - Mobile medical service administrative requirements	
Paragraph c.	H&S
G.18 - Authority and responsibilities for the radiation protection program	
Paragraph b.	H&S
Paragraph f.	H&S
G.21 - Supervision	H&S
G.22 - Written directives	
Paragraph a.	H&S
Paragraph b.	H&S
G.23 - Procedures for administrations requiring a written directive	
Paragraph a.	H&S
G.24 - Suppliers for sealed sources or devices for medical use	C
G.25 - Training for radiation safety officer	B
G.26 - Training for authorized medical physicist	B
G.27 - Training for authorized nuclear pharmacist	B
G.29 - Provisions for experienced radiation safety officer, medical physicist, authorized user and nuclear pharmacist	B



G.30 - Recentness of training	B
G.32 - Possession, use, and testing of instruments to measure the activity of unsealed radioactive materials	
Paragraph a.	H&S
Paragraph b.	H&S
G.33 - Calibration of survey instruments	
Paragraph a.	H&S
Paragraph b.(except iii)	H&S
Paragraph c.	H&S
G.34 - Determination of dosages of radioactive material for medical use	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
G.36 - Requirements for possession of sealed sources and brachytherapy sources	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
G.37 - Labels	H&S
G.39 - Surveys of ambient radiation dose rate and contamination	
Paragraph a.	H&S
G.40 - Release of individuals containing radioactive drugs or implants	
Paragraph a.	C
Paragraph b.	C
G.41 - Mobile medical service technical requirements	
Paragraph d.	H&S
Paragraph e.	H&S
G.43 - Decay-in-storage	H&S
G.44 - Use of unsealed radioactive material for uptake, dilution, or excretion studies for which a written directive is not required	H&S
G.46 - Training for uptake, dilution, and excretion studies	B
G.47 - Use of unsealed radioactive material for imaging and localization studies for which a written directive is not required	H&S
G.48 - Radionuclide contaminants	
Paragraph a.i.	H&S
Paragraph b.	H&S
G.51 - Training for imaging and localization studies	B
G.52 - Use of unsealed radioactive material for which a written directive is required	H&S
G.53 - Safety Instruction	
Paragraph a.	H&S
G.54 - Safety precautions	H&S
G.56 - Training for use of unsealed radioactive material for which a written directive is required	B
G.57 - Training for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries) for which a written directive is required	B
G.58 - Training for the oral administration of sodium iodide I-131 in	

quantities greater than or equal to 1.22 gigabecquerels (33 millicuries) for which a written directive is required	B
G.59 - Use of sealed sources for manual brachytherapy	C
G.60 - Surveys after source implant and removal	
Paragraph a.	H&S
Paragraph b.	H&S
G.61 - Brachytherapy sources inventory	
Paragraph a.	H&S
Paragraph b.	H&S
G. 62 - Safety Instruction	
Paragraph a.	H&S
G.63 - Safety Precautions for patients or human research subjects receiving brachytherapy	H&S
G.64 - Calibration measurements of brachytherapy sealed sources	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph e.	H&S
G.65 - Therapy-related computer systems	H&S
G.67 - Training for use of manual brachytherapy sources	B
G.68 - Training for ophthalmic use of strontium-90	B
G.69 - Use of sealed sources for diagnosis	C
G.70 - Training for use of sealed sources for diagnosis	B
G.71 - Use of sealed sources in a remote afterloader unit, Teletherapy unit, or gamma stereotactic radiosurgery unit	C
G.72 - Surveys of patients and human research subjects treated with a remote afterloader unit	
Paragraph a.	H&S
G.73 - Installation, maintenance, adjustment, and repair	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
G.74 - Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
Paragraph e.	H&S
G.75 - Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S
G.76 - Dosimetry equipment	
Paragraph a.	H&S
Paragraph b.	H&S
G.77 - Full calibration measurements on teletherapy units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S

Paragraph e.	H&S
Paragraph f.	H&S
G.78 - Full calibration measurements on remote afterloader units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
Paragraph e.	H&S
Paragraph f.	H&S
Paragraph g.	H&S
Paragraph h.	H&S
G.79 - Full calibration measurements on gamma stereotactic radiosurgery units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
Paragraph e.	H&S
Paragraph f.	H&S
G.80 - Periodic spot-checks for teletherapy units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
Paragraph e.	H&S
G.81 - Periodic spot-checks for remote afterloader units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
Paragraph e.	H&S
G.82 - Periodic spot-checks for gamma stereotactic radiosurgery units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
Paragraph e.	H&S
Paragraph f.	H&S
G.83 - Additional technical requirements for mobile remote afterloader units	
Paragraph a.	H&S
Paragraph b.	H&S
Paragraph c.	H&S
Paragraph d.	H&S
G.84 - Radiation surveys	
Paragraph a.	H&S
Paragraph b.	H&S
G.85 - Five-year inspection for teletherapy and gamma stereotactic radiosurgery units	

Paragraph a.	H&S
Paragraph b.	H&S
G.86 - Therapy-related computer systems	H&S
G.88 - Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B
G.119 - Report and notification of misadministrations	C
G.120 - Report and notification of a dose to an embryo/fetus or a nursing child	C
G.121 - Reports of leaking sources	C

#### Matters for Future Consideration

With the new, emerging technologies (such as the various intravascular brachytherapy types and the use of monoclonal antibodies), the committee must try to stay on top of regulatory issues that may arise as these uses become more common place.

As more and more states are adopting licensing or registration standards for diagnostic or therapeutic technologists, consideration should be given to working towards a consolidated standard that would assure techs who meet the requirements in one state, will be adequate in any other state in which they might work.

The committee should continue to fine tune requirements for mobile PET use.

**Part G – Part 35 Cross-Reference Guide**

<b><u>Part G Section</u></b>	<b><u>Part 35 Section</u></b>
G.1	35.1
G.2	35.2
G.3	35.5
G.4	35.6
G.5	35.7
G.6	35.10
G.7	35.11
G.8	35.12
G.9	35.80
G.10	35.13
G.11	35.14
G.15	35.15
G.16	35.18
G.17	35.19
G.18	35.24
G.19	35.26
G.20	NONE
G.21	35.27
G.22	35.40
G.23	35.41
G.24	35.49
G.25	35.50
G.26	35.51
G.27	35.55
G.28	NONE
G.29	35.57
G.30	35.59
G.31	NONE
G.32	35.60
G.33	35.61
G.34	35.63
G.35	35.65
G.36	35.67
G.37	35.69
G.38	NONE
G.39	35.70
G.40	35.75
G.41	35.80
G.42	NONE
G.43	35.92
G.44	35.100
G.45	NONE
G.46	35.190
G.47	35.200

<u>G.48</u>	<u>35.204</u>
<u>G.49</u>	<u>Reserved</u>
<u>G.50</u>	<u>NONE</u>
<u>G.51</u>	<u>35.290</u>
<u>G.52</u>	<u>35.300</u>
<u>G.53</u>	<u>35.310</u>
<u>G.54</u>	<u>35.315</u>
<u>G.55</u>	<u>NONE</u>
<u>G.56</u>	<u>35.390</u>
<u>G.57</u>	<u>35.392</u>
<u>G.58</u>	<u>35.394</u>
<u>G.59</u>	<u>35.400</u>
<u>G.60</u>	<u>35.404</u>
<u>G.61</u>	<u>35.406</u>
<u>G.62</u>	<u>35.410</u>
<u>G.63</u>	<u>35.415</u>
<u>G.64</u>	<u>35.432 and 35.433</u>
<u>G.65</u>	<u>35.457</u>
<u>G.66</u>	<u>NONE</u>
<u>G.67</u>	<u>35.490</u>
<u>G.68</u>	<u>35.491</u>
<u>G.69</u>	<u>35.500</u>
<u>G.70</u>	<u>35.590</u>
<u>G.71</u>	<u>35.600</u>
<u>G.72</u>	<u>35.604</u>
<u>G.73</u>	<u>35.605</u>
<u>G.74</u>	<u>35.610</u>
<u>G.75</u>	<u>35.615</u>
<u>G.76</u>	<u>35.630</u>
<u>G.77</u>	<u>35.632</u>
<u>G.78</u>	<u>35.633</u>
<u>G.79</u>	<u>35.635</u>
<u>G.80</u>	<u>35.642</u>
<u>G.81</u>	<u>35.643</u>
<u>G.82</u>	<u>35.645</u>
<u>G.83</u>	<u>35.647</u>
<u>G.84</u>	<u>35.652</u>
<u>G.85</u>	<u>35.655</u>
<u>G.86</u>	<u>35.657</u>
<u>G.87</u>	<u>NONE</u>
<u>G.88</u>	<u>35.690</u>
<u>G.89</u>	<u>35.1000</u>
<u>G.90</u>	<u>35.2024</u>
<u>G.91</u>	<u>35.2026</u>
<u>G.92</u>	<u>35.2040</u>
<u>G.93</u>	<u>35.3045</u>
<u>G.94</u>	<u>35.3047</u>
<u>G.95</u>	<u>35.2060</u>

<u>G.96</u>	<u>35.2061</u>
<u>G.97</u>	<u>35.2063</u>
<u>G.98</u>	<u>35.2067</u>
<u>G.99</u>	<u>35.2070</u>
<u>G.100</u>	<u>35.2075</u>
<u>G.101</u>	<u>35.2080</u>
<u>G.102</u>	<u>35.2092</u>
<u>G.103</u>	<u>35.2204</u>
<u>G.104</u>	<u>NONE</u>
<u>G.105</u>	<u>35.2310</u>
<u>G.106</u>	<u>35.2404</u>
<u>G.107</u>	<u>35.2406</u>
<u>G.108</u>	<u>35.2432</u>
<u>G.109</u>	<u>35.2433</u>
<u>G.110</u>	<u>35.2605</u>
<u>G.111</u>	<u>35.2630</u>
<u>G.112</u>	<u>35.2632</u>
<u>G.113</u>	<u>35.2642</u>
<u>G.114</u>	<u>35.2643</u>
<u>G.115</u>	<u>35.2645</u>
<u>G.116</u>	<u>35.2647</u>
<u>G.117</u>	<u>35.2652</u>
<u>G.118</u>	<u>35.2655</u>
<u>G.119</u>	<u>35.3045</u>
<u>G.120</u>	<u>35.3047</u>
<u>G.121</u>	<u>35.3067</u>
<u>G.122</u>	<u>NONE</u>
<u>G.123</u>	<u>NONE</u>

**Analysis of Comments  
on  
Part G  
Use of Radionuclides in the Healing Arts  
from 2000 SSRCR**

In preparation for the revision of the SSRCR, comments were solicited on the August, 2000 draft version of Part G. On the following pages are listed the comments received on Part G, Use of Radionuclides in the Healing Arts, and the analysis and summary of actions taken by the committee. There were many comments regarding corrections of references and misspelled words that are not included here, but have been corrected in the rule text. The comments are organized in order of rule sections, and are identified by reviewer number. A list identifying the reviewers is found at the end of the comments.

Reviewer #1; Review and implement consistent use of:

- \* capital letters on Agreement State and Licensing State, e.g. they aren't capitalized in G.86.
- \* 'Agency, Nuclear Regulatory Commission,...' Decide what to say about Licensing States and about Non-Agreement States and do so consistently.
- \* exposure vs exposure, e.g. in "Output," G.33 et al.

*Committee Response: The above have all been reviewed and changed as necessary.*

Reviewer #1 G.1 I would delete the first clause of the last sentence because it is circular in stating that these regs apply to the persons to whom they apply. Surely the purpose of the sentence was to afford exemptions, but only to specific persons. This might be tacked on to the preceding sentence, "The requirements...of these regulations are in addition to...others...unless specifically exempted. Perhaps better is the loose convention, among the SSR Parts, to deal with general exemptions and prohibitions in an early section, e.g. G.3, as well as other passages for exemptions related to the topic of the sub-part or section, as you do in G15, 17, etc.

*Committee Response: The clause was left as is because it is thought that it better specifies who the rule affects.*

The following comments refer to G.2 - Definitions:

Reviewer #3 "Accredited institution" is only used for Nuclear Medicine Tech T&E. Therefore why not ref. Joint Review Committee of Nuclear Medicine Technology? [See [www.jrcnmt.org](http://www.jrcnmt.org)]

*Committee Response: The definition has been changed to include nuclear medicine technology and radiation therapy technology and the parenthetical phrase has been deleted entirely.*

Reviewer #'s 1 and 4 Your definition of "Agreement State" is close to the definition in A.2, but seems to me flawed by the word 'Commission,' not defined elsewhere, instead of 'Nuclear Regulatory Commission.'" G.1 ¶1 Sentence 3 states that Part G is in addition to and not substitution for other Parts. Why not just leave the definition of Agreement State to be inferred along with others in Part A?

*Committee response: The definition of Agreement State has been deleted from Part G, which means the definition in Part A is in effect for this Part as well.*



Reviewer #1 Under "Authorized medical physicist," it seems to me that the range of authorized uses should be limited to "the medical use of radioactive material." I hope you won't instead redefine radioactive material.

*Committee Response: This definition is a compatibility category B and is worded essentially the same as the NRC text.*

Reviewer #5 Authorized Medical Physicist (2) is missing part of sentence "Is identified as a medical physicist on an Agency, NRC, or ..."

*Committee Response: This has been corrected.*

Reviewer #1 In the "Authorized" definitions, the phrase, "an Agency, Nuclear Regulatory Commission or Agreement State" strikes me as an inconsistent and incomplete series. In A.2, "'Agency' means [cite appropriate State agency]," and 'the Agency' is often used in the SSRCR for the person promulgating the regulation. What others might be 'an Agency' authorized to permit medical use of Rad. Mat.? In addition to the NRC and Agreement States, non-agreement states authorize the medical use of NARM; Ray U. of PA RCP mentioned one to me. Also, did you intend to exclude Licensing States from this passage? Do other Agencies issue permits that identify an individual as a medical physicist? Do NRC and Agreement States issue such 'permits'? The text of the 'Authorized's' is repeated in G.10[b].

*Committee Response: These definitions are compatibility category B and are worded essentially the same as the NRC text.*

Reviewer #1 In the authorized medical physicist definition, add the phrase "specific medical use" in the first line to identify the type of license.

*Committee Response: The phrase has been added as recommended.*

Reviewer #9 Change the definition of "Brachytherapy" so that instead of listing "by surface, intracavitary or interstitial application" you say "... up to a few centimeters to the treatment site."

*Committee Response: The committee thought it best to leave the list of application types, but did add intraluminal to the list.*

Reviewer #1 In defining "Brachytherapy," aren't plated, embedded and activated radiation sources intended to contain radioactive material in such a manner as to prevent the escape of any radioactive material, the definition of sealed source? Or are these constructions allowed, perhaps intended, to infuse the radioactive material into the surrounding tissue? If the former, then why not stay with the A.2 definition, "Brachytherapy?"

*Committee Response: A plated source is not always expected to maintain its integrity. It is possible for the plated material to "release" from the matrix when it comes into contact with other solid objects. An example would be Sr-90 eye applicators. When tested for leakage, the area containing the plated material is not wiped because the plated radioactive material would surely be removed. However, it is intended that use of a Sr-90 plated source to deliver a radiation dose to the surface area of a patient be encompassed in the definition of brachytherapy source.*

Reviewer #'s 3 and 7 In the definition of "Brachytherapy" list of anatomical applications should include intravascular.

*Committee Response: We have added text that now encompasses surface, intracavitary, intraluminal, or interstitial applications of radiation.*

Reviewer #1 Regarding "Dedicated check source," the intent of a check source is for demonstration that a radiation detector responds to the type of radiation the source emits; and where a particular check source is repeatedly used with the same geometry, it can determine the consistency of the instrument's response to that radiation source. "Constant operation" doesn't accurately convey the concept of "consistent response" to the same source in the same position with respect to the detector.

*Committee Response: The definition has been changed to use "consistent response" rather than "constant operation".*

Reviewer #3 The definition for "Dentist" would read better as...means an individual licensed to practice dentistry by the state in which the Agency is located.

*Committee Response: This definition has been reworded for better clarity.*

Reviewer #3 The definition of "Diagnostic clinical procedures manual" should not dictate the content. Suggest the following, ...means a collection of written procedures approved by the authorized user(s) to convey acceptable delivery of medical procedures; where each approved diagnostic procedure typically delineates the following: approved clinical indications, patient preparation, contra-indications, drug or imaging sequence conflicts, radiopharmaceutical, route of administration, dosage, and an imaging/counting protocol."

*Committee Response: In this case, the definition is specifying the minimally acceptable criteria for a diagnostic clinical procedures manual. As such, it specifies the committee has determined content, which is based on discussions with state personnel, NRC staff, and committee advisors.*

Reviewer #'s 1 and 5. Elsewhere in the rule text (e.g. G.22b.v) acronyms are used in place of "High, "Low, "Medium, and "Pulsed dose rate afterloaders, so the acronyms (HDR, etc.) should be added to the definitions of these terms.

*Committee Response: The acronyms have been added in parentheses.*

Reviewer #9 In the definition for HDR, LDR and MDR, replace the phrase "... at the point or surface where the dose is prescribed." to "... at the treatment site."

*Committee Response: The definitions were changed as suggested.*

Reviewer #3 In the definition for "Management", delete or persons' delegate or delegates, either they have authority to manage, and are acceptable, or they don't.

*Committee Response: This change was made because it is understood that there are times when someone in administration cannot be available for notification, but if, for example, the chief nuclear medicine technologist is designated to act on behalf of the administration for this duty, radiation safety and patient safety and concern are best served.*

Reviewer #9 In the definition for "Manual brachytherapy", use a word other than "manual" in the definition. You should not use a part of the words you are defining in the definition.

*Committee Response: The committee agrees with you, but was unable to determine a word or words that could be used that would leave a clear definition.*

Reviewer #3 In the definition for "Medical use", you should add ...under the direction and supervision of an ...."

*Committee Response: Because this definition is assigned a compatibility category C, the committee decided to leave it as it is. Supervision can be interpreted as including the direction of an individual.*

Reviewer #7 Explain what is meant by the term "medical disciplines" in the definition of "Medical institution".

*Committee Response: This term has been in use for over a decade in this definition, and the committee believes that it is commonly known that it means types of use (ex: diagnostic, radiopharmaceutical therapy, sealed source brachytherapy, etc.), therefore the definition was not changed.*

Reviewer #2 Definition of mobile medical service states "transportation of radioactive material and its medical use. My concern is with the "and" as unit doses may be delivered to the mobile service while they are at the client's address. Since delivery to the client's address of use is prohibited unless the client has a specific license, perhaps the definition can be modified to either address receipt by the mobile service or delete the reference to transportation.

*Committee Response: The word "and" has been changed to "or". In the SSR's "or" means and/or.*

Reviewer #1 Please consider restricting "Mobile medical service" to "Mobile nuclear medicine service."

*Committee Response: There are already numerous mobile therapy facilities using HDRs. Additional rules have been added to Part G for this type of use.*

Reviewer #3 The definition of "Nuclear Med Tech" change and to and/or, and add "...under the direction and supervision of an authorized user,...."

*Committee Response: The committee believes supervision can be interpreted as including the direction of an individual. We are changing the definition to make it more precise.*

Reviewer #3 The definition of "Nuclear Med and Rad Therapy Technologies" could well be omitted.

*Committee Response: These definitions are needed if an Agency decides to include the minimum training and experience requirements in the new Part G.*

Reviewer #3 In the definition of "Output" change to "...brachytherapy source, ~~or a teletherapy,~~ remote...."

*Committee Response: For clarification, we have added a comma after "brachytherapy source".*

Reviewer #3 For the definition of "Preceptor" change to "...who provides and ~~or~~ directs the training and exp...."

*Committee Response: Were we to change the "or" to "and", we would not be able to accept the dean of a medical school's program as the preceptor. We left the definition as it is.*

Reviewer #1 For "Physician," 'doctor of medicine' would parallel the form 'doctor of osteopathy' where 'medical doctor' does not.

*Committee Response: The committee agrees, and has revised the definition.*

Reviewer #'s 4 and 5 For "Prescribed dosage" (2) delete reference to G.67 which is for sealed sources for diagnostic use and shouldn't be in definition relating to activity of radioactive drugs.

*Committee Response: The references have been corrected.*

Reviewer #4 In the definition for "prescribed dose", in (3) add "manual" in front of brachytherapy, and in (4) add "brachytherapy" in front of afterloaders.

*Committee Response: These words were added to the definition.*

Reviewer #3 In the definition of "Radioactive drug" change it to ...that may be prescribed and used on or administered to patients or human research subjects as an aid in the diagnosis, treatment and/or (prevention of disease...condition.) collection of research data.

*Committee Response: "Prescribed" is defined in pharmacy rules. The committee believes "aid in the diagnosis" covers your suggested "collection of research data". We therefore left the definition as it is.*

Reviewer #9 In the definition for "Radioactive drug", add "based on its radioactive properties" to the end of the definition.

*Committee Response: The committee did not see that this addition would clarify the definition, and therefore did not change it.*

Reviewer #1 Why is "Sealed source" defined here, and with so little variation from that in Part A? Surely 'escape' includes leakage.

*Committee Response: This definition has been assigned a compatibility category B, and is worded essentially the same as the NRC text. The Part A definition should also be changed to this new wording.*

Reviewer #9 Change the definition of "Sealed source" to the ANSI definition.

*Committee Response: The committee did not change this definition because of its' compatibility category B designation.*

Reviewer #3 Change the definition of "Sealed source" to "...of the radioactive material during typical use."

*Committee Response: The committee did not change this definition because of its' compatibility category B designation.*

Reviewer #3 Def. "Sealed Source & Device Registry" changed to "...that contains active ~~all~~ the registrations...." Never has and never will contain ALL, stays ~3 mos behind & has no in-active registrations.

*Committee Response: The committee has changed this definition to drop the word "all", changed the word "generated" to "maintained", and deleted "and the Agreement States". This deletion is because the NRC is including all SSDR's regardless of their origin. We are also asking for this definition to be included in Part A.*

Reviewer #1 The definition "Sealed Source and Device Registry" would be better placed in Part C, or Part A. One of the NRC staff that maintain the registry agreed with me recently that among the NARM S&D's in the registry there may be some issued by a state that was at the time, may still be, a non-agreement state. Ray U. in PA RCP recalled a device registration issued by

Pennsylvania radiation control. So it seems that the range of issuers should be expanded to 'Nuclear Regulatory Commission; its predecessors or state radiation control programs.' Did FDA issue S&D registrations? I've called but not connected with FDA staff.

*Committee Response: The committee has changed this definition to drop the word "all", changed the word "generated" to "maintained", and deleted "and the Agreement States". This deletion is because the NRC is including all SSDR's regardless of their origin. We are also asking for this definition to be included in Part A.*

Reviewer #7 You should not use the word "very" in the definition of "Stereotactic radiosurgery".

*Committee Response: The committee agrees, and has dropped "very" from the definition.*

Reviewer #1 Part G is the third to define "Temporary job site," so I expect the SSR will eventually have 6 or 8. Would it not suffice to use adjectives on this phrase, "temporary job site for wireline, ...for industrial radiography, ... for nuclear medicine?"

*Committee Response: The committee has added the words "as used in this part" to the definition because each SSR part that uses this term needs a unique definition.*

Reviewer #1 In the definition of "Unit dosage" add the underlined text ...prepared in accordance with the regulations for applications described in G.44, G.46, G.50, G.47 or G.52;

*Committee Response: Text has been revised.*

Reviewer #1 In the definition for "Unit dosage" - Should the G.34 constraints of recentness, accuracy etc. be added to this list?

*Committee Response: The references are corrected to properly reflect the types of use, but is not meant to refer to users. So the experienced user rule is not referenced.*

Reviewer #1 G.3 restates the record retention text of D.1111 with only a few words of clarification added that do not alter the requirements. There are many requirements from other Parts that are not reiterated in Part G. May I suggest that instead of G.3 you just mention in the Records sub-Part that retention requirements are given in D.1111 G.3 would then be available to deal with exemptions if you cared to use it for that; or it might be marked 'reserved.'

*Committee Response: The committee felt that this statement should be included in this Part because there are records requirements in Part G that are not in other Parts.*

Reviewer #'s 2, 4, 5, 7 and 14 G.4a. Change Nuclear Regulatory Commission to Agency.

*Committee Response: This change has been made.*

Reviewer #9 In G.4a., require the licensee to obtain prior informed consent from the human research subjects.

*Committee response: The word "prior" has been added to the rule text.*

Reviewer #1 G.4c - I expected to see 'and other applicable Parts' following 'complying with...this Part'

*Committee Response: Part G does give exceptions to other Parts, and this text must, therefore, remain as is.*

Reviewer #1 G.6a & d - Doesn't the time between publication and implementation vary among states? I expected to see "(insert number of) months from ..."

*Committee Response: This text is purely an example, as the state Agency will place whatever date they see fit in the text.*

Reviewer #1 G.7a. - Add "prepare" to the list . . .

*Committee Response: The committee has added "prepare" to the text.*

Reviewer #1, 3 and 9 G.7 has two sub-sections labeled 'a'

*Committee Response: This has been corrected.*

Reviewer #1 G.8b.ii & c.ii. - "... submit procedures required by..." Specifying written procedures might be helpful.

*Committee Response: The committee believes the current text is quite clear.*

Reviewer #9 G.8a. - Allow an authorized representative of management to sign the application.

*Committee Response: The committee believes the licensee should know and agree with what is placed in the application. If a consultant signs as an authorized representative, the licensee won't necessarily know what they will be required to do as a licensee. We did not adopt this change.*

Reviewer #1 In G.8d the G.7's should I suppose be G.8's. Also the word 'other' in relation to G.86 would help the reader understand the subject, e.g. "An application for a license or amendment for medical use other than those addressed in G8.b and G8.c, as provided for in G.86, must also include..."

*Committee Response: The references were corrected. The committee believes the opening phrase of G.8d. already clearly states your point.*

Reviewer #2 G.9.d, Recommend that the authorized user who is "immediately available to communicate" with the mobile service be added to the list of potential individuals to be informed of administration of radioactive materials.

*Committee Response: The administration of the customer is responsible for the contract with the mobile service, and is, therefore who we required to be notified. The authorized user only needs to be immediately available via phone, not physically present. Generally, the authorized user is available via cell phone.*

Reviewer #1 Why isn't the G.10 text on license amendments in the G.8 section, which is titled "...License, Amendment or Renewal?" It seems quite out of place in following the section on mobile Nuclear. Med.

*Committee Response: G.10 includes amendment requirements for both G.8 and G.9 (which describes additional licensing requirements for mobile nuclear medicine applicants). If it were placed in G.8, it could be interpreted to not apply to mobile nuclear medicine licensees.*

Reviewer #1 G.10 bracketed b.i citations are a mess. See my note re "Authorized user"

*Committee Response: This section has been removed from the rule and offered as optional text through the rationale.*

Reviewer #1 G.10[b] repeats the text of definitions, which definitions might instead and more safely just be cited.

*Committee Response: This text includes the "experienced" rule section provisions of G.29. That is why we listed the references individually rather than as a group reference.*

Reviewer #2 G.10.e and G.11.b.iv.: G.10.e requires a license amendment **before** changing the areas of use and contradicts the notification requirement "no later than 30 days after" when the licensee has added to or changed the areas where radioactive material is used.

*Committee Response: G.10 e. and G.11b.iv. are now properly reconciled, and no longer contradict each other.*

Reviewer #9 In G.10 add a requirement to amend the license "prior to the release of facilities for unrestricted use".

*Committee Response: The additional requirement has been added to the rule.*

Reviewer #3 G.10 Omit [b. i, ii, iii, iv, & v].

*Committee Response: The original unbracketed b. was taken out of the rule text, and referenced in the Rationale. The original bracketed b. was made a permanent part of the rule text.*

Reviewer #14 G.10d. - Need to change the word "orders" to "receives." An Agency's authority is over what a licensee "receives, possesses, uses" but not "orders."

*Committee Response: This change has been made.*

Reviewer #3 G.11a. Remove [a.]. New users not complying with Visiting Physician, should have credentials submitted prior to use, not after.

*Committee Response: The original bracketed a. has been removed from the rule text and moved to the Rationale.*

Reviewer #3 G.11b.i. - Remove all workers except the RSO. No Notice of Violation should be issued for not removing a retired user from the license in a timely manner. Could result in excessive amendments and the workers exact exit date is not crucial information.

*Committee Response: All individuals except the RSO have been removed from this rule.*

Reviewer #5 G.11b.iv. - Change G.46 to G.47; how about adding G.67 (aren't we interested in where they use the devices?)

*Committee Response: We have added diagnostic sealed source locations to this rule text.*

Reviewer #1 In G.15, the sentence seems too cryptic without identifying the subject as the 'other medical uses' identified in ...

*Committee Response: The committee disagrees, and believes the rule is quite clear as to what is referenced.*

Reviewer #'s 1 and 5 G.16a.iii - Regarding safety standards, you'll want 'this Part' instead of 'this Chapter,' and would it be in order to cite "radiation protection standards of this Part and Part D" ?

*Committee Response: Changed "this Chapter" to "these regulations". All Parts of the SSR'CR's*

are encompassed with this wording.

Reviewer #3 G.16b.ii. Are you sure you want mobile services performing human research?

*Committee Response: The committee removed references to human research.*

Reviewer #9 In G.18a., allow the approval in writing to be by the licensee's management "or authorized representative".

*Committee Response: The committee believes the licensee should know and agree with what is placed in the application. If a consultant signs as an authorized representative, the licensee won't necessarily know what they will be required to do as a licensee. We did not adopt this change.*

Reviewer #9 In G.18d., delete the words "duties and responsibilities" because the RSO's duties and responsibilities are normally established through the licensing process.

*Committee Response: The committee believes that the duties and responsibilities should be established, in writing, by the licensee. We left the text as is.*

Reviewer #1 G.18f, replace '2' with 'two'.

*Committee Response: The text was changed to reflect NRC text.*

Reviewer #1 G.18.h requirements for records pursuant to G.18a. & b. (licensing actions) and d. (details of the RSO position) surely should go on to require documentation that the radiation safety committee members meet the requirements of G.18.f and records of their meetings and actions per G.18g.

*Committee Response: G.18h. Only refers to the written requirements of this rule. The committee has added requirements for maintaining minutes of each required meeting in G.18g. It should be noted that the NRC rule has no minimum meeting requirements for a Radiation Safety Committee. Therefore, G.18g. which specifies minimum meeting requirements for the Radiation Safety Committee, will be bracketed in the final rule.*

Reviewer #6 G.18g. - I don't think that meeting only once every 12 months is enough. Too many things can go downhill in that period of time. Yes, I know it says "as necessary" but I know our licensees would not meet any more often than stated.

*Committee Response: This text has been added as bracketed text because the NRC rule has no statement regarding the frequency of meetings. The committee believes that there should be some statement because it gives the Agency a rule to help inspection when a problem arises that should have been addressed by the committee. An Agency can put any time frame they wish in the rule.*

Reviewer #9 G.18g. - When a licensee is authorized for therapeutic uses of radioactive material, the committee should be required to meet every 3 months.

*Committee Response: This text has been added as bracketed text because the NRC rule has no statement regarding the frequency of meetings. The committee believes that there should be some statement because it gives the Agency a rule to help inspection when a problem arises that should have been addressed by the committee. An Agency can put any time frame they wish in the rule.*

Reviewer #1 G.19a. RPR modifications are described and authorized, but what constitutes it is



not defined. Would this include Agency approved safety procedures manual? This needs clarification.

*Committee Response: The committee feels this text is quite clear. If the change does not require an amendment as described in G.10, and the change is in compliance with the rules, the licensee may make the change (and follow a.iii. and iv.).*

Reviewer #5 G.20a.[iv. footnote doesn't make any sense! The context makes it appear that if the patient is really bad off, anyone can order test, study or treatment. Footnote is meant to address production of written directive, not ordering!

*Committee Response: The text with the referenced footnote has been taken out of the regular rule text. It has, however, been offered as optional text in the rationale for those who wish to be more restrictive. This footnote wording appears to clearly state that the revisions (whether written or oral) are only to be given by an authorized user.*

Reviewer #3 G.20a.iv. [G.20a/c] While this appears to be most appropriate, political pressures following NRC's handling of this issue left a national decay on this stance of who shall interpret. Making it now difficult to recapture or enforce. There are those, commonly financially motivated, that claim that this would infringe on or tighten medical practice issues, that are not within our charge, but of those State agencies specifically created to oversee medical practice. This should be deleted.

*Committee Response: The committee believed that this rule text should be left in place as optional text. The alternate G.20 has been moved to the rationale, but also retains this text.*

Reviewer #14 G.20a.i. - Suggest revising this to "Prescribe the radiopharmaceutical dosage and/or dose to be administered for medical use to patients or human research subjects; through the issuance of a written directive or reference to the diagnostic clinical procedures manual and... Note: Diagnostic clinical procedures manual is not defined nor required in the rule.

*Committee Response: Diagnostic clinical procedures manual is in the definitions, and this rule places the requirements for it into the rule. The committee left the rule as is.*

Reviewer #6 G.20b. - I don't agree that only medical physicists can do leak testing. We have a few nuclear med. techs that are capable of doing this. If procedures are submitted and reviewed and they have the necessary counting equipment, I think someone other than a medical physicist can do the leak testing. I may agree with having the physicist leak test the brachytherapy sources but G.36 says any sealed source.

*Committee Response: Section G.36 covers leak testing of sealed sources and does not require the test to be performed by the physicist.*

Reviewer #3 G.21a. Change to "...user, unless prohibited by license condition, shall....", and remove G7b.

*Committee Response: Although the committee understands the recommendation, we have decided to leave the text as is. This text mirrors the NRC text, and the reference is clear.*

Reviewer #1 G.21a.i. specifications on topics on which to instruct supervised individuals seems to me not quite as good as, nor to completely satisfy, that of J.12.

*Committee Response: Rule J.12 affects all licensees. G.21a.i. is an additional requirement for medical users.*

Reviewer #1 G.21 you've opened the topic of instruction of workers, those under supervision of an authorized user or.... Rather than leave the question unanswered for the reader, I believe it necessary to state explicitly in Part G whether the other workers are subject to or exempt from the rest of the posting and instruction requirements of Part J, particularly in regard to the authorized users. Also note that the numerous passages of training requirements identify general principles but these cannot be expected to include the specific workplace requirements in Part J. The posting and instruction of workers, at least to invoke Part J, might fit in the passage on supervision as a duty assigned to the RSO. The requirements of J.12 are mentioned again in G.53.

*Committee Response: Rule J.12 affects all licensees. G.21 is an additional requirement for medical users. Although the committee has added recommended rule text for minimum training and experience requirements for technologists, this does not relieve the licensee of the requirements of G.21.*

Reviewer #12 G.21a.ii. Add "written directive procedures" to the list.

*Committee Response: This text has been added.*

Reviewer #14 G.22a.i. and iii. - I have a problem using the word "immediately" here. (Webster defines "immediate" as "occurring, acting, or accomplished without loss or interval of time.") If, because of the patient's condition, there is an emergency situation, the authorized user, after issuing the oral written directive, should be directing attention to the exam and not paperwork. I suggest changing this back to the NRC language "as soon as possible."

*Committee Response: The text has been changed to "as soon as possible".*

Reviewer #1 You might delete the footnote on G.22a. Since it is in the footnote for G.20a.iv, or you might put the footnote in brackets [ ].

*Committee Response: The footnote in G.20a.iv. has been deleted, and would only be included if the Agency decides to adopt the alternate text offered in the rationale.*

Reviewer #9 G.23a.i. - Require the licensee to verify the ID of the patient by "two independent means".

*Committee Response: The committee believes that if the licensee truly does verify the ID of the patient, that is enough. Requiring them to use two independent means in the rules is too prescriptive.*

Reviewer #1 G.23b.iv, would it be in order to cite G.64 in regard to computer calculations?

*Committee Response: G.23b.iv refers to a broader area of computer dose calculations than G.64 does, so no reference is used here.*

Reviewer #1 G.24. NRC allows non-commercial transfers of SS&Ds from other Part 35 licensees.

*Committee Response: The rules do not approve the receipt of a source or device that does not have a valid SSDR sheet. That is why if such a transfer is to occur, the receiving licensee will need to be specifically licensed to receive the source or device.*

Reviewer #3 G.25a. Don't want to encourage nor refuse NMT's where they appear the best RSO option; however, reference to their type of authorization should read G44 and ~~G46~~ G47. Don't see what this section has to do directly with G.18., and apart from G.29.

*Committee Response: The committee deleted the bracketed text of G.25a.ii. because this rule is a compatibility category B. The reference to G.18 is to assure that the radiation safety officer fulfills the duties specified in G.18b.,d. and e.*

Reviewer #1 G.25a.i. Add "or another Agreement State" after NRC.

*Committee Response: The committee did add Agreement State in this rule text, and also added a footnote stating that an adopting Agency may wish to include Licensing State. Licensing State was not included because of the compatibility category B designation for this rule.*

Reviewer #1 G.25a.ii. How do we know whether Registered &/or Certified Technologists have the required 200 hours of radiation safety training by virtue of the RT(NM) &/or CNMT?

*Committee Response: The committee deleted the bracketed text of G.25a.ii. because this rule is a compatibility category B. Also, accepted specialty boards' certification processes must meet the training and experience requirements of G.18b.*

Reviewer #9 G.25b.i.(2) - Change the time required for supervised experience from one year to six months.

*Committee Response: This rule is a compatibility category B, and cannot be less restrictive.*

Reviewer #4 G.25b.i.(2) - Add another section...Using emergency procedures to control radioactive material.

*Committee Response: This additional section is being added.*

Reviewer #'s 2 and 4 G.26a. Add "or an Agreement State" after NRC.

*Committee Response: Agreement State has been added.*

Reviewer #4 G.26b.i. - Need to add text equivalent to 35.433 (decay of ophthalmic sources).

*Committee Response: The equivalent text has been added to section G.64.*

Reviewer #4 G.26b.ii. - At the end of the paragraph, add the following text "for each type of therapeutic unit for which the individual is requesting authorized medical physicist status".

*Committee Response: This text has been added.*

Reviewer #'s 2 and 4 G.27a. Add "or an Agreement State" after NRC.

*Committee Response: Agreement State has been added.*

Reviewer #7 How will G.28 affect state licensure laws?

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #10 G28. It is unclear whether this section is being deleted, as the title is in brackets.

*Committee Response: G.28 is offered as optional text for states that currently have no*

*minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #10 G.28.a. iv. - Allows a nuclear medicine technologist to have training limited as follows: "Has performed full-time nuclear medicine for a minimum of two years during the past five-year period", requiring only certification in writing by an authorized user. This does not require any formal didactic training.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #14 G.28(a)(4) - In Texas, we require "40 hours" of classroom and lab training and up to 3 months on-the-job training if they are X-ray technologists (ARRT(R)) with no other Nuclear Medicine training. Does this mean the SSRs are indicating that with 80 hours of training someone can perform nuclear medicine procedures? This needs further consideration.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #10 G.28.a. v. - Allows a nuclear medicine technologist to have training limited as follows: "Has completed 80 hours of training and experience in basic radionuclide handling techniques...", including both classroom, lab, and work experience; and written certification by a preceptor authorized user. It is unimaginable that a competent nuclear medicine technologist can be educated in two weeks.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #3 G.28a.v.(2) Recommend changing to "Work experience, constituting no less than six months of full-time practice, under the supervision of...."

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #7 G.28 - It is interesting that 80 hours is O.K. for people to do nuclear medicine, and you require 200 hours for radiation therapists. Both have the capability to do therapy (either drug or source).

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #10 G.28.b. iv. - Allows a radiation therapy technologist to have training limited as follows: "Has performed as a full-time radiation therapy technologist for a minimum of two years during the past five-year period". This does not require any formal didactic training.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #14 G.28(b)(4) - Does this mean the SSRs are indicating that with 200 hours of training someone can perform as a radiation therapy technologist? This needs further consideration.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #10 G.28.b. v. - Allows a radiation therapy technologist to have training limited as follows: "Has completed 200 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of radioactive material" including classroom, lab, and work experience This requires only 5 weeks of training.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #3 G.28b.v.(2) Recommend changing to "Work experience, constituting no less than six months of full-time practice, under the supervision of..."

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #10 G.28 - Most states, including the state of New Jersey, require enrollment in a state-certified training program for 2 years. Even if a technologist is not certified by the appropriate certification board, he/she should at least have the requisite training and be board eligible.

*Committee Response: G.28 is offered as optional text for states that currently have no minimum requirements for technologists. States that already have minimum training and experience requirements, or require licensing or certification of technologists do not need this rule.*

Reviewer #4 G.29a. And b. - Add references to broad license permits.

*Committee Response: The reference to broad license permits has been added.*

Reviewer #3 G.29 The heading is mis-leading and could be better titled, "Grand fathering of individuals previously authorized as a RSO...."

*Committee Response: The title has been changed to "Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist.*

Reviewer #1 Will you wish to add "...and G.30" (requiring training and experience within 7 years) to the several citations of training requirements that do not now mention G.30?

*Committee Response: The current rules do not constantly refer to recentness of training, and although the rule section has been moved toward the front of the Part, it is only stated once in the rule with no additional references.*

Reviewer #8 G.31 - For many years, the nuclear cameras were tested with Flood and Bar Phantoms and tested well. But things are changing. Some of the cameras in use for the last 10 years are incapable of making a Bar image. Most or all of the Pet machines cannot! There are newer methods recommended by manufacturers, showing uniformity by computer-generated tests and other measurements of center of rotation, etc. This problem is handled by using the factory recommendations.

*Committee Response: This optional text states the minimum acceptable QC is following the manufacturer's recommendations.*

Reviewer #3 G.31 Suggests that the licensee's procedures for Quality of patient data collection devices (e.g., cameras and counters) are an assessment of medical practice and liability. Should this equipment be addressed at all, suggest the following: "Testing of Diagnostic Equipment. Each licensee shall establish procedures for evaluating the function of diagnostic equipment and their essential components prior to patient administrations so as to ensure its operative status during scheduled exams. These tests shall be performed as often as the equipment is used, prior to patient administration, and in accordance with written procedures.

*Committee Response: The committee believes the term "testing" is most often equated with calibration of equipment. Quality control procedures have been required for decades on dose calibrators or gamma cameras, either by rule, or by license condition. It is believed that the current wording is clear.*

Reviewer #8 G.32 - Paragraphs a. and b. are O.K. Paragraph c. is a problem. For dosage calibrator constancy and accuracy are valid, useable tests for present. Linearity is not valid for PET procedures due to narrow range (5 to 10 mCi) of dosages. "Geometry Dependence" does not test geometry. It only checks attenuation of a liquid source of Tc 99m by diluting the source with additional liquid. This is a fertile source for regulatory violation but contributes nothing to enhance safety. This test is not recommended by any manufacturer that I know. They do not use this procedure to test their product. The procedure is in the operating manual because the NRC wants the test to be done. The employment of the dosage calibrator for PET is to measure positron emitting nuclides which produce coincident emission of annihilation photons of 511 Kev. All of the work is done with these high energy photons. Leave in the last Paragraph about records. Delete the previous one.

*Committee Response: The optional text in section c. of this rule states the tests are to be made "as appropriate". Geometrical variation is testing the units variations in the active counting area. These possible variations are important to the licensee counting doses in containers of various sizes and geometries.*

Reviewer #3 G.32b.&c. As calibrations invoke and are written to reflect an annual event, suggest you change to "...shall calibrate and test ...", "...each instrument calibration and test...." This way daily constancy and quarterly linearity will clearly be captured.

*Committee Response: The committee agrees. We have changed the word "calibrate" to "test". In this case, the word "test" includes calibration, as well as geometry, constancy and linearity.*

Reviewer #9 G.32b. - At the end of the sentence add ", whichever is more restrictive."

*Committee Response: Although the committee understands your reasoning, we believe the Agency should be comfortable with whatever standards or instructions are used. If an Agency*

*does not agree with the manufacturer's instructions, they should discuss their concerns with the manufacturer and/or the Agency that issued the SSDR (if applicable).*

Reviewer #8 G.33 - There is nothing wrong with this section, except that "many" are doing it a little bit differently and a little bit better. Most of the calibrators are using sources for accuracy on each range, and check the accuracy in each range with a calibrated pulser that is calibrated to the GM tube, i.e., it produces a pulse rate to match cpm with displayed cpm on the GM meter. I think that this an improvement.

*Committee Response: This rule does not prohibit the use of pulsers, but requires the meter to be calibrated, with the probe, in the presence of a radiation field.*

Reviewer #1 G.33. The text on calibration of rad. meters is a unique contribution to the SSRCR, but it needs work.

*Committee Response: The committee is importing the new rule text of Part E.9b. to maintain consistency throughout the rules. This text will be inserted in G.33b.*

Reviewer #13 G.33a.ii. ANSI N323A - 1997 doesn't agree with the criteria. It states (in Section 4.2.1.1) that linear readout instruments, after adjustment, shall be checked near the endpoints of each scale (approximately 20% and 80% of full scale). In Section 4.2.1.2 it states for logarithmic instruments calibration shall be checked at a minimum of one point per decade. In Section 4.2.1.3 digital readout instruments may be calibrated at one or two points per decade depending on linearity of response. This is not a change over the previous standard (ANSI N323-1978), therefore, I suspect that the original wording of this area came from the NRC rulemaking. I recommend care in changing wording in this section because it may be a USNRC compatibility issue.

*Committee Response: The committee discussed this rule text and decided to use the recently completed requirements from Part E.9 to maintain consistency in all the Parts. This will not affect compatibility with the NRC.*

Reviewer #1 G.33b.i, if all scales of a meter could be calibrated to 1 rem/h, the instrument would better serve around teletherapy beams than to detect traces of radioactive contamination. Subsequent requirements for survey meters seem not to require response as high as 1 rem/h.

*Committee Response: This rule encompasses all survey meters required by this Part. The word "required" in G.33b.i. helps delineate the type of unit being calibrated, which is specified in other rules of this Part, and is dependent on the type of radioactive material use of the licensee.*

Reviewer #5 G.33b. I know we talked about this...still, shouldn't corrections factors be required for errors less than 20%?

*Committee Response: The committee discussed this change, but decided to use the recently completed requirements from Part E.9 to maintain consistency in all the Parts.*

Reviewer #1 G.33 should require that all calibration, not just the dosimeters in G.74, be performed with radiation sources traceable to national or international standards recognized by the Agency, per the A.2 definition of calibration.

*Committee Response: This rule encompasses all survey meters required by this Part. The word "required" in G.33b.i. helps delineate the type of unit being calibrated, which is specified in other rules of this Part, and is dependent on the type of radioactive material use of the licensee.*

Reviewer #1 G.33d. A survey instrument can be checked for response to any check source that

emits the appropriate radiation, but I suppose the 'proper operation,' or consistent response, of a particular survey instrument must be determined with the particular check source that was dedicated to that instrument.

*Committee Response: Although this rule text is optional, the committee recommends it be included to help assure consistent operation of survey meters. The committee changed the words "proper operation" to "consistent response" to better reflect the intent of this rule.*

Reviewer #3 G.33d. Suggest including this little NRC check test to help verify function and a relative gauge of consistency. This is especially important with instruments used in the mobile service.

*Committee Response: Although this rule text is optional, the committee recommends it be included to help assure consistent operation of survey meters. The committee changed the words "proper operation" to "consistent response" to better reflect the intent of this rule.*

Reviewer #3 G.34c. Add "An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA."

*Committee Response: The committee believes your suggested text is covered by the text "or equivalent provisions..."*

Reviewer #3 G.34c. Suggest removing the option, "...or combination of volumetric measurements and mathematical calculations,..." This type of assessment is inaccurate due to typical low volumes being handled. Licensees outside of unit dose option should buy and calibrate a dose calibrator.

*Committee Response: If we remove volumetric measurements, we feel we are not adequately covering pure beta emitters.*

Reviewer #5 G.35b. and c., G.46 should be G.47 but why include at all since neither G.44 or G.47 have lists (not even in brackets!)

*Committee Response: References to any other sections have been removed. So any radioactive material with a half life less than or equal to 120 days in amounts not exceeding 15 mCi can be used as calibration or reference sources.*

Reviewer #1 G.35b & c refer to lists that I don't find, certainly not in the cited G.44 or 46. Perhaps instead of 'lists' you meant to say 'Any radioactive material used in medical applications authorized under the provisions of G.44 and 47, with a half-life ... in individual amounts not to exceed...'

*Committee Response: References to any other sections have been removed. So any radioactive material with a half life less than or equal to 120 days in amounts not exceeding 15 mCi can be used as calibration or reference sources.*

Reviewer #9 G.36a. At the end of the sentence add "and as specified in the U.S. NRC registry of sealed sources and devices.

*Committee Response: The committee believes that an Agency generally approves, at a minimum, what is specified in the SSDR. Anything outside that would have to be reviewed and approved by the licensing Agency.*

Reviewer #3 G.38 Inappropriate for rule. Particularly if licensee wants to move into RAD



waste storage.

*Committee Response: This optional text is not new. The committee recommends its inclusion to help reenforce ALARA requirements.*

Reviewer #9 G.38 - Include requirements for syringe shields.

*Committee Response: The committee discussed inclusion of syringe shields, but decided to let ALARA prevail. As a reminder, though, we added the bracketed G.38 text regarding vial shields.*

Reviewer #1 G.39 What is the utility of a weekly survey of radioactive drug and waste storage areas? Did you wish to verify that not all were removed, or to measure the radiation dose rate in the area?

*Committee Response: The storage areas have a dynamic inventory, and should be checked at least weekly to assure exposure rates are within limits and that no spill and subsequent contamination has occurred.*

Reviewer #9 G.39 - Change title from "Surveys" to "Monitoring" for Ambient...

*Committee Response: The word "survey" has been used and defined for many years, and the committee saw no reason to change it.*

Reviewer #7 G.39 - Is it my understanding that weekly surveys will not be required in areas where radioactive sources are stored?

*Committee Response: The NRC has deleted the equivalent to sections G.39b. through G.39g. The committee has placed the old rule text in brackets to remind Agencies that they can include them if they do not wish to fall back on the less specific Part 20 requirements. Obviously we consider radioactive sources radioactive material, so if this text is adopted, they would have to survey that area at least each week.*

Reviewer #3 G.39a. Suggest removing "...requiring a written directive...." It is believed to be prudent to survey these locations daily even when handling diagnostic RAM not requiring the directive.

*Committee Response: Although daily wipe tests have been required in the past, this additional 'filter' was added to help make the rule more risk informed.*

Reviewer #3 G.39b. - g. OK. Better here than in a Regulatory Guide.

*Committee Response: The committee agrees, and recommends adoption of these rule sections.*

Reviewer #1 G.39f, the conversion to Bq of 2000 dpm should be rounded to the same number of significant digits, which I suppose is 30 Bq but surely not three significant figures.

*Committee Response: We started with 2000 dpm to get 33.3 becquerels, so technically, we suppose we should change the 33.30 to 33.33. However, counting 0.3 Bq is a bit of a stretch, much less 0.03 Bq.*

Reviewer #14 G.39e. - It seems excessive to require a wipe test every day if the facility is using unit doses. Suggest revising this to read: A licensee shall survey for removable contamination each day of use all areas where generators and bulk radioactive drugs are prepared for use or administered and each week where radioactive materials are stored.

**Question:** Does "administered" include a patient's room or critical care or intensive care unit if

the drug was administered there?

*Committee Response: The committee agrees with your comment regarding surveys when only unit doses are used, and has changed the rule text. As to your question regarding whether a patient's room or intensive care unit must be surveyed if a radioactive drug is administered to a patient in these locations, the committee believes that any location where a radioactive drug is administered should be surveyed. Most facilities place an absorbant pad under the injection site, and take the pad back to Nuclear Medicine and count it as the survey.*

Reviewer #1 It's time now to establish the considerations that are to be given by the licensee, medical physicist..., mortician and especially crematorium for the disposition of a cadaver containing radioactive material. A significant contribution could be made in G.40 or G.54b, if only to require the RSO to establish a form containing guidance and providing for certain specific info on the cadaver. Such a requirement in Part G would put pressure on some other CRCPD working groups to compile applicable text and citations of EPA and other pertinent regs and guidance.

*Committee Response: The committee agrees, and is adding rule text in G.40 to cover licensee requirements when a cadaver contains radioactive material.*

Reviewer #7 G.40 - Am I clear on the release of patients that those with temporary implants may be released if G.40b. is met?

*Committee Response: You are correct. Although you won't see any cesium implant patients released because the exposure rate is too high, and the patient is often immobilized, you will see I-125 eye plaques and the such being released, only to return for the removal of the sources.*

Reviewer #3 G.40b. Change to "...or guardian, with instructions, including written instructions, on...."

*Committee Response: Although we have left the text the same as the NRC rule, we have a footnote that points the reader to the rationale. In the rationale we recommend the text be changed to require both "oral and written instructions" for all released patients.*

Reviewer #3 G.40c. - f. The level of accountability appears reasonable.

*Committee Response: The committee agrees, and recommends adoption of these rule sections.*

Reviewer #9 G.40a. - Recommend that the Maximum TEDE to any other individual from exposure to the released individual not be allowed to exceed 1 mSv (100 mrem).

*Committee Response: While the committee agrees in principle with your recommendation that there be a single maximum exposure allowed for a member of the general public, we see no discernable hazard from the 5 mSv (500 mrem) limit. However, we have general concerns regarding the accuracy and accountability of assuring the 5 mSv limit not being exceeded. Please see the rationale for more information.*

Reviewer #11 G-40d. The way this section is written in the CRCPDs SSRs as well as the way it is written in 10CFR35.75, it appears that if you use a method other than those listed in G-97a, then no records are required. I don't think that is the intention of the proposed reg.

*Committee Response: On the contrary, the committee interprets these rules to be rather specific. G.40d. requires the licensee to keep a record in accordance with G.97. G.97 first requires the licensee to make a record anytime the licensee releases a patient in accordance with G.40.*

Reviewer #9 G.40e. Records of instruction for every released patient should be maintained, not just for breast-feeding women.

*Committee Response: We have changed the text in G.40b. to require the licensee to give verbal and written ALARA instructions to all patients to be released. However, we do not see the need to maintain records of the instruction except in the cases that offer the highest risk (breast-feeding women).*

Reviewer #9 G.40 - Please insert a release mechanism for Bexxar®.

*Committee Response: The ultimate release of any patient, regardless of the drug, is to be based on the exposure potential to members of the public. This exposure potential takes many things into account, depending on the drug, and its radiological and biological factors. Those factors that make Bexxar® a more likely candidate for patient release should already be covered in G.40a. If the licensee's basis for release does not appear reasonable, the Agency should step in and question the licensee.*

Reviewer #1 G.41e, if survey instruments are to have one or more dedicated check sources, "Check each survey instrument for proper operation with its own dedicated check source..." not just any check source. See my comment on the definition of dedicated check source. Would someone who was able to obtain a disk file of this draft please search for and review 'check' in these regards.

*Committee Response: The very term "dedicated" indicates that the same source must be used with any given survey instrument. And by not specifying what instruments are to be checked, the intent is to include all survey instruments.*

Reviewer #1 I'd suggest that you add the requirement of written procedures, and periodic review by appropriate employees, for response to spill, theft, loss, trouble with a therapy source (G.59b) or unauthorized departure of a nuclear medicine patient (in addition to your G.72 & G.73g. text on therapy device problems). I was recently reminded of the magnitude of this long established need when I noticed a reference to Robert Taft's *Radium Lost and Found*. Among the applications of radioactive material, surely the hospitals have by far the greatest, least restrained traffic of individuals who have little or no knowledge of radiation protection. Such a response procedure requirement might fit ahead of the specific medical procedures that begin with G.44; it might fit as an RSO duty in G.18e.ii.; much of it would fit as G.39j. except the walk-away patient.

*Committee Response: The committee has added text regarding the "walk away patient" in G.119. The rules require that the licensee submit emergency procedures for review by the Agency. The Agency should assure that all possible emergency situations are properly covered in the submitted procedures.*

Reviewer #7 Is it the intent of the regulations for G.41 to be used for diagnostic radioactive drugs, or does this also include radioactive drugs for therapy. And what about sealed sources for therapy or diagnostic? We have a facility that uses I-125 seeds for localization. How would this fit into the mobile scenario?

*Committee Response: This section does encompass all uses of radioactive material. If the material is a sealed source, it falls under G.41b. in that the licensee shall bring all the radioactive material to be used into the client's address, and remove any unused radioactive material before leaving. If the I-125 seeds are manufactured as a sealed source, then they can fall under the auspices of G.35 as a calibration or reference source. Otherwise, it would fall under G.41b.*

Reviewer #14 G.41(d) - Revise to read: Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent; ~~1. At a minimum, the check for proper function required by paragraph d. of this section shall include a constancy check.~~

*Committee Response: The referenced text was changed as you recommended.*

Reviewer #9 In G.42, don't require it to be stored in the shippers radiation shield and container. Just require it to be stored in a radiation shield and container.

*Committee Response: The text has been changed.*

Reviewer #14 G.43(a)(iii) - In the current Part G, the lead-in language for this paragraph is "before disposal in ordinary trash....," which makes sense. However, generators are shipped back to the supplier. Is this paragraph really necessary?

*Committee Response: If the licensee ships the used generator back to the supplier, then they are not holding it for decay-in-storage, and their actions are not regulated by G.43.*

Reviewer #9 G.44c. and d. - Besides an FDA NDA, include IND and PLA.

*Committee Response: G.44c. and d. refer to research protocols. FDA approved NDA's and PLA's would be encompassed under G.44a. and b.*

Reviewer #1 G.45 requirement for survey instrument range to 50 mrem/h is inconsistent with the G.33 requirement for 1000 mrem/h.

*Committee Response: This is because these meters are only to be used in programs that have uptake, dilution or excretion studies.*

Reviewer #1 G.46,... The training requirements are general principles. The Part J requirements, at least J.11 - 12, for review of the specific workplace details seems to me in order, or instead an exemption and justification for it.

*Committee Response: This, and all training and experience requirements, are assigned a compatibility category B, and must be included for compatibility.*

Reviewer #1 The measurement of contaminants in nuclear medicines required in G.48 are, I suppose, not always taught with radiochemistry under the general requirements of G.46c.i.(d). If Part G is to regulate a facility that has numerous individuals preparing dosages, and associated turnover of these persons, a requirement of written procedure and periodic review of it by the users seems in order, and for determination of dosage (G.34) as well.

*Committee Response: The levels of contaminants spelled out in G.48 are those that are generally accepted standards.*

Reviewer #'s 1, 2 and 4 G.46a. Add "or an Agreement State" after NRC.

*Committee Response: This text has been added.*

Reviewer #1 G.46b. Include "on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope".

*Committee Response: Since this rule has been assigned a compatibility category B, the Part G text virtually mirrors the NRC text. The NRC text does not include broad scope licensee permits.*

Reviewer #9 G.46c. - Change the text to read "Has successfully completed 60 hours..."

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #9 G.47c. - We would like clarification of the difference between FDA approved and FDA accepted.

*Committee Response: The FDA does not use the term 'approved', but rather 'accepts' protocols. In the rules, we use the term 'approved' only in conjunction with the Radioactive Drug Research Committee, and only use FDA 'accepted' protocols.*

Reviewer #1 G.49 involves the limits in Part D; tell the reader whether you mean the limits for 'occupational' or for 'members of the public.'

*Committee Response: Releases to the air would be effluent, and there is only one column which specifies the maximum concentrations allowed as effluent in air (Table 2 Column 1).*

Reviewer #1 G.49d., please tell me how to calculate the time needed after release of a gas to reduce its concentration in the area to a particular value using only info on activity of the gas and air exhaust rate. It seems to me that this passage omits a factor or two for the calculation.

*Committee Response: Upon further discussion, the committee has decided to delete rule text that requires the rooms to be at negative pressure to surrounding areas, evacuation times to be calculated and posted, and six month ventilation checks. The licensee will be required to explain how they determined that the air concentrations in the rooms where a spill occurs were less than the limits of Part D.*

Reviewer #8 I have visited this topic too many times and in too many places. I am happy that the NRC is finally on my side. The exposure to personnel and patient is totally dependent on the calculation of an external exposure from a source that only emits a puny little gamma ray. The calculation is only related to time and quantity of radioactivity, and not the concentration in air.

*Committee Response: Upon further discussion, the committee has decided to delete rule text that requires the rooms to be at negative pressure to surrounding areas, evacuation times to be calculated and posted, and six month ventilation checks. The licensee will be required to explain how they determined that the air concentrations in the rooms where a spill occurs were less than the limits of Part D.*

Reviewer #1 G.49f., have the radiation control authorities established that the readings of air flow meters are accurate?

*Committee Response: These meters can and should be calibrated to NIST standards on a regular basis. However, upon further discussion, the committee has decided to delete rule text that requires the rooms to be at negative pressure to surrounding areas, evacuation times to be calculated and posted, and six month ventilation checks. The licensee will be required to explain how they determined that the air concentrations in the rooms where a spill occurs were less than the limits of Part D.*

Reviewer #9 In G.49, delete d. and e. Change f. to d. and g. to e. Insert the following:

- f. Re-entry into a room following spill of a gas or volatile shall require the use of a monitoring instrument.

*Committee Response: Upon further discussion, the committee has decided to delete rule text that requires the rooms to be at negative pressure to surrounding areas, evacuation times to be calculated and posted, and six month ventilation checks. The licensee will be required to explain how they determined that the air concentrations in the rooms where a spill occurs were less than the limits of Part D.*

Reviewer #'s 2 and 4 G.51a. Add "or an Agreement State" after NRC.

*Committee Response: The committee has added this text.*

Reviewer #1 G.51b. Include "on a permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope".

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #9 G.51c. - Change the text to read "Has successfully completed 700 hours..."

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #'s 2 and 4 G.51c.2.(f) Add "of radioactive drugs" in the text.

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #1 G.51c.i(2)(g) you might cite G.48 re radiochemical purity.

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #9 G.52 - We would like clarification of the difference between FDA approved and FDA accepted.

*Committee Response: The FDA does not use the term 'approved', but rather 'accepts' protocols. In the rules, we use the term 'approved' only in conjunction with the Radioactive Drug Research Committee, and only use FDA 'accepted' protocols.*

Reviewer #1 G.53 cites Part C as having constraints on visitors to hospital patients, and G.61 cites D.301a.i and iv. in this regard. I recognize that D.301a.i. is appropriate here, but note that D.301b. addresses access by the public, D.601f explicitly addresses hospital visitors, and you might do something under D.602b. My copy of the Dec. 1995 Part D does not have a passage D.301a.iv. I scanned Part C again and noticed no mention of constraint on hospital visitors or any individual other than the licensee.

*Committee Response: The reference has been changed to Part D. D.301b. States "If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals". The committee believes that this quite clearly includes visitors to patients whose rooms are restricted areas.*

Reviewer #9 In G.54 do you need to address surveys of the surrounding rooms and release criteria?

*Committee Response: It is the intent of the NRC to allow Part 20 requirements to be followed without reference in this section of Part 35. The licensee will be required to meet Part D limits for exposure rates surrounding the patient's room, and for release of the room after the patient has been discharged.*

Reviewer #2 Page G37, footnote for G.55: Revise to read "Experience with at least 3 cases in Category (2) also satisfies the requirement in Category (1)."

*Committee Response: The text has been corrected.*

Reviewer #'s 2 and 4 G.56a. Add "or an Agreement State" after NRC.

*Committee Response: The committee has added this text.*

Reviewer #9 G.56b. - Change the text to read "Has successfully completed 700 hours..."

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #1 G.56b. cites the training requirements G.55, 56,57, but perhaps you wanted the use provisions of G.52.

*Committee Response: These are category B items of compatibility, and have been written to mirror the NRC text.*

Reviewer #5 G.56b. text missing "Is an authorized user on a license issued... under G.52 or equivalent..."

*Committee Response: This has been corrected.*

Reviewer #9 Is the 700 hours in G.56b. intentional? Seven hundred hours vs. 80 hours for I-131 only?

*Committee Response: This is intentional. The NRC has changed the number of hours required to be an authorized user for all unsealed radionuclides for therapy except oral sodium I-131 from 80 to 700. This is based on the higher risk involved in the use of unsealed radionuclides for therapy. However, the NRC has retained the 80 hour training requirements for oral sodium I-131. This is not what the SR-6 committee recommends, but the NRC has assigned it a compatibility category B.*

Reviewer #9 Delete section G.56b.i.(2)(g), which reads: "Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs containing radioactive material; and"

*Committee Response: This rule has been assigned a compatibility category B by the NRC, and therefore is maintained in the text.*

Reviewer #10 G57 and G58 - Both of these sections are completely encompassed in brackets. Does this indicate that they are to be deleted from the document?

*Committee Response: These rules were originally in brackets because the committee, based on*

health and safety factors, does not recommend adoption of them. Although the committee still believes these rules are a detriment to the health and safety of the patient and the public, the committee has removed the brackets to these rule sections because the NRC assigned them as compatibility category B. However, we have added a footnote that tells the reader that these rules have significant health and safety implications, and the reader should refer to the rationale for further information. The committee chair requested an explanation from the NRC regarding their basis for assigning a B compatibility to all the training and experience requirements, because it is our belief that these rules do not meet the criteria to be assigned a B compatibility. However, the NRC has not responded to our request.

Reviewer #3 G57 and G58 These should not be bracketed. There has been no problem with this requirement in Texas that has had multiple authorized users in this category for years.

*Committee Response:* These rules were originally in brackets because the committee, based on health and safety factors, does not recommend adoption of them. Although the committee still believes these rules are a detriment to the health and safety of the patient and the public, the committee has removed the brackets to these rule sections because the NRC assigned them as compatibility category B. However, we have added a footnote that tells the reader that these rules have significant health and safety implications, and the reader should refer to the rationale for further information. The committee chair requested an explanation from the NRC regarding their basis for assigning a B compatibility to all the training and experience requirements, because it is our belief that these rules do not meet the criteria to be assigned a B compatibility. However, the NRC has not responded to our request.

Reviewer #5 The citation at the end of [G.57c.i(2)] seems confused in its notation. Also, please verbally state the topic for which you are citing a specification, not just the section number. Similarly for the citation at the end of [G.57c.iii].

*Committee Response:* These are category B items of compatibility, and have written to mirror the NRC text. The brackets have been removed, but the rationale should be read before adopting G.57 and G.58.

Reviewer #'s 2 and 4 G.57a. Add "or an Agreement State" after NRC.

*Committee Response:* The committee has added this text.

Reviewer #5 G.57b. text should be "Is an authorized user on a license issued by... under G.52 or equivalent"

*Committee Response:* To be an authorized user under G.56 or G.58 indicates that the individual has been approved by the Agency, so the text was not changed.

Reviewer #'s 2 and 4 G.59 At the start, it is fragmented. Should be more like "A licensee shall use only brachytherapy sources for therapeutic medical uses:"

*Committee Response:* The committee added "A licensee shall use only brachytherapy sources for medical uses:"

Reviewer #5 G.59 introductory text appears to be missing!

*Committee Response:* Introductory text has been added.

Reviewer #1 G.59 is a sentence fragment; a verb is needed, e.g. 'Manual brachytherapy is authorized for a.... or b...



*Committee Response: The committee added "A licensee shall use only brachytherapy sources for medical uses:".*

Reviewer #9 In G.60b. Recommend changing the word "removed" to "accounted for" at the end of the sentence.

*Committee Response: Although the committee understands your recommendation, the survey is only going to tell you if all the sources are absent or removed from the patient. It cannot account for the number of sources present or retrieved. Accountability of brachytherapy sources is covered in G.61.*

Reviewer #'s 2 and 4 G.62a.i. "Radiation therapy" should be replaced by "brachytherapy".

*Committee Response: The text has been changed so that "radiation therapy" is replaced with "brachytherapy", and all text following "brachytherapy sources" in G.62a.i. has been deleted.*

Reviewer #9 Why is there no requirement to survey areas adjacent to the therapy patient's room in G.63?

*Committee Response: It is the intent of the NRC to allow Part 20 requirements to be followed without reference in this section of Part 35. The licensee will be required to meet Part D limits for exposure rates surrounding the patient's room.*

Reviewer #14 G.63b. is a little awkward, suggest this be revised to read: "A licensee shall have emergency response equipment available near each treatment room emergency response equipment to respond to a source that inadvertently becomes:

- (i) inadvertently dislodged from the patient; or
- (ii) inadvertently lodged within the patient following removal of the source applicators.

*Committee Response: The committee agrees, and the text has been changed.*

Reviewer #14 In G.64b., revise this to read: "A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph a of this section."

*Committee Response: The committee agrees, and the text has been added in brackets.*

Reviewer #'s 2 and 4 G.67a. Add "or an Agreement State" after NRC.

*Committee Response: The committee has added this text.*

Reviewer #1 G.67 Replace "Uses authorized under G.58" to "radiotherapy".

*Committee Response: The NRC has assigned this section as a compatibility category B. The committee decided the current rule text (which mirrors the NRC's) was adequate.*

Reviewer #1 G.67b.ii. Replace "who meets the requirements of G.65 or G.66, and" with "at a medical institution".

*Committee Response: The NRC has assigned this section as a compatibility category B. The committee decided the current rule text (which mirrors the NRC's) was adequate.*

Reviewer #9 G.67b. - Change the text to read "Has successfully completed a structured educational program..."

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #4 In G.67b.i.(2)(c), replace the word "sealed" with "brachytherapy".

*Committee Response: The text has been changed to mirror the NRC text.*

Reviewer #9 G.67b.ii. - Change the text to read "Three years of full time supervised clinical experience..."

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #'s 2 and 4 G.68a. Add "or an Agreement State" after NRC.

*Committee Response: The committee has added this text.*

Reviewer #1 Is a written directive required for ophthalmic use of Sr-90 (addressed in G.68)? What of sealed source diagnostic procedures (G.69)? Perhaps you'd add text in G.58 to require a written directive for any sort of rad therapy? Would you then wish to move the diagnostic use of sealed sources to precede the procedures that do require a written directive?

*Committee Response: G.22 already specifies when a written directive is required. Specifically, a written directive is required any time a therapy dose or dosage is to be delivered. The organization of the rule follows the organization of the revised Part 35, with very few exceptions. The committee decided to keep this section in the same order as Part 35.*

Reviewer #10 G69 and G70, Could you give me some examples of the type of use to which this pertains?

*Committee Response: Primarily, this would be things like bone densitometry studies using Gd-153 or I-125 sources.*

Reviewer #7 G.70 - Who can operate a bone densitometer? Only the AU?

*Committee Response: As with other uses in Part G, the use of the licensed bone densitometer must be under the supervision of the authorized user.*

Reviewer #4 In G.71, add the word "radiosurgery" between "stereotactic" and "units".

*Committee Response: The text has been changed.*

Reviewer #4 In G.73.b., add the word "radiosurgery" between "stereotactic" and "units".

*Committee Response: The text has been changed.*

Reviewer #9 G.73c. Is allowing the authorized medical physicist to install sources in low-dose remote afterloader units compatible with the Sealed Source and Device Registry sheets?

*Committee Response: Although the afterloader units are to be installed and have initial testing permed by the manufacturer's representative, we are not aware of any low-dose rate afterloader*

units that require the manufacturer's representative to load new sources.

Reviewer #2 G.74a.ii. - I disagree with allowing anyone in the room "during treatment".

*Committee Response: There may be certain situations (particularly with low, medium and pulsed dose rate remote afterloader units), an individual may need to be present during the treatment. The licensee has to determine that necessity based on ALARA and medical need.*

Reviewer #9 G.74a.ii. - Does this rule allowing individuals to be in the room during the therapy procedure only apply to low dose-rate afterloaders?

*Committee Response: No, it applies to all devices covered in G.71.*

Reviewer #'s 2 and 4 G.75g. Change to read "A licensee shall have applicable emergency response equipment available near each treatment room, to respond to a source:".

*Committee Response: The committee has changed the text to be very close to your suggestion.*

Reviewer #14 G.75g. - This is a little awkward, suggest this be revised to read: A licensee shall have applicable emergency response equipment available near each treatment room emergency response equipment, as, to respond to a source that inadvertently:

- (1) Remained inadvertently remaining in the unshielded position; and
- (2) Inadvertently lodged within the patient following completion of the treatment.

*Committee Response: The committee agrees with you and has revised the text.*

Reviewer #13 G.76a.i. I see you underlined traceable to the NIST. This calibration is really different and extremely difficult primarily because of the geometry of measurement while keeping exposures reasonable to the people making the measurements. The measurement is so difficult that NIST actually performs some of the measurements for initial patient work until the hospital or AAPM labs can develop procedures to give the needed accuracy. The serious consequences of an inaccurate dose require extreme measurement measures.

*Committee Response: This text is virtually the same as the current dosimetry system calibration requirements, and was not pointed out as a problem area in discussions with medical physicists during the rule making process. The committee decided to keep the text as is.*

Reviewer #7 Does Part 35 require the authorized user and the medical physicist to be physically present for an HDR procedure? Do you know the compatibility of this?

*Committee Response: Yes, 35.615(f)(2) requires the authorized user and the medical physicist to be physically present during the initiation of all patient treatments. The compatibility category is D(H&S).*

Reviewer #1 G.80c. - Change "promptly" to "as soon as possible".

*Committee Response: The committee considered your recommendation, but decided to allow the individual Agencies to determine what "promptly" meant.*

Reviewer #'s 2 and 4 G.81a.i. - Change "At the beginning of each day of use" to "Before the first use".

*Committee Response: The recommended text was not used because it would be easy to interpret it to mean that the licensee only had to perform the spot checks before the initial use of the remote afterloader unit, and never again.*

Reviewer #9 G.81c. - Suggest that the authorized medical physicist be required to review the results of the spot checks prior to the next medical treatment instead of within 15 days.

*Committee Response: The committee does not believe that this is reasonable. The technologist, dosimetrist or whoever performs the spot checks, is to know the acceptable tolerances for the check. If the spot check results fall outside these tolerances (set by the authorized medical physicist), all use of the unit should stop until the problem is corrected by the authorized medical physicist or manufacturer.*

Reviewer #4 G.82b.ii. - Add the sentence "The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spotcheck".

*Committee Response: This text has been added.*

Reviewer #1 G.82e. Change "prompt" to "as soon as possible".

*Committee Response: The committee considered your recommendation, but decided to allow the individual Agencies to determine what "promptly" meant.*

Reviewer #2 G.84.a., 1<sup>st</sup> sentence, 2<sup>nd</sup> line: Delete "make to".

*Committee Response: The text has been changed to make it more clear.*

Reviewer #1 G.84, the readers would appreciate a description of the text in D.501, 'general survey requirements.' And add the s for plural.

*Committee Response: The committee did change the tense to plural, but feels the licensee should read the rule in Part D. In this instance, the committee did not believe the referenced rule should be reiterated.*

Reviewer #'s 2 and 4 G.88a. - Add "or an Agreement State" after NRC.

*Committee Response: The committee has added this text.*

Reviewer #9 G.88b.i. - Change the text to read "Has successfully completed a structured educational program..."

*Committee Response: This rule text has been assigned a compatibility category B, and the NRC did not include your suggested text. The committee made the NRC advisors aware of your suggestion, and if it is changed in the final NRC text, we will make the change to Part G.*

Reviewer #9 G.89 seems to be contradictory. What about the FDA. Reference G.5 includes State Pharmacy Act.

*Committee Response: Section G.5 also states that "Nothing in this Part relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices". Therefore, the committee sees no contradiction in the rule.*

Reviewer #10 G.93 - This section requires record retention for 3 years after the event. Most medical records regulations dealing with retention of patient medical information require that information on minors (unborn children or children under the age of 21 years) be retained for the requisite number of years after the child's 21st birthday. In this instance, that would be until the minor's 24th birthday. This principle should be applied to all radiation dose record retention requirements.

*Committee Response: Individual states may have varying records retention requirements, however, this 3 year time frame is the minimum period of time the records should be retained.*

Reviewer #1 G.93 and G.119 Change "misadministration" to "medical event".

*Committee Response: The committee does not recommend the use of the term "medical event" because we believe that any procedure performed on a patient is a medical event. We believe the term "misadministration" is a much more concise and proper term.*

Reviewer #1 G.96 - 'radiation survey' should be inserted before 'instrument calibrations'.

*Committee Response: The committee has added the word "survey" in front of the word "instrument" in the first sentence.*

Reviewer #1 G.108-9 - the signature requirement belongs on G.109 and not G.110, as I understand G.64c. & d.

*Committee Response: The authorized medical physicist is required to sign when they perform the full calibration of either brachytherapy sources, including strontium 90 sources. G.108 refers to calibrations of brachytherapy sources other than strontium 90, while G.109 refers to the strontium 90 source calibrations.*

Reviewer #14 In G.114b.v. add a requirement for the authorized medical physicist's signature after reviewing spot check results.

*Committee Response: The text has been added.*

Reviewer #1 In G.119 and G.120 '...report to the agency any...' Perhaps you'll wish to also require 'users' to promptly report misadministrations to the RSO.

*Committee Response: Licenses are normally issued to a hospital or private practice corporation, not to an authorized user. The regulatory responsibility, therefore falls on the licensee, not individual users listed on the license. That is why the users are not specified in the rule.*

Reviewer #1 G.119a. Change "administrations" to "an event".

*Committee Response: The committee has changed the text.*

Reviewer #1 G.119d.i.(3) & (4), and G.119e. Change "misadministration" to "event".

*Committee Response: The committee has changed the text in G.119d., but has left the term "misadministration" in G.119e. We feel that the term "misadministration" is the more proper term in this context.*

Reviewer #9 Reports of all safety related failure of gamma knives, remote HDR's Teletherapy units and mobile HDR should be included in rule G.119.

*Committee Response: This section is specifically for misadministrations to patients. If the reason for the misadministration is a failure of the equipment, it should be included in the report. Although frequent problems with a device are not required to be reported in these rules, the FDA does have voluntary reporting for such problems, and such problems should be obvious when reviewing spot checks during an inspection.*

Reviewer #4 Add "and Notification" to the title text of G.120.

*Committee Response: The text is added.*

Reviewer #4 In G.120b.ii., add "of the child" after the word "system".

*Committee Response: The text has been added.*

Reviewer #1 G.121 requires report of a leaking source. It is perhaps better composed than the text of that requirement in D.1208 or C.22d.iii.(5), but an explanation should be given for the reiteration of this one of the many requirements in other Parts that seem applicable to the persons subject to Part G.

*Committee Response: This text is included in Part G because the specific leak testing requirements for sealed sources authorized in Part G are detailed in G.36.*

## List of Reviewers

Reviewer #1 - Terry Divine  
Reviewer #2 - Cheryl Rogers  
Reviewer #3 - Consolidated comments from the Texas Bureau of Radiation Control  
Reviewer #4 - NRC  
Reviewer #5 - Terry Frazee  
Reviewer #6 - Vickie Jeffs  
Reviewer #7 - Debbie Gilley  
Reviewer #8 - John Hidalgo  
Reviewer #9 - Consolidated comments from the Illinois Department of Nuclear Safety  
Reviewer #10 - Julie Timmons, M.D.  
Reviewer #11 - John Feeney  
Reviewer #12 - David Walter  
Reviewer #13 - Robert Lommier  
Reviewer #14 - Cathy Fontaine