# 2003 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 and G.47.

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. C28k.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:

| Rule Section | Compatibility Designation |
|---|---|
| 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 |

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| 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 | |

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| 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 |

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| 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 | |

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| 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

| Part G Section | Part 35 Section |
|---|---|
| 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 |

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

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