

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER DICUS  
SUBJECT: **SECY-99-201 - DRAFT FINAL RULE - 10 CFR PART 35,  
"MEDICAL USE OF BYPRODUCT MATERIAL"**

Approved x <sup>w/comments</sup> Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS:

See attached comments.

Aneta Joy Dicus  
SIGNATURE

December 22, 1999  
DATE

Entered on "AS" Yes x No \_\_\_\_\_

Commissioner Dicus' comments on SECY 99-201:

I commend the staff for an extremely well-written and concise summary of the concerns raised by various members of the public, the Agreement States, the medical community and the licensees. In particular, I would like to express my personal thanks for the NRC staff efforts to reach out and obtain feedback from the seven facilitated public workshops have been held since August 1997.

I have summarized my specific comments on each of the major issues as outlined below:

1. **Formal risk assessment.** I note that for the first time, the proposed final rule for 10 CFR Part 35 uses risk insights and operational experience to establish sound requirements that focus both licensee and regulatory resources on operational issues commensurate with their importance to health and safety. Accordingly, I agree with the staff to not perform a formal risk assessment at this time. To perform such an assessment would most likely be at a significant cost in terms of staff time and contractor dollars, as well as a potential delay of perhaps five years for the final rule. Considering that the revised rule is considerably more risk-informed than the current version, I believe that it would be more of a detriment to all stakeholders to delay at this time. I would, however, include additional information in the *Statements of Consideration* (see page 9 of the draft final Federal Register Notice, attached) which provides the many reasons why a formal risk assessment is not necessary (i.e., additional 5-year delay in the rulemaking, considerable staff and contractor costs, as well as the revised rule being risk-based).
2. **Radiation Safety Committee (RSC).** I support the requirement for an RSC to be required for two or more different types of uses under Subpart E, F and H, or two or more types of units under Subpart H. Licensee management should have the flexibility it needs to decide in how best to address the issues of concern in its radiation protection program.
3. **Training and Experience (T&E) Requirements.** Any increase to the T&E requirements for physicians (primarily endocrinologists) who administer I-131 for diagnostic or therapy, beyond 80 hours does not appear to be justified based on the lack of a history of radiation safety problems over the past 50 years in this area. The NRC focus should be on radiation safety and not the practice of medicine (i.e., clinical proficiency). Moreover, because the NRC has a responsibility for establishing a national program for these types of requirements, I believe that the training requirements should be consistent between NRC and the Agreement States, and accordingly, request that the compatibility level for this requirement be upgraded to Compatibility Level "B" (see item 4 below).
4. **Compatibility Levels Regarding T&E Requirements (§35.390).** I do not agree with the SR-6 Committee plans to recommend to the States that they require a T&E requirements of 700 hours for endocrinologists. Historically, there has been no evidence to support a claim that this specialty of medicine has been less cautious in handling radioactive iodine than a radiologist or a nuclear medicine physician. I believe that a differing T&E requirement for endocrinologists would be problematic across the nation, and would most likely lead to additional medical consultation, training and treatments by other physicians, ultimately affecting the medical treatment to the patient. The NRC staff

has done an admirable job in bringing together the facts from all sides on this issue, and I believe that due to the transboundary issues associated with this discipline, it is imperative that the compatibility level be changed from Level "C" to "B" to ensure a consistent framework in the nation.

5. ***The Calibration of Sources and Instruments.*** I agree with the revisions made to §§35.60, 35.62, and 35.432 which will require that licensees calibrate instrumentation in accordance with nationally recognized standards (per Public Law 104-113, *National Technology Transfer Act*) and address manufacturer concerns regarding the proper use and calibration of Sr-90 eye applicators. These changes make the requirements for instruments and sources more adaptable to new technology and are more performance-based.
6. ***Notification Following a Medical Event [§ 35.3045(e)].*** I note that the majority of comments received from physicians, the ACMUI, and the Patient Rights Advocate request deletion of the requirement for licensees to notify and provide a written report to the patient or responsible relative after a medical event. As I have indicated before in SECY-98-128, I am on record as opposing Federally mandated requirements for notification of patients regarding misadministrations. I continue to believe that the proposed reporting levels for medical events cannot be justified on the basis of any real risk to either the patient(s) or the public. Reporting, in and of itself, implies that these events result in direct harm to the patient, when they often result in no effect on the patient. Because NRC's mission is to also ensure adequate protection of the public's health and safety, I believe that keeping a requirement in Part 35 for such notification is redundant to existing State laws and medical ethics, incorrectly allows intrusion by NRC into professional activities, and penultimately interferes with the doctor-patient relationship. It is for these reasons I believe there should be no NRC requirement for notification following a medical event.
7. ***Reporting Threshold for Unintended Exposure to an Embryo, Fetus and Nursing Child (§ 35.3047).*** I agree with the staff's proposal to place this requirement in Part 35, and to raise the reporting threshold to 50 millisievert (mSv) (5 rem). The most important issue concerning this threshold is that the requirement is a *reporting* requirement, not a dose limit. I believe that the 50 mSv (5 rem) reporting threshold is justified for several reasons: (1) as stated in Report 54 of the National Council of Radiation Protection and Measurements, the risk to the embryo/fetus is "...considered to be negligible at 5 rad or less when compared to other risks of pregnancy..."; (2) there are no known deterministic effects of radiation exposure noted in the embryo, fetus, or nursing child at 5 mSv (500 mrem); and (3) the proposed lower threshold of 5 mSv (500 mrem) would likely require mandatory pregnancy tests for every woman of childbearing age who receives a diagnostic procedure, potentially negatively impacting the choice of treatment and the practice of medicine.

As a final note, I believe that this requirement should be placed in Part 35, rather than Part 20, as was originally suggested, since Part 20 excludes the practice of medicine, or exposure from medical events.

8. ***Patient release criteria (§35.75).*** While I can understand the issues many of the States face with regard to increasing responses to radiation alarms at municipal landfills,

I continue to support the proposed final rule that establishes the current dose-based patient criteria of 5 mSv (500 mrem) per year. NRC has experienced great success in working with the licensee, local landfill operators, and regional offices to better understand, establish, and set appropriate levels and procedures for alarms on a case-by-case basis. If however, a State wanted to be more prescriptive in this area, there appears to be nothing in the proposed rule which would prevent them, for justified reasons, for setting more stringent limits.

I am in agreement with Commissioner McGaffigan's position that while the SR-6 Committee believes that the licensee needs to provide adequate and appropriate instruction to the released patient to help ensure that exposures to members of the public are as low as is reasonably achievable, I do not agree with the SR-6 recommendation that licensees that have released patients *in accordance with the regulations* be held responsible for confirmed excessive exposures and release of contaminated items to municipal landfills.

9. **Specialty Boards.** I agree with the staff's recommendations to notify specialty boards that we will begin accepting requests for recognition of such boards before publication of the final 10 CFR Part 35. It is a large step forward that Part 35 will no longer incorporate a listing of specialty boards whose diplomats automatically fulfill the T&E requirements for RSOs. This change represents a large burden reduction for medical licensees.
10. **Medical Policy Statement.** I agree with the staff's recommendation to revise the Medical Policy Statement, consistent with the changes that this Staff Requirements Memorandum (SRM) conveys, and complete the final Part 35 rulemaking package to the Commission approximately three months from the date of that SRM.
11. **Regional Inspector and License Reviewer Training.** I support the staff's recommendation that NRC staff performing medical inspections will receive training in the final Part 35 as well as in any guidance documents associated with the rulemaking. I would expand this training to include license reviewers and regional managers, so that they too, become quite familiar with the significant revisions in Part 35. I would encourage the training to be completed in all of the regions as soon as Part 35 is finalized, just as was done for the Part 20 regional training sessions.
12. **No Need for a Public Briefing.** I do not believe that there is a need for a public briefing on the draft final rule. I would rather the staff spend its limited resources on finalizing the rule, Medical Policy Statement, and corrections to the FRN so that this rule can be completed within the established timeframes.
13. **Use of International System of Units.** Per the final NRC Metrication Policy (effective on June 19, 1996), the final rule should be revised to consistently use the International System of Units (SI) first, with the English unit shown in brackets (see attachments for examples). Per this policy, even if the incoming comments are only in English units, the SI units should be in parentheses after that, encouraging the use and understanding of the metric units for radiation protection.
14. **Changes to the FRN.** In addition to the changes above, additional changes to the FRN are attached.

(4) Developing licensing, inspection, and enforcement policies and procedures to support the rule.

Many of these commenters offered possible ways of evaluating risk and asked that stakeholders be allowed to participate in assessing risk. Some commenters indicated that NRC should establish a risk-benefit "filter" to evaluate this and future rulemakings. They believed this approach would be useful in dealing with emerging technologies. They also believed that if NRC had a structured framework for risk analysis, appropriate regulations could be developed to deal with the real risk to the patient, public, and worker.

Other commenters asked that we consider all types of risk before publishing the final rule, e.g. absolute, relative, comparable, perceived, cost, and "pseudo risks." Commenters discussed these types of risks in the following terms and offered the following comments on each type of risk. While most comments were directed at diagnostic nuclear medicine, many of the statements would also apply to therapeutic uses of byproduct material.

*as they are viewed in the regulation of medicine*

*Absolute risks* are real health effects (deterministic, stochastic) that include harm to the patient, public, <sup>or</sup> and worker<sup>s</sup>. Commenters indicated that diagnostic nuclear medicine procedures do not present measurable health effects to the patients, workers, and the public.

*Relative risks* are the risks of diagnostic nuclear medicine relative to other diagnostic medical procedures that are currently unregulated for the end-user. The side-effects from many non-radiological medical procedures involve higher risks of harm to the

SI SI  
patients than microcurie and millicurie amounts of byproduct material that are used for tracer and localization and imaging studies, where there is no observable radiological or pharmaceutical effect. X

*Comparable risks* are risks of diagnostic nuclear medicine as compared to other industrial risks (radiological and non-radiological) and other human activities that are acceptable to the general public.

*Perceived risks* involve the public perception of safe and unsafe uses of radiation that eventually influence the licensee to comply with unnecessary NRC requirements in order to compete in the market place. <sup>one</sup> The commenter noted that most cancer patients are willing to accept higher risks for the benefit of cure. <sup>is</sup> The commenter believed that the large number and prescriptiveness of the current regulations add to the misconception that the public has of radiation. By reducing needless requirements on low-risk nuclear medicine, the public perception will adjust accordingly, so that NRC regulatory oversight is less burdensome to licensees. X X

*Cost risks* result in overspending on the low risk activities. This economic imbalance creates a higher risk for other areas that do not receive the resources that would otherwise be available. X

*Pseudo risks* are unreal risks in which there is no harm associated with the activity or event, e.g., landfill alarms <sup>as a result of inadvertent disposal of</sup> to short-lived, low-activity radioactive waste from diagnostic nuclear medicine. X

Response. In March 1997, the Commission directed the revision and restructuring of Part 35 into a risk-informed and, where appropriate, more performance-based regulation. This direction was part of the Commission's overall decision to decrease oversight of lower-risk activities, such as diagnostic nuclear medicine, while retaining oversight of high-risk activities.

Before initiating the rulemaking, the Commission thoroughly reviewed several extensive assessments, including the external review and related report conducted by the National Academy of Sciences-Institute of Medicine (NAS-IOM), "Radiation in Medicine, A Need for Regulatory Reform;" a 1993 NRC internal senior management review and report, and the Commission's Strategic Assessment and Rebaselining initiative. During the development of the overall revision of Part 35, we considered information on risk provided by members of the public and professional societies, professional medical standards of practice, and event databases maintained by NRC to determine where oversight of lower-risk activities could be decreased and where continuation, or even broadening, of the regulations governing higher-risk activities was needed. In addition, throughout the development of the proposed rule and associated proposed guidance, public workshops were held and early opportunities for comment from potentially affected parties were provided. These interactions included significant discussions on the risk associated with medical uses of byproduct material.

While we did not perform a formal risk assessment, we believe that we have adequately evaluated and considered the risks associated with use of byproduct material in medicine. We have eliminated requirements in the current Part 35 that are contained elsewhere in the Commission's regulations, such as the radiation protection requirements in Part 20. Part 35 licensees will continue to be required to comply with these requirements, such as the ALARA

*State the reasons why we didn't perform a risk assessment*

*i.e. like 5 yrs + lots of \$\$ without any future benefit to public / state holders.*

NRC licensees are encouraged to audit their own activities and discover and correct their own violations. A voluntary program of inspection by an accrediting organization is one method to accomplish this goal. For example, if accrediting organizations were noted to be successful in discovering violations and assuring that those violations are corrected, the frequency of inspections at accredited facilities could be decreased. Under this scenario, some NRC inspections could still be performed to verify the effectiveness of the voluntary program undertaken by the accrediting organization, but the overall number of inspections performed by the NRC would be reduced.

In summary, we believe the proposal for involvement of professional accreditation boards and organizations in the inspection program has merit and should be further developed in an ongoing dialogue. In the interim, the NRC will continue to inspect nuclear medicine licensees but will also continue to make improvements to the program, especially in the area of focusing the inspection program on risk.

*We should  
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Issue 2: What changes should be made in the inspection process as a result of the revised Part 35?

*[ See  
Answer  
p. 20 ]*

Comment. Commenters expressed a concern that NRC inspections were too detailed and focused on records and use of checklists. Some commenters asked that NRC inspectors focus on radiation safety program management. They indicated that, if the program was managed properly, there would be no need to evaluate program records or the written procedures. Commenters believed the inspectors should be satisfied if the big picture does not indicate a violation because the final rule will be less prescriptive, risk-informed, and

instrumentation cases, the manufacturer's guidance. Conversely, some commenters believed that we, as regulators, had the role of defining the minimum level of practice necessary to directly enhance safety. The commenters indicated that there are some limited cases where those practicing are not following "voluntary" standards of practice; therefore regulations were needed. Finally, some commenters questioned our role in regulating an activity that is also regulated by another government agency or by the state.

Response. In developing the final rule in therapeutic uses of sealed sources, we consulted several AAPM reports, including the reports from Task Groups 40, 56, and 59, and Report No. 54. In developing several other sections of the rule, we also consulted various other nationally recognized bodies' reports including American National Standards Institute, Inc. (ANSI), ACR, American College of Medical Physics (ACMP). We understand that these and other standards of practice are often voluntary, and as such, medical professionals are not required to follow them. Therefore, we limited the requirements to the performance standard to be achieved and allowed the licensee to select among the various performance standards to meet the objective of the regulation. We believe that this provides the licensee significant flexibility in designing its radiation protection program.

We agree that, in some cases, the licensed community must comply with several different Federal and state regulations for a single type of use. For instance, in the case of sealed radioactive sources for therapeutic medical uses, the licensed community must comply with FDA regulations for devices and must also comply with NRC regulations on the use of the radioactivity in or on humans. Whenever possible, we reviewed the various state and Federal regulations, including other NRC regulations, to limit duplication of requirements.

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EXAMPLES

We recognize that physicians in training will not dedicate all of their time specifically to the subject areas in § 35.290(c)(1)(ii) and will be attending to other clinical matters involving the diagnostic use of the material under the supervision of an AU (e.g., reviewing case histories or interpreting scans). Even though such clinical matters are not specifically required by the NRC, such supervised work experience may be counted toward the supervised work experience to obtain the required 700 hours.

We agree that the training and experience requirements should be increased for individuals who would like to use byproduct material for which a written directive is required. In the final rule, § 35.390, Training for use of unsealed byproduct material or for use of unsealed byproduct material that requires a written directive, the hours have been increased from 80 hours to 700 hours. We believe this increase is needed because these physicians would be authorized to elute generators and prepare radioactive drugs as well as administer a wide variety of radionuclides requiring written directives and thus the associated radiation risks of the use could be greater. In addition, the work experience in the administration of such dosages to patients must specifically include at least three cases in each of the following categories for which the individual is requesting AU status:

1. Oral administration of less than or equal to <sup>1.22 gigabecquerel (GBq)</sup> 33 millicuries of sodium iodide I-131; X
2. Oral administration of greater than <sup>1.22 GBq</sup> 33 millicuries of sodium iodide I-131; X
3. Parenteral administration of any beta-emitter or a photon-emitting radionuclide with a photon energy of less than 150 keV; and/or
4. Parenteral administration of any other radionuclide.

Response. In the final rule, §§ 35.392 and 35.394 have been added to specifically address oral administrations of sodium iodide I-131. These sections do not increase the duration of training for an endocrinologist over the current requirements in §§ 35.932 and 35.934.

In the final rule, § 35.392 was added to provide the training and experience requirements for physicians who only seek authorization for the oral administration of sodium iodide I-131 in dosages less than or equal to 1.22 gigabecquerel (GBq) (33 millicurie<sup>S</sup>) and do not seek authorization to prepare radioactive drugs using generators and reagent kits. To qualify as an AU under this limited authorization, an individual must have 80 hours of classroom and laboratory training and supervised work experience that includes 3 cases involving the oral administration of sodium iodide I-131 in dosages less than or equal to 1.22 GBq (33 millicurie<sup>S</sup>). We have not specified a breakdown between the number of hours of didactic (i.e., classroom and laboratory) and supervised work experience to allow licensees flexibility in designing and implementing training programs. Therefore, the number of hours of classroom and laboratory training and supervised work experience needed to adequately address the required subject areas can vary with individual training programs. These individuals may not prepare unsealed byproduct materials using generators and reagent kits. X

Also, in the final rule, § 35.394 was added to provide training and experience requirements for physicians who only seek authorization for the oral administration of sodium iodide I-131 in dosages greater than 1.22 GBq (33 millicurie) and do not seek authorization to prepare radioactive drugs using generators and reagent kits. This limited authorization requires 80 hours of classroom and laboratory training and work experience that includes 3 cases

to have adequate instrumentation. Information on the types of instruments is available in NUREG-1556, Vol. 9,<sup>11</sup>



Issue 3: Should the term “dose calibrator” be replaced with the term “radionuclide calibrator” in the training and experience requirements for unsealed byproduct material?

Comment. Commenters suggested that we replace the term “dose calibrator” with the term “radionuclide calibrator” in proposed §§ 35.50, 35.55, 35.290, 35.292, 35.390, 35.920 and 35.930.

Response. The reference to “dose calibrators” in §§ 35.50, 35.55, 35.290, and 35.292 has been deleted and replaced with “instruments used to determine the activity of dosages.” (Proposed §§ 35.920 and 35.930 were deleted by the final rule.) As stated under the discussion on § 35.60, this change recognizes that there are various types of instruments that can be used to measure the activity of unsealed byproduct materials. Therefore, we believe individuals should have experience with the different types of instruments and not limit them to only experience with dose calibrators.

Issue 4: Were there any other changes made to the rule between the proposed and final rule?

Response. Yes. References in the proposed rule to § 35.290 have been changed to § 35.190 and references to § 35.292 have been changed to § 35.290. This was done because the training and experience requirements in proposed §§ 35.290 and 35.292 were moved to

EVEN IF Q IS NOT IN BI, NRC ANSWER (PER NRC METRICATION PAIR SHOULD SHOW STATE mrem) BOTH).

Add 5 units

mSV

Issue 1: Who should approve whether a visitor is allowed to receive a dose up to ~~0.5~~ 500 X

Comment. A commenter suggested that the RSO, not the AU, should be the appropriate individual to approve the merits of allowing a visitor to receive up to ~~0.5 rem~~ 500mrem. X

Response. AUs have the primary responsibility for the health and safety of their patients. They are also responsible for determining, depending on the patient's conditions, whether visitors can visit their patients and with what limitations. Therefore, we believe the AU should approve whether a visitor is allowed to receive a dose up to ~~0.5 rem~~ 500mrem. However, the AU may consult with the RSO at any time regarding visitor control. X

Issue 2: Should visitors be allowed to receive a dose up to ~~0.5 rem~~ 500mrem. X

Comment. The commenter stated that the proposed rule did not meet any standard for justifying an increased exposure to someone visiting a hospitalized (confined) patient. The commenter indicated that one of the reasons for the increased dose limit in § 35.75 was the economic benefit of allowing the patient or human research subject to be released from control earlier. He went on to state that in the case of the proposed revision to § 20.1301, there was no economic benefit to the licensee and that NRC was basing this change on an emotional benefit to the patient rather than an economic benefit.

Response. The justification for this change was discussed in detail in the Statements of Consideration for the proposed rule and in the associated draft Regulatory Analysis. It is X

see ( FR )

informed physicians will make decisions that are in the best interest of their patients. However, NRC has a secondary, but necessary, role with respect to the radiation safety of patients. <sup># ↗</sup> the NRC will, when justified by the risk to patients, regulate their radiation safety, primarily to assure that the use of radionuclides is in accordance with the physician's directions.

**Issue 2:** Were there any other changes made in this section between the proposed and final rule?

**Response.** Yes. We replaced the word "prescribes" with the phrase "contains the" in the first sentence of the section because Part 35 contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing medical use.

### **Section 35.2 Definitions.**

We received numerous comments on the definitions. Commenters asked us to revise, delete, or add definitions for terms used in the rule. We have also added some new terms in this section because of changes made in other sections of the rule. Public comments and our response to the comments, as well as the reasons for other changes to this Section, are presented below in alphabetical order of the terms.

#### **Area of use**

**Issue1:** Were there any other changes made in this definition between the proposed and final rule?

An AU for medical use under § 35.500 may be a physician, dentist, or podiatrist. An AMP could only be an AU, named in the license, if the AMP meets the criteria in the definition of AU in § 35.2, including the training and experience criteria cited in that section.

Issue 2: Were there any other changes made in this definition between the proposed and final rule?

Response. Yes. In addition to restructuring the definition, to make it more readable, we substituted the word "individual" for the word "physicist." This change was made so that the definition of the term would be similar to the definition for an RSO.

We also revised the definition for the AMP to include individuals identified as an AMP on (1) a permit issued by a Commission master material licensee or (2) a permit issued by a Commission master material license broad scope permittee where that permittee has been given authorization to issue permits designating AMPs. This change, which was also made to the definitions of "ANP," "RSO," and "AU," accounts for the fact that an AMP may be named on a permit issued by a master material licensee. For example, in the first case identified above, if a master material licensee has issued a permit that recognized a particular individual as an AMP, under this definition, the individual would continue to meet the requirements for an AMP under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating AMPs, under this definition, an AMP on the permit would also meet the requirements for an AMP under an NRC license.

*This is not defined in Rego. only in Guidance Document*

*X*  
*Reference should be made to NUREG-1556, Volume 10.*

Authorized Nuclear Pharmacist

This change, which was also made to the definitions of "ANP," "AMP," and "RSO," accounts for the fact that an AU may be named on a permit issued by a master material licensee. For example, in the first case identified above, if a master material licensee has issued a permit that recognizes a particular individual as an AU, under this definition the individual would continue to meet the requirements for an AU under an NRC license. In the second case, if a master material licensee chooses to issue a broad scope permit to a hospital and that hospital has authorization to issue permits designating AUs, under this definition an AU on the permit would also meet the requirements for an AU under an NRC license.

We also added a reference to new sections in the final rule that lists the training and experience requirements for individuals using only <sup>I-131</sup>iodine-131 in quantities that would require a written directive (§§ 35.392 and 35.394) and for using strontium-90 for ophthalmic treatments (§ 35.491).

*ALREADY PREVIOUSLY ADDRESSED*

### Brachytherapy

Issue 1: Were there any other changes made in this section between the proposed and final rule?

Response. Yes. We added a definition for brachytherapy. This was done because we believe it is important to define such a term as it is used in Part 35 so that the regulated community and regulatory agencies have a clear understanding of what we mean when we use the term in the rule.

### Brachytherapy source

requirements." The commenter believed that NRC, when identifying physicists, was defining a specific position too narrowly, with delineated duties and responsibilities representing only a portion of the duties and responsibilities of physicists who are involved in radiation safety.

Response. We have not defined the term in Part 35 because it is not used in Part 35. Physicists meeting the requirements for an "authorized medical physicist" or "Radiation Safety Officer" would be recognized on the license as an AMP or RSO, respectively.

#### High Dose-Rate Remote Afterloader and Low-Dose Rate Remote Afterloader

Issue 1: Should there be another category of "afterloader," such as a "non-remote" or "beta-only" afterloader?

Comment. A commenter stated that the proposed afterloader definitions don't distinguish between the beta device that delivers more than 2 Gray/hour (Gy/h) to a target tissue and less than 0.002 Gy/h to the remainder of the body from the afterloader capable of delivering a lethal whole body dose. The proposed definitions will result in confusion for licensees and inspectors. The commenter recommended that another category such as "non-remote" or "beta-only" afterloaders be developed.

Response. We have not distinguished between beta and photon-emitting remote afterloaders in the definition. The purpose of the definition is to categorize afterloaders into different groups based on the dose rate (i.e. high, medium, or low) of a remote afterloader. Requirements for the devices are found in Subpart H. The final rule only addresses use of photon-emitting afterloaders. Use of beta-emitting afterloaders is being addressed on a case-

sources (e.g., seeds, ribbons) are manually inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

### Medical Use

Issue 1: Should the definition of the term "medical use" include the term "byproduct material"?

Comment. A commenter recommended the term "byproduct material" be deleted from the definition of the term "medical use" because the regulations use the term "byproduct material for medical use," which is redundant. The commenter did not believe it necessary to include the term "byproduct material" in the definition of "medical use" and then to modify the term "medical use" with the phrase "byproduct material" in the regulations. The commenter stated that deleting the term "byproduct material" from the definition "requires the least amount of correction and simplifies compatibility by Agreement States."

Response. We recognize that there is some redundancy in using the phrase "Medical use of byproduct material." However, we believe that this level of redundancy in some requirements is not objectionable if it helps to clarify the specific requirements. *of the AEA.* X

### Medium dose-rate remote afteloader

Issue 1: Is there a need for definition of the term "medium dose-rate remote afterloader"?