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Vol. 9

Consolidated Guidance About Materials Licenses

Program-Specific Guidance About Medical Use Licenses
Appendix BB
Summary of Public Comments on Drafts and NRC Responses

Final Report

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ABSTRACT

As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository. NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," dated October 2002, is the ninth program-specific guidance document developed for the new process. It is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States.

On March 24, 2002, the NRC issued for public comment a draft of NUREG-1556, Volume 9. Comments were received during public meetings held at the NRC in Rockville, Maryland on April 25, 2002, and April 29, 2002, and during a 60-day public comment period that ended on June 4, 2002. This report serves as an appendix (BB) to the final report issued in October 2002. It provides a summary, analysis, and response to public comments received on the March 2002 draft. It also includes comments and responses on a draft of NUREG-1556, Volume 9 published for public comment in August 1998 (See 63 FR 45270). This material appeared as Appendix Z in the March 2002 draft of the guidance document.

The public input addressed in this report assisted the NRC staff in revising NUREG-1556, Volume 9 to ensure that the guidance contains the necessary information to assist applicants for licenses for the medical use of byproduct material in preparing their license applications. In particular, the staff considered public comments when determining what types of information applicants need to complete NRC Form 313, "Application for Material License" and NRC Form 313A, "Training and Experience and Preceptor Statement." Public input also assisted the NRC staff in revising NUREG-1556, Volume 9 to provide an overview of the types of licenses issued by the NRC; the commitments and responsibilities that must be undertaken by a licensee; applicable regulations; the process for filing a license application; and the contents of applications for different types of medical uses of byproduct material. As a result, NUREG-1556, Volume 9 provides a description, on an item-by-item basis, of the information to be provided by an applicant on NRC Form 313. Based on public input regarding user-friendliness of NUREG-1556, Volume 9, the staff included indicators in the guidance to alert applicants for particular types of medical uses to material that pertains to those types of uses. Public input also contributed to the revisions of the appendices to NUREG-1556, Volume 9. The staff revised the appendices to include (1) copies of necessary forms; (2) a sample license application and completed licenses for different types of medical uses of byproduct materials; and (3) examples of the types of documents, such as implementing procedures, that may need to be prepared for use in programs to comply with applicable regulations for medical use.

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FOREWORD

This report summarizes the public comments received by the NRC on draft NUREG-1556, Volume 9, "Consolidated Guidance About Material Licenses: Program-Specific Guidance About Medical Use Licensees," Revised Draft Report for Comment, released on March 24, 2002. The report also provides NRC staff responses to the comments. It also includes comments and responses on a draft of NUREG-1556, Volume 9 published for public comment in August 1998.

The NRC announced two public meetings and the availability of draft NUREG-1556, Volume 9 for a 60-day comment period ending on June 4, 2002. The purpose of the public comment period and public meetings was to receive comments on the draft guidance. In the *Federal Register* notice (67 FR 16468) and the Abstract of the March 2002 draft, the staff asked the public to comment on the following questions:

"1. Level of Detail and Format: Is the format and level of detail in the guidance appropriate for first-time applicants? Should the guidance be more general in describing acceptable methods of meeting 10 CFR Part 35 requirements? If so, please provide suggestions for revisions. Discussion about the pros and cons of providing extensive detail about safety and other procedures would be especially helpful.

"2. Model procedures: Are the model procedures helpful as written? Should they be retained or rewritten? If so, please provide suggestions for revisions.

"3. Licensing Guidance Specific to Diagnostic Nuclear Medicine: The staff is considering development of a summary of the licensing requirements for diagnostic medical use of byproduct materials. Is such a document desirable? What should be provided in the guidance? How long should it be?

"4. Other Guidance: Are there additional voluntary industry consensus standards or other publically available documents that should be considered for reference in NUREG-1556, Volume 9?"

Commenters were requested to relate their comments to specific sections and/or appendices in the NUREG.

The NRC received 15 letters commenting on NUREG 1556, Volume 9. Excerpts from the comment letters are quoted verbatim in this summary, unless otherwise indicated. References to sections or appendices in the comment letters are to the March 2002 draft of the guidance. Inserts or clarifications by the NRC staff are indicated by square brackets.

The two public meetings to review the draft guidance were conducted as facilitated roundtable discussions. The first, held on April 25, 2002, addressed NUREG-1556, Volume 9 from the standpoint of therapeutic uses of byproduct materials. The second, held on

April 30, 2002, addressed the guidance from the standpoint of diagnostic uses. Participants included representatives of medical, pharmaceutical, and patient advocacy interests, Agreement States, the Organization of Agreement States, the U.S. Food and Drug Administration, and the NRC staff. Transcripts of the discussions at each meeting, totaling several hundred pages, were prepared and are available on NRC's web site. Summaries of the discussions are presented in this document. In some cases separate statements by individual participants are treated as a single comment; in other cases when two or more participants made similar comments, a single summary was prepared that incorporates the points made by each commenter. Some statements made in the meetings have been edited to enhance clarity or provide context. Whenever possible, key phrases used by the commenters are included in the summary. Significant inserts or clarifications by the NRC staff are indicated by square brackets.

This document is organized as follows:

- Part 1 contains comments from letters and the two public meetings that address the four sets of questions posed by the NRC (listed above). NRC staff responses to these comments are also included. Comments are identified by source, using reference numbers which appear in parentheses at the end of each comment; the index numbers refer to the commenters listed in Table 1.

- Part 2 includes comments and responses on specific sections of the March 2002 draft. The NRC staff reorganized the guidance document substantially between the March 2002 draft and the final version. Therefore, cross-references to the final guidance appear in square brackets so that readers can compare the draft and final versions.

- Part 3 contains comments and responses on a draft of NUREG-1556, Volume 9 published for public comment in the *Federal Register* in August 1998 (63 FR 45270). This material appeared as Appendix Z in the March 2002 draft of the guidance document.

TABLE 1
LIST OF COMMENTERS

Document Number	Organization	Author	Date
T1	NRC-Convened Roundtable	Verbatim Transcript	April 25, 2002
T2	NRC-Convened Roundtable	Verbatim Transcript	April 30, 2002
L1		David Nicolas Schaaf	May 1, 2002
L2	University of Iowa Health Care	James A. Ponto, Chief Nuclear Pharmacist, Department of Radiology and Professor, College of Pharmacy	April 25, 2002
L3	Gamma Corporation	Ronald Frick	April 30, 2002
L4	MCP Hahneman School of Medicine; American Society of Nuclear Cardiologists (ASNC)	William A. Van Decker	May 16, 2002
L5	American College of Nuclear Physicists (ACNP) and Society of Nuclear Medicine (SNM)	William R. Uffelman, General Counsel and Director of Public Affairs	June 3, 2002
L6		Daniel J. Miron, Health Physicist (RSO)	June 3, 2002
L7		Michael J. Smith (RSO)	May 15, 2002
L8	Radiation Safety Officer, VA Medical Center	Peter G. Vernig	June 5, 2002
L9	Louisiana Department of Environmental Quality	Mary Haik	June 5, 2002
L10	Society of Nuclear Medicine (SNM)	Jeffrey Seigel	March 18, 2002
L11	VA Medical Center Denver	Peter G. Vernig, (RSO)	May 1, 2002
L12	Iowa Department of Public Health - Bureau of Radiological Health	George F. Johns, Jr.	May 10, 2002
L13	Professional Council, American Association of Physicists in Medicine (AAPM)	Mike Gillin, Chair	May 17, 2002
L14	American College of Radiology (ACR), American Society for Therapeutic Radiology and Oncology (ASTRO), and American Association of Physicists in Medicine (AAPM)	Harvey L. Neiman, Chairman, ACR Board of Chancellors; Nora A. Janjan, President, ASTRO; Robert Gould, President, AAPM	June 4, 2002
L15	Illinois Department of Nuclear Safety	Joseph G. Klinger, Chief, Division of Radioactive Materials	June 17, 2002
L16	NRC Internal Stakeholder Comments	NRC Staff	Various dates during editing and revision

PART 1: COMMENTS ON QUESTIONS RAISED BY NRC ABOUT NUREG-1556, VOLUME 9

Q1 Level of Detail and Format: Is the format and level of detail in the guidance appropriate for first-time applicants? Should the guidance be more general in describing acceptable methods of meeting 10 CFR Part 35 requirements? If so, please provide suggestions for revisions. Discussion about the pros and cons of providing extensive detail about safety and other procedures would be especially helpful.

Comment:

Participants in the two public workshops stated that to increase the user-friendliness of the document the NRC staff should view the guidance document as a living document that can be amended as experience is gained during the implementation of 10 CFR Part 35. The performance-based philosophy adopted in the new 10 CFR Part 35 and NUREG-1556, Volume 9 will be new to many in the materials field. The NRC should recognize that the guidance is a living entity and ensure that the document consistently reflects changes as circumstances bring them to users' and the NRC's attention. (T1)(T2) NRC should establish a process whereby the guidance document can be maintained as a living document. This process should be flexible to allow for changes that reflect experience with the new regulations. (T1)(T2)(L14)

Response:

The NRC staff will examine avenues, consistent with the availability of personnel and other resources, to keep guidance, including guidance for uses under 10 CFR 35.1000, for the licensing of medical use of byproduct material up-to-date and relevant.

Comment:

A web-based document with hyperlinks to the referenced and relevant sections of 10 CFR Parts 35, 19, 20, and other reference documents would allow the user to access the reference documents easily. The web-based guidance also should include actual forms that can be downloaded and then filed by the end user. While most participants in the public workshop supported the use of web-based guidance, they recognized that all licensees may not have access to the Internet. The NRC should be sensitive to their needs by providing frequent updates to the paper form of the guidance. (T1)(T2)

Response:

NUREG-1556, Volume 9, 10 CFR Part 35, and NRC Form 313A are available on the NRC's web site. NUREG-1556, Volume 9 may also be obtained on CD-rom or in paper form by request. The web version of 10 CFR Part 35 has internal links in order to assist the reader. Other suggestions for improving the guidance will be considered by NRC staff, including consolidation of relevant documents onto one CD-rom with links between relevant documents. The NRC staff is exploring methods to enable submission of applications for licenses in

electronic format via computer and will examine the feasibility of extending this to applications for medical use. See also Section 5.2, "Electronic Applications," in NUREG-1556, Volume 9.

Comment:

Other user-friendly improvements that the NRC should adopt include the following:

- State the minimum requirements for compliance at the beginning of each section,
- Insert sample applications and the licenses resulting from those applications, and
- Insert a key or "crosswalk" to help users understand which portions of the guidance apply only to diagnostic applications. (T1)(T2)

Response:

The revised guidance has been reorganized so that all sections for which a response is required on NRC Forms 313 and 313A are grouped together. The revised guidance explicitly indicates when a response is not required. Further, a new Table 1.1 serves as a guide to applicants in determining which sections of the NUREG-1556, Volume 9 are applicable to various types of applications for use of byproduct materials. Each section also includes a new "applicability box" that indicates which uses are subject to each section. Sample applications and example licenses appear in revised Appendices E and F.

Comment:

"[E]ach appendix should be referenced under each individual topic number to which it could potentially apply for easier cross-referencing, much like the regulatory references which are included in the body of the guidance." (L15)

Response:

The staff reorganized the appendices and added cross-references to facilitate use by applicants.

Comment:

"A document in the format of NUREG-1736, 'Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation' for 10 CFR Part 35 would be more useful to both first-time and past applicants. This format with a statement of requirements makes each applicant aware of the minimum requirements that are required by regulation. Such a document would only be useful if it is continuously kept updated as regulations change." (L6)

Response:

In many cases, the NRC staff chose not to restate regulations in the guidance to avoid duplication. The format used for Volume 9 is consistent with that of other guidance documents in the 1556 series and has been found to be a useful means of presenting guidance. Changes

were made in order to make the document easier to use and to delineate more clearly between regulatory requirements and supplemental information.

Comment:

"The following figures included in the document are useless in helping the applicant apply for a license: Figures 8.1, 8.2, 8.3, 8.7, 8.9, 8.13, 8.14, 8.15, 8.16, 8.17. These are types of figures that might be useful in a brochure explaining medical use regulations to a member of the public, but are of no benefit to a first-time or past license applicant." (L6)

Response:

The NRC staff removed all of the figures from the guidance except Figures 8.8 and 8.12, which are now Figures 8.1 and 8.2, respectively.

Comment:

"The format, as written, is a license application document and the title may be misleading. Although all other volumes of NUREG-1556 have been published as final and the NRC staff will most likely not change this title, the title should be 'Consolidated Guidance About Material Licenses - License Application Guidance About Medical Use Licenses' since the document is actually guidance on filling out a NRC Form 313." (L6)

Response:

NUREG-1556, Volume 9 contains information that goes beyond that needed to apply for a license for use of byproduct materials under 10 CFR Part 35; therefore, the original title was retained.

Comment:

"The format and detail are not appropriate for first-time applicants and the guidance should be more general in describing acceptable methods for meeting 10 CFR 35 requirements." (L6)

"For first-time applicants preparing an application, the level of information provided in the NUREG is limited. We believe the Commission is missing an opportunity to provide its 'clients' with information that could be useful when preparing and implementing a radiation safety program. Although existing licensees would most likely find cause to critique the guidance extensively on details of implementation, the Commission should be reminded that this guidance is used primarily by first-time applicants and secondarily as a reference for existing licensees. The individual appendices should be tailored towards meeting regulatory and safety needs, and the applicant encouraged to adopt these or develop alternate procedures that meet their specific needs." (L15)

The guidance is important for ensuring that license applicants provide all of the information that must be reviewed before a licensing decision can be made. Therefore, the guidance should

be thorough and detailed, especially for more naive users or users who do not have assistance from health physicists or consultants. (T2)

It is difficult for the guidance to be complete and specific, which is desirable, without being prescriptive. (T2)

Response:

When revising the guidance, the NRC staff sought to strike a balance between the differing points of view expressed above. The overall objective was to consolidate existing guidance on licensing of the medical use of byproduct materials to provide sufficient detail that enables all types of users to submit license applications containing the information necessary to support a licensing decision. The staff sought to ensure that the guidance is complete without being prescriptive by differentiating between information that must be provided by applicants and information which is useful, but the submission of which is not required.

Stakeholders suggested that inclusion of a sample license application would be useful. The NRC staff selected an example that addressed the most frequent types of applications received by the NRC and that commenters stated would be most useful, that is, an example application for uses approved under 10 CFR 35.100 and 35.200. In addition, the revised guidance document more clearly indicates that applicants either may use the procedures suggested in the guidance, which represent *one method* of achieving compliance, or may adopt alternative procedures.

Comment:

"The bulk of the model procedures that are indeed procedural are helpful as written (i.e., App I [Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program], J [Model Procedures for Dose Calibrator Calibration], N [Emergency Procedures], O [Model Procedures for Ordering and Receiving Packages], P [Model Procedure for Safely Opening Packages Containing Radioactive Material], Q [Model Leak Test Program], T [Model Procedures for Safe Use of Licensed Material], as well as portions of R [Model Procedure for Area Surveys] and U [Release of Patients or Human Research Subjects Administered Radioactive Materials]). Those procedures that are conceptual in nature are of limited value (i.e., K [Suggested Medical Licensee Audit], L [Model Procedures for an Occupational Dose Program], M [Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits], and S [Procedures for Developing, Maintaining, and Implementing Written Directives]) and are more useful to existing licensees rather than applicants due to the nature of the information. These sections need to be more prescriptive for new applicants who may not be familiar with assessing doses to the public, conducting internal audits, etc." (L15)

Response:

The NRC staff recognizes that the needs of first-time applicants and those responsible for small programs are different from those of more experienced applicants or those responsible for larger programs. Changes, including guidelines identifying the sections of the guidance that should be reviewed by applicants for different types of uses of byproduct material, were adopted

to make the document more useful to first-time applicants, e.g., by adding "applicability boxes" for each section to indicate when applicants for different types of use should attend to the material covered therein. However, the NRC staff concluded that making NUREG-1556, Volume 9 more prescriptive, as requested by some commenters, would be inappropriate and contrary to the NRC's emphasis on risk-informed and performance-based guidance. Therefore, the NRC staff revised the guidance to remove unnecessary prescriptiveness while retaining information that may be useful to first-time applicants.

Comment:

"The NRC states that this document 'provides guidance on NRC criteria for evaluating a medical use license application' (See Page 1-1). The NRC staff is using this document for license review 'while not suggesting that details in the guidance are prescriptive' (See Page iv). By using this guidance as criteria for license review the NRC is making this guidance prescriptive. In the past the NRC required licensees who submit or implement procedures that are less restrictive than the guidance to justify its implementation even if it is compliant with the applicable rules and regulations. . . . Hopefully this will not continue in the future.

"10 CFR 30.32(b) allows the Commission to request the additional information that is requested in this guidance document. This provision is being overused and this overuse is putting additional regulatory burdens on licensees that are not reflected in the regulatory analysis of the revised medical use regulations. Use of this provision should be limited to applicants and licenses that have shown poor past history of compliance with the applicable rules.

"In Chairman Meserve's letter to Congress dated February 11, 2002, he stated the following regarding the concerns of licensees:

> 'We believe that many of these concerns are more reflective of licensing and inspection practices under the current rule -- practices we seek to modify in connection with the revised rule. Based on this feedback, the NRC agrees that the licensing and inspection guidance should be improved and that the license reviewers and inspectors will need to be trained to implement the revised rule effectively and efficiently. We have committed to undertake this reform.'

"Unfortunately, this guidance has not significantly changed from the first draft dated August 1998 and this promised reform is not reflected in the March 2002 draft. The publication of the March 2002 draft shows that the current licensing and inspection practices will be hard to change in current NRC staff." (L6)

Response:

The NRC staff indicated in the guidance that it is not intended to establish "*de facto*" regulation by stating the following:

> "NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. This approach is intended to be less prescriptive and to allow for the implementation by licensees that may be specific to their

needs while meeting the regulatory requirements. By supplying examples, NRC seeks to provide information to meet the needs of applicants for licensure, without being prescriptive. Guidance in this document represents one means acceptable to NRC staff of complying with NRC regulations and is not intended to be the only means of satisfying requirements for a license" (NUREG-1556, Volume 9, page iii).

In connection with this effort, many of the citations to the regulations have been changed, including the deletion, in most cases, of the reference to 10 CFR 30.32(b).

The March 2002 draft of the guidance was substantially revised to clearly delineate between information that must be supplied as part of a license application and program-related guidance, i.e., information that need *not* be supplied.

Comment:

"The guidance for 10 CFR 35.1000 uses should be published in this guidance or in a similar guidance." (L6)

Response:

The NRC web site contains guidance for licensing of certain sealed sources or devices under 10 CFR 35.1000. This guidance currently pertains to:

- Y-90 microspheres (e.g., MDS Nordion Y-90 TheraSphere®),
- liquid brachytherapy (e.g., Proxima Therapeutics' GliaSite® Radiation Therapy System), and
- intravascular brachytherapy (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

The guidance will be updated when necessary to address comments from stakeholders. New entries will be added as additional uses are identified for licensing under 10 CFR 35.1000. Comments in reference to Regulatory Issue Summary (RIS) 2002-19, "New Modalities to Be Regulated under 10 CFR 35.1000" (October 21, 2002), should be sent to: U.S. Nuclear Regulatory Commission, Attn: Materials Safety and Inspection Branch, Mail Stop: T-8 F5, Washington, D.C. 20555. Guidance for licensing under 10 CFR 35.1000 will be revised in future revisions of NUREG-1556, Volume 9.

Comment:

"[The following procedures] seem to be procedures that the NRC staff is asking for specific commitments. In signing a license application the licensee is committing to developing, implementing and maintaining these and all other procedures related to the regulations that are applicable to the license. Please comment on why these commitments are needed but not separate commitments for all procedures." The commenter listed the following topics: Area surveys; Procedures for Administrations Requiring A Written Directive; Safe Use of Unsealed Licensed Material; Spill Procedures; Emergency Response for Sealed Sources or Devices

Containing Sealed Sources; Patient or Human Research Subject Release; and Waste Management. (L6)

Response:

The NRC staff revised the guidance to clearly identify when written procedures must be submitted as part of a license application, as required by 10 CFR Part 35. In several instances, Part 35 requires applicants to commit to develop and maintain procedures. In these instances, the suggested "Response from Applicant" in NUREG-1556, Volume 9 includes this statement. When the regulatory requirements in Part 35 are very explicit about the contents of the procedures that the licensee must develop, maintain, and implement (e.g., procedures for administrations requiring a written directive), a request for the commitment was not included because it is unnecessary to re-state regulations because licensees must follow the regulations.

Comment:

The guidance should be consistent and use either dose-based or dose-rate based units as was done with Part 35. (T1)

Response:

To the extent possible, consistent units have been used throughout the document. The NRC staff added a discussion on the units used in Section 1.1 of the guidance.

Comment:

One commenter in the workshop argued that the guidance is not consistent in the safety-related levels that it cites. When you're doing a leak test, there's a .005 micro-curie limit or level. Point 005 micro-curie is 11,100 dpm, a little different than a 200 dpm level for your wipe test, which corresponds, by the way, to only 90 picocuries. Also when you're wipe-testing an incoming package, according to DOT regulations, that's only 22 dpm per centimeter square, which would be 2200 dpm per hundred centimeter square. Another thing in here is major or minor spills are classified based on activity, not potential dose or dose rate. For example, I-131, the difference between a major and minor spill is one millicurie. Less than a millicurie, which happens to be billions of disintegrations per minute is considered a minor spill. Yet if 200 dpm are found, a factor of millions less, that sets in motion a number of things. And lastly, this decay in storage, where you're allowed to dispose of material that's indistinguishable from background. The rule only says indistinguishable from background. In the guidance, it specifies that background should be low, less than .05 millirems per hour at surface, which corresponds to 44,000 dpm, again, not consistent, because you can dispose of 44,000 dpm, according to the guidance, but have to worry about wiping 200 dpm if it's on the floor. (T2)

Response:

Several commenters raised the same or similar issues in comments regarding Appendix R. Refer to the discussion of comments on Appendix R in Part 2 of this document as they relate to control of contamination, including the trigger level of 200 dpm.

Several of the issues raised in these comments go beyond the scope of guidance in NUREG-1556, Volume 9. Apparent inconsistencies derive from differing bases for the limits/levels discussed by the commenters; these levels relate to their intended purposes. For example, contamination limits for shipping of radioactive materials are set by the U.S. Department of Transportation and are not used by the NRC as guidance on control of contamination in the workplace or for release of contaminated areas or equipment for unrestricted use. Likewise, rules and guidance for management of radioactive waste and leak testing of sources are not appropriate for use in the context of contamination control.

The classification of spills as "major" or "minor" is one that is commonly used. However, as noted in the guidance, the procedures are models and licensees may adopt other procedures, consistent with requirements of 10 CFR 20.1101, for classification of spills.

Comment:

The guidance should address all regulations that apply to the application of radioactive materials for medical use. For example, the NUREG discusses transportation and lists all the requirements of Part 49. It therefore seemed appropriate to the commenter that it would also have some type of guidance for users of xenon on how they can comply with Part 20. If, in fact, this guidance is to be the sole place where somebody has to go for guidance, there are several things missing, and it ties back to what was taken out of Part 35 in many cases and now left under Part 20 auspices. (T2)

Response:

The NRC staff feels that it would be impractical to provide guidance on all regulations that might apply to medical use of byproduct material; to do so would be unnecessarily duplicative of other guidance. However, guidance documents on requirements in other Parts of 10 CFR (e.g., Parts 19, 20, and 30) are available and referenced at appropriate points in NUREG-1556, Volume 9. A summary of DOT regulations that are most pertinent to medical licensees is also provided in Appendix Z.

Comment:

"[A]dditional guidance should be provided on security in light of recent events. The medical community is especially sensitive to this, because large numbers of patients, visitors, interns, volunteers, and students are often in relative close proximity to radioactive materials. In contrast, industrial facilities can restrict the public to remain outside of their fence line and are familiar with the backgrounds of most employees. Use of Safeguards Advisory dated October 16, 2001, would be a good place to start with this guidance." (L15)

Response

The NRC is reviewing security issues in light of recent events. However, detailed guidance on security is under development and is not being included in NUREG-1556, Volume 9 at this time.

Q2 Model Procedures: Are the model procedures helpful as written? Should they be retained or rewritten? If so, please provide suggestions for revisions.

Comment:

"Many times throughout Appendix Z [Public Comments and NRC Responses on Draft] of NUREG-1556, Volume 9 the 'NRC Staff Response' included the following, or similar, statements: 'Licensees may either adopt the model procedures or develop their own procedures to meet the requirements, as applicable.' [See NUREG-1556, Volume 9, page Z-41.] The above statement shows that either this document or the final rule published on April 24, 2002, does not take 'a risk-informed, performance-based approach to medical use licensing.' If this document and the final rule were each risk-informed and performance-based they would each contain the same requirements. The NRC staff should not be using model procedures to make license conditions that are more restrictive then the regulations. This is exactly what the NRC is doing by publishing these model procedures, especially for smaller or new licensees that will be more likely to just commit to the model procedures, [a]lthough the NRC staff does not acknowledge this. This view is also repeated several times by the comments presented in Appendix Z. The cost savings of implementation of these new regulations will be less than stated by NRC staff if these model procedures are published as written." (L6)

"These model procedures are not useful as written and should either be removed from the document or rewritten to show minimum compliance levels required by the regulations." (L6)

Response:

The guidance explicitly states that the model procedures are provided for informational purposes. The model procedures simply illustrate one method of complying with the requirements. The NRC staff revised the model procedures to clarify that they are not minimum requirements, nor are they intended to be, except where the model procedures include specific regulatory requirements. (For example, applicants need not adopt the model procedure for waste disposal in Appendix W of NUREG-1556, Volume 9, but the procedure that they do use must meet the requirements of 10 CFR 20.1101 and 35.92).

Comment:

Participants' concerns regarding inspection relate to those voiced about model procedures, because inspectors often review a licensee based on their adherence to the model procedures. The participants strongly support the "paradigm shift" to a risk-informed, performance-based approach to regulations, especially with regard to inspection. They advocate the inspectors examining whether problems exist within a facility rather than whether the facility adheres to prescriptive requirements in the model procedures. The licensee should be inspected on whether the procedures meet the regulations. (T1)(T2)

The participants cited unnecessarily prescriptive provisions in the guidance, and said the main source of these prescriptive provisions is the model procedures. NRC should format the guidance so that model procedures do not become regulation by default where license reviewers and inspectors view the model procedures as minimum standards or minimum performance

requirements. The temptation to treat model procedures as de facto regulations could be alleviated by indicating more than one model procedure, and by not referring to the model procedures as "preferred." Participants cited examples of where the license reviewer inserts license conditions that have no basis in either the guidance or the rule. (T1) (T2)

Response:

As stated above, the guidance was revised to emphasize that the model procedures are provided for informational purposes. They simply illustrate one method for complying with the rules. The NRC staff inserted explicit language to this effect at the beginning of each model procedure. The NRC staff is revising inspection manuals to reflect the risk-informed, performance-based approach.

Comment:

One way of presenting alternatives might be a logic tree with multiple options for selecting a procedure. Another suggestion involves adding a disclaimer in bold type at the beginning of each model procedure that states, in bold, "This is a model; it is not minimum requirements." The NRC and stakeholders should coordinate in reviewing the practice guidelines used by each of the professional organizations and the NRC should use those guidelines to develop a series of options for model procedures. (T1)

NRC should also recognize that some users find the model procedures useful as written, and should try to balance the needs of those users to have prescriptive "recipes" for compliance against those who need more general guidelines. (T1)(T2)

Response:

In the interest of balancing the needs of various applicants for specific guidance versus general guidance, the NRC staff chose not to insert a logic tree with multiple options. Instead, the NRC staff revised the model procedures and inserted explicit language stating that the model procedures are provided for informational purposes.

Comment:

When incorporating or referencing professional standards, the NRC should be sensitive to the fact that those standards often refer back to the guidance, thereby creating either a loop that does not provide useful information to the licensee or inconsistencies between the NRC standards and the professional standards. (T1)(T2)

Response:

The NRC staff recognizes that its regulatory requirements will be reflected in professional standards. The NRC revises guidance to reflect new experiences, needs, and regulatory approaches, and it anticipates that national professional standards also will be updated as regulations and guidance change. In order to eliminate implied standards, certain sections of the guidance were deleted. For example, Sections 8.5, 8.8, 8.16, 8.17, 8.19, 8.21, 8.30, 8.33, 8.34,

and 8.35 were revised in NUREG-1556, Volume 9 to remove material that was considered unnecessarily prescriptive or that was not clearly supported by regulatory requirements in Part 35. Similar revisions were made to several appendices to NUREG-1556, Volume 9. In particular, the appendix on Model Procedures for Dose Calibrator Calibration was deleted.

Comment:

Many of the model procedures may be more suitable for therapeutic than diagnostic users. (T2)

Response:

The revised guidance is a comprehensive document covering all types of uses. The NRC staff restructured the guidance to enable users to identify sections that are applicable to particular types of uses.

Q3 Licensing Guidance Specific to Diagnostic Nuclear Medicine: The staff is considering development of a summary of the licensing requirements for diagnostic medical use of byproduct materials. Is such a document desirable? What should be provided in the guidance? How long should it be?

Comment:

One stakeholder suggested that having separate guidance documents for diagnostic and therapeutic applications requires users to be aware of updates to two documents. (L11)

Participants in the public workshops differed in opinion about whether the guidance should be divided into two separate documents, one for diagnostic applications and one for therapeutic applications. Participants discussed the inconvenience of following two separate guidance documents for those who use both applications, and the difficulty in determining which provisions apply to which application by those using only one application. Suggested solutions included inserting a "crosswalk" that identifies which provisions apply to diagnostic applications only as well as dividing the guidance into two documents. (T1)(T2)

A draft outline of a book focused solely on diagnostic applications under the new Part 35 and NUREG-1556 was also proposed. (L5)

Participants in the public workshop commented that although there is a benefit to presenting a single source for medical uses, it would appear that there might be an advantage to publishing guidance that is "modality specific." For example, licensees using radiopharmaceuticals for only diagnostic purposes might find the draft guide cumbersome. Further, mobile medical services, which are also included, would appear to have a limited interest in Volume 9 as a whole. (T1)(T2)

"[T]his document is licensing guidance for all medical uses (except 10 CFR 35.1000)." Therefore, there is no need for another document. (L6)

"We encourage the Commission to develop guidance specific for diagnostic nuclear medicine licensees. These types of licensees, in general, have limited expertise in developing radiation safety programs that can be readily implemented and maintain compliance with existing regulations. There would appear to be a great need for guidance in this area, particularly as it would apply to small clinics using radioactive material where expertise from a radiation oncology department would not be available. Some of these licensees are unaware of the basic license requirements such as maintaining an RSO/Authorized user on site. We have had several cases where these individuals have left the facility indefinitely while nuclear medicine procedures continue without their oversight. The document would not necessarily need to be long, given the revisions to the regulations, nor would it need to outline a plethora of procedures for submittal and review. However, the guidance should provide a general outline of the necessary elements that would need to be addressed in a radiation safety program and some procedures which could be used to meet that goal. Some of the referenced procedural appendices above would be appropriate. However, even some of those such as instrument calibration and leak testing of sources would probably not be necessary as those tasks are usually deferred to a service licensee." (L15)

Response:

The NRC staff agrees that a single guidance document addressing all types of medical uses of byproduct material is necessary to provide a comprehensive source of information for all applicants for licenses under 10 CFR Part 35. NUREG-1556, Volume 9 was developed as part of a series of guidance documents that consolidates guidance for materials licenses. NUREG-1556, Volume 9 was extensively revised to make it easier for different categories of applicants to find sections relevant to their applications.

The NRC staff recognizes the need for a shorter guidance document for diagnostic applications of byproduct material. The American College of Nuclear Physicians and the Society of Nuclear Medicine (ACNP / SNM) published a Guide for Diagnostic Nuclear Medicine in October 2002. The NRC is making this document available in print, on its web site, and on CD-rom. The availability of the SNM's Guide from the NRC was announced in NRC Regulatory Issue Summary 2002-23, "Availability of Guide for Diagnostic Nuclear Medicine" (November 27, 2002).

Q4 Other Guidance: Are there additional voluntary industry consensus standards or other publically available documents that should be considered for reference in NUREG-1556, Volume 9?

Comment:

Manufacturers (e.g., manufacturers of dose calibrators) will need to revisit their recommendations because many of them have simply adopted the NRC's requirements for calibrating. (T2)

Response:

The NRC staff recognizes that manufacturers may need to reassess their recommendations from time to time. 10 CFR 35.60 now allows licensees to calibrate instrumentation in accordance with nationally recognized standards or the manufacturer's instructions. The Appendix entitled "Model Procedures for Dose Calibrator Calibration" was deleted from the guidance to avoid the appearance of setting a national standard and to leave manufacturers free to adopt appropriate recommendations for calibrations that are not tied to NRC guidance.

Comment:

Some American National Standards Institute (ANSI) or American Association of Physicists in Medicine (AAPM) standards contain language, such as "should" or "shall," that may be misunderstood by unsophisticated users who as a consequence may improperly implement the standards. (T2).

Response:

The comment raises questions that are beyond the scope of guidance in NUREG-1556, Volume 9. It is the responsibility of the respective organizations to determine when to use the two terms.

Comment:

"Several NRC Staff Responses refer to 'Table I of Federal Register Volume 63, Number 222, Page 64134' and the fact that 'This table does not include radionuclides traditionally used in medicine.' (See NUREG-1559, Volume 9, page Z-13). The NRC staff should develop a similar table for radionuclides currently used in medicine so licensees can develop their own procedures that are risk-informed and performance-based using good NRC guidance. Since this table was developed using the D and D, Version 1, computer code that is accepted by NRC staff for decommissioning, this development should be easily completed and included in this guidance. This would be very useful guidance from the NRC." (L6)

Response:

The cited table provides screening levels for certain radionuclides for use in decommissioning. It is beyond the scope of this revised guidance to develop additional guidance on decommissioning.

Comment:

"With regards to referencing other guidance or consensus standards we suggest that you include a detailed reference, if not a summary, of the NRC guidance related to inspection and enforcement of the various aspects of a radiation safety program in a medical environment. Although not an industry standard, that guidance is somewhat consensus-based and more importantly a major part of the Commission's overall redesign of the regulation of medical use of radioactive material. Compliance issues should be discussed for the benefit of the applicant in at least some degree so they know what to expect when developing their procedures and before committing to them in the application." (L15)

Response:

The NRC staff developed new and revised inspection procedures (IPs) to reflect the risk-informed, performance-based approach taken in 10 CFR Part 35. The NRC staff revised the IPs to take into account public comments received during a public meeting conducted on June 6, 2002 and received in writing during a 60-day public comment which ended on June 21, 2002. These public involvement activities afforded stakeholders the opportunity to participate in shaping inspection and enforcement procedures. Transcripts of the public meeting are available as described in the availability statement for NUREG-1556, Volume 9. IPs are referenced in the Foreword and Section 3 of NUREG-1556, Volume 9 and on the NRC's web site. The IPs are relatively brief and readily accessible at <<www.nrc.gov/reading-rm/doc-collections/insp-manual/>>. The NRC staff believes that summarizing them in the licensing guidance would be redundant and lengthen it unnecessarily. Issues related to enforcement are beyond the scope of guidance in NUREG-1556, Volume 9.

PART 2: COMMENTS ON SPECIFIC PARTS OF NUREG-1556, VOLUME 9

This Part is organized according to the Table of Contents of NUREG-1556, Volume 9. Each entry in the Table of Contents is included. When NRC received no comments on a particular portion of the guidance, that fact is noted. Some sections and appendices were rearranged and renumbered or deleted during editing after publication of the March 2002 draft of NUREG-1556, Volume 9. Therefore, references to section numbers in the March 2002 draft of NUREG-1556, Volume 9 are followed by a cross-reference, appearing in square brackets, to the corresponding section in the final NUREG-1556, Volume 9 published in October 2002.

Section 1 [Section 1.1] Purpose of Report

Comment:

Page 1-3 should be corrected. "One roentgen does not equal 1 rad. They are approximately equal." (L3)

Response:

NRC agrees with the comment. The document has been revised to indicate that 1 roentgen is approximately equal to 1 rad.

Section 1.1 [Section 1.2] Licenses

No comments.

Section 1.1.1 [Section 1.2.4] General in Vitro License

No comments.

Section 1.1.2 [Section 1.2.1] Specific License of Limited Scope

No comments.

Section 1.1.3 [Section 1.2.2] Specific License of Broad Scope

No comments.

Section 1.2 [Section 1.3.1] The 'As Low as Is Reasonably Achievable (ALARA)' Concept

No comments.

Section 1.3 [Section 1.3.2] Written Directive (WD) Procedures

No comments.

Section 1.4 [Section 1.2.3] Research Involving Human Subjects

No comments.

Section 2 [Section 2] Agreement States

No comments.

Section 3 [Section 3] Management Responsibility

Comment:

"Section 3, page 3-1, bullet item 5, should include designation of financial resources as part of management's responsibilities. Frequently, radiation safety programs fail because they are not being afforded appropriate financial resources." (L15)

Response:

The NRC staff agrees that management responsibilities include provision of adequate resources. The guidance was revised to specify that an institution's management is responsible for "provision of adequate *financial and other* resources" (emphasis added).

Section 4 [Section 4] Applicable Regulations

No comments.

Section 5 [Section 5] How to File

No comments.

Section 5.1 [Section 5.1] Paper Application

Comment:

Workshop participants suggested amending or eliminating the text box on page 5-1 that says "Using the suggested wording of responses in this report will expedite NRC's review." (T2) One commenter stated that NRC should stress that use of the model procedures in NUREG-1556, Volume 9 is only one suggested method for demonstrating compliance with the revised Part 35 and recommended that the guidance document should say the following: "These are model procedures that the NRC believes will, with high probability, achieve compliance with regulatory targets if properly implemented. They are not minimum standards and should not be used as a benchmark or standard for judging the adequacy of a licensee's procedure." The commenter suggested that this sentence should replace the second text box on page 5-1 and it should appear as the introductory text box of each model procedure. (L14)

Response:

The NRC staff agrees that the sentence in the text box on page 5-1 should be deleted. That sentence, and similar sentences on pages 8-2 and 9-2, could suggest to applicants that the model procedures are preferred by the NRC. The sentence was removed from pages 5-1, 8-2, and 9-2. Although the NRC staff does not agree with the specific language suggested by the commenter, the staff revised the Abstract, Foreword, and Overview sections of the guidance to explain that the information provided in the document, including the model procedures, is not intended to be the only means of satisfying the requirements for a license. For example, the following statement appears in the Overview:

> "Guidance and model procedures provided in this NUREG that are not required to be submitted are for illustrative purposes to guide licensees in developing their programs. Use of the word 'should' implies 'may' and is not intended to mean 'must' or 'shall;' the procedures provided in this guidance are intended to serve only as examples."

Section 5.2 [Section 5.2] Electronic Application

No comments.

Section 6 [Section 6] Where to File

No comments.

Section 7 [Section 7] License Fees

Comment:

Workshop participants stated that because the NRC is obligated to obtain 100 percent fee recovery and because the developmental work for rules and guidance is included in the fee base, fees to NRC materials licensees are increased. Participants suggested that the NRC and stakeholders should consider approaching Congress as a collective community to argue that the rule development should not be part of the fee base. (T1)

Response:

The issue raised in this comment relates to matters outside the scope of the guidance. The position of the participants was noted by the NRC staff.

Section 8 [Section 8] Contents of an Application

Comment:

Commenters and workshop participants stated that, in general, Section 8 is too prescriptive. Information is requested that is not required by 10 CFR §§ 35.12 and 35.15. (L14) (T1) (T2)

Response:

The staff notes that in addition to 10 CFR 35.12 and 10 CFR 35.15, other sections of Part 35, as well as Parts 19, 20, 30, 32, and 33, contain requirements regarding the submission of information in applications for a license. However, the NRC staff carefully reviewed Section 8 and considered whether the information to be provided in each suggested "Response from Applicant" was supported by an existing regulatory requirement. The staff removed prescriptive statements from Section 8 that are not supported by regulatory requirements.

Section 8.1 [Section 8.1] Item 1: License Action Type

No comments.

Section 8.2 [Section 8.2] Item 2: Applicant's Name and Mailing Address

Comment:

"In Section 8.2, the applicant is to be a legal entity but may be an individual under specific circumstances. The guidance should clarify how this status is to be demonstrated or how the Commission will verify the legal status of an applicant." (L15)

Response:

NRC Form 313, Item 13, includes a statement indicating that an applicant signing the form must have appropriate authorization to make binding commitments on behalf of an institution, or to sign on behalf of himself or herself if acting in a private capacity. In either case, as noted in the guidance (See note in Section 8.30, "Item 13: Certification") and on the form, it is a criminal offense to make a willful false statement or representation on the application. The NRC staff therefore believes it is not necessary to rely on a separate verification procedure.

Section 8.3 [Section 8.3] Item 3: Address(es) Where Licensed Material Will Be Used or Possessed

No comments.

Section 8.4 [Section 8.4] Item 4: Person to Be Contacted about this Application

Comment:

NRC should emphasize the importance of the actual licensee understanding what the requirements are and to what they are committed, rather than allowing the licensees to completely depend on a contractor who completes and files the application (T1).

Response:

The NRC requires an applicant to sign a certification on NRC Form 313 that contains the following statement:

"The applicant understands that all statements and representations made in this application are binding upon the applicant."

"The applicant and any official executing this certification on behalf of the applicant ... certify that this applicant is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30, 32, 34, 35, 36, 39, and 40, and that all information contained herein is true and correct to the best of their knowledge and belief."

"Warning. 18 U.S.C. Section 1001 Act of June 25, 1948, 82 Stat. 749 makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction."

Applicants, therefore, are put on notice concerning the obligations they are assuming and are required to become familiar with the regulatory requirements.

Section 8.5 [Section 8.5] Item 5: Radioactive Material

Comment:

"In Section 8.5, NRC should include a reference to inclusion of blood irradiators and a reference to NUREG-1556, Volume 5, for additional information, as many medical licensees process blood for their use." (L15)

Response:

The NRC staff has added material addressing blood irradiators and a reference to NUREG-1556, Volume 5, "Program-Specific Guidance About Self-Shielded Irradiator Licensees."

Comment:

One commenter stated that page 8-7 should not include a requirement for the manufacturer's name and model number for sources and survey equipment. According to this commenter, it is very restrictive and unnecessarily burdensome to require this information on sources. The commenter concluded, based on the guidance, that if the vendor on the license could not deliver the product, the licensee would need a license amendment to purchase the isotope from another vendor. "For some applications (e.g., permanent 1-125 prostate seeds) there are approximately 12 different products that are equivalent from the clinical and radiation safety perspectives. The guidance should specify that the acceptable entry on the application be: "any source listed in the Sealed Source and Device Registry (SSDR) that meets the source strength and use requested." Suggest inserting in the column titled: "Chemical/physical form," "sealed source as specified in the sealed source device registry." Licensees should not have to submit license amendments when vendors are changed." (L14) Another commenter stated that the chemica1/physical form of sealed sources should be able to be listed as "Sealed sources as approved in the Sealed Source and Device Registry." The Sealed Source and Device Registry includes the manufacturer and model number so this statement would comply with 30.32(g)(1). (L6) Participants in the workshops on NUREG-1556, Volume 9 made similar comments. One participant noted that page 8-9 of the Regulatory Guide asks for identification of the sealed source, manufacturer and

name, and model number, which is not called for in the regulation. If a licensee changes manufacturer or vendors the licensee could be required to submit a license amendment to obtain the source. 10 CFR Part 35.200 requires devices to be in the SSDR but doesn't say anything about having to identify the particular source. The participant suggested that one alternative would be to submit the certificate or a copy of the certificate to the NRC. Another would be simply to indicate that the source is listed in the SSDR. (T2)

Response:

10 CFR 30.32(g) provides that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either (1) identify the source or device by manufacturer and model number as registered with the Commission under §32.210 or with an Agreement State, or (2) contain the information identified in § 32.210 (which is the information that must be submitted for review of a sealed source or a device containing a sealed source. However, most applicants would not be in a position to provide all of the safety information for a source or device required under 10 CFR 32.210(c), and therefore they would have to comply with 10 CFR 30.32(g)(1). A reference to the SSDR is not adequate to meet this requirement. Applicants should include manufacturer and model numbers for devices that they anticipate using, including alternatives that would be used if the licensee changed manufacturer or vendor, so that the licensee will not be required to amend the license every time the model or manufacturer changes.

Comment

A commenter stated that "[t]he NRC currently allows licensees to request 'As needed' amounts of material for uses now covered in 35.300 and 35.400. The NRC should continue this practice of licensing and not require total amount for these uses as stated in page 8-7." The same commenter noted that Table 8.1 , entitled "Sample Format for Byproduct Material" lists "maximum amount." The commenter asked if these are the maximum amounts that the NRC will allow on a license or are they just for demonstration purposes? According to the commenter, the 10 CFR 35.300 and 35.400 maximum amount should be "As needed," stating that this is a currently acceptable amount on a license and should continue to be acceptable. (L6)

Response:

The maximum amount of byproduct material and the commensurate risk posed by the material for uses under §§ 35.300 and 35.400 can be substantially greater than the maximum amounts under §§ 35.100 and 35.200, where "As needed" is an acceptable response. In order to issue a license, the Commission must find that facilities and equipment are adequate to protect health and minimize danger to life and property (10 CFR 35.18(a)(2) and 33.33(a)(2)). In order to enable the NRC to make the necessary determination, the guidance states that applicants should specify the amounts requested under §§ 35.300 and 35.400. Information about quantity is also useful for determining the adequacy of training and experience for certain applicants. The table referenced by the commenter was deleted from the guidance.

Comment:

One commenter noted that according to page 8-8 applicants should make a separate entry if requesting more byproduct material for *in vitro* testing than is allowed under 10 CFR 31.11. The commenter asked whether, if a specific licensee stays below the limits listed in § 31.11, the material is considered general license material or the licensee must follow their specific license (e.g., waste disposal requirements)? (L6)

Response:

Material obtained under a specific license must be used and controlled under the terms of the specific license conditions. Therefore, material for *in vitro* testing included on the specific license is subject to waste disposal requirements.

Section 8.6 [Section 8.7] Item 5: Financial Assurance and Recordkeeping for Decommissioning

No comments.

Section 8.7 [Section 8.6] Item 5: Sealed Sources and Devices

Comment:

One commenter noted that on page 8-12 it appears that 10 CFR § 30.32(g) is inconsistent with a risk-informed, performance-based philosophy of regulation. Requiring a licensee to submit the manufacturer's name and model number for each requested sealed source and device (except for calibration, transmission, and reference sources authorized by 10 CFR § 35.65) is extremely restrictive. This results in a license amendment every time a vendor is changed. (L14) Participants in the workshop on therapeutic uses also noted this issue. (T1)

Response:

The guidance accurately reflects the requirements of 10 CFR 30.32(g). Changes to the regulations are beyond the scope of the guidance, but the NRC recognizes that licensees may need to seek alternate sources of supply for certain types of sealed sources. Therefore, the guidance was revised to indicate that applicants could anticipate their needs and request authorization for sealed sources that might be acquired from alternate vendors, thereby avoiding the need to apply for a license amendment.

Comment:

Commenters recommended that the NRC include a reference in Section 8.7 to inclusion of blood irradiators and a reference to NUREG-1556, Volume 5, for additional information, as many medical licensees process blood for their use. (L15)

Response:

The NRC staff addressed this comment in response to a similar comment concerning Section 8.5. A reference to blood irradiators and to NUREG-1556, Volume 5 was added to the guidance.

Comment:

A commenter suggested deleting the paragraph on page 8-13 referring to National Institute of Standards and Technology (NIST) traceability. (L14)

Response:

10 CFR 35.432(a)(1) of the rule requires a licensee, before the first medical use of a brachytherapy source on or after October 24, 2002, to have determined the source output or activity using a dosimetry system that meets the requirements of 35.630(a). 10 CFR 35.630(a)(1) requires a licensee to have a calibrated dosimetry system that has been calibrated using a system or source traceable to NIST. Therefore, the staff does not agree that deleting the paragraph is appropriate.

Comment:

Material in Section 8.7 was briefly discussed in Section 8.5. This information should be revised and included in 8.5. There is no benefit of this information being separated from 8.5. (L6)

Response:

The staff believes that the section contains additional, important guidance specifically concerning sealed sources and is retaining it as a separate section. However, the section has been moved to place it directly after Section 8.5.

Section 8.8 [Section 8.8] Item 6: Purpose(s) for Which Licensed Material Will Be Used

Comment:

One commenter stated that providing the information specified in Table 8.3 ["Radiopharmaceuticals Used in Therapy"] should not be necessary for licensees who need limited authorization for therapeutic uses of radioactive material. "It should be considered adequate to list the nuclide(s), maximum individual unit activity, and total maximum possession (potentially 'As Needed'). Nothing is gained in terms of achieving a performance-based objective by restricting the request to a specific compound or specific treatment. It should be adequate to reference any drug approved by the FDA used within the practice of medicine by an authorized user." (L15)

Workshop participants stated that Table 8.3 is too prescriptive. Some suggested deleting the table, while others suggested modifications, such as removing the last column indicating therapeutic uses. (T1) One commenter also stated that Table 8.3 should be removed. The

commenter argued that the "Agent" and "Form" information is already covered by Item 5 of the application form and the "Route of Administration" information is not required because Item 6 is asking for the purpose of use of the material listed in Item 5. "Route of Administration" has nothing to do with the purpose of use. The commenter stated that the applicable information from Table 8.3 could be incorporated into Table C.2, which provides guidance on responding to Items 5 and 6 on NRC Form 313: "Radioactive Material and Use." (L6)

Response:

The section has been revised to clarify what information should be provided by applicants for different types of medical use of byproduct materials. Although Table 8.3 was initially included as background information, the table was deleted because the NRC staff concluded that it could be misinterpreted to imply that information must be supplied about the form, route of administration, and therapeutic use of unsealed byproduct material under 10 CFR 35.300 as part of an application.

Comment:

Participants in the workshop on therapeutic uses noted that Page 8-16 says, "In manual brachytherapy several types of treatments are available. These may include ..." and then it lists all of the traditional brachytherapy uses. One participant noted that this implies that the licensee is limited to these uses, although that is not the intent of 35.400, which is to allow a specific scope licensee to use any sealed source for any purpose allowed by the sealed source and device registry (SSDR). The guidance should be modified to indicate that these are examples. The NRC also should insert a paragraph explaining 35.400, paragraphs a through b, to clarify the meaning of the regulation and the options available to a specific licensee. (T1)

Response:

The following sentence was added to the "Discussion" in the section of the guidance on "Purpose(s) for Which Licensed Materials Will Be Used" to clarify that the examples given in the guidance are not intended as limitations: "References to particular diagnostic or treatment modalities in this section are intended to be examples and are not intended to imply that licensees are limited to these uses." Details concerning various modalities were also removed. Additional detail about applications for use under 10 CFR 35.400 was not added to the guidance because the staff concluded that applications for such uses are infrequent and licensee-specific, making it difficult to include examples that would be generally useful.

Comment:

Page 8-18: third paragraph down: Appears to be a typo: "The radiation[?] can be ion implanted …" (L3)

Response:

This phrase was removed as part of the revision to the discussion of 35.1000.

Comment:

Page 8-15: "insert following the first sentence 'However, if applying for all material authorized under 10 CFR § 35.300 the information shown in table 8.3 is not required. Table 8.3 provides examples of data entry if you are applying for a license under 10 CFR §§ 35.392 or 35.394 only and indicates iodine use for specific therapy treatment.'" (L14)

Response:

Table 8.3 was removed from the guidance, thereby removing the need for clarification.

Comment:

Participants in the workshop on guidance for therapeutic applications of byproduct materials asserted that the discussion on § 35.1000 on page 8-18 reflects the 1998 time frame, and that the NRC should examine the reasoning in the Supplementary Information and the responses to comments to determine whether the philosophy for adding § 35.1000 to the regulation could be reflected in the guidance document. This would help applicants determine how § 35.1000 applies to a new modality or a new application and use. (T1)

The guidance should talk about when § 35.1000 is truly an appropriate mechanism to use, versus just saying if it doesn't fall in D through H in the rule.(T2)

"The NRC needs to redraft the guidance for 10 CFR § 35.1000. This guidance should discuss the process for triggering a licensing action under this provision of the rule. . . . This guidance should also discuss the process for determining when a licensing action under 10 CFR § 35.1000 should be transferred to a new part of the regulation. The intent of 10 CFR § 35.1000 should be spelled out clearly, which the regulated community understands to be to facilitate the timely licensing of a new technology or a use of radioactive material that does not fall under existing parts of the regulation and to provide an arena for testing proposed regulatory and licensing requirements, but not to serve as a permanent substitute for regulation." (L14)

Response:

This section of the guidance document was revised to indicate clearly that 10 CFR 35.1000 will only be used to license those uses that are not covered by10 CFR Part 35, Subparts D, E, F, G, and H. The NRC staff continues to believe that the reasoning in the Supplementary Information for the final rule remains valid. The Supplementary Information explains that Subpart K was added to Part 35 ". . . so that there would be codified regulatory requirements and a more clearly defined process to obtain a license, or a license amendment, for a new medical use of byproduct material or radiation from byproduct material . . ." (67 FR 20321). The NRC staff believes that the guidance is consistent with this philosophy. Further, the Supplementary Information explains that the NRC intends ". . . to evaluate each technology on a case-by-case basis and to work with the ACMUI [Advisory Committee on the Medical Use of Isotopes], the medical community, the public, and the developers of the new technology, as appropriate, to determine the specific risks associated with the technology and any additional regulatory requirements for the medical use of the technology" (67 FR 20321). Because of the nature of

this inquiry, the information to be supplied will vary from case to case and cannot be predicted in advance nor specified in other than general terms in the guidance.

The NRC will develop separate guidance as new applications are identified and reviewed. For example, see the response to comments on guidance for 10 CFR 35.1000 under Q1 on page 1-6.

Comment:

Participants in both of the workshops on NUREG-1556, Volume 9 expressed concern about how certain monoclonal antibodies used in therapy would be licensed under 10 CFR Part 35. The commenters suggested that one of these antibodies, Zevalin, should be licensed under 10 CFR 35.300 rather than 35.1000. They pointed out that the antibody is licensed by the FDA and that monoclonal antibody therapy has been in use for over two decades. In the commenters' view, therefore, Zevalin is not an "emerging technology." (T1)(T2)

Response:

The NRC is licensing the use of Zevalin under 10 CFR 35.300. The NRC staff has concluded that it will not use FDA approval as a basis for determining whether a particular use of byproduct material should be licensed under 10 CFR 35.1000 or under another section of 10 CFR Part 35. In addition, the staff no longer uses the term "emerging technology" in the guidance as a criterion for determining that byproduct material might be licensed under 10 CFR 35.1000.

Comment:

Participants in the workshop on guidance for diagnostic uses of byproduct material stated that more information must be submitted, according to the terms of the rule, in an application under § 35.1000, than is indicated by the guidance. All of the regulatory requirements should be listed. (T2)

Response:

Because the precise nature of new applications of byproduct material is not predictable, the NRC did not provide detailed guidance for licensing under 10 CFR 35.1000. Instead, applications will be considered on a case-by-case basis. 10 CFR 35.12(d) provides a list of specific information that must be supplied, and in addition § 35.12(d)(2) specifies that the applicant must provide "any other information requested by the Commission in its review of the application." The Supplementary Information for the revisions to Part 35 explained the information needs as follows:

> "The NRC clarified the regulatory text in § 35.12(d) to make it clear that the information in paragraph (d)(1) must be submitted in addition to the information required by other paragraphs in this section. Paragraph (d) was added because the current rule does not provide for the efficient licensing of 'emerging technologies' (i.e., those medical uses that are not specifically included in Subparts D through H. Paragraph (d)(1) provides a

generic list of all the information needed by NRC to approve a medical use that is not specifically addressed in those Subparts. The specified information is needed because we must verify that the byproduct material will be handled safely. At this time, and because of the evolving nature of 'emerging technologies,' it is not possible to be more specific about the necessary information. Applicants for 'emerging technology' licenses are encouraged to consult with the NRC staff about the required information during the application process" (67 FR 20280).

Comment:

It was not envisioned that an emerging modality that is initially licensed under § 35.1000 stays there forever. One of the things that this document does not do is provide any guidance as to what sort of time frames or triggers might, in fact, then cause a modality to "emerge," such that we then generate a stand-alone provision under Part 35 that is unique for that modality. (T2)

Response:

The staff agrees that a modality licensed under § 35.1000 may ultimately become licensed under other, possibly new, sections of Part 35. However, the staff believes that attempting to provide guidance on the process or timetable by which that change would come about is premature. Experience with the implementation of § 35.1000 will be necessary before guidance of the type requested by the commenter can be prepared, if needed.

Comment:

For intravascular brachytherapy (IVB) specifically, participants suggested adding a new section of the rule (e.g., 35.700) to address IVB. (T1)

Response:

This comment goes beyond the scope of revisions to guidance (the suggestion is to revise 10 CFR Part 35). The NRC staff notes that this issue was also addressed in Section III of the Supplementary Information (67 FR 20322), as follows:

> "Intravascular brachytherapy is a very complex field with a number of methodologies and radionuclides being evaluated for use. Currently, the NRC is regulating intravascular brachytherapy as a sealed source therapy. Because no single standard protocol for intravascular brachytherapy has been established, the Commission, with input from the ACMUI, the medical community, and the public, will review the technology in light of that protocol to determine if new regulatory requirements are needed for this use. Pending development of those regulatory requirements, an applicant will be able to submit a license application or amendment request, under the provisions of §§ 35.12 and 35.1000, to incorporate the new modality into their licensed program."

See also the discussion of 10 CFR 35.1000 and IVB on page 1-6.

Comment:

"This section should emphasize the process of licensing a new modality under this provision and not dwell unnecessarily on any specific emerging technology (e.g., intravascular brachytherapy [IVB]) or duplicate modality-specific license guidance published elsewhere." (L14)

"We disagree with the Commission's conclusions that intravascular brachytherapy systems should continue to be considered as an 'emerging technology' in the final regulation and being treated as such in the guidance. At this juncture in time at least three readily available systems now have received FDA approval, have been listed in the SSD Registry, and are being widely distributed to specific licensees not of broad scope. Although these systems may not have been specifically addressed in the regulation, at a minimum the Commission should include their latest policy guidance for this technology as an appendix for easy reference and distribution." (L15)

Response:

The staff agrees that the discussion in the guidance concerning uses under 10 CFR 35.1000 should not emphasize a particular technology or modality. Therefore, references to IVB were removed. The NRC staff believes that some of the confusion regarding the classification of new applications of byproduct material relates to the use of the term "emerging technology" as a possible criterion. The term "emerging technology" has been removed from the guidance on § 35.1000. The NRC is reviewing new technologies on a continuing basis. As these reviews are completed, guidance specific to the new application is being issued, e.g., recent NRC guidance on licensing of sealed sources or devices under § 35.1000, which addresses Cordis, Novoste, and Guidant IVB Systems, discussed on page 1-6.)

Comment:

Participants in the therapeutic workshop discussed several possible methods for clarifying how to distinguish between a medical use that would be licensed under § 35.300 and one licensed under § 35.1000. Some suggested that technologies approved by FDA are not emerging, and therefore fall under Part 35.300. Other participants disagreed and stated that there are real problems with the idea that anything that is FDA-approved should automatically be under the regular regulations. Another suggestion called for the threshold for emerging technologies to be whether the technology fits into Subparts D through H. If not, then the technology is subject to 35.1000. Another possibility was to use criteria similar to those used in other medical coding systems. Both the services and the products themselves require coding for reimbursement, and there is a CPT process within the Centers for Medicare, Medicaid Services regarding codes. NRC could use the status of a particular technology or device in that process as an indicator of acceptance. If it is not widely used, the technology is given an investigational code by CPT, and this provides a clear indication that the medical community has looked at that and judged it as "not ready for prime time." The Medicare coverage office is a resource to other agencies. They look at a lot of these questions in depth and that is another resource in terms of their own process that they have for evaluating questions from a payment point of view. Other resources that NRC might use include a group outside of Philadelphia called Hayes, which does

technology assessments on a subscription basis for insurance companies and a Blue-Cross/Blue-Shield technology assessment process that could be made available to the agency and to the advisory committee as they determine the threshold for emerging technologies. (T1)

Part 35.1000 covers use of "byproduct material or a radiation source approved for medical use," and says nothing about investigational status or unapproved devices. In addition, there is nothing about emerging technology in the rule, so the addition of emerging technology casts a shadow. There are seven types of medical use in Part 35, and one of those seven types is "other." It is appropriate to be other, therefore be careful not to add something to the guidance that is not in the rule. (T1)

Response:

The staff has considered the suggestions concerning criteria to determine when new uses should be licensed under 10 CFR 35.1000. Based on its review of the suggestions, the staff concluded that it will not use either FDA approval or medical coding systems as the basis for deciding whether a new use should be licensed under 10 CFR 35.1000 or Subparts C through H. The staff categorized types of medical use of byproduct material based on such factors as risk, physical form of the byproduct material, and the type of training and experience necessary to become an authorized user under 10 CFR Part 35. Neither FDA approval nor medical coding systems are relevant to the assessment of risk or the training and experience needs for authorization. The same reasoning applies to other criteria suggested by commenters.

The NRC staff agrees with the suggestion that the threshold for making a determination to license a "new technology" under 10 CFR 35.1000 should be based on whether the technology "fits into" Subparts D through H. If not, then the use would be licensed under 10 CFR 35.1000.

Section 8.9 [Section 8.9] Item 7: Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

Comment:

A commenter expressed concern with Section 8.9 regarding training of responsible individuals, arguing that at a minimum the section should contain a summary of the revised regulations regarding the significant change in emphasis on training, availability of the list (future or otherwise) of recognized boards at the NRC's web site, need for preceptor statements and use of Form 313. In addition, the Commission will need to revise the guidance and potentially Form 313 to reflect 10 CFR 35.14 regarding the submission of permits used by master materials licensees or broad scope licensees. The commenter stated that the information found in Appendix G on what would constitute acceptable continuing education and experience was helpful. (L15)

Response:

The NRC staff believes that the requirements for training and experience for authorized users, radiation safety officers, authorized medical physicists and authorized nuclear pharmacists

are sufficiently detailed in the regulations, on NRC Form 313A and in NUREG-1556, Volume 9. Additional guidance on how to complete NRC Form 313A was added as new Appendices D and E, which include instructions and examples of completed NRC Forms 313 and 313A. More information appears in the Supplementary Information "V: Summary of Changes Made Between the Current Part 35 and the Revised Part 35" (67 FR 20249); and on the NRC's web site at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html> under the topic "Part 35 Stakeholder Workshop Presentations." The recognition of certification boards under 10 CFR Part 35 is an ongoing process and it would be impractical to revise the guidance with sufficient frequency to keep a list of recognized boards up to date. The NRC is providing information about the status of recognition of certification boards on its web site at the above location under the topic "Specialty Board Certifications Recognized by NRC." The NRC staff believes that the regulations and guidance are sufficiently clear about what information is needed to satisfy the requirements of 10 CFR 35.14 and therefore did not modify the guidance or NRC Form 313A.

Comment:

One commenter suggested that the second paragraph on page 8-21 should include text that is highlighted, bolded, or otherwise has attention brought to it, noting that many Curricula Vitae are submitted that provide no information relative to the safe use of requested radioactive material from individuals who wish to be authorized on a license. (L15)

Response:

The staff revised the paragraph to emphasize the information that must be submitted.

Comment:

One commenter suggested adding the following text to the second paragraph on page 8-21 describing the Radiation Safety Committee: "The committee description might include membership, meeting frequency, quorum and areas of oversight. Minutes should be maintained." (L14)

Response:

The staff disagrees that the suggested text should be added to the guidance. The requirements in 10 CFR Part 35 pertaining to the Radiation Safety Committee (RSC) were made less prescriptive, in order to give licensees greater flexibility in structuring the composition and operation of the RSC. 10 CFR 35.24(f) now provides the basic requirements for RSC membership. The staff does not consider it appropriate to reintroduce more detailed and prescriptive requirements in guidance.

Comment:

Guidance could be helpful on the frequency of Radiation Safety Committee meetings, since inspectors will be driven to look for the RSC to meet after certain events occur. The guidance should specify what the triggers for RSC meetings might be. The guidance also should address membership of the RSC, and what topics the RSC needs to focus on. (T2)

Response:

The staff concluded that specifying the frequency and/or triggers for RSC meetings would be unnecessarily prescriptive. The guidance addresses minimum membership of the committee, but does not specify the topics that the RSC should focus on or attempt to define when the RSC should meet.

Section 8.10 [Section 8.10] Item 7: Radiation Safety Officer (RSO)

Comment:

"The Delegation of Authority and written agreement of the RSO seem to be unnecessary documents to be submitted in a license application. Submission of this information is not required by §35.12." (L6)

Response:

Section 8.10 has been revised to remove the statement that an applicant should provide the Delegation of Authority and written agreement of the RSO.

Section 8.11 [Section 8.11] Item 7: Authorized Users (AUs)

Comment:

In Section 8.11, clarify what comprises acceptable recentness of training. (L15)

Response:

10 CFR 35.59 provides that training and experience must have occurred within seven years preceding the date of the application. Because the guidance also repeats this requirement, no change is necessary. The discussion of Section 35.59 in Section III of the Supplementary Information includes the following:

> "If the training and experience was not obtained within 7 years preceding the date of the application, the continuing education and experience requirements for an individual would be reviewed on a case-by-case basis, with input from the ACMUI, as necessary" (67 FR 20294).

Further discussion in Section V of the Supplementary Information includes the following:

> "The NRC expects that (1) either the individual has been board certified or has completed the training specified in the alternative pathway within the 7 years preceding the date of the application; or that (2) the individual has had related continuing education and experience since completing the required training and experience requirements" (67 FR 20346).

Section 8.12 [Section 8.12] Item 7: Authorized Nuclear Pharmacist

Comment:

In Section 8.12, clarify what comprises acceptable recentness of training. (L15)

Response:

10 CFR 35.59 provides that training and experience must have occurred within seven years preceding the date of the application. The guidance repeats this requirement, and was revised to include a reference to 10 CFR 35.55 and 35.980, the sections that establish the training and experience requirements for an authorized nuclear pharmacist. See also the response to a comment on what comprises acceptable recentness of training for Authorized Users in Section 8.11, above.

Section 8.13 [Section 8.13] Item 7: Authorized Medical Physicist (AMP)

Comment:

In Section 8.13, clarify what comprises acceptable recentness of training. (L15)

Response:

10 CFR 35.59 provides that training and experience must have occurred within seven years preceding the date of the application. Because the guidance repeats this requirement, no change is necessary. See also the response to a comment on what comprises acceptable recentness of training for Authorized Users in Section 8.11, above.

Section 8.14 [Section 8.31] Item 8: Safety Instruction for Individuals Working in or Frequenting Restricted Areas

Comment:

"Page 8-30, 3rd main paragraph: the reference to 10 CFR 5.310 should be to 35.310." (L3)

Response:

The citation was corrected.

Section 8.15 [Section 8.14] Item 9: Facilities and Equipment

Comment:

Information is requested in this section [and/or in the following section on Facility Diagram] that is not required by regulation. For example, there is no requirement in Part 35 that detailed facility-shielding calculations and materials must be submitted. The license application should

require a statement of intent to comply with the regulations, but details concerning shielding or calculations are not required. (T1) (T2)

"Neither 10 CFR Part 20 or 35 requires that detailed facility shielding calculations and materials be submitted.... The license application should require a statement of intent to comply with the regulations, but detailed shielding reports or calculations are not required. This section is too prescriptive. In light of September 11, 2001 it would be better if this information were not available in the public domain." (L14)

Response:

The guidance has been revised to specify that shielding calculations should be provided for areas of use covered by 10 CFR 35.600. Under provisions of 10 CFR 35.18(a)(3), licenses are issued by the Commission after if finds the applicant equipped and committed to observe the safety standards established by the Commission in Title 10 of the Code of Federal Regulations for the protection of the public health and safety. A similar provision appears in 10 CFR 30.33(a)(2), which requires that an applicant's facilities and equipment must be adequate to protect health and minimize danger to life or property for the Commission to issue a license. For the types of use licensed under 10 CFR 35.600, information about shielding, including detailed shielding calculations, is useful to the NRC staff in making the necessary assessment.

Section 8.16 [Section 8.15] Item 9: Facility Diagram

Comment:

Page 8-33: requiring the listing of rooms to be used to house I-131 patients is overly prescriptive. Participants in the public workshop asserted that licensees have not been required to list these rooms on the license in the past, and that a commitment to perform the required surveys around any room used for this purpose should be sufficient. These commenters stated that a problem would arise if the room that is listed on the license is unavailable, and there is a therapy patient who needs to be treated as an inpatient, because the licensee will be required to wait for the lengthy amendment process to add an additional room. (T1)

Response:

The NRC staff agrees that providing a list of rooms used for I-131 therapies is not specified in 10 CFR Part 35 and the guidance was changed accordingly. However, the staff views the identification of rooms in which I-131 is used or prepared as important. The quantities of I-131 used in therapy can reach several hundred mCi, resulting in the need to shield or control access to nearby areas that might normally be unrestricted for purposes of radiation protection. The staff believes that a description of rooms where byproduct material is prepared, used, administered, and stored is important to ensure that the licensee's facilities are adequate to protect health and minimize danger to life or property. However, licensees have the flexibility to change areas of use for byproduct material used under 10 CFR §§ 35.100 or 35.200, provided that the NRC is notified within 30 days (10 CFR 35.14(b)(4). Type A broad scope licensees are exempted from these requirements under 10 CFR 35.15(f).

Comment:

"There is no regulatory basis for requiring fixed shielding for pulsed dose-rate brachytherapy. These devices are designed for use in hospital rooms with minimal structural modification and use restriction of hourly and weekly workload, rather than shielding, to maintain compliance with 10 CFR Part 20 limits." (L14)

Response:

The section was revised to specify that if applicants are proposing to use portable shielding they should describe the alternative equipment and administrative procedures they propose to use for evaluation and approval by NRC.

Comment:

"Figure 8.8 does not include all adjacent areas. If the figure is used for demonstration of what should be to be submitted by licensees, all adjacent areas should be included. Do adjacent areas include areas above and below all areas of use?" (L6)

Response:

Figure 8.8 was revised and now appears as Figure 8.1 to provide a model facility diagram. The "Discussion" and "Response from Applicant" in this section have all been revised to specify that the applicant should provide a description of all adjacent areas, including those areas above and below the area of use, where applicable. As shown in the example, Figure 8.1, word descriptions of adjacent areas may be sufficient.

Comment:

A commenter stated that two contradictory statements are included on page 8-33 and asked which is correct:

> "Use of byproduct material in a room that is not described in the license application requires prior NRC approval through a license amendment, except for areas of use where byproduct material is used in accordance with 10 CFR 35.100 and 10 CFR 35.200."
>
> "In addition, if radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, submit additional room diagrams only if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams provided."

The commenter argued that the second statement contradicts §35.13(e) and proposed that a solution to this contradiction would be to allow licensees to submit supporting documentation that shows the criteria that the license will use in selecting radiopharmaceutical therapy and brachytherapy patient rooms that are adequate to protect health and minimize danger to life or property. (See 10 CFR Part 30.33(a)(2)). According to the commenter, this would allow the licensee flexibility in assigning patient rooms for these therapies. However, the commenter

concluded that this solution would most likely need a rulemaking to implement due to the requirements in §35.12. (L6)

Response:

The NRC staff deleted these statements from the guidance. The guidance now specifies the following with respect to changes in area of use:

> "Licensees are required by 35.13 to obtain a license amendment before adding to or changing an area of use identified in the application or on the license, except for areas of use where byproduct material is used only in accordance with 10 CFR 35.100 or 10 CFR 35.200."

The guidance also now explains, with respect to the addition of rooms for therapeutic use of byproduct material, what information should be submitted in support of the license amendment:

> "If radiopharmaceutical therapy and brachytherapy patient rooms are added after the initial license is issued, additional room diagrams should be submitted if the room design (including shielding) and the occupancy of adjacent areas are significantly different from the original diagrams supplied. A written description should be submitted for simple changes."

As noted by the commenter, a rule change would be needed to remove the requirements in 10 CFR Part 35 to obtain a license amendment to change areas of use except for those under 10 CFR 35.100 and 35.200 (See 10 CFR 35.13(e)-(f); rule changes are beyond the scope of changes to guidance. Note, however, that, under 10 CFR 35.15(c), Type A, broad scope licensees are exempted from the provisions of § 35.13(e) regarding additions to or changes in the areas of use at the addresses identified in an application or on a license.

Comment:

"Section 8.16 indicates that a diagram of patient rooms where therapeutic quantities of radioactive material are used must be submitted. This would appear to be largely unnecessary. Licensees must demonstrate compliance with restricted and unrestricted exposures by calculation or monitoring. Records of such should be reviewed during inspections. Submission of diagrams does little to ensure such requirements would be met. This would be one area that would be better served as a performance-based item requiring less oversight." (L15)

Response:

The NRC staff disagrees that submission of such diagrams is not helpful. This information will assist NRC in making the determinations required under 10 CFR 35.18(a)(3) and 10 CFR 30.33(a)(2). However, as noted in response to the preceding comment, when licensees are applying to add rooms for therapeutic uses, if the room design and the occupancy of adjacent areas are not significantly different from the original diagrams supplied by the licensee, a written description rather than a diagram is sufficient.

Section 8.17 [Section 8.16] Item 9: Radiation Monitoring Instruments

Comment:

"In regards to Section 8.17, it seems capricious to require service licensees either to submit a statement that confirms procedures contained in Appendix J of NUREG-1556, Volume 18 will be followed or to submit the actual procedures to be used for instrument calibration, while allowing medical licensees who wish to perform their own calibrations to simply state that they will develop and implement an acceptable calibration procedure." (L15)

Response:

This section has been revised to delete the requirement to submit actual procedures. Instead, the "Response from Applicant" includes a statement that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations. Alternatively, a statement can be submitted to document that the applicant has developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.

Comment:

"A response from the applicant regarding calibration is not required by the regulations. In applying for and receiving a license, the licensee accepts the requirements in the applicable regulations for the type of license issued." (See 10 CFR 30.34(a)). (L6)

Response:

10 CFR 20.1501(b) requires a licensee "to ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured." In addition, 10 CFR 35.61 establishes requirements for calibration of survey instruments. The staff also agrees that § 30.34(a) makes a licensee subject to all valid rules, regulations, and orders of the Commission, including the regulatory provisions listed at the beginning of the section on Radiation Monitoring Instruments in the guidance. The "Response from Applicant" for this section of the guidance therefore continues to include a request for a statement from the applicant that radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations and/or a statement that the applicant has developed and will implement and maintain written survey meter calibration procedures in accordance with 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61.

Comment:

One commenter suggested that page 8-40 be revised. The commenter noted that "10 CFR § 35.61(b) states: A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20%." The commenter then argued that "there are 2 basic reasons that the indicated exposure rate would not be within 20% of the true exposure rate: (a) the meter is non-linear and/or has not been adjusted to be accurate, and (b) the meter is linear and adjusted to be accurate for a given energy, but the

energy response of the meter results in over/under response due to differences in the energy spectrum of the radiation emitted from isotopes other than that in which it was calibrated." According to the commenter, "energy response should not be a reason to disallow the use of a meter, provided that the energy response is known for the meter and an appropriate correction factor is used." The commenter stated that, for example, "in radiation therapy, one typically uses the same meter to measure the exposure rate for Cs-137, Ir-192, I-125, and Pd-103. The energy range is from 21 keV for Pd-103 to 660 keV for Cs-137. Many meters commonly used today are not accurate across this wide range of energies. Licensees should not be forced to buy separate meters for each application. Instead, appropriate correction factors should be allowed for each energy range." (L14)

Response:

The staff agrees with the commenter that one survey meter may be adequate for some licensees. However, licensees must be capable of making measurements of radiation level in order to ensure compliance with regulatory requirements and may not use a survey instrument if the difference between the indicated exposure rate and calculated exposure rate is more than 20%. In some cases, the use of correction factors may be adequate, so long as meter readings can be corrected to be accurate within 20% of true exposure rates. NRC staff also notes that correction charts should be readily available and users should be knowledgeable about how to use them. Users may find it more convenient to have instruments available, such as ion chambers, that are designed to measure radiation fields independent of photon energy over the range of photon energies that may be encountered.

Comment:

One commenter asked if this document is included in the category of "nationally recognized standards (e.g., ANSI) or the manufacturer's instructions?" If not, the commenter argued, use of model procedure in Appendix J would not be in compliance with the regulations. (See 10 CFR 35.60(b)). References should be added to the procedure if it is based on a nationally recognized standard. (L6)

Response:

The staff removed the appendix entitled "Model Procedures for Dose Calibrator Calibrations" from the revised guidance to avoid the appearance of setting a standard.

Comment:

"The licensee should be able to submit documentation showing criteria for the selection of equipment that 'are adequate to protect health and minimize danger to life or property.'" (Citing 10 CFR Part 30.33(a)(2)). According to the commenter, this would most likely require a rulemaking due to the requirements in §35.12. (L6)

Response:

The NRC's approach is consistent with that suggested by the commenter, varying somewhat in the detail of what the guidance suggests for submission. The staff continues to believe that the information requested is useful for making a determination to issue a license under provisions of 10 CFR 35.18(a)(3) as well as 30.33(a)(2). Thus, the staff decided to keep the wording used in the March draft of the guidance to describe information to be submitted with an application to describe survey instruments.

Section 8.18 [Section 8.17] Item 9: Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material

Comment: One commenter stated that page 8-42, 3rd paragraph, implies that dose calibrator calibrations are accomplished by shipping them to commercial facilities periodically. The commenter did not know of any requirement to be specifically licensed to do routine dose calibrator testing. Such testing is performed by individual licensees according to their procedures. References to the specifically licensed facilities should be removed so that readers are not confused, because no such references to these special calibration facilities are included in the regulations. (L3)

Response:

The staff revised the text of the "Response from Applicant" accordingly.

Comment:

A commenter suggested revising page 8-41 to state explicitly when dose calibrators are required. (L14)

Response:

The guidance was revised in Section 8.17 under "Discussion" to specify when dosage measurement is required by 10 CFR 35.63 for licensees who prepare patient dosages. A similar discussion is provided in Section 8.18, specifying when an applicant must possess a calibrated dosimetry system for uses licensed under §§ 35.400, 35.600, and potentially under 35.1000.

Comment:

"In Section 8.18, it is not clear from the regulations nor the text of the discussion if the Commission intentionally did not address the issue of frequency of calibration of instruments used to measure the activity of unsealed materials in order to allow flexibility or if an oversight was involved. The regulation itself defers to instrument manufacturers or national standards. The guidance should provide clarification of this issue if the implication is to follow the recommended frequencies as part of the procedures. Elsewhere in the regulations, frequencies for calibrations and checks of other equipment are specified." (L15)

Response:

Calibration of dosage measuring devices in accordance with nationally recognized standards or the manufacturer's instructions is required by 10 CFR 35.60(b). Therefore, specifying procedures for frequencies of calibration checks could potentially result in an alternate standard and be inconsistent with the NRC's intention to make 10 CFR Part 35 less prescriptive.

Section 8.19 [Section 8.18] Item 9: Dosimetry Equipment – Calibration and Use

Comment:

One commenter suggested that it is not necessary to specify a manufacturer's name and model number, and recommended deleting the third bullet on page 8-44. (L14)

Response:

The "Response from Applicant" under the topic "Therapy Unit – Calibration and Use," was revised to delete the instruction to submit information to identify instrument type, manufacturer, and model number.

Comment:

The reference for ordering AAPM documents/reports should be changed to Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from http://www.medicalphysics.org. See page 8-44. (L14)

Response:

The reference was changed as recommended in the comment.

Comment:

"Page 8-43: This states than an AMP must calculate current activity of Sr-90 applicators, yet it also says there is no AMP specified for brachytherapy sources. Table C1 states that 'Authorized Medical Physicist' is applicable to facilities applying for use of materials in 35.400. Please clarify whether or not AMP's are required for manual brachytherapy or not." (L3)

Response:

10 CFR 35.433(a) specifies that 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. Therefore, Table C.1 is correct with respect to that type of use. However, no equivalent requirement exists for other types of manual brachytherapy uses under 35.400. The paragraph noted by the commenter has been revised to clarify that an AMP is not specified for brachytherapy sources, except for calculating the activity of Sr-90 sources, and Table C.1 has been clarified as well.

Comment:

A commenter suggested inserting references to the AAPM, ACR, and ACMP as nationally recognized bodies on page 8-43 in addition to the references already present to the ANSI. (L14)

Response:

The staff inserted references to additional groups into the guidance.

Comment:

On page 8-44, "Footnote 3 should read 'For brachytherapy sources, "first medical use" is defined as the first use following the effective date of the revised 10 CFR Part 35.'" (L14)

Response:

The staff agrees and has revised the footnote so that it reads as suggested by the commenter.

Comment:

On page 8-44: "[i]n the second bullet, delete the reference to 10 CFR § 35.432. This is not an appropriate reference here." (L14)

Response:

The reference to 10 CFR 35.432 was deleted.

Comment:

"The guidance in Section 8.19, page 8-46, regarding PDR remote afterloaders suggests that the primary care provider check to ensure the device has not moved, was kinked, etc., but does not provide guidance as to what frequency should be used. If this is found in an industry or consensus standard, it should be inserted here. If the frequency is simply left to the physician's discretion, then the statement in the guidance should be deleted." (L15)

Response:

The staff believes that the guidance provided is important and should be retained. However, stipulating the frequency of such checks, as the commenter suggests, would be overly prescriptive. The NRC staff believes that requirements for training and for written directives, as well as good professional practices, create strong incentives for the licensee to ensure that devices are working properly and to develop procedures for checking on their operation at appropriate intervals.

Section 8.20 [Section 8.19] Item 9: Other Equipment and Facilities

Comment:

"Regulations address therapy related computer systems (10 CFR 35.457 and 657). However, the guidance only gives passing mention of this topic for Subpart H applications (pg. 8-82) and none for Subpart F. Issues of acceptance testing should be addressed by the guidance as well as specific reference to some of the nationally recognized protocols the Commission used in its discussion. The regulatory caveat of 'acceptance testing must include, as applicable, verification of' should be expounded to provide guidance as to what conditions would determine applicability. This would appear to deserve its own section within Item 9 if not included in 8.20 as 'other equipment.'" (L15)

Response:

The NRC staff does not agree that additional guidance should be included on the subject of acceptance testing because it would be unnecessarily prescriptive to expand upon the requirements in 10 CFR Part 35.

Comment:

On page 8-45, the fourth paragraph of the Discussion section should be edited to remove the words "permanently mounted in each therapy treatment room that is equipped with an emergency power supply" from the description of the beam-on radiation monitor. (L14)

Response:

The discussion was revised to state that one method of meeting the requirements of 10 CFR 35.615(c) is with a beam-on radiation monitor permanently mounted in each therapy treatment room and equipped with an emergency power supply. A phrase was added indicating that applicants may also propose an alternative to a permanently mounted monitor.

Comment:

"On page 8-47, delete the level of detail in the description of facilities. Delete the description of pulsed dose rate (PDR) requirements, as they are too prescriptive and not grounded in regulations. There is no regulatory basis for requiring fixed shielding for pulsed dose-rate brachytherapy. The description in 10 CFR § 35.615 is sufficient. These devices are designed for use in hospital rooms with minimal structure modification and use restriction of hourly and weekly workload, rather than shielding, to maintain compliance with 10 CFR Part 20 limits." (L14)

Response:

The NRC staff revised the description of the alarm system for pulsed dose-rate afterloader facilities to clarify that the details provided in the guidance are only suggested for consideration by applicants. The guidance was revised to allow for the possibility of applicants using

alternatives other than fixed/structural shielding to maintain compliance with dose limits in 10 CFR Part 20 by adding a statement to indicate that applicants may submit information on alternatives to fixed shielding as part of their facility description.

Section 8.21 [Section 8.20] Item 10: Radiation Protection Program

Comment:

On page 8-48, "In the discussion paragraph, delete the second sentence, which states 'the table in Appendix C may be helpful in determining what information must be provided when requesting a license.'" (L14)

Response:

The staff considers Table C.2 to be particularly useful to applicants for assisting them in determining what information must be supplied as part of a license application. Many commenters noted that Table C.1 is also useful as an aid to determining how to fill out an application based on type of use. The introduction to Appendix C has been revised to give more explicit directions on how the tables in the appendix may be used. The phrase quoted by the commenter has been revised to cite Tables C.1 and C.2 in particular.

Section 8.22 [Section 8.37] Item 10: Audit Program

Comment:

"In Section 8.22, Item 10, page 8-50, last paragraph, NRC does not require submittal by an applicant of an audit program for its radiation protection program, which is required to be performed annually by the licensee. [S]ince procedures in all other sections will be performance based, [the NRC] should seriously consider requiring submittal of the audit program to help ensure that a meaningful audit of the radiation safety program will be performed annually and that appropriate corrective measures will be taken in a timely manner." (L15)

Response:

The NRC staff revised the guidance with the objective of making it less prescriptive and more performance-based. The NRC staff determined that to include a requirement for submission of audit procedures as part of an application would be inconsistent with that approach. Further, Part 35 does not contain such a requirement.

Comment:

On page 8-50, the reference to Appendix K ["Suggested Medical Licensee Audit"] implies that unless Appendix K is not applicable, it must be followed. Revise the text to clearly state that Appendix K is only a suggested guide. (L14) (T1)

Response:

The text under "Discussion" in the section on "Audit Program" was revised to clearly indicate that the procedures in Appendix L, "Model Medical Licensee Audit" (formerly Appendix K), are suggested guidance which represent one acceptable way to meet requirements for an audit program. NRC staff also clarified the discussion to indicate that some sections of the appendix may not be pertinent to every licensee, review, or audit.

Section 8.23 [Section 8.22] Item 10: Occupational Dose

Comment:

*"*Section 8.23 indicates that an applicant must provide a description of facilities and equipment used for monitoring exposures as well as a statement that written procedures for monitoring exposures will be implemented and maintained. However, the stated criteria indicate that applicants must either monitor exposures or demonstrate that exposures are not likely to exceed ten percent of the allowable limits in 10 CFR Part 20. The information provided in this section concerns the need for monitoring and gives no mention of the alternate of maintaining evidence used to show that monitoring is not required for review during inspection. The Department suggests that information be added to this section regarding how an applicant can demonstrate that exposures are not likely to exceed ten percent of the limit. Does the applicant need to submit documentation of this demonstration to NRC or just maintain it for inspection? The Department also is curious to learn how the Commission anticipates enforcing the monitoring requirement if it is determined during inspection that dosimetry is not exchanged at the 'preferred' frequency for the various monitoring devices. What portion of 10 CFR 20 will be cited?" (L15)

Response:

A sentence was added to the "Discussion" to indicate that review of dosimetry histories may be helpful in assessing potential doses, and should be part of a licensee's procedures for assessing occupational doses. Information about demonstrating that exposures are not likely to exceed ten percent of the allowable limits in 10 CFR Part 20 is provided in Appendix M, "Model Procedures for an Occupational Dose Program." The discussion of frequencies for exchange of personnel monitors was revised to indicate that licensees should follow the recommendations of NVLAP accredited processors for advice on exchange frequency and proper use of monitoring devices. Discussion of policies for inspection and enforcement go beyond the scope of the guidance in NUREG-1556, Volume 9. Guidance for inspectors is provided in the NRC Inspection Manual at IMC 2800 (Materials Inspection Program) and, for medical licensees, in Inspection Procedures (IPs) 87130-87134.

Comment:

With respect to occupational dose, "no response should be necessary. Licensees should understand that they need to comply with all applicable regulations before a license is approved. A licensee should not have to repeatedly state that they need to comply with the applicable

regulations. Issues regarding occupation dose should be and usually are addressed during inspections." (L6)

Response:

In order to issue a license under 10 CFR Part 35, the NRC must determine that an applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property and that the applicant is equipped and committed to observe the safety standards established by the Commission for the protection of the public health and safety. The information requested in this section is important to assist the staff in making this determination. This section of the guidance was revised to be consistent with that issued for compliance with 10 CFR Part 20 contained in NUREG-1736, "Consolidated Guidance: 10 CFR Part 20 – Standards for Protection Against Radiation" (1995). In particular, the "Response from Applicant" was adapted from NUREG-1736.

Comment:

Facilities and equipment should have already been described in Item 9 of Form 313. (L6)

Response:

The NRC staff believes that a separate discussion of devices and procedures for assessing occupational dose under Item 10 on NRC Form 313 is appropriate. This information is distinct from that requested under Item 9 on NRC Form 313, which deals with other facilities and equipment.

Comment:

On page 8-51, there is no reference to the NRC Regulatory Issue Summary 2002-06, released April 16, 2002. This RIS is also not referenced in Appendix A. There could be some discussion providing specific guidance for licensees who receive occupational exposures from medical x-ray radiation, while wearing protective apparel; perhaps a short discussion should be included on how the licensee should apply this RIS. (L9) (T1)(T2)

Response:

The NRC staff added references to the RIS. In addition, a description of relevant material covered in RIS 2002-06 was added to the text of this section.

Section 8.24 [Section 8.32] Item 10: Public Dose

No comments.

Section 8.25 [Section 8.27] Item 10: Minimization of Contamination

Comment:

One commenter asked what benefit is expected from requiring the applicant to submit a description of how facility design and procedures will minimize contamination. The commenter stated that information regarding facility design should be submitted in Item 9. A first-time license applicant will have the training and experience necessary to implement the necessary procedures to minimize contamination. When NRC staff approves a RSO, AU, or ANP they should be confident that the licensee staff should implement appropriate procedures. These procedures should not need to be submitted to the NRC for review, but reviewed during inspections. (L6)

Another commenter stated that the entire paragraph titled "Response from Applicant" should be deleted because it is not supported by regulation. (L14)

Another commenter stated that the new requirement on pages 8-56 and 8-57 regarding minimization of contamination is confusing and unnecessary. NUREG-1556 provides little guidance as to what NRC expects facilities to submit. Stakeholders assert that the practice of nuclear medicine currently produces no waste that requires burial, so the issue with generating excess waste should not be a concern for NRC. Also, because there is no problem for decommissioning, as all materials decay to background within months, issues of contamination are already adequately addressed in survey and spill procedures. (L3)

Response:

The staff continues to believe that the guidance in the section on Minimization of Contamination is useful; therefore, it was retained. The "Response from Applicant" was revised to indicate that a response is not required if the information provided in the applicant's responses satisfies the criteria in other sections of the guidance pertaining to Facility and Equipment, Facility Diagram, Radiation Protection Program, Safety Program, and Waste Management. The staff retained the discussion of minimization of radioactive waste volumes because some licensees may possess and use byproduct materials that can not be disposed of by decay-in-storage due to the half-life of the material and/or limitations on space for storage.

Comment:

"[Section] 8.25, Minimization of Contamination, asks applicants to submit a description of how facility design and procedures for operation will minimize contamination. However the guidance includes only an appendix for a model survey program. What information regarding facility design is expected? Should all areas where radioactive materials are used be equipped with negative airflow when compared to surrounding rooms? Should benches and floor be made of non-porous surfaces? If submission of this type of information is necessary, then guidance in that aspect should be provided. Similarly, what procedures for operation to minimize contamination are necessary to be submitted?" (L15)

Response:

As noted in the response to the previous comment, the staff has revised the "Response from Applicant" on minimization of contamination to clarify that if the responses satisfy the criteria in other specified sections of the guidance, then no response is necessary for this item. The staff believes that including a requirement in the guidance to submit more information in a license application would be unduly prescriptive.

Section 8.26 [Section 8.38] Item 10: Operating and Emergency Procedures

Comment:

A commenter noted that Section 8.26 indicates the licensee must develop, implement and maintain procedures for various elements, including conducting contamination surveys. Yet, those procedures do not need to be submitted. The commenter stated that in this guidance the Commission should clarify the requirements of 10 CFR 20 regarding application of ALARA, as it is within these procedures that ALARA is best applied. It is a disservice to the applicant/licensee not to summarize those materials in this guidance. For example, under the revised performance-based and risk-informed rule, it is not clear if it would be considered acceptable to eat, drink, smoke, apply cosmetics, or conduct other hand to face actions in areas where radioactive materials are being used. Although the practice may not be ALARA, if no intake or exposure occurs as a result, it would appear there is likely no violation of 10 CFR 20 or 35. In the past, such activities would be prohibited by license condition or through reference to a submitted procedure. If such procedures are no longer submitted, how would these basic safety precautions, (i.e., proper use of personal protective equipment, disposal of radioactive materials into labeled containers, appropriate use of personnel monitors, etc.) be enforced? What extent of procedures would the licensee/applicant be expected to have available? This item also suggests that submission of emergency procedures is unnecessary. Yet, in subsequent section (8.38), submission is necessary. The commenter contends that there are therapeutic quantities of loose forms of material that are used that pose equivalent risk levels to those from sealed sources. Given this fact, some form of equity should be reached as to when such procedures need to be submitted for review. (L15)

Response:

Extensive description of what is considered ALARA under the requirements of 10 CFR Part 20 is beyond the scope of this guidance. The guidance was revised to indicate that applicants are not required to submit information on operating and emergency procedures.

Section 8.27 [Section 8.39] Item 10: Material Receipt and Accountability

Comment:

On page 8-63, in the discussion of records of molybdenum concentrations, the guidance refers to concentration measured and recorded. A statement could be included that if you perform this test with each elution, you would not be in violation of the ALARA principal. There is a potential disconnect for someone who wants to follow the package insert and measure

each elution, who might be considered to expose themselves unnecessarily, because they performed that test. A statement that nothing in the Part 35 regulations precludes a more frequent testing should be included in the guidance document. (T2)

Response:

NRC noted in the Supplementary Information for the proposed rule (67 FR 20302) in its discussion of 35.204, Issue 1, that the requirement in 35.204((b) to measure the first eluate after receipt of a generator "does not preclude more frequent evaluations of the Mo-99 concentrations." Licensees would be expected to balance risk of exposure from performing the test with the benefits derived from making more frequent measurements.

Section 8.28 [Section 8.40] Item 10: Ordering and Receiving

No comments.

Section 8.29 [Section 8.33] Item 10: Opening Packages

Comment:

The guidance should require a response from applicants that they have developed and will implement and maintain written package opening procedures because licensees are required by 10 CFR 20.1906 to develop procedures for safely opening packages in which radioactive material is received. (L16)

Response:

The NRC staff concluded that a response from applicants was not necessary on this topic because the applicant is already required by both 10 CFR Part 20 and Department of Transportation regulations to monitor packages for surface contamination and to establish procedures to open packages safely. The NRC staff concluded that it would be sufficient to allow applicants to follow use a risk-informed, performance-based approach to developing procedures for safely opening packages.

Section 8.30 [Section 8.41] Item 10: Sealed Source Inventory

No comments.

Section 8.31 [Section 8.42] Item 10: Use Records

No comments.

Section 8.32 [Section 8.45] Item 10: Leak Tests

No comments.

Section 8.33 [Section 8.23] Item 10: Area Surveys

Comment:

The Area Survey section on page 8-65 should only include information on area surveys. Delete the information that more appropriately belongs in section 8.35 on safe use of unsealed material. (L14)

Response:

The NRC staff concluded that the contents of the section are appropriate because it covers all areas that should be considered for area surveys. The discussion referenced by the comment has been edited to clarify its pertinence to surveys.

Section 8.34 [Section 8.34] Item 10: Procedures for Administrations Requiring a Written Directive

Comment:

The guide should require a response from applicants that they have developed and will implement and maintain written procedures for administrations requiring a written directive in accordance with 10 CFR 35.41. (L16)

Response:

The NRC staff concluded that a response from applicants that they would develop, implement, and maintain written procedures for administrations requiring a written directive was not necessary since regulations require licensees to do so. 10 CFR 35.40, "Written Directives," and 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive," provide explicit requirements concerning written directives that must be satisfied for all administrations of byproduct material for which a written directive is required. The regulatory requirements include provisions on dating and signing written directives; when oral directives are acceptable and the deadlines for documenting an oral directive; the contents of the written directive; procedures for making a written revision to a directive; retention requirements for the directive; and requirements for verification procedures.

Section 8.35 [Section 8.24] Item 10: Safe Use of Unsealed Licensed Material

No comments.

Section 8.36 [Section 8.26] Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources

Comment:

"Under Section 8.36, if a licensee is opting to perform service and maintenance of therapy systems there should be inclusion of the procedures to be followed for such activities along with

the submitted level of training and experience of the individual. The submittal may be as simple as confirming service will only be in accordance with the manufacturer's service manual and recommendations, or it may be as involved as specifically developed procedures unique to the device which would have to be reviewed and evaluated on a case-by-case basis." (L15)

Response:

The staff modified the "Response from Applicant" to specify that, if the applicant requests that an employee trained by the manufacturer is to be authorized to perform such activities as installation, repair, etc., then the applicant must provide sufficient information to allow the NRC to evaluate the application, including the manufacturer's training certification and a description of the training and experience for the use requested.

Section 8.37 [Section 8.25] Item 10: Spill Procedures

No comments.

Section 8.38 [Deleted] Item 10: Emergency Response for Sealed Sources or Devices Containing Sealed Sources

No comments.

Section 8.39 [Section 8.35] Item 10: Patient or Human Research Subject Release

Comment:

This section of NUREG-1556, Volume 9 is not consistent with other NRC guidance, which currently requires 200 dpm per 200 square centimeters for I-131. In contrast, NUREG-1556, Volume 9 allows the release of a patient who has had as much as 200 millicuries of I-131. Such a person could create contamination in excess of 200 dpm per 200 square centimeters. Commenters at the workshop on guidance for therapeutic uses of byproduct material asserted that the requirements are not risk-based, citing three sets of guidance, ICRP Publication 57, a series of International Atomic Energy Agency recommendations, and ANSI Standard N13-12 (1999) that recommend trivial levels in the area of tens of thousands of dpm per hundred square centimeters. (T1)

Response:

Refer to discussion of comments on Appendix R, "Model Procedure for Area Surveys," where the topic of setting trigger levels for decontamination is discussed, including the status of NRC rulemaking activities that relate to these issues.

Section 8.40 [Section 8.46] Item 10: Safety Procedures for Treatments Where Patients Are Hospitalized

Comment:

On page 8-77, the third bullet should read: "Visibly post a 'Radioactive Materials' sign on the patient's room" rather than "on the patient's door, " citing 10 CFR §§ 35.315 and 35.415. (L14)

Response:

The text has been edited to make the change suggested by the commenter.

Comment:

"Section 8.40, page 8-78, references 10 CFR 20.1801 for security of radioactive material in storage from unauthorized removal or access. The paragraph then goes on to suggest that rooms where patients are hospitalized must be secured to prevent unauthorized access or removal of radioactive material. Is NRC implying that the treated patient could be subject to theft of implanted/administered material? Also, material in these cases is not considered in storage. The Commission should reconsider the language used to more clearly describe its intent (i.e., control spread of potential contamination perhaps)." (L15)

Response:

The section has been edited to clarify that the requirement pertains to security for licensed material temporarily stored in the patient's room.

Section 8.41 [Deleted] Item 10: Procedures for Device Calibration, Safety Checks, Operation, and Inspection

Comment:

"Within Section 8.41, in the discussion of operation of the remote afterloader, the guidance should mention the degree of involvement necessary by members of the treatment team and who should comprise that team. This information previously had been part of the NRC's policy and guidance regarding afterloaders. Portions of this guidance as well as the standard conditions have since become codified so a commitment to the makeup of the team should not be unduly burdensome or unreasonable." (L15)

Response:

The staff believes that adding detail of this kind in the guidance would be overly prescriptive because this information is not required by Part 35. The section has been removed from the guidance.

Comment:

"The reference for ordering AAPM documents/reports should be changed to Medical Physics Publishing (MPP), 4513 Vernon Boulevard, Madison, WI 53705-4964 or ordered electronically from http://www.medicalphysics.org. See page 8-86." (L14)

Response:

The section has been removed from the guidance. However, the staff has placed the reference for ordering AAPM documents/reports in appropriate places in the guidance, including Appendix AA.

Comment:

On pages 8-78 to 8-86, "all of the parenthetical that reference ANSI should be expanded to recognize other nationally recognized bodies such as AAPM, ACT, and ACMP." (L14)

Response:

The section has been removed from the guidance. However, at other appropriate points, the staff has incorporated references to other nationally recognized bodies.

Comment:

Suggest adding to the end of the first bullet on 8-81: ". . . functioning properly, or a redundant or replacement source indicator light is shown to be functional." (L14)

Response:

The section has been removed from the guidance.

Section 8.42 [Section 8.36] Item 10: Mobile Medical Service

Comment:

On page 8-87, replace the second sentence, last paragraph with: "However, a single client site may be authorized only for a single class of service for each mode of service." The commenter explained that a provider may choose to utilize a class 3 provider for mobile HDR, but desire class 1 services for mobile gamma cameras. For a given service, the client site will only have one level of service. (L14)

Response:

The staff removed the discussion of different "classes" of mobile medical service because it was misleading. The change included deletion of "Class 3" mobile medical services; NRC staff concluded that the type of service categorized as "Class 3" in the draft guidance was not a medical use and therefore guidance on this use is not appropriate for discussion in

NUREG-1556, Volume 9 – guidance on medical use of byproduct material. Licensees who perform services such as transport of byproduct materials are subject to other NRC regulations.

Comment:

"Class 3 mobile service providers addressed under Section 8.42 should be referred to other guidance in the development of appropriate license submittals. At a minimum the mobile service applicant should be made plainly aware that the license to be issued will not allow use in or on humans. Also, within this section it is suggested that actions limited to imaging of a previously injected patient may not be considered a licensed activity for the imaging service. This situation should be further described, as it would appear that only under a discrete situation within a very narrow interpretation of regulations would this be true. In fact inclusion of this cited statement would appear to be more confusing to the applicant than warranted and could be deleted." (L15)

Response:

The text discussing "Class 3" has been removed from the guidance. The staff concluded that the type of service provided was not part of medical use and therefore was not appropriately included in this guidance. Licensees who perform services such as transport of byproduct materials are subject to other NRC regulations.

Comment:

The guidance should require a Response from Applicant under the discussion of Mobile Medical Service because the information discussed (as well as information provided in the appendix on Mobile Medical Service, Appendix V) must be submitted in order for a license for Mobile Medical Service to be issued. (L16)

Response:

The staff agrees that mobile medical service license applicants must submit certain information. However, the information that must be submitted by a mobile medical service license applicant is already included in the information described in the Response Required category of Sections 8.1 through 8.30 of NUREG-1556, Volume 9. A mobile medical service license applicant will be aware of the information that must be submitted if it reviews the balance of the guidance document, and listing the required responses under Section 8.36 would be unnecessarily redundant.

Section 8.43 [Section 8.47] Item 10: Transportation

Comment:

*"*This section seems to be appropriate for background information but not as guidance. If the appendix dealing with transportation remains as an appendix, this discussion should be moved to an appendix as an introduction." (L14)

Response:

This section has been moved to a newly created section of the guidance addressing program-related topics for which no response is required from applicants on NRC Form 313. In addition, a note has been placed at the beginning of the section stating that the section is included because this topic is a key element of a licensee's program but no response is required from an applicant on NRC Form 313.

Section 8.44 [Section 8.28] Item 11: Waste Management

Comment:

One commenter suggested that Section 8.44, Item 11, page 8-90, should be revised to specify that the licensee must submit waste disposal procedures with the application, including calculations demonstrating that expected concentrations of effluents as a result of waste disposal will be below regulatory limits (i.e., disposal via the sewer, evaporation, etc.). The commenter inquired whether the Commission would consider on-site incineration worthy of submission and review or would the affirmation that the effluent will be compliant with the regulations be considered acceptable? The commenter stated that the NRC's "commitment to develop" statement is unacceptable for waste disposal that could (and does) end up in the public domain. The commenter also suggested that a statement be added to this section about responsibilities of the licensee for waste discovered in the public domain, arguing that the Commission has circumvented this issue for which the states ultimately have had to respond. The commenter stated that it was difficult to reconcile the Commission's approach of "as long as it's less than 500 mrem" (regarding patient release criteria) while at the same time insisting that other release of material achieve an ALARA limit of 25 mrem or less. (L15)

Response:

The NRC generally does not require procedures for disposal of radioactive waste to be submitted as part of license applications for medical use of byproduct material. Licensees are required to comply with 10 CFR 20.2004 and 20.2002 to dispose of licensed material by incineration. Issues concerning waste discovered in the public domain are outside the scope of this guidance.

Comment:

"On page 8-91 the discussion section is written too prescriptively. The words 'should' and 'must' should be deleted unless a specific regulation is cited (e.g., bullet 2, last bullet)." (L14)

Response:

The discussion in this section was revised to be less prescriptive.

Comment:

On page 8-92, "it is not clear that the second bullet on this page is supported by regulation. Clarification is needed or this should be deleted." (L14)

Response:

The staff clarified the statement to indicate that applicants proposing to dispose of licensed material by incineration must comply with 10 CFR 20.2004.

Comment:

On page 8-93, "the discussion under the paragraph titled: 'Returning sources' is inaccurate. Some brachytherapy sources are allowed to decay in storage as an acceptable disposal method. Change the first sentence to state: 'For material with a half-life ($t_{½}$) > 120 days contained in brachytherapy, teletherapy, and GSR sources, the only option for disposal is transfer to an authorized recipient as specified in 10 CFR § 20.2001(a)(I).'" (L14)

Response:

The discussion of returning sources was deleted, with the exception of the discussion related to nuclear pacemakers.

Section 8.45 [Section 8.29] Item 12: Fees

No comments.

Section 8.46 [Section 8.30] Item 13: Certification

No comments.

Section 9 [Section 9] Amendments and Renewals to a License

Comment:

"In Section 9, second paragraph, the following conditions should also require an amendment:

- Release of a restricted area.
- Change to a less restrictive operating procedure or equipment modification that potentially affects occupational/non-occupational exposures including survey frequencies or release of effluents.
- Changes in waste disposal practices.
- Change in anything under 35.19." (L15)

Response:

The NRC staff does not agree with the comment. The listed items are not specifically included under either Part 30 or Part 35 as requiring a license amendment, and therefore the

change recommended by the commenter has not been made. However, if these items are included as license conditions, as implied by the comment use of the word "condition," then changing the condition would require a license amendment.

Section 10 [Section 11] Termination of Activities

Comment:

"In Section 10, page 10-1, references to the appropriate decommissioning standards should be made. Licensees must submit records of close-out surveys and obtain NRC/State approval prior to release of the entire site or a portion thereof for unrestricted use. This should be made clear in this section." (L15)

Response:

This section has been extensively revised to parallel guidance in NUREG-1556, Volume 12, "Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution" (December 2002), which reflects NRC's most recent guidance on termination of activities. References were added to NUREG-1727 and NUREG/BR-0241. These documents contain guidance concerning decommissioning of facilities and termination of licenses, including instructions on close-out surveys and approvals required prior to release of sites for unrestricted use. The "Response from Applicant" clarifies the obligations of licensees upon termination of licenses.

Appendix A [Appendix AA] List of Documents Considered in Development of this NUREG

Comment:

"NRC should review and update this appendix. Many of the references contained in this appendix are out of date. In addition, suggest incorporating Appendix W, 'Transportation' in this appendix since Appendix W simply provided a list of references related to transportation of radioactive materials." (L14)

Response:

The staff updated the list of references. Annotations indicate when NRC documents used in the preparation of the guidance have been superceded. The appendix listing DOT regulations has been retained as a separate appendix because it serves as a source of references to regulations on the specific topic of transportation of radioactive materials rather than as a more general list of documents used in preparation of the guidance.

Appendix B [Appendix A] NRC Form 313

No comments.

Appendix C [Appendix C and Appendix F] License Application Checklists and Sample Licenses

Comment:

The examples in Appendix C should not subdivide the uses into specific categories. The regulations merely state "any," and "any" should not be limited. (T1)(T2)

Response:

Table C.2 has been edited, when appropriate, to indicate that the response "Any" is acceptable for Form or Manufacturer/Model No. for byproduct material licensed under 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300.

Comment:

Because Form 313 does not require the information contained in Tables 8.3 and Appendix C, Table C.2, and the purpose of both tables is to aid the applicant in filling out Form 313, both tables should be deleted. (L14)

Response:

The staff agrees that Table 8.3 was misleading and that table was deleted. The staff believes Table C.2 provides useful guidance on how to respond to Form 313 and is retaining that table, which has been edited to be consistent with Form 313.

Comment:

A commenter suggested that the NRC:

- "Change 'diagnosis and treatment of hyperthyroidism' to 'quantities less than or equal to 1.22 gigabecquerels (33 millicuries)' as per terminology in 10 CFR 35.394;"
- "Change 'thyroid carcinoma' to 'quantities greater than 1.22 gigabecquerels (33 millicuries)' as per terminology in 10 CFR 35.394;"
- "Delete 'treatment of cardiac dysfunction' because this term is not specifically identified in 10 CFR Part 35, and will be included in 35.392 and/or 35.394;"
- "[C]hange 'Iodine I-131 for treatment of hyperthyroidism and cardiac dysfunction' to 'sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)' to be consistent with 10 CFR 35.392;" and
- "Delete detailed requirements for decay-in-storage as license conditions because these requirements are already covered in 10 CFR 35.92. Also, note that the license condition currently specifies holding waste for at least 10 half-lives, which is not a requirement in 10 CFR 35.92." (L2)

Response:

The discussion of various modalities that dealt with the first four items in the above comment was deleted from the text of Section 8.8 of the guidance and the associated text of Table C.2 of

Appendix C. The discussion of waste disposal was retained to provide guidance to applicants for use of byproduct material under 10 CFR Part 35 who also apply for possession and use of byproduct materials licensed under other parts of Title 10, e.g., non-medical uses which are not licensed under 10 CFR Part 35. The condition in sample licenses to hold byproduct material for decay in storage for 10 half-lives was retained to maintain consistency with guidance on this topic contained in NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses – Guidance About Administrative Licensing Procedures."

Comment:

In Appendix C, Table C.3 on page C-9, Item 7: ANP, the "[w]ritten certification signed by a preceptor should only be required in addition to the option of description on training and experience. The options of previous license naming the individual as ANP and board certification should be stand-alone criteria that would not require preceptor certification. This differs and is in conflict with criteria stated in 10 CFR 35.55 and described in NUREG-1556, Volume 9, Section 8.12, Item 7 on pages 8-27 and 8-28." (L2)

Response:

Table C.3 has been revised to clarify the alternative ways in which applicants may document the adequacy of training and experience for ANPs and to be consistent with regulatory requirements, including the case when the signature of a preceptor is required. The revisions to Table C.3 parallel changes also made to the Response from Applicant section in NUREG-1556, Volume 9, Section 8.12, which discusses training and experience for ANPs.

Comment:

In Appendix C, pages C-21 and C-22, Items 13-15, "delete leak testing requirements for sealed sources as license conditions because these requirements are already covered in 10 CFR 35.67." (L2)

Response:

The sample license for "Medical Institution Limited" (now located in Appendix F) was revised to clarify that the leak testing requirements cited therein apply to "sealed sources not associated with 10 CFR Part 35 use." The condition requiring leak testing for sealed sources was retained because it pertains to sources that are not licensed under 10 CFR 35.67.

Comment:

Appendix C contains only sample licenses. Since this is a guide to prepare an application it would be much more useful to have sample applications for 35.100, 35.200, and 35.500. (T2)

Response:

A sample license application for use of byproduct material under 10 CFR 35.100 and 10 CFR 35.200 has been added as a new appendix, Appendix E. The NRC staff concluded, based on the

experience of Regional licensing staff, that applicants for 10 CFR 35.100 and 10 CFR 35.200 uses would find the sample license application most useful. No sample application was prepared for uses under 10 CFR 35.500 because staff concluded that applications for such uses, like applications for 10 CFR 35.400 and 10 CFR 35.600 uses, were substantially less frequent, that such licenses are very situation-specific (making it difficult to write a sample that would be generally useful), and that applicants for these uses commonly need to enlist the services of a consultant or request assistance from NRC staff during the application process.

Comment:

The matrix in Appendix C is confusing. It should be redone in "plain language." (T2)

Response:

The matrix was edited to include expanded explanations of how to use the matrix, along with expanded explanations of how to use Tables C.2 and C.3. The sample license application in Appendix E provides an illustration of how Tables C.2 and C.3 may be used in a license application.

Comment:

"In Table C.2, page C-4, last row, I-131, second column: specify 'I-131 sodium iodide liquid or capsules' instead of 'any,' because other I-131 radiolabeled therapy products (e.g., antibodies) will likely become available in the near future." (L2)

Response:

The staff determined that the use of the term "any" is appropriate because it is consistent with the requirements of 10 CFR 35.100, 35.200, 35.300, which specify "any unsealed byproduct material prepared for medical use." Requiring applicants to specify chemical or physical form would go beyond regulatory requirements and be unduly prescriptive. Use of the more general term "any" also permits the use of other unsealed (liquid) forms of byproduct material. (See also the discussion of licensure of the use of Zevalin, a labeled antibody, under 10 CFR 35.300, in the discussion of comments on "Purpose(s) for Which Licensed Material Will Be Used.")

Comment:

"Appendices C and K should be redrafted to provide an example application, license and licensee audit program for each of the seven categories of medical use as specified on page 8-14. This would replace tables C.2. and C.3. Table C.l must be revised to reflect the final language of Section 8." (L14)

Response:

Additional examples of sample licenses have been added in Appendix F. However, the staff concluded that an example of a license application and an audit program for each of the seven categories of medical use would not be helpful and would lengthen the document considerably,

while being unnecessarily duplicative. Numerous commenters at the public workshops encouraged the NRC to find ways to shorten the guidance. An appendix describing a model audit program that can be revised for each of the categories of use is still included in this guidance. Tables C.1, C.2, and C.3 have been revised to be consistent with Section 8.

Comment:

"Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use. This table should be revised to reflect the final language of section 8. The following items should be clarified at a minimum.

i. It should not be necessary to submit the manufacturer's name and the model number of the sealed source requested or the survey instrument.
ii. Also, there is no requirement to indicate whether patients will be released under 10 CFR § 35.75 on form 313 " (L14)

Response:

The guidance on providing information the manufacturer's name and model number of the sealed source in an application for a license was retained because it is required by 10 CFR 30.32(g). The draft guidance did not contain a request for information about survey instruments in Table C.2 for Items 5 and 6 on NRC Form 313; therefore, no change in the guidance was needed.

The request for information on whether patients would be hospitalized until release pursuant to 10 CFR 35.75 was removed from Table C.2.

Comment:

"Table C.3. Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal. This table should be revised to reflect the final language of section 8. The following items should be clarified at a minimum.

i. Item 8: Safety Instruction for Individuals Working in or Frequenting Restricted Areas. Form 313 needs to be clarified in regard to what is required for submittal. It is not clear what the intent is of the 'N/A' for this item on page C-10. Suggest inserting the language from page C-13 Item 10 Audit Program.
ii. Item 9. Facility Diagram. In light of September 11,2001, NRC should reconsider the public availability of the type of information required in the suggested response. Additionally, there is no justification in the regulation for the prescriptiveness of this information.
iii. Item 9. Radiation Monitoring Instruments. 10 CFR Part 35 does not require that a licensee specify 'The instrument type, sensitivity, and range for each type of radiation detected ...' as indicated in the first bullet of the Response from Applicant. This provision should be revised to reflect the current regulation.
iv. Item 9. Dose Calibrator and Other Dosage Measuring Equipment. There is no regulation that requires a backup dose calibrator. A facility could switch to unit doses. Secondly, there is no requirement that the person performing the calibration be authorized by the NRC or an Agreement State.

v. Item 9. Other Equipment and Facilities. There is no requirement that private rooms be used for unsealed source therapy treatments. In addition the level of detail requested seems unnecessary.
vi. Item 10. Audit Program. Suggest inserting the text under the suggested response on page C.10, Item 8 and deleting the existing text.
vii. Item 10. Occupational Dose. There is no requirement to submit the 'facilities and equipment used for monitoring occupational doses.'
viii. Item 10. Minimization of Contamination. The level of detail is unwarranted. There is no regulation requiring a description of how the facility's design and the operation procedures facilitate decommissioning." (L14)

Response:

Many of the comments appearing above deal with topics that were discussed in the corresponding Sections of the guidance that make reference to Appendix C (and new Appendix F). Table C.3 was edited to make the guidance internally consistent. This applies in particular to comments iii, vii and viii. The respective sections of the guidance were edited, as needed, to make them consistent with regulatory requirements and to remove overly prescriptive requirements.

With respect to comment i, the staff believes that "N/A" is adequately explained as "Not Applicable" in the introduction to Table C.1. The sample license application in Appendix E provides illustrations of the use of N/A on pages E-2, E-3, E-4, and E-8 through E-11.

The staff NRC retained the request for information discussed under comments ii and v for the reasons discussed in response to comments on the section of the guidance dealing with "Facility Diagram" (See p. 2-18). The staff agrees with the assertion in comment v regarding private rooms in that10 CFR 35.315 (a)(1) refers to either a private room or a room shared with another individual who has received therapy with unsealed byproduct material. Therefore, the requirement to use private rooms for sealed source therapy procedures was removed from Table C.3.

The staff agrees with comment iv — that there is no requirement for backup dose calibrators — and modified the text accordingly. The description of qualifications for the person performing the calibration was modified to be consistent with regulatory requirements in 10 CFR Part 35 and the requirement that the person be authorized by the NRC or an Agreement State has been removed.

The changes suggested in comment vi were not made because the request to submit information about an audit program was deleted from the guidance. Table C.3 also was revised by deleting Item 8 because no response is required for this item.

Appendix D [Appendix G] Information Needed for Transfer of Control

No comments.

Appendix E [Deleted] Guidance on Financial Assurance Determination

No comments.

Appendix F [Appendix I] Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Comment:

"The last sentence of the Model Delegation of Authority on page F-2, which states: It is estimated that you will spend - hours per week conducting radiation protection activities should be deleted." (L14)

Response:

The staff does not agree that the sentence should be deleted. The staff's position is that management and the RSO should come to a mutual understanding of the approximate time required to perform the RSO functions. Otherwise, an individual, such as an authorized user, may be appointed RSO, but may not have sufficient time to devote to the duties of an RSO.

Appendix G [Appendix B] NRC Forms 313A and 313B

Comment:

Licensees and other stakeholders should be offered an opportunity to comment in writing on Form 313A. (T1) (T2)

Response:

NRC Forms 313A and 313B were combined into a new Form 313A. The revised form was made available on the NRC's web site during the 60-day comment period for this guidance that ended on June 4, 2002. It was also available to stakeholders for comment during the two public meetings conducted in April, as well as during a 60-day comment period related to the review of the form by the Office of Management and Budget (OMB) that ended on September 30, 2002. Several changes to the form were made in response to public comments.

Comment:

Form 313A could be misinterpreted to require data to be provided on classroom hours, etc. when the intent of the new Part 35 was to be less prescriptive. (T2)

Response:

Detailed instructions on how to fill out Form 313A are provided in a new appendix, Appendix D, that has been added to Volume 9. The staff expects that this guidance will enable applicants to fill out the form without misinterpreting its requirements.

Comment:

"This section should be redrafted to reflect that the existing Subpart J is valid for a two-year transition period. Specific comments on NRC Form 313A will be provided in response to the Office of Management and Budget request for comments. At a minimum the form should indicate that medical physicists are licensed in some states." (L14)

Response:

The staff agrees with the comment pertaining to Subpart J. The text preceding Form 313A in Appendix G of the March 2002 draft has been removed in the revised Appendix B where the form is located. A new appendix, Appendix D, has been added to the guidance explaining how to fill out Form 313A. This appendix references Subpart J and explains how applicants seeking to demonstrate training and experience satisfying the requirements under Subpart J should fill out Form 313A.

The staff included a section in Appendix D discussing how an experienced authorized user, authorized medical physicist, authorized nuclear pharmacist, or radiation safety officer could document the required training and experience.

A discussion of licensure of medical physicists by States was not included in the guidance because it is not relevant to NRC licensing and authorization of medical pharmacists under 10 CFR Part 35.

Comment:

Participants in the public workshops asserted that Form 313A is overly complex and confusing, especially for cardiologists who are applying to be authorized user or who are serving as preceptors. "The cardiology community's most important issue relates to Page 1, number 4. This portion of the document makes it appear that the 200-hour didactic course requirement is still in place. It would be nearly impossible to give the information NRC asks for in this section without a didactic course. The blocks on location, clock hours, and dates of training should be eliminated in favor of one block that the preceptor may check labeled 'requirement satisfied.' Also a parenthetical phrase should be added to 'OTHER' indicating that it is not applicable for diagnostic authorized user candidates." (L4)

Response:

The staff has developed the form to be used by applicants for all types of uses. The purpose of the detailed instructions in Appendix D is to ensure that applicants understand what types of information must be provided in order for the NRC staff to determine that requirements of 10 CFR Part 35 have been met before issuing a license. Use of a check-off item to indicate the requirement was satisfied would not provide sufficient information to enable the NRC staff to make the determinations necessary to issue a license or grant authorizations. The various blocks appearing on the form to describe type of training correspond to the requirements in 10 CFR Part 35. Discussion of "didactic training" was added in new Appendix D, Item IV, to indicate that various combinations of types of training may be used to satisfy training and experience

requirements. There is, however, no requirement to have 200 hours of didactic training. The suggestion to qualify the "OTHER" block under description of training was not adopted because it is clear that this block would have an entry only when it would be necessary to adequately document training and experience of applicants.

Comment:

"Other suggestions include the following:

- Page one, Part 1, number 1: perhaps other e.g., examples could be used such as those applying for an authorized user license;
- Number 2 add 'to practice' after licensed to clarify that the question refers to a medical license or allied health professional license;
- Number 3: it is unclear what is meant by category
- Page two, number 5b: add, 'therapeutic only' after Supervised Clinical Case Experience.

These changes will help to alleviate confusion, particularly for those applying for a diagnostic authorized user license." (L4)

Response:

Appendix D now includes examples of how applicants for authorized user may fill out NRC Form 313. NRC staff is of the view that it is not necessary to add "to practice" after "licensed" in block 2 of the form to clarify that the information being requested refers to a holder of a medical license or allied health professional license because the phrase "For Physicians, Podiatrists, Dentists, Pharmacists" is sufficient. The term "category" was retained in block 3 as being appropriate to designate the information needed. The illustrative examples appearing in Appendix D may help clarify this term. The instructions in Appendix D clarify that the term "category" refers to certification specialty or subspeciality if the board recognizes more than one certification specialty. Some specialty boards have multiple subspecialities such as board certifications by the American Osteopathic Board of Radiology in diagnostic radiology or radiology, or board certifications by the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology. The particular requirements for some subspecialities may not be sufficient to meet the training and experience requirements for another subspeciality. The suggestion to add "therapeutic only" to the title for block 5b was not adopted because information about supervised clinical case experience is necessary to document training and experience to qualify as an AU under provisions of 10 CFR 35, Subpart J for non-therapeutic applications of byproduct material, e.g., those falling under 10 CFR 35.100 and 10 CFR 35.200.

Comment:

Form 313A for reporting the experiential components contains errors and is confusing about how experience would be reported. The back page of 313A, item number 10 refers to "independently operat[ing] a nuclear pharmacy" but the regulations do not use this term. This wording should be "function as a nuclear pharmacist." (T1)

Response:

The staff does not agree that the form should be revised as requested by the commenter. An applicant seeking to be an authorized nuclear pharmacist could obtain either of two different preceptor statements. The preceptor statement under 10 CFR 35.55 should certify that the applicant has the necessary training and experience to "function as a nuclear pharmacist." The preceptor statement for authorization under 10 CFR Subpart J, § 35.980, should certify that the applicant can "independently operate a nuclear pharmacy. The note above Item 10 on Form 313A explains that the preceptor statement in Item 10 must be used for nuclear pharmacists meeting the requirements of Subpart J and that Item 11 is to be used for nuclear pharmacists meeting the requirements of 10 CFR 35.55 (as well as all other individuals for whom a preceptor statement is required).

Comment:

NRC should clarify who is the preceptor and who is the supervisor and why two attestations are required. Form 313A contains a new term that does not appear in the regulations, and requires two signatures at least. Item number nine now includes a supervising individual, but there is no definition of the supervising individual. The form says that this is a person who supervised the training and experience indicated above. Then on the next page is the preceptor approval and certification. (T1)

Response:

NRC defined the term "preceptor" in 10 CFR 35.2 as the individual "who provides or directs the training and experience required for an individual to become an authorized user, and authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer." The preceptor is responsible for certifying that the individual has achieved a level of competency sufficient to function as an AMP, ANP, AU, or RSO. Therefore, an applicant can have only one preceptor. An applicant may, however, have more than one supervisor, depending on the type of training and experience received. The training and experience requirements under both Subpart J and 10 CFR Part 35, as revised, specify that certain types of training and experience must be "supervised." Under Subpart J, for example, Section 35.900 requires an applicant for RSO to have had one year of experience "under the supervision" of an RSO or an authorized user. Under 10 CFR 35.290, work experience is required "under the supervision of an authorized user." If an applicant had more than one supervisor, all supervising individuals' names must be provided on Form 313A.

Comment:

Form 313A, Section 3, Certification: increase the size of the "specialty board" column to accommodate lengthy titles, and adjust the size of the month and year column to allow for larger "specialty board" column. (T1)

Response:

Applicants who need additional space to respond may use separate sheets that are attached to the form.

Appendix H [Appendix J] Model Training Program

Comment:

Refresher training should include topics with which the individual is not involved frequently and requires reaffirmation. Topics for refresher training need not contain review of procedures or basic knowledge that the trainee routinely uses and is familiar with. Many of the topics in the list provide no added benefit. Section 8.14 discussed above ties in with Appendix H. Many of these items are unnecessary and should be deleted. Change "will contain" to "may contain" in all the training sections. (T1)

Appendix H is too long. Much of the annual training that it lists is redundant. It needs to be emphasized that it includes a "shopping list" of what can be incorporated into the training program. (T2)

Response:

The staff agrees with the comment that refresher training can be structured to address procedures or knowledge that the trainee does not routinely use or with which the trainee is not already familiar. However, these subjects can vary from situation to situation. The staff added an introductory paragraph to Appendix J explaining that Appendix J is intended to be a set of examples of topics to be chosen from for training, based on the experience, duties, and previous training of trainees. The introduction also states that topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. The staff retained the material in this appendix because it has been found to be useful for a wide variety of applicants who have differing needs for training depending on the type and scope of their byproduct materials utilization programs.

Comment:

"The paragraph titled Model Training Program for Medical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources on page H-1 should be rewritten to state the following: 'Personnel will receive instruction, as appropriate, before assuming duties with, or in the vicinity of, radioactive materials, during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of instruction or training and the name(s) of the attendee(s) and instructor(s).'" (L 14)

Response:

The addition of the words "as appropriate," recommended by the commenter, would not change the meaning of the paragraph, because the paragraph does not specify the type of training to be given, only the circumstances in which training should be given.

Comment:

The paragraph titled Additional Training for Authorized Medical Physicists on page H-3 should be deleted, as it is not required by the regulation. (L14)

Response:

The paragraph referenced in the comment serves as a reminder that 10 CFR 35.51(b)(1) requires an AMP to have training and experience in the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, or 35.652 to have appropriate training and experience, as applicable. Therefore the paragraph was not deleted.

Appendix I [Appendix K] Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program

Comment:

"Due to the significant errors in this appendix that would result in many constraints that are unnecessary for assurance of proper calibration and function, the AAPM and ACR are committed to forming a Task Group to develop a model procedure to demonstrate the compliance with Part 35 requirements to address radiation monitoring instrument specifications for those described in the current Appendix I and model survey instrument calibration program requirements. AAPM and ACR request that NRC withdraw the current Appendix I from the draft and indicate that this appendix is being revised and will be published at a later date.

"Examples of problems in Appendix I are:

a. Under 'Equipment Selection' the emphasis is sensitivity/efficiency and totally disregards accuracy. This would lead one to believe that a meter equipped with a NaI(TI) probe is always the best choice. In NCRP No.112, the NCRP lists three uses of portable instruments - Detection/search, relative response, and exposure control. For the detection/search perhaps a NaI(TI) probe has the edge (although they are expensive, fragile, and at times too sensitive). However, for exposure control where the response priorities (in order of importance) are accuracy, precision, and sensitivity NaI(TI) is a poor choice because of its' energy dependence (worse that an end-window GM.) The discussion of selection should also include portable ion chambers and energy-compensated GM survey meters." (L14)

Response:

The staff welcomes the commitment by the AAPM and ACR to develop a model procedure for selection and calibration of survey instruments. Until such a model procedure has been developed, however, the staff believes that it will be helpful to applicants to continue to provide a model procedure in NUREG-1556, Volume 9. The introduction to the appendix emphasizes that applicants may either adopt the model procedure or adopt alternate procedures. Therefore, the staff does not agree that the appendix creates unnecessary constraints, because applicants are neither required to adopt the procedures in the appendix nor precluded from adopting alternative procedures.

The material provided on equipment is clearly only a limited summary of selected criteria, and NRC does not agree that it provides a misleading emphasis on NaI probes. In addition, Section 8.16, on radiation monitoring instruments, and Section 8.23, on area surveys, make it clear that applicants should consider a wide range of factors in selecting survey meters. The instruments listed under "Response from Applicant" for Section 8.16 provide guidance to applicants on the selection available.

Comment:

"b. Under 'Model Procedures for Calibrating Survey Instruments' Appendix I states 'one should use radioactive sealed source(s) that (among other things) - approximate the same energy (e.g., Cs-137, Co-60) as the environment in which the calibrated device will be employed.' The range of energies being detected/measured in a Nuclear Medicine imaging lab range from primary gamma energies of 30 to 364 keV (511 if you count PET) plus all the associated scattered photons. A single source cannot test the response of the meter over the range of energies found in clinical practice. Ideally energy independent or energy compensated meters would be employed. The licensee should be allowed to use factors determined by measurements at different energies or be allowed to use manufacturers or published energy response curves for the meter." (L14)

Response:

The staff agrees that a single source may not be sufficient to test meter response over the range of energies potentially found in the clinical practice of some applicants. The guidance therefore specifies that "sealed source(s)" should be used, in order to clarify that more than one source may be needed. In addition, as noted in the introduction to the appendix, alternatives to this model procedure for calibrating survey instruments may be adopted by applicants. Depending on the particular energies likely to be detected/measured in the applicant's facility, the applicant may describe one or more calibration sources in its procedures.

10 CFR 35.61(a)(1) specifies that a licensee shall "calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source." Use of manufacturer's or published energy response curves for the meter, as suggested by the commenter, may not satisfy the regulatory requirement.

Comment:

"Page I-3: This procedure allows for calibration of fewer than two points for each scale or decade, in the case of logarithmic or digital readout instruments, yet the regulations in 35.61 make no such exception." (L3)

Response:

The staff agrees with the comment. The model procedure was revised to call for calibration at two points on each scale for instruments with digital and logarithmic readouts.

Appendix J [Deleted] Model Procedures for Dose Calibrator Calibration

Comments:

Page J-l: "change 'Repair or replace the dose calibrator if there is an error of greater than 10% for the tests indicated' to 'Repair or replace the dose calibrator if there is an error of greater than 10% for constancy or accuracy tests; determine and use mathematical correction factors in situations where linearity or geometry effects exceed 10%.' This revision provides consistency with the wording on page K- 7, item A-4 regarding mathematical correction of dosage assays." (L2)

Page J-2, Constancy, # 4: "change 'Using one of the sources, repeat the above procedure for all commonly used radionuclide settings ...' to 'Perform tests in accordance with nationally recognized standards or the manufacturer's instructions' to be consistent with the wording in Appendix K, page K-7." (L2)

Page J-4: "add another section describing a model test for evaluation of geometry effects of different containers; for example, 'After determining the geometry effects for various volumes of a given radionuclide in standard glass vials and in plastic syringes, determine the geometry effects of the different containers by withdrawing various volumes (i.e., over the range of volumes to be used) from the standard glass vial into plastic syringes. For each volume, assay the standard glass vial before and after withdrawal and assay the syringe. Calculate correction factors by the following formula: Correction factor for contents in a plastic syringe = (assayed activity in vial before withdrawal - assayed activity in vial after withdrawal) + assayed activity in syringe. Repeat for each radionuclide to be used.'" (L2)

Page J-3: typo in the second sentence: "Some sleeves are to used sequentially." (L3)

"Page J-5, item 3 under Accuracy: Should require the recording of the current activity. Item 4: Should read 'if the test results to not agree, within +/- 10%, with the current activity of the reference sources.' The certified activity is only accurate on the day of calibration. Decayed activities must be determined by the licensee, and are not 'certified.'" (L3)

Rethink the model procedure, because linearity is an important test. [But] ... out of the four tests, it's the most difficult one to do ... [T]he primary reason why linearity fails, if there's really, truly a failure of linearity as opposed to operator measurement error, is loss of voltage to

the chamber. And on almost all those calibrators, there's a test button where you push it in, and it reads out 150 volts. If [you obtain that reading] you're pretty much assured that your linearity [is ok]. Just recommend to people [to] push that test button and see that you've got 150 volts on your dose calibrator. Drop the geometry test completely. (T2)

Since the rule states that manufacturer's specifications and nationally recognized standards can be used, this procedure would be needed only if licensees don't receive manufacturer's instructions when they purchase a dose calibrator. (T2)

Response:

The staff did not make revisions based on these comments because the appendix on "Model Procedures for Dose Calibrator Calibration" was deleted to avoid the appearance of setting a national standard and to leave manufacturers free to adopt appropriate recommendations for calibrations that are not tied to NRC guidance.

Appendix K [Appendix L] Suggested Medical Licensee Audit

Comment:

The commenter supports the concept of an audit list but considers the level of detail provided in Appendix K too extensive. (L14)

Response:

This appendix is not intended to provide a list of topics or level of detail that must be adopted by licensees. Instead, it provides suggestions for items that may be included in audits. A note at the beginning of the appendix indicates that all of the topics may not be applicable to every license and may not need to be addressed during each audit. NRC staff determined that retaining a detailed list of items to consider when planning an audit program would be useful to first-time licensees. NRC staff revised the title of the appendix to read, "Model Medical License Audit" and removed "suggested" from the title to better indicate that the information is provided to assist applicants and should not be construed as a minimum requirement.

Comment:

"See comments on Appendix C redraft. We suggest that a sample licensee audit be developed for each of the seven categories of use and combined with a sample application and license." (L14)

Appendix K should be redrafted to provide an example application, license and licensee audit program for each of the seven categories of medical use as specified on page 8-14. This would replace tables C.2. and C.3. Table C.l must be revised to reflect the final language of section 8. (T1)

Response:

The NRC staff concluded that adding several examples of model audits is unnecessary and that the material provided in the guidance is of sufficient breadth and detail to enable licensees to identify appropriate elements of an audit particular to their program.

Appendix L [Appendix M] Model Procedures for an Occupational Dose Program

Comment:

"NRC needs to apply risk-informed, performance-based paradigm to the implementation of 10 CFR Part 20. Examples of changes to this appendix are:

a. External Exposure. (Page L-4). The third paragraph should be rewritten to state: 'If an individual's dosimeter is lost, the licensee should evaluate the need to perform and document an evaluation of the dose the individual received and add it to the employee's record. This evaluation should be based on the employee's exposure history and that of co-workers performing similar functions. If the dose is not likely to approach the legal limit, then it might not be necessary to add the calculated exposure to the employee's dose record.'" (L14)

Response:

The staff disagrees that the calculated exposure could be ignored and not added to employee's dose record. In order to demonstrate compliance with 10 CFR 20.1201 an evaluation should be conducted to obtain the best estimate available of the dose the individual received, and that dose should be added to the employee's record. Therefore, the staff did not adopt the language suggested by the commenter.

Comment:

"b. Investigational Levels - External Dose Monitoring. (Pages L-4 - L-6) Suggest inserting as an introduction to Table L.l: 'The following investigation levels are not meant to be new dose limits. The intent of investigation levels is to serve as check points above which the results are considered sufficiently important to justify investigation.'" (L14)

Response:

The NRC staff agrees that it is useful to indicate that new exposure limits are not being set in model procedures. The first paragraph in the section on "Investigational Levels – External Dose Monitoring" now includes the following statement: "NRC has emphasized that the investigational levels in this program are not new dose limits but, as noted in ICRP Report 26, 'Recommendations of the International Commission on Radiological Protection,' investigational levels serve as check points above which the results are considered sufficiently important to justify investigation."

Comment:

One commenter suggested inserting the following on page L-6 between sentences two and three in the first paragraph: "Examples of situations which may require higher investigational levels are (but not limited to) nuclear medicine technologists who also perform positron emission tomography (PET) studies, radiologists who perform fluoroscopy in addition to being an AU, and personnel involved in a large manual brachytherapy program." (L14)

Response:

The NRC staff recognizes that workload factors may need to be considered in setting investigational levels. The staff also recognizes that licensees may find that the number of investigational levels appropriate for their activities may be one, two, or more. Licensees may wish to have investigational levels that are specific to a particular work activity to better identify areas for achieving a lower occupational exposure. Licensees may find the suggested investigational levels in the examples are either too high or too low for a particular work activity.

Comment:

The discussion of ALARA programs should be rewritten to clarify that the licensee has full discretion to select whatever investigation levels they want. (T1)

Response:

The introductory paragraph for the appendix states that applicants may adopt alternate procedures to those presented in the models. This statement applies to all topics covered in the appendix so no change was made to the discussion of ALARA programs.

Comment:

One commenter suggested the following rewrite be substituted for the third paragraph on page L-7:

"If a licensee determines that a program for performing thyroid uptake bioassay measurements is necessary, a program should be established. The program should include:

i. adequate equipment to perform bioassay measurements,

ii. procedures for calibrating the equipment, including factors necessary to convert counts per minute into becquerel or microcurie units,

iii. the technical problems commonly associated with performing thyroid bioassays (e.g., statistical accuracy, attenuation by neck tissue),

iv. the interval between bioassays,

v. action levels, and

vi. the actions to be taken at those levels.

For guidance on developing bioassay programs and determination of internal occupational dose and summation of occupational dose, refer to Regulatory Guide 8.9, Revision 1, 'Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program,' dated July 1993, Regulatory Guide 8.34, 'Monitoring Criteria and Methods to Calculate Occupational Radiation Doses,' dated July 1992, and NUREG-1400, 'Air Sampling in the Workplace,' dated September 1993." (L14)

Response:

The staff agrees with the comment and the text on pages M-6 to M-7 in the appendix on "Model Procedures for an Occupational Dose Program" was modified accordingly.

Comment:

Problems of perception may be caused by some of the investigational dose levels in Part L, even though the guidance says dose levels are not being added in. For example, if you are under 500 millirem you have to do nothing. There's an investigational level, too, of 30 percent of the 500 or 1,500, and if you are below the 1,500 you don't have to do anything, either. But if you are above the 1,500, you might have to do something unless you reestablish ALARA. (T2)

Response:

The suggested Investigation Levels are representative of what is commonly used, absent information that indicates that others may be more appropriate. The guidance on page M-4 states "a new, higher Investigational Level may be established for [an] individual or group on the basis that it is consistent with good ALARA practices. Justification for new Investigational Levels should be documented." The NRC staff believes that this is sufficient to indicate that alternative procedures may be adopted and that licensees are not tied to a particular value for setting Investigation Levels.

Appendix M [Deleted] Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Comment:

Appendix M is overly prescriptive. The only examples are from HDR units. If examples are given, use the approach followed in Part 20, which had a separate reference document outside the NUREG that provided Q & A's. (T2)

Include the recent Information Notice on waiting rooms, and the conflict between Part 35 and Part 20. (T2)

"Examples given are trivial and overly simplified. As presented, they minimize the professional expertise of the qualified individual making these determinations. New examples should be provided. The following are the items that should be considered in evaluating demonstration of public exposure dose:

- Volatile radioisotopes (e.g., xenon or iodine-131) - Discharges to the sanitary sewage system

- Demonstration of adequate facility design to maintain public exposure levels from nuclear pharmacies, therapy devices, patients having received therapeutic doses and are hospital bound, etc." (L14)

Response:

The staff concluded that the examples provided in the appendix were unnecessary and deleted overly prescriptive text. Although the appendix was deleted, useful information was retained by incorporating it into the text of Section 8.32, "Public Dose" of the guidance. A reference to Information Notice 94-09 was added to the text of the guidance in Section 8.32.

Appendix N [Appendix N] Emergency Procedures

Comment:

Appendix N is overly prescriptive. (T2)

Response:

The staff revised the guidance to state explicitly that the model procedures are provided for informational purposes and should not be construed as minimum requirements.

Comment:

"As written, the emergency procedures for this guidance are not appropriate since they only include a model procedure for teletherapy. Model emergency procedures should be developed as appropriate for the modalities licensed in accordance with 10 CFR § 35.600. Sample procedures may be adopted from the manufacturers' emergency procedures or professional national organizations for guidance." (L14)

Response:

The staff determined that it would not attempt to develop emergency procedures for all of the modalities licensed in accordance with 10 CFR 35.600, but that licensees should rely on the manufacturers' emergency procedures or guidance developed by professional associations. Therefore, the emergency procedures for teletherapy were removed from Appendix N. A reference to NCRP Report No. 111, "Developing Radiation Emergency Plans for Academic, Medical, and Industrial Facilities," was added to the appendix. This report provides helpful information for applicants. Finally, the title of the appendix was revised to make it clear that applicants may either use this appendix as a model or develop alternative procedures to meet the requirements of 10 CFR 20.1101.

Comment:

With respect to page N-2, the first sentence should read: "Assemble a spill kit that contains the following items, as appropriate:" (L14)

Response:

The staff revised the text referenced in the comment to indicate that a spill kit *may* contain the listed items.

Appendix O [Appendix O] Model Procedures for Ordering and Receiving Packages

No comments.

Appendix P [Appendix P] Model Procedure for Safely Opening Packages Containing Radioactive Material

Comment:

The first bullet on page P-l should reflect the regulatory language in 10 CFR § 71.87(i) for consistency. (L14)

Response:

The text in the bullet-list was revised to delete the detail referred to by the commenter.

Comment:

"Everywhere it states: 'notify the RSO immediately' should be changed to state: 'notify the RSO or appropriate supervisory personnel immediately.' The RSO may not always be on the premises." (L14)

Response:

The staff agrees with the comment. The text was revised to state: "notify the RSO or the designee of the RSO immediately . . . ." Similar changes were made elsewhere in the guidance.

Comment:

On page P1, the model procedure for safely opening packages, there's a statement about wiping and serving packages in excess of type "A" quantities. This is actually a Part 71 problem that's tied to a Part 20 problem that's carried over to Part 35. The guidance refers to an excess of type "A" quantities and it has 13.5 curies listed per moly. Although 13.5 curies is what's listed in Part 71, Title 49 of the DOT regulations really establishes the A2 values. For moly 99, the A2 value is 20 curies. So in Volume 9 that should say 20 curies of moly 99. (T2)

Response:

The Type A quantity for Mo-99 is 20 curies for domestic shipments and the text was modified to clarify this point (See 10 CFR 71, Table A-1, footnote c.).

Appendix Q [Appendix Q] Model Leak Test Program

Comment:

"Page Q-2: states that the records of leak tests will be kept in accordance with 35.2067. The suggested procedure states that the record is to include a description of the method used to measure each sample, yet the regulation in 35.2067 does not require this." (L3)

Response:

The introductory statement for this appendix indicates that the procedures are models and applicants may adopt alternative procedures. The text was also changed to be less prescriptive.

Appendix R [Appendix R] Model Procedure for Area Surveys

Comment:

"This appendix needs to be redone to reflect consistency of current scientific knowledge. The following illustrate typical problems with the current text." (L14)

"a. Ambient Radiation Levels - Bullet 3. There is no requirement for monthly surveys of laboratory areas, weekly surveys of use, storage, and waste areas, or quarterly surveys of source storage rooms. These items should be deleted." (L 14)

Response:

The survey frequencies provided in the appendix are not intended to be mandatory, and the staff agrees that there is no regulatory requirement that they be used. The introductory paragraph for Appendix R states that applicants "may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70."

Comment:

"b. Ambient Radiation Levels - Bullet 4. It is not necessary that the RSO be notified in all cases in which the trigger level is exceeded. Conceivably a nuclear medicine patient may happen to be sitting in a chair on the other side of a wall and a reading> 0.1 mrem/hr would result. In addition, an area may be restricted because an exposure rate greater than 5 mrem/hr may exist. Table R.1 does not have a regulatory basis, and would seem to create new rules." (L14)

Response:

The text relating to notification of the RSO was changed, as discussed in the response to the previous comment. In addition, the introduction to Appendix R alerts applicants that they "may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70." The introduction to Appendix R also states "Guidance for developing alternate trigger levels for contamination in restricted areas" is included in the appendix, and this statement clearly applies to the Ambient Dose Rate Trigger Level for restricted areas presented in Table R.1. Furthermore, the introduction to Table R.1 states that it provides "example trigger levels." Applicants should understand from these statements in the guidance that the levels in Table R.1 are not mandatory.

Comment:

"c. Contamination Surveys. The regulatory basis for this section is unclear. This section needs to be re-written to demonstrate compliance with the new 10 CFR Part 35 rule." (L14)

Response:

The regulatory basis for conducting surveys is established in 10 CFR 35.70, 10 CFR 20.1101, and 10 CFR 20.1501. As discussed above, the procedures for contamination surveys contained in Appendix R are not mandatory, and applicants may adopt alternatives. Changes were also made to Appendix R to make it less prescriptive.

Comment:

Commenters expressed concern that Appendix R contains requirements that were explicitly excluded from the new Part 35. They argued that Appendix R goes beyond both Part 35 and Part 20. Specifically, the appendix ignores numerous guidance documents that recommend decontamination in areas of tens of thousands of dpm per hundred square centimeters, and the guidance still requires 200 dpm for a patient room. Appendix R also ignores NRC's own example of releasing a patient with 150 or 200 millicuries going home and their home becomes contaminated. Additionally, the recommended surveys in Appendix R insert almost every provision that was removed from the rule. Appendix R should be deleted and rewritten starting with ANSI standard N13-12. (L3) (T1)

Commenters stated that in Table R.3 the 200 dpm/100 square centimeter removable contamination limit for I-131 is too low and should be increased. The limit in this table was not based on the potential for radiation dose due to the residual contamination. (L10) (T2)

A commenter at the workshop on guidance for diagnostic use of byproduct material argued that one of the most obvious disconnects between the revised rule and the current guidance occurs in Appendix R, that is, Model Procedures for Survey, with regard to both ambient and wipe tests. According to the commenter, the old Part 35 had things like the 200 dpm removal contamination limit, but that has been removed from the revised Part 35. According to the commenter, Part 20 is a little more open and just talks about surveys and monitoring that you have to do that's reasonable, etcetera. But in Appendix R, put back is the 200 dpm removal

contamination limit, among a lot of other things that Part 35 takes out, that one could say is not even in keeping with Part 20. (T2)

One commenter attached an article from which the following is excerpted: "The release criteria in 10 CFR 35.75 and room decontamination guidance in NUREG-1556 are inconsistent. . . . The proposed revision to 10 CFR 35 removes the limits on removable contamination levels in 35.315. This should be a welcome change for licensees, since decontaminating areas to below 200 dpm/100cm^2 can be a challenge. Although it is proposed that this requirement is removed from the regulations, the NRC has apparently chosen to retain this decontamination level for I-131 and other isotopes as guidance in draft NUREG-1556V9 table R3. . . . While it is commendable that NRC is finally removing the requirement to decontaminate to unreasonable levels, they are doing a disservice to many radiation safety personnel, by retaining the unreasonable levels as guidance. In the field of medical health physics, particularly, many of the people with radiation safety duties are neither devoted full time to those duties, nor are they health physicists. Faced with the choice of writing a procedure or accepting official NRC guidance, many of them will accept the guidance which in this case is unreasonably restrictive." (L11[1])

Response:

As discussed previously, the introduction to Appendix R states clearly that applicants "may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 20.1101, 10 CFR 20.1501, and 10 CFR 35.70." Appendix R has been revised to add guidance for developing alternate trigger levels for contamination in restricted areas, and the introduction draws the attention of applicants to the possibility of developing alternate trigger levels.

The commenters' discussion of trigger levels related both to surveys of radiation levels and to surveys for control of contamination. The approaches recommended for both of these categories of surveys are based on current, commonly accepted practices referenced in Appendix R. These practices are not specific to licensees under 10 CFR Part 35, but are followed by licensees for other uses of byproduct material.

The NRC staff notes that the trigger levels provided in Table R.1 for ambient dose rates are commonly used and have been found useful for maintaining doses at ALARA levels. However, the values appearing in Table R.1 are not intended to be regulatory limits, and licensees may develop other trigger levels.

[1] Vernig, Peter and Miron, David, *In Search of Reasonable Room Decontamination Guidance,* RSO Magazine, pp.13-14, July/August 2000. Comment L10 also cited this article.

The NRC is conducting an ongoing review of its approach for control of solid materials, including trigger levels. In particular, on October 25, 2002, in SRM-SECY-02-0133[2], the Commission directed the NRC staff to initiate an enhanced participatory rulemaking on the control of solid materials.

The recommendations appearing in Appendix R are based on current, commonly accepted practice such as that appearing in RG 1.86, "Termination of Operating Licenses for Nuclear Reactors" (June 1974). This guidance will continue to be in effect during the rulemaking directed in SRM-SECY-02-0133. This rulemaking will, in part, examine other issues raised by stakeholders in comments on NUREG-1556, Volume 9. The Commission directed the staff to consider implementing or endorsing ANSI N13.12 as required under the National Technology Transfer Act. Appendix R was not rewritten using the ANSI N13.12 standard as a basis for the control and release of contaminated materials because the standard has not been adopted by the NRC.

Comment:

Workshop participants raised issues about the clarity of the language in describing the types of surveys needed to assess radiation levels and levels of contamination in Appendix R, pages R-1 through R-4. Participants also expressed concern about requiring surveys on an overly frequent basis. (T2)

Response:

Different frequencies for conducting different types of surveys, based on the experience of those who find these frequencies to be useful, are suggested in the guidance. However, as previously stated, the model procedures represent one acceptable method that may be used to demonstrate compliance with the regulatory requirements. Licensees may develop alternative procedures that meet regulatory requirements.

Appendix S [Appendix S] Procedures for Developing, Maintaining, and Implementing Written Directives

Comment:

One commenter suggested several separate changes to Appendix S:

"a. Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources - F. There is no regulatory requirement for independent checks of full calibration. This item should be deleted." (L14)

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[2] "SECY Papers" and Staff Requirement Memos (SRMs) are available at the NRC's web site, <<http://www.nrc.gov>> in the "Electronic Reading Room" in "Collection s of documents by type," "Commission Documents." SECY papers are issue papers that the NRC staff submits to the Commission to inform them about policy, rulemaking, and adjudicatory matters. SRMs serve to document decisions of the Commission on SECY paper and any related tasks assigned to the staff with the date due. See SECY-02-0133 and SRM-SECY-02-0133.

Response:

The staff revised the guidance to state explicitly that the model procedures are provided for informational purposes and should not be construed as minimum requirements.

Comment:

"b. Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources - G. The second sentence should be deleted. One does not necessarily measure the transmission through every block, bolus, and compensating filter material prior to use, nor after source replacement." (L14)

Response:

The staff agrees and deleted this material from the guidance.

Comment:

"c. Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources. This section would be better served if teletherapy, GSR, and remote afterloading were not lumped together." (L14)

Response:

The staff concluded that it was appropriate to address the material in this section in a single set of procedures in order to avoid undue repetition and duplication. The staff recognizes that applicants with different modalities will need to identify all of the provisions that might be applicable to their modality. However, modality-specific material is identified in Appendix S.

Comment:

"d. 10 CFR § 35.41 does not require audits of patient cases in conflict with p. S-5. While audits are frequently useful program review tools, there is no requirement for the proscriptive QMP-like audit specified in S-5." (L14)

Response:

The staff agrees with the comment; the suggestion that audits be performed based on statistically selected samples was deleted from the guidance.

Comment:

The provision regarding compliance with technical quality assurance procedures for photon-emitting devices in 35.600 states that 35.441 requires audits for samples and that licensees must have an audit procedure. This provision has no regulatory basis in the new Part 35. (T2)

Response:

The discussion in this section has been revised to make it less prescriptive. The introductory paragraph to this appendix also indicates that the procedures provided are models and that applicants may develop their own procedures.

Appendix T [Appendix T] Model Procedures for Safe Use of Licensed Material

Comment:

"The fourth procedural item advocates the use of 'syringe shields for reconstitution of radiopharmaceutical kits and administration of radiopharmaceuticals to patients, except when their use is contraindicated (e.g., recessed vein, infants). In these exceptional cases, use other protective methods, such as remote delivery of the dose (e.g., use a butterfly needle).' The use of syringe shields is certainly a wise precaution to reduce exposure when drawing doses from prepared kits. However, the continued assertion that syringe shields are to be used in all cases (except where contraindicated by recessed veins or age) fails to take into consideration that most modern nuclear medicine department utilize single unit, pre-prepared doses of radiopharmaceuticals provided by commercial pharmacies. No distinction is being made between the differences in both time and geometry when cradling a syringe being drawn from a radioactive vial versus holding a syringe pre-prepared for injection." (L7)

"The continued requirement of syringe shields in almost all situations is also contrary to the NRC's stated goal of *placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. This approach is intended to be less prescriptive and allow for the implementation by the licensees that may be specific to their needs while meeting regulatory requirements*. A more performance-based approach would be to require syringe shields only when drawing doses from radioactive kits. For single unit, pre-prepared doses of radiopharmaceuticals supplied by a commercial nuclear pharmacy, the RSO should have the discretion to compare extremity exposures to Level I and II ALARA action limits and specify syringe shield use accordingly. Under the current regulations, the RSO has the discretion to eliminate extremity monitoring altogether, if the exposures received are less than 10% of the occupational limit. Yet there is little latitude in the use of syringe shields, despite low extremity exposures." (Emphasis in original) (L7)

Response:

As the Supplementary Information for the final rule indicates, use of syringe shields is not required by the revised rule:

> "Syringe or vial shields can be used to maintain exposures ALARA. However, we believe licensees should have flexibility to determine whether syringe or vial shields should be used. Thus, we have deleted the requirements to shield the syringe or vial. However, deletion of the requirement does not prohibit the licensee from using syringe or vial shields. When syringe shields or vial shields are used by a licensee, the final rule requires the licensee to label the shields, if the label on the syringe or vial is not visible." (67 FR 20297)

The guidance in Appendix T is consistent with this approach, and does not require the use of syringe shields. Instead, it is clearly stated in the guidance that "[t]his model provides acceptable procedures for safe use of unsealed licensed material. You may either adopt this model procedure or develop your own procedure." The NRC staff agrees that many factors, including those listed by the commenter, may need to be considered by licensees when developing procedures for use of syringe shields.

Comment:

"The syringe shield requirements recognize exceptions only for recessed veins or age. There appears to be no consideration given to the increased difficulty in performing an injection with a shield due to:

(1) the increased weight
(2) the additional manipulation time
(3) the change in angle of injection
(4) the reduced sensitivity for the technologist during the injection
(5) the difficulty using syringe shields with some injection apparatus.

The last item especially can be a source of spills during the injection process. Other facilities have also reported problems with syringe shields and injection apparatus. To illustrate these points, a review of one facility's syringe shield use with radiopharmaceuticals obtained from commercial nuclear pharmacies in a single unit, pre-packaged form is attached to the comment letter." (L7)

Response:

The guidance does not establish a requirement to use syringe shields. The factors listed by the commenter could be included by a licensee in a procedure addressing the use of syringe shields. Because Appendix T is a model, an applicant may adopt another procedure that better addresses its particular situation. As noted in the response to the previous comment, licensees have the flexibility to determine whether to use syringe shields. In making this decision, they should also consider the need to maintain exposures ALARA.

Comment:

Appendix T addresses only radiopharmaceuticals. It doesn't talk about devices, either therapeutic or diagnostic. (T2)

Response:

Other sections of the guidance, particularly portions of Section 8, address, in detail, topics such as radiation monitoring, occupational dose, accountability, facilities and equipment, shielding, and radiation surveys. These topics are pertinent to both therapeutic and diagnostic devices.

Comment:

"The tenth bullet on page T-1 is inconsistent with Appendix R." (L14)

Response:

The discussion after Table R.5 recommends a frequency of weekly for contamination surveys for the 'Medium' category listed in the table. The statement referenced by the commenter is consistent with this recommendation so no change was made. Note also that the procedures in both appendices are models and that applicants and licensees may develop and implement alternative frequencies for testing for contamination.

Comment:

Page T-2: "Requiring all of this information on each syringe is unreasonable, and conflicts with 35.69. In addition, recording of the nuclide should not be required if the radiopharmaceutical is already recorded. The date of calibration activity estimation is also useless unless the time is also recorded, but this procedure only requires labeling with the date. This procedure should be modified to match Part 35.69." (L3)

Response:

The appendix, which is a model, does not require the information discussed in the comment but reflects the broad range of information that might be placed on a syringe. Licensees, in developing their own procedures, can select the amount and type of information to include, provided that requirements of 10 CFR 35.69 and 20.1904 are met.

Comment:

"Page T-2: The last item on this page states that licensed materials must be secured if not under constant surveillance of an Authorized User. The reference to authorized users should be removed, or should be reworded to include individuals under their supervision." (L3)

Response:

The guidance was revised to state that the material should be secured when not under the surveillance and control "of an individual authorized under the NRC license (or such an individual's designee)."

Appendix U [Appendix U] Release of Patients or Human Research Subjects Administered Radioactive Materials

Comment:

General comment: "[T]his entire appendix is written too prescriptively. Example: page U-20 states 'an occupancy factor of 0.25 is not considered appropriate when . . . .' Suggest, 'Because of XYZ, occupancy factors of at least XXX are generally used when . . . .'" (L14)

Response:

The NRC staff reviewed the guidance to identify statements that could be considered prescriptive and revised them in accordance with the approach that the appendix is a model and is not mandatory. In particular, the text referenced in the comment was revised to indicate that the occupancy factor of 0.25 *may not* be appropriate.

Comment:

"The option to follow different guidelines in unique situation should be preserved. The language of B.1.2 ('The following occupancy factors may be used . . .') should be softened so the section does not read like a regulation." (L14)

Response:

The word "may" is permissive. Thus, the suggested change was not made.

Comment:

One commenter noted that Appendix U under Supplement B.3 - Internal Dose (page U-26) states that "internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose." In example 4, internal dose is divided by the permissible TEDE of 0.5 rem (rather than the calculated external dose) to arrive at 3%. However, in example 5, internal dose is divided by the calculated external dose (Thyroid Cancer) to arrive at "about 24%." The example then states, "thus, the internal dose and the external dose must be summed." The commenter argued that, when calculated this way, the percentage will always be 24% and it will always have to be added. The commenter therefore recommended the following changes: In example 4, reword the sentence to read "internal doses may be ignored in the calculations if they are likely to be less than 10% of the permissible dose of 5 millisievert (0.5 rem), because the internal dose would be significantly less than the uncertainty in the external dose." In example 5, the percentage should be calculated as in example 4 (i.e., divide by the permissible dose) and the example rewritten. If the licensee uses Equation B-6 to calculate internal dose and divides by the permissible TEDE of 0.5 rem, the 10% value will be reached at about 95 mCi. (L14)

Response:

The text referenced in the comment was revised to indicate that the basis for calculation of the external dose included the use of an occupancy factor of 0.25 (which results in an external dose of approximately 0.5 rem). The staff revised the text referenced in the comment to clarify that internal doses may be ignored in calculations of *total dose* if they are likely to be less than 10% of the external dose; because *incremental* dose *due to this source is small in comparison to* the *magnitude of* uncertainty in the external dose.

In Example 5, the ratio of internal dose to external dose, 0.24, is dependent upon the values of parameters used in equations B-5 and B-6. Since these parameters may vary, the ratio of the values calculated using the two equations will not necessarily be a constant. Therefore, no

change was made to the guidance relating to the assertion that "the percentage will always be 24%."

Comment:

"Using Equation B-5 with the appropriate values from Table U.6 to calculate external dose and adding the internal dose calculated using Equation B- 6, the permissible TEDE is reached at about 180 mCi. Thus, for those patients where an occupancy factor of 0.25 is appropriate (i.e., most patients), the common dosage of 200 mCi will require hospitalization."

"Equation B-6 yields 'a rough estimate of the maximum likely committed effective dose equivalent from internal exposure.' It was developed for 'worker intakes during normal workplace operations.' It is noted that 10-6 is the common rule of thumb for fractional uptake, but that 10-5 is used to add a degree of conservatism. If 10-6 were used in equation B-6, internal dose would not be an issue. Reference B-4 demonstrates that, in general, for the 39 subjects 10-6 is an appropriate factor. However, in reference B- 5, 10-5 is appropriate for half of the six hyperthyroid treatments. The two individuals with the highest uptakes in reference B-5 were 3 year and 4 months old. However, Equation B-6 uses a dose conversion factor of 53 rem/mCi. The EDE for a child (ICRP-53 - 15% thyroid uptake) can be over 4 times higher."

"An article quoted by the NRC does identify the dose from internal contamination as a potentially significant fraction on the permissible TEDE. However, for the one thyroid cancer example in the article, the internal contamination was approximately 10^{-7} of the release activity. In the late 1970s, patients receiving outpatient hyperthyroid dosages were typically given minimal precautions, whereas thyroid cancer patients were hospitalized for several days, released when their residual activity was below 30 mCi, and given extensive precautions. The article does therefore support (with limited data) the fact that providing proper instruction will significantly limit the internal dose to other individuals."

"Patients can be released from licensee control if the TEDE to any other individual 'is not likely' to exceed 5 mSv (0.5 rem). The individual likely to receive the highest dose is the patient's spouse. For a spouse, following proper precautions, both internal and external dose can be significantly reduced and the permissible TEDE is not likely to be exceeded. Recently published data demonstrate that using Equation B-5 to calculate external dose is conservative and that measured doses are typically significantly less. New data on internal contamination of individuals from patients released containing high activity I-131 radiopharmaceuticals is needed."

"Also, for children, following the proper precautions will significantly reduce their dose and extra precautions in the form of special instructions are warranted."

"Recommendation: Either eliminate the estimation of internal dose in the Appendix Q calculation of the TEDE with the stated assumption that following proper precautions will limit both external and internal dose and that internal dose is expected to be a small fraction of the external dose. Alternately, since internal dose is a defined part of the TEDE, modify B.3 – Internal Dose to use a fractional uptake of 10^{-6} and rewrite the text to emphasize the importance of proper instruction to keep the uptake at or below 10^{-6}." (L14)

"Section B.1.2 - Occupancy Factors to Consider for Patient-Specific Calculations should be rewritten to include additional instructions for families with small children in order to help assure that the external and internal dose is kept ALARA. The inclusion of enhanced guidance for small children would be an important improvement of Appendix U." (L14)

Response:

The staff agrees that providing proper instruction will limit the internal dose to other individuals and that it may be appropriate to modify assumptions about uptake when small children are in the family of patients discharged under provisions of 10 CFR 35.75. Therefore, the following text was added at the end of section B.1.1:

> "If information about a particular patient implies the assumptions were too conservative, licensees may consider case-specific conditions. Conversely, if young children are present in the household of the patient who is to be discharged, conservative assumptions about occupancy may be appropriate."

Appendix U also contains guidance suggesting that patients who have received byproduct materials should not hold or cuddle children. These factors, taken in combination, should be sufficient to compensate for uncertainties in the already conservative assumptions about uptake fractions for children and result in adequate protection of them.

The model procedures presented in Appendix U represent one way licensees may make assessments related to release of patients under 10 CFR 35.75. The additional information presented by the commenter is consistent with factors that licensees may wish to consider in developing their programs but the staff concluded that further modification of Appendix U is unnecessary.

Comment:

"Supplement B - Procedure for Calculating Doses Based on Patient-Specific Factors. This section states that release may be based on 'shielding by tissue' but does not have such a term in the equation. Recommend the inclusion of a multiplier B_p, where B_p is the patient specific shielding.

$$D(t) = 34.6\ G\ B_p\ Q_o\ T_p\ E\ (1- e^{-O.693\ t\ /Tp})\ /\ r^2$$

Note also in Equation B-1, T_p is written as T." (L14)

Response:

The staff believes that there is too much variability from subject to subject for the prediction of B_p values. Therefore, no change was made.

Comment:

"In Table U.l, pages U-5 and U-6, in Table U.2, pages U-8 and U-9, and in Table U.3, pages V-10 and V-11, delete accelerator/cyclotron radionuclides (e.g., Ga-67, In-111, I123, TI-201) because state regulations vary." (L2)

Response:

The footnotes for Tables U.1 to U.3 indicate that Agreement State regulations may vary and that the information about materials not regulated by the NRC is for the convenience of the licensee. Therefore, no change was made.

Appendix V [Appendix V] Guidance for Mobile Services

Comment:

The final bullet in the discussion of Mobile Medical Services With Remote Afterloader Devices discusses baseline surveys. The guidance suggests that the surveys include source housing with the source in the shielded position and all areas adjacent to the treatment room with the source in the treatment position. "This is reasonable as a baseline. However, the next sentence requires the baseline to be verified following relocation of the unit. This would require that a radiation survey would need to be performed about the treatment room (including roofs) at each site each day of use. This should be changed to require a survey of the source housing to demonstrate shielding integrity. Re-surveys of the treatment room should be performed following alterations of the treatment room, which would affect shielding. For class 2 and class 3 providers, most treatment rooms are shielded in concrete. It would be unreasonable to require a new survey of the room unless something has changed." (L14)

Response:

This section of the appendix has been revised to make it consistent with the body of NUREG-1556, Volume 9 and to require that licensees maintain doses within applicable limits.

Comment:

"Given the various nuances associated with mobile medical services, it would be worth consideration as a separate guidance and certainly part of any developed guidance directed at diagnostic use of radioactive materials." (L15)

Response:

Although separate guidance for mobile medical services might be useful, the NRC staff concluded that guidance on mobile medical services also should be retained in NUREG-1556, Volume 9 because of the number and extent of inquiries from applicants received on the topic.

Comment:

"a. Page V-1 indicates there are 'three types' of mobile service, but they list two different 'third types' for a total of four types." (L15)

Response:

See Responses to Comments on "Section 8.42 [Section 8.36] Item 10: Mobile Medical Service," in which there is discussion of deletion of "class 3" mobile medical service. Parallel revisions were made to the appendix on this topic.

Comment:

"b. Page V-3 indicates the section referring to the 'Client Site' is only for therapy. It is not clear if diagnostic use is prohibited, unregulated, or simply absent from the discussion. It goes on to indicate therapy sites must be listed by address." (L15)

Response:

Given that the referenced text relates "only to therapeutic uses of byproduct material," discussion of other modalities seems unnecessary and would not be relevant.

Comment:

"Diagnostic sites should also be listed if radioactive material is to be delivered to that site, as pharmacies are not authorized to deliver radioactive materials to sites not listed on a license." (L15)

Response:

The staff disagrees that delivery by a nuclear pharmacy should be covered by this discussion. The preparation and delivery of materials to a diagnostic site by a nuclear pharmacy is not regulated as mobile medical service. Discussion of a third class of mobile medical service was deleted from the guidance for this reason.

Comment:

"c. Page V-3 should mention the surveys that must be performed surrounding the vehicle to ensure exposures do not exceed 2.0 mrem in any one hour and 100 mrem in a year." (L15)

Response:

The staff agrees with the comment and added text regarding this requirement on page V-3.

Comment:

"d. Page V-4 does not mention that the source holders must be approved as DOT containers or that sources must be placed in approved containers prior to their transport." (L15)

Response:

The staff does not agree that a discussion of DOT requirements is necessary. However, a summary of DOT requirements most pertinent to medical licensees appears in Appendix Z. Mobile medical service providers should refer to appropriate DOT rules and guidance for information related to safe transportation of radioactive materials.

Comment:.

"e. Page V-4 indicates that each client must perform all the checks of the instruments. More accurately, the client is responsible for those checks. Those mobile service individuals may perform the checks and simply transfer paperwork to their client. Other sections of this guidance indicate equipment checks must be performed each day, not at each site. Consideration needs to be given to services provided to multiple sites in a single day." (L15)

Response:

The NRC staff agrees that different procedures are to be followed depending on what the mobile medical service provider and client are authorized to do under their respective licenses. The provider should be aware of what their clients are licensed to do as it relates to their responsibilities for compliance with NRC rules, on a site-by-site and client-by-client basis, if need be. Service providers should refer to the sections of the guidance that apply to the services they propose to provide in addition to the guidance provided in Section 8.36.

Comment:

"f. Page V-6 does not mention decontamination equipment maintained on board the vehicle. This information must be identified in a submittal per regulation." (L15)

Response:

In general, guidance on information that must be submitted by applicants for mobile medical services in accordance with 10 CFR Part 35 is the same as that which applies to other types of licensees. The guidance for mobile medical service providers is intended to reflect those regulatory requirements that apply specifically to them. The requirement for submitting information relating to safety procedures with an application is in § 35.12, which provides that applicants must submit procedures required by 10 CFR 35.610, 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645. Section 8.21 of the guidance reflects regulatory requirements that, before using materials under 10 CFR 35.600, the applicant must develop, document, submit, and implement written safety procedures for emergency response. Section 8.36 on Mobile Medical Service states that, in addition to 10 CFR 35.80 and 10 CFR 35.647, mobile medical service licensees must comply with all other applicable regulations and that applicants should "review

Sections 8.1 through 8.30" of NUREG-1556, Volume 9 for guidance that may apply to their particular use of byproduct material.

Comment:

"g. Page V-6 indicates predetermined calculations of exposure rates for an unshielded therapy source should be performed, yet, there is no mention of the same type of evaluation for any other diagnostic or reference sources. This appears to be inconsistent." (L15)

Response:

The NRC staff agrees that therapy sources are one of many potential sources of exposure that should be addressed as part of emergency procedures. Predetermined calculations of exposure rates from unshielded therapy sources as part of emergency procedures for mobile medical services are appropriate because of the risk associated with the high exposure rates that could occur with such sources. The dose rates associated with diagnostic or reference sources are generally much less than those associated with sources used in therapy, and therefore are substantially less likely to be high risk sources for which an advance evaluation involving calculation of exposure rates would be necessary. Hazards associated with use of byproduct material such as calibration sources are normally assessed as part of routine aspects of the radiation safety program.

Comment:

"h. Page V-7 does not mention any required hazardous materials training (per DOT) for transporting the sources. This should be added." (L15)

Response:

For the reasons discussed in response to comment d, above, licensees should refer to guidance and rules of the DOT. No change was made to guidance regarding hazardous materials training.

Appendix W [Appendix Z] DOT Requirements for Transportation

No comments.

Appendix X [Appendix W] Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return

Comment:

"Page X-1, Decay-in-Storage, last sentence (continued on page X-2): delete 'the radionuclides disposed' because this information is not required in 10 CFR 35.2092." (L2)

Response:

The staff agrees with the comment. The sentence was revised to say: "Record the disposal date, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the person who performed the disposal."

Appendix Y [Appendix H] NRC Form 314

No comments.

Appendix Z [Appendix BB, Part 3] Public Comments and NRC Responses on Draft

Comment:

Stakeholders suggested changes to NRC's comment response procedures. They argued that the 60-day comment period is too short to get feedback from multiple users about changes in the guidance document. Stakeholders prefer that this guidance be issued as an interim guidance so that the NRC's incorporation of comments received during the comment period can be evaluated prior to issuance of a final document. This suggestion also follows the idea that the guidance should be a living document that can be amended as users begin working under the new Part 35. (T1)

Response:

While the staff understands that 60 days is a short amount of time to assess the guidance and submit comments, the Commission is limited by the need to have the guidance "finalized" by the time the new 10 CFR Part 35 goes into effect. NRC will continue to accept and encourage feedback on the guidance as users begin implementing the new regulations.

Comment:

NRC should have formal guidelines that allow stakeholders to understand response criteria in terms of time. Currently, stakeholders find it difficult to get government agencies to respond and suggest that a formalized mechanism for NRC to receive and respond to additional stakeholder input after the comment period ends. The formal process for responding to stakeholders' comments outside of the comment period should be consistent throughout the regions. (T1)

Response:

The staff recognized that the time available for public involvement was limited but the NRC was constrained by the need to make guidance available before the effective date of revised 10 CFR Part 35 on October 24, 2002. Nevertheless, stakeholders were extensively involved in the development of the guidance, as described in the Abstract and Foreword of this document. See also the NRC web site at <<http://www.nrc.gov/public-involve.html>>. The process followed was consistent with NRC procedures for public involvement in the development of rules and guidance.

PART 3: COMMENTS AND RESPONSES ON 1998 DRAFT OF NUREG-1556, VOLUME 9 (formerly Appendix Z to Revised Draft Report for Comment, March 2002)

The following text was included in the March 2002 draft of NUREG-1556, Volume 9 as Appendix Z. It contains a summary of public comments on the Draft Report which was distributed for comment in 1998 and NRC staff responses to the comments.

Table Z.1 Comments Provided by the American College of Nuclear Physicians, California Chapter, Dated November 9 and December 2, 1998.

Location	Subject	Comment
Entire Document	Request that the Commission review the basis for the rule and guidance	At the public meeting on the Proposed Part 35 and NUREG-1556, Volume 9, a representative from SNM and ACNP put the following critical questions to the NRC Commissioners: • Apparent determination by the Commission that the Atomic Energy Act has misinterpreted for over 40 years and that in fact NRC has responsibility for controlling the practices of nuclear medicine and nuclear pharmacy in order to ensure "patient radiation safety." • NRC's newly found power apparently now extends to determining which radiopharmaceuticals are allowed to be given to patients, in what doses, and for what medical conditions, and extends as well to how the drugs are prepared. • NRC has now published in the *Federal Register* that it has the power to practice medicine and pharmacy in 50 states without a license and without seeing patients. • The Commission has determined that it cannot use concepts of relative risk in its risk assessment because it is forbidden to do so by the Atomic Energy Act. However, it is theoretically impossible to have a "risk informed" role in medicine if relative risk is not considered.
NRC Staff Response: The aforementioned comments appear to address the 10 CFR Part 35 Rule Text, which is not within the scope of this document. Additionally, NUREG-1556, Volume 9, makes no attempt to establish additional requirements for medical licensees.		

Location	Subject	Comment
Entire Document	Document ignores recommendations of the Institute of Medicine	All of these documents (NUREG-1556, Volumes 9 and 11 and the proposed revision of 10 CFR Part 35) ignore and fail to implement the recommendations in the report from the Institute of Medicine (IOM) of the National Academy of Sciences.
NRC Staff Response: The IOM recommendations concerned the regulation of the medical uses of byproduct, source, and special nuclear material. ACNP-CA's comment appears to apply to the proposed revision of 10 CFR Part 35 and not the guidance document, per se. NUREG-1556, Volume 9, is intended to provide guidance, not requirements, for medical licensees.		
Entire Document	Document is not risk related and performance based	The NRC promised that both the revised Part 35 and the NUREGs would be risk related and performance based. They are neither!
NRC Staff Response: We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 9 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections.		
Entire Document	Document reveals an increase in regulations and other requirements and increased costs	The NRC also stated that regulatory activity and costs would be decreased, but a review of the proposed Part 35 and the two latest NUREGs (NUREG-1556, Volumes 9 and 11) reveals an increase in regulations and other requirements and increased costs.
NRC Staff Response: We do not believe that NUREG-1556, Volume 9, reveals an increase in regulations, requirements, or costs. Volume 9 does not create any regulations. Also, since the NUREG was designed to reduce the amount of information submitted during the amendment and/or licensing process, the cost to the licensee should be reduced.		
Entire Document	NRC limited areas of public comment	The NRC had promised to have an open and unbiased review of these documents, but they again violated their trust by limiting the areas of public comment only to the questions unilaterally framed by the NRC.
NRC Staff Response: Public comment on NUREG-1556, Volume 9, was requested, and desired, in all areas. There was no limiting of the areas for public comment.		

Location	Subject	Comment
Entire Document	Insufficient comment period established by NRC	We and other organizations had requested a one year delay in order to permit time for an honest discourse between the NRC and interested parties in order to resolve these many important problems. Instead, I was recently informed that the NRC has extended the comment period for only one month. This is apparently not a month for discussion of outstanding problems, but merely another month to comment on these flawed documents. Again, we urge a one-year delay for a reconsideration of Part 35, as well as NUREG-1556, Volume 9.
NRC Staff Response: This comment appears to apply only to the proposed revision of Part 35 and not to NUREG-1556, Volume 9. NRC accepted comments on the draft NUREG until finalized approximately 2 years later. We, therefore, believe that the period available for comment was sufficient.		
Entire Document	Development of procedures	The Proposed Part 35 package restricts qualified nuclear medicine physicians from freely choosing among drugs for various patient conditions by limited procedure by procedure licensing.
NRC Staff Response: The comment appears to address the 10 CFR Part 35 Rule Text, which is not within the scope of this document. NUREG-1556, Volume 9, makes no attempt to establish additional requirements for medical licensees. The license restriction to a type of medical use for a given authorized user reflects the amount of training achieved by the authorized user. 10 CFR Part 35 mandates the amount of training required for each type of medical use.		
Appendix L	Model Procedures for an Occupational Dose Program	NRC's thyroid bioassay requirements for Na I-131 are outdated and unnecessary. All commercial products are stabilized against volatility, and have been so for over 10 years. NRC has been sent the full scientific database at least three times showing extremely low volatility. Why cannot NRC understand and use these data? In California, thyroid bioassay is not required when using stabilized products.
NRC Staff Response: The detailed procedures were replaced with a referral to the appropriate Regulatory Guides and NUREG that cover this subject in greater detail.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	Another example is limits, in dpm/100 cm^2 of removable contamination. First, the whole concept of numerical limits is flawed, and the old 2000 dpm/100 cm^2 for all radionuclides except I-131, which was 200, is already arbitrary and capricious. Only radiation absorbed dose matters. However, without a shred of scientific justification, NRC lowers the 2000 to 1000, keeps the 200 for I-131, and makes a limit of 20 dpm/100 cm^2 for I-125. Radiation absorbed dose from such levels of I-125 are absurdly minuscule. We do not even have equipment that can detect this. Background in a NaI (TI) system at the I-125 setting is commonly about 30 cpm, and in a typical liquid scintillation counter is about 35 cpm. Efficiency for a NaI (TI) bioassay system is about 1%.
NRC Staff Response: We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and the other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, since medical licensees do not normally use transuranics or unsealed I-129.		
Appendix X	Model Procedure for Waste Disposal by Decay-In-Storage, Generator Return, and Licensed Material Return	The requirement in Appendix X to remove the sharps from the sharps box to avoid any shielding is a massive OSHA violation. It could, for example, kill workers from hepatitis B or C, or AIDS.
NRC Staff Response: The model procedures provide acceptable procedures for waste disposal. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. However, the statement made in the NUREG is "because the waste will be surveyed with all shielding removed, the containers in which the waste will be disposed of must not provide any radiation shielding for the material." This would allow the sharps to remain within the sharps box, as long as the sharps box did not provide radiation shielding for the material. If this is not true, the licensee should consider another type of disposal container to use as a sharps box.		

Table Z.2 Comments Provided by the American College of Nuclear Physicians/Society of Nuclear Medicine, Dated December 16, 1998.

Location	Subject	Comment
Entire Document	Use of Professional Organizations to Develop Guidance	The NUREG includes numerous areas that cannot be understand or should not be included. Following are a few examples (among the many detected) of the problems with this NUREG and strongly recommend that NRC retract this document until such time that a workshop with stakeholders can be convened. The purpose of the workshop would be to go over the model procedures to determine which, if any, are necessary to maintain compliance with 10 CFR Part 20. Licensees, in order to make the licensing process as easy as possible, are likely to incorporate the model suggestions made by NRC. If these suggestions are incorrect, scientifically or medically flawed, then patient safety could be in jeopardy. The NRC should get out of providing model procedures as the benchmark for what they would accept. This only takes away the flexibility of licensees and leads them to accepting bad suggestions from the agency. If the licensee is incapable of operating a nuclear medicine department in compliance with the standards of 10 CFR part 20, without the NRC's model procedures, we suspect they are unqualified to be licensed. We reiterate that this NUREG should be retracted until such time that a workshop with stakeholders can be convened to go over the procedures to determine which, if any, are necessary to maintain compliance with part 20.
NRC Staff Response: NRC sought to develop the NUREG licensing guidance concurrently with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although there are drawbacks to this method, NRC believes that the benefits of this method outweigh the drawbacks. Additionally, we believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. The model procedures were developed using multiple references, including documents issued by ANSI, ICRP, NCRP, and AAPM. Additionally, we have incorporated several clarifications to these procedures based on specific comments supplied by stakeholders. We believe that licensees will find these model procedures useful when developing their own procedures.		

Location	Subject	Comment
Appendix C	License Application Checklist and Sample Licenses	Page C-11: At bottom of page, in box #9, in sentences A, B, and C, the NUREG refers to "procedure approved in 10 CFR 35.100" or 35.200, or 35.300. First of all the regulations do not refer to "procedures," but to "studies." Secondly, there is no NRC regulatory mechanism to approve any patient study. Does this mean that only specific procedures that are approved by NRC will be acceptable? We recommend that there be no restriction on the use of byproduct material for medical purposes as long as the authorized user meets the Training and Experience requirements of §§ 35.100, 35.200, and 35.300.
NRC Staff Response: The language found in License Condition 9 reflects the type of medical use requested by the licensee. The condition also relies on the training and experience attained by the authorized users and limits the types of use (e.g., 35.100, 35.200, etc.) to those for which the licensee has appropriately trained authorized users. However, we agree that the word "study" is used in 10 CFR 35.100 and 10 CFR 35.200, not "procedure," and we have revised the license condition accordingly.		
Appendix I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	Pages I-3, 4, and 5: By our account, and that of certified health physics professionals asked for opinions, an incomplete formula for determination of counting efficiency is provided. Additionally, the instructions are incomplete, and if followed as written could lead to gross underestimation of removable contamination in certain situations. This situation leads to our concern about other areas that seem incomplete.
NRC Staff Response: The efficiency calculation referenced in the NUREG is the absolute efficiency. This efficiency is dependent on the counting geometry. A notation to this effect was added to the discussion. Additionally, the calculation was revised to clarify that the true counts of the calibration source applies to the 2π emission rate from the calibration source. However, applicants are not required to implement the model procedure and may instead elect to use the intrinsic efficiency, which no longer includes the solid angle subtended by the detector and has much less of a dependence on the counting geometry.		

Location	Subject	Comment
Appendix N	Emergency Procedures	• Page N-3: The section entitled "Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides." Sentence #3 is the most obvious example of NRC's lack of knowledge of medical practice. Very few RSO's are properly trained to enter the operating room during a surgical procedure or are knowledgeable enough about surgery to tell a surgeon how to operate? • The title of this section is "Emergency Surgery." Based on our calculations, it is impossible for a surgeon or personnel to get enough radiation exposure from a patient during a procedure to warrant the statement. Surgeons have far more to worry about than some radiation exposure. They worry about infection and saving the patient's life. These flaws illustrate a pattern throughout the NUREG that places requirements that have not been reviewed into the regulations.

NRC Staff Response:

- Item 3 under "Emergency Surgery of Patients Who Have Received Therapeutic Amounts of Radionuclides" does not discuss the presence of the RSO in the operating room. The item states that "the RSO will direct personnel in methods to keep doses ALARA during surgical procedures." Therefore, this item does not require RSO presence within the operating room.

- The use of the phrase "emergency surgery" does not necessarily imply a radiation emergency. The emergency may be, for example, heart failure that results in open heart surgery.

Table Z.3 Comments Provided by the Cleveland Clinic Foundation, Dated December 4, 1998.

Location	Subject	Comment
Section 8.31	Use Records	Change "Prescribed dosage and activity at the time of determination, or a notation that the total activity is less than 1.1 mega-Bq (30 μCi)" to "Prescribed dosage and activity at the time of determination (unless already recorded in a clinical procedure manual, or on a dosage list of routine clinical procedures) or a notation that the total activity is less than 1.1 mega-Bq (30 μCi)."
NRC Staff Response: This comment appears to apply only to the proposed revision of 10 CFR Part 35, i.e., 10 CFR 35.2063, and not the guidance document.		

Table Z.4 Comments Provided by the Kettering Medical Center, Dated September 15, November 11 and December 4, 1998.

Location	Subject	Comment
Appendix L	Occupational Dose-Investigational Levels	• The investigational levels used in monitoring external exposures as listed in Table L.1 Investigational Levels (NUREG-1556) should be changed. Those levels do not reflect the current limits as defined in 10 CFR Part 20. Only the whole body level is correct in terms of current regulations. The extremities limits listed are too high and the skin of whole body is too low. Also, the lens of the eye should be separately listed to correctly reflect the current regulations. • Historically, the Investigational Levels I and II were 10% and 30% of the allowable annual dose limits in the Model ALARA program (Reg. Guide 10.8, rev. 2) for most medical programs. When those occupational dose limits were changed in 1994 with the revision of 10 CFR Part 20, many medical programs changed the Investigational Levels I and II to reflect the new regulations. In providing annual radiation safety instructions, I find that radiation workers can better relate to these investigational levels if these limits are expressed in terms of a percentage of the current allowable limits; therefore, I would propose the following revision to Table L.1, "Investigational Levels": – Investigational Level I (mrem per calendar quarter): whole body, head and trunk, active blood forming organs, gonads - 125; lens of eye - 375; and skin or any extremity - 1250 – Investigational Level II (mrem per calendar quarter): whole body, head and trunk, active blood forming organs, gonads - 375; lens of eye - 1125; skin or any extremity - 3750.
NRC Staff Response: Table L.1 is part of a model procedure and, therefore, not required. The model procedures provide acceptable procedures for an occupational dose program. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Nonetheless, we agree that Table L.1 should be revised to be consistent with Part 20 dose limits (e.g., the skin and extremity investigational levels should be the same, etc.). We used the following limits to revise the table: Investigation Level I when occupational dose reaches 10% of the annual limit and Investigational Level II at 30% of the annual limit.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Finally, we note that the new 10 CFR 35 eliminates many requirements for surveys (bioassays, Xe-133 traps, etc.). However, 10 CFR 20 still requires an active ALARA program. The effect is that the burden of proof is now on the users to demonstrate either that we do not need to make a particular survey or that we are making adequate surveys to ensure that no one is being exposed excessively. When we are inspected neither we nor the inspectors can merely appeal to the regulations. We must demonstrate to the inspector's satisfaction that we have an adequate ALARA program in place. We are concerned that this subtle distinction between parts 35 and 20 may be missed, especially in smaller institutions. We ask that the NRC, perhaps in the replacement of Reg Guide 10.8, make clear the requirements of 10 CFR part 20.
NRC Staff Response: The discussion of deletion of survey requirements from 10 CFR Part 35 can be found in the Statements of Consideration for the Rulemaking. With regard to guidance on the ALARA concept, please refer to Item 1.2 in the NUREG. This section describes the requirements in 10 CFR 20.1101 and references several documents that provide the NRC staff position on ALARA.		
N/A	Draft Regulatory Guide DG-0007	Draft Regulatory Guide DG-0007 was used to prepare a distribution license for F-18 fludeoxyglucose (FDG) for a clinical PET center. The guide was most useful. The guide and our application were well received by the State's Bureau of Radiation Protection. The NRC may or may not have had FDG in mind when the guide was prepared but it worked well for FDG. Its real worth is demonstrated by the fact that it isn't item specific and applies equally to byproduct as well as accelerator produced material.
NRC Staff Response: Draft Regulatory Guide DG-0007 has not been referenced in NUREG-1556, Volume 9, and therefore no response is necessary.		

Table Z.5 Comments Provided by the University of California, Los Angeles, Dated December 21, 1998.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	The "Acceptable Surface Contamination Levels in Unrestricted Areas" found in Table R.3 of draft NUREG-1556, Volume 9, are about 3-10,000 times more restrictive for the same radionuclide than for decommissioned licensees, which appear in Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination." These should be the same or less restrictive for medical licensees. Additionally, why is there not a constant factor rather than an enormous range of factors between the two tables. Please send the scientifically valid analysis upon which Table R.3 is based. If there is no analysis, and it seems highly likely that there is not, please remove this section from the NUREG.
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Table Z.6 Comments Provided by the University of California, Dated November 10, 1998.

Location	Subject	Comment
Entire Document	Use of Guide	• The new draft "Consolidated Guidance about Materials Licenses," NUREG-1556, Volume 9 is a well-developed guidance and resource document. However, it is extremely important that this be adopted as a "guide" and that the license reviewers be instructed to treat it as such. The licensees must not be asked, as the past practice, to either commit in following the "guide" or submitting alternate procedures. It should simply be a guide for those who need advice. • Most modern equipment has manufacturers recommended quality control testing which is superior to certain of procedures in the guide, which are now obsolete.
NRC Staff Response: • We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 9 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections. • More specific examples would be helpful. The model procedures were developed using multiple references, including documents issued by ANSI, ICRP, NCRP, and AAPM. Additionally, we have incorporated several clarifications to these procedures based on specific comments supplied by stakeholders.		

Location	Subject	Comment
Section 8.21	Radiation Protection Program	NRC form 313, included in Appendix B of NUREG-1556, Volume 9, is supposedly intended to eliminate the previous requirement for detailed procedures. Item 10, "Radiation Protection Program," however, amplifies the concerns regarding the Commission's continued request for detailed and prescriptive procedure. Draft NUREG-1556, Volume 9, page 78, requires the license[e] to submit information on the proposed radiation protection program to minimally include the following items (as applicable): Audit Program, Leak Tests, Operating and Emergency Procedures, Material Receipt and Accountability, Area Surveys, Occupational Dose, Public Dose, Transportation, Minimization of Contamination, Mobile Nuclear Medicine, Procedures for Administrations Requiring WDs. This appears a simple shifting of commitments from the previous format of a checklist to submitting the information as a text. It is not a change in philosophy as discussed during the San Francisco workshop (August 19-20, 1998), nor is it compatible with the written documents distributed by the Commission. It is business as usual, provide details as part of the license application and be held to it as part of the license, and deviations are either violations or need pre-approval, prescriptive rather than performance-based criteria. The only shift is now the licensee has to define the prescriptive details, which will be used, presumably this qualifies as non-Commission prescribed details. The Commission must move away from this degree of prescriptive licensing in "action" as well as in words. The Commission must define the criteria such as maximum permissible occupational doses, acceptable contamination levels, waste disposal criteria, etc. and allow the licensee to develop their own criteria internally to achieve the prescribed goals. To continue with asking detailed procedural submittal defeats the entire process defined even in the "risk informed" approach.
NRC Staff Response: Section 8.21, Item 10, states that the applicant/licensee should consider the following functional areas (Audit Program, Leak Tests, etc.). The section refers the applicant to Appendix C, which explains when detailed information must be submitted for a license. Of the 11 items discussed in the comment, only two require submitting detailed procedures. Many additional items require procedure development by the licensee without NRC review prior to licensing. Therefore, the licensee is given flexibility in developing and revising procedures.		

Table Z.7 Comments Provided by National Physics Consultants, Ltd, Dated November 12, 1998.

Location	Subject	Comment
Entire Document	Submission of Radiation Safety Procedures	Regarding the direction of the proposed changes, we agree with the goal to make Part 35 and the licensing process less prescriptive. Some of the current requirements in Regulatory Guide 10.8 are excessive for smaller facilities. A lot of time and effort has gone into complying with the more prescriptive requirements but resulted in no benefit to the radiation safety program. Further, the prescriptiveness prevented reasonable variations in the more minor procedures and record-keeping documents that have no real impact on the radiation safety program. Giving more latitude to the licensees in these areas is admirable. We agree that it is unnecessary to submit as many radiation safety procedures in the licensing process. A lot of time was unnecessarily spent arguing with license reviewers about minor details in these procedures. And a lot of facilities were required to accept procedural details that have no safety impact and are excessive for the particular facility. However, these details are considered necessary by the license reviewer simply because the detail is in the licensing guide and the reviewer is uncomfortable accepting alternatives. In general, we agree and support the changes from Regulatory Guide 10.8 that have been incorporated in this NUREG.
NRC Staff Response: No response necessary.		

Location	Subject	Comment
Section 8.16	Figure 8.8: Facility Diagram for Nuclear Medicine Suite	In Section 8.16, Facility Diagram, it is stated that the rooms used to confine patients for radiopharmaceutical therapy or manual brachytherapy treatments be included in the application. This is inappropriate for facilities that do not perform a lot of these procedures. Many facilities do not have a specified room for these therapies, but identify the room prior to each therapy. Further, in most facilities, including those facilities which have identified preferential rooms to be used, the rooms are not used exclusively for these therapies. There is sufficient guidance available on selecting rooms for these therapies and on assuring that radiation levels outside the room are within limits. The statement to submit diagrams of therapy rooms should be qualified to specify those rooms which are dedicated to these therapy procedures.
NRC Staff Response: General requirements for issuance of specific licenses, under 10 CFR 30.33(a)(2), state that an application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This requirement concerns licensing and is appropriate in consideration of health and safety concerns. The statement to submit diagrams of therapy rooms should be specific to those rooms that are dedicated to radiopharmaceutical therapy or manual brachytherapy procedures. Diagrams of rooms proposed for therapy treatments will be submitted at the initial time of licensing. If additional patient rooms are used in the future, room diagrams should only be submitted if the room design (including shielding) and occupancy of adjacent areas are significantly different from the original diagrams provided. The guidance in this area has been revised to reflect this change.		

Location	Subject	Comment
Section 8.17	Radiation Monitoring Instruments	In Section 8.17 it is stated that the response in an application is to include the type, sensitivity and range of the survey instruments. This is more than necessary and goes counter to the new direction of Part 35 and this regulatory guide. A commitment to possess survey meters adequate to meet the requirements of Part 35 and Part 20 should be sufficient. This is reflected in the discussion of the reason 35.220 is being deleted presented in the August 13, 1998 *Federal Register* publication of the proposed rule to revise Part 35. Further, we should not need to get into discussions with license reviewers over what is the better instrument to use. This should be evaluated by inspectors on site. Often, the choice of instrument is a matter of preference, not that one meter works and another does not work. In the current licensing process, we do not identify survey meters. It seems to us there should be less of a need to identify survey meters in the proposed licensing process. Also, there are recommendations for survey equipment in Appendix I of the NUREG. If necessary, these recommendations can be expanded. In the same paragraph it is stated that the response in an application is to include what is done when the survey instrument is being calibrated or repaired. This request should be eliminated. It is the licensees responsibility to have the necessary equipment available. The licensee should be able to make that decision at the time it is needed to be made. Situations change, equipment availability changes, and needs change. If I were to write a license application today and had to address this question, I would list every solution I could think of (rental, loaner, etc.) to give the facility options. So why ask the question. Again, this question is not asked in the current licensing process and it should certainly not be asked in the future.
NRC Staff Response: General requirements for issuance of specific licenses, under 10 CFR 30.33(a)(2) state that the application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This requirement concerns licensing and is appropriate in consideration of the health and safety concerns. It is, therefore, mandatory for an application to include a description of the characteristics of the survey instruments. Replacement of survey instruments with comparable survey instruments is discussed in Section 8.21, and does not require a license amendment.		

Location	Subject	Comment
Section 8.18	Dose Calibrator and other Dosage Measuring Equipment	In Section 8.18 it is stated that the response in an application is to include the make and model of the dose calibrator. This is unnecessary for the same reasons as stated above for survey instruments, but more so. The make and model is totally irrelevant. Again this paragraph also asks what will be done if the dose calibrator is being repaired, etc. This is an unnecessary question for the same reasons as stated above for survey instruments.
NRC Staff Response: General requirements for issuance of specific licenses, under 10 CFR 30.33(a)(2), state that the application will be approved if the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. This requirement concerns licensing and is appropriate in consideration of health and safety concerns. It is, therefore, mandatory for an application to include a description of the dose calibrator. Section 8.21 describes minor changes to the Radiation Protection Program and provides an example of replacement of instrumentation with comparable instrumentation, which does not require a license amendment.		
Section 8.23	Occupational Dose	In Section 8.23 film badges and TLDs are listed for personnel monitoring devices. Optically stimulated dosimeters should also be listed. Appendix L should also be so modified.
NRC Staff Response: It is not within the scope of this document to address specific manufacturers of personnel monitoring equipment. However, optically stimulated dosimeters have become increasingly popular among licensees. Optically stimulated dosimeters will be incorporated into Section 8.23 because the monitor is NVLAP-approved. The first sentence of the fifth paragraph under discussion has been revised to read "If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry, such as film badges, optically stimulated luminescence dosimeters (OSL) or thermoluminescent dosimeters (TLDs), that personnel will use." Additionally, the following revision was made to the first full paragraph on page L-3: "External dose is determined by using individual monitoring devices such as film badges, optically stimulated luminescence dosimeters (OSL), or thermoluminescent dosimeters (TLDs)."		

Location	Subject	Comment
Appendix I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	• In Appendix I a sodium iodide probe is recommended for detection of I-125, etc. A thin-window GM probe (pancake or thin end-window) is very adequate. The detection efficiency for thin-window GM's for I-125 is similar to that of scintillation probes. The additional cost of a NaI probe is not justified. A thin window will detect I-125 at a level sufficient to meet Part 20 requirements. Wipe testing can be used to evaluate removable contamination. The recommended equipment should include thin window GM's as acceptable. • Also in Appendix I, it is stated that, for medium to high energy gamma emitters, a GM is acceptable, but a NaI probe is preferred. While a NaI probe is more sensitive, it is more difficult to calibrate, more difficult to interpret results due to extreme energy dependence, more cumbersome to use, and more costly. After years of experience, it is clear that a GM is sufficiently sensitive to meet regulatory requirements. Again, removable contamination should be evaluated by wipe tests. We strongly request that the statement that NaI probes are preferred be removed.

NRC Staff Response:

- The third paragraph under Equipment Selection on I-1 has been changed to read "Low energy gamma emitters, such as I-125, can be detected with a sodium iodide (NaI) probe or a thin window GM probe (pancake or thin end-window). If the sodium iodide probe possesses a thin window and thin crystal, the detection efficiency is approximately 20%. If a pancake or thin end-window GM probe is used, the detection efficiency is significantly lower, and care should be taken to ensure that the GM probe is capable of detecting the trigger levels."

- The fourth paragraph under Equipment Selection on I-1 has been changed to read "Medium-to high-energy gamma emitters, such as I-131, can be detected with either GM or sodium iodide probes, depending on the required sensitivity. In general, the sensitivity of GM probes is much lower than for sodium iodide probes."

- Additionally, a table similar to that found in "The Health Physics & Radiological Health Handbook, Revised Edition, 1992" will be added to the NUREG to assist applicants in the proper selection of instruments.

Location	Subject	Comment
Appendix I	Radiation Monitoring Instrument Specifications and Model Survey Instrument Calibration Program	In Appendix I, it is suggested that well counters used for wipe test analysis and uptake probes used for bioassays have their efficiencies evaluated annually. The efficiency needs to be determined initially and occasionally as needed (such as after repair), but not on any specified frequency. More importantly, an energy calibration/check should be performed each day of use to correct for any gain shifts and a constancy check should be performed each day of use with a long lived source. Equipment on which the results of these two checks are satisfactory will not have a change of efficiency. Also, these checks assure the efficiency has not changed daily as opposed to annually. Please modify these sections. It is actually more important to periodically check energy resolution and chi-square, as these factors are sensitive indicators of equipment failure, are more likely to change than efficiency, and can have as great an effect on wipe test results as a change in efficiency.
NRC Staff Response: Because most well counters and uptake probes are of the NaI(Tl) variety, degradation of the crystal over time can dramatically effect the efficiency of the instrument. The model procedure provides for an annual efficiency determination. However, the licensee may adopt a different frequency as long as the instrumentation is calibrated periodically, in accordance with 10 CFR Part 20. Appropriately calibrated instrumentation is necessary for surveys, including: package wipe tests, bioassays, leak tests, and area contamination wipes. We agree that a daily check of the instrument is beneficial in identifying instrumentation problems early and have added this to the model procedure.		

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	In Appendix J: • Under constancy, there is a statement that "We will consider the use of two or more sources . . . " This statement should be removed. First, there is no physical reason to use two sources for constancy. It is a misconception that a second source is of value. After evaluating thousands of dose calibrators, we have never seen a case where a change in constancy has been seen with one source but not a second source. Also, as the statement says "We will consider . . . ", there is no requirement to do anything and the statement can be ignored. There is no value in the statement and it is often counterproductive. Facilities are occasionally put in the position to defend the use of only one source to inexperienced inspectors. • Under accuracy in Appendix J, there is the statement "We will consider using at least one reference source whose activity is within the range of activities normally assayed." The function inferred is provided in the linearity check. If there is a proven need for a source in this activity range, then the statement should be more definitive. Otherwise it should be removed. We would not recommend this higher activity source as it is of no value and only adds to costs.

NRC Staff Response:

- The Constancy paragraph on page J-1 has been changed to "Constancy means reproducibility in measuring a constant source over a long period of time. We will assay with a relatively long-lived dedicated check source such as Cs-137, Co-60, cobalt-57 (Co-57)[3], or radium-226 (Ra-226)[1] using a reproducible geometry each day before using the calibrator."

- The Accuracy paragraph on page J-5 has been revised to "Accuracy means that, for a given calibrated reference source, the indicated activity (e.g., mCi) value is equal to the activity value determined by NIST or by the supplier that has compared that source to a source that was calibrated by NIST, corrected for decay. Certified sources are available from NIST and from many radionuclide suppliers."

[3] Co-57 and Ra-226 are not subject to NRC licensing; the appropriate State agency should be consulted to determine requirements for possessing this material.

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	In Appendix J, under linearity, shield method, the methodology for data analysis is unduly complicated. The concept of determining the "equivalent decay time" of a sleeve is from Regulatory Guide 10.8. That view was the way the author of 10.8 looked at the sleeve method at that time. The more straightforward analysis with the sleeves is to simply determine the ratios of the readings between sleeves. If a sleeve reduces the reading by a factor of, say, 10 on day one, it should always reduce the reading by a factor of 10. Both suppliers of sleeve kits recommend a calculational method using ratios, not equivalent decay time. This is a much simpler technique. Also, the calculational method in Appendix J is incomplete. A couple of steps are missing.
NRC Staff Response: The model procedure was revised to ensure that the essential objectives of the manufacturer's guidance were incorporated. The ratio dependence statement was incorporated.		
Appendix L	Model Procedures for an Occupational Dose Program	The requirement for providing personnel dosimetry to minors and to declared pregnant workers must be increased to 0.1 rem. This was a recent change in Part 20.
NRC Staff Response: The appendix and Section 8.23 were revised to incorporate the changes in 10 CFR 20.1502.		
Appendix R	Model Procedure for Area Surveys	The acceptable removable surface contamination level in unrestricted areas for I-125 is stated at 20 dpm/100 cm^2 in Table R.3. This is an excessively low value. It is below most facilities MDA's for their counting equipment. There is no justification for this value to be so low. The ALI's (as a comparator) for I-125 and I-131 are nearly the same. We suggest the values for I-125 be set equal to the values for I-131.
NRC Staff Response: We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, since medical licensees do not normally use transuranics or unsealed I-129.		

Location	Subject	Comment
Appendix V	Guidance for Mobile Services	In Appendix V, page V-2, a statement is made that, for Class 2 mobile services, a description and diagram of the client site must be provided. This is inappropriate for diagnostic nuclear medicine procedures. For Class 2 nuclear medicine providers, the material is taken into the facility by the mobile service, used, and then all radioactive material, including waste, is removed. A survey is performed to assure no residual contamination remains. There is no need to list each site. Also, the sites to which services are provided are very variable. A requirement to list each site would be counterproductive to the benefits of a mobile service.
NRC Staff Response: The model procedures for mobile diagnostic service providers were revised to delete the requirement to submit facility diagrams. Section 8.42 was revised accordingly.		

Table Z.8 Comments Provided by the University of Cincinnati, Dated November 10, 1998.

Location	Subject	Comment
Entire Document	Term "shall" versus "could"	Items within the guidance that are required by regulation should be so noted by using the word "shall." Items within the guidance that are not required by regulations should be so noted by using the word "could."
NRC Staff Response: Excluding the model procedures, we exercised the philosophy that information required by regulation is designated by using the word "shall" and items that are not required are designated by using the word "should." The term "will" is used in the model procedures to avoid ambiguity so that the licensee's staff clearly understands what is required by the procedure (if the licensee adopts the model procedure). However, we noted that in some cases, outside of the model procedures, the terms were incorrectly used and we have corrected these in the final version of the document.		
Entire Document	Non-submittal of licensing information	Most of the recommended wording for license applications is very general, i.e., a statement by the applicant indicating agreement to comply with a specific regulation. Since this allows a licensee to modify the Radiation Safety Program in a more timely, and less expensive manner, we like this approach, with reservations. We are concerned that by not requiring the licensee to provide specific procedures inspectors will cite for errors or incidents, no matter how minor and how conceivable with foresight. If the NRC uniformly changes to a licensee oversight that is based on "consistent compliance with regulations (to provide) reasonable assurance that licensed activities will be conducted safely" (page 3-1 of NUREG-1556, Volume 9), the concern should be unfounded and/or known.
NRC Staff Response: This appears to be a comment on the inspection process and inspection procedures to be used by NRC in conjunction with the revised 10 CFR Part 35 and not the NUREG, per se. We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement.		
Section 4	Applicable Regulations	On page 4-1 the statement in the box about compliance with DOT regulations should include the fact that NRC requires compliance with DOT regulations whether the transportation is or is not done "in commerce." This distinction is often not understood and/or known.
NRC Staff Response: 10 CFR Part 71 requires that licensees who transport licensed material on public highways or who may offer such material to a carrier for transport comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. The regulation does not include an exemption for licensed material that is transported out of commerce, and therefore, no revision is necessary in the NUREG.		

Location	Subject	Comment
Section 7	License Fees	On page 7-1, the second paragraph talks about exemption from fees. Unless there are medical licensees who are exempted from fees, the mention of exemptions is not necessary.
NRC Staff Response: Most, but not all, NRC licensees are subject to fees. Therefore, the mention of exemptions in this section is applicable.		
Section 8.5	Radioactive Material	Page 8-6 indicates applicants must list the manufacture[r]'s name and model number for ALI brachytherapy sources to be used. For standard brachytherapy this is not practical. A recent order for I-125 seeds determined individual seeds and seeds on a ribbon had different model numbers, even though the seeds used were exactly the same. We suggest that licensees be allowed a more generic approval for standard brachytherapy sources.
NRC Staff Response: 10 CFR 30.32(g) states that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either: • Identify the source or device by manufacturer and model number as registered with the commission under 32.210 of this chapter or with an Agreement State; or • Contain the information identified in 32.210(c). The sealed source and device registry is catalogued according to the manufacturer's name and model number. Therefore, this information must be provided.		
Section 8.8	Purposes for Which Licensed Material will be Used	The NUREG states "unsealed byproduct material in therapy involves the administration of a radiopharmaceutical, . . . , to diagnose, treat or palliate a particular disease." The statement is either unclear or wrong. Written directive dosages may be used to diagnose disease; however, therapy dosages are not used to "diagnose" disease. The statement needs to be changed to apply to written directive dosages or the word "diagnose" needs to be removed.
NRC Staff Response: The word "diagnose" was deleted from text referring to unsealed byproduct material in therapy administrations.		
Section 8.9	Individual(s) Responsible for Radiation Safety Program and Their Training and Experience	On page 8-19, the last paragraph, the NUREG states, "Senior management should delegate to the RSO and, if applicable, the RSC in writing, sufficient authority . . . " Though not required by regulation, the University of Cincinnati believes this is a good requirement.
NRC Staff Response: No response necessary.		

Location	Subject	Comment
Section 8.26	Operating and Emergency Procedures	Criteria states "Before using licensed material, licensees must do the following: Develop, implement and maintain specific operating and emergency procedures." Maintaining the procedures should occur during use not before use.
NRC Staff Response: NUREG-1556, Volume 9, was revised to reflect the distinction.		
Sections 8.27-8.44	Phrase "No response is Necessary"	In some sections, e.g., Ordering and Receiving, Sealed Source Inventory and Safety Procedures, the NUREG indicates there is no response from the applicant for this item. Since there are regulatory requirements associated with the item and the NRC is addressing the item why is there "no response necessary"?
NRC Staff Response: 10 CFR 20.1906 does not require the licensee to develop procedures for ordering or receiving packages. Additionally, the various other sections that do not require a response are based on regulations that do not specifically require development of procedures. Therefore, no response by the applicant during the licensing process is required.		
Section 8.31	Use Records	• This Section does not agree with the regulations as drafted. Specifically, this document indicates radiopharmaceutical dosage records are required to include: the radionuclide, the generic name or its abbreviation or trade name, and the patient's or human research subject's name and identification number if one has been assigned. However, the drafted regulations require the radionuclide (or the generic name or its abbreviation or trade name) and the patient's or human research subject's name or identification number if one has been assigned. • Requirements for brachytherapy use records should be individually bulleted like the radiopharmaceutical records. This will help licensees ensure they do not miss a required item. • Though it may seem unquestionable, it may be useful to indicate that brachytherapy inventory numbers must add up (i.e., temporary implants totals before and after should be equal; permanent implant total before should equal used and returned).
NRC Staff Response: • The NUREG was revised to be consistent with 10 CFR 35.2063. • The brachytherapy record requirements are bulleted. • A note to ensure that sources "add up" was included.		

Location	Subject	Comment
Section 8.32	Leak tests	The first sentence on page 8-61 should make it clear that a contractor performing leak testing must be approved (or licensed) by the NRC or Agreement State.
NRC Staff Response: The NUREG was revised to include the statement that a contractor must be authorized by NRC or an Agreement State.		
Section 8.33	Area Surveys	The 5th bullet on page 8-62 indicates licensees should consider performing a radiation survey of the room of a patient undergoing temporary brachytherapy after implantation to look for a dislodged source. In most cases when the afterloading is done in the room this survey would be impossible due to the radiation being emitted from the patient.
NRC Staff Response: The suggested survey to ensure accountability does not have to be an ambient exposure rate survey with a survey instrument, but may instead include a visual check to ensure that a source has not been misplaced. This distinction was added.		
Section 8.35	Safe Use of Unsealed Licensed Material	On page 8-63, last paragraph, it is the quantity of volatile or potentially volatile radioactive material that needs to be assessed for air emissions, not the quantities of (all) radioactive materials.
NRC Staff Response: The NUREG was revised to reflect the change in the last paragraph, line 3 from "radioactive material" to "volatile or potentially volatile licensed material."		
Section 8.44	Waste Management	On page 8-82, why is such detail required for compaction of radioactive waste at medical institutions? Is there a regulation requiring this detail in an application? The compaction of radioactive waste, such as generated at a medical institution, has few, if any, safety issues beyond those encountered with the use of the material. Compactors do not make the radioactive material volatile and other types of airborne radioactive material from the compaction of medical institution are not probable.
NRC Staff Response: Compacting does not make radioactive material volatile, but volatile (and non-volatile, dispersible) materials can be released during compaction. 10 CFR 20.1101 requires a licensee to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. Subpart K of 10 CFR Part 20 includes waste disposal. Additionally, 10 CFR 30.33(a)(2) requires that an applicant's proposed equipment and facilities are adequate to protect health and minimize damage to life and property.		

Location	Subject	Comment
Section 8.44	Waste Management	• On page 8-83, the second paragraph, removal or obliteration of caution radioactive material is only required for radioactive waste that is disposed of in the regular trash after decay-in-storage. Removal or obliteration of the labels on waste that is to be disposed of as radioactive is not a good health physics practice, as it has the potential for unnecessarily increasing radiation exposure. The removal or obliteration of the label should be a guidance under "DIS" not a general guidance for waste disposal. • On page 8-83, the last paragraph, return to the vendor is not the only option for brachytherapy sources. They could be disposed of at a licensed LLRW site, at a significant cost, or transferred to another licensee.
NRC Staff Response: • The NUREG was changed to clarify that removing or obliterating labels from empty or adequately decayed containers going to non-radioactive trash must be done in accordance with 10 CFR 35.92 and 10 CFR 20.1904. • The language found in the NUREG allows for transfer of sources to an authorized recipient. Therefore, this does not limit the return of sources to the vendor.		
Appendix L	Model Procedures for an Occupational Dose Program	Since dose limits have been changed from quarterly to annual only, why weren't the recommendations for external (page L-4) ALARA investigational levels changed from quarterly to annual?
NRC Staff Response: We agree with this comment and have revised the guidance accordingly.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• There was not sufficient time to compare the contamination levels for unrestricted areas listed in appendix R of this guide with those listed in the guidance for unrestricted release during decommissioning. The levels should be comparable. • The contamination level for I-125 and I-129 in Table R.3 appears at first glance to be overly restrictive. The radiation risks from these radionuclides are more equivalent to the other isotopes of iodine than transuranics. In comparison, if the group listing on page R-6 is used, I-129 is significantly a lower hazard than the other isotopes of iodine. (Note: I-125 is not included in the group listing on page R-6; however, the University of Cincinnati would expect it to be included in group III or IV.)
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129. Also, I-125 was added to Group 2 in Table R.4, which is consistent with its ranking in the other tables of this appendix.		
Appendix W	Transportation	More detailed guidance for DOT is recommended. Some licensees unknowingly miss DOT requirements. Guidance that applies the regulations to situations commonly found with medical licensees, versus just listing applicable regulations, would be very beneficial.
NRC Staff Response: 10 CFR Part 71 requires that licensees who transport licensed material on public highways or who may offer such material to a carrier for transport, comply with the applicable requirements of the DOT that are found in 49 CFR Parts 170 through 189. To further assist licensees in locating transportation requirements, the following statement was added: "For additional transportation information, licensees may consult DOT's 'A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials' or contact the DOT, at http://www.dot.gov."		

Table Z.9 Comments Provided by Allegheny University Hospitals, Dated November 1, 1998.

Location	Subject	Comment
Appendix G	Documentation of Training and Experience	Remodeling needs to be accomplished of the Training and Experience Documentation forms in Appendix G. The term "clock hours" should only refer to the 80/40 required hours of training by the rule. Related radiation exam scores should probably read "name of approved radiation safety test passed" and scores should be reported only pass/fail. Point number 6 on "Formal Training" almost certainly relates to therapy. There should be separate forms for diagnostic documentation versus therapy documentation to keep the approach risk-based. NRC form 313B once again asks for "clock hours" of specific isotope use which is not a proposed requirement of the rule. The safety experience for diagnostic isotopes is similar and should be able to be extrapolated to all isotopes in 35.200.

NRC Staff Response:

- The term "didactic training" was revised to "classroom and laboratory training." Therefore, "clock hours," as used under item #4, refers to the hours spent in the classroom and laboratory.
- Because an exam component has been deleted from 10 CFR Part 35, documentation of the exam was deleted from the forms.
- Item #6 on NRC Form 313A applies to all 10 CFR 35.400 and 10 CFR 35.600 medical users. To clarify, a note to this effect was added.
- Form 313B documents the work experience, including the number of cases and hours spent involved in the cases, and therefore assists the licensee and the regulatory body in determining whether appropriate experience has been gained by the prospective user.

Table Z.10 Comments Provided by the American Society of Nuclear Cardiology, Dated November 12, 1998.

Location	Subject	Comment
Appendix G	Documentation of Training and Experience	Ministerial changes are necessary to NRC forms 313A and 313B: • "Clock hours" should clearly refer only to the required 120 hours of radiation safety training. • "Related radiation exam score" should read "Approved Radiation Safety Test Passed" and results should be reported pass/fail. • There should be separate forms for diagnostic versus therapy to match a risk-based approach. • Clarification of "organization approving program" is necessary. • Demonstration of individual isotope clock hours is not part of the rule. We assume the safety principles can be extrapolated to all isotopes in 35.200.

NRC Staff Response:

- The term "didactic training" was revised to "classroom and laboratory training." Therefore, "clock hours," as used under item #4, refers to the hours spent in the classroom and laboratory.
- Because an exam component has been deleted from 10 CFR Part 35, documentation of the exam was deleted from the forms.
- Because most items refer to both diagnostic and therapy prospective users, an additional form was not created.
- An example of the ACGME has been given for "organization approving program."
- Form 313B documents the work experience, including the number of cases and hours spent involved in the cases, and therefore assists the licensee and the regulatory body in determining if appropriate experience has been gained by the prospective user.

Table Z.11 Comments Provided by The Community Hospital, Undated.

Location	Subject	Comment
Entire Document	Issuance of NUREG in Final	The issuance of the NUREG before completing the revision of 10 CFR Part 35, is inappropriate.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrently with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of this method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflect the final regulatory requirements.		

Table Z.12 Comments Provided by Paul J. Early, Dated December 17, 1998.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	The 200 dpm/100 cm^2 wipe test requirement cannot be justified. Please refer to the calculations that were presented at the program in Rockville, MD by Dr. Carol Marcus.
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Table Z.13 Comments Provided by Robert Forrest, CHP, Dated November 11, 1998.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	I-125 is included with I-129 and transuranics in Table R.3, "Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm^2." Some justification for the inclusion of I-125 with transuranics should be given.
NRC Staff Response: We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		
Appendix U	Release of Patients or Human Research Subjects Administered Radioactive Materials	Example 2, Thyroid Cancer, in Supplement B to Appendix U shows a release calculation for the administration of 200 mCi of I-131 using the standard assumptions. In the example the patient is deemed releasable because the calculated dose to a member of the general public is 453 mrem and therefore less than the 500 mrem limit. This calculation does not include a contribution for internal dose which is shown in example 4, Internal Dose. This example states that internal doses may be ignored in the calculations if they are likely to be less than 10% of the external dose. In the 200 mCi dose example the dose from internal is 106 mrem which is 23.4 % of the dose from external. Because the internal is greater than 10% of the external, the internal should be included in the calculation. The patient receiving a 200 mCi dose would therefore not be releasable based on the standard assumptions. Either the example should be corrected or the internal requirement should be modified.
NRC Staff Response: We agree with this comment and have revised Example 2 to use 150 millicuries instead of 200 millicuries. According to the calculation, this would result in an estimated dose of 340 millirem. We have also added a fifth example on how to calculate internal dose that includes a calculation for the internal dose using 150 millicuries. This results in an internal dose estimate of 80 millirem, and therefore, a total dose of 420 millirem.		

Table Z.14 Comments Provided by the Health Physics Society, Dated December 14, 1998.

Location	Subject	Comment
Entire Document	Issuance of NUREG in Final	The issuance of the NUREG is inappropriate before completing the revision of 10 CFR Part 35.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrent with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.		

Table Z.15 Comments Provided by the Illinois Department of Nuclear Safety, Dated December 16, 1998.

Location	Subject	Comment
Section 8	Contents of an Application	• Section 35.12 of the proposed regulation requires a separate license application for each medical use of byproduct material. For your consideration, IDES allows a facility to submit one license application covering several uses of radioactive material, as long as such activity is under one management and one qualified RSO. This consolidates the licensing and inspection activities for a particular site, and allows licensees to submit one set of procedures for generic issues such as emergency notifications, waste handling, and receipt, use and transfer. • Section 8 of the medical NUREG contains information to be included in an application. It is unfortunate that the application form is not detailed enough for licensees to use as a checklist. For example, licensees could have the option to indicate the use of a model program presented in an appendix or develop their own procedure. Additional "check boxes" could be created for standard uses of radioactive material.
NRC Staff Response: • The comment appears to address the proposed 10 CFR 35.12 and not the NUREG, per se. However, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements. • A checklist was added to Appendix C as requested.		

Location	Subject	Comment
Entire Document	Section Numbering	Pages 8-6, 8-8 and 8-11 were confusing because they all have the heading "ITEM 5" yet cover three different subjects. The application form and page 8-6 match with "ITEM 5: RADIOACTIVE MATERIAL." Unfortunately, page 8-8 contains requirements for financial surety. This requirement should be in a separate location, and maybe even tied to a separate item on the application form. Page 8-11 addresses "ITEM 5: SEALED SOURCES AND DEVICES" which appears to be a subset of "ITEM 5: RADIOACTIVE MATERIAL" on the application form. Maybe if the sections were numbered as 8.5A and 8.5B, it would be clearer that Section 8 deals with the content of an application, the number after the decimal refers to the appropriate section of the application, and the alpha characters are subsections for those application sections. This same comment refers to the multiple ITEM 7s, 9s and 10s.
NRC Staff Response: The section numbering chosen reflects the numbering used in Volume 1 of the NUREG-1556 series. A key component of the numbering is the Item Number taken from the license application (NRC Form 313). Therefore, whenever "Item 5" is listed, the section refers to Item 5, "Radioactive Material," on NRC Form 313.		
Section 8.7	Sealed Sources and Devices	On page 8-11 of the NUREG, the Criteria for sealed sources and devices requires applicants to submit information, yet the Response from Applicant states, "No response is necessary." This should be changed to: "The applicant shall submit the information as described above." Consider a generic provision in the NUREG that would allow possession of any radionuclide in sealed form, provided that such source or source/device combination has been approved by the FDA for medical use, and has been evaluated by the NRC or an Agreement State and is listed in the Registry of Sealed Sources and Devices. The maximum activity would be limited by the amount authorized on the evaluation sheet.
NRC Staff Response: The response to Section 8.7 was revised to read: "If possession of sealed source(s) or device(s) is requested, the applicant shall submit the information as described above."		

Location	Subject	Comment
Section 8.14	Training for Individuals Working in or Frequenting Restricted Areas	On page 8-29, training requirements, the NUREG states that "All individuals working with or around licensed materials should receive training . . . " The paragraph continues to explain that in addition, if the individual is likely to receive doses over 1 mSv in a year, they must also have training as required by 10 CFR 19.12. Appendix H, however, states that personnel shall be instructed before starting duties around radioactive materials and during annual refresher training. This Appendix appears to be establishing a requirement different from those in the regulations. 10 CFR 19 appears to only require training if an individual is likely to receive doses in excess of 1 mSv, and does not mention refresher training requirements. The rules should be modified to specify the actual intent of the regulations, rather than try to clarify the intent through guidance.
NRC Staff Response: 10 CFR 19.12 requires training of individuals who work in the vicinity of licensed material and, in the course of employment, are likely to receive 100 millirem in a year. 10 CFR 35.27, 35.310, 35.410, and 35.610 require additional instruction for medical personnel. In addition, it is prudent for licensees to train all individuals involved with activities with licensed material, and therefore, we have included a suggestion that these individuals be trained (see Section 8.14). Appendix H of the NUREG provides a model training program that includes training for all personnel who work in the vicinity of radioactive materials. The model procedures provide acceptable procedures for training. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements, as applicable.		
Section 8.21	Radiation Protection Program	Item 10 on the application and the corresponding sections in the NUREG contain many instances where no response is necessary from a licensee, or a licensee must commit to developing and implementing certain procedures. Rather than require licensees to state that they will develop procedures, IDES intends to review those procedures as part of the licensing process. It is more important to ensure a licensee has adequate procedures in place before radioactive material is used, rather than discover during an inspection that there are significant problems due to inadequate procedures.
NRC Staff Response: In this NUREG, NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Appendix L contains information about bioassay programs. Specifically, Page L-7 states, "For each patient or human research subject receiving radiopharmaceutical therapy, the licensee should measure the thyroid burden of each individual who prepares or administers a dosage of iodine-131 NaI . . . " It is unclear why an applicant should develop an internal bioassay program for those cases where I-131 is used, because it is unlikely, even under typical accident conditions, that an individual would exceed 10% of the regulatory limits. 10 CFR 20 requires monitoring of intakes if individuals are likely to receive greater than 10% of the ALI. Years of data gathered by medical facilities have demonstrated that individuals are not likely to exceed 10% of the ALI. Appendix L should either address the kinds of documentation that NRC would want the facility to have should it decide not to perform bioassays, or mention the fact that there are circumstances for which licensees may not need to perform bioassays.
NRC Staff Response: The detailed procedures were replaced with a referral to the appropriate Regulatory Guides and NUREG that cover this subject in greater detail.		

Table Z.16 Comments Provided by Mallinckrodt, Inc., Dated December 16, 1998.

Location	Subject	Comment
Entire Document	Term "should" versus "must"	Guidance documents should be written to provide the licensee a suggested way to deal with the NRC regulations. For this reason the guidance document should contain suggested language such as "could" and "may." NUREG-1556 contains "must" language that implies that the guidance document must be followed in order for the licensee to be in compliance. Most experienced nuclear medicine departments have developed outstanding practices to deal with radiation safety, often times superior to what is being proposed in the guidance document. This should be allowed, and encouraged. NUREG-1556 needs to be revised to provide for suggested compliance methods rather than mandatory methods.
NRC Staff Response: Except in the model procedures, we exercised the philosophy that information required by regulation is designated by using the word "shall" and items that are not required are designated by using the word "should." The term "will" was used in the model procedures to avoid ambiguity so that the licensee's staff clearly understands what is required by the procedure (if the licensee adopts the model procedure). However, we noted that in some cases outside the model procedures, the terms were incorrectly used and have corrected this in the final version of the document.		

Table Z.17 Comments Provided by Mobile Testing, Dated October 10, 1998.

Location	Subject	Comment
Appendix C	License Application Checklist	Table C.1 is an especially helpful checklist. This should also improve the completeness of submitted license applications increasing overall efficiency of all parties.
NRC Staff Response: No response necessary.		
Appendix R	Model Procedure for Area Surveys	The increase in the acceptable surface contamination level from 2000 to 20000 dpm/100cm^2 for Tc99m is appropriate. Equipment availability and calibration at the proposed level will be improved as discovery of possible contamination is unchanged.
NRC Staff Response: No response necessary.		

Table Z.18 Comments Provided by the Nuclear Energy Institute, Dated December 16, 1998.

Location	Subject	Comment
Entire Document	Issuance of NUREG in Final	NEI has not commented on the NUREG at this time as this document is based on the proposed rule. Given the significant changes to the rule recommended by NEI, we do not believe it to be useful to comment on the Standard Review Plan until the NRC has considered our proposed changes to the rule.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrent with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.		

Table Z.19 Comments from Public Meetings on 10 CFR Part 35.

Location	Subject	Comment
Entire Document	Terms "should" and "could" versus "shall"	The concern with the guidance document is, so many times, guidance documents are taken to be requirements. The inspector may say your procedure doesn't follow with the guidance document, therefore they turn around and cite you. Words like "shall" can go either way. "Shall" could mean should or "shall" could mean could. A guidance document should be guidance and should be filled with language such as "could," not language of "shall" and "should."
NRC Staff Response: Except for in the model procedures, we exercised the philosophy that information required by regulation is designated by using the word "shall" and items that are not required are designated by using the word "should." The term "will" was used in the model procedures to avoid ambiguity so that the licensee's staff clearly understands what is required by the procedure (if the licensee adopts the model procedure). However, we noted that in some cases outside the model procedures, the terms were incorrectly used and corrected this in the final version of the document.		
Section 1	Purpose of Report	Clarify the word "guide" or "guidance" in the regulations. Also, dealing with other regulatory agencies, state or local agencies, these guides often become de facto regulations. We need to go further with the guidance document. Why are the procedures requirements to begin with? There is no valid reason for most of them. The smaller institution does require some guidelines, however the guidelines have been so prescriptive in the past that there's a lot of concern. An experienced nuclear medicine department knows how to write their own procedures, they know how to do things properly. They don't need a guidance document. Who needs a guidance document is a new department or a department that's adding nuclear medicine.
NRC Staff Response: This appears to be a comment on the inspection process and inspection procedures to be used by NRC in conjunction with the revised 10 CFR Part 35 and not the NUREG, per se. As stated in Section 1, "Purpose of Report," the report provides guidance to an applicant in preparing a medical use license application. Therefore, we believe that this guidance will be useful to all medical applicants/licensees.		

Location	Subject	Comment
Section 1	Purpose of Report	• In terms of whether any guidelines are needed, it would be better to have the guidelines but to have them developed by people who are more knowledgeable in the field – for example, by members of AMP, ABS, et cetera. Then better guidelines will follow. • The licensees are feeling that they're going to be forced into accepting the model procedures. The procedures are terrible and medically very bad. They, health physics-wise, have no validation. Some of them are dangerous and against regulations of other regulatory agencies. You have to ask whether you need these procedures at ALI. The development of a procedure and a policy for what a technologist should do if they don't understand something – that's ridiculous. If a technologist doesn't understand something, they ask. There doesn't need to be a policy and procedure development. Neither do we need policies and procedures for the decrease in generation of radioactive waste. We don't accept these prescriptive and unacceptable directions on how to do things. The bottom line is if there hasn't been a safety issue, what are you even bothering with? There is no problem if no one is getting overdosed, if Part 20 is okay? When you talk about a performance standard, you mean things are safe. You have replaced precise, prescriptive regulation with vague, prescriptive regulation and you are calling it a performance standard and it is not.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrent with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, we believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. The model procedures were developed using multiple references, including documents issued by ANSI, ICRP, NCRP, and AAPM. We have incorporated several clarifications to these procedures based on specific comments supplied by stakeholders. We believe that licensees will find these model procedures useful when developing their own procedures.		

Location	Subject	Comment
Section 1	Purpose of Report	• NRC is following through with their usual methodology, which involves the 90-day period for public comment, regardless of the magnitude of the rule. I would recommend that the NRC follow through with their procedures and publish something, but just not make it a final rule. I also think that the NRC would serve the licensed community very well if a draft license application review document that would accompany the rule was published. • As the rule is about to change with the incorporation of public comments, the NUREG document would no longer make sense in many respects and, therefore, another NUREG document along with the new proposed rule-making should be published.

NRC Staff Response:

- This comment appears to apply only to the proposed revision of 10 CFR Part 35 and not to NUREG-1556, Volume 9. NRC accepted comments on the draft NUREG until finalized approximately 2 years later. We, therefore, believe that the period available for comment was sufficient. With regard to the comment on publishing a draft license application review document along with the rule, NUREG-1556, Volume 9 is this document.

- Before the final NUREG was issued, references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.

Location	Subject	Comment
Appendix J	Model Procedures for Dose Calibrator Calibration	• If you look at geometry, there's three different types. NRC addresses only the volumetric geometry changes in their particular NUREG. • The one area where the volumetric changes (geometry requirement) in the NRC regulations fall short is the fact that they assume that correction factors, which may be measured and usually are measured with tech-99m, are applicable across the board to all isotopes, and that's incorrect.

NRC Staff Response:

- Appendix J states that geometry independence means that the indicated activity does not change with volume or configuration. The model procedure considers both volume and configuration.

- Most nuclear medicine dosages involve technetium-99m. Therefore, it is prudent to perform geometry independence tests with the most frequently used radionuclide. However, we agree that the NUREG should address the issue of evaluating geometry variance for gamma emitters with energies significantly different from technetium-99m and for beta emitters. Therefore, the NUREG was revised to reflect this distinction.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Here is another risk analysis example for the standard of 200 dpm per 100 cm^2 for maximum I-125 removable contamination. The model I chose was a situation where the maximum allowable was on the package, that 50 percent of what was on the package was transferred to a worker's hands, that 50 percent of what was on his hands was transferred to the lips, and everything on the lips was swallowed and that there is a high normal uptake to the thyroid gland. There is the reference for the calculations. The dose to the thyroid is two 1000th of a millirad, the effective dose equivalent 0.000058 millirem EDE. If you look at current radiation detectors that nuclear medicine people have in their labs; a thyroid uptake probe, which is also used as a bioassay probe, has about a one percent efficiency for I-125 and 35 counts per minute background at the I-125 peak, which means that you would be counting 0.2 counts per minute for the 35 count per minute background. You can't do that with any accuracy. Even if you use a liquid scintillation counter, and most nuclear medicine departments don't have that, you're still in trouble. It has a higher efficiency, but a 30 count per minute background is typical. The bottom line here is that the standard is scientifically absurd and is unattainable with present radiation detection instrumentation. • The above argument focuses on dpm at the removal down to 20 dpm per 100 cm^2, that in the guidance is admittedly absurd.
NRC Staff Response: Table I of *Federal Register* Volume 63, Number 222, Page 64134, "Acceptable License Termination Screening Values of Common Radionuclides for Building Surface Contamination" provides screening levels for specific radionuclides. This table does not include radionuclides traditionally used in medicine. We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Table Z.20 Comments Provided by the National Institutes of Health, Dated November and December, 1998.

- (The commenter provided comments which included marked-up text, as appears below. Additions suggested by the commenter appear in **bold**, text suggested for removal is rendered as ~~strike out~~ text.)

Location	Subject	Comment
Entire Document	Development of NUREG	In addition to our input on the proposed revision to Part 35, enclosed is a critique of NUREG-1556, Volume 9, "Program-Specific Guidance About Medical Use Licenses." In our opinion this NUREG was developed prematurely, since the Regulation had not yet been finalized. The content of the NUREG does not track with the proposed regulation and, in numerous areas, is not technically competent. The Commission should strongly consider withdrawing the NUREG until a proper job of Rulemaking is accomplished. The NUREG should then be developed with the assistance of stakeholders who have the expertise to advise the NRC how to develop appropriate risk based procedure recommendations.
NRC Staff Response: NRC sought to develop the licensing guidance NUREG concurrently with the proposed regulation in an effort to better serve the regulated community. This method allowed the regulated community to comment on the proposed rule and the proposed licensing guidance simultaneously. Although this method has its drawbacks, NRC believes that the benefits of the method outweigh the drawbacks. Additionally, before the final NUREG was issued, all references to 10 CFR Part 35 were reviewed to ensure that statements made in the NUREG reflected the final regulatory requirements.		

Location	Subject	Comment
Entire Document	Risk Analysis	Thank you for the extension of 34 days to develop additional comments on the 10 CFR Part 35 revision and its associated regulatory guidance, NUREG-1556, Volume 9. As has been stated in earlier comments out of this office, we believe that the revision of Part 35 is being rushed to completion without having performed the appropriate and essential comprehensive risk analysis of the activities proposed to be regulated. No where is the lack of the appropriate risk based methodology more apparent than in the implementation document, NUREG-1556, Volume 9. The guidelines, procedures and limits proposed in this document for the most part are NOT risk-based and are, in fact, inconsistent with the regulations of 10 CFR Part 20.
NRC Staff Response: We believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement. Because of this, the guidance in Volume 9 was designed to reduce the amount of detailed information that a licensee is required to submit to NRC for review during the licensing process. The adequacy of the licensee's procedures, implementation of the procedures, and the ability of the licensee through these procedures to meet specific performance indicators, will be evaluated during inspections.		
Section 8	Contents of an Application	Page 8-1, 2nd to last paragraph, change order: Short sentence responses, "NA" or "N" responses to Items 5 through 10 . . . should be changed to "NA, N, or short sentence responses to Items 5 through 10 . . . "
NRC Staff Response: The revision was made accordingly.		

Location	Subject	Comment
Section 8.6	Financial Assurance and Recordkeeping for Decommissioning	• Page 8-8, last paragraph: "where licensed material ~~is~~ was used or stored, ~~spills or spread of contamination~~ **any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread)** and leaking sealed sources ~~(see Figure 8.2)~~. • Delete reference to/and Figure 8.2. Figure 8.2 has no relevancy. • Page 8-9: The regulations given in 10 CFR 30.35 are very clear; much more so than the paraphrased comments on page 8-9. The requirements for financial assurance for unsealed vs sealed sources should be more clearly identified in this guide. Suggestion to add the following: "Most medical use applicants and licensees do not need to take action to comply with the financial assurance requirements because: a. either their total inventory of unsealed licensed material does not exceed the limits in 10 CFR 30.35 **(10E5 times the applicable quantities set forth in appendix B)**, or the half life of the unsealed byproduct material used does not exceed 120 days; or b. **If the total inventory of sealed sources does not exceed the limits in 10 CFR 30.35 (10E10 times the applicable quantities of appendix B). Examples are shown in Table 8.2.**

NRC Staff Response: The following response is provided in corresponding bullets to the comments.

- Revised to: "Even if no financial assurance is required, licensees are required under 10 CFR 30.35(g), to maintain records important to decommissioning in an identified location (see Figure 8.2). These records must, in part, identify all areas where licensed material is (or was) used or stored and any information relevant to spills (e.g., where contamination remains after cleanup procedures or when there is reasonable likelihood that contaminants may have spread) and leaking sealed sources."

- Figure 8.2 is relevant because it illustrates recordkeeping for compliance with 10 CFR 30.35(g).

- The existing wording provides accurate guidance for compliance with 10 CFR 30.35 and clearly states why most medical applicants and licensees need not take any action to comply with 10 CFR 30.35. Therefore, no revision is necessary.

Location	Subject	Comment
Section 8.6	Financial Assurance and Recordkeeping for Decommissioning	• Table headings in 10 CFR 30, Appendix B are incorrect. Page 8-10, 2nd paragraph: Table 8.2 is not all-inclusive without the changes indicated below; the licensee may be led to believe that the authorization is only for the three radionuclides listed in table 8.2. Recommended change: "NRC will authorize **sealed source** possession exceeding the limits **given in 10 Part 30.35 (d)** ~~shown in Table 8.2~~ without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange for no more than 30 days. **Examples are shown in Table 8.2.**"
NRC Staff Response: • The table headings in Appendix B to 10 CFR 30 (i.e., "Material" and "Microcuries") are correct. The relation between the comment and the NUREG is unclear. • Revised to: "NRC will authorize sealed source possession exceeding the limits given in 10 Part 30.35(d) without requiring decommissioning financial assurance, for the purpose of normal sealed source exchange for no more than 30 days. Table 8.2 shows examples of the limits for select sealed sources."		
Section 8.8	Purpose(s) for Which Licensed Material Will Be Used	Pages 8-14 to 8-19: These pages describe methods of therapy treatments, in unnecessarily excessive detail. These descriptions are available in the literature and in textbooks, and need not be included in this Regulatory Guide.
NRC Staff Response: The section was revised to remove textbook information.		

Location	Subject	Comment
Section 8.10	Radiation Safety Officer	• The training requirements are subject to change based on changes in Part 35, and a radiation safety exam is not necessary for the RSO; a description of training and experience is sufficient. • Page 8-23, 3rd bullet: " . . . AND . . . Written certification, signed by a preceptor RSO, that the above training and experience has been satisfactorily completed." This is unnecessary given the professional and experience qualifications of health physicists. This is also asking for a contract between a preceptor RSO and the NRC, which may put a preceptor at potential risk should unforseen circumstances arise. • Page 8-23, 6th bullet: "Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in Subparts B or J are met." Review on a "case-by-case" basis is not only too discretionary, but it will be extremely time consuming for the NRC to review each case, and then to defer to ACMUI if necessary. This may cause unacceptable delays in the assignment of AUs. The NRC should rely on the licensee's internal review system, which is always available for NRC review.

NRC Staff Response:

- The final NUREG was revised to reflect the requirements in the final regulation.

- Preceptor certification is a requirement of 10 CFR Part 35. The language chosen reflects the language used in the regulation.

- NRC review of training and experience is not too discretionary. The review is initially performed by comparison with the applicable requirements found in Subpart B. If the requested individual does not meet the training requirements provided for in the regulations, the license reviewer may request additional information from the licensee or may, in rare cases, refer the training and experience to the ACMUI for review. Referrals to the ACMUI are normally made for new types of medical use not previously described in the regulations or guidance. This distinction was added to this section.

Location	Subject	Comment
Section 8.11	Authorized Users	• Pages 8-23 through 8-25: The training requirements are subject to change based on changes in Part 35, and a radiation safety exam is not necessary. The NRC's views on the duties of an AU are unclear; the training requirements are not always going to be commensurate with these duties, i.e., for in vitro and animal research, calibration of survey instruments, and other uses that do not involve the intentional exposure of humans. • Must the licensee "notify the NRC within 30 days if an AU permanently discontinues his/her duties . . . " for AUs who do not use byproduct material for human use? Would it not be sufficient for the licensee to keep an updated file which is subject to NRC review?
NRC Staff Response: • The final NUREG was revised to reflect the requirements in the final regulation. Responsibilities of authorized users are clearly listed in the discussion part of this section. • With regard to authorized users, the notification requirements in 10 CFR 35.14 apply only to authorized users involved in medical use.		
Section 8.11	Authorized Users	Page 8-25, 7th bullet of page: "Descriptions of training and experience will be reviewed using the criteria listed above. This documentation will be reviewed on a case-by-case basis to determine whether the applicable criteria in 10 CFR Part 35 are met. If the training and experience do not appear to meet . . . the NRC may request the assistance of its ACMUI." Review on a "case-by-case" basis is not only too discretionary, but it will be extremely time consuming for the NRC to review each case, and then to defer to ACMUI if necessary. This may cause unacceptable delays in the assignment of AUs. The NRC should rely on the licensee's internal review system, which is always available to the NRC for review.
NRC Staff Response: NRC review of training and experience is not too discretionary. The review is initially performed by comparison with the applicable requirements found in 10 CFR Part 35. If the requested individual does not meet the training requirements provided for in the regulations, the license reviewer may request additional information from the licensee or may, in rare cases, refer the training and experience to the ACMUI for review. Referrals to the ACMUI are normally made for new types of medical use not previously described in the regulations or guidance. This distinction was added to this section.		

Location	Subject	Comment
Sections 8.12, 8.13, and 8.14	Training Requirements	Training requirements are subject to change based on changes in Part 35. Radiation safety exam is not necessary.
NRC Staff Response: The final NUREG was revised to reflect the requirements in the final regulation.		
Section 8.18	Dose Calibrator and Other Dosage Measuring Equipment	• Page 8-40, 2nd paragraph: "Currently no alpha emitting nuclides are used in unsealed form in medicine. Therefore guidance is not provided in this document on the measurement of these radionuclides." Research involving alpha-labeled monoclonal antibodies for cancer therapy is rapidly progressing, and it is likely that use of this technique will occur in the near future. The authors of this guide should consider addressing model procedures for alpha measurement, i.e., emerging technology. • Page 8-40, 3rd paragraph: "Equipment used to measure dosages that emit gamma~~, alpha, or~~ **and** beta radiation must be calibrated for the applicable radionuclide being measured (per the above NUREG discussion regarding alpha emitters).
NRC Staff Response: NRC believes that it is best to provide guidance on alpha-labeled monoclonal antibody measurement when the research results in more wide-spread use. In accordance with 10 CFR 35.60, all instruments used to measure byproduct material (including alpha emitters) must be calibrated. Therefore, no revision appears necessary in response to the second comment.		
Section 8.19	Dosimetry Equipment – Calibration and Use	Page 8-41, 3rd paragraph, Discussion: "The applicant must possess a calibrated dosimetry system . . . to perform calibration measurements of sealed sources **to be used for patient therapy**." (Sealed sources are used for many procedures – as markers, irradiators, etc. This guide must indicate that this ITEM 9 refers to sealed sources used for therapy.)
NRC Staff Response: NRC agrees with the proposed revision and added "to be used for patient therapy."		

Location	Subject	Comment
Section 8.21	Radiation Protection Program	• Page 8-46 "Additionally, any calculations or measurements used to demonstrate compliance with NRC regulation must be representative of typical quantities in use or maximum patient doses." Unclear as to which this sentence requires. Which does the NRC really want, representative of typical quantities in use or maximum patient doses – is it one or the other at the licensee's discretion? • Page 8-46, under bulleted item: "Material Receipt and Accountability" – should include only "Ordering and Receiving" through "Use" records bullets. The remaining items: Patient or Human Research Subject Release, Safety Procedures for Therapy Treatments . . . , Safety and Device Calibration Procedures, Administration Requiring a Written Directive, Safe Use of Unsealed Licensed Material, Maintenance of Therapy Devices Containing Sealed Sources, Spill Procedures, Emergency Response for Sealed Sources . . . , should be placed under different headings. For example, change "Minimization of Contamination" to "Minimization of Exposure and Contamination," and include "Area Surveys," "Spill Procedures," "Leak Tests," and "Safe Use of Unsealed Licensed Material." "Emergency Response for Sealed Sources or Devices . . . " should be included under "Operating and Emergency Procedures." Also, add a heading, "Patient Use," under which the following should be included: "Administrations Requiring a Written Directive," "Patient or Human Research Subject Release," and "Safety Procedures for Therapy Treatments Where Patients are Hospitalized." Add heading "Equipment Performance," under which "Maintenance of Therapy Devices Containing Sealed Sources" and "Safety and Device Calibration Procedures" are included.
NRC Staff Response: • The referenced sentence was deleted. • The items "Ordering and Receiving" through "Use Records" were subset under "Material Receipt and Accountability." The additional changes were not made, because many of the remaining items are part of the radiation protection program and require development of various "Operating and Emergency Procedures."		

Location	Subject	Comment
Section 8.23	Occupational Dose	Page 8-50, 1st paragraph: "If external dose monitoring is necessary, the applicant should describe the type of personnel dosimetry~~, i.e., film badges or thermoluminescent dosimeters (TLDs)~~, that will be used~~ by personnel~~." **Whole body dosimeters may be composed of film, thermoluminescent (TLD), or optically stimulated luminescence (OSL) detectors. Extremity (ring) dosimeters may be composed of TLD or OSL detectors.** Also, the second half of this paragraph is redundant and therefore should be omitted.~~: "if occupational workers handle licensed material, the licensee should evaluate the need to provide extremity monitors [ie., required if likely to receive a dose in ...] in addition to whole body badges."~~
NRC Staff Response: The first sentence was revised to include OSL dosimeters. The remainder of the paragraph is not redundant because it: (1) discusses the licensee's responsibility to evaluate the need to provide extremity monitoring; and (2) provides guidance on where dosimeters should be worn.		
Section 8.24	Public Dose	• Perhaps NUREG-1556 could provide more guidance on "security" of radioactive material; reference "EGM 98-004." • Page 8-52, under "Discussion": " . . . Public dose is controlled, in part, by ensuring that licensed material is secured ~~(e.g., located n a locked area)~~ to prevent unauthorized access or use." Licensees should be able to use their own discretion as to how they will secure from unauthorized access.
NRC Staff Response: • It is inappropriate for the NUREG to discuss specific NRC Enforcement Policies. As a general overview, the applicant was referred to NUREG-1600, "General Statement of Policy and Procedures on NRC Enforcement Actions," in Section 8.22. • NRC agrees that licensees should be able to use their own discretion as to how licensed material will be secured from unauthorized access. Therefore, an example of how licensed material may be secured was given rather than prescribing a single acceptable method.		

Location	Subject	Comment
Section 8.24	Public Dose	• Page 8-53, 2nd paragraph: "Licensees can determine the radiation levels adjacent to licensed material either by **direct measurement**, calculations, or a combination of direct measurements and calculations using some or all of the following . . . " • Page 8-53, 4th paragraph: " . . . During NRC inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, **or both**, that the total effective dose equivalent to the individual likely to receive the . . . "
NRC Staff Response: • The proposed revision to paragraph 2, Page 8-53, was made accordingly. • The proposed revision to add "or both" was made in paragraph 4, page 8-53.		
Section 8.25	Minimization of Contamination	Reference Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions," which provides comments on acceptable fixed and loose contamination limits.
NRC Staff Response: Tables R.2 and R.3 of Appendix R were referenced in this section.		

Location	Subject	Comment
Section 8.26	Operating and Emergency Procedures	• References to 10 CFR 35 are not consistent with the numbering in Part 35. • Page 8-54, 3rd bullet: Add the words "written directive." "Instructions for administering licensed material in accordance with the **written directive** (WD)." • Page 8-55, under Discussion: "Applicants shall develop operating and emergency procedures that minimize radiation ~~safety risks, while keeping radiation exposures ALARA.~~"**exposure consistent with the ALARA principle."**
NRC Staff Response: • The final NUREG was revised to reflect the appropriate references from the final regulation. • Abbreviations are found on page xvii. Written Directive was previously abbreviated in Section 1.3. • To keep the sentence consistent with 10 CFR 20.1101, it was changed to: "Applicants shall develop, document, and implement specific procedures as part of a radiation protection program (e.g., operating and emergency procedures) based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA."		
Section 8.26	Operating and Emergency Procedures	• Page 8-55, 3rd sentence in 3rd paragraph under "Discussion:" " . . . The change in emphasis when an operation or autopsy is to be performed is due to the possible exposure of the hands and face to relatively intense beta radiation (if present) **in addition to the gamma component.** • Page 8-56, 1st paragraph: "The NRC must be notified when licensed material in excess of 10 times the quantity specified in Appendix C to part 20 **is discovered to be** lost or stolen."
NRC Staff Response: • The revision is unnecessary because the existing text states, "possible exposure to . . . beta radiation." Since gamma rays are mentioned in the second sentence of the existing text, it would be redundant to mention it when discussing an operation or autopsy. • The phrase "after its occurrence becomes known to the licensee" was added.		

Location	Subject	Comment
Sections 8.27 - 8.34 and Appendix Q	Various Sections	References to Part 35 are incorrect.
NRC Staff Response: The final NUREG was revised to reflect the appropriate references from the final regulation.		
Section 8.28	Ordering and Receiving	NUREG-1556 should include a statement that if the licensee ships radioactive material from their facility, that the licensee must ensure that the receiver has a license to receive the material.
NRC Staff Response: The proposed revision refers to transfer, yet Section 8.28 deals with ordering and receiving exclusively. Therefore, the revision is inappropriate. Section 8.44, "Waste Management," includes a reminder that licensees verify that the waste recipient is properly authorized to receive the material prior to transfer.		
Section 8.33	Area Surveys	• Page 8.62: A survey of the patient's bed linens is suggested. The NRC should also suggest that a survey of all trash exiting the patient's room be surveyed. • If the new proposed Part 35 is only going to require a semi-annual inventory of sealed sources, then this guide should be revised to only require a semi-annual survey of sealed source storage areas instead of quarterly surveys. • The section regarding Contamination Surveys should reference Regulatory Guide 8.23 "Radiation Surveys at Medical Institutions."
NRC Staff Response: • The proposed revision was made. • The final NUREG was revised to reflect the requirements in the final regulation. • As indicated in the references, Regulatory Guide 8.23 was used in formulation of this NUREG.		

Location	Subject	Comment
Section 8.44	Waste Management	• Page 8-81: 49 CFR should be included in the list of referenced regulations at the beginning of this section. • Page 8-82, 2nd bullet, 1st item: It should be clarified that only excreta from patients is exempt, not fluids. Blood is not exempt.
NRC Staff Response: • 10 CFR 71.5 requires compliance with 49 CFR. Therefore, a reference to 49 CFR is not needed. • The existing text makes no reference to patient fluids. The existing text references "excreta from patients." Since "fluids" are not referenced and blood is not excreted from patients, the proposed revision is unnecessary.		
Appendix F	Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation Authority	• Page F-2: Model Delegation of Authority: The requirement for signatures of the Management Representative and the RSO should be deleted. The position of RSO is a professional one, and the duties and responsibilities of ensuring the safe use of radiation is inherent in this occupation. The successful performance of the Radiation Safety Program and of the RSO is constantly reviewed by the NRC via inspections, license applications, and informal communications; the request for a contractual signature is unwarranted. • In addition, the following: "It is estimated that you will spend _____ hours per week conducting radiation protection activities" must be removed. What is the purpose of contracting a time commitment? Successful completion of 10 CFR 35 requirements should be the criteria used for judging a successful radiation safety program; the amount of time spent doing so is irrelevant.
NRC Staff Response: • 10 CFR 35.24 requires the RSO's agreement in writing to be responsible for implementing the radiation protection program. 10 CFR 35.24 also requires that the licensee establish, in writing, the RSO's authority, duties, and responsibilities. • Appendix F is a model procedure. The model procedures provide acceptable procedures for the RSO's duties and responsibilities, and a sample delegation of authority. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. NRC believes that management and the RSO should come to a mutual understanding of the approximate time required to perform the RSO functions. Otherwise, an individual, such as a physician authorized user, may be appointed RSO, but may not have sufficient time away from his or her regular physician duties to accomplish the RSO functions.		

Location	Subject	Comment
Appendices G and H	Various Appendices	Subject to change in accordance with final 10 CFR 35 document.
NRC Staff Response: The final NUREG was revised to reflect the requirements from the final regulation.		
Appendix J	Model Procedures for Dose Calibrator Calibration	• Page J-1, 1st paragraph: "We will consider repair, replacement, or arithmetic correction, **as applicable**, if the dose calibrator falls outside the suggested tolerances." • "After repair, adjustment, or a relocation to another building **which is likely to affect performance** of the dose calibrator, we will repeat the above tests before use" • Page J-1, middle of the page: "We will assay at least one relatively long-lived source such as Cs-137, Co-60~~, cobalt 57~~ (Co-57, or ~~radium 226 (~~Ra-226)." • Page J-2: Add to list and to list on J-6 under accuracy: **"A sticker will be affixed to the dose calibrator to indicate the dates of the linearity (and accuracy) checks."** • Page J-5: Delete from NUREG-1556 all references that say "Subtract background from the indicated activity to obtain the net activity," and simply state to **"measure background and record the net activity."**
NRC Staff Response: • This sentence was deleted and the note describing the regulatory requirements was inserted instead. • The proposed revision results in ambiguity in terms of what is likely to affect performance of the dose calibrator. Therefore, no revision was made. • The proposed revision deletes the meaning of two abbreviations. Since this is the first time in this document that Co-57 and Ra-226 have been abbreviated, the full terms are needed here. • The proposed revision does not appear to add value, because a record of the test is required. Therefore, the revision is unnecessary. • The phrase "subtract background from the indicated activity to obtain the net activity" has been deleted from this appendix.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-1: Add a paragraph before ALARA, entitled, Occupational Dose Limits, and add some definitions and explanations. For example: • The occupational dose limits for adults is given in 10 CFR 20.1201: (1) Annual limit, which is the more limiting of: (i) The total effective dose equivalent (TEDE or HE) being equal to 5 rem (0.05 Sv). The TEDE is the sum of the deep dose equivalent (DDE or Hd) from penetrating external radiation, and the committed effective dose equivalent (CEDE or HE,50) from internal radiation exposure. Or, (ii) the sum of the deep dose equivalent and the committed dose equivalent (CDE or HT,50) to any individual organ or tissue other than the lens of the eye being equal to 50 rem (0.05 Sv). And (2) The annual limits to the lens of the eye, to the skin, and to the extremities, which are: (i) An eye dose equivalent of 15 rems (0.15 Sv), and (ii) A shallow-dose equivalent (HS) of 50 rems (0.50 Sv) to the skin or to any extremity. • The deep dose equivalent is the dose received from external penetrating radiation at a point on the whole body located at a tissue depth 1000 mg/cm^2 (1 cm) below the skin surface. • The shallow dose equivalent is the dose received averaged over a 1 cm^2 area, located 7 mg/cm^2 (0.0007cm) below the skin surface. • The CDE (HT,50) is the cumulative dose received by an organ that will be received from an intake of radioactive material during the 50-year period following the intake. • The CEDE is the sum of the CDE to each individual organ multiplied by the organ weighting factor. CEDE = _ $[H_{T,50}w_T]$
NRC Staff Response: The suggested definitions for dose limits appears unwarranted. A reference to the definitions in 10 CFR 20.1003 was added to this appendix.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-1: Edit the 1st paragraph by placing the 1st sentence under "External dose Exposure" prior to the 1st sentence of the 1st paragraph, i.e., **"The mechanism by which doses to individuals from exposure to radiation is evaluated is called dosimetry. Dosimetry is required for individuals likely to receive in 1 year a dose in excess of 10% of the applicable . . . "** • Page L-1, 3rd paragraph under "External Dose exposure": Add: "There are three **occupational** dose limits included in . . . " • Page L-2, 1st paragraph, add: " . . . (i.e., adult, minor, **or the fetus** of a declared pregnant woman)." • Page L-2, 1st bullet: add: "For adults **occupational workers** who are likely to receive an annual dose in excess of any of the following . . . " • Delete the bulleted information on Page L-2 which enumerates 10% of each limit. It is sufficient to say that **"monitoring devices for external dose is required when an occupational worker or minors are to receive 10% of the applicable limits."** The individual numbers representing 1/10th of these values need not be listed. • Page L-3: 1st paragraph: "External dose is determined by using individual monitoring devices such as film badges **or optically stimulated luminescence (OSL) badges,** or thermolurninescent dosimeters ~~(DDE)~~ **TLD's.**"
NRC Staff Response: • We agree with the proposed revision. • The proposed revision to the third paragraph on page L-1 is unwarranted because the Appendix is titled, "Model Procedures for an Occupational Dose Program." • We agree with the proposed revision. • The proposed revision to the first bullet on page L-2 is unwarranted because the Appendix is titled, "Model Procedures for an Occupational Dose Program." • The individual numbers representing one-tenth of the limits are provided for ease of reference. • The following revision was made: "External dose is determined by using individual monitoring devices such as film badges, optically stimulated luminescence dosimeters (OSL), or thermolurninescent dosimeters (TLDs)."		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Delete Page L-3, 6th paragraph.: ~~"If the licensee determines that extremity monitoring is required, it may be appropriate to use an extremity dosimeter for some, but not all, radiation exposure. The licensee could supply an extremity dosimeter when exposure is non-uniform. When exposure is uniform, the shallow dose equivalent measured by a torso dosimeter would be representative of the shallow dose equivalent to the extremities, and separate extremity monitoring would not be needed."~~ Add: **Extremity dosimeters are required when the extremities are likely to receive 10% of the applicable limit.** This 6th paragraph is very confusing. If the exposure is uniform, then the 5 rem to the whole body is the limiting dose; extremity monitoring is therefore of no concern because the extremity limit is 10 times the whole body dose. Radiation fields are never static or uniform over the entire body when radioactive material is handled; exposure to the hands is always higher because of distance and/or torso shielding (i.e., beta shields or leaded shields) factors. NUREG-1556 should simply state that extremity dosimeters are required when the extremities are likely to receive 10% of the applicable limit. This information can determined by using historical extremity dosimetry data, or by considering the radionuclide used and expected amount of time it will be handled yearly.
NRC Staff Response: The sixth paragraph of page L-3 was deleted. The proposed revision was not added because this issue was already addressed in the appendix.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-4 Investigation Levels – External Dose Monitoring: The presentation of investigation levels does not reflect updated version of yearly dose limits in 10 CFR 20. Why are the Investigation Levels in terms of dose per quarter; this is inconsistent with the updated dose limits which are based on a yearly, not quarterly period. Why are the lens of eyes combined with the whole body, head and trunk, active blood forming organs, or gonads, and why are the extremity and skin of the whole body investigational levels different when their dose limits are the same? Why is there not a separate investigation for lens of the eyes? Also, why not just state "whole body," the "head and trunk, active blood forming organs, or gonads" are implied by this definition; similarly for the "hands and forearms, feet and ankles which are defined as "extremities." • The dose thresholds per quarter which would require investigation, according to this section, are much too conservative. The Investigation Level I per quarter for the whole body (etc.) is only 2% of the annual limit, the "hands and forearms, feet and ankles" is 3.7%, and "the skin of the whole body" is 1.5% of the annual limits. For the whole body, this means that an investigation must be performed for an average dose of 42 mrem per month! Additionally, personnel who will not receive 500 mrem in a year, and who are therefore not monitored, may reach 125 mrem in a quarter. The preferred investigation action guideline would be a threshold of a certain reasonable percentage of the yearly annual dose. For example, **"Investigation Level I when occupational dose reaches 10% of the annual limit, and Investigational Level 2 at 30%."**

NRC Staff Response:

- Table L.1 is part of a model procedure and, therefore, not required. The model procedures provide acceptable procedures for an occupational dose program. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Nonetheless, Table L.1 was revised to be consistent with 10 CFR Part 20 dose limits (e.g., the skin and extremity investigational levels are the same, etc.).

- We agree with the proposed revision.

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-6 Internal Dose exposure: This section is poorly constructed, and does not include clear and concise information regarding the definitions and use of ALIs and DACs. • Page L-6, 1st paragraph: "With respect to internal exposure, you are required to monitor your occupational intake of radioactive material and assess the resulting dose if it appears likely that you will to receive greater than 10% of the ALI from intakes in 1 year . . . " • Page L-6: Switch paragraphs 2 and 3, and other additions/deletions throughout the page: "For each class of each radionuclide, there are two **Annual Limit on Intakes** (ALIs), one for ingestion and one for inhalation. The ALI (μCi) is that quantity of radioactive material that, if taken into the body of an adult worker **over the course of a year** by the corresponding route would result in a committed effective dose equivalent (CEDE) of 5 rems (0.05 Sv) (**known as the "SALI" - "S"for stochastic)**, or a committed dose equivalent of 50 rems **(known as the "NALI" - "N" for non-stochastic) . . . "**

NRC Staff Response:

- Much of this section has been revised. For instance, the text regarding how to operate a bioassay program, pages L-7 to L-20, was deleted. The detailed procedures were replaced with a referral to the appropriate Regulatory Guides and NUREG that cover this subject in greater detail.

- We agree with the proposed revision.

- The suggested changes to page L-6 do not appear to add much value to the guidance. Therefore, no revision was made in response to these suggestions.

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	• Page L-6, paragraph 3: ~~"Exposure to airborne radioactivity at a level of 1 DAC for 1 year...)~~ **The Derived Air Concentration (DAC) for each class of radionuclide is the concentration of airborne radioactivity (µCi/ml) that, if an occupational worker were to be continuously exposed for 2000 hours (1 year), would result in a committed effective dose equivalent of 5 rems (0.05 Sv), or a committed dose equivalent of 50 rems (0.5 Sv)** to any individual organ or tissue, again, with no . . . " **The ALI and DAC for each radionuclide in a specific chemical form is listed in 10 CFR Part 20, Appendix B.** • Page L-6, 5th paragraph: "The **total** effective dose equivalent (TEDE) concept ~~described above~~ makes it possible to combine both the internal and external doses in assessing the overall risk to the health of an individual. The 10 CFR 20 ~~dose methodology evaluates the doses to all major body organs~~ **ALI and DAC numbers** reflect the doses to all principal organs that are irradiated, **and will indicate the committed effective dose equivalent (via the SALI) or the committed dose equivalent to an individual organ (via the NALI) due to an intake of a particular radionuclide compound. The ALI and DAC were derived by multiplying a unit intake by the appropriate organ weighting factors WT, for the organs specifically targeted by the radionuclide compound,** and then summing the organ-weighted doses to obtain a whole body risk-weighted "effective dose." **Per 10 CFR 20 Appendix B, when an ALI is defined by the stochastic dose limit, this value alone, is given. When the ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses.**
NRC Staff Response: The proposed revisions, with minor changes, were incorporated.		

Location	Subject	Comment
Appendix L	Model Procedures for an Occupational Dose Program	Page L-6, Add**: If the intake consists of a mixture of radionuclides, then: [ALI/Intake] < 1.** Suggestion, give examples: Total effective dose equivalent: If the dose is external only, then TEDE = deep dose equivalent for whole body. If the doses are internal only, then: 1) Ingestion: TEDE (Intake/ALI) x 5 rem; 2) Inhalation: TEDE (Concentration/DAC) (Number of hours exposed)/ 2000 hours) x 5 rem. If the doses are internal and external: TEDE = [deep dose equivalent] + [(Intake/ALI) x 5 rem] + [(Concentration/DAC) (Number of hours exposed)/ 2000 hours) x 5 rem].
NRC Staff Response: The suggested addition to sum external and internal doses, excluding the examples, was included in a separate section titled "Summation of External and Internal Doses."		

Location	Subject	Comment
Appendix M	Guidance for Demonstrating that Individual Members of the Public will not Receive Doses Exceeding the Allowable Limits	The step-by-step tabulated example of calculation method for determining that allowable limits are met, Pages M-5 - M-7 are excessive, and quite confusing. Table M.2 can be replaced by simplifying the example. An abbreviated (prototype) suggestion is given below: • Step 1: Consider distance from unshielded source only. Using the inverse square law: $I_2d_2^2 = I_1d_1^2$, $1_2 = I_1d_1^2/d_2^2$. (Define terms . . .). I_1 = 5000 mrem/hr $(3.28 \text{ ft})^2 / (15 \text{ ft})^2$ = 239 mrem/hr. Yearly dose = 239 mrem/hr x 24 hrs/day x 365 days/year = 2.09×10^6 mrem/year. • Step 2: Include Occupancy Factor: ~~Joe~~ Reviews ~~his~~ assumptions **and make a realistic estimate**, ~~recognizes~~ by considering that the ~~secretary is not at the desk~~ **chair and desk are not occupied 24 hours/day; recalculate the annual dose using an occupancy factor**; ~~he decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk,~~ keeping his other assumptions constant . . . Yearly dose = [Dose rate at the location] x [occupancy factor], Yearly dose = [239 mrem/hr] x [(5 hours/day)(3 days/week)(52 weeks/year)] = 1.86×10^5 mrem/year. • Step 3: Include Source Use Factor. Yearly dose = [Dose rate at the location] x [occupancy factor] x [Fraction of time the source is exposed], [Fraction of time source exposed] = Max exposure time per patient x number of patients per day], [Fraction of time source exposed] = {1 minute x 16 patients per day}/1440 minutes per day}, [Fraction of time source exposed] = 0.011, Yearly dose = [Dose rate at the location] x [occupancy factor] x [Fraction of time the source is exposed], Yearly dose = 1.86 x 10^5 mrem/year x 0.011 = 2046 mrem/yr. Step 4: Include shielding. $I = I_o e^{-ux}$ (Define terms) etc.
NRC Staff Response: The proposed revisions delete specific instructions that could result in confusion. Furthermore, the existing guidance appears accurate and easy to follow. Therefore, the proposed revision is unnecessary.		

Location	Subject	Comment
Appendix N	Emergency Procedures	• Appendix N should distinguish between spills in restricted and unrestricted areas. This guide should also reference Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions." • Minor spills of Liquids and Solids. Changes: – No comment – Prevent the spread of contamination by covering the spill with **"cram"- labeled** absorbent paper. Carefully identify the boundaries of the spill. – **Wearing gloves and protective clothing such as a lab coat and booties,** clean up the spill using ~~disposable gloves and~~ absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a **"cram"- labeled** bag for transfer . . . – Survey the area with a ~~low-range~~ radiation ~~detector~~ survey meter **sufficiently sensitive to detect the radionuclide.** – **Smear the area to ensure contamination is below limits.**

NRC Staff Response:

- The guidelines for responding to spills may be used for spills both in restricted and unrestricted areas. As discussed previously, Regulatory Guide 8.23 was used in development of this NUREG (see the Abstract).

- The proposed revision, "Prevent the spread of contamination by covering the spill with 'cram'-labeled absorbent paper. Carefully identify the boundaries of the spill." is unnecessary because the absorbent paper is typically used to blot the spill and is promptly disposed of as radioactive waste. Therefore, labeling absorbent paper that is used quickly and then disposed of is unnecessary. Also, the boundaries of the spill will not necessarily be known until the survey (see Step 4) is performed.

- We agree with the proposed revision, "Wearing gloves and protective clothing such as a lab coat and booties, clean up the spill using absorbent paper. Carefully fold the absorbent paper with the clean side out and place in a caution radioactive material-labeled bag for transfer . . . "

- The following revision was made to the last two bullets: "Survey the area with a low-range radiation detector survey instrument sufficiently sensitive to detect the radionuclide. Smear the area to ensure contamination is below trigger levels . . . "

Location	Subject	Comment
Appendix N	Emergency Procedures	• Minor spills of Liquids and Solids. Changes, cont.: – **Additional decontamination efforts may be required to achieve acceptable levels listed in Regulatory Guide 8.23 "Radiation Safety Surveys at Medical Institutions**." – ~~Report the incident to the RSO.~~ The RSO does not need to be informed of minor spills, unless it involves skin contamination or the spill occurred in an unrestricted area. This requirement as to whether or not to involve the RSO for a minor spill should be at the discretion of the RSO whom should also be permitted to delegate responsibility to staff. • Major Spills of Liquids and Solids. Changes: – Clear the area. Notify all persons not involved in the spill to vacate the room **after they have monitored their shoes**. – Prevent the spread of contamination by covering the spill with **cram-labeled** absorbent paper, but do not attempt to clean it up. To prevent the spread of contamination, **clearly indicate the boundaries of the spill, and** limit the movement of all personnel who may be contaminated.

NRC Staff Response:

- As discussed previously, Regulatory Guide 8.23 was used to prepare this document (see Abstract).
- RSO notification of minor spills provides a means for the RSO to become aware of potentially unsafe practices or procedures that need refinement. Therefore, no revision was made.
- If an individual was not involved with the spill, there is no need for the individual to monitor his/her shoes before leaving the room. Therefore, no change was made.
- We agree with the proposed revision to major spills, except if an individual was not involved with (or near) the spill, there may not be a need for the individual to monitor his/her shoes before leaving the room.

Location	Subject	Comment
Appendix N	Emergency Procedures	• Major Spills of Liquids and Solids. Changes, cont.: – ~~Shield the source if possible. Do this only if it can be done without further contamination or a significant increase in radiation exposure.~~ Shielding the source is extremely impractical, and most probably unnecessary. – ~~Close the room and lock or otherwise~~ Secure the area to prevent entry. – Notify the RSO immediately. – ~~"... if contamination remains, induce perspiration by covering the area with plastic...."~~ For skin contamination it is not good to induce perspiration by covering the area. This could lead to absorption through the pores and an internal intake. It is better to decontaminate the area until no more contamination can be removed, or until skin becomes irritated. Take measurements with meter and calculate the skin dose in the worst case scenario; if the dose is less than 10% of the annual limit, then it is best to leave it alone.

NRC Staff Response:

- Shielding the source may be practical in some situations when the exposure rate is excessive; therefore, we have retained this item.
- The deletion of the phrase "close the room and lock" was not accepted, because this phrase includes an example of securing the contaminated area.
- Add the caveat that the RSO should consider inducing perspiration (instead of washing the skin to the point of irritation, because this increases blood flow to the skin surface resulting in an increased potential for intake).

Location	Subject	Comment
Appendix N	Emergency Procedures	• Page N-2, 1st paragraph: "For some spills of short-lived radionuclides, the best spill procedure may be restricted access pending complete decay." This advice is very misleading as written. Per 10 CFR 30.50 (b), twenty four hour report to the NRC is required for: 1) an unplanned contamination that: (i) Requires access to the contaminated area . . . to be restricted for more than 24 hours by imposing . . . or by prohibiting entry into the area; (ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B . . . ; (iii) Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination . . . " Change this sentence to: "For some spills of radionuclides **with half-lives shorter than 24 hours, in amounts less than five times the lowest ALI, an alternative** spill procedure may be to restrict access pending complete decay." • Page N-2, Table N-1, Relative Hazards of Common Radionuclides: What is the basis upon which the quantities in this table were determined to distinguish between major vs. minor spills? • Page N-2, Spill Kit: This type of detail is unnecessary. Enumeration of number of items is unnecessary. If the licensee states in their application that they will adopt the precautions outlined in Appendix N, Spill Kit, the licensee should not be held to requiring exactly 6 pairs of gloves, 2 lab coats, etc. The list is incomplete; urine bioassay cups, for example, are also important to have.
NRC Staff Response: • We agree with the proposed revision. • The precursor to Table N.1 was Table J-1 found in Regulatory Guide 10.8, Revision 2. Table J-1 was based in part on NCRP Report No. 30, "Safe Handling of Radioactive Materials." • The list was modified to be more generic, consistent with the list provided in Volume 11 of this NUREG series, "Program-Specific Guidance About Licenses of Broad Scope."		

Location	Subject	Comment
Appendix N	Emergency Procedures	• Pages N-3, Item 2 and N-4, Item 3: NRC does not need to give guidance to prevent possible splashing of "foreign materials." Change: "The surgeon and the personnel involved in the surgical procedures will wear protective gear for ~~the~~ **eye** protection ~~of the eye~~ from possible splashing of ~~foreign materials, as well as from beta radiation~~ **radioactive material**." • Page N-4, Item #4 under "Autopsy of Patients Who Have Received Therapeutic Amounts of Radionuclides" should not be so specific. The NRC has no right to dictate how a pathologist performs an autopsy. Certainly removing an entire block of tissue containing the nuclide would limit the radiation exposure, but the NRC does not have to be that detailed. • The RSO should not have to be informed of any hazard associated with Emergency Surgery or an Autopsy. The RSO should determine the criteria in which he/she is to be notified and the NRC should not dictate when the RSO be notified of a situation. Let the RSO manage the program as he/she deems appropriate.
NRC Staff Response: • The following revision was made: "Protective eye wear will be worn by the surgeon and any personnel involved in the surgical procedure for protection of the eyes from possible splashing of radioactive material and exposure from beta radiation (if applicable)." • The model procedures provide acceptable procedures for responding to an emergency involving licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. • The model procedures provide acceptable procedures for responding to an emergency involving licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. However, RSO notification of radiological hazards associated with emergency surgery or autopsy is appropriate because the RSO is responsible for day-to-day oversight of the radiation safety program.		
Appendix O	Model Procedures for Ordering and Receiving Packages	Page O-1: Under Model Guidance, the NRC references "written records." This should be changed to permit electronic records as well as written records.
NRC Staff Response: The reference to "written" was deleted.		

Location	Subject	Comment
Appendix P	Model Procedure for Safely Opening Packages Containing Radioactive Material	• There are references in Appendix P that require immediate notification of the RSO (e.g., damaged package received, etc.). This should be less restrictive and permit notification of the RSO or DESIGNEE. • Page P-1, Item 4: "Monitor the external surfaces **and at 1 meter** for radiation levels . . . "

NRC Staff Response:

- The model procedures provide acceptable procedures for opening packages containing radioactive material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. However, RSO notification of radiological hazards associated with leaking packages is appropriate since the RSO is responsible for day-to-day oversight of the radiation safety program.

- The existing guidance corresponds with the applicable wording in 10 CFR 20.1906(b)(2). Therefore, a revision is unnecessary.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Page R-1: Relocate the 1st paragraph (bullets under "Facilities and Equipment") to Page R-2 under "Contamination Surveys." • Page R-2, Table R.1: Why is the trigger ambient dose rate for unrestricted areas 0.05 mR/hr (50 μR/hr); this is about the ambient background radiation level!? And assuming that this was indeed the NUREG intended level, there is then an inconsistency between: page R-1 "Radiation level surveys will consist of measurements with a survey meter sufficiently sensitive to detect 0.1 mR/hr." How then would one measure the trigger level of 0.05 mR/hr? • Also, the trigger levels outlined in Table R.1 "Ambient Dose Rate Trigger Levels" do not specify at what distance these readings should be obtained.

NRC Staff Response:

- We agree with the proposed revision.
- We agree that the suggested trigger level for unrestricted areas is too low. The model procedure was revised to indicate a trigger level of 0.1 mR/hr for unrestricted areas.
- NRC expects licensees to use good technique to perform ambient dose rate surveys. In general, the probe should be positioned close to the surface being measured without touching the surface.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Page R-3, 4th bullet: "The area will be either decontaminated, shielded, or posted and restricted from use if unable to decontaminate." This is misleading because 10 CFR 30.50(b)(i) requires 24 hour notification, as applicable, if an area is restricted to allow for decay. • Page R-4, Table R.2: The sample nuclides given are not comprehensive enough compared to what is used in the medical field today. For example, Y-90, Lu-177, and Sm-153 are not included. The limits in this table are more restrictive than those outlined in Table 2 "Recommended Action Levels For Removable Surface Contamination in Medical Institutions" and there is no justification for making these limits more restrictive. Why the change? • Table R.3 can be used for unrestricted areas and equipment. The NRC does not need to make the decontamination limits so restrictive for I-125. The material (I-125) is more benign than I-131 and the only reason it appears in the more restrictive category is that it has a longer half-life. This is unnecessary and should be taken into consideration before this guide is finalized.

NRC Staff Response:

- A statement was added to remind licensees of the reporting requirement in 10 CFR 30.50 for contamination events.

- Table R.2 was revised to include Y-90, Lu-177, and Sm-153 in the P-32, etc., category. Table R.2 was previously included in Regulatory Guide 10.8, Revision 2 (1987), as Table N-1. Table 2, "Recommended Action Levels For Removable Surface Contamination in Medical Institutions," is from Regulatory Guide 8.23, Revision 1 (1981). Both tables provide similar action levels for removable surface contamination and may be used by the licensee. However, because of the similarities and to reduce confusion, only one table was provided in the NUREG.

- We agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• Page R-5: The section on Alternate Survey Frequency is confusing and not user friendly. In the NRC's attempt to simplify the criteria for alternate survey frequencies, they have made it more complicated and unnecessarily so. What is the NRC's criteria for placing certain nuclides in the specific groups as outlined on page R-6? Also, there is no explanation of how the table is to be used, although those who are familiar with International Atomic Energy Agency Safety Series may recollect the way to use the data. • It is our strongest recommendation that Appendix R, "Model Procedure for Area Surveys," be withdrawn and redone. A technically comprehensive risk analysis should be performed to establish contamination limits based on the potential for byproduct material nuclides actually used in medical procedures to deliver dose to an individual.

NRC Staff Response:

- The alternate survey frequency was based on IAEA Safety Series 115. We agree that Table R.4 should be revised to exclude radionuclides that are not used in medicine. Additionally, a discussion on how to use the table was provided immediately under the title, "Alternate Survey Frequency."

- As discussed previously, we believe that NUREG-1556, Volume 9, is risk-related and performance-based. NRC recognizes the low risk associated with many licensed activities and the ability of medical licensees to develop safe procedures without direct NRC involvement.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	Unfortunately, the NRC has cited ambient dose and contamination limits that are unnecessarily low and/or impractical to measure in the real world. For example, how many medical programs would be capable of measuring external dose rates of 0.050 mrem/hour (50 prem/hour) in unrestricted areas? (This is the Ambient Dose Rate Trigger Level cited in Table RA) How many could adequately and efficiently measure the limit set in Table R.3 of 20 dpm/ 100 cm^2 set for I-125, I-129 and transuranics?
NRC Staff Response: We agree that the suggested trigger level in Table R.1 should be revised to 0.1 mR/hr for unrestricted areas. We also agree that the suggested trigger level documented in Table R.3 of 20 dpm/100 cm^2 set for I-125 and I-129 appears low. This value and other values in the table were chosen to be consistent with the values provided in guidance for release of facilities and equipment (Policy and Guidance Directive FC 83-23). However, consistent with the grouping used in Table R.2, I-125 was moved to be grouped with I-131. Additionally, transuranics and I-129 were deleted from this table, because medical licensees do not normally use transuranics or unsealed I-129.		

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	• The primary purpose of limiting contamination is to prevent potential ingestion, inhalation or absorption of radioactivity by those working in a contaminated area or by those who contact contaminated materials; i.e. to prevent internal dose. The Part 20 regulatory limit of 0.02 mSv/hr for ambient dose rates within restricted areas is sufficient to require that contaminated materials be cleaned to the extent that those external dose rates are not exceeded where contamination is present. It is most unfortunate that footnote 6 of Table R.3 is inconsistent with the regulations of Part 20, in that it requires that the limit for radiation levels from surface contamination should be .002 mSv/hr average and 0.01 mSv/hr maximum at a distance of one centimeter (!) from the surface. This unnecessary "rachet-down" of the regulatory limit should be eliminated. • Is 1 % or 0.1 % of the allowable occupational dose conservative enough? If so, then surface contamination levels in the 100,000's of dpm would be acceptable for most nuclides. Allowable levels for fixed contamination could be even higher. Whatever limit(s) are set they should be based on a percentage of the ALI for a nuclide, not a number which "seems" like a good idea.

NRC Staff Response:

- The model procedures provide acceptable procedures for area surveys. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Nonetheless, the rationale for using the values in Table R.3 is described above.

- As described in the *Federal Register* Notice dated November 18, 1998, Volume 63, Number 222, Pages 64132-64134, "Supplemental Information on the Implementation of the Final Rule on Radiological Criteria for License Termination," the criteria to replace the values in Policy and Guidance Directive FC 83-23 need to be developed. Therefore, except for the minor changes described above, no change to Table R.3 has been made pending development of the final criteria.

Location	Subject	Comment
Appendix R	Model Procedure for Area Surveys	Given that the external ambient dose rate limit is met, then to what activity should one decontaminate for removable or fixed contamination to prevent possible internal dose? The table below lists a number of nuclides, some of which are common in medical facilities, others of which have value in facilities which also do biomedical research. The table lists the nuclide, the group (hazard classification?) into which the NRC has placed that nuclide in the table within Appendix R, the Annual Limit on Intake (ALI) for ingestion for that nuclide in both pCi and dpm, and the respective activities in dpm for the 100 mrem, 5 mrem and 0.5 mrem internal doses, based on the ALI. These dpm values should be kept in mind when reviewing Tables R.2 "Acceptable Surface Contamination Levels in Restricted Areas in dpm/100 cm^2" and R.3, "Acceptable Surface Contamination Levels in Unrestricted Areas in dpm/100 cm^2."

Nuclide	Group	ALI (pCi)	ALI (dpm)	2.0% ALI (dpm)	0.1 % ALI (dpm)	0.01% ALI (dpm)
			5000 mrem	**100 mrem**	**5 mrem**	**0.5 mrem**
H-3	4	80,000	1.776E+11	3,552,000,000	177,600,000	17,760,000
C-14	3	2,000	4.44E+09	88,800,000	4,440,000	444,000
P-32	3	600	1.33E+09	26,640,000	1,332,000	133,200
P-33	n/a	6,000	1.33E+10	266,400,000	13,320,000	1,332,000
S-35	3	10,000	2.22E+10	444,000,000	22,200,000	2,220,000
Cl-36	2	2,000	4.44E+09	88,800,000	4,440,000	444,000
Ca-45	2	2,000	4.44E+09	88,800,000	4,440,000	444,000
Cr-51	3	40,000	8.88E+10	1,776,000,000	88,800,000	8,880,000
Ni-63	3	9,000	2.00E+10	399,600,000	19,980,000	1,998,000
Ga-67	n/a	7,000	1.55E+10	310,800,000	15,540,000	1,554,000
Tc-99m	4/2	80,000	1.78E+11	3,552,000,000	177,600,000	17,760,000
I-125	n/a	40	8.88E+07	1,776,000	88,800	8,880
I-131	2	30	6.66E+07	1,332,000	66,600	6,660
Tl-201	3	20,000	4.44E+10	888,000,000	44,400,000	4,440,000

NRC Staff Response: We agree that the criteria to replace the values in Policy and Guidance Directive FC 83-23 need to be developed, as described above. Therefore, except for the minor changes described previously, no change to Table R.3 has been made pending development of the final criteria. Additionally, the values in Table R.2 have not been revised at this time pending development of the final criteria.

Location	Subject	Comment
Appendix S	Procedures for Developing, Maintaining, and Implementing Written Directives	• A great deal of detail specified in Appendix S is not necessary if the NRC changes 10 CFR 35. The NUREG should not be finalized until the revision to Part 35 is complete so that the required information is accurately reflected. • Page S-5: The section on Review of Administrations Requiring a Written Directive is confusing as written. The NRC should be less prescriptive.

NRC Staff Response:

- The final NUREG was revised to reflect the requirements from the final regulation.

- The existing language appears clear. The model procedures provide acceptable procedures for administrations that require a written directive. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements.

Location	Subject	Comment
Appendix T	Model Procedures for Safe Use of Licensed Material	• Page T-1, 1st bullet: "wear lab coats or other protective clothing at all times in areas where radioactive materials are used." This is too restrictive. This would require anyone entering a laboratory where RAM is used to wear a lab coat. A lab coat only needs to be worn when working with RAM not when in RAM use area. Suggest: "Wear lab coats or other protective clothing **whenever working with radioactive material**." • Page T-1, 5th bullet: "do not store food . . . in any area where licensed material is stored or used." This is too general, please define "area." Does it refer to an area that is used only to store RAM or does it refer to RAM stored in refrigerator located in a lab wherein RAM work is performed? • Page T-1, 7th bullet: Please delete this entire bullet, and replace with a general statement such as: "**Wear extremity dosimeters, if required, when handling radioactive material**." All the examples of such instances is unnecessary. • Page T-1, 10th bullet: The decay method is not always applicable, per 10 CFR 30.50 (b).

NRC Staff Response:

- The model procedures provide acceptable procedures for safe use of licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Furthermore, contamination may be present in areas where radioactive materials are used. Therefore, an individual may become contaminated by being present in an area where radioactive materials are used even if the individual is not using radioactive material. Therefore, no revision was made.

- The model procedures provide acceptable procedures for safe use of licensed material. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements. Additionally, the proposed revision appears unnecessary because an area of use or storage may include a room or a refrigerator.

- We agree with the proposed revision and have incorporated the suggested change.

- The following revision of the tenth bullet on page T-1 was made, " . . . If necessary, decontaminate the area."

Location	Subject	Comment
Appendix X	Model Procedure for Waste Disposal by Decay-in-Storage, Generator Return, and Licensed Material Return	• Page X-1, 1st bullet: It is not within this NUREG guide's authority to prescribe how biomedical waste will be segregated for disposal, other than to ensure that radioactive waste is properly disposed. Segregation of biomedical waste is under the auspice of the licensee's Occupational Safety program. • Page X-1, 3rd bullet, 2nd item: "Check the radiation detection survey meter for proper operation **and current calibration status**." • Page X-1, 3rd bullet, 4th and 5th items: "Remove any shielding from around the container or generator column." . . . "Monitor, at contact all surfaces of each individual container." What is the logic behind removing shielding and monitoring each individual container? Doing so may present a significant biological hazard. All containers, i.e., MPW boxes, syringe boxes, will provide some measure of shielding. Why is it inappropriate for this shielding to be advantageously used as an exposure reduction method, especially for short-lived biomedical radioactive material? • Page X-1, 3rd bullet, 7th item: "Discard as in-house waste only those containers that cannot be distinguished from background" What are considered to be the "containers"? – MPW boxes, syringe boxes? Does this conflict wit items 4 and 5 above?

NRC Staff Response:

- The model procedures provide acceptable procedures for waste disposal. Licensees may either adopt the model procedures or develop their own procedures to meet the requirements.
- The suggested revision was added to the third bullet on page X-1.
- The shielding that is typically removed is lead that is separate from an inner plastic container (e.g., needle box, plastic bag). Therefore, the shielding can be removed without compromising the barrier to the biological hazard. Prior to disposal as non-radioactive waste, the shielding must be removed in order to confirm that the licensed material held for decay has decayed to background levels.
- "Container," as used here, may include trash bags full of waste, generator columns, or biohazard (needle) boxes. These examples were included in the NUREG.

Location	Subject	Comment
Appendix X	Model Procedure for Waste Disposal by Decay-in-Storage, Generator Return, and Licensed Material Return	Page X-1, 3rd bullet, 7th item: "Record the disposal date, ~~the radionuclides disposed;~~ the survey instrument used, ~~the background dose rate, the dose rate measured at the surface of each waste container;~~ and the name...." There is no need to include the radionuclide because it has decayed and no longer exists. There is also no need to document the background and surface dose rates, which will be at background radiation levels. The surveyor is responsible for ensuring that the proper disposal criteria are met; maintaining additional superfluous documentation is burdensome.
NRC Staff Response: Recording the radionuclide is a means of accounting for licensed material from "cradle to grave." Documenting the background and surface dose rates records which results were used to determine that the waste met DIS provisions for disposal. Therefore, no change was made in response to the proposed revision.		

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Appendix BB

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As part of its redesign of the materials licensing process, the United States Nuclear Regulatory Commission (NRC) is consolidating and updating numerous guidance documents into a single comprehensive repository. NUREG-1556, Vol. 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Medical Use Licenses," dated October 2002, is the ninth program-specific guidance document developed for the new process. It is intended for use by applicants, licensees, and NRC staff and will also be available to Agreement States.

On March 24, 2002, the NRC issued for public comment a draft of NUREG-1556, Volume 9. Comments were received during public meetings held at the NRC in Rockville, Maryland on April 25, 2002, and April 29, 2002, and during a 60-day public comment period that ended on June 4, 2002. This report serves as an appendix (BB) to the final report issued in October 2002. It provides a summary, analysis, and response to public comments received on the March 2002 draft. It also includes comments and responses on a draft of NUREG-1556, Volume 9 published for public comment in August 1998 (See 63 FR 45270). This material appeared as Appendix Z in the March 2002 draft of the guidance document.

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