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67FR16467
(6)

June 3, 2002

Chief, Rules and Directives Branch
Mail Stop T6-D59
U.S. Nuclear Regulatory Commission
Washington, DC, 20555-0001

RE: Comments on draft NUREG-1556 Vol 9 dated March 2002

I am pleased to comment on the draft NUREG-1556, Vol 9 dated March 2002. I am a health physicist who has been the radiation safety officer (RSO) at a medical facility holding a specific license of limited-scope from the NRC for the past six years, with nine years of experience in health physics. Below are my comments and concerns regarding the draft guidance:

The following comments address the commission's specific requests for comments listed on page iii.

1. Level of Detail and Format: 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.
   a. I feel that a document in the format of NUREG-1736 "Consolidated Guidance: 10 CFR Part 20..."[1] 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. Unfortunately, this updating has not happened with most Regulatory Guides and NUREGs that NRC staff has published, including NUREG-1736 that is now more then two-years out of date.
   b. 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.
   c. 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.
   d. Also the "NUREG" designation in the report number is misleading, especially for first-time applicants. First time applicants may think that the report contains new regulations that were implemented at the time the report was published. The title "Regulatory Guide" is a better choice of title. Since this comment does not directly relate to the draft guide please forward this comment to NRC staff that can address this issue.
   e. Many times throughout Appendix Z of NUREG-1556, Vol. 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."[2]

[1] NUREG-1736, "Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, D.C., October 2001.
[2] NUREG-1556, Vol. 9, page Z-41.

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Add - R. Broseus (RWB)

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."[3] 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. Although 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 then stated by NRC staff if these model procedures are published as written.

   f. The guidance for 10 CFR Part 35.1000 uses should be published in this guidance or in a similar guidance

2. Model Procedures: 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.
3. Licensing Guidance Specific to Diagnostic Nuclear Medicine: As far as I can tell this document is licensing guidance for all medical uses (except 10 CFR 35.1000). I don't see a need for another document.
4. Other guidance: 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."[4] 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 DandD, 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.

The following are additional comments regarding the document (no comments are made regarding teletherapy and mobile medical service equipment or procedures.):

1. 8.5 Item 5: Radioactive Material.
   a. The NRC currently allows licensees to request "As needed" amounts of material for use 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.
   b. 31.11 is mentioned on page 8-8. If a specific licensee stays below the limits listed in 31.11 is this material considered general license material or must the licensee follow their specific license (e.g. waste disposal requirements)?
   c. Table 8.1 Sample Format for Byproduct Material lists "maximum amount." Are these the maximum amounts that the NRC will allow on a license or are they just for demonstration purposes? 10 CFR 35.300 and 35.400 maximum amount should be "As needed." This is a currently acceptable amount on a license and should continue to be acceptable.
   d. The chemical/ 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

[3] NUREG-1556, Vol. 9, page xiv.
[4] NUREG-1559, Vol. 9, page Z-13.

Device Registry includes the manufacturer and model number so this statement would comply with 30.32(g)(1).

2. 8.7 Item 5: Sealed Sources and Devices. This section was briefly discussed in 8.5. This information should be included in 8.5 and revised to reflect my statement in 1.d. above. I do not see a benefit of this information being separated from 8.5.
3. 8.8 Item 6: Purpose(s) for which licensed material will be used: Table 8.3 "Radiopharmaceuticals Used in Therapy" should be removed as a requirement for the information that needs to be submitted. The "Agent" and "Form" are already covered by Item 5 of the application and "Route of Administration" is not required since 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 applicable information from Table 8.3 could be incorporated into Table C.2 "Items 5 and 6 on NRC Form 313: Radioactive Material and Use."
4. 8.10 Item 7: Radiation Safety Officer (RSO): 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.
5. 8.16 Item 9: Facility Diagram.
   a. 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?
   b. The following two contradictory statements are included on page 8-33. Which statement is true?
      i. "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."
      ii. "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 second statement contradicts §35.13(e). A solution to this contradiction would be to allow licensee's 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."[5] This would allow the license flexibility in assigning patient rooms for these therapies. The compliance of following these criteria should be reviewed during inspections. This solution would most likely need a rulemaking to implement due to the requirements in §35.12.
6. 8.18 Item 9: Dose Calibrator and Other Equipment Used to Measure Dosages of Unsealed Byproduct Material.
   a. Is this document included in the category of "nationally recognized standards (e.g. ANSI) or the manufacturer's instructions"?[6] If not, use of your model procedure in Appendix J

[5] 10 CFR Part 30.33(a)(2).
[6] NUREG-1559, Vol. 9, page 8-42.

would not be in compliance with the regulations.[7] References should be added to the procedure if it is based on a nationally recognized standard.

b. 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."[8] Once again this would most likely require a rulemaking due to the requirements in §35.12.

c. 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 license issued.[9]

7. 8.23 Item 10: Occupational Dose:
   a. Facilities and equipment should have already been described in Item 9 of Form 313.
   b. 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.
8. 8.25 Item 10: Minimization of Contamination: I do not see the benefit in submitting a description of how facility design and procedures will minimize contamination. 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.
9. 8.29 Item 10: Opening Packages: See note below.
10. 8.33 Item 10:Area surveys: See note below.
11. 8.35 Item 10: Procedures for Administrations Requiring A Written Directive: See note below.
12. 8.35 Item 10: Safe Use of Unsealed Licensed Material: See note below.
13. 8.37 Item 10: Spill Procedures: See note below.
14. 8.38 Item 10: Emergency Response for Sealed Sources or Devices Containing Sealed Sources: See note below.
15. 8.39 Item 10: Patient or Human research Subject Release: See note below.
16. 8.44 Item 11: Waste Management: See note below.

NOTE: Numbers 9 through 16 above 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.

17. The NRC states that this document "provides guidance on NRC criteria for evaluating a medical use license application"[10] The NRC staff is using this document for license review "while not suggesting that details in the guidance are prescriptive."[11] By using this guidance as criteria for license review the NRC is making this guidance prescriptive. In the past the

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[7] 10 CFR 35.60(b).
[8] 10 CFR Part 30.33(a)(2).
[9] 10 CFR 30.34(a).
[10] NUREG-1559, Vol. 9, Page 1-1
[11] NUREG-1559, Vol. 9,Page iv

NRC required licenses that submit or implement procedures that are less restrictive then the guidance to justify its implementation even if it is compliant with the applicable rules and regulations. I have had to do this type of justification in the past. Hopefully this will not continue in the future.

18. 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 burden 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.

Thank you for the opportunity to comment on the draft guidance. Should you have any questions regarding these comments, please do not hesitate to contact me at (262) 681-9329.

Sincerely,

Daniel J. Miron