NRCREP - RE: NUREG-1556, Volume 13, Revision 1 Comments

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To: <nrcrep@nrc.gov>
Date: 08/01/2007 10:03 AM
Subject: RE: NUREG-1556, Volume 13, Revision 1 Comments

Please find attached comments concerning the draft NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Commercial Radiopharmacy Licenses"; Draft Guidance Document for Comment. Federal Register Vol. 72, No. 127, July 3, 2007, which are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR).

Sincerely,

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VIA EMAIL

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**RE: NUREG-1556, Volume 13, Revision 1, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Commercial Radiopharmacy Licenses"; Draft Guidance Document for Comment. Federal Register Vol. 72, No. 127, July 3, 2007.**

These comments concerning the draft NUREG-1556, Volume 13 are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR). CORAR members include manufacturers and shippers of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instrumentation used in medical applications. CORAR membership also includes operators of commercial nuclear pharmacies, including those that also produce and distribute PET radiopharmaceuticals. CORAR has an interest in ensuring that diagnostic and therapeutic products can be made available as needed for the timely delivery of quality patient treatment and care and the regulation of both byproduct and accelerator-produced radioactive material to ensure the safety of workers, patients and other members of the public.

**General Comments**

CORAR had expressed a number of comments to NRC when the original version of NUREG-1556 Vol. 13 was published for comment in 1999. The current draft revision acknowledges our input, and we appreciate the consideration given by NRC on the comments although we are disappointed in the response to some of them. Some of those comments are reiterated in the specific comments below.

One general comment concerns the issue of "grandfathering" of authorized nuclear pharmacists who, as discussed in the proposed rule published on July 28, 2006, "will not be required to meet new training and experience requirements as long as their duties and responsibilities under the new license do not significantly change." There is no such discussion of grandfathering in the draft Volume 13, and this omission could be critical to ensuring the continued supply of accelerator produced radiopharmaceuticals. Specific guidance on

grandfathering of authorized nuclear pharmacists should be added to section 8.7.2 and any other relevant sections of the draft NUREG.

**Specific Comments**

**1. Section 8.2. Timely Notification of Transfer of Controls**

It is often difficult or impossible for licensees to meet this requirement, as often the RSO is not at a level to be made aware of such a change in the business prior to its execution. The best that can be expected in some cases is for immediate notification to be made when the RSO is made aware of the change.

**2. Section 8.5.2. Financial Assurance and Recordkeeping for Decommissioning**

CORAR agrees with the statement in this section that "most radiopharmacy applicants and licensees do not need to take any action to comply with the financial assurance requirements" because they possess radionuclides that have half-lives no greater than 120 days. We believe that it would be very useful to licensees for NRC to add to this discussion a statement to the effect that a decommission plan would also not be needed. This also may be particularly relevant in some states where licensees had been required to establish a plan, regardless of the need to obtain financial surety, for activities such as pharmacy renovation involving only a portion of the facility. NRC decommissioning requirements need to be a matter of strict compatibility for Agreement States.

**3. Section 8.6.1. Distribution and redistribution of Sealed and Unsealed Materials**
**Section 8.6.2. Preparation of Radiopharmaceuticals**

CORAR commented in 1999 on the original draft of Vol. 13 that the discussion in this section needed to include the characterization of the compounding of non-FDA approved radiochemicals as a nuclear pharmacy, and that NRC should state a position on acceptability of this practice. NRC responded in Appendix U of the proposed draft Vol. 13 that "fitness of a particular radiochemical for use in compounding radiopharmaceuticals for ultimate use in medicine is outside NRC's regulatory authority, and therefore, discussion of this issue is not appropriate in this guidance document."

CORAR maintains that it *is* within the scope of NRC's regulatory authority to require a license to manufacture and distribute radiopharmaceuticals where an operation is using non-FDA approved radiochemicals to compound "radiopharmaceuticals" and FDA considers this subject to "manufacturing" requirements rather than within the scope of pharmacy practice.

**4. Section 8.6.1. Distribution and redistribution of Sealed and Unsealed Materials**

CORAR recommends that discussion be added to this section to address the transfer of radioactive material from nuclear pharmacies to mobile nuclear medicine operations at temporary locations other than those specifically listed on a radioactive material license.

**5. Section 8.6.1. Page 9-13. For redistribution of calibration and reference sealed sources**

CORAR commented in 1999 on the original draft of Vol. 13 that it opposed the requirement for an applicant to confirm that the manufacturer's labeling and packaging will not be altered for redistribution of sealed sources, as an unnecessary burden on nuclear pharmacies. NRC responded in Appendix U of the proposed draft Vol. 13 with the statement that "if the packaging is not specified in the approval for initial distribution, then other persons may repackage the source or device for redistribution." CORAR suggests that NRC add this statement to section 8.6.1 of NUREG-1556, Vol. 13.

**6. Section 8.9.2. Facilities and Equipment for PET Radiopharmacies**

In the discussion it states, "the majority of the radioactive effluents at a PET radiopharmacy are produced during the synthesis of the PET radiopharmaceutical." A reference is also made in this section to Appendix R as it provides more information on effluent monitoring. CORAR agrees that at least in some cases PET radionuclides do contribute to the profile of radioactive gaseous effluents. However, with the highlighted discussion here on PET, NRC should provide some detailed guidance on monitoring PET effluents and demonstrating compliance with relevant limits. There also is no such guidance in Appendix R.

**7. Section 8.10.1. Audit Program**

CORAR members have operations that are subject to the regulatory requirement to conduct annual audits of their radiation protection programs. CORAR commented in 1999 on the original draft of Vol. 13 that it is imperative that NRC recognizes the efforts of a licensee to identify and take appropriate actions for self-identified deficiencies and not to penalize the licensee for its pro-active regulatory compliance program. NRC responded in Appendix U of NUREG-1556, Vol. 13, by stating that NRC enforcement policy (NUREG-1600) specifically affords inspectors the authority to withhold the issuance of a Notice of Violation for licensee-identified violations in those cases where it is warranted and appropriated.

CORAR appreciates this position but believes it does not go far enough because of the subjective nature of applicability and ongoing exposure of licensees to judgmental variability between inspectors. CORAR has addressed this issue separately with NRC in March 2007 in response to NRC Enforcement Policy; Proposed Plan for Major Revision, Federal Register volume 72, No. 16, page 3429, January 25, 2007. At that time CORAR commented that the Policy should address issues involving licensee disclosure of findings and other information as a result of audits conducted independent of NRC inspections. With regard to audits conducted by or on behalf of licensees, NRC should not require that the results of such audits be disclosed nor should NRC inspectors request copies of audit reports or findings. In addition, audit reports or findings should not be used by NRC to trigger NRC enforcement investigations.

In addition to the relief from civil penalty provided for Severity Level I – III violations in the current Policy, NRC should not cite a Notice of Violation for any non-reportable compliance problems self-identified and promptly and effectively corrected by the licensee. It would be reasonable for NRC to expect the finding, identification of root cause, and corrective action to be documented by the licensee for future reference. Alternatively, NRC could disposition these as Non-Cited Violations.

NRC should ensure that discussion in section 8.10.1 of NUREG-1556, Vol. 13 reflect these recommendations. Reference to the Enforcement Policy should be maintained so that any revisions to it will be incorporated by reference into this licensee guidance document.

**8. Section 8.10.2. Radiation Monitoring Instruments**

NRC in this section suggests that an applicant may respond with a statement that equipment used will meet the radiation monitoring specification published in Appendix J. Table J-1 in Appendix J includes a list of instrument types and "specifications" intended to "help applicants and licensees choose the proper radiation detection equipment for monitoring the radiological conditions at their facilities." However, a review of Table J.1 concludes that there really aren't any useful specifications provided. For example, energy ranges specified are "all energies." Efficiencies are specified as "moderate" or "high." These are very general and non-specific terms. We recommend that NRC include a table that includes real specifications that would be more useful to

those who need this level of technical guidance.

**9. Table 8.2. Record Maintenance**

Table 8.2 should be expanded to include the retention of written directives for three years in accordance with 35.2040-2041.

**10. Section 8.10.4. Occupational Dose**

NRC in recent years has paid significant attention to the issue of extremity dose and occupational monitoring at commercial nuclear pharmacies. CORAR and its members have approached NRC and have established a partnership in an effort to investigate the issue and develop needed guidance on methodologies for monitoring extremity dose to demonstrate compliance with 20.1201(a)(2)(ii). CORAR believes that guidance on extremity dose monitoring is warranted and strongly recommends that this section include discussion on this.

**11. Section 8.10.4. Occupational Dose**

This section should provide some guidance on whether an evaluation conducted to determine that an individual's dose is not likely to exceed 10% of the applicable limit needs to be conducted initially or at a recurring (e.g. annual) frequency thereafter. CORAR believes that the evaluation only needs to be conducted initially unless there is a change in the procedure or operation that could result in a higher exposure.

**12. Section 8.10.5. Public Dose**

There is discussion in this section on the need for licensees to control air emissions so that the constraint level of 0.1 mSv is not exceeded. However, there is no mention in this section of methods acceptable to NRC to demonstrate compliance with the constraint level. CORAR recommends that NRC provide in this section an acceptable method (e.g. EPA COMPLY code), or make reference other NRC guidance that provides a method for demonstrating compliance with the constraint level.

**13. Section 8.10.6. Safe Use of Radionuclides and Emergency Procedures**

Discussion in this section states, "licensees are responsible for the security and safe use of all licensed material from the time it arrives." CORAR recommends that NRC clarify the distinction between *delivery* of radioactive material by the carrier and *receipt* by the authorized consignee. This has implications with respect to the security of material in transport and obligations to report lost or missing shipments of radioactive material. It would be helpful for NRC to specify, or provide a reference that specifies, when a transfer from one licensee to another has been completed and at what point is security of the material transferred from the consignor to the consignee. It has been clarified by U.S. DOT in 49 CFR 171.8 regarding the definition of "unloading incidental to movement" that the cycle of transportation ends when delivery is made. This needs to be taken into consideration by NRC for additional discussion in this section.

**14. Figure 8.8. Use of Appropriate Shielding**

The picture intends to show the use of appropriate shielding in a nuclear pharmacy operation. Compared to actual nuclear pharmacy operations, it suggests a situation that does not employ best practices with regard to ALARA. For example, there are multiple unshielded containers in proximity to the extremities and no evidence of any remote or extended handling devices within reach. The handling is also done on a bench top

that would be unacceptable for dispensing of radiopharmaceuticals. This picture should be left out of the guidance or replaced with a more acceptable example.

**15. Page 8-46. Emergency Procedures**

The term "radionuclides" instead of "radioisotopes" should be used here and throughout the document.

**16. Figure 8.10. Page 8-49**

The figure shows improper monitoring technique. The detector needs to be placed as close to the object being surveyed without making contact.

**17. Page 8-60. Disposal By Decay-In-Storage (DIS)**

NRC suggests that waste held for decay should be held until a date when "ten half-lives of the longest-lived radioisotope have transpired." Other recent NRC guidance has dropped this requirement and only requires that residual radioactivity be determined to be indistinguishable from background prior to disposal. The guidance in this section should be made consistent with other NRC guidance.

**18. Appendix K. Table K.1. Standard Occupancy Factors**

CORAR recommends that NRC incorporate into Table K.1 the occupancy factors from NCRP Report 147 (page 31) for planning and assessing public dose.

**19. Appendix R. Air Stack Release Monitoring**

The reference to ANSI N13.1 (1969) should be revised to refer to the update 1999 version.

CORAR appreciates the opportunity to comment on the draft NUREG-1556, Vol. 13. Please contact us if there are any questions concerning these comments.

Sincerely,

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