Doris Mendiola - RE: Comments on draft NUREG 1556, Volume 9, Rev.2

From: "Fisher, Darrell R" <dr.fisher@pnl.gov>
To: "Torre Taylor" <TMT@nrc.gov>
Date: 08/30/2007 4:23 PM
Subject: RE: Comments on draft NUREG 1556, Volume 9, Rev.2
CC: "Ashley Tull" <amt1@nrc.gov>

8/02/07
72 FR 42442
(2)

Torre Taylor , Health Physicist
Project Manager for
Energy Policy Act NARM Guidance Writing Team

Dear Torre,

Please find attached my comments (due August 31) on draft NUREG 1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses, Program-specific Guidance About Medical Use Licenses," as requested in your letter dated July 26, 2007.

Sincerely,

Darrell R. Fisher (member of ACMUI)
229 Saint St.
Richland, WA 99354

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From:	"Fisher, Darrell R" <dr.fisher@pnl.gov>
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Comments on: NUREG-1556, Vol. 9, Rev. 2, "Consolidated Guidance about Materials Licenses, Program-specific Guidance about Medical Use Licenses"

Comment due date: August 31, 2007

Comment submitted by: Darrell R. Fisher (member of ACMUI)
229 Saint St.
Richland, WA 99354

Expertise: Health physics, medical physics, and radioactive materials for medical use.

General comments:

This is a 458-page document. Some of the document seems to be excessively wordy and repetitive. Any effort to provide a shorter, briefer guidance document would probably be appreciated by prospective and current licensees.

The words "is intended to" throughout could be removed, in most cases. For example, "This report provides guidance..." instead of "This report is intended to provide guidance..." and so forth throughout.

Other examples of unnecessary words include:

applicants should be aware that
a considerable amount of
the licensee is reminded that
it should be noted that
it is anticipated that
applicants are reminded of recentness of

Also throughout, this reviewer noted several inconsistent uses of "mCi" and "mci" for millicuries.

Overview, page 1-7. Add text as underlined: The quality factor used in 10 CFR 20 for alpha particles is 10. This will show the reader that the value 10 was taken from 10 CFR 20. Clarification is needed because the RBE for alpha emitters is determined experimentally and may vary widely for given circumstances. Quality factor is an upper limit on the RBE, chosen by committee, and the quality factor recommended by ICRP is 20. Therefore, it would be helpful for the reader to know why the NRC uses a value of 10 for the quality factor in this document, and where it was obtained.

Page 8-34, under 8.14 Item 7: Authorized Medical Physicist (AMP). The text states that "an AMP is directly involved with the calculation and administration of the radiation dose." Instead, the text should read: "an AMP is directly involved with radiation therapy treatment planning." The AMP would not normally be involved in administration of therapy radiation to a patient.

Page 8-42 under 8.17 Item 9. The text states that "Usually, it is not necessary for a licensee to possess a survey meter solely for use during sealed source diagnostic procedures, unless the procedure involves localization of radioactive seeds, since it is not

expected that a survey will be performed each time such a procedure is performed." However, the text fails to mention the importance of having a survey meter on hand during and after a brachytherapy seed implant to look for seeds that may have been misplaced, that may have fallen to the floor, or that may remained in equipment after the procedure. Furthermore, these seeds are used for therapeutics, not diagnostic procedures as the text incorrectly suggests.

Page 8-43, under 8.18 Item 9: Dose Calibrator. Throughout this section, the text implies that a dose calibrator measures dosages. More correctly, the dose calibrator measures activity or radioactivity, not dosages. The text describes "instruments (e.g., dose calibrators) used to measure patient dosages." Instead, it would be more correct to state that the dose calibrators are used "to measure the radioactivity present in a syringe, tube, vial, or capsule." Further, the text states that "As described in 10 CFR 35.63, dosage measurement is required for licensees who prepare patient dosages." More correctly, this sentence should read "...measurement is required for licensees who prepare radiopharmaceuticals for administration to patients."

Page 8-47. Correct spelling should be as follows (underlined): "When patients are treated with I-131 sodium iodide, sources of contamination include . . ."

Page 8-78. The statement is given that: "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." I question the accuracy of this statement. The beta dose from tissue surfaces is only a small part of the total from within the body. Most of the beta radiation is locally absorbed, except for small amounts present on tissue surfaces. The major dose to man is still gamma from brehmsstralung, even during an operation or an autopsy. The skin dose to hands is negligible. I have experience doing this kind of work with the assistance from radiation monitoring specialists.

Page 8-79. The statement is given that: "Licensed materials must be tracked from 'cradle to grave,' from receipt (from another licensee or from its own radionuclide production facility) to its eventual transfer/disposal in order to ensure accountability; identify when licensed material could be lost, stolen, or misplaced; and ensure that possession limits listed on the license are not exceeded." However, there seems to be a thought disconnect between proper tracking "from cradle to grave" and inadvertent losses of material by theft. Further, it will NOT BE POSSIBLE, in advance, to anticipate how licensed material would be lost, stolen, or misplaced if the licensee is doing everything possible to prevent loss and theft. There could be almost an unlimited number of ways that theft or loss could happen and times when it could happen. Further, there seems to be a disconnect between the concept of theft or loss and the concept of possession-limit tracking. I recommend that you separate the distinctly different concepts of tracking possession limits and safeguarding against theft or loss.