Doris Mendiola - Comments on draft NUREG 1556, Volume 13, Rev.1

From: "Fisher, Darrell R" <dr.fisher@pnl.gov>
To: <tmt@nrc.gov>
Date: 07/30/2007 10:19 PM
Subject: Comments on draft NUREG 1556, Volume 13, Rev.1
CC: "Ashley Tull" <amt1@nrc.gov>

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72 FR 36526
(3)

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

Dear Torre,

Please find attached my comments on draft NUREG 1556, Vol. 13, Rev. 1, as requested by Ashley Tull in her e-mail message to me dated Thursday June 21, 2007

Sincerely,

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

<<Comments on NUREG 1556-13.doc>>

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Comments on: NUREG-1556, Vol. 13, Rev. 1, "Program-Specific Guidance about Commercial Radiopharmacy Licenses."

Comment date: July 30, 2007
Comment submitted by: Darrell R. Fisher (member of ACMUI)
229 Saint St.
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Section 8.6.1, page 8-11: In the definition of radioactive drugs, *radiobiologics* [*radio* Latin emitting rays; *bio, bios* Greek life, living; *logics, logica* Latin of reason, guiding principles] seems to be an incorrect choice of word and incorrect usage in this context. Monoclonal antibodies are non-living chemicals that may be considered as biological agents or radioactive drugs because they function in a certain way in living systems by seeking out cell-surface antigens, but the term *radiobiologics* is not a standard synonym for radiolabeled monoclonal antibody.

Section 8.6.1, page 8-16: If discrete Ra-226 sources are to be redistributed for beneficial reuse and reconfigured as targets for accelerator irradiation to produce new radioactive materials, the requirements in this section appear to be overly restrictive and inhibitive of this practice. For redistribution of discrete sources of radium-226, it may be impossible to confirm that the discrete sources of radium-226 will be obtained by a [or from a??] manufacturer authorized to distribute it. For most legacy sources, it will not be possible to identify the manufacturer. Manufacturer-supplied package inserts may not have been produced. Limitations on the ability of a licensee to alter Ra-226 packaging may prevent Ra-226 from being recombined into larger-activity sources for use in configurations that are necessary to use Ra-226 as a target for new isotope production. An example would be the use of Ra-226 to produce Ra-225, which decays to Bi-213 for medical applications.

Section 8.7, page 8-18. The commentary that "management responsibility and liability are sometimes underemphasized or not addressed in applications and are often poorly understood by licensee employees and managers" appears to be inappropriate and unnecessary in this guidance document. It should not be the purpose of this document to assume the competence of some applicant organizations. Delete text.

Section 8.7.3, page 8-22. The statement that "applicants should pay particular attention to the type of radiation involved...For example, someone experienced with gamma emitters may not have appropriate experience for high-energy beta emitters" seems unnecessary if the student has met the requirements in the text above and has studied the characteristics of ionizing radiation. Again, the NRC appears to be judging competency based on the assumption that a situation could exist where a trained authorized user understands gamma rays but not beta particles. Delete text.

Section 8.10.6, page 8-45. The Guidance assumes the radiopharmacy uses only Mo-99/Tc-99m generator systems, when many other types of generators are available or

could be developed in the future. The elution breakthrough test is applicable to any radionuclide generator system in the radiopharmacy, not just Mo/Tc. Examples of other generator systems include: Sr-82/Ru-82, Sr-90/Y-90, Ac-225/Bi-215, Ac-227/Ra-223, and Ge-68/Ga-68.