Mendiola, Doris

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Sent:	Monday, August 15, 2011 8:44 AM
To:	Rulemaking Comments
Cc:	Huston, Thomas E.; Bhalla, Neelam
Subject:	Comments on 10 CFR Part 35; NRC-2008-0175
Attachments:	VHA comments for Part 35 rulemaking.docx

I am attaching Veterans Health Administration comments on proposed rulemaking for 10 CFR Part 35.

The NRC reference is NRC-2008-0175.

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The Veterans Health Administration (VHA) is a federal agency with a master materials license. A master materials licensee has regulatory authority to issue permits, complete inspections, and take other actions similar to those of regulatory agencies.

The specific comments below are based on VHA experience with implementation of a master materials license with medical uses under 10 CFR Part 35.

§ 35.12 Application for license, amendment, or renewal.

Revise this section, as needed, to provide for electronic submission of applications.

§ 35.13 License amendments.

Delete the requirement for a licensee to confirm information on the Sealed Sources and Device Registry since access by licensees to that registry is restricted.

Add an exception to paragraph (h) for any sealed sources received as either an exempt quantity or a generally licensed source.

Add an exception to paragraph (h) for any sealed sources received under §35.65(b).

§ 35.14 Notifications.

Add the "maximum amount to be possessed at any one time" (or equivalent text) to the information that must be provided as part of notification in § 35.14(b)(6).

§ 35.50 Training for Radiation Safety Officer.

Change text referencing master materials licensee in § 35.50(c)(2) to be consistent with text in § 35.2 and § 35.14(a).

§ 35.65 Authorization for calibration, transmission, and reference sources.

Modify the restriction proposed in § 35.65(a)(1) to allow for the use of sealed sources meeting paragraph (b) conditions to be used for § 35.200 purposes. For example, low activity transmission sources meeting the current regulation (< 30 millicuries) are contained in some imaging equipment such as PET scanners. Also, some licensees use spot markers as reference sources to help with determining anatomical location. If the proposed text is adopted, many medical use licensees might be required to stop use of these sources, obtain the device-specific training per § 35.590 and then wait on an amendment adding § 35.500 use to resume critical patient care activities which are now interpreted as authorized under § 35.65.

Another option is simply to delete § 35.65(a)(1) as unwarranted since a significant health and safety issue to drive this change is not evident.

Delete the restriction established in § 35.65(a)(2) related to aggregating sealed sources since this apparent anomaly is best addressed by restrictions on manufacturers of the sealed sources rather than a medical licensee.

§ 35.390 Training for use of unsealed...

Delete the proposed case experience requirements for administering patient doses by the impractical categories of photon energy, beta radiation, and alpha radiation.

Consult with physician professional society and residency program directors to develop a more generic case experience requirement for lower energy radiation.

Revise the other sections in the draft rulemaking, as needed, to be consistent with this proposed change.

§ 35.400 Use of sources...

Revise this section to clarify which of the limitations and conditions in a Sealed Source and Device Registry for a brachytherapy source are applicable for radiation safety or for other safety or use restrictions and which are subject to change based on authorizer user clinical judgment.

§ 35.500 Use of sources...

See comment above for § 35.400 to revise the section to clarify the statements about limitations and conditions of use.

§ 35.600 Use of sources...

See comment above for § 35.400 to revise the section to clarify the statements about limitations and conditions of use.