

**Mendiola, Doris**

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**From:** Williams, Gary E [Gary.Williams3@va.gov]  
**Sent:** Tuesday, December 21, 2010 9:21 AM  
**To:** Rulemaking Comments  
**Cc:** Huston, Thomas E.; Adams, Craig L.  
**Subject:** Comments on 10 CFR Part 37 guidance document; Docket ID NRC-2010-0194  
**Attachments:** Part 37 guidance comments Dec 21 2010.docx

I am attaching comments from the Veterans Health Administration, National Health Physics Program, for the draft 10 CFR Part 37 guidance document.

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## **NHPP general comments**

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. As a federal agency, VHA has an on-site internal law enforcement agency and established methods to complete security clearances for any workers who might require unescorted access to category 1 or category 2 radioactive materials.

The draft 10 CFR Part 37 guidance document does not provide adequate descriptions or clarifications in the questions and answers to outline how these regulations might be applicable to a master materials licensee or to a federal agency in general. The lack of clarifications in the questions and answers is similar to the lack of clarifications for the previously issued increased controls and will likely result in continued confusion during Nuclear Regulatory Commission (NRC) compliance inspections at VHA facilities.

Since the proposed Part 37 has received significant stakeholder feedback and is subject to be changed in significant sections, NHPP is not providing detailed comments for each of the sections in the draft guidance. Rather, the expectation is that a revised guidance document will be issued to be consistent with the final Part 37.

The general NHPP comments below are provided for context about the sections in the guidance that should have explicit clarifications for the unique differences for a master materials licensee or federal agency. These comments also reflect the continued NHPP experience with implementing increased controls in a federal health care environment.

## **NHPP comments for sections in draft 10 CFR Part 37 guidance document**

### **§ 37.3 Definitions.**

Provide a definition or explanation for a master materials license and a permit issued by such a licensee.

Indicate a master materials licensee is also a license issuing authority.

Indicate that a determination of trustworthiness and reliability is also based on § 37.3.

### **§ 37.21 Personnel access....**

Delete the section for reporting compliance with the regulations or, if the section is in the final regulations, indicate differences for a permittee under a master materials license.

For individuals approved as provided in § 37.29, this section should be revised to clarify explicitly which "investigation elements" are not applicable.

### **§ 37.23 Access authorization....**

If external approval for reviewing officials is retained as a regulatory requirement, then add a clarification for a master materials licensee to approve reviewing officials at the permittee level facilities as provided in § 37.29.

For individuals approved as provided in § 37.29, this section should be clarified to state explicitly which subsections in the final regulations are applicable and must be followed.

For any individuals approved or not approved as provided in § 37.29, the requirement to have or maintain a list of persons not approved for access should be explicitly excluded since existing federal guidelines for security reviews are applicable.

### **§ 37.25 Background investigations**

For individuals approved as provided in § 37.29, this section should be clarified to state explicitly which subsections in the final regulations are applicable and must be followed.

### **§ 37.29 Relief from...**

Clarify that inspectors under a master materials licensee are also not required to comply with this section in the regulations.

Clarify in this section of the guidance document whether any persons approved under a federal security review program have to be reapproved after a specified time interval.

### **§ 37.31 Protection of information**

For individuals approved as provided in § 37.29, this section should be clarified to state explicitly which subsections in the final regulations are applicable and must be followed.

### **§ 37.33 Access authorization program review**

For individuals approved as provided in § 37.29, this section should be clarified to state explicitly which subsections in the final regulations are applicable and must be followed.

### **§ 37.41 Security program**

Clarify in this subsection that a permittee updates the regulatory office of the master materials licensee rather than an NRC regional office.

Clarify in this subsection that any licensee is restricted in detection and assessment by available technology and resources such as using the wording "...without undue delay detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material as outlined in their security plan."

Clarify in this subsection that a permittee reports to the regulatory office of the master materials licensee.

#### **§ 37.43 General security program requirements**

Clarify in this subsection that the security plan and implementing procedures can be in the same document or group of documents.

Add wording to clarify that the protection of information refers to the written security plan or procedures only. The wording should preclude unwarranted interpretations during a regulatory inspection about what information or discussions to restrict by indicating the following: "access to copies of their written security plan and implementing procedures and...disclosure of substantive details of the plan or procedures that might facilitate unauthorized access."

#### **§ 37.45 LLEA coordination and notification**

Clarify requirements and guidelines for coordination by a licensee or permittee under a master materials license that has an on-site LLEA.

#### **§ 37.49 Monitoring, detection, and assessment**

Clarify in this subsection that any licensee is restricted in detection and assessment by available technology and resources with wording such as "monitor and detect without undue delay all unauthorized entries into its security zones as outlined in their security plan."

#### **§ 37.55 Security program review**

Clarify the frequency for annual reviews as follows: an annual frequency not to exceed 14 months between the dates of the reviews.

#### **§ 37.57 Reporting of events**

Clarify the reporting requirements by a licensee or permittee under a master materials license that has an on-site LLEA as follows: For a licensee or permittee under a master materials license with an on-site LLEA, reporting in this subsection is required only after the on-site LLEA has confirmed the attempted, actual, or actual activity related to theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material.

#### **§ 37.71 Additional requirements...**

Clarify possible access, including procedural steps, for a licensee to the NRC license verification system.

#### **§ 37.101 Form of records**

Clarify in this section the concept of "safeguards with tampering with" to preclude any unwarranted interpretations during a regulatory inspection about the requirements for records with wording such as the following: The requirements in § 37.43 for protection of information are not applicable to this section.