

**Rulemaking Comments**

---

**From:** Williams, Gary E [Gary.Williams3@va.gov]  
**Sent:** Friday, September 17, 2010 10:38 AM  
**To:** Rulemaking Comments  
**Cc:** Huston, Thomas E.  
**Subject:** Comments on 10 CFR Part 37; RIN 3150-AI12; NRC 2008-0120  
**Attachments:** Part 37 comments Sep 17.docx

I am attaching comments from the VHA National Health Physics Program.

Gary E. Williams  
Director, National Health Physics Program Veterans Health Administration North Little Rock, Arkansas W 501-257-1572; C 501-256-5331

DOCKETED  
USNRC

September 17, 2010 (2:50pm)

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

Template = SECY-067

## **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 fails to provide descriptions in most sections to outline how the regulations are applicable to a master materials licensee or a federal agency. This lack of descriptions follows the pattern of the previously issued increased controls and will likely result in confusion during Nuclear Regulatory Commission (NRC) compliance inspections at VHA facilities.

The specific NHPP comments below are provided to establish within the regulations an explicit statement of differences for a master materials licensee or federal agency.

In addition, NHPP has other comments related to regulatory sections that are based on NHPP experience with implementing increased controls in a health care environment.

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

### **§ 37.3 Definitions.**

Add the following definition for use in various subsequent sections in the regulation.

*Master materials license* means a material (byproduct, source, and/or special nuclear material) license issued to a Federal organization authorizing use of material at multiple permittees and geographic sites. The licensee has regulatory authority to issue permits for possession and use of material under the license and provides oversight and internal inspections of licensed activities at the permittees and sites. This type of licensee is a duly authorized representative for the commission.

Revise the following definition as indicated for clarification.

*License*, except where otherwise specified, means a license for byproduct material issued pursuant to the regulations in parts 30 through 36 and 39 of this chapter **or a permit issued by a master materials licensee.**

Revise the following definition as indicated for clarification.

*License issuing authority* means the licensing agency that issued the license, i.e. the U.S. Nuclear Regulatory Commission or the appropriate agency of an Agreement State **or a master materials licensee that issues a permit;**

Revise the following definition as indicated for clarification.

*Trustworthiness and reliability* are characteristics...A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation or as provided for in § 37.29.

#### § 37.21 Personnel access....

Delete the following section as being unnecessary since current implementation of the NRC order for increased controls is an adequate basis to conclude the current licensees will transition to compliance with the new regulations.

~~(3) By (30 days after the final rule is published in the Federal Register), each licensee that is authorized to possess a category 1 or category 2 quantity of radioactive material on (effective date of this rule) shall submit information concerning the licensee's compliance with the requirements of this subpart to the appropriate NRC regional office specified in § 30.6.~~

If the section above is retained, then revise last sentence as follows.

...to the appropriate NRC regional office... or for a permittee under a master materials licensee to the master materials licensee.

Delete the following requirement for the reviewing officials to have unescorted access to category 1 or category 2 quantity of radioactive material. The licensee should have the option to designate a reviewing official but not also authorize that individual for approval for unescorted access. This requirement is unduly restrictive on management options for a licensee.

#### ~~(v) Reviewing officials.~~

Delete the following section as being redundant to previous sections about who is to be approved for unescorted access. Also, this section introduces new criteria for approval (individuals with job duties that require unescorted access) that is not otherwise used in the regulations. If considered necessary to limit approvals, then section § 37.21(c)(1) should be modified by inserting the word "only."

~~(3) Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.~~

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

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

Revise the sections for the reviewing official to delete the requirement for NRC approval and, instead, require licensee executive management to designate reviewing officials.

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

For individuals approved as provided in § 37.29, each subsection in this section should be revised to state explicitly which subsections are applicable and must be followed.

For individuals approved or not approved as provided in § 37.29, the requirement to maintain a list of persons not approved for access should be explicitly excluded.

### **§ 37.25 Background investigations**

For individuals approved as provided in § 37.29, each subsection in this section should be revised to state explicitly which subsections are applicable and must be followed.

### **§ 37.29 Relief from...**

Revise the following subsection as indicated for clarification.

(g) Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act **or master materials licensee employees conducting inspections under their license authority;**

Subparagraph (k) should have an explicit statement about whether persons approved under a government program have to be reapproved after a specified time interval.

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

For individuals approved as provided in § 37.29, each subsection in this section should be revised to state explicitly which subsections are applicable and must be followed.

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

For individuals approved as provided in § 37.29, each subsection in this section should be revised to state explicitly which subsections are applicable and must be followed.

### **§ 37.41 Security program**

Revise this subsection as indicated to remove the unnecessary requirements to have a security program when category 1 or category 2 radioactive material is not possessed nor expected to be possessed.

(2) A licensee that is authorized to possess at least a category 2 quantity of radioactive material but does not possess an aggregated quantity that equals or exceeds the category 2 threshold shall develop **and implement** a security program in accordance with the requirements of this subpart at least 90 days before a **the** licensee aggregates radioactive material to a quantity that equals or exceeds the category 2 threshold, ~~the licensee shall implement its security program~~. The licensee shall provide written notification to the NRC regional office specified in § 30.6 of this chapter **or for a permittee under a master materials licensee to the master materials licensee** that the licensee is now implementing ~~it's~~ **a** security program as follows:

Revise this subsection to reflect a licensee is restricted in detection and assessment by available technology and resources.

b) General performance objective. Each licensee shall establish, implement, and maintain a security program that is designed to monitor, and 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**.

Delete the following section as being unnecessary since current implementation of the NRC order for increased controls is an adequate basis to conclude the current licensees will transition to compliance with the new regulations.

~~(d) Information submittal and notification. By (30 days after the final rule is published in the Federal Register), each licensee that is authorized to possess a category 1 or category 2 quantity of radioactive material on the effective date of this regulation shall submit information concerning the licensee's compliance with the requirements of this subpart to the appropriate Regional Administrator.~~

If the section above is retained, then revise last sentence as follows.

...with the requirements of this subpart to the appropriate Regional Administrator **or for a permittee under a master materials licensee to the master materials licensee regulatory authority**.

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

Add subsection to provide for the security plan and implementing procedures to be in the same document or group of documents.

**(a)(5) The security plan and implementing procedures can be combined into the same or a group of related documents consistent with the licensee's administrative practices, if the required elements for a security plan are included.**

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. See the example

below for one subsection. The other subsections should also be revised to indicate the required protection of information.

(1) Except as provided in paragraph (d)(8) of this section, licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to copies of their written security plan and implementing procedures and unauthorized disclosure of substantive details of the plan or procedures that facilitate unauthorized access.

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

Add a subsection to clarify requirements for coordination by a licensee or permittee under a master materials license that has an on-site LLEA. The subsection should preclude unwarranted interpretations during a regulatory inspection about the extent that coordination must be documented.

(d) For a licensee or permittee under a master materials license with an on-site LLEA, coordination requirements in this subsection are considered to have been completed if the security plan and implementing procedures establish methods for LLEA response at the facility.

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

Revise this subsection to reflect a licensee is restricted in detection and assessment by available technology and resources.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without undue delay all unauthorized entries into its security zones as outlined in their security plan.

Revise this subsection to reflect a licensee is restricted in detection and assessment by available technology and resources. Revise the subsection for response with the same changes.

(b) Assessment. Licensees shall immediately assess without undue delay each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion zones as outlined in their security plan.

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

Revise the frequency for reviews as follows.

Each licensee shall ensure that the security program is reviewed at an annual frequency not to exceed 14 months between the dates of the reviews.

### **§ 37.57 Reporting of events**

Add a subsection to clarify requirements for reporting by a licensee or permittee under a master materials license that has an on-site LLEA. The subsection should preclude unwarranted interpretations during a regulatory inspection about reporting to NRC.

(d) 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 to licensees to the NRC license verification system.

### **§ 37.101 Form of records**

Clarify in this section the concept of "safeguards with tampering with" to preclude unwarranted interpretations during a regulatory inspection about the requirements for records.

...The licensee shall maintain adequate safeguards against tampering with and loss of records. The requirements in § 37.43 for protection of information are not applicable to this section.

### Specific NRC Questions for Reviewing Official

(1) Does the reviewing official need to be fingerprinted and have a FBI criminal records check conducted? No, the reviewing official should be approved at the licensee level.

(2) Are the other aspects of the background investigation adequate to determine the trustworthiness and reliability of the reviewing official? Yes.

(3) Are there other methods that could be used to ensure that the reviewing official is trustworthy and reliable? Yes, defer to the licensee management to review and approve the reviewing official using best business practices.

(4) Does the requirement to fingerprint the reviewing official place too large of a burden on the licensee? Yes.

(5) Do Agreement States have the necessary authority to conduct reviews of the nominated individual's criminal history record? NHPP does not have a comment.

### Specific NRC Questions for Background Investigations

NHPP does not have a comment for these questions.

Specific NRC Questions for Protecting Security-Related Information

- (1) Do the Agreement States have adequate authority to impose the information protection requirements in this proposed rule? NHPP does not have a comment.
- (2) Can the Agreement States protect the information from disclosure in the event of a request under a State's Freedom of Information Act, or comparable State law? NHPP does not have a comment.
- (3) Is the proposed rule adequate to protect the licensees' security plan and implementing procedures from unauthorized disclosure, are additional or different provisions necessary, or are the proposed requirements unnecessarily strict? The sections should be clarified to indicate that only written copies of the plan and procedures are being protected.
- (4) Should other information beyond the security plan and implementing procedures be protected under this proposed requirement? No, the regulations should be explicit to indicate that only written copies of the plan and procedures require protection.
- (5) Should the background investigation elements for determining whether an individual is trustworthy and reliable for access to the security information be the same as for determining access to category 1 and category 2 quantities of radioactive material (with the exception of fingerprinting)? Yes, if the information restriction is to the written plan and procedures, then approval requirements should be similar.

Specific NRC Questions for Temporary Jobsites

NHPP does not have a comment for these questions.

Specific NRC Questions for Reporting Requirements

- (1) Are these the appropriate items and thresholds to be reported to the LLEA? Yes.
- (2) Are these the appropriate items and thresholds to be reported to the NRC? Yes, if confirmed by the LLEA at a facility with an on-site LLEA.
- (3) Should suspicious activities be reported? If they are reported, what type of activities should be considered suspicious? No, the concept of suspicious activities is ill-defined and reporting should not be required unless a theft, sabotage, or diversion is confirmed by the LLEA.
- (4) Is the timeframe for reporting appropriate? Yes.

Specific NRC Questions for Transfers of Radioactive Materials

NHPP does not have a comment for these questions.

Received: from mail1.nrc.gov (148.184.176.41) by OWMS01.nrc.gov  
(148.184.100.43) with Microsoft SMTP Server id 8.1.393.1; Fri, 17 Sep 2010  
11:34:47 -0400

X-Ironport-ID: mail1

X-SBRS: 5.6

X-MID: 22500657

X-IronPort-Anti-Spam-Filtered: true

X-IronPort-Anti-Spam-Result:

AhkBAL4nk0zNhEq+nGdsb2JhbACBRaB0AQEBAQEICwgJESLDKIMKgjYE

X-IronPort-AV: E=Sophos;i="4.56,383,1280721600";  
d="scan'208,217";a="22500657"

Received: from gw21.firstenergycorp.com (HELO firstenergycorp.com)  
([205.132.74.190]) by mail1.nrc.gov with ESMTP; 17 Sep 2010 11:34:46 -0400

In-Reply-To:

<377CB97DD54F0F4FAAC7E9FD88BCA6D026011792D9@HQCLSTR01.nrc.gov>

To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>

Subject: RE: Comments on Proposed Rule, Docket ID NRC-2008-0554

MIME-Version: 1.0

X-KeepSent: FA8C54CE:98E48B6E-852577A1:005554F3;  
type=4; flags=0; name=\$KeepSent

X-Mailer: Lotus Notes Release 7.0.3 September 26, 2007

Message-ID:

<OFFA8C54CE.98E48B6E-ON852577A1.005554F3-852577A1.00559374@FirstEnergyCorp.com>

From: <cjwartz@firstenergycorp.com>

Date: Fri, 17 Sep 2010 11:34:43 -0400

X-MIMETrack: Serialize by Router on mail01/Servers/FirstEnergy(Release 8.5.1FP2HF393 |  
June

17, 2010) at 09/17/2010 11:34:43,

Serialize complete at 09/17/2010 11:34:43,

Itemize by SMTP Server on GW13/Servers/FirstEnergy(Release 8.5.1FP2|March

17, 2010) at 09/17/2010 11:34:42 AM,

Serialize by Router on GW13/Servers/FirstEnergy(Release 8.5.1FP2|March 17, 2010) at  
09/17/2010 11:34:43 AM,

Serialize complete at 09/17/2010 11:34:43 AM

Content-Type: multipart/alternative;

boundary="=\_alternative 00559373852577A1\_="

Return-Path: cjwartz@firstenergycorp.com