

Doris Mendiola - FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM

From: "Frazee, Terry (DOH)" <Terry.Frazee@DOH.WA.GOV>  
 To: <TMT@nrc.gov>  
 Date: 08/02/2007 8:39 PM  
 Subject: FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM  
 CC: "Schwab, Kristen (DOH)" <Kristen.Schwab@DOH.WA.GOV>, "Scroggs, Arden (DOH)" <Arden.Scroggs@DOH.WA.GOV>, "Elsen, Mike (DOH)" <Mike.Elsen@DOH.WA.GOV>, "Fordham, Earl W (DOH)" <Earl.Fordham@DOH.WA.GOV>, "Robertson, Gary (DOH)" <Gary.Robertson@DOH.WA.GOV>

7/3/07  
 72 FR 06526  
 (5)

Please accept the attached comments on FSME-07-061. Thanks!

From: Elsen, Mike (DOH)  
 Sent: Thursday, August 02, 2007 4:34 PM  
 To: Frazee, Terry (DOH); Fordham, Earl W (DOH); Robertson, Gary (DOH); Scroggs, Arden (DOH)  
 Cc: Schwab, Kristen (DOH)  
 Subject: FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM  
 Importance: High

RECEIVED

2007 AUG -3 AM 9:39

RULES AND DIRECTIVES  
 BRANCH  
 CHANG

All-

Here are the comments that Kristen had on the draft guidance. I don't believe that any other comments are being sent by this office. Can we go ahead and email them to the point of contact? Thanks

Mike

From: Schwab, Kristen (DOH)  
 Sent: Thursday, August 02, 2007 2:59 PM  
 To: Elsen, Mike (DOH)  
 Cc: Scroggs, Arden (DOH); Demaris, Curt (DOH)  
 Subject: FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM  
 Importance: High

Mike-

These comments are due **today** (of course) NOT July 30th as letter says. I only have 4, but a few of them are worth getting in. I believe all we have to do is send them via email??

-Kristen

From: Elsen, Mike (DOH)  
 Sent: Thursday, June 28, 2007 12:07 PM  
 To: Schwab, Kristen (DOH)  
 Subject: FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM

SUNSI Review Complete  
 Template = ADM-013  
 file://C:\temp\GW\00002.HTM

E-REDS = ADM-03  
 Add = M. Taylor (TMT)

08/03/2007

Do you want or have time to review?

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**From:** Fordham, Earl W (DOH)  
**Sent:** Thursday, June 28, 2007 9:36 AM  
**To:** Elsen, Mike (DOH)  
**Subject:** FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM

Are you interested in providing any comments?

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**From:** Gwendolyn Davis [mailto:gxd@nrc.gov]  
**Sent:** Thursday, June 28, 2007 9:41 AM  
**To:** Fordham, Earl W (DOH)  
**Subject:** FSME-07-061, Opportunity to Comment on Draft NRC Guidance on NARM

All Agreement States Letter FSME-07-061 is contained in the attached file, and can be located in ADAMS at: ML071780411

Agreement States letters are posted at the FSME web site:  
<http://nrc-stp.ornl.gov/>

Thank you.

**Mail Envelope Properties** (46B277D9.7AF : 21 : 59311)

**Subject:** FW: FSME-07-061, Opportunity to Comment on Draft NRC Guidance  
on NARM  
**Creation Date** 08/02/2007 8:33:32 PM  
**From:** "Frazee, Terry (DOH)" <[Terry.Frazee@DOH.WA.GOV](mailto:Terry.Frazee@DOH.WA.GOV)>  
**Created By:** [Terry.Frazee@DOH.WA.GOV](mailto:Terry.Frazee@DOH.WA.GOV)

**Recipients**

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DOH.WA.GOV

Gary.Robertson CC (Gary (DOH) Robertson)  
Earl.Fordham CC (Earl W (DOH) Fordham)  
Mike.Elsen CC (Mike (DOH) Elsen)  
Arden.Scroggs CC (Arden (DOH) Scroggs)  
Kristen.Schwab CC (Kristen (DOH) Schwab)

**Post Office**

TWGWPO02.HQGWDO01

**Route**

nrc.gov  
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<b>Files</b>	<b>Size</b>	<b>Date &amp; Time</b>
MESSAGE	2031	08/02/2007 8:33:32 PM
TEXT.htm	4878	
FSME-07-061.doc	34816	
Mime.822	57730	

**Options**

**Expiration Date:** None  
**Priority:** High  
**ReplyRequested:** No  
**Return Notification:** None

**Concealed Subject:** No  
**Security:** Standard

## OPPORTUNITY TO COMMENT ON DRAFT NRC GUIDANCE ON NARM (FSME-07-061)

The following are my comments on draft NUREG-1556, Volume 13, Revision 1(FSME-07-061).

### 1.) **Forward** (page x):

The second paragraph, 3<sup>rd</sup> sentence should read:

This expanded definition includes the material that is *produced*, extracted or converted after extraction for use for a commercial, medical, or research activity.

### 2.) **8.5 Item 5: Radioactive Material: 8.5.1 Unsealed and/or Sealed Byproduct Material** (page 8-5):

The fourth paragraph reads:

It should also be noted that NRC's regulatory authority includes the new byproduct material produced prior to August 8, 2005. As a result, neither NRC, an Agreement State, or a non-Agreement State may have performed a safety evaluation of the sealed source or device. Therefore, the sealed source or device may not have an Sealed Source and Device Registry (SSDR) registration certificate. 10 CFR 30.32(g) provides information that must be submitted for these types of sources.

This paragraph is written poorly and the intent of the paragraph is unclear. The paragraph should be rewritten to clearly express the intent.

### 3.) **8.9.2 Facilities and Equipment for Pet Radiopharmacies** (page 8-30):

#### **Discussion:**

#### Shielding/ Remote Handling Equipment

The guidance should separate the shielding discussion from the remote handling equipment discussion. Descriptions of shielding should be provided for the transfer lines when transferring material from the cyclotron to the hot cell, and between the hot cell and the chemistry synthesis unit. Descriptions of shielding should also be provided for the physical hot cell, chemistry synthesis unit, both short lived and long lived (from target rebuilding) waste.

The applicant should describe the remote handling equipment that will be used (i.e. manipulators in the hot cell, automatic transfer lines to move material between process stations).

#### Effluent Control and Monitoring

Examples of engineered controls to reduce the amount of material released should include the use of gas-trapping bags to capture the effluent from the chemistry synthesis unit. It is a common practice to hold up the high activity, short lived effluent in a bag for decay. This method is extremely effective in substantially reducing the amount of activity released as

effluent to the air from a manufacturer of PET radiopharmaceuticals. If gas-trapping bags are used the applicant must address the location, shielding, and handling (emptying) of these gas-trapping bags.

The applicant should discuss the location of, and calibration and reliability testing procedures and frequencies for the real-time effluent (stack) monitor.

Additional Equipment not Addressed/ Comments

The applicant should also discuss the procedures/ controls in place to assure the integrity of the transfer lines are not compromised prior to a transfer. A loss of material during a transfer from the cyclotron to the hot cell could result in a substantial amount of high activity material being spilled, potentially causing a high personnel exposure.

Figure 8.4 should appear in section 8.9 not 8.10; Figure 8.4 should be moved to page 8-31 and the information on page 8-31 should be moved to page 8-32.

- 4.) Why was the information in Appendix M replaced completely? The Appendix M information contained in the original NUREG 1556 vol 13 appeared to be informative and beneficial.