PR 20,30,31,32,33,35,50,60,61,62,72,110, 150, 170 and 171
(71FR42952)

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

33

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

SEP 07 2006

In Reply Refer To: 598/115HP/NLR

Secretary
ATTN: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Re: RIN 3150-AH84

Dear Sir or Madam,

We are enclosing our Veterans Health Administration comments on the proposed rule and requirements for the expanded definition of byproduct material.

We strongly support incorporation of naturally occurring and accelerator-produced (NARM) radioactive materials into the definition of byproduct material. Your regulatory approach for this revised definition is consistent with our long standing policy for NARM.

If you have any questions, please contact Gary E. Williams at (501) 257-1571.

Sincerely,

E. Lynn McGuire
Director, National Health Physics Program

Enclosure

Template = SECY-067

SECY-02

Enclosure to Veterans Health Administration (VHA) Letter Regarding RIN 3150-AH84

Comments on "Requirements for Expanded Definition of Byproduct Material"

1. 71 FR 42953: The discussion under the section about current regulatory structures for naturally occurring and accelerator-produced (NARM) does not note some licensees, such as master materials licensees, have established self-regulation requirements for NARM use. For completeness, the master material licensees' role should be described.

2. 71 FR 42953: The discussion under the section about other federal agencies' regulatory authority over NARM does not note some federal licensees, such as the master materials licensees, have established self-regulation requirements for NARM use. For completeness, the master material licensees' role should be described.

3. 71 FR 42962: The discussion under the section about a general license for devices in 10 CFR 31.5 does not address consistency with 10 CFR 35.65 which authorizes sealed source possession. The discussion should clarify regulatory requirements for sealed sources under 10 CFR 35 that are generally licensed under 10 CFR 31.5 also. In addition, this section does not address possible alternative licensing methods for a generally licensed sealed source subject to registration requirements and fees but might be listed as a sealed source on a specific license and achieve the same level of regulatory oversight and tracking. Further, this discussion does not clearly indicate whether the new regulatory requirements are for sealed sources that underwent a Sealed Source and Device (SS&D) registration or for any sealed sources (i.e., legacy source not registered).

4. 71 FR 42962: The discussion under the section about calibration and reference sources in 10 CFR 31.8 does not address consistency with 10 CFR 35.65 which authorizes sealed source possession. The discussion should clarify regulatory requirements for sealed sources under 10 CFR 35 that are also generally licensed under 10 CFR 31.5.

5. 71 FR 42963: The discussion under the section about a regulatory framework for accelerator-produced radioactive material notes different licenses or authorizations under either 10 CFR 30 or 10 CFR 32.72. The discussion is not clear about whether a single license might include both authorizations or whether separate licenses are required by definition. The discussion should be revised to clarify the licensing methods.

6. 71 FR 42967: The discussion under the section about license application and annual fees is not clear in providing the average professional staff hours for the licensing categories. Rather, the total fee is stated. To assist stakeholders in reviewing this proposed rulemaking, the average and total professional staff hours should be listed by categories to include inspections, licensing, and administrative or management oversight. The breakdown for these categories should be in 0.25 FTE units. Any possible changes in the annual fee for existing licenses that might require an amendment based on this proposed rulemaking should be listed by categories and in 0.25 FTE units.

7. 71 FR 42968: The discussion under the section about license application and annual fees for the production of accelerator-produced radioactive materials is not clear whether the category is only for commercial production licenses under 10 CFR 32, or might be applied to an existing license under 10 CFR 30 that might be amended to authorize noncommercial distribution to a consortium. The category applicability should be clarified.

8. 71 FR 42968: The discussion under the section about license application and annual fees for the proposed fees does not provide adequate information for stakeholder evaluation. To assist proposed rulemaking review, the average and total professional staff hours should be listed by categories to include, as a minimum, inspections, licensing, and oversight. This category breakdown should be in 0.25 FTE units.

9. 71 FR 42969: The discussion under termination of the waiver for government agencies is not consistent with an earlier discussion under 71 FR 42954 that concluded the radioactive materials would continue to be used in a manner protective of public health and safety. The later discussion appears to equate regulatory oversight with outcomes which are more protective of public health and safety. The basis should be explained for concluding the waiver is acceptable for a time period but then must be terminated.

10. 71 FR 42969: The discussion under implementation strategy addresses a transition plan for the states, a termination of the waiver for government agencies, and an implementation period but does not outline stakeholder or licensee information dissemination. A strategy should be established to assist the stakeholders with implementation of the proposed rulemaking. An example area for assistance to stakeholders is to outline proposed revisions to regulatory guidelines.

11. 71 FR 42978: The discussion under plain language asks for stakeholder comments about the clarity and effectiveness of the language used. For the rulemaking discussion and other sections, the language is clear, effective, and consistent with plain language guidelines. For regulation revisions, the wording is stilted, difficult to follow, numbered and arranged in confusing formats, and not consistent with plain language guidelines.

12. 71 FR 42987: The requirements under several sections related to a master materials license address "a permit issued by a Commission master material license broad scope permittee" with the implications a broad-scope permittee is required to issue such a permit. In most cases, the permittee might issue an authorization or other type of document for an authorized user. The regulatory requirement should be revised as follows: "a permit, or other authorization, issued by a Commission master material license broad-scope permittee."

13. Under the proposed rulemaking, any specific license applications authorizing prostate brachytherapy must identify, per 10 CFR 30.32(g), source manufacturers and model numbers of Palladium-103 brachytherapy sources. This requirement could be avoided by amending 10 CFR 30.32(g) to remove the requirement for identifying manufacturers and model numbers for sources authorized for any medical uses, specifically those per 10 CFR 35.400. In addition, the proposed rulemaking is unclear about how some legacy Radium-226 sources, greater than 5 μCi

and thus not eligible for a general license, can be specifically licensed per 10 CFR 30.32(g) requirements.

14. 71 FR42981: Regarding the proposed "byproduct material" definition in 10 CFR 20.1003, (3)(i), and (3)(ii)(B), the wording "produced, extracted, or converted after extraction, before, on, or after August 8, 2005," is confusing and ambiguous. The phrase "before, on, or after August 8, 2005," appears to be meaningless and unnecessary. Furthermore, it is not clear whether this phrase refers only to material "converted after extraction," or to material "produced, extracted, or converted after extraction."

15. 71 FR42982: Regarding the proposed "byproduct material" definition in 10 CFR 30.4, (2)(i), and (2)(ii)(B), the wording "produced, extracted, or converted after extraction, before, on, or after August 8, 2005," is confusing and ambiguous. The phrase "before, on, or after August 8, 2005," appears to be meaningless and unnecessary. Furthermore, it is not clear whether this phrase refers only to material "converted after extraction," or to material "produced, extracted, or converted after extraction."

16. 71 FR 42986: The proposed 10 CFR 32.59 requires testing for leakage "with a filter paper" and "application of moderate finger pressure." This is overly prescriptive, prohibiting use of other materials and requiring the use of the fingers.

17. 71 FR 42988: The cyclotron definition is unclear, especially stating particles are "bent."

From: Lydia Chang
To: Evangeline Ngbea
Date: Thu, Sep 14, 2006 4:34 PM
Subject: Fwd: VHA comments on NARM rulemaking

Hi Van:

One more thing. I got an advance copy from the Veterans Affairs last week, but it is not yet on the docketed comment letters that you had processed so far. Could you please check to see if you have received the official copy and docket it. When I spoke to Gary Williams last week, he was in the process of sending the comment letter to SECY. Thanks...

Lydia C.

>>> "Williams, Gary E" <Gary.Williams3@va.gov> 09/07/2006 11:19 AM >>>

Lydia,I am sending you an advance copy of the VHA comments on the NARM rulemaking. Please let me know if you have any questions or comments. <<2006 09 07 NRC NARM Response.pdf>> Gary E. WilliamsNational Health Physics ProgramVeterans Health AdministrationNorth Little Rock, Arkansas(501) 257-1572

Mail Envelope Properties (4509BCD8.39C : 13 : 10704)

Subject: Fwd: VHA comments on NARM rulemaking
Creation Date Thu, Sep 14, 2006 4:34 PM
From: Lydia Chang

Created By: LWC1@nrc.gov

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2006 09 07 NRC NARM Response.pdf	264019	Thursday, September 14, 2006 4:27 PM

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