DOCKET NUMBER
PROPOSED RULE PR 30,31,32 +150
(71FR00275)

(4)

CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

3911 Campolindo Drive
Moraga, CA 94556-1551
(925) 283-1850
Fax: (925) 283-1850
E-mail: corar@silcon.com

Henry H. Kramer, Ph.D., FACNP
Executive Director

March 8, 2006

DOCKETED
USNRC

March 9, 2006 (9:36am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary,
U.S. Nuclear Regulator Commission
Washington, D.C. 20555-001

Attn: Rulemaking and Adjudications Staff.

Reference: **RIN 3150-AH41, Proposed Rule**
Exemptions from Licensing, General Licenses,
and Distribution of Byproduct Material:
Licensing and Reporting Requirements.
Federal Register Vol,71, No.2, January 4, 2006.

The attached comments on the above referenced proposal rule are submitted on behalf of the Council on Radionuclides and Radiopharmaceuticals (CORAR)[1]. CORAR members who manufacture and distribute radiochemicals commonly send exempt quantities to the research community and are consequently affected by the proposed rule.
CORAR appreciates the opportunity to comment and would be glad to provide clarification or additional information.

Yours Sincerely,

Leonard R. Smith, CHP
Cochairman, CORAR Manufacturing Quality and Safety Committee.

[1] CORAR members include the major manufacturers and distributors of radiopharmaceuticals, radioactive sources and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications for industrial, environmental and biomedical research and quality control.

Template = SECY-067

SECY-02

CORAR COMMENTS TO THE NRC PROPOSED RULE "EXEMPTIONS FROM LICENSING, GENERAL LICENSES AND DISTRIBUTION OF BYPRODUCT MATERIAL: LICENSING AND REPORTING REQUIREMENTS."

General Comment.

Considering that the Energy Policy Act of 2005 changed the definition of byproduct material to include accelerator produced material and that the NRC has since issued waivers of the NRC jurisdiction to allow existing State authorities to continue regulating, it would be helpful to explain how byproduct material is defined in this proposed rule.

Specific Comments.

1. **Page 281, column 3, paragraph 3: "Amending the label... would impose a cost on licensees who commercially distribute exempt quantities..."**

   CORAR confirms that changing the label could be quite costly for some licensees who commercially distribute exempt quantities.

2. **Page 286, column 1, paragraph 6: "... byproduct material is transferred for use under 30.18 of this chapter or the equivalent regulations of an Agreement State..."**
   See also paragraph 9.

a. It would be helpful if the NRC clarified the jurisdiction between NRC and Agreement States as it applies to exempt quantity distribution.
b. Only the NRC has regulations for distributing exempt quantities of byproduct material. It is not therefore clear why the current and proposed rules refer to equivalent regulations of an Agreement State.
c. We do understand that Agreement States have regulations for distributing exempt quantities of NARM but not for byproduct materials.

3. **Page 286, column 1, paragraph 10 " For each radionuclide in each chemical and physical form, the report should indicate the total quantity of each radionuclide and the chemical and physical form, transferred under the specific license.**

a. This requirement will be excessively burdensome for certain commercial manufacturers and distributors. One CORAR member typically distributes hundreds of different radiochemicals in each business day in various physical forms.
b. Currently NRC regulations allow all these radiochemicals to be classified as "radiolabeled research compounds".
c. CORAR recommends that this practice be retained and the NRC explain this in the final rule.
d. It would be useful if the NRC specified the names that may be used by licensees for other commonly distributed materials.

From: "Smith, Leonard" <Leonard.Smith@perkinelmer.com>
To: <SECY@nrc.gov>
Date: Thu, Mar 9, 2006 7:34 AM
Subject: RIN 3150-AH41. Exemptions From Licensing...

Please see attached comments.

Debbie Priddle
PerkinElmer Life and Analytical Sciences
549 Albany St
Boston, MA 02118
Phone: 617-350-9464
Fax: 617-350-9658
Debbie.Priddle@PerkinElmer.com <mailto:Debbie.Priddle@PerkinElmer.com>

Mail Envelope Properties (441020D3.C89 : 24 : 60553)

Subject:	RIN 3150-AH41. Exemptions From Licensing...
Creation Date:	Thu, Mar 9, 2006 7:30 AM
From:	"Smith, Leonard" <Leonard.Smith@perkinelmer.com>
Created By:	Leonard.Smith@perkinelmer.com

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Mime.822	116661	

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Expiration Date:	None
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