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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Attention: Rulemakings and Adjudications Staff

Re: RID 3150-AI12/NRC-2008-0120

Dear Madame Secretary:

On behalf of Fred Hutchinson Cancer Research Center ("Hutchinson Center") I would like to thank you for this opportunity to provide comment on the Nuclear Regulatory Commission's June 15, 2010 Notice of Proposed Rulemaking relating to the physical protection of byproduct material (Federal Register, Vol. 75, No. 114).

Founded in 1975, the Hutchinson Center is a nonprofit research organization based in Seattle, Washington. Its mission is to prevent, diagnose and treat cancer, HIV/AIDS and other diseases. The Hutchinson Center, together with its clinical and research partners, the University of Washington, Seattle Children's and the Seattle Cancer Care Alliance, comprise the Fred Hutchinson/University of Washington Cancer Consortium. The Consortium is among 40 National Cancer Institute-designated comprehensive cancer centers.

In pursuit of its mission, the Hutchinson Center employs and trains hundreds of scientists engaged in the pursuit of new discoveries to prevent and cure disease and to ease human suffering. The Hutchinson Center operates four research irradiators in two locations under its Radioactive Materials License (WN-L042-1) and has been operating in compliance with the Commission's Increased Control Orders subject to the Agreement State oversight of the Washington State Department of Health's Office of Radiation Control.

The nature of the Hutchinson Center's research and training program requires that large numbers of individuals be screened for unescorted access to the irradiators. During the 2009 calendar year, the Hutchinson Center irradiators logged in over 1400 uses. An average of approximately 300 users must obtain clearance for unescorted access and there is a frequent turnover dictating that an estimated 60 additional users per year be cleared. The costs associated with compliance with the current program operating to comply with the Increased Control Orders are approximately \$11,000 per year. We estimate that to comply with the enhanced requirements outlined in the proposed rule the Hutchinson Center could incur additional costs of approximately \$23,000 per year and one-time costs of \$30,000.

Although we applaud the Commission's efforts to establish a more comprehensive approach to establish security requirements for use of category 1 and category 2 quantities of radioactive material, we urge the Commission to reconsider its plan to adopt a rule that would impose costly and burdensome new requirements on licensees such as the Hutchinson Center. The Commission's Increased Control Orders adequately protect public health and safety and promote the Commission's common defense and security objectives. There is no need to revise them in a manner that will unreasonably impede research carried out by the Hutchinson Center and other similarly situated licensees.

We believe that the Commission can fulfill its objectives by electing one or possibly a combination of the following three alternative approaches:

Exemption from New Requirements for Certain Licensees Based on Size, Configuration and/or Characteristics of Irradiators Covered by License

The Hutchinson Center's four irradiators are of a type and configuration that would render the probability of their use in an act of terrorism as extremely unlikely. They are stationary and each weighs in excess of 1000 pounds. They are secured within segregated and separately locked facilities on a secure campus requiring separate authorized keycard access to both the buildings themselves and the irradiator rooms 365 days per year. In the case of licenses covering irradiators with these types of characteristics, the Commission should elect to exempt them from application of the new security measures.

Limited Exemption from New Requirements for Licensees with State-Approved Security Plans

Since the Hutchinson Center compliance with the Increased Control Orders is already monitored closely in Washington (an Agreement State), another alternative would be to provide a limited exemption to licensees who consistently meet the requirements currently imposed as part of the Increased Control Order as determined by the Agreement State oversight agency. The Commission could establish criteria for the assessment of licensees' security programs. If a particular licensee's program is determined by the Agreement States' oversight agency to be inadequate, corrective action could be initiated in a more "hands on" and localized manner to meet Commission objectives.

Modify Proposed Rule to Eliminate Costly, Unduly Burdensome and Ineffective Requirements

The provisions of the proposed rule that are unduly burdensome and costly and that would unreasonably and negatively impact on the research program of the Hutchinson Center include the following:

1. Expanding the background investigation scope to include full credit history and local criminal background checks. Requiring the Trustworthiness and Reliability Reviewing Official to submit to a background check is acceptable, but nomination to and approval by NRC should not be required (§§ 37.23, 37.25 and 37.27).
2. Security Plan training and retraining on an annual basis would be unduly burdensome due to the large volume of users requiring unescorted access (§37.49). The additional

resources required to implement this program could be better used by the Hutchinson Center to carry out its critical public health mission.

3. The monitoring, detection and assessment requirements are unduly onerous for a facility such as the Hutchinson Center. The mandate that the Hutchinson Center maintain the capability to detect without delay attempted unauthorized entry into the security zone should be eliminated or defined in a more concrete manner for the sake of clarity in enforcement (§37.49).

We respectfully request that one or a combination of these alternatives be considered as the Commission develops the final rule provisions.

Thank you so much for the opportunity to provide input on the proposed rule.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence Corey", with a long horizontal flourish extending to the right.

Lawrence Corey, M.D.
President & Director

cc: Mr. Busby
Ms. Gainer
Mr. Shaeffer
Mr. Wang
Ms. Williams

Rulemaking Comments

From: Clarke, Linda C [lclarke@fhcrc.org]
Sent: Tuesday, January 18, 2011 3:00 PM
To: Rulemaking Comments
Subject: Docket ID NRC-2008-0120: Comments on behalf of Fred Hutchinson Cancer Research Center
Attachments: NRC-2008-0120 comments.pdf

Please see attached comments to NRC-2008-0120 by Lawrence Corey on behalf of Fred Hutchinson Cancer Research Center.

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To: <Rulemaking.Comments@nrc.gov>
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