



January 18, 2011

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January 19, 2011 (10:15 am)

Secretary  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001  
Attn: Rulemakings and Adjudications Staff

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

**Re:** Comments on Physical Protection of Byproduct Material, Proposed Rule [Docket No. NRC-2008-0120, See 75 FR 33902 (June 15, 2010)]

Dear Ms. Annette Vietti-Cook:

The American Society for Radiation Oncology (ASTRO) appreciates the opportunity to provide comments to the U.S. Nuclear Regulatory Commission (NRC) on the Proposed Rules for the Physical Protection of Byproduct Material. ASTRO is concerned that these proposed rules could significantly impede patient access to life-saving radiation oncology treatments.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapy. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy.

#### **Introduction**

While ASTRO appreciates the importance of the security of byproduct materials, we feel that the proposed rules, if implemented, may cause significant hardships to many institutions, both financially and in terms of patient access to care. Additionally, we recognize that when the Increased Control (IC) Orders were issued in 2005, they were done in such a way that public comment was not sought, and that these proposed rules retroactively allow for public comment on the IC. However, we believe that the IC Orders are sufficient and should not be enhanced as proposed. *We believe that the NRC should maintain the IC Orders as they are and put them in a form that allows for public comment such that they can be formally codified.*

ASTRO is specifically concerned with the following proposals:

- Costs for implementing the increased security requirements; and
- Definition of aggregated.

#### **Costs for implementing the increased security requirements**

ASTRO has concerns that under the proposed rules, the costs for implementing the new security requirements may be so prohibitive that facilities may decide not to offer radiation therapy services. Those facilities that are already implementing the IC would have to add additional security measures, and those facilities that are not already implementing the IC would be forced

to incur significant financial costs to implement the new security requirements. Physical plant upgrades will most likely incur the greatest cost – both monetarily, and in terms of the time it will take to complete the necessary physical upgrades. Additionally, there will be added costs to run background, credit and employment checks on those employees requiring unescorted access to the materials of concern. These costs not only include conducting the checks, but also the time needed to fully evaluate the results.

In addition to monetary costs, there is significant concern that the required checks could result in lost jobs for employed foreign nationals and United States citizens at these institutions and facilities. Inaccurate or inadequate data received during credit checks, background checks and past employment checks could lead to denial of employment for those who would otherwise be employable. This is especially concerning during an economic downturn. Highly qualified individuals could potentially be denied employment based on a credit, background or past employment check that does not meet the standards set forth by that institution, as the proposed rules do not offer any criteria by which the reviewing official should make decisions about granting unescorted access to individuals.

Finally, we are concerned that the new requirements could force employment decisions based on incomplete information. This could lead to significant legal implications for an institution and those individuals involved in the hiring and review process. Particularly in the absence of guidance, the way these policies would intersect with current labor laws, such as the Equal Employment Opportunity Act, need to be investigated.

**Definition of aggregated**

The proposed rule defines *aggregated* as: “accessible by the breach of a common physical barrier, whether the material made accessible is a single sealed source, multiple sealed sources, or multiple sources of bulk radioactive material.”

Institutions that have materials that may, according to the definition of “aggregated”, equal category 2 levels or higher, may require both significant time to implement and financial investment to comply with the new rules. Not only will a security plan have to be developed and implemented, but the institution will now have to perform credit and background checks, all of which would require the institution to expend significant resources.

Instead of upgrading their facilities to comply with the new regulations, we are concerned that the proposed definition of aggregated could lead institutions to choose to store the materials, including waste, in separate locations. This practice would allow those facilities to keep enough material separate so that the definition does not apply, and thereby avoid the need to implement the new security rules. Besides causing a logistical problem for the institution (keeping track of the materials, etc.), this work-around may inadvertently increase the risk to the security of these materials.

The proposed rule states that if a licensee is authorized to possess at least a category 2 level of material, but doesn't actually possess that much, the licensee must still develop a security plan and run credit and background checks on personnel. This proposed requirement also may prove

January 18, 2011

ASTRO Comments on Physical Protection of Byproduct Materials

Page 3

costly because a licensee possessing a category 2 level of material will need to implement the plan even if they only possess the material for a short time, such as a period of a few days during a source exchange.

### **Conclusion**

While we appreciate the need to ensure the safety of all Americans and protect this potentially dangerous material, we believe that most institutions have sufficient security plans in place. We believe the added regulatory and bureaucratic burden this proposed rule imposes will negatively impact patient care. The implementation of these rules and the significant added costs of compliance could delay patient access to life-saving treatments.

In sum, we maintain that the status quo is sufficient to ensure the protection of these materials while at the same time not limiting patient access to radiation therapy services. Should the NRC feel that additional security requirements are absolutely necessary, we welcome the opportunity to work with the agency to ensure that patient access to life-saving radiation therapy services and security are maintained in a mutually agreeable fashion.

Thank you for affording ASTRO the opportunity to provide comments on the Physical Protection of Byproduct Material. We look forward to working with the NRC on this issue. Please contact Cindy Tomlinson, Manager of Regulatory Affairs at 703-839-7366 or [cindy@astro.org](mailto:cindy@astro.org) if you have any questions.

Sincerely,



Laura I. Thevenot  
Chief Executive Officer

Cc: Merri Horn, Office of Federal and State Materials and Environmental Management Programs

# PUBLIC SUBMISSION

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**Docket:** NRC-2008-0120  
Physical Protection of Byproduct Material

**Comment On:** NRC-2008-0120-0070  
Physical Protection of Byproduct Material; Extension of Comment Period

**Document:** NRC-2008-0120-DRAFT-0108  
Comment on FR Doc # 2010-25397

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## Submitter Information

**Name:** Cindy Tominson  
**Organization:** ASTRO

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## General Comment

Please find attached comments from the American Society for Radiation Oncology on Physical Protection of Byproduct Material, Proposed Rule [Docket No. NRC-2008-0120, See 75 FR 33902 (June 15, 2010)]

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## Attachments

**NRC-2008-0120-DRAFT-0108.1:** Comment on FR Doc # 2010-25397

## Rulemaking Comments

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**From:** Gallagher, Carol  
**Sent:** Wednesday, January 19, 2011 8:37 AM  
**To:** Rulemaking Comments  
**Subject:** Comment on Proposed Rule - Physical Protection of Byproduct Material  
**Attachments:** NRC-2008-0120-DRAFT-0108.pdf

Van,

Attached for docketing is a comment from Laura Thevenot on the above noted proposed rule (3150-A112) that I received via the regulations.gov website on 1/18/11.

Thanks,  
Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by OWMS01.nrc.gov  
([148.184.100.43]) with mapi; Wed, 19 Jan 2011 08:37:07 -0500  
Content-Type: application/ms-tnef; name="winmail.dat"  
Content-Transfer-Encoding: binary  
From: "Gallagher, Carol" <Carol.Gallagher@nrc.gov>  
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>  
Date: Wed, 19 Jan 2011 08:36:45 -0500  
Subject: Comment on Proposed Rule - Physical Protection of Byproduct Material  
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Material  
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