Washington University in St. Louis

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Environmental Health & Safety **Radiation Safety Office**

PR 30,32,33,34,35,36,37,39,51,71 and 73 (75FR33901)

January 18, 2011

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

Submitted to: http://www.regulations.gov

RE: Docket No. NRC-2008-0120, RIN 3150-AI12 (June 15, 2010)

SUBJECT: Comments on the Physical Protection of Byproduct Material Proposed Rule [75 FR 33902]

Dear Sir/Madam:

Washington University in St. Louis (WU) appreciates the opportunity to provide written comments on the physical protection of byproduct material proposed rule. One of NRC's missions is to ensure adequate protection of public health and safety, common defense and security, and the environment while enabling the use of radioactive materials for beneficial civilian purposes. As noted in the NRC draft policy on the protection of Cs-137 CsCl sources [75 FR 37483], this mission is best accomplished by implementing the following principles:

- The safety and security of risk-significant sources is an essential part of the NRC's mission; and
- Licensees have the primary responsibility to securely manage and to protect sources in their possession from misuse, theft, and radiological sabotage.

WU endorses these long-established principles and accepts our security responsibilities with regard to these kinds of sources. And so, we offer the following comments in support of establishing effective and reasonable security measures which also enable the continued use of

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these kinds of sources to provide essential benefits to society, especially in the medical care of patients.

Washington University endorses and fully supports the comments and recommendations made by the NRC Advisory Committee on the Medical Use of Isotopes in its January 5, 2011 report (see attachment). In 2006, we implemented the requirements of the NRC Increased Controls License Orders (IC Orders), and have continued to maintain a strong and effective security program. As a result of our experience in working under the IC Orders, we offer two additional comments for your consideration in this rulemaking.

- Washington University supports NRC's efforts to develop regulations which provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material. We believe that further explanation is needed to judge how the additional access authorization requirements proposed in the new Part 37 support reasonable assurance of security. We believe the draft regulatory analysis [NRC-2008-0120-0038] supporting the development of the proposed rule does not recognize the costs that licensees, like Washington University, have incurred and the effective security programs that are now in place under the IC Orders. In addition, we believe the draft regulatory analysis does not accurately reflect the costs associated with the proposed access authorization requirements. In our review of proposed rulemaking documents, Washington University has reviewed the costs associated with implementing and operation of our security program under the IC Orders. Due to the information security requirements of the IC Orders, we have chosen not to share these cost details beyond what we included in our July 15, 2010 information collection comment letter [NRC-2008-0120-0044]. We hope that NRC reaches out to licensees, like Washington University, to obtain these kinds of cost details to improve the draft regulatory analysis and do so in ways that licensees can assure their compliance with the IC Orders.

- Washington University appreciates the efforts of the NRC to quickly establish the IC Orders in response to our country's actions following the attacks of 9/11. We understand that the short time frame given to develop and implement additional security measures for category 1 and category 2 sources was challenging, and necessitated the choice of a one-size-fits-all model with prescriptive requirements that was applied to many different sources, devices, and uses. We ask the NRC to re-evaluate the model adopted at that time, rather than add more prescriptive requirements. Instead, we encourage the NRC to apply its Risk-Informed and Performance-Based Plan (RPP) to develop a regulatory model which takes into account more variables of security risk in determining security requirements, and allowing flexibility in how licensees develop effective and reasonable security programs. We believe this approach will enhance the understanding, implementation and future development of NRC's new security regulations.

We feel that the plan recommended by the ACMUI for this rulemaking reflects the principles of regulation outlined in President Obama's January 18, 2011 Executive Order on Improving Regulations and Regulatory Review.

Thank you for your consideration of our comments and recommendations. Washington University remains committed to working with the NRC to provide more details of our experiences, to help to develop effective and reasonable security regulations, and to continue the secure, safe, and essential uses of category 1 and category 2 sources in medical therapy and research. If you have any questions concerning these comments or would like additional explanation, please contact me at 314-362-2988 or langhors@wustl.edu.

Sincerely,

Susan M. Langhorst, Ph.D., CHP
Radiation Safety Officer

Attachment: NRC Advisory Committee on the Medical Use of Isotopes
Comments on Proposed Part 37
January 5, 2011

Advisory Committee on the Medical Use of Isotopes (ACMUI)
Comments on Proposed Part 37
January 5, 2011

Subcommittee Members: D. Gilley, MPA (Chairman); S. Langhorst, PhD, D. Fisher, PhD

Charge: To provide comments on the proposed Part 37 rulemaking entitled, "Physical Protection of Byproduct Material."

Introduction

Radioactive materials in medicine and research have benefited society and are essential for disease diagnosis, cancer therapy, hematology research, and sterilization of blood and blood products needed for transplantation. Radioactive materials are used safely for many other applications, including medical supplies sterilization, food irradiation, and industrial and manufacturing quality assurance. Research irradiators using cesium (Cs-137) chloride sources are essential to continuing medical advances in science for genetic, metabolic and cancer studies. The proposed Part 37 regulation entitled "Physical Protection of Byproduct Material" was published on June 15, 2010 (75 Federal Register, p. 33902), and public comments were due on October 13, 2010; an extension to January 18, 2011 was granted in October 2010 (75 Federal Register, p. 62330).

The Advisory Committee on Medical Use of Isotopes (ACMUI) has prepared comments at the request of NRC on the potential "Impact of Part 37 Proposed Security Rule and National Source Tracking System on the Medical Community" with specific attention to gamma stereotactic, high dose rate remote afterloader (HDR), teletherapy and blood irradiator devices. The Committee submits the following comments and recommendations on the proposed rules for NRC consideration.

ACMUI Comments

- The ACMUI acknowledges all medical licensees' efforts to implement and comply with the current Increased Controls License Orders (EA-05-090 and EA-07-305), which have required medical licensees expend significant financial and personnel resources.

- The ACMUI supports the general concept of physical security for radioactive materials to prevent the theft or illegal diversion of Category 1 and 2 quantities, and agrees with the NRC stated objective that the proposed rulemaking is to "provide reasonable assurance of preventing the theft or diversion of Category 1 and 2 quantities of radioactive material." (75 Federal Register, p. 33902)

- The ACMUI agrees that the security requirements should be established as part of NRC regulations and the current Increased Controls License Orders eventually be rescinded.

- The ACMUI agrees with the NRC assessment that the current regulations and license orders assure that adequate security is in place for Category 1 and 2 byproduct materials (75 Federal Register, p. 33905).

- The ACMUI is concerned that the proposed Part 37 regulations will add additional confusion which may result in reduced security of Category 1 and 2 sources. Some examples of this concern are as follows.

  - The term "Trustworthiness and Reliability Official" is replaced by "Reviewing Official", and these individuals will now be required to have unescorted access to Category 1 and 2 byproduct materials because that is the only way that the NRC can require that these individuals undergo FBI fingerprint background checks. Due to the personal information that the Increased Controls License Orders required to be collected, many medical licensees utilized their Human Resource staff to choose Trustworthiness and Reliability Officials. Requiring these individuals to have access to radioactive materials, who would otherwise have no reason for this access, to justify the requirement for FBI fingerprint background checks seems convoluted in its logic.

  - The requirements for judging the trustworthiness and reliability of an individual have been greatly expanded with little justification provided on why the expansion is needed, or how it results in the establishment of reasonable security.

    - The requirement of full credit checks seems especially unreasonable in light of the current economic environment, and could be extremely burdensome to collect and check for accuracy. Gathering information on credit history can be more challenging when the individual has no credit history or has lived outside of the U.S. The proposed Part 37 would allow licensees document their unsuccessful attempts to obtain credit history and financial responsibility. The need for the credit check does not seem to be consistently applied.

    - Obtaining criminal history reports for the past 10 years can be costly, especially for those individuals who have lived outside of the U.S. States other countries may not be able to accommodate this increase in criminal history report requests. The draft guidance document for Part 37 does not provide much guidance on what is considered local with regard to criminal history reports, e.g., does the term local only include the State or country of residence, nor does it include other States or countries where the individual worked or lived nearby.

    - The proposed Part 37 will impact medical licensees who have previously not been impacted by the Increased Controls License Orders based on their license limits rather than their possession of single sources of Category 1 or 2 quantities. Educating and inspecting these new licensees will impact NRC staff resources, and could diminish their focus on ensuring security compliance for existing Category 1 and 2 sources.

  - The proposed physical protection requirements placed on licensees to coordinate with and to notify the local law enforcement agency for use and transport of Category 1 and 2 quantities cannot be achieved by the licensee alone, and thus seem unreasonable.

- The ACMUI is concerned that costs of the proposed Part 37 regulations have not been adequately considered in determining reasonable security costs. Three cost options are presented in the NRC draft regulatory analysis for Part 37, but they do not seem to be fully developed to provide adequate justification that the proposed part 37 provides reasonable security.

  - It is not clear whether real licensee cost-to-date for implementing the Increased Controls License Orders were considered in cost calculations.

  - The number of individuals requiring trustworthiness and reliability assessments per licensee was 12. Was this estimate based on the overall number of licensees currently under the Increased Controls Orders, the number of trustworthiness and reliability officials reported to NRC, and the number of individuals who have completed the NRC FBI fingerprint background checks? This is a low estimate for the number of assessments for medical licensees, especially when considering the additional number of individuals needing trustworthiness and reliability assessments impacted by the proposed 10 CFR 37.43(d)(3). A major research medical licensee could have a few hundred individuals in their access authorization program.

  - Option 1 of the cost analysis is inappropriate in its benefits/savings versus costs/burdens (draft regulatory analysis Exhibit 4-4) because it assumes no increased security efforts have been made. Instead, Option 1 should have considered the Increased Controls License Orders were in place with their existing qualitative security benefits similar to those listed in Option 2. An additional cost option determining the cost of implementing a new Part 37 with equivalent requirements as are in place with the Increased Controls License Orders would be helpful in this review.

- The ACMUI understands the need to quickly develop and implement the Increased Controls License Orders required the NRC to establish a one-size-fits all model for all types and uses of Category 1 and 2 sources. The ACMUI is concerned that the proposed Part 37 builds off of and expands the requirements of a one-size-fits all model.

- The ACMUI is concerned that the ultimate impact of the proposed Part 37 on medical licensees will be to increase the costs of diagnostic and therapeutic procedures, and further impede research and development of new medical procedures, that rely upon the use of Category 1 and 2 quantities of byproduct materials, ultimately denying patients access to essential medical care.

- The proposed Part 37 does nothing to improve the security of radioactive sources that could be introduced into the U.S. from foreign origins. The ACMUI believes the requirements in the proposed Part 37 will impact most on legitimate medical users of radioactive materials, but provide little protection against actual external threats.

ACMUI Recommendations

The ACMUI recommends NRC consider the following actions.

- **Change the proposed Part 37 to implement the existing requirements contained in the Increased Controls License Orders to minimize confusion of implementing new requirements and to maintain the established security levels for Category 1 and 2 sources during this change from order requirements to regulations.**

- **Begin work on developing strategic rulemaking, which may need to include changes in legislative authority, to develop the newly established Part 37 with a more risk-informed and performance-based model for security requirements for Category 1 and 2 quantities.** The NRC should consider the following during this strategic development effort.

  - Evaluate the feasibility and costs for NRC to conduct all the background checks and the trustworthiness and reliability determinations in a similar manner as does the CDC for access to Select Agents. This centralized coordination, which should also cover licensees in Agreement States, would probably result in more consistent trustworthiness and reliability evaluations at reduced costs, and with the potential to allow the individual to move their trustworthiness and reliability status from one licensee to another.

  - Work with law enforcement groups to determine effective ways that local law enforcement agencies can know of and provide emergency response support to licensees with Category 1 and 2 sources.

  - Evaluate benefit/savings versus cost/burden for different types and quantities of Category 1 and 2 materials, and different uses of these sources, which also allow licensees to develop procedures that allow flexibility between use of the access authorization controls and physical protection systems.

  - Re-evaluate the need to include the accumulation consideration for access authorization control, and aggregated but not co-located materials consideration for a security plan to develop reasonable limits when the additional security of Part 37 is really needed.

  - Work with States and law enforcement groups to determine effective ways to support transport of Category 1 and 2 materials.

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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-0110
Comment on FR Doc # 2010-25397

Submitter Information

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General Comment

Please see attached comment letter from Washington University in St. Louis.

Attachments

NRC-2008-0120-DRAFT-0110.1: Comment on FR Doc # 2010-25397

Rulemaking Comments

From: Gallagher, Carol
Sent: Wednesday, January 19, 2011 8:44 AM
To: *Rulemaking Comments*
Subject: Comment on Proposed Rule - Physical Protection of Byproduct Material
Attachments: NRC-2008-0120-DRAFT-0110.pdf

Van,

Attached for docketing is a comment from Susan Longhorst on the above noted proposed rule (3150-AI12) 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 08:45:07 -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 08:44:25 -0500
Subject: Comment on Proposed Rule - Physical Protection of Byproduct Material
Thread-Topic: Comment on Proposed Rule - Physical Protection of Byproduct
Material
Thread-Index: Acu33vxt6xUEPuOYQy+eqV3dupVXMA==
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<6F9E3C9DCAB9E448AAA49B8772A448C55EE2F4D4EC@HQCLSTR01.nrc.gov>
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