

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

59

## PUBLIC SUBMISSION

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

DOCKETED  
USNRC

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

January 11, 2011 (2:15 pm)

**Document:** NRC-2008-0120-DRAFT-0101  
Comment on FR Doc # 2010-25397

OFFICE OF SECRETARY  
RULEMAKINGS AND  
ADJUDICATIONS STAFF

## Submitter Information

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**Submitter's Representative:** Susan M. Langhorst

**Organization:** NRC ACMUI

**Government Agency Type:** Federal

**Government Agency:** NRC

## General Comment

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

RE: RIN 3150-AI12; Docket: NRC-2008-0120; Comments on 10 CFR Parts 30, 32, 33, et al., Physical Protection of Byproduct Material; Proposed Rule

Dear Sir/Madam:

On behalf of the Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes (ACMUI), I provide you with the attached comments and recommendations approved by the Committee at its January 5, 2010 public teleconference.

Thank you for consideration of these comments and recommendations. If you have any questions do not hesitate to contact me.

Leon S. Malmud, MD  
Chairman, ACMUI

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## Attachments

**NRC-2008-0120-DRAFT-0101.1:** Comment on FR Doc # 2010-25397

**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.

## Rulemaking Comments

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**From:** Gallagher, Carol  
**Sent:** Tuesday, January 11, 2011 9:44 AM  
**To:** Rulemaking Comments  
**Subject:** Comment on Proposed Rule - Physical Protection of Byproduct Material  
**Attachments:** NRC-2008-0120-DRAFT-0101.pdf

Van,

Attached for docket is a comment from Leon Malmud on the above noted proposed rule (3150-AI12) that I received via the regulations.gov website on 1/7/11.

Thanks,  
Carol

Received: from HQCLSTR01.nrc.gov ([148.184.44.79]) by OWMS01.nrc.gov  
([148.184.100.43]) with mapi; Tue, 11 Jan 2011 09:45:10 -0500  
Content-Type: application/ms-tnef; name="winmail.dat"  
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From: "Gallagher, Carol" <Carol.Gallagher@nrc.gov>  
To: Rulemaking Comments <Rulemaking.Comments@nrc.gov>  
Date: Tue, 11 Jan 2011 09:44:27 -0500  
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