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January 19, 2011 (10:15 am)

Attn: Rulemakings and Adjudications Staff
Secretary, U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville MD 20555-0001

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Subject: Docket ID NRC-2008-0120; Comments of the American College of Radiology Addressing the NRC's Proposed Rule on Physical Protection of Byproduct Material (75 FR 33902)

Dear NRC Rulemaking and Adjudications staff:

The American College of Radiology (ACR)—a professional organization representing more than 34,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to submit comments addressing the Nuclear Regulatory Commission's (NRC) proposed rule (NRC-2008-0120; 75 FR 33902) on the physical protection of Category 1 and 2 quantities of byproduct material. Given the complexity and extensiveness of the proposed rule, the NRC rulemaking staff should be commended both for their flexibility in extending the public comment period and their various efforts to directly educate stakeholders. The ACR encourages the NRC's outreach activities to continue after promulgation of the final rule.

General Comments

As a general comment, the ACR supports the adoption of NRC's existing physical protection requirements into federal regulation and subsequent rescission of the nontransparent Increased Control (IC) Orders. That said, the ACR does not support NRC's expansion of the requirements above and beyond the IC Orders without concrete justification that the security benefits of doing so outweigh the associated implementation costs and administrative burden shouldered by licensees. The IC Orders were disruptive and costly for medical licensees when implemented several years ago, and more prescriptive requirements without demonstrated necessity may result in certain life-saving radiological procedures not being readily available to patients in need. The ACR recommends that rulemaking staff review the transcripts of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) meetings from the past several years in which the committee members discuss the costs and burdens of the IC Orders on medical facilities that use Category 2 sources to provide care to patients.

Additionally, the ACR supports the NRC's decision to limit the applicability of the proposed 10 CFR Part 37 to Category 1 and 2 sources. However, we note that not all Category 2 sources are realistically in danger of being tampered with, particularly in large medical facilities with exhaustive security controls in place to protect the individuals, medications/controlled substances, and hazardous items and materials on location. Furthermore, if a large medical facility's security measures are breached, sealed sources in medical devices are generally not readily accessible even by technicians with highly specialized skills and tools.

Specific Comments

Proposed 10 CFR 37.41(a)(1) - Source Aggregation

The ACR has heard from some medical stakeholders concerned that the source aggregation changes in the proposed rule could expose their facilities to the security program requirements even though these licensees had not needed to implement the previous IC Orders. The ACR is opposed to Part 37 requirements being applied to medical licensees who had not been under the IC Orders due to the additional resources and operational disruptions needed to develop and implement a security program.

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Proposed 10 CFR 37.25 - Background Investigations

It is questionable as to whether a credit history evaluation should be a required component of the background investigation conducted by the licensee to determine the trustworthiness and reliability of an applicant for unescorted access authorization. These evaluations require allocated resources by licensees, and there is little information in the notice of proposed rulemaking that supports the added expenditure. Credit history seems to be a poor indicator of the intentions of an individual, particularly in these economic times in which trustworthy individuals seeking employment can have a previous bankruptcy or foreclosure due to circumstances outside of their control. Credit history captured by the major agencies is also sometimes inaccurate—evaluations of the same individual typically vary from agency to agency. Furthermore, there is a high level of ambiguity as to what licensees should look for when reviewing credit history in terms of potential warning signs of malevolence.

Additionally, a local criminal history review per the proposed 10 CFR 37.25(a)(7) seems redundant with the Federal Bureau of Investigation (FBI) identification and criminal history records check in the proposed 10 CFR 37.25(a)(1). It would be helpful if NRC explained in the preamble of the final rule how local criminal history checks can provide indications of intent to use radioactive materials illegally when FBI checks do not.

Likewise, the proposed rule provides little explanation as to why verification of true identity in 37.25(a)(2) and verification of military history in 37.25(a)(5) are needed for security purposes in addition to the FBI identification check in 37.25(a)(1) and employment history evaluation in 37.25(a)(3), respectively. While redundancy may or may not be the desired objective of these new requirements, they represent additional expenditures for licensees despite questionable security benefits. If these requirements are promulgated, NRC should provide examples in the preamble of the final rule of circumstances in which individuals approved for unauthorized access under the IC Orders were identified incorrectly by the FBI, or in which reference checks failed to unearth false claims of previous military service.

Proposed 10 CFR 37.23(b) - Access Authorization Program Requirements - Reviewing Official

Under the previous IC Orders, Human Resources specialists would serve as a licensee's reviewing official for trustworthiness and reliability, as unescorted access authorization is effectively a prerequisite of employment for certain individuals at medical facilities with Category 2 sources. This would no longer be the case if the proposed requirements in 10 CFR 37.23(b)(2) were promulgated because the reviewing official his/herself would be required to have unescorted access to Categories 1 and 2 quantities of radioactive materials. In recent public meetings, NRC staff explained that the reason for this proposed requirement was to ensure that reviewing officials underwent FBI fingerprint checks. However, this presents a potential health and safety risk if someone with Human Resources training but no knowledge of radioactive materials has unescorted access; and a problem of practicality if someone with advanced radiation safety training must perform the duties of a Human Resources specialist.

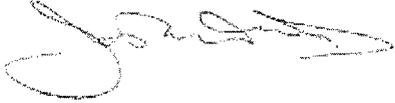
Additionally, the proposed 10 CFR 37.23(b)(5) requires that NRC approve the reviewing official nominated by the licensee—a step that was not required in the IC Orders. Presumably, NRC's approval process for licensees' reviewing officials will take additional time and resources on the part of the agency—costs that will need to be recovered through increased fees. It is unclear what criteria the NRC will use in evaluating reviewing officials, and what under what time constraints the agency will need to respond to the licensee's nomination. If this requirement is in the final rule, NRC should also indicate a brief turnaround time for getting back to the licensee—for example, 5 business days—as employment of the reviewing official by the licensee ultimately depends on the ability of this individual to be approved by NRC.

Proposed 10 CFR 37.45 - LLEA Coordination and Notification

It is unclear how, after the requisite requests and notifications of the proposed 10 CFR 37.45, failure of the Local Law Enforcement Agency (LLEA) to coordinate fully with the licensee would impact the status of a license to possess Category 1 and 2 quantities of byproduct material. Given that cooperation with the licensee is effectively voluntary on the part of the LLEA, it should be the purview of the NRC or Agreement State to ensure the LLEA works with the licensee in the requested manner. Licensees should not be held accountable for noncooperation or lack of resources on the part of the LLEA.

Thank you in advance for your consideration of these comments. Please contact Gloria R. Romanelli, Esq., Senior Director, Legislative and Regulatory Relations; or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 202-223-1670 if you have questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Patti". The signature is fluid and cursive, with a large initial "J" and a long horizontal stroke extending to the right.

John A. Patti, MD, FACR
Chair, Board of Chancellors
American College of Radiology

Rulemaking Comments

From: Michael Peters [mpeters@acr.org]
Sent: Tuesday, January 18, 2011 8:03 PM
To: Rulemaking Comments
Cc: Gloria Romanelli
Subject: Docket ID NRC-2008-0120; Comments of the American College of Radiology
Attachments: acr_comments_part37nprm_1-2011.pdf

Please see the attached comments from the American College of Radiology (ACR) regarding the NRC's proposed rule on Physical Protection of Byproduct Material (Docket ID NRC-2008-0120).

Thank you,

Michael Peters

Director of Legislative and Regulatory Affairs

American College of Radiology

505 9th Street, NW, Suite 910

Washington, DC 20004

mpeters@acr.org

202-223-1670

www.acr.org

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From: Michael Peters <mpeters@acr.org>
To: <Rulemaking.Comments@nrc.gov>
CC: "Gloria Romanelli" <GRomanelli@acr.org>
Return-Path: mpeters@acr.org
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