



American Association of Physicists in Medicine

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USNRC

June 22, 2009 (2:00pm)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

June 18, 2009

Mr. Robert McDougall, Project Manager
Division of Intergovernmental Liaison and Rulemaking
Office of Federal and State Materials and Environmental Management Programs
U.S. Nuclear Regulatory Commission
MS-T-8F-42
Washington, D.C. 20006

Subject: Preliminary Draft Rule Language for Physical Protection of Byproduct Material
(Proposed Part 37, Subpart C)

Dear Mr. McDougall:

On behalf of the American Association of Physicists in Medicine (AAPM),¹ the following comments on the preliminary draft rule language for the physical protection of certain byproduct materials are submitted for your consideration as solicited in a May 1, 2009 *Federal Register* notice (FRN). We appreciate this early opportunity to provide input into the rulemaking process and we look forward to providing comments on the proposed rule once published.

In general, the preliminary draft physical security requirements for use and storage of aggregate

¹ The American Association of Physicists in Medicine's (AAPM) mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,700 medical physicists.

quantities of category 1 and category 2 radioactive material, proposed for Subpart C of the new Part 37 appear consistent with the security orders issued by the U.S. Nuclear Regulatory Commission (NRC) to applicable licensees. As noted in the FRN, this draft preliminary language is part of a 3-prong approach to promulgate NRC physical protection requirements for these materials. AAPM submitted comments on the draft preliminary language for background investigation and access control requirements proposed for Subpart B of the new Part 37 in a letter dated June 1, 2009. Obviously, we have considered the language in all 3 notices when developing the specific comments on draft Subpart C which are attached to this letter.

Again, we thank you for the early comment opportunity and look forward to reviewing the proposed rule during the public comment period. If you would like to discuss these comments further, please contact Lynne Fairbent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email at lynne@aapm.org or me at 720-854-7515 or via email at dpfeiffer@bch.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Douglas E Pfeiffer". The signature is written in a cursive, flowing style.

Douglas Pfeiffer, M.S,
Chair of Government and Regulatory Affairs Committee
AAPM

AAPM Specific Comments on Preliminary Draft Rule Language for Part 37 Subpart C

Section 37.3, “Definitions”:

As stated in AAPM’s comment letter dated June 1, 2009 on the preliminary rule language for Part 37 Subpart B, NRC should ensure that terms defined in Subpart C, which are also used in Subpart B but not defined there, do not negatively impact the intent of or conflict with Subpart B requirements. Examples of such terms are “approved individual” and “escorted access.”

§ 37.3 – Definition. Category 1. The reference to Appendix A is not clear as there is no Appendix A attached to the April 2009 Preliminary Draft Language Subpart C. Is the reference to Appendix A 10 CFR Part 20? Unclear definition, especially with regard to aggregated sources.

§ 37.3 – Definitions. Category 2. The reference to Appendix A is not clear as there is no Appendix A attached to the April 2009 Preliminary Draft Language Subpart C. Is the reference to Appendix A 10 CFR Part 20? In addition, this definition is not clear, especially with regard to aggregated sources. Will this now mean that two or more Ir-192 High Dose Rate sources in the same room during source changes will need to meet all of the requirements of Part 37?

Section 37.1201, “Security Program”:

As stated in AAPM’s comment letter referenced above, clarification is needed on whether aggregation of radioactive material is intended to be captured by Part 37. Specifically, draft Subpart C uses the term “aggregated quantity” but Subpart B does not, e.g., § 37.21. The regulatory approach in Subpart B and C should be consistent with regard to whether aggregated quantities are captured. Also, the previously issued security orders for category 1 and category 2 materials were applied to aggregated quantities of radioactive material that meet or exceed the Category 1 or 2 thresholds. If aggregate quantities are intended to be captured, conforming edits in at least one citation, e.g., § 37.1201(d) should read, “each licensee that possesses *an aggregate quantity of* category 1 or category 2 ~~quantity of~~ radioactive material.....”

Clarification and consistency is needed when using quantity limits. For example, when the intent is to capture sources or aggregates greater than cat 2, then that should be stated clearly. If it is important to distinguish between cat 1 and cat 2, then those terms should specifically be used.

Item § 37.1201 (a)(2). Clarification of the phrase, “until the licensee seeks to possess radioactive material...” Specifically, it is suggested that the phrase “before taking possession” be used consistent with the apparent intent of item (3) of this section and § 37.21(a)(3) in Subpart B.

Item § 37.1201 (c) Clarification of the phrase, ‘must include program features, as appropriate...’ Specifically, clarification should be provided on who decides what is appropriate or not and the criteria for the decision.

Item § 37.1201 (d)(1)-(3) Since this information has already been submitted as part of the Increased Control order, clarification should be provided stating whether the licensee must resubmit the information.

Item § 37.1201 (d)(3) Clarification should be provided explaining whether this section applies to co-locating HDR machines in the same room.

Section § 37.1203, “General program requirements”:

Item § 37.1203 (a)(2)(iii). This requirement states that the licensee should notify NRC and affected local law enforcement agencies within 6 months after a revision to the security program is made. NRC should consider adding a “significance threshold” for what types of program modifications warrant such notifications so that resources are not expended by all parties to track more minor, administrative changes that do not reach certain security significance.

Item § 37.1203 (c)(3) – this appears to add a whole new training requirement for the program along with 37.1207(b). Need we add special training only for those with access, why not incorporate into annual radiation safety training overall, otherwise we are talking about holding additional training only for those with access.

Item 37.1203(c) does not specify the required frequency of training. Is only initial required. Under what conditions is refresher or supplemental training required?

Item § 37.1203 (c)(5). This item requires records of initial and supplemental training as required by Subpart F but there does not appear to be any requirement to conduct or recording of periodic refresher training. NRC should consider whether refresher training should be required and, if so, add appropriate requirements.

Section § 37.1207 Personnel Access Records

Item § 37.1207 (b) – This requirement appears to be a change from the order and will now require the licensee to train the vendor individuals having written verification as to being trustworthy and reliable. Please provide clarification for this change.

Item § 37.1207 (b) – Please clarify is this allows non-verified access.

Section § 37.1209 Monitoring, Detection and Assessment

Item § 37.1209(a)(3)(i)(B) – Clarification is needed as to whether or not video surveillance is allowed , if it is it not allowed, must it be direct visual surveillance?

Section § 37.1213 LLEA Coordination and Notification Requirements

Item §37.1213(a)(1) – Clarification of the phrase, ‘...and to coordinate to the extent practicable...’ How will this be inspected or enforced? Who decides what defines ‘to the extent practicable’? (also see 37.1213(a)(2)).

Item §37.1213(b)(2) – As written, it is very unclear what the licensee must do to comply with this requirement.

Item § 37.1213(b)(3) – As written this requirement is also not clear: how long do we wait for a response from LLEA before the 3-day clock starts?

Rulemaking Comments

From: Lynne Fairobent [lynne@aapm.org]
Sent: Saturday, June 20, 2009 10:27 PM
To: Rulemaking Comments
Cc: Douglas Pfeiffer; robert.macdougall@nrc.gov.; Melissa Carol Martin
Subject: RIN 3150-AI12 AAPM comments Part 37 Subpart C
Attachments: AAPM comments Part 37 part C 06-18-09.pdf

Attached please find comments from AAPM re: RIN 3150-AI12 Part 37 Subpart C.

Lynne

Lynne A. Fairobent, AAPM Legislative and Regulatory Affairs Manager
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Received: from mail1.nrc.gov (148.184.176.41) by TWMS01.nrc.gov
(148.184.200.145) with Microsoft SMTP Server id 8.1.358.0; Sat, 20 Jun 2009
22:26:57 -0400

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X-SBRS: 2.9

X-MID: 3216499

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Received: from acpgate.acp.org ([149.28.97.150]) by mail1.nrc.gov with ESMTP;
20 Jun 2009 22:26:42 -0400

Received: from ACP-MTA by ACPGate.acp.org with Novell_GroupWise; Sat, 20 Jun
2009 22:26:42 -0400

Message-ID: <4A3D6217.2830.002B.3@AAPM.ORG>

X-Mailer: Novell GroupWise Internet Agent 7.0.3

Date: Sat, 20 Jun 2009 22:26:31 -0400

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CC: "Douglas Pfeiffer" <dpfeiffer@bch.org>,
<robert.macdougall@nrc.gov.>,

"Melissa Carol Martin" <melissa@therapyphysics.com>

Subject: RIN 3150-AI12 AAPM comments Part 37 Subpart C

MIME-Version: 1.0

Content-Type: multipart/mixed; boundary="=__PartC2E9B847.2__="

Return-Path: lynne@aapm.org