# POLICY ISSUE
## NOTATION VOTE

May 29, 2003 SECY-03-0088

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: DENIAL OF PETITION FOR RULEMAKING (PRM-34-5) AMERSHAM CORPORATION, NOW KNOWN AS AEA TECHNOLOGY QSA, INC.

PURPOSE:

To obtain Commission approval for the Federal Register notice, the letter to the petitioner, and the letters to Congress.

BACKGROUND:

By letter dated March 28, 1996, the Amersham Corporation (now known as AEA Technology QSA, Inc.) submitted PRM-34-5, requesting the U.S. Nuclear Regulatory Commission (NRC) to amend its regulations in 10 CFR 34.20, "Performance requirements for industrial radiography equipment," by removing reference to associated equipment in § 34.20, clarifying the current regulations for radiography equipment performance standards that the petitioner believes are not clearly defined, and amending § 34.28 to require routine inspection and maintenance of associated equipment.

In SRM-SECY-02-0202 (March 27, 2003), the Commission approved the staff's recommendation to deny the petition for rulemaking (PRM-34-5) submitted by Amersham Corporation, subject to the staff revising guidance and inspection procedures and issuing a regulatory issue summary in order to align NRC's guidance and practice with the applicable regulations.

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The Commission disapproved the draft Federal Register notice, the letter to the petitioner, and the letters to Congress and directed the staff, in consultation with the Office of the General Counsel, to revise and resubmit these documents. The SRM contained nine items to be addressed by the staff. The staff has significantly revised the documents to more adequately reflect the health and safety basis as to why the petition is being denied and to provide a clear discussion of the existing regulations. The reasons for the 7-year delay in NRC's response to the petitioner are provided in: (1) the draft Federal Register notice (Attachment 1), "Public Comments on the Petition," (2) the letter to the petitioner (Attachment 2), and (3) the letters to Congress (provided as background information for the Commission).

SRM Items 1 through 6 are addressed in Attachment 1. SRM Item 7 is addressed in Attachment 2 and the letters to Congress.

Regarding SRM Item 8, NMSS currently provides instructions to teams revising guidance documents to identify and remove text that may infer or be misinterpreted as additional requirements to regulations. For example, NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses–Program-Specific Guidance about Medical Use Licenses," (October 2002) was edited in this manner. In its ongoing review of guidance documents that are available to the staff, Agreement States, or licensees, NMSS will ensure that the documents do not contain additional requirements or misinterpretations of the current regulations.

SRM Item 9 will be addressed by updating the information in the Rulemaking Activity Plan (SECY-03-0045, March 26, 2003) to include additional information for petitions that were received 2 or more years ago, i.e., reasons for delays in resolving/closing petitions, whether the petitioners are aware of the basis for delays and are being kept informed about the status of their petitions, and options that would allow the schedules to be expedited. The updated information will be provided to the Commission by June 30, 2003. The staff provides the Rulemaking Activity Plan (RAP) to the Commission on an annual basis and future versions of the RAP will include the additional information for petitions received more than 2 years before the date of the RAP.

DISCUSSION:

In its petition, Amersham Corporation requested NRC to amend § 34.20 by removing reference to "associated equipment." The petitioner believes that associated equipment should not be subject to the sealed source and device (SSD) review process. The petitioner argued that the radiation safety evaluation and registration under § 32.210 apply specifically to SSDs and do not apply to other equipment. The petitioner asserted that for industrial radiography equipment NRC expanded its interpretation of § 32.210 to include associated equipment, and such an interpretation is not appropriate without rulemaking. The petitioner pointed out that NRC's interpretation, which requires licensees to ensure that associated equipment has been registered under § 32.210, has added unnecessary regulatory burden.

Additionally, the petitioner wanted the American National Standards Institute (ANSI) N432–1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (ANSI N432) which is incorporated by reference in § 34.20, to be used as guidance for good manufacturing practices and not as a regulatory approval checklist. The petitioner also requested that § 34.28 be amended to reflect appropriate inspection and

maintenance requirements for all the radiography equipment, including “associated equipment.” Finally, the petitioner pointed out that the current version of § 34.20 only requires that the equipment meet the performance standards in ANSI N432, and does not state that this involves regulatory approvals.

In the draft Federal Register notice (Attachment 1), the staff revised the section entitled “Reasons for Denial” to: (1) indicate that NRC has discontinued registration of associated equipment under § 32.210 and will complete conforming changes to guidance documents; (2) clarify the applicable requirements that are sufficient to maintain safety and provide the basis for denying the petition; (3) explain the historical context wherein NRC determined to incorporate by reference ANSI N432 in § 34.20; and (4) remind the licensee that inspection and maintenance of associated equipment is currently required in § 34.31. In brief, the staff’s rationale in the draft Federal Register notice for denying the petitioner’s request includes the following points:

- The current requirements do not require associated equipment to be registered and are sufficient to maintain safety; therefore, the staff determined the NRC practice of registering associated equipment under § 32.210 was not only not required, but was also an unnecessary regulatory burden;

- The staff obtained risk information that indicated denial of the petition was appropriate;

- The intent of the petitioner’s request to remove associated equipment from the sealed source and device registration process is achieved without rulemaking by revising NRC implementation guidance;

- Historically, the NRC has determined that manufacturers had not uniformly and fully implemented the national consensus standard for design and construction of radiography equipment that was needed to improve radiation safety and, therefore, disagreed with the petitioner’s point that NRC inappropriately used ANSI N432 as a regulatory checklist when the standard was originally intended to serve as guidance for good manufacturing practices;

- The current requirements are performance-based because a licensee is not prohibited from modifying associated equipment unless the design of replacement components would compromise the design safety features of the system; and licensees are required to complete routine inspection and maintenance to identify components for replacement before component failure or unsafe performance could occur;

- The level of compatibility between the Agreement State regulations and the existing NRC requirements is not affected by revising NRC practice and implementation guidance; and

- Use of guidance rather than rulemaking provides flexibility for Agreement States to revise their policy and guidance to meet unique situations and local conditions.

The staff discontinued the NRC practice of reviewing associated equipment under § 32.210(c). By October 1, 2003, the staff will revise the appropriate guidance and inspection procedure and will issue a regulatory issue summary (RIS) to replace the existing information notice in order to align NRC's implementation to the current requirements. The Agreement States have indicated that they also do not intend to register associated equipment.

For these reasons, the staff finds that the arguments presented in the petition do not support rulemaking to revise the performance requirements for industrial radiography equipment.

COORDINATION:

The Office of the General Counsel has no legal objection to the denial of this petition.

RECOMMENDATIONS:

That the Commission:

1. Approve publication of the Federal Register notice announcing the denial;

2. Inform appropriate Congressional committees; and

3. Note that a letter is attached for the Secretary's signature (Attachment 2), informing the petitioner of the Commission's decision to deny the petition.

***/RA/***

William D. Travers
Executive Director
for Operations

Attachments:
1. Draft Federal Register notice
2. Letter to the Petitioner

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