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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(301) 415-5795

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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

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

[Docket No. PRM-34-5]

Amersham Corporation (now known as

AEA Technology QSA, Inc.); Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM-34-5) submitted by Amersham Corporation (now known as AEA Technology QSA, Inc.). The petitioner requested that the NRC amend its regulations that specify performance requirements for industrial radiography equipment by removing the reference to associated equipment, clarifying provisions in the current regulations that the petitioner believes are not clearly defined, and by requiring routine inspection and maintenance of associated equipment.

The NRC reviewed the petitioner's request and concluded that rulemaking is not necessary to achieve the intent of the petitioner's request to remove associated equipment from the sealed source and device (SSD) evaluation and registration process for manufacturers of industrial radiography equipment in 10 CFR 32.210, "Registration of product information." The

NRC also explored rulemaking to amend its regulations for self-certification of associated equipment to authorize manufacturers or industrial radiography licensees to complete the radiation safety evaluation of associated equipment. The NRC obtained risk information that did not clearly support self-certification of associated equipment. The NRC disagreed with the petitioner's point that NRC inappropriately uses American National Standards Institute (ANSI), N432–1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (ANSI N432) as a regulatory checklist when the standard was originally intended to serve as guidance for good manufacturing practices. The NRC determined that its regulations are performance-based in this regard. Section 34.20 allows modification of associated equipment by a licensee or manufacturer unless the replacement component would compromise the design safety features of the system. Finally, § 34.31 requires routine inspection and maintenance of associated equipment. Therefore, additional rulemaking is not warranted.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and NRC's letter to the petitioner may be examined at the NRC Public Document Room, Public File Area O1F21, 11555 Rockville Pike, Rockville, MD. These documents also may be viewed and downloaded electronically via the rulemaking website.

The NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/reading-rm/adams.html. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Thomas Young, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-5795, e-mail tfy@nrc.gov.

SUPPLEMENTARY INFORMATION:

The Petition

On June 18, 1996 (61 FR 30837), the NRC published a notice of receipt of a petition for rulemaking filed by the Amersham Corporation (now known as AEA Technology QSA, Inc.). The petitioner requested that the NRC amend its regulations in 10 CFR 34.20, "Performance requirements for industrial radiography equipment," by removing the reference to "associated equipment" in § 34.20. The petitioner believes that associated equipment should not be subject to the 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, the 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 of 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.

Public Comments on the Petition

The notice of receipt of the petition for rulemaking invited interested persons to submit comments. The comment period closed on September 30, 1996. NRC received eight comment letters from industry, individuals, and an Agreement State. The majority of the commenters supported the petition. The main reasons cited by these commenters were related to excessive costs in replacing associated equipment that was already fit for use and would not need to be replaced for any other reason. The NRC’s interpretation of the rule required licensees to replace unregistered equipment with equipment that had been registered under § 32.210 after prototype testing of the equipment demonstrated that the equipment met the performance requirements in ANSI N432, which is incorporated by reference in § 34.20.

Since the comment period closed, NRC has explored the concept of licensee or manufacturer self-certification of associated equipment with members of industry and counterparts in the Agreement States. The NRC completed the generic assessment and special team inspections published in NUREG-1631, “Source Disconnects Resulting from Radiography Drive Cable Failures” (June 1998). An NRC contractor used performance criteria in § 34.20 to complete tests on portable industrial radiography systems described in NUREG/CR-6652, “Safety Testing of Industrial Radiography Devices,” (January 2000). An NRC contractor provided a risk assessment to compare regulation of associated equipment under various regulatory approaches. The NRC developed a risk-informed and more performance-

based approach for self-certification of associated equipment and asked the Agreement States to evaluate the approach. During the time since the comment period closed, NRC monitored the use of associated equipment via various sources of information, such as inspection reports, event notifications, and enforcement actions.

Reasons for Denial

Over the last several years, NRC has completed several analyses that indicated rulemaking is not necessary to achieve the intent of the petitioner's request; therefore, NRC is denying the petition for the following reasons.

1. Current NRC regulations do not require associated equipment to be registered and the regulations are sufficient to maintain safety. The NRC determined that the practice of registering associated equipment under § 32.210 was not only not required, but was also an unnecessary regulatory burden. Therefore, NRC has discontinued the practice of registering associated equipment and will align NRC's implementation by revising the appropriate guidance and inspection procedure and will issue a regulatory issue summary (RIS) to convey these changes to the regulated community.
2. Although § 34.20(a)(1) states that associated equipment must meet the performance requirements in ANSI N432, § 34.20(b)(3) allows a licensee to modify associated equipment, unless the design of any replacement component would compromise the design safety features of the system. The NRC has dealt with the issue of requiring performance criteria in 10 CFR Part 34 for several decades, as follows.

   The Advance Notice of Proposed Rulemaking published March 27, 1978 (43 FR 12718) announced the NRC's intention to complete rulemaking to improve safety by

including radiography equipment performance requirements in the regulations. ANSI N432 was being developed at that time and was issued in 1981. In 1980, an ad hoc Radiography Steering Committee composed of NRC personnel and State officials representing the Conference of Radiation Control Program Directors, Inc., was formed to draft recommendations for improving radiation safety. The steering committee developed recommendations for radiography equipment design safety that were similar to the performance criteria in ANSI N432. Because it appeared that all manufacturers of radiography equipment were not using ANSI N432 nor uniformly or completely implementing the performance criteria, NRC concluded that rulemaking was necessary to ensure that manufacturers would implement ANSI N432 to improve radiation safety for workers. The NRC published the final rule on January 10, 1990; 55 FR 843 that incorporated by reference ANSI N432 into § 34.20. Incorporation by reference is the formal process that allows the NRC to refer to industry standards that are already published elsewhere and that need to be available to afford fairness and uniformity in the administrative process. Incorporation by reference substantially reduced the volume of material to be published in the rule. As referenced in § 34.20, ANSI N432 has the force of law and is treated as if it were published in full in the Federal Register.

To maintain safety, a licensee must ensure that prototype testing of all associated equipment (including customized associated equipment) meets the performance requirements of ANSI N432. This requirement prevents substandard associated equipment from being developed by a licensee. Alternatively, under § 34.20(a)(2), a licensee may submit an engineering analysis to NRC for review without repeating a prototype test for similar associated equipment. This performance-based approach is a key factor for denying the petitioner's request regarding the implementation of ANSI N432.

3. At the time of the petitioner's request to amend § 34.28 in 1996, NRC had already proposed rulemaking for routine inspection and maintenance of associated equipment. NRC published the overall revision of 10 CFR Part 34 (May 28, 1997; 62 FR 28948) to incorporate § 34.31, "Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments," that contains performance-based requirements to ensure that associated equipment will function as designed. Currently, § 34.31 requires the licensee to perform visual and operability checks on associated equipment before use on each day that the equipment is to be used to ensure that the equipment is in good working condition. If equipment problems are found, the equipment must be removed from service until repaired. Section 34.31 also requires the licensee to have written procedures for inspection and routine maintenance of associated equipment at intervals not to exceed three months, or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired. Replacement components must meet design specifications.

NRC obtained risk information for the regulation of associated equipment under § 34.20 and applied the screening considerations in SECY-00-0213, "Risk-Informed Regulation Implementation Plan" (October 2000), to determine that the petitioner's request was amenable to a risk-informed approach. An NRC contractor provided risk information that concluded as long as associated equipment is manufactured to meet the performance requirements of a national standard (i.e., ANSI N432), the regulation is sufficient to maintain safety as written.

NRC discontinued the practice of registering associated equipment under § 32.210 to reduce, what NRC determined to be, unnecessary regulatory burden. The NRC will revise the

appropriate guidance and inspection procedure and will issue a RIS to replace the existing information notice to align NRC's implementation of § 34.20(a)(1) as follows:

1. As a matter of convenience for manufacturers and their customers, a manufacturer may register associated equipment under the § 32.210 process, but is not required to do so. For example, if a manufacturer's application to register a device also designates the model numbers for associated equipment to be used with the device, then NRC will also indicate the model numbers for the associated equipment in the registration certificate for the device so that the customer understands which model of associated equipment is compatible with the device. For the radiation safety evaluation of a sealed source and device combination under § 32.210(c), all the components of an industrial radiography system must be evaluated together to ensure that there is no interference with the sealed source or the device or degradation of safety for the system over the expected life cycle of the system. A manufacturer may register an entire system comprised of compatible components (including associated equipment) or various sealed source and device combinations (excluding associated equipment). The NRC does not intend to revise current registrations for industrial radiographic equipment to remove references to associated equipment.

2. NRC will revise NUREG-1556, Volume 2, "Consolidated Guidance about Materials Licensees–Program-Specific Guidance about Industrial Radiography Licenses," (Final Report, August 1998) to remove statements that indicate that associated equipment must be specifically approved or registered by NRC or an Agreement State. Instead, the guidance will state that manufacturers or distributors of industrial radiography equipment may voluntarily include items of associated equipment that are compatible with their sealed sources and devices when they are registered. Appendix F contains Information

Notice 96-20, “Demonstration of Associated Equipment Compliance with 10 CFR 34.20," (IN-96-20) that will be replaced by a RIS.

3. NRC will revise Inspection Procedure 87121, “Industrial Radiography Programs” (December 31, 2002). Currently, the procedure appropriately directs an inspector to examine available associated equipment, interview the workers about inspection and maintenance procedures and awareness that associated equipment needs to comply with § 34.20, and observe work in progress that involves use of associated equipment. An additional statement is needed to prompt an inspector to consider the licensee’s equipment modification process to confirm that the design safety features of the system were not compromised by a replacement component of associated equipment that was modified by the licensee (i.e., either the licensee or manufacturer completed prototype testing that demonstrated the component met the performance criteria in ANSI N432 or NRC or an Agreement State has reviewed an engineering analysis of the modification).

4. NRC will issue a RIS to replace IN-96-20 and emphasize a more performance-based approach to make it clear that:

   - manufacturers of industrial radiography equipment may, but are not required to, designate compatible components (including associated equipment) for use with their sealed sources and devices that are registered under the § 32.210 process;
   - under § 34.20(b)(3), a licensee is allowed to modify associated equipment unless the design of any replacement component would compromise the design safety features of the system;
   - a licensee’s modification process must account for prototype testing or engineering analysis of a replacement component against the performance

criteria required in § 34.20 for any component that was modified for use in licensed activities;

- to comply with § 34.20, a licensee should demonstrate that modifications to associated equipment: (1) will not create material incompatibility that may degrade a source or device over their expected useful life times; (2) will not diminish the performance of associated equipment in expected use environments over the expected life time of the associated equipment; (3) will not allow a source to inadvertently exit the system; and (4) will not compromise expected safe use of the system; and
- enforcement action would be considered for a licensee who completes modification of associated equipment that compromises the design safety features of the system. The NRC Enforcement Policy (NUREG-1600) includes an example involving possession or use of unauthorized equipment which degrades safety in the conduct of licensee activities.

The NRC has determined that alignment of the NRC implementation to the existing NRC requirements maintains the same level of compatibility between the Agreement State regulations and the existing NRC requirements. Also, use of revised NRC guidance rather than rulemaking to achieve the petitioner's intent provides Agreement States the flexibility to revise their policy and guidance to meet unique situations and local conditions.

In conclusion, no new information has been provided by the petitioner that calls into question the requirements. Existing NRC regulations provide the basis for reasonable assurance that the common defense and security and public health and safety are adequately protected; therefore, rulemaking does not appear to be warranted.

For the reasons cited in this document, the NRC denies this petition.

Dated at Rockville, Maryland, this _____ day of _____ , 2003.

For the Nuclear Regulatory Commission.

_____
Annette Vietti-Cook,
Secretary of the Commission.

Ms. Cathleen Roughan
Regulatory Affairs Manager
AEA Technology QSA, Inc.
40 North Avenue
Burlington, MA 01803

Dear Ms. Roughan:

I am responding to the petition for rulemaking, dated March 28, 1996, that you submitted to the U.S. Nuclear Regulatory Commission (NRC) on behalf of Amersham Corporation (now known as AEA Technology QSA, Inc.). Your petition was docketed as PRM-34-5 and requested 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, by clarifying the current regulations for radiography equipment performance standards that you believe are not clearly defined, and by amending § 34.28 to require routine inspection and maintenance of associated equipment.

The notice of receipt of the petition was published in the Federal Register on June 18, 1996 (61 FR 30837). The comment period closed on September 30, 1996. Eight comment letters were received. The reasons for our extensive delay to respond to your requests are provided on pages 4 and 5 of the enclosed Federal Register notice.

NRC has considered the petition and your supporting rationale. For the reasons provided in the enclosed Federal Register notice, your petition for rulemaking is denied. In summary, the petition is being denied because we have determined that registration of associated equipment is not required. Therefore, we are changing NRC practice contained in guidance and inspection procedures, to not include associated equipment in the registration process. This information will be provided to affected internal and external stakeholders via a regulatory issue summary (RIS). In addition, we believe it is important to retain the reference to 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 ensure that radiography equipment meets the minimum performance criteria to protect health and minimize danger to life and property. At the time of your request to amend § 34.28, NRC had already proposed rulemaking to include routine inspection and maintenance of associated equipment in § 34.31, as stated in the current regulations.

The Federal Register notice denying the petition is being transmitted to the Office of the Federal Register for publication.

Sincerely,

Annette Vietti-Cook
Secretary of the Commission

Enclosure: Federal Register notice