

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 Web site.

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.

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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