

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