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FILE

MEMO TO : All Industrial Radiography Licensees

FROM : Kenneth W. Wangler, P.E.
Manager
Radiation Control Program
Division of Air Quality

RE : NRC Regulatory Issue Summary 2005-010: "Performance-Based Approach for Associated Equipment in 10 CFR 34.20"

Date : July 6, 2005

Enclosed is a copy of the United States Nuclear Regulatory Commission (NRC) Regulatory Issue Summary 2005-010: "Performance-Based Approach for Associated Equipment in 10 CFR 34.20". This Regulatory Issue Summary was issued to explain the performance-based approach NRC has decided to take regarding the regulation of associated equipment used in an industrial radiography system.

It is expected that you will review this information for applicability to your licensed activities and consider actions, as appropriate, to ensure the safe and legal use of radioactive materials in the State of North Dakota.

This notice is for your information only. No specific action nor written response is required. If you have any questions concerning this issue, please contact the NRC technical personnel listed in the attachment; or contact North Dakota's Radiation Control Program at 701.328.5188.

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Enc:

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555-0001

JUN 2005
Received
Air Quality

June 10, 2005

NRC REGULATORY ISSUE SUMMARY 2005-10 PERFORMANCE–BASED APPROACH FOR ASSOCIATED EQUIPMENT IN 10 CFR 34.20

ADDRESSEES

All industrial radiography licensees and manufacturers and distributors of industrial radiography equipment.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to explain the performance-based approach NRC has decided to take regarding the requirements in 10 CFR 34.20, "Performance requirements for industrial radiography equipment," which addresses the regulation of associated equipment used in an industrial radiography system. This RIS supersedes and replaces Information Notice 96-20, "Demonstration of Associated Equipment Compliance with 10 CFR 34.20." No specific action or written response is required.

BACKGROUND

In the *Federal Register* notice (68 FR 41757, July 15, 2003), NRC announced its denial of the petitioner's request for rulemaking to remove from 10 CFR 34.20 the term "associated equipment." The notice also explained that NRC's practice of registering associated equipment under 10 CFR 32.210, "Registration of product information," which was previously described in Information Notice 96-20, had been discontinued. This RIS supersedes and replaces Information Notice 96-20.

SUMMARY OF ISSUE

To maintain safety, each licensee must take special care to ensure that all associated equipment (including modified or customized associated equipment) meets the minimum performance criteria required in 10 CFR 34.20. A licensee that modifies associated equipment is required to demonstrate by actual testing or an alternative analysis that the performance of the radiographic system and individual items of associated equipment meet the criteria in 10 CFR 34.20. The results of actual testing or analysis must demonstrate that the replacement component will not compromise the design safety features of the industrial radiography system. Compliance with the performance criteria prevents a licensee from using substandard associated equipment.

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PERFORMANCE REQUIREMENTS FOR ASSOCIATED EQUIPMENT

The performance requirements for associated equipment are set forth in the paragraphs of 10 CFR 34.20, described below:

- paragraph (a)(1), incorporates by reference the American National Standards Institute (ANSI) N432–1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (ANSI N432) which specifies the design and method of qualifying (testing) industrial radiography equipment, including equipment that NRC has defined as "associated equipment;"

- paragraph (a)(2), provides for an engineering analysis as an alternative to actual testing, to demonstrate the performance of individual radiography equipment components;

- paragraph (b)(3), allows associated equipment to be modified unless the replacement component would compromise the design safety features of the industrial radiography system;

- paragraph (c)(5) and (8), respectively address crushing and kinking tests for a guide tube and the standard test for tensile strength of an exposure head;

- paragraph (e), allows a licensee or vendor to apply a realistic torque to the drive mechanism during the life cycle test.

The regulations require a licensee to use industrial radiography equipment that has been manufactured and tested to meet radiation safety performance criteria under 10 CFR 34.20. The life cycle test in ANSI N432 is an evaluation of the endurance of a source or device. To test the life cycle of an industrial radiography source or exposure device, all components of the industrial radiography system (including the associated equipment) must be assembled and operated for the duration of the test. This requirement, NRC determined, is sufficient to maintain safety and a separate regulatory approval for associated equipment is not needed as long as the associated equipment meets the minimum criteria in 10 CFR 34.20.

Attachment 1 to this RIS contains additional information about definitions and applicable requirements, certificates of registration for a sealed source or device, custom-built items of associated equipment, acceptable methods to demonstrate compliance, inspection and licensing guidance, and inspection and maintenance procedures. Attachment 2 indicates the availability of reference documents that are cited in this RIS and Attachment 1.

ENFORCEMENT POLICY

The NRC Enforcement Policy, Supplement VI, provides examples of violations in each of the four severity levels as guidance in determining the appropriate severity level for violations in the area of fuel cycle and materials operations, including industrial radiographic operations. An example of an activity that would normally result in the NRC issuing a Severity Level III Notice of Violation is possession or use of unauthorized equipment or materials in the conduct of licensee activities that degrades safety. Based on this example, enforcement action would be considered for a licensee that used associated equipment that had not been tested or analyzed

to meet the performance requirements or that used modified associated equipment that compromised the design safety features of an industrial radiography system and threatened or did not protect the health and safety of workers or members of the public.

AGREEMENT STATE COMPATIBILITY

NRC has determined that the information provided in this RIS does not change the level of compatibility of the Agreement State regulations to the existing NRC requirements. Use of the information in this RIS continues to provide Agreement States with the flexibility to revise their policy and guidance to meet unique situations and local conditions and to ensure an orderly, uniform implementation of the performance-based approach for associated equipment.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because it is informational, and does not represent a departure from current regulatory requirements.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

NRC has determined that this action is not subject to the Small Business Regulatory Enforcement Fairness Act of 1996.

PAPERWORK REDUCTION ACT STATEMENT

This RIS requires no specific action or written response. If you have any questions about this summary, please contact one of the individuals listed below or the appropriate regional office.

Patricia K. Holahan, Acting Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
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Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under Electronic Reading Room/Document Collections.

Attachments:
1. Additional Information and Applicable Requirements Regarding Associated Equipment
2. Availability of Reference Documents
3. List of Recently Issued NMSS Generic Communciations

ADDITIONAL INFORMATION AND APPLICABLE REQUIREMENTS REGARDING ASSOCIATED EQUIPMENT

Definitions

10 CFR 34.3, "Definitions," defines associated equipment as equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source [e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube, and collimator when it is used as an exposure head]. 10 CFR 34.3 defines the following items of associated equipment: collimator, control (drive) cable, control (drive) mechanism, control tube, exposure head (source stop), and guide tube. 10 CFR 34.3 defines the following radiographic equipment and related terms: radiographic exposure device, s-tube, sealed source, source assembly, source changer, and storage container.

Licensees should be aware of the specific meaning of the terms indicated above. The requirements applicable to items of equipment depend on how the equipment is defined in 10 CFR 34.3. It is important to distinguish between items of equipment that are considered to be associated equipment and items of equipment that are not. In some cases, there may be no regulatory requirements that apply to an item of equipment; in other cases, an item of equipment may be a component of a source or device that is required to be specifically authorized for use. Following are two examples that illustrate important distinctions which determine regulatory requirements for an item of equipment.

The first example distinguishes certain types of collimators that are not associated equipment and are not required to meet the performance criteria in ANSI N432. Various types of collimators are used as radiation safety devices for industrial radiographic operations. In many cases, the exposure head at the end of the guide tube is inserted into a collimator. This type of collimator is not an item of associated equipment because the source does not come in contact with the collimator. This type of collimator is not subject to the performance requirements in 10 CFR 34.20 or the evaluation process in 10 CFR 32.210. However, if a collimator does come in contact with the source because it also acts as a source stop (exposure head), then it falls within the scope of the definition of associated equipment that is subject to the performance requirements in 10 CFR 34.20.

The second example distinguishes the connector that is located between the sealed source and the control (drive) cable. 10 CFR 34.3 defines the source assembly to include the connector, stating, "Source assembly means an assembly that consists of the sealed source and a connector that attaches the source to the control cable." The connector is a component of the source assembly and is, therefore, not an item of associated equipment. The source assembly is subject to the requirements in 10 CFR 30.32, "Application for a specific license." 10 CFR 30.32(g) indicates that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the sealed source or the device as registered under 10 CFR 32.210 or with an Agreement State or must include the information identified in 10 CFR 32.210(c). The manufacturing processes used to attach the connector to the source cable and to the control (drive) cable are also subject to evaluation by NRC or an Agreement State under these requirements.

Portable industrial radiographic systems typically include a two-piece connector (swivel coupling design) to attach the source assembly to the control (drive) cable in order to operate the system. The performance-based requirement in 10 CFR 34.20(c)(1) indicates that the coupling must be designed such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions. The Statements of Consideration at 55 FR 843 (January 10, 1990) include a response to comments received for 10 CFR 34.20(c)(1). The response indicates, "NRC's source and device registration process will ensure compliance with this performance requirement by requiring NRC approval before the newly designed connectors could be used." The sealed source or device evaluation process ensures compliance with the performance criteria in the rule. Both pieces of the two-piece connector are subject to evaluation under 10 CFR 30.32(g) or 32.210(c).

Sealed Source and Device (SS&D) Certificate of Registration

NRC determined that the previous practice of registering associated equipment under 10 CFR 32.210 was not only not required, but was a regulatory practice that imposed an unnecessary burden on licensees and for NRC and the Agreement States which are authorized to evaluate SS&Ds. Therefore, this practice has been discontinued. NRC does not intend to independently revise current SS&D certificates of registration only to remove references to associated equipment. If it becomes necessary to amend a current SS&D certificate of registration, the applicant may remove or update the information about associated equipment in the application.

As a matter of convenience, an SS&D applicant under 10 CFR 32.210 may describe the associated equipment that was used in the life cycle test for the radiographic source or device that is being registered; however, there is no requirement to do so. If an applicant wants the associated equipment to be included on the certificate of registration, the application which describes associated equipment must include sufficient information to demonstrate that the performance criteria were met for associated equipment under 10 CFR 34.20. If a certificate of registration does not identify the associated equipment that was used in the system along with the source or device, then each end-user (licensee) must demonstrate that the items of associated equipment which the licensee uses in the system meet the performance criteria under 10 CFR 34.20 and do not compromise the design safety features of the system.

NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses–Applications for Sealed Source and Device Evaluation and Registration," (Final Report, April 2004), Section 4.6, "Radiography Equipment," indicates that there is no requirement to identify associated equipment for an SS&D certificate of registration. Note–In Section 15, "Glossary," the definition of "associated equipment" was intended to be removed and should be disregarded because it has been superceded by Section 4.6.

Custom-Built or Unique Items of Associated Equipment

Associated equipment specifically designed and constructed to the order of a single licensee must comply with the performance criteria in 10 CFR 34.20. There is no requirement to register custom-built or unique items of associated equipment. However, when modified or custom-built associated equipment introduces components or fabrication methods that differ from those that

were used in the endurance test for a source assembly or exposure device that was previously registered, the licensee must demonstrate compliance with the requirements in 10 CFR 34.20 before the equipment can be used for industrial radiographic operations. For example, licensees must obtain information demonstrating that modified guide tubes and exposure heads will withstand tests that demonstrate the equipment will maintain its integrity in normal use and likely accident conditions.

Acceptable Methods to Demonstrate that Associated Equipment Complies with 10 CFR 34.20

The performance-based approach that NRC has decided to take for associated equipment recognizes that a licensee has latitude to use modified components, unless the design of any replacement component would compromise the design safety features of the system. Further guidance about testing or an alternative analysis to testing is described in NUREG-1556, Volume 3, Revision 1, Section 10.5, "Prototype Testing." The NUREG addresses appropriate methods a licensee may use to demonstrate the ability of a modified industrial radiography system to maintain its integrity when subjected to conditions of normal use and likely accident conditions.

For example, information about an equivalent system that was previously registered may be used to demonstrate safety and integrity of the modified system, if the design of the modified system and its intended normal and likely accident conditions of use are identical or similar to the previously registered system. In some cases, an engineering analysis or operational history with supporting documentation may be sufficient for a licensee to justify the use of a modified system without repeating, e.g., an endurance test. However, when an appropriate comparison to the previously registered system is not possible because a licensee is unable to obtain appropriate information about previous prototype testing, engineering analysis, or operational history for the previously registered system or item of associated equipment, then the licensee must complete actual testing of the modified system and the individual items of associated equipment to demonstrate compliance with 10 CFR 34.20.

NRC contracted a testing laboratory to complete actual testing of three industrial radiography systems from three manufacturers. The contractor developed procedures to test the systems and individual items of associated equipment to meet the performance criteria in 10 CFR 34.20. In a similar manner, a licensee could contract a testing laboratory or manufacturer of industrial radiography equipment to test or analyze a modified system or component that will be used in a system that was previously licensed or registered.

If a licensee needs to modify associated equipment, the licensee should adopt and implement a suitable engineering procedure or plan to ensure that a modified component will not compromise the design safety features of the industrial radiographic system. Implementation of such a procedure or plan should demonstrate that modifications to the equipment: (1) will not create material incompatibility that may degrade a sealed source or device over the expected useful life time; (2) will not diminish the performance of the system in expected use environments and in likely accident conditions over the expected life time of the various system components; (3) will not allow a source to inadvertently exit the system; and (4) will not initiate

or propagate equipment failures resulting in a "source disconnect." An endurance test for a modified system should indicate that the modified component does not interfere with the performance of the components of the system that were previously registered.

Examples of the performance-based approach that NRC has decided to use for 10 CFR 34.20 are included in the following paragraphs to illustrate situations when a licensee must complete testing or analysis of associated equipment to demonstrate that the associated equipment meets the performance criteria in 10 CFR 34.20 and does not compromise the design safety features of the system.

It is acceptable for a licensee to assume that no further testing is needed for associated equipment which is listed along with the source or device as an entire system on the certificate of registration because the associated equipment has already been verified to meet the performance criteria in 10 CFR 34.20 when the associated equipment is used with the source or device. However, a licensee that substitutes associated equipment into an industrial radiography system that was registered as an entire system which specified the associated equipment must demonstrate that the reconfigured system meets the performance criteria under 10 CFR 34.20.

It is acceptable for a licensee to assume that associated equipment that is used as the manufacturer intended as described in the SS&D certificate of registration meets the performance criteria under 10 CFR 34.20. The SS&D certificate of registration indicates the principal use, normal conditions of use, and the limitations on use for the source or device. However, a licensee that uses associated equipment in a manner that was not intended by the manufacturer as described in the SS&D certificate of registration for the source or device must describe the conditions of use for the equipment and obtain information about performance of the equipment under these conditions of use to demonstrate compliance with 10 CFR 34.20. Conditions of use include, for example, extremely hot or cold operating temperature, excessive vibration or shock, high concentrations of corrosive materials, and underwater usage.

Inspection and Licensing Guidance

NRC is revising inspection and licensing guidance to incorporate the explanation provided by this RIS. Inspection Procedure 87121, "Industrial Radiography Programs," directs an inspector to follow a performance-based approach to examine available associated equipment, observe work in progress that involves use of associated equipment, and interview workers about the inspection and maintenance procedures and the worker's awareness that associated equipment must comply with the performance criteria in 10 CFR 34.20.

If the associated equipment appears to be modified or defective, the inspector should verify whether or not the licensee had developed and implemented a testing program to demonstrate that modified components meet the performance criteria in 10 CFR 34.20. The inspector should alert the inspection supervisor who may extend the inspection and request an SS&D reviewer to evaluate the licensee's modification of the equipment. The expectation is that the design safety features of the industrial radiography system were not compromised by a

replacement component of associated equipment that was modified by the licensee. Before using the modified system, the licensee is required to demonstrate that the replacement component meets the performance criteria in 10 CFR 34.20.

NUREG-1556, Volume 2, "Consolidated Guidance about Materials Licensees–Program-Specific Guidance about Industrial Radiography Licenses" (Final Report, August 1998) is being amended to remove statements that indicate associated equipment must be specifically approved or registered by NRC or an Agreement State. Instead, the guidance will state that vendors or distributors of industrial radiography equipment may voluntarily include the items of associated equipment that were used in the system with their SS&Ds that are registered under 10 CFR 32.210. To include associated equipment in the certificate of registration, the vendor's application must include information that demonstrates the associated equipment meets the minimum criteria in 10 CFR 34.20. Also, copies of this RIS will be inserted into Appendix F to replace Information Notice 96-20.

Inspection and Maintenance Procedures

NRC completed a generic assessment and special team inspection which was published in NUREG-1631, "Source Disconnects Resulting from Radiography Drive Cable Failures" (June 1998). The inspection team observed that, in general, radiography exposure devices appeared to be in good working order, showing no evidence of damage, abuse, or lack of maintenance. By contrast, the associated equipment (i.e., control mechanisms, including drive cables) often appeared to be damaged, in disrepair, and lacking maintenance.

NUREG-1631 emphasized the importance of a licensee's understanding and commitment to the operating and use conditions specified by a vendor (manufacturer or distributor) of an industrial radiography system which, if exceeded, could compromise the safety and reliability of the system. This is particularly true of items of associated equipment, including drive cables. A licensee should be vigilant to inspect and maintain associated equipment in order to avoid component failures that could result in unnecessary radiation exposures to workers and members of the public.

A licensee's equipment inspection and maintenance program should prevent particular equipment problems that may develop from excessive uses where harsh or abusive conditions exist that may cause a component to fail. 10 CFR 34.31, "Inspection and maintenance of radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments," requires a licensee to perform visual and operability checks on associated equipment before use on each day 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. In addition, the licensee is required 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. Replacement components shall meet design specifications. If problems are found, the equipment must be removed from service until repaired. Records are required for equipment problems and any maintenance performed.

AVAILABILITY OF REFERENCE DOCUMENTS

Below are the titles of the reference documents along with the URLs and the ADAMS accession numbers (e.g., MLxxxxxxxxx)., if available. The URLs link directly to the documents that are posted on the NRC's public web site. For documents without an URL, 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. If no URL or ADAMS accession number is indicated for the document then send a written request for a single, paper copy of the document to the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or contact the PDR noted above.

1. Federal Register notice (68 FR 41757, July 15, 2003), Denial of a petition for rulemaking [Docket No. PRM-34-5, Amersham Corporation] ML050620568

2. 10 CFR Part 32, Specific domestic licenses to manufacture or transfer certain items containing byproduct material http://www.nrc.gov/reading-rm/doc-collections/cfr/part032/

3. 10 CFR Part 34, Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations http://www.nrc.gov/reading-rm/doc-collections/cfr/part034/

4. American National Standards Institute (ANSI) N432–1980, Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography, (ANSI N432) ML050840139

5. NRC Enforcement Policy http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf

6. NUREG-1556, Volume 3, Revision 1, Consolidated Guidance About Materials Licenses–Applications for Sealed Source and Device Evaluation and Registration, (Final Report, April 2004) ML041340618 http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v3/r1/

7. Inspection Procedure 87121, Industrial Radiography Programs, http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/ip87121.pdf

8. NUREG-1556, Volume 2, Consolidated Guidance about Materials Licensees–Program-Specific Guidance about Industrial Radiography Licenses (Final Report, August 1998) http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v2/

9. NUREG-1631, Source Disconnects Resulting from Radiography Drive Cable Failures (June 1998)