

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

April 4, 1996

NRC INFORMATION NOTICE 96-20: DEMONSTRATION OF ASSOCIATED EQUIPMENT
COMPLIANCE WITH 10 CFR 34.20

Addressees

All industrial radiography licensees and radiography equipment manufacturers.

Purpose

The U.S. Nuclear Regulatory Commission is issuing this information notice to inform radiography licensees of acceptable methods to demonstrate that their associated equipment used in radiographic operations meets the regulations in 10 CFR 34.20. It is expected that recipients will review the information for applicability to their facilities and consider appropriate actions. However, this information notice does not contain any new requirements; therefore, no specific action nor written response is required.

Description of Circumstances

Section 34.20 of 10 CFR Part 34 specifies performance requirements for radiography equipment. Paragraph (d) of 10 CFR 34.20 provided that all newly manufactured radiographic exposure devices and associated equipment (manufactured after January 10, 1992) acquired by NRC licensees must meet Section 34.20 requirements. Paragraph (e) of 10 CFR 34.20 provides that all radiographic exposure devices and associated equipment in use by NRC licensees after January 10, 1996, must comply with the requirements specified in 10 CFR 34.20. NRC amended the regulations in 10 CFR 34.20 to permit licensees to use an alternate value of torque for performance testing criteria and to allow licensees to use engineering analysis to demonstrate that a modest change in an already approved design is acceptable without the need to perform prototype testing. The changes were published in the Federal Register as a final rule on May 31, 1995.

NRC Information Notice (IN) 95-58: "10 CFR 34.20; Final Effective Date," issued on December 18, 1995, to all radiography licensees, reminded licensees of the final effective date implementing the regulations in 10 CFR 34.20. IN 95-58 also reminded licensees that associated equipment used with radiography cameras (i.e., source assemblies, drive cables, guide tubes, control tubes, source stops, etc.) were subject to 10 CFR 34.20 requirements. IN 95-58 went on to explain that, previously, certain associated equipment had not been independently registered and/or evaluated by the NRC or the Agreement States (AS). This includes drive cables, guide tubes, and source stops. Most new

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camera models and their basic associated equipment were registered as part of the gamma radiography system as described in the American National Standard N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography." Therefore, information concerning certain associated equipment to be used with the devices was included as part of the overall system evaluation and registration process. Some manufacturers have also been labeling their equipment with an identifier, such as the manufacturer's logo, to indicate that the equipment meets the requirements of 10 CFR 34.20. IN 95-58 went on to remind licensees that 10 CFR 34.20 makes the licensee responsible for ensuring that equipment meets regulatory requirements.

NRC and AS review and evaluate radiography-associated equipment (guide tubes, exposure heads, and collimators) as well as sealed sources, radiographic exposure devices (cameras) and source changers for compliance with 10 CFR Part 34. On completion of this evaluation, acceptable components are identified on a registration certificate. Information is also included in a National Registry System maintained by NRC. Regulatory authorities use this information in their licensing and inspection activities.

Discussion

The regulation on performance requirements for radiography equipment -- Section 34.20 -- require that the radiographic exposure device and all associated equipment must meet the requirements of ANSI N432-1980, and other specific requirements listed in 10 CFR 34.20. Associated equipment includes source assemblies, drive cables, guide tubes, control tubes, cranks, "J" tubes, collimators, exposure heads, and source stops.

In particular for guide tubes, 10 CFR 34.20(c)(5) states, "The guide tube must have passed the crushing tests for the control tube as specified in ANSI N432 and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use." In addition, 10 CFR 34.20(c)(8) requires that the connection between the guide tube and exposure head be able to withstand the tensile test for control units specified in ANSI N432. Since Section 8.9 of ANSI N432-1980 specifies that radiography systems must withstand the endurance test described in that section, licensees must demonstrate that guide tubes and exposure heads will withstand the endurance test.

Recently some questions were raised concerning what constitutes an exposure head vs. a guide tube. Exposure heads may be a separate or integral part of a guide tube. NRC's analysis of associated equipment (i.e., collimators, guide tubes, exposure heads) has shown that there is little risk of obstruction of source travel for equipment that guides a source assembly a distance less than

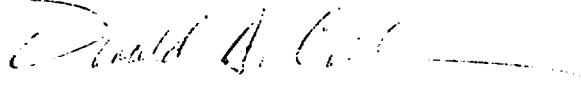
10 times the length of the source capsule. NRC's analysis included a review of equipment designs and incidents involving source travel obstructions. Based on these findings, NRC's policy is that associated equipment that guides a source assembly a distance greater than 10 times the length of the source capsule (i.e., exposure heads, "J" tubes, jet engine probes, source stops) is considered a guide tube and must meet the testing requirements for guide tubes. In addition, NRC's policy is that only associated equipment that comes in contact with the source (e.g., collimators that slip over the end stop) must meet the applicable testing requirements.

The NRC has identified several ways licensees can demonstrate that their radiography equipment meets 10 CFR 34.20 requirements. First, the most direct method would be that the equipment has been labeled by the manufacturer pursuant to a registration certificate. (If the label has worn off, you should contact the manufacturer or have support information as described below.) Alternatively, licensees can make this demonstration if they can provide a document trail to registered associated equipment. The equipment will be considered to meet the requirements, if the licensee has in its possession one of the following for each piece of equipment:

- (a) A purchase order(s) listing the radiography equipment that can be tied-back to a registration certificate; or,
- (b) Documentation from the manufacturer verifying that the equipment the licensee is using was approved and registered with the NRC or AS. The documentation must clearly identify which equipment meets the requirements; or,
- (c) A signed NRC or AS recognized checklist(s) certifying that the licensee has evaluated its equipment, and that it meets the specifications of the checklist. In order for the checklist to be recognized, it must have been provided by the manufacturer of the equipment and approved by the NRC or AS. As of this date, only one checklist has been approved. See Attachment 1 for the recognized checklist.

If a licensee possesses and intends to use radiography equipment that is not labeled by the manufacturer, or that the licensee cannot demonstrate that it meets 10 CFR 34.20 requirements, then the licensee must submit an application for a custom evaluation. Attachment 2 includes information on how to file an application for custom evaluation. Equipment cannot be used in radiographic operations until it has been approved for use by NRC or an AS.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.


Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material
Safety and Safeguards

Attachments:

1. Recognized Checklist for Associated Equipment
2. Custom Evaluation of Associated Equipment
3. List of Recently Issued NMSS Information Notices
4. List of Recently Issued NRC Information Notices

Contact: Thomas W. Rich, NMSS
(301) 415-7893

Attachment filed in Jacket

Checklist for Amersham's Model 591 Controls

To assure the associated equipment you are using are approved Amersham manufactured accessories, please perform a side by side comparison against a known (i.e., flying A is legible or Pos are available) Amersham manufactured piece. Perform a detailed mechanical and visual inspection of your equipment against the following checklist. If you have any questions, please call Amersham for assistance.

Amersham Controls:

1. ___ All controls have a yellow polyvinyl housing with a 9/16 inch outer diameter.
2. ___ The fittings are 3 inches long (including the hex nut).
3. ___ The hex nut is 11/16 inch.
4. ___ Check the fittings for swage marks, the fittings will have 3 single swage marks \approx 1/8 inch wide and \approx 1/2 inch apart or 4 single swage marks \approx 1/8 inch wide and \approx 1/2 inch apart.
5. ___ The first swage mark is typically 3/8 inch from the end.
6. ___ The thread pattern for the control connector is 5/8"-18.
7. ___ The 661 connector assembly will have an indentation \approx 1/2 inch wide band behind the jaws, for newer units this will be covered with a red stripe, but this stripe may have worn off on the older models.

To the best of my knowledge the piece of equipment identified below (the equipment must be uniquely identifiable, either by labeling, marking, or tagging, or other means to signify which piece of equipment is certified as meeting the conditions of this checklist) has been manufactured after 1964, meets the conditions of this checklist, and is the same design as a similar piece of equipment that has been registered and approved by the NRC.

Specify Equipment (i.e., Guide Tube)
Include Identifier/Labeling

Signature

Printed or Typed Name

Amersham Model 402, 489, and 676 Guide Tubes

To assure the associated equipment you are using are approved Amersham manufactured accessories, please perform a side by side comparison against a known (i.e., flying A is legible or POs are available) Amersham manufactured piece. Perform a detailed mechanical and visual inspection of your equipment against the following checklist. If you have any questions, please call Amersham for assistance.

Amersham Guide Tubes:

1. ___ Housing should be yellow polyvinyl with either a 5/8 inch or 3/4 inch outer diameter.
2. ___ The fittings are yellow iridited steel, the threaded fittings consist of 1 inch 18 thread.
3. ___ The fittings for both the threaded fitting and the source stop fitting will have 2 single swage marks approx 1/4 inch apart.
4. ___ The Amersham standard source stops are made from aluminum and are 2 1/2 inches long.

To the best of my knowledge the piece of equipment identified below (the equipment must be uniquely identifiable, either by labeling, marking, or tagging, or other means to signify which piece of equipment is certified as meeting the conditions of this checklist) has been manufactured after 1964, meets the conditions of this checklist, and is the same design as a similar piece of equipment that has been registered and approved by the NRC.

Specify Equipment (i.e., Guide Tube)
Include Identifier/Labeling

Signature

Printed or Typed Name

CUSTOM EVALUATION OF ASSOCIATED EQUIPMENT

The information provided below applies to custom registration of associated equipment.

Product Registration

Either the manufacturer, distributor, or user of the radiographic equipment can submit the information outlined in 10 CFR 32.210 for evaluation.

If the applicant is located within the jurisdiction of the U.S. Nuclear Regulatory Commission, the application should be sent to the following address:

U.S. Nuclear Regulatory Commission
Sealed Source Safety Section
Mail Stop T-8-F-5
Washington, DC 20555

Otherwise, the applicant should submit the information to the appropriate Agreement State.

Application Contents

General:

Licenses are required to use only radiography equipment, including exposure heads and source guide tubes, that meets the requirements specified in 10 CFR 34.20. The regulations require that the exposure device and all associated equipment must meet the requirements in American National Standard N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," and other specific requirements listed in 10 CFR 34.20. The standard defines the requirements for the design and method of qualifying (testing) prototypes of gamma radiography systems.

Refer to Regulatory Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material" for information on what types of information needs to be included in your application.

Specific:

Applications for registration for the equipment must, at a minimum, include the following documentation:

1. A demonstration, either by testing or by engineering analysis, that prototypes of the associated equipment meets the appropriate tests listed below;
2. A list of all radiographic exposure equipment with which the equipment will be used, and an explanation of how the equipment is compatible with each piece of equipment;
3. Details of how the associated equipment will be identified, such as by labeling, marking, or tagging, as meeting the requirements of Section 34.20;
4. Complete specifications, including materials, details of construction, and complete dimensions of each component of the equipment; and
5. Likely environments (i.e., temperature, pressure, vibration, humidity, impact) and conditions of use of the equipment.

Prototype Tests

Each associated equipment design (e.g., source guide tube, collimator, exposure head) must either pass the appropriate tests listed below, or by engineering analysis demonstrate that the designs would likely meet the test requirements.

NRC's policy is that associated equipment that guides a source assembly a distance greater than 10 times the length of the source capsule (i.e., exposure heads, "J" tubes, jet engine probes, source stops) is considered a guide tube and must meet the testing requirements for guide tubes.

Source Guide Tube Tests

Source guide tubes are required to meet the following:

- a. The crushing test specified in Section 8.6 of ANSI N432-1980;
- b. a kinking resistance test that closely approximates the kinking forces likely to be encountered during use;
- c. the endurance test specified in Section 8.9 of ANSI N432-1980; and
- d. the tensile tests specified in Section 8.7 of ANSI 432-1980 for control units.

Exposure Head and Collimator Tests

Exposure heads and collimators that are not considered guide tubes, need only meet the tests listed in item c, and d above.

Engineering Analysis

Engineering analysis will be considered in lieu of actual testing if the analysis is based on a similar design that has been tested in accordance with the standard and has been approved by the NRC or Agreement State. The engineering analysis, at a minimum, must compare the tested design against the associated equipment you want evaluated and address the effects of the materials of construction (i.e., wear resistance, strength, corrosion properties), the wall thickness, the length (i.e., resistance), any bends, bend angles and the minimum bend radii over which the bends will be produced (curvature), and any other properties that would have an effect on the outcome of the endurance test.

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LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-18	Compliance With 10 CFR Part 20 for Airborne Thorium	03/25/96	All material licensees authorized to possess and use thorium in unsealed form
96-04	Incident Reporting Requirements for Radiography Licensees	01/10/96	All Radiography Licensees and Manufacturers of Radiography Equipment
95-58	10 CFR 34.20; Final Effective Date	12/18/95	Industrial Radiography Licensees.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/6/95	All Uranium Recovery Licensees.
95-51	Recent Incidents Involving Potential Loss of Control of Licensed Material	10/27/95	All material and fuel cycle licensees.
95-50	Safety Defect in Gammamed 12i Bronchial Catheter Clamping Adapters	10/30/95	All High Dose Rate Afterloader (HDR) Licensees.
95-44	Ensuring Compatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Connectors	09/26/95	All Radiography Licensees.
95-39	Brachytherapy Incidents Involving Treatment Planning Errors	09/19/95	All U.S. Nuclear Regulatory Commission Medical Licensees.
95-29	Oversight of Design and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel Systems storage installation designers and fabricators.

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-19	Failure of Tone Alert Radios to Activate When Receiving a Shortened Activation Signal	04/02/96	All holders of OLs or CPs for nuclear power reactors
96-18	Compliance with 10 CFR Part 20 for Airborne Thorium	03/25/96	All material licensees authorized to possess and use thorium in unsealed form
95-03 Supp. 1	Loss of Reactor Coolant Inventory and Potential Loss of Emergency Mitigation Functions While in a Shutdown Condition	03/25/96	All holders of OLs or CPs for PWR power plants
96-17	Reactor Operation Inconsistent with the Updated Final Safety Analysis Report	03/18/96	All holders of OLs or CPs for nuclear power reactors
96-16	BWR Operation with Indicated Flow Less Than Natural Circulation	03/14/96	All holders of OLs or CPs for boiling-water reactors
96-15	Unexpected Plant Performance During Performance of New Surveillance Tests	03/08/96	All holders of OLs or CPs for nuclear power reactors
96-14	Degradation of Radwaste Facility Equipment at Millstone Nuclear Power Station, Unit 1	03/01/96	All holders of OLs or CPs for nuclear power reactors
96-13	Potential Containment Leak Paths Through Hydrogen Analyzers	02/26/96	All holders of OLs or CPs for nuclear power reactors
96-12	Control Rod Insertion Problems	02/15/96	All holders of OLs or CPs for nuclear power reactors

OL = Operating License
 CP = Construction Permit