

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

December 18, 1995

NRC INFORMATION NOTICE 95-58: 10 CFR 34.20; FINAL EFFECTIVE DATE

Addressees:

Industrial Radiography Licensees

Purpose:

The U.S. Nuclear Regulatory Commission is issuing this information notice (IN) to remind addressees of the effective date implementing a final provision of 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. This notice also advises recipients of the Commission's plans for enforcement action to address failures to meet 10 CFR 34.20. However, this IN does not contain any new requirements; therefore, no specific action or written response is required.

Background:

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 Section 34.20 of 10 CFR Part 34. Section 34.20, and other changes to 10 CFR Part 34, were published in the Federal Register (55 FR 843) as a final rule on January 10, 1990. As stated in the Federal Register notice, the effective date of the final rule was January 10, 1991. 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 10 CFR 34.20 requirements. The statement of considerations for the final rule provided notice that failure to implement the requirements for equipment by the required date may be considered a Severity Level III Violation. Such violations are considered for civil penalty assessments.

After publication of the final rule, NRC transmitted copies of the notice to each of its radiography licensees at that time. Copies of the notice were also provided to each of the Agreement States so that they might share the information with their radiography licensees. Further information identifying and explaining the effective dates of the various provisions of the rule was also provided in the March-June 1990 (NUREG/BR-0117 Nos. 90-1 and -2) issues of the NMSS Licensee Newsletter.

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I&E Notice 95-058

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RETURN TO REGULATORY CENTRAL FILES

Discussion:

The NRC reminds its industrial radiography licensees that after January 10, 1996, only radiographic exposure devices and associated equipment which complies with the requirements specified in 10 CFR 34.20 and is authorized by the license, shall be used in industrial radiography operations conducted within NRC's jurisdiction. NRC also reminds Agreement State licensees working in areas of NRC jurisdiction under reciprocity (10 CFR 150.20) that they are also subject to these requirements. The regulations in 10 CFR 34.20 apply to all radiography equipment. This includes portable, mobile, and fixed radiography cameras (both pipeliner and "crank-out" type devices), source changers, and other associated equipment used with radiography cameras, i.e., source assemblies, drive cables, guide tubes, control tubes, source stops, etc. Some provisions of 10 CFR 34.20 only apply to certain types of equipment. For example, 10 CFR 34.20(c) only applies to "crank-out" cameras, while 10 CFR 34.20(a) and (b) apply to all radiography cameras and all associated equipment. As another example, the criteria specified in 10 CFR 34.20(c)(9) only applies to the source changer used in conjunction with a "crank-out" device.

The requirements in 10 CFR 34.20 require licensees to ensure that all equipment they will use in radiographic operations after January 10, 1996, complies with the applicable requirements. Since publication of NRC's final rule, the radiography equipment manufacturers have worked to develop radiography devices and associated equipment that complies with 10 CFR 34.20 criteria. In some instances, existing equipment already complies with the regulatory requirements. Attachment 1 lists the radiography cameras, radiography systems, and sealed sources that have been recognized by NRC as meeting 10 CFR 34.20 requirements.

Traditionally, certain associated equipment has not been independently registered and/or evaluated by the NRC or the Agreement States. This includes drive cables, guide tubes, or source stops. With the new camera models introduced, the manufacturers and NRC have taken the system approach as denoted in the American National Standard N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," now required by regulations. Therefore, information concerning the drive cables to be used with the devices was included as part of the overall system evaluation. However, older "associated equipment" items may not have been evaluated as part of a device registration process. Licensees are reminded that 10 CFR 34.20 makes the licensee responsible for ensuring that the equipment meets regulatory requirements. The licensee should obtain information from the equipment manufacturer which shows the equipment complies with 10 CFR 34.20 criteria, including any required testing. Equipment that has not been registered will, at minimum, require prototype testing to meet the requirements of 10 CFR 34.20. If a similar piece of equipment has already met the test requirements, then an engineering analysis may be used in lieu of actual testing. The engineering analysis can be performed by the user or the manufacturer and submitted to the appropriate regulatory authority for evaluation and approval.

Your present license may include equipment whose use must be discontinued after January 10, 1996. In this instance, the NRC regulations effective January 10, 1996, take precedent over authorizations previously provided in a license. For example, if your license contains an Amersham Model 900, you are not authorized to continue using this device after January 10, 1996. Please also note that you may need to amend your license to include additional equipment that complies with 10 CFR 34.20.

Exemptions will not normally be considered for portable radiographic devices that do not comply with 10 CFR 34.20. If uninterrupted use of a device which does not comply with 10 CFR 34.20 is intended, then an exemption request should be submitted prior to January 1, 1996, to allow the staff adequate time to process the request. Exemptions to 10 CFR 34.20 may be considered only for limited special or unique cases, where the licensee can demonstrate that the engineered safety features, use limitations, and procedures would compensate for not meeting the requirements and afford similar or increased radiation safety protection. An example of a limited special or unique case would include a nonportable device used in a fixed radiographic facility.

Performance of radiography after January 10, 1996, with equipment which does not comply with the requirements of 10 CFR 34.20 is a violation of Commission requirements. In accordance with example C.8 of Supplement VI of the Commission's Enforcement Policy, such violations are considered violations of significant regulatory concern and may be categorized at Severity Level III and subject to civil penalties. In light of the notice that has been given licensees to meet this regulation, the time that has been provided licensees to achieve compliance, and the importance of meeting the requirements of 10 CFR 34.20, the NRC intends to levy a civil penalty without considering the normal civil penalty assessment process pursuant to Section VII.A.1 of the Enforcement Policy. Accordingly, a civil penalty of \$5,000, the base Severity Level III civil penalty, may be assessed for each camera a licensee uses after January 10, 1996, that does not meet the requirements of 10 CFR 34.20. If during an inspection, the NRC identifies that a licensee is not meeting the regulation, the licensee will need to suspend any operation with nonconforming cameras. Failure to do so may be considered deliberate violations and may subject the licensee to significant civil action, including license revocation, and to criminal sanctions. Individuals responsible for such violations may be subject to sanctions for violating 10 CFR 30.10, rule on "Deliberate Misconduct."

However, the Commission intends to exercise its enforcement discretion for licensees who make a good faith effort to comply with 10 CFR 34.20 before the effective date of the rule. Therefore, a licensee who performs radiography after January 10, 1996, with equipment that does not meet 10 CFR 34.20 will not be subject to civil penalties or suspension of operations for such violations if the licensee has evidence that on or before January 10, 1996, it in good faith ordered equipment for prompt replacement that meets the requirements of 10 CFR 34.20. It should be noted that Agreement State licensees conducting radiography under reciprocity will be subject to these regulatory requirements and enforcement policy.

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts 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

Contacts: J. Bruce Carrico, NMSS (For general information)
(301) 415-7826

Thomas W. Rich, NMSS (For device information)
(301) 415-7893

Attachments: 1. List of Approved Equipment
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

Attachments filed in Jacket

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List of Models That Meet 10 CFR Part 34 Requirements

 CAMERA(S)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
660 A	AMERSHAM	ACTIVE	Co-60 110mCi, Cs-137 10.8Ci, Yb-169 20Ci, Tm-170 200Ci, Ir-192 120Ci
660 AE	AMERSHAM	ACTIVE	Co-60 110mCi, Cs-137 10.8Ci, Yb-169 20Ci, Tm-170 200Ci, Ir-169 120Ci
660 B	AMERSHAM	ACTIVE	Co-60 110mCi, Cs-137 10.8Ci, Yb-169 20Ci, Tm-170 200Ci, Ir-192 140Ci
660 BE	AMERSHAM	ACTIVE	Co-60 110mCi, Cs-137 10.8Ci, Yb-169 20Ci, Tm-170 200CI, Ir-192 140Ci
660 SYSTEM	AMERSHAM	ACTIVE	Co-60 110mCi, Cs-137 10.8Ci, Yb-169 20Ci, Tm-170 200Ci, Ir-192 140Ci
676 A	AMERSHAM	ACTIVE	Co-60 330Ci, DU 168 kg
676 AE	AMERSHAM	ACTIVE	Co-60 330Ci, DU 168 kg
676 B	AMERSHAM	ACTIVE	Co-60 330Ci, DU 168 kg
676 BE	AMERSHAM	ACTIVE	Co-60 330Ci, DU 168 kg
680 A	AMERSHAM	ACTIVE	Co-60 110Ci, DU 129 kg
680 AE	AMERSHAM	ACTIVE	Co-60 110Ci, DU 129 kg

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List of Models That Meet 10 CFR Part 34 Requirements

CAMERA(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
680 B	AMERSHAM	ACTIVE	Co-60 110Ci, DU 129 kg
680 BE	AMERSHAM	ACTIVE	Co-60 110Ci, DU 129 kg
684 A	AMERSHAM	ACTIVE	Co-60 11Ci, Ir-192 240Ci, DU 68 kg
684 AE	AMERSHAM	ACTIVE	Co-60 11Ci, Ir-192 240Ci, DU 68 kg
684 B	AMERSHAM	ACTIVE	Co-60 11Ci, Ir-192 240Ci, DU 68 kg
684 BE	AMERSHAM	ACTIVE	Co-60 11Ci, Ir-192 240Ci, DU 68 kg
741 A	AMERSHAM	ACTIVE	Co-60 33Ci, Ir-192 240Ci, DU 90 kg
741 AE	AMERSHAM	ACTIVE	Co-60 33Ci, Ir-192 240Ci, DU 90 kg
741 B	AMERSHAM	ACTIVE	Co-60 33Ci, Ir-192 240Ci, DU 90 kg
741 BE	AMERSHAM	ACTIVE	Co-60 33Ci, Ir-192 240Ci, DU 90 kg
865	AMERSHAM	ACTIVE	Ir-192 240Ci, DU 18 kg
IR-100	INDUSTRIAL NUCLEAR	ACTIVE	Ir-192 120Ci, DU 14.5 kg
SPEC 150	SPEC	ACTIVE	Ir-192 150Ci, DU 17 kg
TITAN	NORDION	ACTIVE	Ir-192 140Ci

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List of Models That Meet 10 CFR Part 34 Requirements

 SOURCE(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
32	INDUSTRIAL NUCLEAR	ACTIVE	Ir-192 120Ci
33	INDUSTRIAL NUCLEAR	ACTIVE	Ir-192 120Ci
702	RTS	ACTIVE	Ir-192 120Ci
848	AMERSHAM	INACTIVE	Cs-137 30Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
866	AMERSHAM	ACTIVE	Cs-137 30 Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
87702	AMERSHAM	INACTIVE	Ir-192 120Ci
87703	AMERSHAM	ACTIVE	Ir-192 120Ci
87704	AMERSHAM	INACTIVE	Ir-192 120Ci
88	INDUSTRIAL NUCLEAR	ACTIVE	IR-192 120CI
89911	AMERSHAM	ACTIVE	IR-192 240CI
89912	AMERSHAM	ACTIVE	IR-192 240CI
89913	AMERSHAM	ACTIVE	IR-192 240CI
89914	AMERSHAM	ACTIVE	IR-192 240CI
89916	AMERSHAM	ACTIVE	IR-192 240CI
89921	AMERSHAM	ACTIVE	IR-192 240CI
89922	AMERSHAM	ACTIVE	IR-192 240CI
89923	AMERSHAM	ACTIVE	IR-192 240CI
89924	AMERSHAM	ACTIVE	IR-192 240CI
90003	AMERSHAM	ACTIVE	Ir-192 240Ci

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List of Models That Meet 10 CFR Part 34 Requirements

 SOURCE(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
91810	AMERSHAM	ACTIVE	Yb-169 20Ci
91811	AMERSHAM	ACTIVE	Co-60 20Ci
91812	AMERSHAM	ACTIVE	Tm-170 20Ci
91813	AMERSHAM	ACTIVE	Ir-192 20Ci
943	AMERSHAM	ACTIVE	Co-60 110Ci
A424-1	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50 Ci, Ir-192 240Ci
A424-10	AMERSHAM	ACTIVE	Co-60 5Ci
A424-11	AMERSHAM	ACTIVE	Co-60 50Ci
A424-12	AMERSHAM	ACTIVE	Co-60 100Ci
A424-13	AMERSHAM	ACTIVE	Co-60 330Ci
A424-14	AMERSHAM	ACTIVE	Co-60 110Ci
A424-15	AMERSHAM	ACTIVE	Co-60 1iCi
A424-16	AMERSHAM	ACTIVE	Co-60 50Ci
A424-17	AMERSHAM	ACTIVE	Co-60 50Ci
A424-18	AMERSHAM	ACTIVE	Co-60 33Ci
A424-19	AMERSHAM	ACTIVE	Co-60 120mCi
A424-2	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-20	AMERSHAM	ACTIVE	Cs-137 30Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci

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List of Models That Meet 10 CFR Part 34 Requirements

 SOURCE(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
A424-22	AMERSHAM	ACTIVE	Co-60 220Ci, Cs-137 10.8Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-3	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-4	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-5	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-6	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-7	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-8	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A424-9	AMERSHAM	ACTIVE	Co-60 220Ci, Cs-137 30Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A453-1	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci
A453-2	AMERSHAM	ACTIVE	Co-60 220Ci, Yb-169 200Ci, Tm-170 50Ci, Ir-192 240Ci

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List of Models That Meet 10 CFR Part 34 Requirements

 SOURCE(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
A58101-8	AMERSHAM	ACTIVE	Ir-192 240Ci
B-16F	SPEC	ACTIVE	Ir-192 100Ci
B-16T	SPEC	ACTIVE	Ir-192 100Ci
C-990	NORDION	ACTIVE	Ir-192 140Ci
G-11F	SPEC	UNKNOWN	
G-13F	SPEC	UNKNOWN	
G-15F	SPEC	UNKNOWN	
G-17F	SPEC	UNKNOWN	
G-19F	SPEC	ACTIVE	Co-60 110Ci
G-1F	SPEC	ACTIVE	Ir-192 240Ci
G-1T	SPEC	UNKNOWN	
G-21F	SPEC	ACTIVE	Co-60 110Ci
G-23	SPEC	ACTIVE	Ir-192 240Ci
G-36	SPEC	ACTIVE	Ir-192 240Ci
G-37F	SPEC	ACTIVE	Co-60 110Ci
G-38	SPEC	ACTIVE	Ir-192 240Ci
G-3F	SPEC	ACTIVE	Ir-192 240Ci
G-40F	SPEC	ACTIVE	Ir-192 240Ci
G-40T	SPEC	ACTIVE	Ir-192 240Ci
G-41F	SPEC	ACTIVE	Ir-192 240Ci
G-41T	SPEC	ACTIVE	Ir-192 240Ci
G-42	SPEC	UNKNOWN	
G-50F	SPEC	UNKNOWN	
G-50T	SPEC	UNKNOWN	
G-60	SPEC	ACTIVE	Ir-192 240Ci

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List of Models That Meet 10 CFR Part 34 Requirements

 SOURCE(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
G-9F	SPEC	UNKNOWN	
N-23	SPEC	INACTIVE	Ir-192 100Ci
T-1	SPEC	ACTIVE	Ir-192 140Ci
T-1F	SPEC	ACTIVE	Ir-192 140Ci
T-2F	SPEC	INACTIVE	Ir-192 140Ci
T-5	SPEC	ACTIVE	Ir-192 140Ci
T-5F	SPEC	ACTIVE	Ir-192 140Ci
T-6	SPEC	ACTIVE	Ir-192 140Ci
T-7F	SPEC	INACTIVE	Ir-192 140Ci

 CHANGER(S)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
500-SU	AMERSHAM	INACTIVE	IR-192 120CI, DU 18 KG
650L	AMERSHAM	ACTIVE	IR192 240CI, CO60 120mCI, CS137 10.8CI, YB169 40CI, TM170 400CI, DU 42 LBS
770	AMERSHAM	ACTIVE	CO-60 550CI, DU 161 KG
771	AMERSHAM	ACTIVE	CO-60 110CI, DU 97 KG
820	AMERSHAM	ACTIVE	Ir-192 1000Ci, DU 100 kg

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List of Models That Meet 10 CFR Part 34 Requirements

CHANGER(S) (continued)

<u>Model</u>	<u>Manufacturer</u>	<u>Status</u>	<u>Description</u>
850	AMERSHAM	ACTIVE	IR-192 240CI, DU 22 KG
855	AMERSHAM	ACTIVE	IR-192 960CI, DU 57 KG
C-1	SPEC	ACTIVE	IR-192 100CI, DU 17KG

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
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 Combatible Use of Drive Cables Incorporating Industrial Nuclear Company Ball-type Male Conectors	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 and Fabrication Activities for Metal Components Used in Spent Fuel Dry Storage Systems	06/07/95	All holders of OLs or CPs for nuclear power reactors. Independent spent fuel storage installation designers and fabricators.
95-28	Emplacement of Support Pads for Spent Fuel Dry Storage Installations at Reactor Sites	06/05/95	All holders of OLs or CPs for nuclear power reactors
95-25	Valve Failure during Patient Treatment with Gamma Stereotactic Radiosurgery Unit	05/11/95	All U.S. Nuclear Regulatory Commission Medical Licensees.

LIST OF RECENTLY ISSUED
NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
95-57	Risk Impact Study Regarding Maintenance During Low-Power Operation and Shutdown	12/18/95	All holders of OLs or CPs for nuclear power reactors.
95-56	Shielding Deficiency in Spent Fuel Transfer Canal at a Boiling-Water Reactor	12/11/95	All holders of OLs or CPs for nuclear power reactors.
95-55	Handling Uncontained Yellowcake Outside of a Facility Processing Circuit	12/06/95	All Uranium Recovery Licensees.
95-54	Decay Heat Management Practices during Refueling Outages	12/01/95	All holders of OLs or CPs for nuclear power reactors.
95-53	Failures of Main Steam Isolation Valves as a Result of Sticking Solenoid Pilot Valves	12/01/95	All holders of OLs or CPs for nuclear power reactors.
95-47, Rev. 1	Unexpected Opening of a Safety/Relief Valve and Complications Involving Suppression Pool Cooling Strainer Blockage	11/30/95	All holders of OLs or CPs for nuclear power reactors.
94-13, Supp. 2	Control and Oversight of Contractors during Refueling Activities and Clarification of Applicability of Section 50.120 of Title 10 of The Code of Federal Regulations to Contractor Personnel	11/28/95	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
CP = Construction Permit

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Coordinated with:

- S. Treby, OGC, No Legal Objection, 11/22/95 per tel. conversation w/P. Santiago
J. Schleuter/K. Stablein, DECS staff, 11/22/95
Email sent to L. Portner and regions on 11/22/95
A. Gallow, OI 11/21/95 per telephone message to P. Santiago
R. Baer/S. Baggett, SCDB, IMNS 11/22/95. K. Ramsey, IMOB 12/14/95