

NRC ENFORCEMENT MANUAL

NUREG/BR-0195, Rev.1

CHANGE NOTICE NO. 1

Insert:

<u>Page/EGM(T)</u>	<u>Issue Date</u>
1. v	12/21/95
2. App.A: 1	12/21/95
3. App.A: EGM 95-003(T)	12/21/95

Remove:

<u>Page/EGM(T)</u>	<u>Issue Date</u>
v	11/94
App.A: 1	11/94

Remarks:

The following remarks correlate to the numbered page changes noted above. Note that a page or group of pages can include more than one revision.

1. Revised Change Notice Index to reflect the issuance of the first Change Notice, including temporary EGM 95-003(T).
2. Appendix A: Revised Temporary Enforcement Guidance Index to reflect the issuance of EGM 95-003(T).
3. Appendix A: added EGM 95-003(T), "Enforcement of 10 CFR 34. 20, "Performance Requirements for Radiography Equipment."

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CHANGE NOTICE - INDEX -

<u>#</u>	<u>EGM</u>	<u>SUBJECT</u>	<u>DATE</u>
N/A	92-01(T)	Programmatic Maintenance Failures (in effect until July 1996)	01/02/92
N/A	95-001(T)	Severity Levels of Violations at Fuel Facilities	03/31/95
1	95-003(T)	Enforcement of 10 CFR 34.20, "Performance Requirements for Radiography Equipment"	12/21/95

APPENDIX A

Temporary Enforcement Guidance

Appendix A contains temporary Enforcement Guidance Memorandums (EGMs). The NRC Enforcement Manual Change Notice Index, located in the front of the Manual, contains a complete chronological listing of Change Notices, including the issuance of temporary EGMs. Temporary EGMs should be filed chronologically in this Appendix.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 21, 1995

EGM 95-003(T)

MEMORANDUM TO: Thomas T. Martin, Regional Administrator
Region I
Stewart D. Ebnetter, Regional Administrator
Region II
Hubert J. Miller, Regional Administrator
Region III
L. Joe Callan, Regional Administrator
Region IV
Roy Zimmerman, Associate Director for
Projects, NRR
Ashok C. Thadani, Associate Director for
Inspection and Technical Assessment, NRR
Elizabeth Q. Ten Eyck, Director, Division of
Safeguards and Transportation, NMSS
Donald A. Cool, Director, Division of
Industrial and Medical Nuclear Safety, NMSS
John T. Greeves, Director, Division of Waste
Management, NMSS

FROM: James Lieberman, Director
Office of Enforcement

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM - ENFORCEMENT OF 10 CFR
34.20, "PERFORMANCE REQUIREMENTS FOR RADIOGRAPHY EQUIPMENT"
(ENFORCEMENT MANUAL - APPENDIX A)

The purpose of this memorandum is to provide interim guidance for enforcement of 10 CFR 34.20, "Performance Requirements for Radiography Equipment," which requires, in part, that each radiographic exposure device and associated equipment meet the requirements specified in American National Standard N432-1980 by January 10, 1996.

In accordance with Supplement VI.C.8 of the Enforcement Policy, a failure to comply with 10 CFR 34.20 is considered a Severity Level III violation. To remove the economic advantage for noncompliance with this requirement, the Commission has approved the use of enforcement discretion (without consideration of the normal civil penalty consideration process) to assess base civil penalties for Severity Level III violations to licensees that use nonconforming radiography equipment after January 10, 1996. In SECY 95-284, the Commission Paper which was the basis of the Commission's approval of this enforcement discretion, the staff stated, in part, that:

In the staff's view, in light of the previous efforts to notify licensees about this requirement, these violations would be considered willful. In accordance with section VI.B.2. of the Enforcement Policy,

the civil penalty assessment process would consider credit for identification and corrective action. The staff believes that a civil penalty is warranted in these cases because of the notice given to licensees, the time provided to licensees to comply, and the importance of meeting the 10 CFR 34.20 requirements. The staff proposes that the Commission authorize the staff to exercise enforcement discretion pursuant to section VII.A.1 to provide for a base Severity Level III civil penalty without considering the normal assessment process for each nonconforming camera that is in use after January 10, 1996. Use of this discretion will minimize resources necessary to apply the normal assessment process. Accordingly, a civil penalty of \$5000 would normally be assessed for each camera a licensee uses after January 10, 1996, that does not meet the requirements of 10 CFR 34.20. A new camera costs approximately \$6000. This should provide the necessary regulatory incentive toward compliance and a clear economic incentive to comply with the regulation.

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. A Confirmatory Action Letter will normally be issued to confirm the suspension. Thereafter, continued use of nonconforming cameras 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, Deliberate Misconduct.

Considering the potential number of licensees that have yet to comply and are in the process of ordering equipment between now and the January 10, 1996, implementation date, the staff would propose that the Commission authorize it to exercise enforcement discretion where licensees made an attempt to comply with 10 CFR 34.20 before January 10, 1996. The staff proposes to accept a licensee ordering replacement cameras on or before January 10, 1996, as a good-faith attempt to meet the regulation. Under this discretion, licensees who perform radiography after January 10, 1996, with equipment that does not meet 10 CFR 34.20, will not be subject to civil penalties for such violations, if the licensee ordered sufficient numbers of equipment on or before January 10, 1996, to allow the licensee to meet the regulation. The use of this discretion, along with a \$5000 civil penalty described above should give a strong incentive to place orders by January 10, 1996. For consistency, the staff intends, for the first 6 months, to have all enforcement actions for violations of 10 CFR 34.20 reviewed by the Office of Enforcement before issuance.

The staff notes that in accordance with Commission policy, suspected willful violations are referred to the Office of Investigations (OI) for investigation. The staff intends to notify OI of these violations but to assign a "low" investigative priority to them. This is because investigation in most cases will not be needed to take a strong regulatory action. Low priority investigations are not ordinarily conducted. However, higher priorities will be assigned to cases where

licensees continue to use nonconforming cameras after being specifically directed by NRC to suspend use of nonconforming cameras.

The Commission approved this enforcement approach by an SRM dated December 15, 1995. Accordingly, each use of a radiographic camera in the performance of radiography which does not meet the requirements in 10 CFR 34.20 will be subject to a separate \$5,000 civil penalty. In addition, a Confirmatory Action Letter should be issued, as noted above, if the licensee is not found to be in compliance.

However, a Notice of Violation without a civil penalty should be issued if the licensee attempted in good faith to comply with 10 CFR 34.20 on or before January 10, 1996. Specifically, 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 34.20².

In order to implement the above guidance in a consistent manner, all enforcement cases involving violations of 10 CFR 34.20, for a period of 6 months, are to be reviewed by the Office of Enforcement (OE); cases should be discussed during the weekly regional enforcement calls. The cases should subsequently be forwarded to OE for a "quick" review (i.e., 48-hour turnover). OE will coordinate, as appropriate, cases with NMSS.

Attached is Information Notice 95-58 (without attachments), which provided notice to licensees of this enforcement approach.

This temporary EGM is being issued concurrently as Change Notice No. 1 of the NRC Enforcement Manual. (Individuals may review the guidance on the electronic version of the Manual on the agency LAN pending distribution of the Change Notice.)

If you have any questions, feel free to contact me.

Attachment: As stated

cc: J. Milhoan, DEDR
H. Thompson, DEDS
J. Goldberg, OGC
F. Gillespie, NRR

² This sentence reflects the modification made by the December 15, 1995 SRM.

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 (55FR843) 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.

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

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