

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

[Docket No. PRM-34-5]

Amersham Corporation, Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by Amersham Corporation. The petition has been docketed by the Commission and assigned Docket No. PRM-34-5. The petitioner requests that the NRC amend its regulations by removing the reference to "associated equipment" from the radiography equipment regulations. The petitioner believes that this amendment would clarify the licensing reviews of sealed sources and radiographic exposure devices to meet the applicable requirements.

DATES: Submit comments by September 3, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except to those comments received on or before this date.

ADDRESSES: For a copy of this petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Docketing and Services Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 am and 4:15 pm on Federal workdays.

For information on submitting comments electronically, see

"Electronic Access" under the Supplementary Information section of this notice.

FOR FURTHER INFORMATION CONTACT: Don Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: (301) 415-6257, or Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone: (301) 415-7163 or Toll Free: 800-368-5642, or E-mail MTL@NRC.GOV.

SUPPLEMENTARY INFORMATION:

Background

The NRC received a petition for rulemaking dated March 28, 1996, submitted by Amersham Corporation. The petition was docketed as PRM-34-5 on April 8, 1996. The petitioner requests that the NRC amend its regulations governing performance requirements for radiography equipment in 10 CFR Part 34.

Petitioner's Request

Amersham Corporation requests that the NRC amend its regulations to remove reference to "associated equipment" from § 34.20 so that continued inspection and enforcement of the rule would be performed on the basis of source and device reviews only. The petitioner believes that the current good operating history and safety record of the associated equipment, when it is used and maintained properly, supports this action. The petitioner further requests that § 34.28 be amended to reflect appropriate inspection and maintenance requirements for all of the radiography equipment, including associated equipment.

Discussion of the Petition

The petitioner believes that the current regulations for radiography equipment standards are not clearly defined; thereby resulting in confusion and noncompliance on the part of the users. The petitioner believes that interpretation of the regulation by the NRC has led to an undocumented requirement for reviews of the associated equipment used by the radiography industry in addition to the reviews of sealed sources and radiographic exposure devices. The petitioner states that the NRC has expanded its reviews to cover associated

equipment without any formal rulemaking taking place, even though § 32.210 applies to the evaluation of sealed sources and devices and not to other equipment. The petitioner asserts that because of the undocumented definition that "associated equipment" is anything that comes into direct contact with the source, the rule in being interpreted and implemented inconsistently.

The petitioner states that ANSI N432, the standard referenced in Part 34, was originally written as guidance for manufacturers on the design and manufacture of standard radiography equipment. Amersham Corporation, a member of the ANSI committee, recently discussed the original intent of this standard with other committee members who agreed the original intent was to serve as guidance for good manufacturing practices and not as a regulatory approval checklist. When the NRC included the standard in Part 34, the industry did not foresee that regulatory approval would cover associated equipment in detail.

NRC requested that Amersham's associated equipment (standard controls and guide tubes) be approved under the affected device registrations, specifically listed on the device sheet by model number. The petitioner states that it realized later that the inclusion of the associated equipment in the regulations placed unexpected restrictions on manufacturers and users.

The petitioner understands that Agreement States do not require that the associated equipment be listed and approved on the device registration sheet as part of the radiography system for the other manufacturers. The petitioner believes that this raises several issues, in addition to putting it at a significant competitive disadvantage. The petitioner indicates that this inconsistency highlights the confusion in the way the rule is being interpreted and implemented for associated equipment. The petitioner states that it adds confusion on the part of users too, concerning regulatory compliance, when similar items are treated in different ways depending on the manufacturer's licensing body.

The petitioner also claims that there is another undocumented requirement that users or manufacturers cannot perform their own certification of associated equipment. The current

version of § 34.20 only requires that the equipment meet ANSI N432; it does not state that regulatory approvals are needed to comply with this regulation.

The petitioner believes that these interpretations are a broad stretch of the original intent of Part 34. The petitioner states that if these are the NRC's formal interpretations of the provisions, they should be submitted as a proposed rule change because they are significantly more restrictive than the current wording of § 34.20 allows and constitute a substantial change in what was the standard practice for sealed source and device reviews.

The petitioner states that since the effective date of the amendments to § 34.20, it has recognized the negative impact in the following areas:

Increased exposures. The petitioner states that because collimators are not being used currently in many of the applications in which they were used before the regulation became effective, there are increased exposures to personnel. Most collimators have not been approved by the NRC or an Agreement State to meet Part 34 because the industry was not aware that the NRC would require testing, a full safety review, and regulatory approval to gain Part 34 endorsement for these parts. Therefore, no approvals were sought before the regulation's effective date. The petitioner asserts that some users are shut down because they are authorized only to conduct radiography with collimators, and approved collimators are not available. In other cases, to keep exposures as low as reasonable achievable (ALARA) as is also required by NRC regulations, users are continuing to work with unapproved collimators. The petitioner asserts that there have been no significant safety problems with the use of collimators in the past.

Economic considerations. The petitioner states that a manufacturer or user in an NRC state must pay a substantial fee to get approvals for the associated equipment. In addition to the fees, some users are purchasing testing equipment or hiring professional engineers to prove a piece of equipment that has been in use for the last twenty years can now be deemed safe after it has been reviewed by the NRC. The petitioner states that fees, the cost of new equipment, and inconsistent interpretations and subsequent enforcement, puts NRC licensees at a competitive economic disadvantage because Agreement states do not require Part 34 compliance for the associated equipment.

Enforcement. The petitioner asserts significant differences exist in the level

of enforcement implemented by the various Agreement States and different NRC regions. Some users have been required to go to extraordinary measures to prove a piece of equipment meets Part 34 requirements; in other cases the regulatory authority is not concerned about the associated equipment. The petitioner notes that because the inspection guidelines for inspecting against the new rule have not been documented, demonstrating compliance is very difficult.

Inability to perform required work. The petitioner states that some licensees require specialized equipment to perform radiography, such as J-tubes, jet engine probes, and other rigid source stops. Under the current interpretation of § 34.20, all specialized equipment must be approved. No user or manufacturer fully understood that all associated equipment, including the specialized equipment, was covered by the rule; therefore, no approvals were sought. Manufacturers believed only a listing of models or a generic description of the specialized equipment would be needed to get Part 34 endorsement.

Reasons for the Petition

The petitioner states that the associated equipment currently in use has a good operational safety history. To prevent licensees from using unacceptable equipment, the petitioner believes they should be required to certify that any equipment used in conjunction with a source or device be able to withstand the environment and use that is expected, using the ANSI N432 standard as a baseline.

The petitioner believes ANSI N432 should be used as guidance for the associated equipment not as a regulatory approval checklist. Considering all the years of manufacturing experience and that none of the associated equipment is deemed critical to safety, there is no need to perform an additional outside review. The petitioner believes that the manufacturer should be allowed to self-certify that the associated equipment is fit for use, whether the certification is based on testing in accordance with ANSI, relying on a good operational history, or comparing it to a similar component.

The petitioner notes that there are some specific applications and environments in which the ANSI requirements cannot be physically met, but the part is still fit for use. The petitioner believes that it is important that fitness for use be considered regardless of the ANSI standard because it will result in a safer product being used.

The petitioner states that the regulatory review adds considerable costs to the user and the manufacturer, without increased safety to the user or the general public. Regulatory review will not result in the manufacturer changing the design or method of manufacture for the associated equipment that has been used successfully from an operational and safety standpoint for the last 40 years.

The petitioner believes very strongly in the importance of proper inspection and maintenance of all the equipment. The petitioner recognizes that 75 percent of customer complaints or problems were the result of inadequate maintenance, improper use, or damage. The petitioner states that the majority of problems that have occurred in the field could have been prevented by requiring that proper inspection and maintenance be performed and that defective equipment be taken out of use. The petitioner has not seen many problems as a result of basic design or construction of the equipment.

Conclusion

The petitioner believes that ANSI N432 is the appropriate reference for equipment requirements; however, it disagrees with the current NRC interpretation that associated equipment requires a regulatory review. The petitioner requests that the NRC clarify its interpretation. If the definition of a sealed source and device in § 32.210 is being expanded to cover the associated equipment, the petitioner believes it must go through a rulemaking change before it becomes a requirement. Because the current interpretation is having a significant economic impact on the entire industry, causing some programs to shut down until it is resolved, the petitioner requests that the NRC temporarily rescind this requirement until it can be clarified.

Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC Electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on this petition also are available for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC rulemaking subsystem on FedWorld can be accessed directly by dialing the toll-free number 800-303-9672. Communication software

parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using the ANSI or VT-100 terminal emulation, the NRC rulemaking subsystem can then be accessed by selecting the "rules menu" option from the "NRC main menu." Users will find the "FedWorld On-line User's Guides" particularly helpful. Many NRC subsystems and data bases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld also can be accessed by a direct-dial telephone number for the main FedWorld BBS, (703) 321-3339, or by using Telnet via Internet: fedworld.gov. If using (703) 321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mall." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC on-line main menu. The NRC on-line area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu, you may return to FedWorld by selecting the "Return to FedWorld" option from the NRC on-line main menu. However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems, but you will not have access to the main FedWorld system.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the rules menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploading files is not allowed; you will only see a list of files without descriptions (normal gopher look). An index file listing all files within a subdirectory and descriptions of those files, is available. There is a 15-minute time limit for FTP access.

Although FedWorld also can be accessed through the Worldwide Web, like FTP, that mode only provides access for downloading files and does not display the NRC rules menu.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555-0001, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

Single copies of this petition may be obtained by written request or telefax ((#01) 415-5144) from: Rules Review

Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, Mail stop T6-D59, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Certain documents related to this petition, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents may also be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this petition as indicated above.

Dated at Rockville, Maryland, this 12th day of June, 1996.

For the Nuclear Regulatory Commission.
John C. Hoyle,
Secretary of the Commission.
[FR Doc. 96-15395 Filed 6-17-96; 8:45 am]
BILLING CODE 7590-01-P

10 CFR Parts 150 and 170

RIN 3150-AF49

Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to clarify that Agreement State licensees can seek reciprocal recognition of their license from the NRC when they are working within areas of exclusive Federal jurisdiction in Agreement States. The proposed amendments would also clarify NRC regulatory requirements for reciprocity and the appropriate fees and filing procedures applicable to Agreement State licensees operating under reciprocity.

DATES: The comment period expires September 3, 1996. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Attention: Docketing and Service Branch.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm on Federal workdays.

For information on submitting comments electronically, see the

discussion under Electronic Access in the Supplementary Information Section.

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These same documents may also be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this rulemaking as discussed under Electronic Access in the Supplementary Information Section.

FOR FURTHER INFORMATION CONTACT:

Hampton Newsome, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-1623, e-mail HHN@nrc.gov or Mark Haisfield, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6196, e-mail MFH@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

Currently, subject to certain restrictions, any person who holds a specific license from an Agreement State may conduct activities permitted by that license in non-Agreement States and offshore waters using an NRC general license. The general license is granted under the authority contained in 10 CFR 150.20, "Recognition of Agreement State Licenses." To meet the requirements of § 150.20, licensees must submit an NRC Form 241 at least 3 days before engaging in the activities (subject to some exceptions as noted in § 150.20). If an Agreement State licensee does not qualify for a general license under § 150.20, the licensee must apply for and obtain a specific license to work in areas of NRC jurisdiction.

Need for Proposed Regulatory Action

The NRC believes that there are several problems with the current regulations in § 150.20 that necessitate a rulemaking. First, the current regulation does not include provisions to allow Agreement State licensees to qualify for an NRC general license when operating in areas of exclusive Federal jurisdiction within Agreement States. Second, there has been some confusion regarding the NRC regulations applicable to Agreement State licensees operating in areas of NRC jurisdiction pursuant to § 150.20. Third, § 150.20 does not reference the appropriate fee requirements applicable to Agreement State licensees who file an NRC Form 241. Finally, there has been some confusion regarding the filing procedures for an NRC Form 241.