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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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AFFIRMATION/DISCUSSION AND VOTE

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Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Monday, September 11, 1989

The Commission met in open session, pursuant to notice, at 10:00 a.m., Kenneth M. Carr, Chairman, presiding.

COMMISSIONERS PRESENT:

KENNETH M. CARR, Chairman of the Commission
THOMAS M. ROBERTS, Commissioner
KENNETH C. ROGERS, Commissioner
JAMES R. CURTISS, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

P R O C E E D I N G S

10:08 a.m.

CHAIRMAN CARR: Good morning, ladies and gentlemen.

This is an affirmation session. We have two items to come before us this morning.

Before I ask the Secretary to lead us through the items for affirmation, do any of my fellow Commissioners have any opening comments they would like to make?

(No response)

CHAIRMAN CARR: If not, Mr. Secretary, you may proceed.

SECRETARY CHILK: Mr. Chairman, the first item is SECY-89-276, a motion for reconsideration filed by Joseph J. Macktal.

The Commission here is being asked to respond to an August 18, 1989 motion by Joseph J. Macktal requesting that the Commission reconsider its decision in CLI-89-14 wherein it declined to disqualify itself from deciding any future matters involving Mr. Macktal.

All Commissioners have approved an order with modifications by Commissioner Curtiss denying the motion for reconsideration.

Would you please affirm your votes?

(Ayes)

SECRETARY CHILK: The second item is SECY-89-194, amendments to 10 CFR Part 34.

The Commission is being asked to approve amendments to 10 CFR Part 34 which apply to industrial radiography. The amendments are intended to reduce radiation exposure to both radiography personnel and the general public from the use of radiographic equipment.

The Commission is also modifying its Enforcement Policy to add a specific example to put licensees on notice that the failure to implement the requirements for dosimetry and equipment may be considered a violation of significant regulatory concern.

All Commissioners have approved the rule and agree with the modifications proposed by Chairman Carr.

Would you please affirm your votes?

(Ayes)

SECRETARY CHILK: I have nothing else sir.

CHAIRMAN CARR: Is there anything else to come before us today?

If not, we stand adjourned.

(Whereupon the affirmation/discussion and vote was concluded at 10:12 a.m.)

CERTIFICATE OF TRANSCRIBER

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Joe Bookbinder

Reporter's name: Joe Bookbinder

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RULEMAKING ISSUE
(Affirmation)

June 28, 1989

SECY-89-194

For: The Commissioners

From: Victor Stello Jr.
Executive Director for Operations

Subject: AMENDMENTS TO 10 CFR PART 34: SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC EQUIPMENT

Purpose: To obtain Commission approval of a notice of final rulemaking.

Issue: Improvement in safety requirements in industrial radiography operations aimed at reducing exposures to radiography personnel and potential exposures to members of the general public.

Summary: This paper recommends amending 10 CFR Part 34 to specify additional safety performance requirements for industrial radiographic equipment, to add additional reporting requirements, and to require that radiographers wear alarm rate meters.

Discussion: Industrial radiography, a technique of nondestructive testing, uses radioactive sources or x-rays to detect flaws in welds and cracks, breaks, etc., in bridges, buildings, and manufactured articles. Most radiographic devices use gamma rays to produce radiographs, although x-rays and neutrons are also used. Approximately 90% of these devices are designed to project a radioactive source out of its shielded position within the device to the working position.

The procedure for taking radiographs is to place a film about the object to be examined, position one end of a guide tube (the other end is attached to the radiographic device) on the other side of the object from the film, crank or project the radioactive source from its shielded position in the device to the end of the guide tube, leave it there for the required length of time, crank the source back into the device, and recover the film for processing.

Contact:
D. O. Nellis, RES
492-3628

Although the procedure appears straightforward, radiation overexposures of radiographers and the general public occur with a frequency that concerns both the NRC and the Agreement States. Additionally, serious injuries and even some deaths (all outside the United States) have occurred as a result of accidental overexposures involving radiography operations. The potential for serious consequences is present because of the high intensity of the radioactive sources used in industrial radiography.

Large overexposures have occurred mainly among radiography personnel, but the most severe consequences have occurred to members of the public. In one case for example, an individual in California picked up a source and put it in his hip pocket and suffered a severe radiation burn. A similar case occurred in India, and in Argentina, a man put a source in his pocket and had to have both legs amputated. In another case, an individual picked up a source and took it home where it caused 8 deaths; a similar case occurred earlier, resulting in 4 deaths. In all cases, a radiation survey could have prevented these exposures by indicating the source was not in the radiographic exposure device. Improved equipment may also have prevented some of these accidents.

Over the decade ending in 1984, entities licensed by the NRC to perform industrial radiography have accounted for more than one half of the reported radiation overexposures greater than 5 rems whole body or 75 rems to extremities. The Agreement States have had similar experience.

Most of the reported radiography overexposures have involved unsuspected unshielded sources and failure to conduct proper radiation surveys at the end of every radiographic exposure. As discussed below, a variety of problems have resulted in unsuspected, unshielded sources. Insufficient experience, inadequate training, work pressures, and the routine, repetitive nature of the work have contributed to the failure to conduct surveys.

NRC data indicate that equipment problems are the initiating event in approximately 40% of all reported overexposure events. The radiographic exposure devices incorporate components such as locks and source guide tubes that are important to radiation safety. On occasion, a component has failed to perform its intended function and that failure, together with the radiographer's failure to follow proper radiological safety practices, has caused unnecessary exposures to the radiographer and others in the immediate vicinity. The type of situations which have been determined to contribute to radiography overexposures are:

(1) The radioactive source moves out of its shielded position after being cranked back into the device due to failure of the securing device (or some other reason).

(2) The source is improperly connected or not connected to the control cable so that it will not retract once it has been projected out of the device.

(3) The source is cranked out of the end of the guide tube and falls to the ground because of connector failure or improper connection.

(4) The source becomes stuck in the guide tube due to damage to the guide tube or due to fraying of the control cable.

In an attempt to reduce serious radiography overexposures which may be the result of equipment problems, the NRC published an Advance Notice of Proposed Rulemaking (ANPRM) on March 27, 1978, (43 FR 12718) that proposed the development of safety requirements for radiographic devices that are licensed under 10 CFR Part 34. Comments on the ANPRM requested that the NRC delay further action until completion of a consensus performance standard in this area. In 1981, a voluntary consensus standard, NBS Handbook 136, American National Standard N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," was issued.

In 1980 an ad hoc Radiography Steering Committee composed of NRC personnel and representatives from California, Louisiana, and Texas, (states that have large numbers of radiography licensees) was formed to draft recommendations for improving radiography safety. Of four task forces established by the Committee, the one on Radiographic Equipment Safety Design was charged with developing recommendations on performance criteria for radiographic devices. In 1984, the Task Force issued its recommendations on performance requirements. These included most of the performance criteria specified in the consensus standard plus additional criteria not found in the standard. One additional item that was suggested during meetings of the Steering Committee was that radiographers be required to wear alarm ratemeters as an additional safety measure in the event the survey meter is defective or is not used as required.

On March 15, 1988, the NRC published for public comment a proposed rule (53 FR 8460) that would require radiographic exposure devices and associated equipment to meet the requirements specified in American National Standard N432 plus a number of additional criteria that were recommended by the Radiographic Equipment Safety Design Task Force described in the previous paragraph. Sixty-eight comment letters were received with the average commenter addressing comments to approximately 10 of the 26 items involved in the rule. Of the 26 items proposed, comments were equally divided on two, opposed

on nine and in favor on 15. The principal opposition was directed to five items; source position indicator, automatic securing of the source, the five-year replacement requirement, need for alarm ratemeters and the proposed trigger levels for alarm ratemeters. A general analysis and resolution of the comments is given in the Supplementary Information section of the Federal Register Notice (Enclosure A) and additional information is included in the Analysis of Comments document (Enclosure D).

The enclosed final rule, which adopts most of the Steering Committee recommendations, is intended to provide additional safety performance requirements for radiographic equipment and recommends, in addition, that a redundant safety device be worn by radiographers as a means of reducing radiography overexposures to both the general public and to radiographers.

Both NRC and the Agreement States regulate equipment manufacturers and radiography licensees in their respective areas. Because the manufacturers distribute nationwide and because a radiography company may have work in several states, it is important that the NRC and the States have the same requirements for radiographic equipment and personnel dosimetry. Accordingly, the Agreement States will be required to implement requirements that are compatible with the NRC's final rule. In January 1987, Texas (an Agreement State) implemented requirements in its regulations which are similar to those being proposed by the NRC.

The action involves no new NRC resource requirements and is not expected to have a significant economic impact on small businesses.

Enforcement Policy:

Accompanying the final rule is a modification to the Commission's General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. This change which is to be made to Supplement VI, "Fuel Cycle and Materials Operations," provides an example by which violations of the requirements of the 10 CFR Part 34 rule change may be categorized. A description of the change is provided in the Federal Register Notice. The purpose of this change to the enforcement policy is to give notice to licensees that a failure to have the equipment required by the rule may be considered a violation of significant regulatory concern.

Coordination:

The amendments in this final rule have been reviewed and concurred in by a number of other offices. The offices of Nuclear Material Safety and Safeguards, Nuclear Reactor Regulation, Governmental and Public Affairs, Analysis and Evaluation of Operational Data, Enforcement, and Administration concur in these amendments. ACRS and CRGR have no comments. The Office of the General Counsel has no legal objections.

Recommendation: That the Commission:

1.(a) Approve publication in the Federal Register of the final amendments to Part 34 (Enclosure A) that would become effective one year after publication in the Federal Register.

(b) Approve publication of the modification to Appendix C to 10 CFR Part 2 as an effective policy statement that would become effective concurrent with Part 34 rule change.

2. Approve the staff's conclusions set forth in the Final Regulatory Flexibility Analysis (Appendix A to Enclosure A) that the benefits to the public health and safety that would result from the implementation of the proposed amendments outweigh the possible economic impact upon small entities. The Chief Counsel for Advocacy of the Small Business Administration will be informed of this rulemaking and the reason for it as required by Section 605(b) of the Regulatory Flexibility Act.

3. Note that:

a. An environmental assessment and a finding of no significant impact have been prepared for this rule (Enclosure C).

b. With respect to the Agreement States, this item will be made a matter of compatibility because it concerns basic safety standards.

c. The Committee on Environment and Public Works, the Committee on Energy and Commerce and the Committee on Interior and Insular Affairs will be informed (Enclosure E).

d. A public announcement will be issued when the Federal Register Notice is filed with the Office of the Federal Register (Enclosure F).

e. Copies of the final rule will be distributed to affected licensees and other interested persons by the Office of Administration.

f. The reporting and recordkeeping requirements contained in the regulation have been approved by the Office of Management and Budget, approval number 3150-0007.

g. A backfit analysis is not required for this proposed rule.

Victor Stello, Jr.
Executive Director
for Operations

Enclosures:
A. Federal Register Notice
B. Regulatory Analysis
C. Environmental Assessment and Finding of No Significant Impact
D. Analysis of Comments
E. Draft Congressional Letter
F. Draft Public Announcement

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Monday, July 17, 1989.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT Monday, July 10, 1989, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for affirmation at an Open Meeting during the Week of July 17, 1989. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

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NUCLEAR REGULATORY COMMISSION

RIN: 3150-AC12

10 CFR Part 34

10 CFR Part 2

Safety Requirements for Industrial Radiographic Equipment

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule and modification of the General Statement of Policy and Procedure for NRC Enforcement.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations that apply to industrial radiography. This rule requires licensees to use only radiographic exposure devices and associated equipment that provide certain additional safety features. This rule also requires radiographers to wear alarm ratemeters. These new requirements are intended to reduce radiation exposures to both radiography personnel and the general public from the use of radiographic equipment. These amendments affect persons licensed to perform industrial radiography and manufacturers of radiographic equipment. The amendments do not affect x-ray radiography or devices incorporating naturally occurring or accelerator produced radioactive material because the regulation of these items is not included in the Atomic Energy Act of 1954, as amended. In addition, the Commission is modifying its Enforcement Policy (10 CFR Part 2, Appendix C) to add a specific example to Supplement VI to reflect the importance of meeting the requirements of the rule.

EFFECTIVE DATE: (12 months from date of publication). The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of _____.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. Nellis, Radiation Protection and Health Effects Branch, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3628.

SUPPLEMENTARY INFORMATION:

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Appendix A - Regulatory Flexibility Analysis

On March 15, 1988, the Nuclear Regulatory Commission published for public comment a proposed rule [53 FR 8460] that would require NRC licensees to use radiographic exposure devices that meet the criteria specified in American National Standard N432, "Radiological Safety for the

Design and Construction of Apparatus for Gamma Radiography," 1981 (Published as NBS Handbook 136) and a number of additional criteria that were recommended by an ad hoc equipment design safety task force. Other requirements included in the proposed rule were additional reporting requirements and a requirement for radiographers to wear alarm ratemeters with the alarm signal set at a dose-rate of 500 mR/hr. The purpose in proposing these amendments to the regulations was to reduce overexposures to both radiographers and the general public by specifying certain safety related performance requirements on radiographic exposure devices and by requiring radiographers to carry a supplemental radiation alarm monitor.

The public comment period was scheduled to end on May 16, 1988, but a number of requests for extension were received and the comment period was extended until August 16, 1988 [May 20, 1988; 53 FR 18096]. All comments received were given full consideration.

Background

Industrial radiography is a technique of nondestructive testing that uses radioactive sources or x-rays to detect flaws in welds, and cracks, breaks or other structural deficiencies in bridges, pipelines and manufactured articles. Most industrial radiography operations are conducted using gamma-ray emitting sources, although x-rays and neutrons can also be used. The procedure for taking radiographs is similar to the procedure used for taking medical x-rays except that a radioactive source is generally used in place of an x-ray machine. The operating principle of all of the devices is similar. Most radiography operations involve projecting a radioactive source out of its shielded position within the

device; however, some devices, such as the so called "pipeliner," utilize a shutter to allow the radiation beam to exit from the device while the source remains in a shielded position within the device.

The general procedure used is as follows: First, a radiation sensitive film is positioned over the area of interest on the item to be examined. Then a radiography exposure device or camera (which contains a sealed gamma-ray emitting source within a radiation shield) is placed nearby. A flexible hollow tube called a "guide tube" is connected to the front of the device, and the other end of the guide tube (to which an exposure head is attached), is positioned opposite the film on the item to be examined. Next, on the back of the device, a "control cable" is connected to the radiation source assembly, sometimes called a "pigtail" (a short length of wire with the source fastened on one end and a connector for the control cable on the other). Use of the "pigtail" allows the connection to be made without directly exposing the radiographer because the source itself remains in its shielded position within the device while the connection is being made. Lastly, a hollow tube through which the control cable moves is connected to the back of the device. The control cable and its tube are then unreeled until the cranking device for operating the cable is approximately ten to twenty feet from the device. This distance provides radiation protection for the radiographer. Next, the radioactive source is cranked or pushed from the radiographic device to the end of the guide tube. This causes the gamma-rays from the source to penetrate the item under examination and expose the film. At the end of the desired exposure time the source is cranked back into the device. A survey is made with a radiation detection device to ensure that the source assembly is in its shielded position, then it is secured in

this position and the film is retrieved for development. The radiographer is then ready to proceed with the next exposure. In some instances, what is referred to as "real time" radiography is performed. This merely involves replacing the film with remotely operated TV fluoroscopic equipment, solid state, or other suitable detection equipment that produces an image in real time without requiring development of a film.

Although the described procedure appears straightforward, and most radiography is performed safely, radiation overexposures to radiographers and occasionally to the general public occur. Accidental radiation overexposures to both radiographers and the public have concerned both the NRC and the Agreement States because the radiation levels of the radioactive sources used in industrial radiography are sufficient to cause serious injury or death.

Industrial radiography performed in the field is of most concern. Unlike many other applications of ionizing radiation which are rigidly controlled and remote from the public, industrial radiography involves the use of high activity sources, sometimes in close proximity to the general public, and is often only under control of the radiographer. The work is generally performed under production pressure and is often performed in adverse weather and environmental conditions. Such conditions can lead to both equipment failure and failure to follow proper safety procedures (e.g., failure to perform the required radiation survey or allowing assistant radiographers to perform the radiography themselves without the direct supervision of the more highly trained and skilled radiographer). Such failures, either singly or in combination, occasionally lead to radiation overexposures. Some of the failures of

radiography licensees to follow NRC requirements have been documented in a recent NRC information notice.[1]

Radiography Related Overexposures

The NRC has been concerned about the number of radiation overexposures among radiographers for several years and has completed, has underway, or is considering, actions intended to reduce the frequency of the overexposures. These actions include: (a) development of a training manual for radiography personnel to help ensure that they understand the need for, and the application of, good radiation protection practices,[2] (b) consideration of several programs to improve training provided to individual radiographers to help ensure that they are adequately trained and are aware of their direct responsibility for safety performance, (c) increasing inspection time spent observing workers performing actual radiography operations, (d) providing additional guidance for reporting events as required by 10 CFR and ensuring that these reports include clear information concerning equipment failures when appropriate, and (e) the establishment of safety requirements for radiographic equipment.

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[1]NRC Information Notice No. 87-45: "Recent Safety Related Violations of NRC Requirements by Industrial Radiography Licensees," September 25, 1987. Single copies of this information notice may be obtained by telephone by interested persons at (301) 634-3273.

[2]NUREG/BR-0024, "Working Safely in Gamma Radiography," S. A. McGuire and C. A. Peabody, 1982. Copies of NUREG/BR-0024 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection or copying for a fee in the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC 20037.

NRC licensees are required to report radiation overexposures to the NRC. Over the decade ending in 1984 industrial radiography has accounted for 1) more than one-half of the overexposures reported by all NRC licensees greater than 5 rems to the whole body or 75 rems to the extremities and 2) almost 60% of the overexposures greater than 25 rems to the whole body and 375 rems to the extremities. Over this same period, radiography accounted for almost 25% of all overexposures reported by NRC licensees.[3]

During the years 1979 through 1983 radiographer overexposures reported to the NRC and Agreement States combined accounted for 18% of all occupational overexposures, although radiographers represent only 4% of all radiation workers. It is believed that many incidents also occurred which did not require reporting but which had the potential for serious overexposure from the high-intensity relatively high-energy gamma-ray sources used.

Three incidents in foreign countries where children or adults have found lost radiography sources and have died from overexposure illustrate the extreme hazard potential involved in radiography overexposures. In other cases involving radiography sources, overexposures have caused acute effects such as burns and necrosis of body tissues. Some examples of incidents which show the extreme hazard potential are:

(1) 1979, California: The source assembly was improperly connected or became disconnected and was cranked out of the end of the guide tube and fell to the ground. No radiation survey was made. An individual

[3]The year 1984 is the most recent year for which complete exposure data has been tabulated for all NRC licensees.

found the source and placed it in his hip pocket and carried it around for about 45 minutes. The individual suffered a severe radiation burn on his right buttock. In 1985 the individual still walked with difficulty and was under periodic medical evaluation. Ten other persons were exposed, two of whom developed radiation burns on their fingers.

(2) 1980, Texas: The source assembly was not properly connected, and the source remained in the guide tube. A proper radiation survey was not made, and the source was stored in the coiled-up guide tube in a room adjacent to a work area. One radiographer received an overexposure of 75 rems, another person received an overexposure of 198 rems and thirty-one persons received exposures ranging from 0.09 to 4 rems. Had another radiography crew not discovered the next day that the source was missing from the device, many others could have been seriously exposed.

(3) 1984, Texas: An assistant radiographer received an overexposure of 7.5 rems for the calendar quarter. Investigation showed that the radiographer did not always lock the source after each exposure as required, nor did he always make the required radiation survey. Subsequent investigation also revealed that the source locking mechanism was defective.

(4) 1984, Morocco: A source assembly became disconnected and fell to the ground. A laborer found it and took it home. Eight members of his family died from overexposure, and several others received significant doses.

(5) 1985, Wyoming: The source assembly was not connected properly or became disconnected. The radiography crew failed to make the required radiation survey, and the source was stored in the coiled-up guide tube in the back of a pickup truck for two days. Three radiographers received

exposures of 22, 7 and 0.6 rem respectively. One unbadged employee and six members of the general public received doses believed to be less than 0.5 rem each.

Studies of radiography exposure data indicate that radiography equipment problems contribute to approximately 40% of all reported overexposures. Equipment problems of the following types frequently play a contributing role:

(1) The source moves out of the shielded position after being cranked back into the device and before being locked, or the locking device is defective and fails to retain the source in the proper position.

(2) The source assembly is not properly connected or becomes disconnected, so that while it may be cranked out of its shielded position in the device, it cannot be retracted and remains in the guide tube.

(3) The source assembly is not properly connected or becomes disconnected and is cranked out through the end of the guide tube and drops to the ground.

(4) The source becomes stuck in the guide tube due to damage to the guide tube or due to fraying of the control cable.

All of these conditions could be recognized by performing a radiation survey after each radiographic exposure (to verify that the source is properly returned to its shielded position within the radiography device). Radiographers are required by the regulations in 10 CFR 34.43(b) to perform such a survey. In many cases, however, the radiation survey instrument is not used, is used incorrectly, or is defective. In Item (1) above, any overexposure would typically involve only the radiographers. In the remaining three items there is considerable potential for exposure to the public as well as to radiography personnel since the

source, either on the ground or in the guide tube, has essentially no shielding.

Previous Regulatory Initiatives

In an effort to reduce the rate and severity of radiography overexposures attributable to equipment problems, the NRC published an Advance Notice of Proposed Rulemaking (ANPRM) on March 27, 1978, (43 FR 12718) announcing that it was undertaking the development of safety requirements for radiographic exposure devices that are licensed under 10 CFR Part 34. Among the several comments received was the suggestion that the NRC delay further action on any rulemaking until completion of a related consensus performance standard. A voluntary consensus standard, National Bureau of Standards (NBS) Handbook 136, American National Standard N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" was issued by NBS in January 1981. The standard incorporates many of the safety design features proposed in the ANPRM; however, it is a voluntary consensus standard. Although there was no regulatory requirement for manufacturers to adopt the recommendations of the standard, recent amendments to 10 CFR Parts 30 and 32 formalized NRC's source and device registration process and will ensure that future radiography devices that are registered with the NRC for the first time meet the requirements of the standard.

In March, 1980, (partly as a result of a serious radiation accident that occurred in California in 1979, example 1 above), an ad hoc Radiography Steering Committee composed of NRC personnel and State officials representing the Conference of Radiation Control Program Directors, Inc.,

was formed to draft recommendations for improving radiography safety. Four task forces were subsequently established by the steering committee to address various aspects of the problem. These task force assignments were: Training and Certification, Radiographic Equipment Design Safety, Inspection, and Collection and Analysis of Incident Data.

In 1982, the NRC published a training manual for industrial radiographers,[2] and in 1984 the equipment safety task force presented its recommendations on performance criteria for radiographic exposure devices[4] to the Radiography Steering Committee and urged that the recommendations be added to the rules as soon as possible. These recommendations include many of the performance criteria specified in the consensus standard together with additional criteria.

The voluntary consensus standard ANSI N432, issued in 1981, is currently under review for possible revision. The revision is expected to incorporate many of the performance requirements in the international standard, ISO 3999, "Apparatus for Gamma Radiography Specification." Some of the performance requirements expected to be incorporated in the revised standard are the same as those recommended by the equipment task force. Publication of the revision of ANSI N432 as a final industry

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[2]NUREG/BR-0024, "Working Safely in Gamma Radiography," S. A. McGuire and C. A. Peabody, 1982. Copies of NUREG/BR-0024 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. A copy is available for inspection or copying for a fee in the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC 20037.

[4]"Radiographic Equipment Safety Performance Criteria," D. Honey (CA), R. Ratliff (TX), R. Wascom (LA), S. Baggett, and A. Tse (NRC), April 30, 1984. For a copy of this report see paragraph heading For Further Information Contact:

standard may take several years. When issued, NRC will consider if additional rulemaking is appropriate or necessary to incorporate the standard.

While the voluntary consensus standard American National Standard N432 has been available since 1981, it does not appear that all manufacturers are actually using the consensus standard nor does it appear that its provisions have been uniformly or completely implemented by radiography equipment manufacturers. Also, some of the equipment currently in use may have been manufactured prior to publication of the standard and may not meet its provisions. As a result, it is assumed that the voluntary consensus standard has had little effect on reducing the number or severity of radiography overexposures. Further, some of the equipment improvements recommended by the Radiography Steering Committee are not included in the standard.

It has been stated earlier that NRC studies indicated that some 40% of the incidents involved equipment problems. Therefore it is felt that regulatory action is needed at this time in order to reduce the number of radiography incidents occurring and possibly to prevent additional serious overexposures that are potentially possible given the high radiation output of the sources used in this industry.

The Radiography Steering Committee also suggested that one means of reducing radiographer overexposures caused by the failure to detect the return of the source to its properly shielded position in the radiographic exposure device, would be to require that radiographers wear alarm meters. These are radiation detection devices that provide an audible alarm at some preset dose or dose-rate or both.

Audible-alarm meters are especially useful when radiographers cannot hold survey meters because they need both hands to perform a job or when they cannot continually look at the survey meter because the operation they are performing requires them to look elsewhere. Alarm meters are not to be substituted for a radiation survey meter but are to be considered a complementary warning device. The use of audible-alarm meters is now a requirement for radiographer trainees in Canada and has proved useful according to Canadian officials.

NRC Regulatory Guide 8.28[5] "Audible-Alarm Dosimeters" discusses a program for the appropriate use of audible-alarm meters. The term "audible-alarm dosimeters" as used in this guide refers to pocket sized radiation detectors that alarm when either a preset integrated exposure or a preset exposure rate is reached. Enquiries have indicated that these dosimeters are used in nuclear power plants on a relatively widespread basis. Few, however, are used in the radiography industry in the United States. Alarm meters are considered reliable and hold up well with proper use. They provide an audible warning to a radiographer when he or she is approaching an exposed source, so that actions can be taken immediately to minimize unnecessary radiation exposure. The steering committee recommended that the use audible-alarm meters be incorporated in the final rule.

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[5]Regulatory Guide 8.28 is available for inspection at the Commission's Public Document Room, 2120 L Street NW., Lower Level, Washington, DC 20037. Copies of the Regulatory Guide may be purchased by calling (202)275-2060 or by writing to the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 37082, Washington, DC 20013-7082.

Public Comments

The NRC received a total of eighty-eight public responses to the proposed rule. Some of the responses were duplicates, some were requests for an extension of the comment period, and some were not relevant to the proposed rule. The number of valid responses to the proposed rule was sixty-eight. The proposed amendments involved twenty-six separate items and the average responder commented on at least ten of the items. All of the comments have been considered and have been included in the Analysis of Comments document which is available for review and copying for a fee at the NRC Public Document Room located at 2120 L Street NW, Lower Level, Washington, DC 20037.

Most of those commenting indicated that they approved of the NRC goals for improving the safety of radiography equipment but many expressed differences of opinion on methods of obtaining these goals. Of the twenty-six items proposed, comments were equally divided on two, opposed on nine, and in favor on fifteen. The principal comments and the NRC response for each of the proposed items are given below.

Section 34.20(a) Radiographic Equipment Must Meet the Requirements of ANSI N432.

Comment:

Twenty-four responses were received on this provision, with the comments essentially divided. The main issue raised by commenters opposed to the requirement involved the maximum allowed radiation levels specified in the ANSI standard. Many felt that the added shielding required to meet

the specified radiation levels would limit the portability of the devices and make them too heavy to handle. One commenter felt that meeting the radiation level requirements of the standard would not be cost effective and felt that the levels on present equipment were not a major contributor to exposure.

Response:

The ANSI standard specifies a maximum radiation level of 50 mR/hr at 5 cm. Part 34 specifies a maximum radiation level of 50 mR/hr at 6 inches (15 cm) for radiographic exposure devices measuring less than four (4) inches from the sealed source to the surface. The existing limit of 50 mR/hr at 6 inches (15 cm) was established when lead was commonly used for shielding and most devices measured about 4 inches (10 cm) in radius. Surface levels, based only on the inverse square law, ignoring buildup and multiple scattering, would then be about 300 mR/hr. With the change-over from lead to depleted uranium shielding in the mid 1960's it was possible to meet the requirement of 50 mR/hr at 6 inches with devices that measured on the order of 2 inches (5 cm) from source to surface of the device. Surface levels, based only on the inverse square law as stipulated above, would then be about 800 mR/hr. Some commenters have stated that measured surface levels have not exceeded 350 mR/hr, but it is not clear that they have corrected these measurements for the effective center of the detector used. Surface measurements on small packages or devices are prone to large errors and are difficult to perform correctly. For example, a true surface reading of 800 mR/hr on a device that measures only 2 inches (5 cm) from source to surface will read about 360 mR/hr at

one inch from the surface, based on the inverse square law. Should the detector used to measure such a surface dose have an effective center of one inch it would read 360 mR/hr for the surface dose rate. An additional problem concerns the size of the detector used to make the measurements. Large area detectors are not recommended for measuring surface dose rates, particularly on small packages or devices, since they provide average readings only and are not likely to detect small voids in shielding materials. The difficulty involved in making surface measurements is recognized in ANSI N432 in that Section 8.1.2 specifies procedures for measuring exposure rates at 50 mm and 1 m from the surface, but no procedure is specified for making the surface measurement.

There is also a problem involving exposure when carrying the smaller devices. The dose rate to the gonads remains the same because the dose rate at 6 inches (15 cm), which is estimated to be the distance from the surface to the gonadal area, is specified to be 50 mR/hr regardless of the size of the device. The dose rate to the thigh (measured at 1 cm depth and assuming that the device is carried against the thigh) however, changes from 260 mR/hr for a device with the source 4 inches from the surface, to 555 mR/hr for a device with the source 2 inches from the surface. The average of two independent studies, one in France and one in the USA, indicates that radiography devices are carried about 6.25 minutes per day or 20.8 hours per year. Annual doses received at the thigh are 5.4 R for the older larger devices and 11.5 R for the newer smaller devices. These considerations no doubt led to specification of the external radiation levels specified in ANSI N432. It should be noted that these radiation levels were published in 1981, that identical levels have been part of the international standard ISO 3999 since 1977 and even

lower levels are being proposed in the European community. The fact that radiographic exposure devices that meet the requirements of ANSI N432, including the external radiation levels specified, are now on the market, seems to refute the contention that such devices would be too heavy to handle. Most portable exposure devices now on the market weigh between 35 and 45 pounds, including those that meet the external radiation levels of the standard. It should also be mentioned that these radiation levels can be attained by use of lower strength radiation sources although this alternative would imply additional costs because of more frequent source replacements. The provision in the final rule accordingly remains the same as in the proposed rule.

Section 34.20(b)(1)-Exposure Device Label.

This provision requires the user to attach a label to the radiographic exposure device that would identify the radionuclide in the device, its activity on the date specified, its model number and serial number and the manufacturer of the sealed source. These same specifications are listed in Section 4.2 of ANSI N432 but it is not clear that they constitute a requirement in the standard. However the standard does provide that the device have a location for attaching this label.

Comment:

Fourteen comments were received on this provision, with twelve approving. The negative comments indicated that the upkeep of the markings could be costly and that the isotope manufacturer must be responsible for providing the label to the user. One commenter proposed that the exposure device label should also include the name, address, and

telephone number of its owner so that the proper persons could be contacted if the device became lost and then found.

Response:

In current industry practice the manufacturer provides a plate to the device user with the changer and the new source. It is the responsibility of the user to attach the plate containing the prescribed information to the radiographic exposure device. The NRC agrees that it would be desirable to include the name, address an ' telephone number of the owner on the label and is including this requir ent in the final rule. It is the responsibility of the user to keep this information current. No other changes are being made to the proposed rule in regard to this provision.

Section 34.20(b)(2)-Exposure Devices Intended as Type B Transport Containers to Meet Part 71 Requirements.

Comment:

There were no negative comments on this provision. Some commenters mentioned that their devices already met this requirement.

Response:

No change is to be made in this provision.

Section 34.20(b)(3)-Modification of Exposure Devices and Associated Equipment is Prohibited.

Comment:

No negative responses were received on this provision. One manufacturer asked if this implies that no modifications may be made without resubmission of designs to the proper NRC or Agreement State authority.

Response:

The purpose of this provision is to prohibit modifications by users that could compromise the safety of the device. One example would be the use of a source assembly different from that approved by the device manufacturer, and which does not meet the QA and QC requirements of the specified source assembly. This provision is not intended to impose design restrictions on manufacturers. The provision stands as originally stated.

Section 34.20(c)(1)-Source Assembly - Control Cable Connection.

The purpose of this provision was to require a coupling between the source assembly and the control cable such that the possibility of an unintentional disconnect could not occur. The recommendation of the equipment task force mentioned previously was that the coupling should require the application of motion in two planes and a positive force in one of these planes to complete the connection.

Comment:

Twenty-two comments were received, fifteen for and seven against the provision. Several commentors from each side indicated that the wording should be changed from technical specifications to performance requirements. They suggested that the wording be patterned after the wording used in the regulations issued by the State of Texas. Basically these

require that the connection shall be designed in such manner that the source assembly will not become disconnected if cranked outside of the guide tube. Most commenters felt that the technical specifications listed in the present wording could prevent designers from developing a connector that would provide the best performance possible.

Response:

This suggestion was adopted and the wording of the provision has been changed to reflect the performance requirement approach used by the State of Texas. Also, NRC's source and device registration process requires NRC approval before the newly designed connectors could be used.

Section 34.20(c)(2)-Require a Readily Visible Source Position Indicator.

The purpose of this provision was to provide the radiographer with additional or supplemental information concerning the position of the radioactive source. It was not intended as a substitute for the use of a survey meter but rather to provide supplementary information much as does a warning light on the gas gauge of an automobile.

Comment:

Forty-two comments were received on this provision, four approved and thirty-eight opposed the provision. Most of those commenting against it felt that the indicator would not be foolproof, could easily fail, and would lead radiographers to neglect the use of the survey meter. Three commenters stated that the indicators on some of the devices now in use are not completely reliable and have not proven to be fail-safe. Three indicated that they did not think it would increase safety. Others pointed

out that most indicators only indicated the position of the source assembly and would not be of use if the source separated from the assembly. Two of those approving the provision noted that the position indicator should only be relied upon as a guide.

Response:

This particular item has long been controversial. At a 1978 NRC meeting convened to discuss the design of radiographic exposure devices, it was generally agreed that it was not possible to design a position indicator that could not fail. It was also pointed out at this meeting that source position indicators consisting of red and green lights were installed on some devices as early as 1958. These failed so frequently that the NRC asked manufacturers to remove them. Also, a provision for such an indicator has been proposed for inclusion in the next revision of the International Radiography Standard, ISO 3999, by the French delegation but there appears to be little support for this from other countries. In view of the continued opposition and past experience with these indicators the NRC has removed the provision.

Note: Proposed paragraph § 34.20(c)(2) has been deleted. It should be noted that proposed rule paragraphs § 34.20(c)(3) through § 34.20(c)(10) as discussed below, are designated as paragraphs § 34.20(c)(2) through § 34.20(c)(9) in the text of the final rule.

Section 34.20(c)(3)-Automatic Securing of Source Assembly.

This provision provides a system to automatically secure the source assembly in the shielded position each time it is cranked back into the

exposure device. The provision eliminates the manual securing which is now required under § 34.22(a) of the current regulations. The provision helps eliminate the problem of the source accidentally moving out of the fully shielded position after it has been cranked back into the device.

Comment:

Thirty-two comments were received on this provision, seven in favor and twenty-five opposed. The majority of those opposed appeared concerned with the additional maintenance needed to keep the automatic securing system operating properly. Four were opposed on the basis of cost. Three pointed out that it could easily be bypassed. One commenter pointed out that existing devices with this provision have failed, and two indicated that the source could be locked outside the device instead of inside. Several also expressed concern that the provision would discourage the use of the survey meter. One commenter would like to include the option of unsecuring the source remotely.

Response:

The NRC does not agree that the automatic securing provision will cause all the problems raised by commenters. Some of the incidents involving overexposures caused by the source slipping out of its shielded position, are due to failure of the radiographer to manually secure the source after each exposure as required by current regulations, or due to excessive wear caused by radiographers using foot operation rather than hand operation in the manual securing. As for the statements regarding by-passing the automatic securing, discouraging the use of survey meters, the NRC does not believe that many persons will deliberately by-pass or ignore such beneficial measures. Appropriate maintenance, coupled with

adequate QA and QC programs, which should be included in the licensee's operations, should eliminate any serious problems with this provision. It should be noted also that the automatic securing reduces the work load on the radiographer by eliminating the manual securing requirement. The provision remains as proposed.

Section 34.20(c)(4)-Require Safety Plugs or Covers.

The purpose of this provision is to prevent the access of water and other matter into the device where they could contribute to malfunctions and wear.

Comment:

Sixteen comments were received on this provision, all favorable. One commenter approved on the condition that the covers or plugs were not integrated as a working, moving function of the device. Another commenter wanted the device to be equipped with a receptacle to hold the plugs or covers and keep them clean. A third commenter felt that the equipment should be required to perform satisfactorily under conditions of mud, sand, water, etc., and leave it up to the manufacturer to determine if plugs or covers were needed to achieve this.

Response:

General design conditions in Section 5.1 of ANSI N432 presently call for exposure devices to be designed with due regard for the need to minimize the entry of water, mud, sand or other foreign matter into the controls or moving parts during use The NRC feels that the use of appropriate plugs or covers during storage or transportation is also necessary but agrees that these need not be integrated into the device. Receptacles for the plugs or covers should be an option of the manufacturer. No change is made in the requirement.

Section 34.20(c)(5)-Labelling of the Source or Source Assembly.

The purpose of this provision is to help minimize overexposures that could occur if a member of the public finds a lost source assembly.

Comment:

Twelve comments were received with eleven in favor. One commenter was concerned that the label might interfere with the operation of the lock or the guide tube. The commenter who was opposed felt that this was not practical and that we should see if it could be done successfully before making it a regulation.

Response:

This provision was made part of Texas regulations on October 1, 1987. Early attempts to use heat shrinkable plastic or soft metal sleeves were not successful. The current method used by most manufacturers involves laser etching of the source assembly. The requirement will remain as written in the proposed rule with the understanding that laser etching or any other successful method will be acceptable.

Section 34.20(c)(6)-Guide Tube Crushing Tests and Kinking Resistance Test.

The purpose of this provision is to prevent the source assembly from hanging up in the guide tube and creating a condition that could lead to radiation overexposures. The crushing tests for control tubes as specified in ANSI N432 should be used for the guide tubes.

The proposed revision to ANSI N432 has a kinking test for such guide tubes and the NRC would find this test acceptable for meeting the requirements of this section. The test referred to is described in its entirety as follows:

Place the projection sheath (guide tube) without connection, on a horizontal surface and fix one of the ends so that it does not move in any way during the test. The length of the projection sheath shall be the maximum length authorized by the manufacturer.

Form a flat closed loop, either on the right or left of the positioning axis, with the fixed end under the loop, and keep the ends crossed by means of a hoop so that the loop cannot come undone under the action of a vertical component of elasticity and the free end can still slide without noticeable friction.

Apply a tractive force to the free end, at a tangent to the loop, reducing the diameter of the loop. The force shall be applied by means of a dynamometer in such a way that it reaches 200 N in 5 seconds. The force shall be maintained at this level for 10 seconds.

Repeat the test 10 times, undoing and redoing the loop at the same point for each test.

If the projection sheath is composed of various parts with connections, restart the test including a connection in the loop. Close the loop as above so that the connection and the crossing point are opposite each other.

Comment:

Ten comments were received on this provision, eight approving, two opposed. Those opposing were persons in the aircraft industry who objected that the special guide tubes they required would not withstand the specified tests.

Response:

Persons who have special requirements should apply to the NRC under § 34.51 for an exemption of the requirement. The provision is unchanged.

Section 34.20(c)(7)-Requirement to Use Guide Tubes.

The purpose of this provision is to ensure that the source assembly will not be cranked out of the camera and fall to the ground.

Comment:

Three comments were received, all approving.

Response

The provision is unchanged.

Section 34.20(c)(8)-Requirement for the Use of Exposure Heads.

The purpose of this provision is to prevent the source assembly from passing out of the end of the guide tube.

Comment:

Eight comments were received on this provision, all favorable.

Response:

The provision is unchanged.

Section 34.20(c)(9)-Require Guide Tube Exposure Head Tensile Test.

The purpose of this provision is to ensure that the exposure head will not easily become dislodged in use.

Comment:

Two comments, both favorable, were received on this provision.

Response:

The provision is unchanged.

Section 34.20(c)(10)-Source Changers.

The purpose of this provision is to prevent exposure of persons when making a source change.

Comment:

Three comments were received on this provision. One commenter believed source changer design to be adequate. One commenter believed that most source changers left something to be desired. One believed that source changers should not be included in this section.

Response:

Because source changers fall within the category of associated equipment, the NRC does not believe that this provision should be relocated. The wording of the final provision has been changed, however, to require a system to assure that the source is not accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

Section 34.20(d)-Compliance of New Devices with § 34.20 After One Year.

The purpose of this requirement is to ensure all newly manufactured devices acquired by licensees meet the performance requirements of

§ 34.20(a) thru (c) after one year from publication of the final rule in the Federal Register.

Comment:

One commenter requested the compliance not be required for two to two and one half years. Some other commenters expressed doubt that manufacturers could meet the requirements in one year. One commenter noted that there was only one type 1R device for Iridium sources and none for Cobalt sources available in the U. S. at the present time.

Response:

The requirement has been changed to require compliance after one year from the effective date of the final rule.

Section 34.20(e)-All Devices in Use to Comply with § 34.20 After Five Years.

The purpose of this provision is to require that all radiographic exposure devices meet all of the provisions of § 34.20 after five years or be retired from use. The choice of five years was based upon discussions with equipment manufacturers and upon NRC experience which indicated that the average lifetime of devices which project a source out of a shielded position is around five years. The NRC recognizes, however, that the average life expectancy is dependent upon the design of the device, the amount of use, the environment at the use site, and the quality of the maintenance program. The choice of a five year implementation period for the rule rather than a more accelerated period was made for a number of reasons. Radiography exposure device manufacturers would probably be unable to manufacture 3500 devices meeting the requirements

of the rule in a much shorter time; the five year period avoids imposing a severe financial impact on the radiography industry, particularly on the small entities; and the number of radiography overexposures occurring per year does not appear to justify a shorter implementation period.

In addition, the gradual use of new models is advisable since additional training will be required for radiographers, and user licensees need additional time to evaluate new models as they become available to assure that they meet expectations under operational field conditions.

Comment:

Twenty-seven comments were received on this provision, two in favor and twenty-five opposed. Most of the comments objecting to the provision challenged the average lifetime of five years for the devices, citing for the most part a ten to fifteen year lifetime. The other major objection was the cost, with one commenter citing a value of over $630,000. One commenter had reservations about setting a time limit for compliance especially when working models for some of the provisions have yet to be developed and tested. Another stated that there is no projection device for cobalt that meets the standard presently available in the U.S. and that current devices, which cost around $15,000, would have to be replaced in five years.

Response:

The NRC is aware that retrofitting of existing radiographic exposure devices to meet the requirements of the rule is not practical and that meeting the requirements of the rule involves the purchase of new equipment that meets all the requirements.

The NRC is aware that the radiography industry is in a period of recession and that, as a result, many smaller radiography firms have gone out of business. A side-effect of this depressed state of the industry has been the creation of a large market in used radiographic exposure devices.

The NRC is concerned that many of the devices now in use by the industry may be from 10 to 20 years old. The devices may no longer be in production and replacement parts may not be available. Emphasis of this point is shown by the intent of one of the larger device suppliers to issue a notice phasing out of service, over a period of 3 years beginning in 1989, certain of the devices it normally services because of unavailability of replacement parts. The NRC believes that many other devices with similar problems not subject to this notice are also in use in the market place. This provision will help to phase out of use such unserviceable and possibly unsafe devices. While many of the commenters feel that this provision poses a financial burden to users and could result in premature replacement of safe and useful equipment, this view is not shared by the NRC. While conceding that the lifetime of many devices may be as much as 10 years, the NRC believes that many of the devices currently in use need to be replaced with devices meeting the criteria of the rule. With regard to the charge that compliance with the new rule would constitute a financial burden, it should be pointed out that all equipment in use at the time of publication of the proposed rule will have been in service for a period of more than seven years at the date required for compliance, and would therefore also have been eligible for a seven year application of its depreciation allowance. This allowance would seem to appreciably reduce the financial burden claimed by the

commenters. In addition, the regulatory analysis for this rule indicates that the cost to the industry resulting from implementation of this provision of the rule is of the order of $4 million dollars on a 1989 present worth basis calculated over the ten year interval from 1990 to 1999. The cost to the individual licensee resulting from implementation of this provision of the rule over the same ten year period is $3636. Annual costs over this ten year period are therefore $400,000 for the industry and $364 for individual licensees. In view of these arguments, the provision remains as proposed except that the five year period will begin after the effective date of the final rule which will be one year after publication in the Federal Register.

Section 34.21-Limit on External Radiation Levels.

The purpose of this provision is to allow equipment received prior to one year after the effective date of the rule to meet the existing radiation levels of the present § 34.21 now redesignated § 34.21(a). After a period of five years from the effective date of the final rule all radiographic equipment except source changers and storage containers will be required to meet the requirements of § 34.20. Source changers and storage containers continue to be regulated under § 34.21(a).

Comment:

Five comments were received on this provision, three approving and two opposed. The principal comments were that reduction of external radiation levels would not be cost effective and that existing levels have not proven to be a radiological health hazard.

Response:

The issue of external radiation levels is extensively discussed in the response to § 34.20(a) and will not be repeated here. The final version of § 34.21 will change from that in the proposed rule to the extent that five years after the effective date will be used in place of five years after publication of the final rule.

Section 34.30-Reporting Requirements.

The purpose of this provision is to provide the NRC with information on problems experienced with radiographic equipment. These requirements are separate and distinct both in content and purpose from those contained in 10 CFR Part 21, "Reporting of Defects and Noncompliance" which implements section 206 of the Energy Reorganization Act of 1974, as amended. By specifying conditions for reporting defects or noncompliance of radiographic equipment under this provision any ambiguity resulting from interpretation of Part 21 provisions is avoided.

Comment:

Sixteen comments were received, six in favor and ten opposed. The principal comments were that item one, involving source disconnects, and item two, involving inability to retract the source, were reasonable reporting items. However item three, involving reporting of failure of any component to perform its function was unclear, open ended, and could lead to large volumes of required reports. Other commenters believed that the costs would be prohibitive and still others commented that licensees would simply refuse to comply with these reporting requirements. One commenter felt that reporting of defective equipment should be reported under 10 CFR Part 21.

Response:

The NRC agrees that item three was ambiguous and has rewritten it to apply only to components critical to safe operation of the device. The NRC does not agree with those commenters who believed that a large volume of reports would be required along with the correspondingly high costs associated with generating such reports.

Section 34.33(a)-Require Wearing of an Alarm Ratemeter.

This provision is intended to provide radiographers in the field with a duplicative or redundant device as a backup to the survey meter the radiographer is supposed to carry. Its purpose is to provide an additional warning of possible hazardous radiation levels in the event the survey meter is defective or misread, in much the same manner that buzzers and lights provide backup warning in automobiles of low or almost empty gas tanks for those who ignore or misread their fuel gauge. It is felt that as warning devices, alarm ratemeters may be able to prevent many overexposures that have occurred as a result of improper surveys.

Comment:

Fifty comments were received on this provision, eighteen approved, thirty-two were opposed. The principal comments of those approving the provision were that the rule should specify an alarm ratemeter instead of dosimeter, that state-of-the-art chirpers should be allowed, that the trigger level of 500 mR/hr was too high, (this is addressed in § 34.33(f)) and that they can malfunction and read zero. One commenter felt that there should also be a requirement that the alarm should go off if the ratemeter is subjected to radiation saturation.

Comments of those opposing the provision were that radiographers will rely on the alarm ratemeter and not use the survey meter, that two-man crews should be required instead, that survey meters with audible alarms should be used instead, that alarm ratemeters do not work in noisy environments, and that they cost too much. Others believed that management and regulatory agencies needed to enforce proper procedures instead of requiring alarm ratemeters. One commenter believed that a hearing test should be required of individuals wearing alarm ratemeters. Another commenter believed that they were completely unnecessary for permanent facilities, and that an exemption from this provision should be granted for such facilities.

Response:

The NRC does not agree with the assumption that radiographers will neglect using survey meters and depend on the alarm ratemeter, nor does it agree that the use of two-man radiography crews will eliminate the need for alarm dosimeters. One of the most recent overexposure incidents involved a two-man crew that was operating with a defective survey meter. Had the crew been using alarm ratemeters, at least one of the radiographers would have been alerted to the abnormal radiation fields present. Survey meters with audible alarms do not provide the same redundancy that separate alarm ratemeters do, primarily because the alarm is connected to the survey meter output and if the survey meter fails, so does the audible alarm. In regard to radiation saturation, most of the alarm ratemeters or alarm dosimeters meet the standard for these devices, ANSI N13.27, which specifies that exposure alarms shall continue to operate in radiation fields one thousand times higher than the highest alarm setpoint.

Typical alarm ratemeters have upper level settings of 10R/hr or greater. Most alarm ratemeters on the market also integrate the exposure and generally provide a chirp for every mR accumulated.

Alarm ratemeters and dosimeters are required to have a sound pressure level of 75 dBA at 30 cm from the device according to ANSI N13.27. This is roughly comparable to the sound of busy street traffic. Although the alarm may not be detectable in high noise environments, radiographers should continue to keep such alarm ratemeters activated and continue to carry an operable and properly calibrated radiation survey meter regardless of the environment.

In regard to the comment that alarm ratemeters are unnecessary for permanent facilities, the NRC believes that the use of such alarm ratemeters should not be required for permanent facilities where other alarming or warning devices are in routine use to warn personnel of high radiation fields. The provision has been rewritten to include this exemption. It should be noted however that the converse is not acceptable. The wearing of alarm ratemeters at permanent facilities cannot be used as a substitute for other alarming or warning devices at such facilities.

Section 34.33(f)(2)-Alarm Ratemeters Must Alarm at a Preset Level of 500 mR/hr.

The purpose of this provision was to set the alarm high enough that the alarm dosimeter will not alarm unnecessarily during normal radiography operations, and still provide a reliable alarm before a radiographer could get within ten feet of a lower activity (10 Ci) unshielded source.

Comment:

Thirteen comments were received on this requirement. All thirteen were opposed. The principal comments were that the trigger level was too high for most working conditions and that the trigger level was too high to check conveniently on a daily basis without the use of a large check source that would require a specific license. One commenter pointed out that around power facilities 500 mR/hr was too low and recommended a trigger level of 100-200 mR/hr above the ambient background rate.

Position:

Radiographers routinely work with radioactive sources whose activities are sufficient to create high radiation areas (>100mR/hr) and radiographers are required to post the boundaries of the high radiation areas with appropriate signs (§ 20.203(c)) and survey the restricted area boundary. Also, calculations based on the inverse square law show that for a 200 Ci Iridium source the radiation field at a normal operator's position (with 21 foot guide tube and 25 foot control tube) is approximately 430 mR/hr. Trigger levels of much less than the 500 mR/hr specified would then trigger an alarm under normal radiography exposures. Also, alarm ratemeters that trigger while radiographers are conducting normal operations would prove annoying and would likely be turned off. In view of these conditions, the trigger level should be set at 500 mR/hr. Those licensees that have a problem with this provision due to the need to work at nuclear power facilities where higher radiation levels may exist, may apply for an exemption under § 34.51.

With regard to the requirement to check the dosimeter alarm at 500 mR/hr on a daily basis, the provision has been rewritten to require a

calibration on an annual basis instead. The requirement for a daily check on the alarm remains unchanged. This can be provided by an electronic check point that corresponds approximately to the response of a 500 mR/hr field.

Finding of No Significant Environment Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required.

The final rule involves engineering design modifications to industrial radiography devices and requires licensees to use only radiography devices and associated equipment that provide certain additional safety features. Radiographers are required to wear alarm ratemeters. No requirements for significant quantities of materials, water, electricity or other forms of energy have been identified and no environmental or radiation impacts are involved.

The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC. Single copies of the environmental assessment and the finding of no significant impact are available from Dr. Donald O. Nellis, Radiation Protection and Health Effects Branch, Division of Regulatory Applications, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301)492-3628.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0007.

Public reporting burden for this collection of information is estimated to average 34 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Records and Reports Management Branch (P-530), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Paperwork Reduction Project (3150-0007), Office of Management and Budget, Washington, DC 20503

Regulatory Analysis

The Commission has prepared a regulatory analysis on this final rule. The analysis examines the costs and benefits of the alternatives considered by the Commission. The regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW, Lower Level, Washington, DC. Single copies may be obtained from Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301)492-3628.

Regulatory Flexibility Analysis

The NRC has prepared a final regulatory flexibility analysis of the impact of this rule on small entities as required by Section 604 of the Regulatory Flexibility Act. The analysis, which is set out in Appendix A of this document, indicates that this rule could have an economic impact of about $5,113 initially, and $1,188 annually on each radiography licensee, 90% or more of which are considered to be small entities. These costs are not considered to be overly burdensome in light of the possible benefits derived.

Modification of Enforcement Policy

The Commission is modifying its General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C (Enforcement Policy) to reflect the Commission's amendment of 10 CFR Part 34. The change to the Enforcement Policy is being published concurrently with the new rule.

The modification to the Enforcement Policy is being made at this time to Supplement VI "Fuel Cycle and Materials Operations" to put licensees on notice that the failure to implement the requirements for dosimetry and equipment by the required date may be considered a violation of significant regulatory concern. The example is to be used as guidance in considering Severity Level III violations of the requirements. The example for Severity Level III is significant because it represents failures associated with the use of equipment and dosimetry designed to minimize overexposures from radioactive materials.

Backfit Analysis

This final rule does not modify or add to systems, structures, components, or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility. Accordingly, NRC has determined that the backfit rule 10 CFR 50.109 does not apply to this final rule, and therefore a backfit analysis is not required for this final rule because these amendments do not involve provisions which impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 2 and 10 CFR Part 34

Part 2 - Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Civil penalty, Enforcement, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Penalty, Sex discrimination, Source material, Special nuclear material, Violations, Waste treatment and disposal.

Part 34 - Byproduct material, Incorporation by reference, Packaging and containers, Penalty, Radiation protection, Radiography, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Part 2 and 10 CFR Part 34:

PART 2 - RULES OF PRACTICE FOR DOMESTIC LICENSING PROCEEDINGS

1. The authority citation for Part 2 continues to read in part as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. Appendix C, Supplement VI, is modified by adding example 9 to paragraph C to read as follows:

Appendix C -- General Statement of Policy and Procedure for NRC Enforcement Actions

* * * * * * *

Supplement VI -- Severity Categories

C. Severity III. * * *

9. Failure, during radiographic operations, to have present or use radiographic equipment, radiation survey instruments, and/or personnel monitoring devices as required by Part 34.

PART 34 - LICENSES FOR RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHIC OPERATIONS

1. The authority citation for Part 34 is revised to read as follows:

AUTHORITY: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Section 34.32 also issued under sec. 206, 88 Stat. 1246 (42 U.S.C. 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 34.20(a)-(e), 34.21(a) and (b), 34.22, 34.23, 34.24, 34.25(a), (b) and (d), 34.28, 34.29, 34.31(a) and (b), 34.32, 34.33(a), (c), (d) and (f), 34.41, 34.42, 34.43(a), (b) and (c) and 34.44 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b); and §§ 34.11(d), 34.25(c) and (d), 34.26, 34.27, 34.28(b), 34.29(c), 34.30, 34.31(c), 34.33(b) and (e) and 34.43(d) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. A new § 34.20 is added under the Equipment Control heading in Subpart B to read as follows:

§ 34.20 Performance requirements for radiography equipment.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) Each radiographic exposure device and all associated equipment must meet the requirements specified in American National Standard N432 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," 1981 (published as NBS Handbook 136). This publication has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a). This publication may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 and from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018, Telephone (212) 642-4900. Copies of the document are available for inspection at the Nuclear Regulatory Commission Public Document Room, 2120 L Street

NW., Lower Level, Washington, DC 20555. A copy of the document is also on file at the Office of the Federal Register, 1100 L Street NW., Room 8301, Washington, DC 20408.

(b) In addition to the requirements specified in paragraph (a) of this section, the following requirements apply to radiographic exposure devices and associated equipment.

(1) Each radiographic exposure device must have attached to it by the user, a durable, legible, clearly visible label bearing the--

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model number and serial number of the sealed source, and

(iv) Manufacturer of the sealed source.

(v) Licensee's name, address, and telephone number.

(2) Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of 10 CFR Part 71.

(3) Modification of any exposure devices and associated equipment is prohibited, unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

(c) In addition to the requirements specified in paragraphs (a) and (b) of this section, the following requirements apply to radiographic exposure devices and associated equipment that allow the source to be moved out of the device for routine operation.

(1) The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must

also be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

(3) The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

(4) Each sealed source or source assembly must have attached to it or engraved in it, a durable, legible, visible label with the words: "DANGER - RADIOACTIVE." The label must not interfere with the safe operation of the exposure device or associated equipment.

(5) 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.

(6) Guide tubes must be used when moving the source out of the device.

(7) An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during radiographic operations.

(8) The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432.

(9) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All newly manufactured radiographic exposure devices and associated equipment acquired by licensees after (insert a date 1 year from the effective date of the final rule) must comply with the requirements of this section.

(e) All radiographic exposure devices and associated equipment in use after (insert a date 5 years from the effective date of the final rule) must comply with the requirements of this section.

3. In § 34.21 the existing paragraph is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 34.21 Limit on levels of radiation for radiographic exposure devices and storage containers.

* * * * *

(b) Paragraph (a) of this section applies to all existing equipment received prior to (insert a date 1 year after the effective date of the final rule). Five years after (insert the effective date of the final rule), § 34.21 applies only to storage containers (source changers) and all other radiographic equipment must meet the requirements of § 34.20.

4. A new heading "REPORTING" is added and a new § 34.30 is added under that heading to read as follows:

§ 34.30 Reporting requirements.

(a) In addition to the reporting requirements specified under other sections of this chapter, each licensee shall provide a written report to the U.S. Nuclear Regulatory Commission; Division of Industrial and Medical

Nuclear Safety; Medical, Academic and Commercial Use Safety Branch; Washington, DC 20555, with a copy to the Director, Office for Analysis and Evaluation of Operational Data, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

(1) Unintentional disconnection of the source assembly from the control cable.

(2) Inability to retract the source assembly to its fully shielded position and secure it in this position.

(3) Failure of any component (critical to safe operation of the device) to properly perform its intended function, and which could potentially cause a radiation hazard, and which is not correctable as part of the licensee's routine maintenance program other than by replacement.

(b) The licensee shall include the following information in each report submitted under paragraph (a) of this section:

(1) A description of the equipment problem.

(2) Cause of each incident, if known.

(3) Manufacturer and model number of equipment involved in the incident.

(4) Place, time and date of the incident.

(5) Actions taken to establish normal operations.

(6) Corrective actions taken or planned to prevent recurrence.

(7) Qualifications of personnel involved in each incident.

(c) Reports of overexposure submitted under 10 CFR 20.405 which involve failure of safety components of radiography equipment must also include the information specified in paragraph (b) of this section.

5. In § 34.33 paragraph (a) is revised to read as follows and a new paragraph (f) is added to read as follows:

§ 34.33 Personnel monitoring.

(a) The licensee may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each such individual wears a direct reading pocket dosimeter, an alarm ratemeter and either a film badge or a thermoluminescent dosimeter (TLD) except that for permanent radiography facilities where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required. Pocket dosimeters must have a range from zero to at least 200 milliroentgens and must be recharged at the start of each shift. Each film badge and TLD must be assigned to and worn by only one individual.

* * * * *

(f) Each alarm ratemeter must--

(1) Be checked to ensure that the alarm functions properly (sounds) prior to use at the start of each shift;

(2) Be set to give an alarm signal at a preset dose rate 500 mR/hr.

(3) Require special means to change the preset alarm function; and

(4) Be calibrated at periods not to exceed one year for correct response to radiation: Acceptable ratemeters must alarm within plus or minus 20 percent of the true radiation dose rate.

6. In Appendix A, Item II.C, "Use of personnel monitoring equipment," is revised to include:

Appendix A

II ***

C ***

3. Alarm ratemeters

* * * * *

Dated at Rockville, MD, this ____ day of _____ 1989.

For the Nuclear Regulatory Commission.

_____
Samuel J. Chilk
Secretary of the Commission

APPENDIX A TO THIS DOCUMENT -- REGULATORY FLEXIBILITY ANALYSIS
FOR AMENDMENTS TO 10 CFR PART 34 ON
SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC EQUIPMENT

The Nuclear Regulatory Commission is amending its regulations that apply to industrial radiography. These amendments impose additional safety performance standards on radiographic equipment and radiographers are required to wear alarm ratemeters. In addition, the amendments require reporting of failures of radiography equipment to meet safety performance standards in the field.

Industrial radiography performed in the field has been of concern to the NRC and the Agreement States for over 20 years, in part because of its high incidence of overexposure (4 to 5 times that of other radiation workers), and in part because of the potential for serious consequences to both the public and radiographers due to the high activity of the radioactive sources used in this industry. Among the actions considered by the NRC to help alleviate the situation are:

(a) A training manual for radiography personnel,

(b) Improved training programs for individual radiographers,

(c) Increasing inspection time observing actual radiographic operations,

(d) Providing additional guidance for reporting events as required by 10 CFR, and

(e) Establishment of safety requirements for radiographic equipment.

The amendments in this rulemaking fall within category (e) above. They are designed to reduce the potential for overexposures by the

imposition of safety performance standards on radiographic exposure devices and associated equipment and by providing some redundancy in detecting exposed sources by requiring the use of alarming ratemeters.

A total of approximately 1,100 radiography licenses are currently in effect, approximately one-third have been issued by the NRC and the other two-thirds by the Agreement States.

Based upon a recent survey of some 355 NRC radiography licensees and discussions with Agreement State personnel in California, Louisiana, and Texas, (which contain most of the non-NRC radiography licensees) the staff has concluded that approximately 90% of all radiography licensees have annual receipts of less than $3.5 million, the criterion for defining "small entities," specified in Section 605(b) of the Regulatory Flexibility Act of 1980.

Most of the radiography licensees are in the business of nondestructive testing in which radiography represents only a part of their total income. A few small firms work only in radiography. In spite of their classification as small entities, the NRC survey cited above indicated that 76% of the licensees had annual receipts of over $500K and most of the remainder had annual receipts exceeding $250K.

The estimated costs to individual licensees resulting from these amendments consist of an initial cost of $3,636 for the purchase of radiography devices and $1,477 for purchase of alarm rate meters, plus an annual cost of $1,188 for replacement of devices and alarm dosimeters, annual calibration of alarm dosimeters, annual maintenance costs, and reporting and labelling requirements.

A breakdown in the annual cost per licensee given above is as follows:

Replacement of exposure devices (over and above the present cost)	$ 404
Replacement of alarm ratemeters	$ 295
Calibration of alarm ratemeters	$ 227
Ratemeter battery replacement	$ 164
Reporting and labelling requirements	$ 98
	$1188

Although the majority of the licensees fall within the category of "small entities" as defined by the NRC, the Commission believes that the initial and annual costs of the new rulemaking which are described above should not have a significant economic impact on most of the licensees because the costs are small compared to their annual receipts. Further, the Commission has concluded that the benefits that would result to radiographers and to the general public as a result of these amendments outweigh the small cost to the licensees. This final rule does not duplicate or conflict with other Federal rules.

REGULATORY ANALYSIS

FOR AMENDMENTS TO 10 CFR PART 34 ON
SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC EQUIPMENT

1. Statement of the Problem

A total of approximately 1,100 firms currently possess radiography licenses to perform industrial radiography (either at fixed locations or at multiple locations) using gamma rays for the nondestructive testing of pipeline weld joints, steel structures, boilers, aircraft parts and other related items and structures. Approximately one-third of these licenses have been issued by the Nuclear Regulatory Commission and the remaining two-thirds by Agreement States. The firms employ an estimated 5,000 radiographers and radiographer assistants on a full- or part-time basis, but it is estimated that another 5,000 radiography supervisors are also actively engaged in the field for a few weeks each year. An estimated 3,500 radiographic exposure devices (currently manufactured by 3 major companies) are in use, producing tens-of-millions of radiographic pictures per year and utilizing in excess of $20 million worth of radiographic film per year.

In general the industry may be characterized as consisting of firms that conduct their radiography at a single location (36%) and those that conduct their radiography at multiple locations (64%). Approximately 90% are considered to be "small entities" under the criterion established in Section 605(b) of the Regulatory Flexibility Act of 1980. Those operators with the fewest radiographers and devices generally perform nondestructive testing by a variety of methods, only one of which is radiography; and the operators are trained in other methods of nondestructive testing as well.

Radiation exposures received by radiographers have been a concern of the NRC and Agreement States for some time. During the years 1979 through 1983, radiographer overexposures averaged 18% of all overexposures although

radiographers represent only 4% of all radiation workers. These overexposures are usually a result of improper procedures or equipment problems, but the numbers due to each are not well known.

NRC exposure data indicate that equipment problems contribute to approximately 40% of all reported overexposure events. Texas data indicate a much lower incidence of equipment problems (2½%), but exhibit such a high incidence of "unknown" reasons for overexposure (65%) compared to (15%) for NRC data that it is probable that additional equipment problems were contributors to some of these "unknowns."

In 1978 the NRC published an Advance Notice of Proposed Rulemaking (ANPRM, 43 FR 12718) to announce that it was undertaking the development of design requirements for radiographic exposure devices licensed under 10 CFR Part 34 as a means of reducing the number of large radiation exposures to personnel caused by equipment failure. Among the many comments received concerning this ANPRM was the suggestion that the NRC delay further action pending completion of a consensus performance standard for such radiographic exposure devices. In January 1981, a consensus standard, NBS Handbook 136, American National Standard N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" was published.

In March 1980, (partly as a result of a serious radiation accident involving a radiographic device that occurred in California in 1979), an ad hoc Radiography Steering Committee was formed, composed of both Federal and State government representatives, to draft recommendations for improving radiography safety. The Steering Committee subsequently established four task forces to address various aspects of the problem: Radiographic Equipment Design Safety; Training and Certification of Radiographers; Inspection; and Collection and Analysis of Incident Data. The proposed amendments discussed in this regulatory analysis are the product of the first task force listed. They would affect two classes of licensees--radiographic equipment manufacturers and industrial radiography companies.

The proposed amendments are needed at this time as a means of reducing radiography exposures to both radiographers and to the general public. Although

the consensus standard mentioned above was published in 1981, in the very competitive radiography industry, it is not clear that all manufacturers are using the consensus standard, the adoption of which is voluntary until required by regulation. As a result, it is assumed that it has not had its full potential effect on reducing either the rate or the magnitude of radiography overexposures. Failure to take appropriate action at this time would only allow the present rate of radiography overexposures to continue and possibly increase, and could lead to possible tragic incidents involving members of the public as well as workers.

2. Objectives

These amendments are intended to achieve reductions in exposures to radiographers and assure that the public health and safety is protected in applications of industrial radiography that utilize sealed radioactive sources, through the imposition of safety performance standards in those areas where the task force has identified problems and suggested solutions. Incorporation of performance standards in the regulations has the advantage of requiring industrial firms to meet the performance standards rather than relying on voluntary compliance.

3. Alternatives

Three alternatives were considered:

(1) Take no action at this time

(2) Propose new regulatory requirements calling for generally specified safety performance standards and a requirement for radiographers to wear alarm dosimeters; simultaneously issuing a regulatory guide that endorses the standard N432 supplemented by additional performance standards and acceptable methods for meeting the alarm dosimetry requirement.

(3) Incorporate the described requirements in the regulations. This involves incorporation by reference of the consensus standard N432

in the regulations, and the incorporation of such other performance standards as were recommended by the equipment task force, plus a requirement for radiographers to wear alarm ratemeters.

4. Consequences

Alternative (1): Take no action at this time

This alternative would probably lead to no change in the status quo. The number of radiographer overexposures would probably remain about the same, and the probability of serious incidents involving members of the public as well as workers would also be unchanged. This alternative leaves the implementation of the consensus standard, NBS Handbook 136, up to the manufacturers of the radiographic exposure devices. This alternative would entail no additional costs to the NRC and only those costs to industry and licensees that were voluntarily accepted in implementing the consensus standard.

Alternative (2): Propose new regulatory requirements calling for generally specified safety performance standards and a requirement for radiographers to wear alarm ratemeters; simultaneously issuing a regulatory guide that endorses the standard N432 supplemented by additional performance standards and acceptable methods for meeting the alarm ratemeter requirement.

Regulatory guides are issued to provide methods acceptable to the NRC for implementing specific parts of the NRC regulations. They are not substitutes for regulations and compliance with a guide is not required unless it is incorporated into a license. In this alternative, the performance standards are specified in a general manner so that, although the methods outlined in the regulatory guide are acceptable to the NRC as a means of meeting the regulatory requirements, there is no requirement for licensees to adopt them. The cost to the NRC for this alternative involves the cost of formally issuing new regulations associated with alarm ratemeters plus the cost of developing and issuing a regulatory guide.

The NRC estimates a staff effort on the order of 12 person-months at a cost of $7000 per person-month for a total NRC implementation cost of approximately $84,000. The cost to the radiography industry is found in Appendix A to this regulatory analysis and is estimated to be a one time cost of $1,625,000 to provide alarm ratemeters to 5,000 radiographers and radiographer assistants and an annual cost of $863,000 for replacement of alarm ratemeters and batteries, calibration of alarm ratemeters, reporting and labelling. To each of the estimated 1,100 radiography licensees these costs represent a one time cost of $1,477, and annual costs of $784. On a 1989 present worth basis, total industry costs are approximately $14.2 million. No costs associated with improvements to radiographic exposure devices are assigned to this alternative as such improvements are not being proposed as new NRC regulations.

Although surveys indicate that approximately 90% of all radiography licensees qualify as "small entities," the costs cited here are not considered to constitute an undue burden on the industry. No legal or other barriers to the adoption of this alternative have been identified.

Alternative (3): Incorporate the described requirements in the regulations. This involves incorporation by reference of the consensus standard N432 in the regulations, and the incorporation of such other performance standards as were recommended by the equipment task force, plus a requirement for radiographers to wear alarm ratemeters.

In this alternative the specific safety requirements are included as part of the regulations through the incorporation by reference of the consensus standard N432. Licensees would be required to incorporate the specific safety requirements in their exposure devices. The cost to the NRC is projected to be somewhat less than that identified in Alternative 2 because there will be no need to prepare a regulatory guide. Assuming an NRC staff effort of 2 person months (at $7,000 per person month) for the promulgation of new regulations, the NRC implementation cost is approximately $14,000.

The cost to industry includes all of the costs identified under Alternative 2 plus the cost associated with the purchase and replacement of radiographic exposure devices. These latter costs are estimated at $4 million on a 1989 present worth basis plus an annual recurring cost commencing in the year 2000 of $444,000. On a per licensee basis these costs are estimated at $3636 and $404 respectively. The bases of these cost estimates are presented in Appendix A. Coupled with the costs discussed under Alternative 2, this produces industry-wide costs on a 1989 present worth basis of approximately $21.4 million. A corresponding value for individual licensees is on the order of $19,500. No legal or other barriers to the adoption of this alternative have been identified.

5. Decision Rationale

The staff proposes that Alternative 3 be adopted. Alternative 1 is not selected because the objective of this action is to improve public health and safety through the reduction of exposures to radiographers and to the general public by the application of safety performance standards for radiographic exposure devices and the required wearing of alarm ratemeters. Alternative 1 appears to offer no hope of accomplishing this objective. Alternative 2 also fails to address the objective because licensees have the option of adopting the performance standards of N432 as they see fit. Alternative 3 appears to accomplish the desired objective.

While the costs of the proposed amendment have been discussed above and are amplified in Appendix A; the benefits have not. The benefits to be derived from a reduction in potential overexposures by the adoption of these amendments in the regulations is difficult to evaluate on a monetary basis. In general, it is not meaningful to specify an average dose received as a result of a radiography overexposure because the dose could vary from a few rems to a dose sufficient to produce radiation sickness, injury, and even death.

Also, in many of the reported incidents the cause of the overexposure is either unknown or not reported. A more appropriate approach to benefits is to consider the potential benefits that might have accrued in specific incidents such as the 1980 overexposure in Texas that resulted in an individual dose of 200 rems and a potential for a much larger dose that was averted by luck; or the incident in Morocco in 1984 that resulted in the deaths of 8 persons.

6. Implementation

The NRC expects that the various requirements of the rule will be made effective one to five years after the effective date of the final rule. All newly manufactured devices acquired by licensees after one year from the effective date of the rule must comply with the requirements of the rule. All devices in use prior to this date must comply with the requirements of the rule after five years from the effective date of the rule. This implementation schedule was chosen to give manufacturers time to incorporate the new provisions of the rule in the new devices and to allow users time to evaluate the new devices. Also it is doubtful that manufacturers would be able to provide 3500 new devices meeting the requirements on a more accelerated schedule and further, the accelerated schedule could impose a severe financial burden on licensees. Regional inspectors will begin inspecting against the provisions of the new regulation one year after the effective date of the final rule.

This action will affect sections of 10 CFR Part 34 of the Commission's regulations. No effects on other existing or proposed requirements have been identified.

APPENDIX A
COST ANALYSIS

1) Replacement of Radiography Exposure Devices

The costs of incorporating the safety performance criteria for radiographic equipment were developed in 1984 by the Task Force on Equipment Safety Performance Criteria[1], a group composed of both NRC and Agreement State representatives. The cost estimates developed relied upon discussions with major equipment manufacturers as well as the informed judgment of the Task Force members.

Independent of the proposed rule, the staff assumes that there is a continuous need to periodically replace 3500 radiographic exposure devices as they wear out. Based on an assumed operating life of ten years per device[2] it is estimated that on average 10% or 350 devices will be replaced annually. Therefore, a major incremental cost resulting from this proposed requirement is the cost of the additional safety features incurred during these annual replacements. This is estimated at $1268 per device, the basis of which is detailed in Table I. The average annual cost to industry is estimated at $444,000 ((350 devices) x $1268)). On a per licensee basis the average annual cost is $404. For reasons explained below, it is assumed these costs commence in the year 2000.

The staff also recognizes that when this requirement becomes effective in 1995 there will be a need for industry to accelerate its replacement of exposure devices. This is because even devices that are serviceable and have useful remaining lives will have to be discarded in 1995 if they do not contain the enhanced safety features prescribed in the rule. To estimate this cost the

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[1]"Radiographic Equipment Safety Performance Criteria," Task Force on Equipment Safety Performance Criteria, April 30, 1984.

[2]The staff recognizes that the useful life per device can very dramatically depending on such factors as its usage rate, variations in model designs, and site specific conditions. However, based on discussions with manufacturers and licensees, 10 years appears to be a reasonable estimate. If these devices prove to be more durable, the corresponding annual costs would be less than those reported here. Alternatively, shorter useful lives will result in higher annual costs.

staff looked at a ten year period encompassing the 1990 to 1999 time frame[3]. Without the rule, it is expected that industry would continue to replace 10% of its exposure devices per year at a cost of $5000 per device. On a 1989 present worth basis (5% real discount rate) the costs incurred between 1990 and 1999 are estimated at $12.867 million. With the rule in place, it is assumed that during the 1990-94 time frame the industry would continue to replace worn out devices at a rate of 350 per year, but in anticipation of the rule would purchase devices with enhanced safety features at a cost of $6268 per device. In addition, in 1995 when all exposure devices must meet the new safety standards, the remaining 1750 devices would be replaced at a unit cost of $6268. On a 1989 present worth basis this cost stream equals $16.844 million. The cost differential between these two expenditure streams, expressed on a 1989 present worth basis, is about $4 million and can be viewed as the incremental cost of replacing the current generation of exposure devices, some of which would still have a serviceable useful life.

2) Purchase of Alarm Ratemeters

Assuming the purchase of one ratemeter for each of the estimated 5000 working radiographers and radiographer assistants at an estimated cost of $325 each, the total cost to the industry would be $1,625,000. For each of the estimated 1100 licensees the cost would be $1477.

3) Annual Cost for Alarm Ratemeter Replacement

If the estimated average lifetime of the alarm ratemeter is taken to be five years, then the 5000 ratemeters will have to be replaced at the rate of 1000 per year. The annual cost to the industry will then be $325,000 and to each of the 1100 licensees $295.

4) Annual Cost for Alarm Ratemeter Calibration

The average cost of calibration of alarm ratemeters is estimated to be $50 each, based on information from persons who provide such services.

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[3]Since this analysis takes into account the incremental costs incurred through 1999, the preceding analysis begins capturing annual costs commencing in the year 2000.

Since the rule requires an annual calibration, the annual cost of calibrating 5000 ratemeters would be $250,000 to the industry and $227 for each licensee.

5) Annual Alarm Ratemeter Battery Replacement

Battery life for alarm ratemeters depends on the count rate, but the average lifetime appears to be around 200 operating hours or approximately one working month. Most use nine volt transistor batteries that cost approximately $3 each. The costs per ratemeter would therefore be about $36 per year. Cost to the industry would be $180,000 and to each of the 1100 licensees $164.

6) Annual Reporting Requirements

Based on records of past incidents involving radiographic exposure devices, it is estimated that the new reporting requirements specified in §34.30 could result in an additional 50 reports annually. Using an estimate of one hour per report and a cost of $60 per hour the annual cost to the industry would be $3000 or approximately $2.75 for each licensee.

7) Annual Labelling Requirements

The new requirements for labelling specified in §34.20(b)(1) are estimated to require about 1.5 labels per year for Iridium devices. This amounts to 5250 labels per year for the estimated 3500 devices currently in use. The estimated time per label is one third of an hour (20 min) and the costs are estimated to be $20 per label (based on $60 per hour). Annual cost to the industry would then be $105,000 and the cost to each licensee would be $95.

Table 1. Costs for Incorporating Performance Criteria (Adapted from Task Force Report)

Performance Criteria*	Cost Range Per Unit ($)	No. of Exposure Devices	Replacement Frequency Per Year	No. of Units Per Year	Annual Cost Range ($/Yr)
a. Source Pigtail label	.5	3500	2.5	8750	4,000
b. Connector	35	3500	2.5	8750	310,000
c. Lock operable only with source shielded	100-200	3500	0.1	350	35,000-70,000
d. Control removable only with source secured in the shielded position	50-100	3500	0.1	350	17,500-35,000
e. Control operation possible only with source connected	50-100	3500	0.1	350	17,500-3500
f. Automatic source assembly trap mechanism	50-100	3500	0.1	350	17,500-35,000
		Total (if lock box criteria implemented separately)			401,500-499,000
		Point Estimate			444,000

*The following performance criteria are already in use, thus, minimum cost is involved:
1. Pull test of pigtail assembly and drive cable assembly.
2. Guide tube performance criteria.
3. Safety plugs for outlet nipple, lock box, and drive cable fittings.
4. Source assembly cannot be moved through the back of the device.
5. Controls to be marked to indicate the direction of cable movement.

Table 2

Summary of Costs

		Alternative 2		Alternative 3	
		Industry	Licensee	Industry	Licensee
1(a)	Purchase of radiography devices*	$ -0-	$ -0-	$4,000,000	$ 3636
1(b)	Annual replacement of radiography devices**	-0-	-0-	444,000	404
2(a)	Purchase of alarm ratemeters***	1,625,000	1,477	1,625,000	1,477
2(b)	Annual ratemeter replacement****	325,000	295	325,000	295
3)	Annual ratemeter calibration****	250,000	227	250,000	227
4)	Annual ratemeter battery replacement****	180,000	164	180,000	164
5)	Annual Reporting requirements****	3,000	3	3,000	3
6)	Annual labelling requirements****	105,000	95	105,000	95
	1989 Present Worth Total Cost*****	$14.2 Million	$12,900	$21.4 Million	$19,450

*This cost is already expressed on a 1989 present worth basis.
**Annual cost assumed to commence in year 2000 and continue for 20 years.
***One time up front cost incurred in 1990.
****Annual costs assumed to commence in year 1990 and continue for 30 years.
*****1989 present worth based on a 5% real discount rate.....captures costs between 1990 and 2020.

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT

REVISION OF 10 CFR PART 34
SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC EQUIPMENT

The Nuclear Regulatory Commission is amending its regulations that apply to industrial radiography to require additional safety features for industrial radiographic equipment and require that radiographers wear alarm ratemeters.

Environmental Assessment

Identification of Final Action

10 CFR Part 34 specifies the radiation safety requirements for radiographic operations, including performance requirements for industrial radiographic devices, personal radiation safety requirements for radiographers and precautionary procedures in radiographic operations. This revision will specify additional performance requirements for industrial radiographic equipment (Sections 34.20), a requirement for reporting equipment malfunctions (Section 34.30), and additional personnel radiation monitoring requirements for radiographers (Section 34.33).

Need for the Final Action

The number of radiation overexposures and potential overexposures of both radiographers and the general public has been a cause of concern to the NRC for a number of years, primarily because the radiation levels of the radioactive sources used in industrial radiography are sufficient to cause serious injury or death. Although a voluntary consensus standard that incorporates many of the proposed performance requirements has been available since 1981, there is

little evidence that all manufacturers have adopted the standard completely in the manufacture of their equipment.

In addition, a recent NRC analysis indicates that some 40% of all radiography incidents involve equipment problems. In view of these facts, it is felt that regulatory action is needed at this time.

Environmental Impacts of the Final Action

The revision of 10 CFR Part 34 should have no environmentally significant impact. The final performance requirements will involve engineering design modifications and will require radiographers to wear alarm ratemeters, but requirements for energy, water, and materials will be insignificant and no environmental or radiation impact will be involved.

Alternatives to the Final Action

As required by Section 102(2)(E) of NEPA (42 USC 4322(2)(E)), possible alternatives to the final action have been considered. The first alternative considered was to take no action at this time. This alternative is not acceptable since the number of overexposures of radiographers and the general public would continue unabated.

A second alternative considered was to incorporate the additional performance requirement into a regulatory guide. However, since regulatory guides are not substitutes for regulations, compliance with a regulatory guide is not required except in those cases where compliance is specified as a licensing condition. This alternative in effect renders compliance voluntary and makes it unacceptable.

Amendment of the existing regulations was chosen as the best alternative.

Alternative Use of Resources

No alternative use of resources was considered.

Agencies and Persons Consulted

Consultations on the rule have been held with Agreement State representatives from California, Louisiana and Texas. Also, discussions regarding the content and purpose of the rule were held with representatives of radiographic device manufacturers and with representatives of nondestructive testing companies involved in radiography.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the final rule.

Based on the foregoing environmental assessment we concluded that this amendment will not have a significant effect on the quality of the environment.

Document Name:
10 CFR 34 ENVIR ASSE ENCL C

Requestor's ID:
COATES

Author's Name:
NELLIS, D

Document Comments:
WFN ECS 2/17/89 KEEP SHEET WITH DOCUMENT

ANALYSIS OF COMMENTS

Enclosure D

ANALYSIS OF COMMENTS

IDENTITY OF COMMENTERS

Docket File Commenter Number	Commenter
1	State of California (Div. of Occupational Safety & Health) Van Nuys, CA
2	MQS Inspection, Inc. Hartford, CT
3	Liberty Mutual Hopkinton, MA
4	MQS Inspection, Inc. Hartford, CT
5	NDTMA Bethel Island, CA
6	Americon Holding Company, Inc. Copley, OH
7	MQS Inspection, Inc. Hartford, CT
8	Consumers Power Jackson, MI
9	NDTMA Bethel Island, CA
10	Riley-Beaird, Inc. Shreveport, LA
11	Amersham Corporation Burlington, MA
12	ASNT Columbus, OH
13	Edwards Pipeline Testing, Inc. Tulsa, OK
14	Combustion Engineering Windsor, CT

ANALYSIS OF COMMENTS (Continued)

IDENTITY OF COMMENTERS

Docket File Commenter Number	Commenter
15	MQS Inspection, Inc. Elk Grove Village, IL
16	Westinghouse Electric Corporation Pittsburgh, PA
17	Empire Steel Castings, Inc. Reading, PA
18	Amersham Corporation Arlington Heights, IL
19	Industrial NDT Company, Inc. North Charleston, SC
20	MQS Inspection, Inc. Hartford, CT
21	Texas Department of Health Austin, TX
22	Bethlehem Steel Corporation Bethlehem, PA
23	Air Transport Association Washington, DC
24	NDTMA Bethel Island, CA
25	NDTMA Bethel Island, CA
26	Carolina Power & Light Co. Raleigh, NC
27	Duke Power Co. Charlotte, NC
28	Department of the Navy Washington, DC
29	Richardson X-Ray, Inc. Alhambra, CA

ANALYSIS OF COMMENTS (Continued)

IDENTITY OF COMMENTERS

Docket File Commenter Number	Commenter
30	Tech/OPS, Inc. Boston, MA
31	MQS Inspection, Inc. Roseville, MN
32	Globe X-Ray Services Tulsa, OK
33	Ultrasonic Specialists, Inc. Houston, TX
34	Connex Pipe Systems Marietta, OH
35	Harrison Steel Castings, Co. Attica, IN
36	Mason & Hanger-Silas Mason Co., Inc. Middletown, IA
37	Northwest Testing Laboratories, Inc. Portland, OR
38	NASA Kennedy Space Center, FL
39	Florida Power Corporation Crystal River, FL
40	Keokuk Steel Castings, Inc. Keokuk, IA
41	Mobile Inspection Service, Inc. Santa Fe Springs, CA
42	North American Testing Co., Inc. Maryland Heights, MO
43	Mason & Hanger-Silas Mason Co., Inc. Amarillo, TX
44	Newport News Shipbuilding Newport News, VA

IDENTITY OF COMMENTERS

Docket File Commenter Number	Commenter
45	Eastern Idaho Vocational-Technical School Idaho Falls, ID
46	Grove Valve & Regulator Co. Oakland, CA
47	X-Ray Inc. Seattle, WA
48	MQS Inspection, Inc. Indianapolis, IN
49	John Deere Foundry East Moline East Moline, IL
50	Larry Van Fleet Richland, WA
51	Electro Alloys, Inc.
52	E. Lewis Cook & Associates Chattanooga, TN
53	Department of the Air Force Kelly AFB, TX
54	Pensacola Testing Laboratories, Inc. Pensacola, FL
55	Duplicate of 54
56	U.S. Nuclear Regulatory Commission Region I King of Prussia, PA
57	George M. Corney Hilton, NY
58	Riley-Beaird, Inc. Shreveport, LA
59	Litton, Ingalls Shipbuilding Pascagoula, MS

ANALYSIS OF COMMENTS (Continued)

IDENTITY OF COMMENTERS

Docket File Commenter Number	Commenter
60	Industrial NDT Services Indianapolis, IN
61	No Identifiction
62	Duplicate of 32
63	L.H. Sherwin Cincinnati, OH
64	Department of the Air Force Bolling AFB, DC
65	Capital X-Ray Services, Inc. Tulsa, OK
66	Union Carbide Corporation North Kansas City, MO
67	American Airlines Tulsa, OK
68	A. Santascelli Burke, VA
69	Quad City Testing Laboratory, Inc. Devenport, IA
70	Fabrication Inspection Services Harvey, LA
71	MQS Inspection, Inc. Roseville, MN
72	Edwards Pipeline Testing, Inc. Tulsa, OK
73	Professional Welding Associates, Inc. Kewaunee, WI
74	Emar Enterprises El Cajon, CA
75	Joseph F. Bush Avondale Industries, Inc. New Orleans, LA

ANALYSIS OF COMMENTS (Continued)

IDENTITY OF COMMENTERS

Docket File Commenter Number	Commenter
76	Boeing Commercial Airplane Co. Seattle, WA
77	Tenneco Gas Transportation Houston, TX
78	Alabama Power Mobile, AL
79	Central Testing Co., Inc. Lake Charles, LA
80	ASNT (Survey) Columbus, OH
81	George R. Henke Napa, CA
82	Arrow NDE Company, Inc. Broken Arrow, OK
83	Combustion Engineering, Inc. Windsor, CT
84	Air Transport Association Washington, DC
85	Rockwell, International Atchison, KS
86	Source Production & Equipment Co., Inc. St. Rose, LA
87	No Identity Given Orlando, FL
88	Teledyne CAE Gainsville, FL
89	RTS Technology, Inc. North Andover, MA

ANALYSIS OF COMMENTS

SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC EQUIPMENT

The NRC received a total of 88 docketed comment letters and one telephone comment for a total of 89 commenters on the proposed rule. As indicated below, a breakdown of these letters resulted in a total of 68 net valid comment letters.

In addition to the comment letters discussed above, the AMERICAN SOCIETY FOR NONDESTRUCTIVE TESTING, INC., (ASNT), a major trade organization which represents a significant number of radiographic equipment users, polled their membership using a survey questionnaire based on the proposed rule. Responses to the ASNT survey amounted to 399 out of the stated ASNT membership of 7000, the majority of which are involved in alternate means of nondestructive testing that involve ultrasound, eddy currents, microwave techniques, ultra violet sensing and others. The replies and the analysis of the survey were recorded as docket number 80 in this docket.

Because the form of the survey was a multiple choice assignment with three choices; AGREE, DISAGREE, NO OPINION, and since it did not track directly the issues addressed in the proposed rule, it was not included in the current analysis of comments. The results of the survey and the NRC assessment of what it infers are addressed at the end of this analysis of comments.

BREAKDOWN OF COMMENTS

Total received	89
Comment on another rule	4
Request for extension only	5
Duplicates	3
Survey letters without comments	8
Request for copy of rule	1
	21

Net valid comment letters ---------- 68
Additional ASNT survey responses ---------- 399

GENERAL DISCUSSION

The proposed rule contained issues expressed both in sections, such as §34.20; paragraphs, such as §34.20 (c); and sub-paragraphs, such as §34.20(c)(3); all of which were open for discussion and comment. This added to a total of 27 separate issues to be commented upon. Most of the commenters did not make comments on all of the issues but a brief review of the comment letters from many of the larger radiography firms indicate that they responded to comments on at least 10 of the 27 issues. In addition commenters provided a number of additional comments or suggestions to the NRC on how to improve on radiography safety. The following analyzes each of the 27 issues in order and this is then followed by a discussion of additional comments and the NRC response to each of them.

§ 34.20(a) DEVICES MUST MEET REQUIREMENTS OF ANSI N432

Twenty four comments were received on this requirement, eleven or 46 percent approved and thirteen or 54 percent were opposed. Principal comments were as follows:

APPROVED

Commenter

8 • This requirement will make the equipment more reliable and safer to operate.

16 • Approve of the requirement but request a formal administrative requirement for the NRC to notify its licensees of any changes in the consensus standard, in addition to the Federal Register notice announcing the change.

18 • Standard specifications are the basis for well constructed radiographic equipment.

APPROVED (Cont'd)

Commenter

30 • Consensus standard assures practicability of the requirement.

86 • Agree with all parts of the standard except the requirement for section on radiation levels.

OPPOSED

Commenter

21 • The radiation levels specified in the standard may prove not to be cost effective. Radiation levels on equipment have not been found to be a major contributor to exposure.

23 • Opposed because the added shielding requirements would make existing devices obsolete after five years and impose a significant financial burden on users of current equipment.

64 • The added shielding required to meet the specified radiation would limit the portability of the devices.

75 • Opposed due to the cost of replacement devices.

79 • Opposed to all the changes required by the standard until the NRC conducts a survey to show that the proposed changes will make overexposures non-existent.

82 • Finds it unbelievable that the only inferred concept to reduce radiation levels is to trash current devices. Not only is this very expensive but present carrying times are of the order of four minutes per day and the device is seldom in contact with the leg or other parts of the body. The devices currently weigh in the order of forty pounds and additional shielding will result in having to carry the device longer and closer to the body.

OPPOSED (Cont'd)

Commenter

88 • Feels that the conditions of the standard should be restricted to field device use only.

Staff Response:

The principal objection to adoption of this provision appears to be the added shielding needed to meet the radiation levels specified in the standard ANSI N432. Commenters should be aware that the existing radiation level limits were established when lead was the commonly used shielding material and radiographic exposure devices measured four inches or more from the source to the outside of the device. With the use of depleted uranium shielding beginning in the mid sixties it was possible to meet the existing radiation levels with devices that measured around two inches from source to surface of the device. This can lead to surface levels of about 800 mR/hr. Independent studies made in France and the United States indicate that the annual dose to the thigh from carrying radiography devices increased from 5.4 R for the older and larger devices to 11.5 R for the newer smaller devices.

Studies such as the above are the probable basis for the levels specified in ANSI N432. It should be pointed out that the levels specified in the standard were published in 1981, that identical levels have been a part of the international standard since 1977, and that the radiography industry has not been unaware of the new requirements. The fact that several radiographic exposure devices now on the market can meet the new radiation levels and still be portable seems to refute the argument of many of the commenters. The staff also see no reason to restrict the requirements of the standard to field devices particularly since the standard applies to portable, mobile, and fixed exposure devices. The staff see no reason to make any changes in this provision.

§ 34.20(b)(1) EXPOSURE DEVICE LABEL

A total of fourteen comments were received on this issue, all but two approved. The negative comments indicated that the markings should be such that

they cannot be mutilated beyond identification and that the upkeep of proper markings could be costly. The other comment was that the isotope manufacturer must be responsible to provide the customer with the proper label and that guidelines should be prepared to specify label dimensions and method of attachment to allow device manufacturers a standard for design specifications.

Staff Response:

Current industry practice is for the manufacturer to provide a plate to the exposure device user with the source changer and new source. The standard does however provide that the device have a location for attaching this plate (see 4.2). It is the responsibility of the device user to attach the plate. The provision will stand as proposed except one additional item, the name, address and telephone number of the owner will be included on the label. It is the responsibility of the user to keep this information current.

§ 34.20(b)(2) REQUIREMENT TO MEET 10 CFR PART 71
§ 34.20(b)(3) MODIFICATIONS NOT TO COMPROMISE SAFETY

No negative responses were received for either of these two issues. One manufacturer however questioned in whose judgment would modifications affect system design and safety. The manufacturer also asked if this implies that no modifications may be made without resubmission of designs to the proper NRC or Agreement state authority.

Staff Response:

No changes are to be made in § 34.20(b)(2). In regard to the comment concerning modifications, the intent of this provision is to prohibit users from making modifications that could compromise the safety of the device. The provision is not intended to impose design restrictions on manufacturers. No changes are to be made in § 34.20(b)(3).

§ 34.20(c)(1) SOURCE ASSEMBLY-CONTROL CABLE CONNECTION

Twenty two comments were received on this requirement. Fifteen, or 68 percent of the commenters approved and seven, or 32 percent were opposed. The principal comments were as follows:

APPROVED

Commenter

7 • Approve but recommend that whatever coupling is adopted that it be made mandatory and standardized to the point of interchangeability regardless of the manufacturer. This concept of interchangeability should also be extended to apply to all components that attach to the exposure devices.

18 • Approve in principle but feel that the wording in the Texas regulations is more appropriate.

19 • An improved standardized design should greatly reduce inadvertent overexposures. Suggests going even further --- eliminate pigtails. This would be the single best safety improvement of all those proposed. (Note that at least one device now in use has no pigtail.)

30 • Approve but feel the wording should state that a positive force is needed to produce a disconnect.

88 • Agree in principle, but the wording is not too clear. Prefers the screw type connector with a lock.

89 • Might be improved by following the State of Texas wording which emphasizes an application oriented approach as opposed to an engineering approach; this would allow future designs and approaches for abnormal situations.

OPPOSED

Commenter

21 • Don't like the wording. Suggest that we change from technical specifications to performance requirements.

OPPOSED (Cont'd)

Commenter

42 • Unsure of the meaning or which connectors would be accepted.

63 • The wording is ambiguous. Also, it should be specified that a positive force is required for a disconnect. Suggests that wording might specify motion in two orthogonal directions.

64 • This would require moving parts that could fail.

65 • The language is too restrictive.

74 • Feels that disconnects will occur even in fail-safe devices.

Staff Response

1. Staff agrees that the wording should be changed to reflect more of a performance oriented approach. The suggestion has been adopted and the wording changed.

§ 34.20(c)(2) SOURCE POSITION INDICATOR

Forty-two comments were received on this requirement. Four, or 10 percent of the commenters approved and thirty-eight, or 90 percent were opposed. The principal comments were as follows:

APPROVED

Commenter

7 • Should be on all cameras but with the understanding that it is only a guide.

8 • Experience has shown that they are not reliable.

Commenter

10 • Not needed, if survey meter is used.

13 • Could lead to false indications. The additional parts needed could fail.

18 • May be an additional guide but it can also fail. Don't think there are adequate statistics to show that it increases safety.

19 • Those in use have not proven to be fail-safe. Retrofitted ones could be worse.

22 • Should not be required even though the idea is good, --- radiographers won't use survey meters.

28 • May result in negative impact as radiographers may rely on indicator instead of survey meter.

30 • Note that the indicator only indicates the position of the pigtail. If the source falls off the pigtail the indicator is of no use.

32 • Do not think it will improve safety.

33 • Would be a disadvantage at the present time --- a crutch to use instead of a survey meter.

38 • Good idea but it should be emphasized that it is only an additional indicator.

40 • Impractical in a permanent installation.

42 • Have an extremely negative feeling towards.

Commenter

49 • We have one, --- it is not 100 percent accurate and also needs maintenance.

59 • OK if a foolproof and easily visible one can be designed.

60 • Unreasonable, will malfunction and be expensive.

67 • Should postpone this requirement until data are acquired to show how it will improve safety.

79 • Keep cameras simple.

81 • Generally negative about all additions to cameras.

Staff Position

This particular item has long been controversial. At a 1978 NRC meeting convened to discuss the design of radiographic exposure devices, it was generally agreed that it was not possible to design a position indicator that could not fail. It was also pointed out at this meeting that source position indicators consisting of red and green lights were installed on some devices as early as 1958. These failed so frequently that the NRC asked manufacturers to remove them. Also, a provision for such an indicator has been proposed for inclusion in the next revision of the International Radiography Standard, ISO 3999, by the French delegation but there appears to be little support from other countries. In view of the continued oppostion and past experience with these indicators the staff have agreed to remove the provision.

§ 34.20(c)(3) AUTOMATIC SECURING OF SOURCE ASSEMBLY

Thirty-two comments were received on this requirement. Seven, or 22 percent of the commenters approved and twenty-five, or 78 percent were opposed. The principal comments were as follows:

APPROVED

Commenter

7 • This feature should have been made mandatory a long time ago. Devices without this feature should be recalled immediately.

22 • The design should incorporate a requirement that failure of the securing mechanism would not prevent a full retraction of the source into its shielded position in the device.

30 • It should avoid inadvertent operator errors.

60 • A good idea if it would work properly.

86 • Strongly approve, but want to include the option of operating the unsecuring operation from a remote position.

OPPOSED

Commenter

8 • Thinks it will add to the complexity of the devices.

18 • Will need added maintenance and it is unclear that it would be cost effective.

19 • Retrofitting will probably result in increased exposures. Models that already have this feature have failed, -- locking the source outside the device rather than inside.

32 • Do not think it will improve safety. Tech-Ops model 900 which has this option can be defeated by taping the locking knob in the upright position.

33 • Could be a problem maintenance wise. Also personnel could by-pass it if it caused aggravation.

35 • Complicates exposure sequence, --- it also could be bypassed.

Commenter

38 • Opposed. Costs too much to modify equipment and replacement costs are also high.

40 • Feel that it is unnecessary. Our procedures presently call for the radiographer to lock the projector and also the cranking device itself.

42 • Extremely negative response. Lack of maintenance or work in hostile condition could cause problems.

43 • Will need maintenance and will not be cost effective. Object to having to manually reset device after each shot.

47 • Will lessen dependence on surveys.

49 • Reduces radiographer's use of survey meter. Also locking devices that secure the control cable greatly increase cable wear.

64 • More parts can cause more malfunctions. Also could keep source out of device.

81 • Present equipment is adequate.

84 • Would reduce the use of survey meters. Also certain procedures on aircraft engines would be impossible with this feature.

88 • Could cause source to be locked out.

Staff Position

The staff does not agree that this provision would cause a problem. Many of the incidents involving sources slipping out of the shielded position is due to wear imposed by foot operation of manual locking mechanisms now on existing radiographic exposure devices. The only change this provision will make would

be to require manual unlocking before the next exposure, something that should also be required if present procedures are followed. The provision will remain as proposed.

§ 34.20(c)(4) REQUIRE SAFETY PLUGS OR COVERS

A total of sixteen comments were received on this requirement. All of them approved. There were only three substantive comments received, as follows:

Commenter

65 • Approve of the requirement as long as the covers or plugs are not integrated as a working, moving, function of the device.

74 • Urges that radiography devices be equipped with a receptacle of some sort to hold the covers or plugs and keep them clean. Taping them to the camera as has been practiced by some radiographers, results in a sticky residue which attracts grit which then works its way into the device when the covers are put in place and tends to cause internal wear of parts.

89 • Equipment should be required to perform satisfactorily under adverse environmental conditions and it should be left to the manufacturer to determine how to achieve this.

Staff Position

General design conditions under Section 5.1 of ANSI N432 presently call for the exposure devices to be designed with due regard for the need to minimize the entry of water, mud, sand, or other foreign matter into the controls or moving parts. The staff feels that the requirements as stated will require users to use appropriate plugs or covers during storage or transportation. No change is to be made in this requirement.

§ 34.20(c)(5) LABELLING OF SOURCE OR SOURCE ASSEMBLY

A total of twelve comments were received on this requirement. One was opposed and eleven approved. Only two substantive comments were received, as follows:

Commenter

64 • The requirement does not pose a problem if it doesn't interfere with the lock or guide tube operation. However a durable tag that is large enough to be visible without unrolling (leading to a large dose to the fingers) and that doesn't interfere with the operation of the source will be very hard to design. Due to size, engraving will also not be visible until serious overexposure has resulted.

88 • Do not think that this is a practical idea. We should see if it can be done successfully before making it a regulation.

Staff Response

This requirement has been an effective part of the Texas radiation control regulations since October 1, 1987, and while there were a few problems initially, these appear to have been solved. Initially heat shrinkable plastic was used but was found to wrinkle, gum up and even caused sources to hang up in the guide tube. The next attempt was to use a soft metal sleeve containing the required information which was to be crimped tightly on the pigtail. This was found to cause some hang ups in sharp S-tube devices. Currently the method used by most manufacturers involves laser etching of the pigtail. For Texas, the words Danger - Radioactive are etched on the source capsule itself and the serial number of the source is etched on the connector end of the pigtail. The requirement will remain as written in the proposed rule with the understanding that any successful method of labelling, including laser etching, will be acceptable.

§ 34.20(c)(6) GUIDE TUBE CRUSHING TESTS AND KINKING RESISTANCE TEST

A total of ten comment letters were received on this requirement, eight approving and two opposed. The only substantive comments came from the aircraft maintenance community and these are listed below:

Commenter

23 • The thin walled guide tubes used to inspect vane pins on aircraft engines would not meet the kinking and crushing tests proposed.

67 • There are occasions when other types of guide tubes are required, such as braided tubes or stainless steel. How does NRC suggest handling these issues from a regulatory viewpoint?

88 • Some of our guide tubes used in power plant turbines will not pass this requirement.

Staff Response

The provision is left unchanged. Crushing tests are specified in the standard and an acceptable kinking test is outlined in the Public Comment section of the Final Rule. Persons who have special requirements may apply for an exemption under § 34.51.

§ 34.20(c)(7) REQUIREMENT TO USE GUIDE TUBES

A total of three comments were received on this requirement. All were approving. One question was raised and this is listed below:

Commenter

18 • What is the implication of conduits in this requirement?

Staff Response

In the American National Standard N432 under definitions is found the following: SOURCE GUIDE TUBE (CONDUIT)

In the International Standard ISO 3999 the same piece of hardware is referred to as: PROJECTION SHEATH

It is simply a matter of usage and the word has no particular significance except to provide some added clarity. The word conduit has been removed.

§ 34.20(c)(8) REQUIRE THE USE OF EXPOSURE HEADS

A total of eight comments were received on this requirement. All were favorable. One commenter suggested combining this with the next requirement.

Commenter

18 • Why not designate all terminations designed to prevent emergence of the source from the guide tube as requiring a pull test when manufactured?

Staff Response

We think that this is what § 34.20(c)(9) actually says. No changes are to be made.

§ 34.20(c)(9) REQUIRE A GUIDE TUBE TENSILE TEST

Only two comments were received on this requirement, both were in favor.

Staff Response

No changes are anticipated for this requirement.

§ 34.20(c)(10) SOURCE CHANGERS

A total of three comments were received on this requirement. The comments received were as follows:

Commenter

1 • Requirements for source changers should be separated out from this paragraph--- more appropriately as a § 34.20(f).

8 • Source changer design is adequate.

88 • Most source changers leave something to be desired.

Staff Response

Since source changers fall within the category of associated equipment, no need is seen for relocating this provision. The words have been changed slightly to help make the intent of the provision more clear.

§ 34.20(e) COMPLIANCE WITH SECTION 34.20 AFTER 5 YEARS

Twenty-seven comments were received on this requirement. Two, or 7 percent of the commenters approved and twenty-five, or 93 percent were opposed. The principal comments were as follows:

APPROVED

Commenter

76 • Approves of the five year limitation here but requests two and one half years for compliance with § 34.20(d).

OPPOSED

Commenter

2 • This would be a financial burden on users. Also lifetime depends on use, environment, and whether lazy S or sharp S tubes are used.

4 • Feels that the government is trying to help industry sell more devices. The five year limit should be extended to ten years.

13 • Seasonal work extends the lifetime of devices as there is less use. Use, work conditions, type of S tube etc. determine lifetime. Would prefer to see a periodic inspection by manufacturers to determine when to recall devices.

15 • Five years is too short. Cobalt 60 devices are used much less than those with Iridium and should have a longer life. Lifetime depends on type, use, and quality of the maintenance program. Replacement of devices with those complying with the rule should be determined by attrition.

18 • Lifetime is determined by how far the source has to be cranked out as well as by type of S tube and amount of dirt in work area. Could consider revalidating equipment as required for Type B packages under Part 71 with manufacturers assessing the safety and need for replacement.

22 • Existing equipment should have a ten year time frame to comply.

26 • Five years is too short. Some devices have a life expectancy of ten to fifteen years. Also replacement costs are high, ours would be $48,000.

27 • The five year grace period will cause a financial burden. Experience has shown that properly maintained equipment will perform in excess of ten-twelve years.

Commenter

28 • Maintenance record and lifetime of devices used by the Navy appear to be well beyond the five year lifetime estimated in the rule. Also the replacement cost would be prohibitive, $637,500. This would not be a prudent use of funds.

32 • Many devices last longer than five years. Propose that attrition determine the replacement of devices. It is also expensive, our estimate of cost is $111,000, over the five years.

38 • The five year service life is excessively conservative, ten to fifteen years is closer to the norm. If enacted this could result in premature replacement of perfectly safe and useful equipment. Our estimated cost for this replacement is $183,000. If this rule is adopted we recommend two to five years for manufacturers to comply and seven to ten years for users.

64 • Have reservations about setting a time limit for compliance with a standard especially when working models for some of the provisions have yet to be developed and tested.

75 • Lifetime should be more like twelve years. Six out of seven devices purchased in 1967 are still working fine at our company.

77 • Five years is unacceptably short. Equipment should be sent back to the manufacturer or an approved service center for appropriate maintenance every two to three years.

82 • There is only one type 1R device available at present and that is only for Iridium. There are no type 1R devices for Cobalt available, at least in the USA. This firm is presently putting on hold any new Cobalt 60 business as present devices cost $15,000, and would be rendered obsolete by the rule. If the rule passes in its present form this firm will probably have to discontinue business.

Commenter

83 • Experience has shown that properly maintained equipment can safely last ten to twenty years. Our replacement costs would be $60,000.

85 • Our cost of replacement would be $150,000.

Staff Response

The staff is aware that retrofitting of existing radiographic exposure devices to meet the requirements of the rule is not practical, and that meeting the requirements of the rule will therefore involve the purchase of new equipment that meets all the requirements.

The staff is aware too, that the radiography industry is in a period of recession and that, as a result, many smaller radiography firms have gone out of business. A side-effect of this depressed state of the industry has been the creation of a large market in used radiographic exposure devices.

The staff is concerned that many of the devices now in use by the industry may be from 10 to 20 years old, no longer in production, and replacement parts unavailable. Emphasis of this point is shown by the intent of one of the larger device suppliers to issue a notice phasing out of service over a period of 3 years beginning in 1989, certain of the devices it normally services because of unavailability of replacement parts. The staff feels that many other devices with similar problems not subject to this notice are also in use in the market place. This provision will help to phase out of use such unserviceable and presumably, unsafe devices. While many of the commenters feel that this provision will pose a financial burden to users and could result in premature replacement of safe and useful equipment, this view is not shared by the staff. While conceding that the lifetime of many devices may be as much as 10 years, the staff feels that many of the devices currently in use need to be replaced with devices meetings the criteria of the rule. With regard to the charge that compliance with the new rule would constitute a financial burden, it should be pointed out that all equipment in use at the time of publication of the prposed rule will have been in service for a period of more than seven years at the date required for compliance, and would therefore also have been eligible for a

seven year application of its depreciation allowance. This allowance would seem to appreciably reduce the financial burden claimed by the commenters. In addition, the regulatory analysis for this rule indicates that the cost to the industry resulting from implementation of this provision of the rule is of the order of $4 million dollars on a 1989 present worth basis calculated over the ten year interval from 1990 to 1999. The cost to the individual licensee resulting from implementation of this provision of the rule over the same ten year period is $3636. Annual costs over this ten year period are therefore $400,000 for the industry and $364 for individual licensees. In view of the arguments presented here the provision remains as proposed except that the five year period shall start from the effective date of the final rule.

§ 34.21 LIMIT ON EXTERNAL RADIATION LEVELS

Only five comments were received on this requirement, three approved and two were opposed. The three comments of significance are listed below:

APPROVED

Commenter

18 • We support the radiation levels of less than 200 mR/hr at the surface or 50 mR/hr at 5 cm. We also suggest a standard such as maximum surface area to be measured or maximum size of the radiation detector to be used. For radiography exposure devices at 5 cm, large differences in measured dose rates are possible dependent upon the detector size.

OPPOSED

Commenter

21 • Requiring all radiographic equipment to meet the levels specified in ANSI N432 will initially cost licensees a great deal more than indicated without corresponding radiation safety benefit. The outside radiation levels on existing equipment has not been found to be a major contributor to radiation exposures to radiography personnel.

Commenter

86 • We support the incorporation of ANSI N432 except for the condition of reduced exterior radiation levels specified for the following reasons:

(1) There is no evidence of a radiological risk associated with current radiation levels. Without indication of a health hazard, reducing limits based on safety concerns is not justified.

(2) The discussion of radiation levels indicated that surface levels could be as high as 800 mR/hr. Our experience with devices manufactured over the past 15 years indicate maximum levels of approximately 350 mR/yr.

(3) It is not possible to meet the proposed external radiation levels with existing devices. Unless there is compelling justification, the pursuit of ALARA and the necessity for compatibility with DOT and ISO specifications will result in an extreme financial impact on the radiography industry.

Staff Response

The issue of external radiation levels was discussed under comments to § 34.20(a) and will not be repeated here. The final version of this provision will now read five years after the effective date of the rule.

§ 34.30 REPORTING REQUIREMENTS

Sixteen comments were received on this requirement, six, or 38 percent approved and ten or 62 percent were opposed. The only substantive comments were those received from persons opposed to the requirement and the principal comments were as follows:

Commenter

8 • Don't agree with this requirement. Think that reporting of defective equipment should be reported under 10 CFR Part 21.

22 • Approve of the additional reporting requirements for the case of a disconnect or of an overexposure. Feel that the other items are normal maintenance problems that occur on an average of ten times per year. The cost of reporting these is underestimated. We feel that reporting ten of these normal maintenance problems per year would cost us $3300.

27 • This reporting is unnecessary unless there is an overexposure. Better enforcement of existing regulations would go a long way toward reducing violations and overexposures.

38 • § 34.30(a)(3) is ambiguous and open ended, excessive and unnecessary. The sheer volume of documents staggers the imagination. Regulatory monitoring is adequately served by § 34.30(a)(1) and (2).

45 • Reporting equipment failures is difficult and impossible to enforce. Licensees will just not do it.

59 • Agree that significant malfunctions should be reported but that other component failures should merely be filed for NRC inspection and review.

64 • Feel that § 34.30(a)(3) is too all encompassing. Suggest that this be rewritten. Also feel that an annual compilation of all these reported equipment failures be published annually by the NRC.

67 • Should make this a data collection requirement only.

88 • It won't work. Some companies can only afford cheap equipment that is prone to more problems. They won't comply because they know that if they report honestly the equipment will be banned by the NRC.

Staff Response

The staff agrees that item three of these provision was ambiguous and has rewritten it to apply only to components critical to safe operations.

§ 34.33(a) REQUIRE WEARING OF AN ALARM DOSIMETER

Fifty comments were received on this requirement. Eighteen, or 36 percent of the commenters approved and thirty-two, or 64 percent were opposed. The principal comments were as follows:

APPROVED

Commenter

18 • We recommend the use of a modern chirper. Also we should specify an alarm rate meter instead of dosimeter.

23 • The requirement has merit, we are considering purchasing some.

27 • This is a good idea and is widely used in the nuclear power industry. However, calibration or daily checks may be a problem. NRC requires a daily check but does not specify how it should be done -- NRC should specify the criteria for such checks.

30 • Specify alarm rate meter instead of dosimeter. Also modern chirpers should not be banned.

44 • Believe in personal alarms for radiographers but should be able to use state-of-the-art chirpers. Trigger level of 500 mR/hr is much too high.

53 • Concur especially in this requirement but specifies that the alarm should also go off if the device is subject to radiation saturation.

60 • Good precaution but don't like the 500 mR/hr level field test as this would result in unnecessary exposure to the radiographer.

APPROVED (Cont'd)

Commenter

64 • Concur in their use. Don't like the 500 mR/hr alarm level. Also should be aware that they can malfunction and read zero.

73 • Feel that this requirement would do more to protect radiographers than any equipment design change.

79 • We have used audible alarms for ten years and they have cut our overexposures to zero.

OPPOSED

Commenter

2 • Does not address problem. If radiographer cannot adequately monitor his survey meter then two man crews should be required.

4 • Don't need if proper surveys are made. Recommends two man crews for all field assignments.

7 • Survey meters with audible alarms and belt clips are available. If radiographer's hands are full he should have an assistant.

8 • Use of alarm dosimeters should be optional, not mandatory.

10 • Unnecessary when a survey meter is in use.

13 • Have mixed emotions --- in the past some employees used them and became too dependent on the alarms.

15 • Reliance on alarm dosimeters could lead to overexposures.

22 • Object. Management and regulatory agencies need to enforce proper procedures instead.

OPPOSED (Cont'd)

Commenter

26 • Will tend to reduce radiographer's use of the survey meters.

28 • Will result in non-performance of radiation surveys and may have a negative impact on safety. This proposed solution fails to address the basic problem of management control and lack of aggressive enforcement.

33 • Object because of start-up cost and maintenance. Also feel that chirpers should be allowed.

34 • Opposed, chirpers do not work in noisy environments, ---also think that a hearing test may be required of individuals wearing alarm dosimeters.

35 • Is of negligible benefit---- just another piece of equipment that could lead to reduced use of survey meters.

38 • Recommend that this requirement be dropped. Also maintenance and calibration could be costly, $7,800 initially and $2,600 annually.

40 • Our strongest objections are to this requirement. Feel that knowledge and experience of radiographers are the most important items. Request an exemption from this requirement for permanent facilities.

45 • Alarm dosimeters are big, bulky and heavy and can get dropped or damaged. Also radiographers may use them in place of a survey.

48 • Object, use of surveys will deteriorate. Money would be better spent on use of two man crews, each with a survey instrument.

49 • Want to require survey meters with pre-set alarms instead of alarm dosimeters.

OPPOSED (Cont'd)

Commenter

59 • Suggest an alarm on the survey meters in use.

69 • Will encourage radiographers to ignore the survey meter.

71 • Alarm dosimeters will promote complacency in the use of survey meters.

81 • Alarm dosimeters will add little to safety but greatly to users expenses.

82 • Feel that chirpers should be considered. Opposed to trigger level of 500 mR/hr. Wants to know why such high dose rates are allowed for alarm dosimeters when dose rates from devices are limited to 50 mR/hr at five cm.

83 • Radiographers will rely on alarm dosimeters instead of the survey meter.

Staff Response

The staff does not agree with the assumption that radiographers will neglect using survey meters. Also survey meters with alarms do not supply the redundancy of a separate alarm ratemeter since the alarm on the survey meter is connected to the survey meter output and it fails any time the survey meter fails. Sound levels generated by alarm ratemeters are generally loud enough for most environments. The provision has been changed to exempt permanent facilities from this requirement since other alarming or warning devices are already required.

§ 34.33(f)(2) ALARM DOSIMETERS MUST ALARM AT A PRESET LEVEL OF 500 MR/HR

Thirteen comments were received on this requirement. All thirteen, or 100 percent were opposed. No commenters approved. Principal comments were as follows:

Commenter

1 • This may require a check source large enough to require a specific license and could add considerably to the cost impact of the rule.

18 • Believe that this level is too high because it is too difficult to test conveniently.

30 • Should specify an alarm rate meter instead of dosimeter. Believe that the level is too high to test conveniently.

39 • The licensee should be given adequate latitude to determine its own alarm level.

40 • We don't want to use them at a permanent facility where there are already adequate alarm systems.

44 • It should not take a 500 mR/hr field to cause an alarm.

47 • The specified alarm level of 500 mR/hr is too high.

53 • Feel that the recommended 500 mR/hr level is too high a rate to trigger an alarm for Air Force needs.

56 • The 500 mR/hr set point would be inadequate around power facilities. Suggest allowing the alarm setting to be at 100-200 mR/hr above background.

60 • Question the need for a daily response test in a 500 mR/hr field.

64 • Do not agree that the alarm trigger be confined to 500 mR/hr dose rate. We presently use a beeper that beeps according to dose rates and also alarms at an accumulated dose that is pre-set by the user.

82 • Commenter does not want his workers working in a 500 mR/hr environment.

Commenter

88 • Alarm dosimeters are a good idea but the 500 mR/hr dose rate is too high.

STAFF POSITION

Calculations for a 200 Ci Iridium source at a normal operator position (21 foot guide tube and 25 foot control tube) show that the radiation level is approximately 430 mR/hr. Trigger levels of much less than 500 mR/hr would cause the alarm to trip during normal operations and thereby defeat the purpose of the alarm. Licensees that have a problem with this provision may apply for an exemption under § 34.51. The requirement for checking the alarm level at 500 mR/hr on a daily basis remains unchanged. This can be achieved by an electronic check point. Calibration requirements have been changed to require them on an annual basis instead. No other changes have been made.

ASNT SURVEY

The ASNT Survey which was discussed briefly on page 7 consisted of 13 multiple choice questions. A sample of the survey questions is given below along with the fraction of respondents responses to each of the questions. The survey does not track the proposed rule and it is difficult to assess. On the surface it appears that the respondents have a favorable outlook on all aspects of the proposed rule but this conclusion is at odds with the results of people who provided direct comments on the rule.

The American Society for Nondestructive Testing, Inc.
Member Survey Regarding:
Proposed Safety Requirements for Industrial Radiographic Equipment

INSTRUCTIONS

Before answering the survey questions, read all the material contained in this packet regarding the proposed rules. Below, in statement format, are the 11 proposed rules which most directly affect industrial radiographic equipment users. For each proposed rule, you are given the choice of agreeing (being in favor of that proposed rule), disagreeing (being opposed to that proposed rule) or offering no opinion. Two demographic questions are also included. Check only one answer per question. Specific comments or questions about the proposed rules should be sent directly to the appropriate NRC address indicated in the enclosed memo. Comments to ASNT may be provided on additional sheet(s) of paper and returned with the survey.

Please return this survey, NO LATER THAN THURSDAY, JULY 28 to:

ASNT
Attn: Tim Strawn
4153 Arlingate Plaza
Caller #28518
Columbus, OH 43228-0518

Thanks for your interest and co-operation in this effort.

QUESTIONS Total Respondents 399

1. Are you currently or have you previously been a user of industrial radiography equipment?

0.995 Yes 0.005 No

2. Are you sending comments on these proposed rules directly to the NRC in addition to returning this survey to ASNT headquarters?

   0.21 Yes 0.79 No

3. Radiography equipment shall incorporate the provisions of ANSI N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" (reference: National Bureau of Standards Handbook 136).

   0.67 Agree 0.18 Disagree 0.15 No Opinion

4. The coupling of the source assembly to the drive cable shall consist of application of motion in two planes and a positive force in at least one of the planes. The coupling must be designed so that it cannot be unintentionally disconnected.

   9.90 Agree 0.05 Disagree 0.04 No Opinion

5. The exposure device shall be equipped with a visual indicator that indicates when the source assembly is in the fully shielded position and the shutter (if any) is closed.

   0.60 Agree 0.35 Disagree 0.05 No Opinion

6. An exposure head or similar device, designed to prevent the source assembly from passing out the end of the guide tube, shall be attached to the outermost end of the guide tube.

   0.86 Agree 0.11 Disagree 0.04 No Opinion

7. Both ends of the exposure device and the drive cable fittings shall be equipped with safety plugs or covers to prevent damage to the source assembly and prevent the entrance of foreign matter.

0.92 Agree 0.05 Disagree 0.03 No Opinion

8. The exposure device shall be constructed to ensure that when the source assembly is cranked back into the fully shielded position in the device, it shall be automatically secured in this position. It shall only be possible to release this securing system by means of a deliberate operation on the exposure device.

0.75 Agree 0.21 Disagree 0.04 No Opinion

9. Exterior radiation levels from exposure devices shall be reduced to the levels specified in ANSI N432. For portable devices the limits are 200 mR/Hr @ surface or 50 mR/hr @ 50mm and 2 mR/hr @ 1 meter. For mobile devices the limits are 200 mR/Hr @ surface of 100 mR/Hr @ 50 mm and 5 mR/hr @ 1 meter.

0.71 Agree 0.19 Disagree 0.10 No Opinion

10. If the licensee receives a device later than one year after the effective date of the final rule, the device would have to meet all of the requirements of the rule at the time it is received and continue to meet them.

0.78 Agree 0.17 Disagree 0.05 No Opinion

11. All radiographic exposure devices not in compliance shall be withdrawn from use after five years from the date of publication of the final rule unless they are retrofitted to comply.

0.68 Agree 0.26 Disagree 0.06 No Opinion

12. Each radiographer and assistant shall wear an alarm dosimeter.

0.61 Agree 0.35 Disagree 0.03 No Opinion

13. Radiography licensees shall report unintentional source disconnects, failures to retract and secure a source, and the failure of any device component to operate as intended.

0.63 Agree 0.31 Disagree 0.06 No Opinion

Document Name:
COMMENTS/ANALYSIS FINAL RULE

Requestor's ID:
MENDIOLA

Author's Name:
DNellis

Document Comments:
Part of a final rule package.

CONGRESSIONAL LETTER

Enclosed for the information of the Subcommittee is a copy of a final rule amending 10 CFR Part 34 that will be published in the Federal Register.

The Nuclear Regulatory Commission is amending its regulations with respect to those licensees engaged in industrial radiography. This amendment will require that radiographic exposure devices meet specified performance standards and will require that radiographers wear alarm ratemeters to provide supplemental warning of unsuspected unshielded radioactive sources. The amendment is expected to help reduce the incidence of serious radiation exposures to radiographers and members of the general public.

The Commission is issuing the final rule with an effective date 1 year after publication in the Federal Register.

Enclosure E

PUBLIC ANNOUNCEMENT
NRC AMENDS ITS REGULATION ON
SAFETY REQUIREMENTS FOR INDUSTRIAL
RADIOGRAPHIC EXPOSURE EQUIPMENT

The Nuclear Regulatory Commission is amending its regulations dealing with industrial radiographic equipment to establish new regulatory requirements in the form of performance standards for such equipment. A requirement for radiographers to wear alarm ratemeters is also included.

The incidence of radiation overexposure of radiographers occurs at a rate that is double that of radiation workers in other fields. This, coupled with the potential for overexposures to the general public from the high intensity radioactive sources used in the radiography industry, has been a matter of concern to the NRC for some time.

Most of the industrial radiography overexposures are the result of inadvertently allowing the radioactive source to remain out of its shielded position in the exposure device because of improper operational procedures or equipment malfunction. This amendment is intended to reduce equipment malfunction and will require a supplemental warning device for radiographers to alert them to the presence of an unshielded radioactive source, whether caused by improper procedures or equipment malfunction.

Enclosure F