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Proposed Rules

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I concur with the Proposed rule except as noted on Page 8467.

Thanks,
F. G. Santarelli

DS10

NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

Safety Requirements for Industrial Radiographic Equipment

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission proposes to amend its regulations that apply to industrial radiography. Licensees would be required to use radiographic exposure devices and associated equipment that provide additional safety features and radiographers would be required to wear pocket alarm dosimeters. The

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 34

Safety Requirements for Industrial Radiographic Equipment

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On March 15, 1988, (53 FR 8460), the NRC published for public comment a proposed rule to require additional safety features on radiographic exposure devices and associated equipment and to require that radiographers wear pocket alarm dosimeters. The comment period for this proposed rule was to have expired on May 16, 1988. Two letters, and two telephone requests which are to be followed by letters, have been received, requesting an extension of the comment period for periods of time that range from 30 to 180 days. One of the commenters is the Non-Destructive Testing Management Association (NDTMA), a major trade organization representing a significant number of radiographic equipment manufacturers and users.

In view of the importance of the proposed rule and the fact that:

- The rule involved major changes in existing radiographic equipment.
- The industry will require significant time to develop their own cost analysis of the impact of the rule to compare with NRC estimates.
- The industry will require significant time to do a survey of actual device lifetimes to compare with NRC estimates and which is necessary for the cost analysis cited above.

The NRC feels that the present comment period of 60 days allows insufficient time to complete the required analyses. For this reason the NRC has decided to extend the comment period for an additional 90 days. The extended comment period now expires on August 16, 1988.

DATES: The comment period has been extended and now expires August 16, 1988. Comments received after this date will be considered if it is practical to do so but the Commission is able to assure consideration only for comments received before this date.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC, 20555 attention: Docketing and Service Branch. Copies of comments received may be examined at the NRC Public Document Room, 1717 H Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. Donald O. Nellis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3628.

Dated at Rockville, MD, this 16th day of May, 1988.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 88-11337 Filed 5-19-88; 8:45 am]

proposed requirements are intended to ...ce radiation exposures to both ...graphy personnel and the general ...ic from the use of radiographic ...pment. The proposed amendments ...ld affect persons licensed to perform industrial radiography and manufacturers of radiographic equipment. The proposed amendments would not affect x-ray radiography or devices incorporating naturally occurring or accelerator produced radioactive material.

DATE: Comment period expires May 16, 1988. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments filed on or before this date.

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

Hand deliver comments to: Room 1121, 1717 H Street NW., Washington, DC, between 7:30 a.m. and 4:15 p.m. Federal workdays.

Copies of a regulatory analysis and a finding of no significant environmental impact prepared for this proposed rule may be examined at: The NRC Public Document Room at 1717 H Street NW., Washington, DC.

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:

Background

Industrial radiography is a technique of nondestructive testing which uses radioactive sources or x-rays to detect flaws in welds, and cracks, breaks and 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 principal of all of the devices is similar. Most radiography operations involve projecting a radioactive source out of its shielded position within the device; some devices, such as the so called "pipeliner," utilize a shutter to allow the radiation beam to exit from a shielded position within the device.

The general procedure 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 on the item to be examined opposite the film. Next, on the back of the device, a "control cable" is connected to the radiation source; this connection is made to the source assembly, sometimes called a "pigtail" (a short length of wire with the source fastened on one end and a connector to the cable on the other). Use of the "pigtail" allows the connection to be made without directly exposing the radiographer. Finally, 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 twenty feet from the device. This distance provides radiation protection for the radiographer. The next step is to crank (push) the radioactive source from the radiographic device to the end of the guide tube. The gamma-rays from the source penetrate the item under examination and interact with 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 is in its shielded position, and the film is retrieved for development. The radiographer is then ready to proceed with the next exposure.

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 its 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, somtimes 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. As a result, errors in following proper safety procedures may be made by radiographers and these occasionally lead to radiation overexposures. In many cases the required radiation survey is not made and in some instances assistant radiographers have been left to perform the radiography themselves without the direct supervision of the more highly trained and skilled radiographer. Some of the failures of radiography licensees to follow NRC requirements have been documented in a recent NRC information notice.[1]

Radiography 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.

Radiation overexposures are required to be reported to NRC by its licensees. Over the decade ending in 1984 industrial radiography has accounted for more than one-half of the overexposures reported by all NRC licensees greater

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[1] NRC Information Notice No. 87-43, "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) 492-7492.

[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, 1717 H Street NW., Washington, DC 20555.

than 5 rems to the whole body or 75 rems to the extremities and 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. (1984 is the most recent year for which complete exposure data has been tabulated for all NRC licensees.)

During the years 1979 through 1983 radiographer overexposures for both NRC and Agreement States combined averaged 18% of all overexposures, although radiographers represent only 4% of all radiation workers. It is believed that many more incidents occur which do not require reporting in which there is a potential for serious overexposure from the high-intensity, relatively high-energy gamma-ray sources used.

The extreme hazard potential involved in radiography overexposures is shown in at least three cases (all incidents in foreign countries), where children and adults have found lost radiography sources and have died from overexposure. In other cases involving radiographers, the 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) *1980, Texas:* The source assembly (pigtail) 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, one other person an overexposure of 198 rems and thirty-one other persons recieved 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.

(2) *1985, Wyoming:* The source assembly (pigtail) 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 and six members of the general public and one unbadged employee received doses believed to be less than 0.5 rem each.

(3) *1979, California:* The source assembly (pigtail) became disconnected, was cranked out of the end of the guide tube and fell to the ground. No radiation survey was made. An individual 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 review. Ten other persons were exposed with two of them developing radiation burns on their fingers.

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

(5) *1984, Texas:* An assistant radiographer received an overexposure of 7.5 rems for the 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 locking mechanism was defective.

Studies of radiography exposure data have shown that the majority of overexposures to radiographers involve improper retraction of the source, failure of the connecting device to hold the source in the fully shielded position once retracted, and failure of the radiographers to properly perform the radiation surveys required by the regulations.

A major factor in many of the reported overexposures is the failure to follow proper safety procedures. However, NRC data indicate that radiography equipment problems contribute to approximately 40% of all reported overexposure events. The principal causes of reported overexposure in which equipment problems played a contributing role are:

(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 (pigtail) 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 (pigtail) 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 radiograph (to verify that the source is in 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 the first of the causes listed above, the overexposure generally only involves radiographers. In the other three there is considerable potential for exposure to the public as well as radiography personnel.

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, NBS Handbook 136, American National Standard N432, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography" was issued in January 1981. Although the standard incorporates many of the safety design features proposed in the ANPRM, it is a voluntary consensus standard. There was no regulatory requirement for manufacturers to adopt the recommendations of the standard but recent amendments to 10 CFR Parts 30 and 32 formalized NRC's source and device registration process and will ensure that future radiography devices 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 3 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.[3] 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 to be incorporated in the revised standard are the same as those recommended by the equipment task force and included in this proposed rule. However, publication of the revision as a final industry standard may take several years. When issued, NRC will consider if additional rulemaking is appropriate or necessary to incorporate the standard.

While 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 dosimeters, (not chirpers). Alarm dosimeters are radiation detection devices that provide an audible alarm at a preset or selectable dose or dose rate. These devices may also have a visual display or dose or dose rate or both. Also, both dose rate alarm and a dose alarm may be incorporated within the same unit.

Audible-alarm dosimeters 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 dosimeters are not to be substituted for a radiation survey meter but are to be considered a complementary warning device. The use of alarm dosimeters 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 alarm dosimeters. 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 dosimeters are considered reliable and hold up well with proper use. They would 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 of alarm dosimeters be incorporated in the proposed rule.

Discussion of the Proposed Amendments

Section 34.20(a)

This paragraph incorporates American National Standard N432 by reference into NRC's regulations and will require that future radiography equipment meet the specifications of this standard. The standard addresses performance requirements for radiography devices, source assemblies, and controls. Examples of the requirements specified in the ANSI standard are:

a. Radiography devices and controls will be classified according to handling and operational characteristics. Crank-out devices will be classified as "Type 1" and pipeliner devices as "Type 2." Remote controls will be designated as "Type R" and local controls as "Type L." Local controls may only be used on Type 2 devices.

b. Exposure devices will be marked with the radiation symbol and will display a radiation warning label.

c. Exposure devices, controls, and source assemblies will be expected to meet certain design and construction criteria. Examples include: resistance to stress of use (e.g., the effects of radiation, temperature, and working conditions); appropriate locking mechanisms; adequate control and guide tube connectors; crank direction markings on the control; and control/lock assemblies that will not allow the source to be exposed unless the control is properly connected and the source assembly-drive cable connection properly made.

d. Prototype exposure devices, controls, and source assemblies will be expected to pass certain tests, such as: shielding efficiency, horizontal and vertical shock, accidental drop, stress, crushing, tensile strength, and endurance.

Present 10 CFR Part 34 requirements which limit exterior radiation levels will be replaced by those specified in the ANSI standard. The existing limit of 50 mR/hr at 6 inches (15 cm) was established when lead was commonly used for shielding and before the use of depleted uranium in radiographic devices. With the use of lead, most of the small devices were close to 4 inches (10 cm) in radius and the maximum surface levels were about 300 mR/hr. With the use of depleted uranium, the distance from source to surface can be on the order of 2 inches (5 cm) and a limit of 50 mR/hr at 6 inches (15 cm) can cause radiation levels of 800 mR/hr at the surface. The ANSI standard would limit exterior radiation levels, on portable devices for example, to 200 mR/hr at the surface or 50 mR/hr at 5 cm but in either case not to exceed 2 mR/hr at 1 meter from the surface. The lower external radiation levels for portable and mobile devices should result in lower exposure rates for users of those devices, particularly to that part

[3] S.A. McGuire and C.A. Peabody, "Working Safely in Gamma Radiography" NUREG/BR-0024, U.S. Nuclear Regulatory Commission, September 1982.

[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.

[5] Regulatory guide 8.28 is available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC. 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.

of the user's body that may be in contact with the surface of the device.

In addition to providing the lower limits, ANSI N432 would provide an alternative to determining radiation levels on the surface of the device. Evaluation of surface radiation levels has frequently caused misunderstandings with respect to acceptable procedures. For almost all kinds of radiation measuring instruments, a determination of surface radiation levels requires a combination of an instrument reading and a calculation. The calculation is needed because the instrument reading reflects the radiation level at some location (often the geometric center) within the radiation sensitive chamber of the instrument, and that radiation level may not be the same as the level at the outer surface of the instrument. Under the alternative to determining radiation levels at the surface of the device, the determination may be made at 5 cm from the surface. By specifying a 5 cm distance, determinations can be made directly with many instruments without resorting to calculations. An acceptable procedure for determining the radiation levels near the radiographic exposure device and the amount of radioactive material that the device can contain is given in ANSI N432. Other procedures also may be used for this determination.

Section 34.20(b)

This paragraph would require that a label be displayed on exposure devices with information identifying the sealed source radionuclide, its activity, and the manufacturer and model number. The paragraph would also require that devices to be used as Type B transport containers meet the applicable requirements of 10 CFR Part 71.

Section 34.20(c)

This paragraph would have "crank-out" type exposure devices and associated equipment meet additional performance criteria not specified in ANSI N432. The major provisions of this paragraph are:

a. Require the use of a source assembly to drive cable coupling which requires motion in at least two directions with a positive force in one direction in order to complete the connection. The coupling would also need to be designed, and the manufacturer would be expected to demonstrate, that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

b. Provide a visible source position indicator on radiography devices. The object of this provision is to assure a means for the radiographer to observe at the device and see a clear indication that the source is or is not in the shielded position. The [illegible] should be designed such that [illegible] readily foreseeable abnormal conditions it would not falsely indicate the position of the source. Designs which use source assembly ball stop as the "trigger" which have been prototype tested in accordance with ANSI N432 would be acceptable. The visual indicator is not intended to substitute for use of a properly functioning radiation survey meter. The indicator is simply another means of providing safety information to the radiographer about the position of the source.

c. Radiography devices would have to provide a system to automatically secure the source assembly when it is cranked back into the device and a deliberate operation would have to be performed on the device in order to release the source assembly. This provision should help to eliminate the problem of the source accidentally moving out of the safe storage position after it is returned to the device.

d. The sealed source or source assembly would be labelled: "danger—radioactive." This assembly is commonly called the "pigtail" and usually consists of a sealed radiation source, ball stop and connector attached to a flexible wire cable. The entire assembly is comparable in size to a pencil. Labelling of the source assembly should help minimize overexposures if a member of the public finds a lost source assembly. The label should be designed to withstand the intense radiation and to not weaken the structural integrity of the source assembly or interfere with its use in the device.

e. The guide tubes to be used with exposure devices would be expected to pass the crushing tests for control tubes as specified in ANSI N432. Also the guide tube must pass a kinking resistance test that closely approximates the kinking forces likely to be encountered during use. 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 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.

In addition, the proposed rule would require the use of an exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube and that the guide tube to exposure head connection be able to withstand the tensile test for control units specified in ANSI N432. The object of these provisions is to ensure the use of appropriately manufactured guide tubes in radiography. The use of an exposure head and an improved source to drive cable connector should be help to eliminate the risk of accidental source loss.

f. The proposed rule would require that source changers provide a system for securing the source assembly in the safe storage position when connecting the drive cable to the assembly. The system should help to reduce unnecessary exposure which could result with a changer where the source is not secure.

g. The proposed rule would prohibit modifications that could compromise the safety features of the system.

Section 34.21(a)

This paragraph continues the present requirements of § 34.21 which limit the radiation levels exterior to radiography devices and certain other equipment. These requirements apply to all existing equipment received prior to one year after the final rule date. The allowance for these limits for exposure devices will be superseded by new requirements five years after publication of the final rule as indicated in § 34.21(b).

Section 34.30

This new section to Part 34 would require licensees to report certain problems they experience with radiographic equipment. Presently,

personnel overexposures are required to be reported to NRC under 10 CFR 20.405. While this section does require that the cause of the overexposure be described, it does not request specific information concerning equipment malfunctions which may have led to the overexposure. 10 CFR Part 21 provides requirements for reporting defects or noncompliance of a basic component in which a defect or failure could cause a substantial safety hazard. However, this part is most applicable to the nuclear power industry and its suppliers. As a result, NRC receives little information concerning radiography equipment malfunctions. The effectiveness of new regulations should be evaluated on a routine basis. This can be best accomplished by requiring licensees to report equipment failures to NRC.

The proposed rule would require licensees to report any event where the source assembly becomes unintentionally disconnected from the drive cable (i.e., failure of the coupling); the source cannot be retracted and secured; or any component of the device fails to operate as intended. The report would include information describing the problem, its cause, identifying the equipment and its manufacturer, when the problem occurred, and the actions taken to correct the problem. If an overexposure occurred in connection with an equipment problem, the report submitted under § 20.405 must also include the above information.

Section 34.33

This section would be amended to include a requirement for the licensee to provide an alarm dosimeter to each radiographer and assistant. The alarm dosimeter would have a pre-set signal which would sound if the individual enters a 500 mR/hr radiation field. The 500 mR/hr set point should be sufficiently low to provide a reliable alarm before a radiographer could get within about 10 feet of a lower activity unshielded source. With higher activity sources, this set point should avoid spurious alarms due to radiation levels close to the camera with the source in the fully shielded position or during routine operations provided radiography personnel are exercising proper use of distance and shielding to avoid unnecessary exposure. The dosimeters would also need to be checked prior to first use each day to ensure that the alarm sounds and would have to be tested on an annual basis for an acceptable response to radiation.

Numerous alarm dosimeter types are on the market, the majority of which provide a digital display of the integrated dose in addition to alarm features. Licensees may find the use of an integrating dosimeter that also incorporates the required dose-rate alarm desirable, but it is to be understood that use of these dosimeters does not relieve the licensee of other requirements in the regulations such as that contained in § 34.33(d) which requires the processing of TLD's or film badges when pocket dosimeters go off scale.

Implementation

As proposed, the dates on which particular requirements become effective depend on when the licensee receives the radiographic exposure device.

If the licensee now has the device or receives a device prior to one year after the effective date of the final rule no immediate action is required.

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.

Five years after the effective date of the final rule all devices would be required to meet all the conditions of the rule or be retired from use. Five years was selected based upon discussions with equipment manufacturers, and upon staff experience that indicates that devices which project the source out of its shielded position have an estimated average lifetime of around 5 years and to minimize the impact on small businesses. However, NRC also recognizes that this average life expectancy is dependent on the device and its amount of use.

Under this proposed schedule equipment manufactures are expected to have a reasonable period to produce exposure devices which satisfy all the new requirements. This schedule would provide users with sufficient time to retire old equipment. The need to implement the new requirement does not appear sufficiently urgent to require earlier dates; however, if a significant decrease in safe performance of devices should occur, an earlier implementation date for particular requirements will be considered.

The NRC requests that persons commenting on the proposed amendments particularly address any anticipated hardships that may result from the proposed implementation schedule. Comments regarding anticipated costs to manufacturers and to users of implementing the proposed amendments will be most useful if they include a breakdown that is keyed to the individual requirements in the proposed amendments.

The proposed amendments would not change the present regulatory requirement that the applicant for a radiography license propose the use of equipment (radiographic exposure device) that is adequate to protect health and minimize danger to health or property. The applicant usually satisfies this requirement with respect to the radiographic exposure device by identifying in the application the manufacturer and model number of the device that will be used. The NRC technical reviewer of the application relates the identified device to safety information that was filed by the radiography equipment manufacturer with the NRC or an Agreement State. If the safety information on file indicates the identified device to be acceptable for licensing purposes, then the regulatory requirement for an adequate radiographic exposure device is satisfied. Recent amendments to 10 CFR Part 30 and 10 CFR Part 32 have formalized the administrative practice under which manufacturers filed safety information concerning their products with the NRC in a process called registration. This formalization of procedures assures that all future models of radiography devices approved for distribution by NRC will at least meet the requirements of NRC regulations and the current requirements of ANSI N432 as described under 10 CFR 32.210.

Summary

The proposed amendments are directed toward improving the safety of radiographic exposure devices and associated equipment and reducing the number of overexposures that occur to both radiographers and the public. The changes proposed are in the form of performance standards because it is recognized by the Commission that the radiography equipment manufacturers should have flexibility in the area of construction and design standards. Also the adoption of voluntary consensus standards in government regulations is recommended in OMB circular No. A-119, "Federal Participation in the Development and Use of Voluntary Standards." In addition, since the revised regulations will require radiography devices to meet the performance standards, a new section is to be added to the regulations to require the reporting of failures to meet these standards, particularly those involving source assembly disconnects and failures of the automatic securing device. The regulations will also be amended to require the use of alarm

dosimeters by radiographers and radiographer assistants.

This rule would apply to all licensees using radiographic exposure devices under 10 CFR Part 34. The rule would also affect the manufacturers of radiographic exposure devices because licensees could not use, and therefore would not purchase, devices which failed to meet the proposed performance standards. Additional costs would be incurred by licensees in the purchase of alarm dosimeters to be used by their radiographers and radiographer assistants and in annual calibration and maintenance of these dosimeters. Some additional costs will also be incurred for labelling under § 34.20(b)(1) and reporting under § 34.30. It is expected that the final rule would impose performance standards on all radiographic exposure devices manufactured one year after the publication date of the effective rule and would require that all radiographic equipment in use meet the performance standards within five years after publication of the final rule. There are an estimated 3,500 radiographic exposure devices in use, including pipeliner type devices. Devices which project the source out of its shielded position have an estimated life-time of around five years so that many, if not all would have to be replaced within five years even if the regulations under consideration are not issued. NRC anticipates that most of the pipeliner type of devices currently in use will meet the proposed requirements.

Impact

The impact on the radiography industry is expected to be moderate. The regulatory analysis accompanying this rule indicates that some 3,500 radiographic exposure devices are currently in use, distributed among approximately 1,100 licensees or approximately 3 devices per licensee. There are also approximately 5,000 radiographers and radiography assistants employed on a full- or part-time basis and an estimated additional 5,000 radiography supervisors who are actively engaged in the field for a few weeks each year. the costs of implementing the proposed changes in radiography devices have been estimated at approximately $150 per device, and the average cost of providing alarm dosimeters to radiographers is $325 per dosimeter. If the average licensee is assumed to have three radiography devices which have an average lifetime of 5 years and 5 full time radiographers the added cost per licensee amounts to $1,625 for the initial purchase of alarm dosimeters and a $930 annual cost for replacement of devices and dosimeters, maintenance reporting, and labelling. The regulatory flexibility analysis, set out in Appendix A of this document presents a more detailed analysis of the costs involved.

Finding of No Significant Environmental 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, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and therefore an environmental impact statement is not required.

The proposed rule will involve engineering design modifications and significant creative engineering may be involved but no requirements for significant quantities of materials, water, electricity or other forms of energy have been identified and no environmental or radiation pollution will be 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, 1717 H Street NW., 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 proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street NW., 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.

The Commission requests public comments on the draft regulatory analysis. Comments may be submitted to the NRC as indicated under the ADDRESSES heading.

Regulatory Flexibility Analysis

The NRC has prepared a regulatory flexibility analysis on 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 the proposed rule could have an economic impact of about $1,625 initially, and $930 annually on each radiography licensee, 90% or more of which are considered to be small entities. These costs are not considered to be overburdensome in light of the possible benefits derived.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size in terms of annual income or revenue and number of employees;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that on a large licensee; and

(c) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities.

Backfit Analysis

This proposed 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, no backfit analysis pursuant to 10 CFR 50.109(c) is required for this proposed rule.

List of Subjects in 10 CFR Part 34

Byproduct material, 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 proposing to adopt the following amendment to 10 CFR Part 34:

PART 3—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)–(c), 34.21(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. 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, 1717 H Street NW., 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. A notice of any change in the material will be published in the **Federal Register**.

(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.

(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 such that the application of motion in two planes and a positive force in one of these planes is necessary to complete the connection. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

(2) The device must be equipped with a readily visible source position indicator which, under normal and reasonably foreseeable abnormal conditions, will not falsely indicate the position of the source.

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

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

(5) 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.

(6) 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.

(7) Guide tube conduits must be used when moving the source out of the device.

(8) 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.

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

(10) Source changers must provide a system for assuring that the source will not be accidentally withdrawn from the changer when the drive cable is being connected to the replacement source assembly.

(d) All new radiographic exposure devices and associated equipment acquired by licensees after (insert a date one year from publication of the final rule in the Federal Register) must comply with the requirements of this section.

(e) All radiographic exposure devices and associated equipment in use after (insert a date five years from publication of the final rule in the Federal Register) 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 shall apply to all existing equipment received prior to (insert a date one year after the publication date of the final rule). Five years after (insert the date of publication the final rule) § 34.21 shall apply only to storage containers and all other radiographic equipment must meet the requirements of § 34.20.

4. Section 34.30 is added 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 to properly perform its intended function.

(b) The licensee shall include the following information in each report submitted under paragraph (c) 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.

(c) Reports of overexposure submitted under 10 CFR 20.405 which involve failure of safety components of radiography equipment must 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 shall 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 dosimeter and either a film badge or a thermoluminescent dosimeter (TLD). 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 dosimeter must—

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

(2) Emit an alarm signal at a preset dose-rate of 500 mR/hr;

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

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

6. In Appendix A, Item II.C is amended to add an item 3. to read as follows:

Appendix A

II * * *

C * * *

3. Alarm dosimeters

* * * * *

Dated at Washington, DC, this 10th day of March 1988.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

Appendix A to This Document—Regulatory Flexibility Anslysis for Amendments to 10 CFR Part 34 on Safety Requirements for Industrial Radiographic Equipment

The Nuclear Regulatory Commission proposes to amend its regulations that apply to industrial radiography. The proposed amendments would impose additional safety performance standards on radiographic equipment and radiographers would be required to wear alarm dosimeters. In addition, the proposed amendments would 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 its 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 proposed in this rulemaking fall within the last action category 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 dosimeters.

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, the staff had concluded approximately 90% of all radiography licensees have annual receipts of less than $3.5 million, the criterion for defining "small entites," 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 the 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 the proposed amendments consist of an initial cost of $1,625 for the purchase of alarm dosimeters and an annual cost of $830 for replacement of devices and alarm dosimeters, annual calibration of alarm dosimeters, and annual maintenance costs. In addition, it is estimated that the reporting requirement on defective equipment and the requirement for labeling the devices specified in § 34.20(b)(1) will result in an annual cost to each licensee of about $100.

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

Replacement of exposure devices	$100
Replacement of alarm dosimeters	325
Annual maintenance of dosimeters	180
Calibration of alarm dosimeters	225
Reporting and labeling	98
	928

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

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