Proposed Rules

Federal Register
Vol. 63, No. 178
Tuesday, September 15, 1998

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 36

[Docket No. PRM–36–1]

American National Standards Institute N43.10 Committee; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) has received and requests public comment on a petition for rulemaking filed by the American National Standards Institute N43.10 Committee. The petition was docketed as PRM–36–1 on June 25, 1998. The petitioner requests that the NRC amend its radiation safety requirements for irradiators to allow the operation of panoramic irradiator facilities without continuous onsite attendance.

DATES: Submit comments by November 30, 1998. 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 received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Rulemakings and Adjudications Staff.

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

For a copy of the petition, write: David L. Meyer, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

You may also provide comments via the NRC's interactive rulemaking website through the home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports the function. For information about the interactive rulemaking website, contact Carol Gallagher, 301–415–5905 (e-mail: CAG@nrc.gov).

FOR FURTHER INFORMATION CONTACT: David L. Meyer, Office of Administration, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001. Telephone: 301–415–7162 or Toll Free: 800–368–5642 or e-mail: DLM1@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

The NRC's current regulations at 10 CFR 36.65 (a) and (b) describe how an irradiator must be attended during operation. The regulations specify that:

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

(1) Whenever the irradiator is operated using an automatic product conveyor system; and

(2) Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in § 35.51(g) must be onsite.

The petitioner states that at the time this regulation was published (February 9, 1993; 58 FR 7715), the intent was to ensure that appropriately trained personnel were available to provide prompt response to emergencies or abnormal event conditions that could occur during the operation of a panoramic irradiator. The petitioner further states that based on case histories of accidents at panoramic irradiators and on the potential for automatic conveyor systems to malfunction, the regulation was designed to ensure that individuals responding to an abnormal event be physically located at the irradiator site to render assistance promptly.

The Suggested Revisions

10 CFR 36.65 (a) and (b)

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond to alarms as described in § 36.51(g) and prepared to promptly render or summon assistance, shall be present onsite whenever it is necessary to enter the radiation room.

(b) At least one individual who has received the training on how to respond to alarms described in § 36.51(g) must be available and prepared to promptly respond to alarms, emergencies, or abnormal event conditions at any time a panoramic irradiator is operating. If the individual is not onsite,

(1) Automatic means of communications must be provided from the irradiator control system to alert the individual to alarms, emergencies, or abnormal event conditions. As a minimum, the automatic communication system must alert the individual to those emergency or abnormal events listed in § 36.53(b);

(2) The irradiator control system must be secured from unauthorized access at any time an irradiator operator is not onsite. This security must include physically securing the key described in § 36.31(a) from being removed from the control console.

10 CFR 36.61(a) ''Inspection and Maintenance''

(17) Operability of automatic communications systems used to alert individuals to alarms, emergencies, or abnormal event conditions if required by § 36.65(b)(1).

10 CFR 36.2 ''Definitions''

Onsite means within the building housing the irradiator or on property controlled by the licensee that is contiguous with the building housing the irradiator.

Grounds for Request

The petitioner states that the current requirements dictate that personnel be employed to maintain adequate coverage on all shifts of a continuously operating panoramic irradiator facility. However, according to the petitioner, based on both domestic and international operational experience with these large irradiators, there is no significant benefit to safety from having an individual onsite as opposed to being available to respond promptly from an offsite location.

In addition, the petitioner states that the number of personnel required to operate and safely manage an irradiator has a substantial impact on the expense associated with conducting business, that personnel expenses in salary,

benefits, insurance, training, and affiliated costs must eventually be passed on to customers. The petitioner offers that employing a minimal number of employees without compromising safety provides an opportunity to optimize cost containment without eroding the facility's financial ability to maintain operations.

Supporting Information

The petitioner states that panoramic gamma irradiators are designed to require minimal or no operator intervention with the system to continue routine operations following start-up. The petitioner notes that although the current regulations require the operator and other individuals to be onsite during routine product processing, their involvement with the irradiator controls or safety systems is minimal while the product is being irradiated during normal operations. The petitioner asserts that human intervention is required only during emergencies or abnormal events. Controlling the response to emergencies and abnormal events, such as those listed in 10 CFR 36.53(b) according to the petitioner, requires intervention by the operator or other appropriately trained personnel to evaluate the situation and determine whether actions need to be taken and what specific action would be required. The petitioner believes that the need to have individuals physically present onsite during operation is governed by the potential need to respond to emergencies and abnormal events.

The petitioner states that at the time part 36 was published, the best method for alerting individuals to emergency or abnormal event conditions was considered to be audible and visible alarm systems that would annunciate within the facility, and that individuals responsible for responding to the alarms would be onsite to answer the alarms promptly. However, the petitioner notes that with recent improvements of communications technology, including wireless communications, and in continuing improvements in process control technology, alerting an individual to an abnormal event in an operating system does not have to rely solely on audible and visible signals within the facility to ensure that the alert is made. The petitioner offers that automated alert systems can now be easily designed to provide an offsite alert to an individual available to respond promptly through technologies such as pagers, cellular telephones, land-line telephones, remote process control monitoring, or other methods. If the offsite individual, according to the petitioner, is located so as to be available to respond promptly, response to alarms could require only a slightly longer time than if the individual were onsite.

The petitioner notes that the irradiator operator makes the first response in the event of an emergency or abnormal event. Under the conditions of the current regulations, the implicit assumption is that, during evening or night shifts when the facility management or the Radiation Safety Officer (RSO) are not assumed to be present, the irradiator operator would respond to the alert and assess the situation. The petitioner states that in typical emergency procedures for panoramic irradiators, one of the first responsibilities of the irradiator operator responding to an alert, is to notify the RSO of the condition, and to rely on the RSO or facility management to provide specific instructions to take in responding to the emergency. Therefore, the initial response by an irradiator operator onsite during an abnormal event would be to secure the irradiator against entry and notify the RSO or other responsible party.

The petitioner states that for response to any emergency situation, appropriate actions must be taken to prevent individuals from entering the radiation room while the sources are unshielded (i,e., to prevent personnel exposures) and to protect the sources from damage. The petitioner lists the 10 emergency and abnormal event conditions identified in 10 CFR 36.53(b) for which a licensee must implement procedures to address. These are: (1) Sources stuck in the unshielded position; (2) Personnel overexposures; (3) A radiation alarm from the product exit portal monitor or pool monitor; (4) Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water; (5) A low or high water level indicator, and abnormal water loss, or leakage from the source storage pool; (6) A prolonged loss of electrical power; (7) A fire alarm or explosion in the radiation room; (8) An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area; (9) Natural phenomena, including an earthquake, a tornado, flooding, or phenomena as appropriate for the geographical location of the facility; and (10) The jamming of automatic conveyor systems.

The petitioner states that 10 CFR part 36, subpart C specifies the design features of a panoramic irradiator that address most of the items from the list in terms of preventing personnel exposures and damage to the sources during an abnormal event. Specifically, the petitioner states that access control system as described in 10 CFR 36.23 will prevent unauthorized entry and protect against personnel exposure (item 2 on the list). In 10 CFR 36.39, the conveyor system must automatically be stopped if the exit radiation monitor detects a source (item 3). Sources must be returned to the shielded position and access controls maintained during a prolonged loss of electrical power as described in 10 CFR 36.37 (item 6). A fire protection system designed to meet the requirements of 10 CFR 36.27 will cause the sources to return to the shielded position in the event a fire is detected, thereby protecting the sources from fire damage (item 7). Unauthorized entry to the radiation room must, under 10 CFR 36.23 (a) cause the sources to return to the shielded position (item 8). If an automatic conveyor system jams, the source rack protection required by 10 CFR 36.35 ensures that some cause other than interference with the source rack is the cause of the jam, which will allow the sources to be safely returned to the shielded position (item 10).

The petitioner contends that in the remaining abnormal event conditions listed in 10 CFR 36.53, appropriate response to the conditions would not necessarily be required immediately. That is, responding to the event would entail some evaluation of the conditions before deciding the proper actions to take. The petitioner believes that having individuals onsite to respond to these conditions would not present a substantive improvement in safety over having the same individual offsite, but available to respond promptly. In particular, the petitioner notes that sources stuck in an unshielded position (item 1 from the list), while potentially causing damage to the product being irradiated if it cannot be independently removed from the radiation room, do not present an immediate threat to personnel, provided the access control system operates in accordance with the 10 CFR 36.23 design requirements. Nor does a stuck source rack, in and of itself, pose a threat to the integrity of the sources. Similarly, detection of a leaking source (item 4) would not require quicker action than could be provided by an offsite individual, as long as the water circulation system is automatically stopped to prevent accumulation of contaminants in the water treatment and filtration system. Water level alarms (item 5) and natural phenomena (item 9) would not present an immediate hazard requiring onsite assistance, provided that the radiation

room access control system is operating properly.

Therefore, the petitioner contends that in considering the design requirements for panoramic irradiators and the potential emergency or abnormal event conditions that are addressed in procedures as well as facility design, response by the licensee would not be substantively impaired if the individual responding to the alarms were not located onsite. The petitioner states that automated communication system using current technology would provide adequate protection of personnel and source integrity by alerting an offsite person who is able to respond promptly.

In considering the potential impacts from the proposed rule change, the petitioner cites that European nations permit unattended operation of irradiators, as requested in this petition. The petitioner states that these irradiators have similar or identical design characteristics to those operating in the United States, in terms of the safety and monitoring systems, as well as in product conveyance. The petitioner notes that there have been no incidents at these irradiators that can be traced to the practice of unattended operations.

NUREG–1345

Review of Events at Large Pool Irradiators

The petitioner notes that in reviewing information notices issued to irradiator operators by the NRC over the past several years that none of the events described in the notices occurred during unattended operations. However, the petitioner notes that NUREG–1345, entitled ''Review of Events at Large Pool-Type Irradiators,'' which summarizes 45 events at Category IV irradiators, specifically mentions three events that occurred during unattended operations. They were:

1. Failure of Pool Water Purification System at RTI, Rockaway, NJ, September 22, 1986.

2. Product Conveyance Jam at Johnson & Johnson, Sydney, Australia, November 13, 1982.

3. Contaminated Water Spill at International Nutronics, Inc., Dover, NJ, December 31, 1982.

The petitioner provides a paragraph summarizing how each event occurred. The petitioner states the situations prompting the first two events (i.e., low water level and product conveyance system jam) are listed in the abnormal event procedures required under 10 CFR 36.53(b). The petitioner offers that under the proposed revision described in this petition, both instances would require notification of the offsite individual. In the first event, there were no offsite consequences or threats to worker or public health and safety, although continued loss of pool water could have presented shielding problems inside the irradiator. In the second event, approximately 15 hours passed between the initiating event (conveyor jam) and the fire, which would have allowed more than adequate time for response and mitigation had the offsite individual been promptly notified.

The third event that occurred during unattended operations resulted not from the irradiator operation, but from operation of a pool water clean-up system. Under existing regulations, attendance during this operation would not be specifically required.

Analysis of Events and Lessons Learned

The petitioner notes that in the ''Analysis of Events and Lessons Learned'' section of NUREG–1345, Category IV irradiator events are grouped into several types and that to evaluate whether the proposed regulatory revision is adequate to protect worker and public health and safety, the potential consequences of each type of event under unattended operations as described in this petition must be examined.

The petitioner states that of the event types listed in NUREG–1345, those described as management deficiencies are not directly related to attendance during operations. That is, the presence of individuals onsite during operations would have no relevance to mitigating potential consequences of management deficiencies, except as may be related to system problems with the irradiator itself.

The petitioner asserts that events stemming from system problems are the most likely type of event that would have adverse consequences from unattended operations and that in NUREG–1345, this type of event is subdivided into: (1) Access control systems; (2) source movement and suspension; (3) encapsulation; (4) pool leakage and pool purification system; and (5) miscellaneous systems. The petitioner notes that in considering whether mitigation of these types of events would be compromised by not having the irradiator operator onsite, the most serious potential consequences would be the failure of the access control systems. The petitioner notes that in NUREG–1345, three of the four events involving the access control system resulted from systems that either were not operating properly or were not designed to meet the criteria as currently specified in 10 CFR part 36. The other event involved an interlock design defect that was corrected through wiring modification.

Unauthorized Access to the Irradiator

The petitioner argues that if the irradiator access control system is designed to meet the requirements of 10 CFR 36, that the primary and backup access control systems will ensure that inadvertent entry to the irradiator is not possible, even under conditions of unattended operation. In addition, the petitioner states that the existing regulations require that the key used to operate the irradiator be the same key used to open the door to the radiation room and that only one such key be in service at the facility. The petitioner proposes in the suggested amendments that physically securing the key from removal would provide an additional layer of protection against unauthorized access to the irradiator.

Other Type of Irradiator Events

The petitioner believes that response and mitigation of other type of events described in NUREG–1345 would not be greatly improved by having an onsite individual to respond as compared to the individual being offsite, but able to respond promptly. For example, source racks stuck in the unshielded position typically require several hours or days to correct; that mitigative and corrective actions in such instances would be accomplished by a team of individuals and would not be done solely by the two people required by the existing regulations to be onsite. The petitioner believes that the small additional delay resulting from an individual offsite being the first to respond to such an abnormal event would not have a discernible effect on the adequacy of response.

As another example, the petitioner states that NUREG–1345 lists several events that resulted in fires in the irradiator, that might be considered to have important consequences for unattended operations. The petitioner states that events in which there was an initiating event from the irradiator system involved a significant time interval between the initiating event, usually a stuck source rack, and the fire. In those events, according to the petitioner, the time delay ranged from approximately nine hours to eleven days, which would allow adequate time for an offsite individual to respond and summon appropriate assistance. The petitioner notes that properly designed source rack protective barriers, as required under 10 CFR 36.35 minimizes

the probability of having a source rack become stuck from product or carrier interference, which further reduces the fire potential in irradiators designed in accordance with 10 CFR 36 part criteria.

Conclusion

The petitioner concludes that the consequences of Category IV irradiator events described in NUREG–1345 would not be increased under the conditions proposed in this petition. The petitioner believes that having an offsite operator with automatic communication capabilities as described in this petition would not appreciably diminish response to and mitigation of abnormal events or emergencies, and would not compromise safety of either the workers or the general public.

For the Nuclear Regulatory Commission.

Dated at Rockville, Maryland, this 8th day of September, 1998.

John C. Hoyle

Secretary of the Commission.

[FR Doc. 98–24714 Filed 9–14–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 76

RIN 3150–AF85

Certification Renewal and Amendment Processes

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that apply to gaseous diffusion plants. In 1994, these regulations established the process by which the NRC would assume regulatory authority for the Paducah and Portsmouth gaseous diffusion plants. These plants first came under NRC oversight on March 3, 1997. While implementing the initial certification and amendment processes specified in the 1994 regulations, the NRC staff identified several areas in these processes that should be revised and improved so that they are more effective and efficient. This proposed rulemaking would modify the process for certificate renewals, establish a process for certificate amendments comparable to the process currently used to amend a fuel cycle license, revise the appeal process for amendments, eliminate the ''significant'' designation for amendments, simplify the criteria for persons who are eligible to file a petition for review of an amendment action, remove references to the initial application because the initial certificates have been issued, and lengthen the time periods associated with filing a petition for review.

DATES: Comments on the proposed rule must be received on or before November 16, 1998. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attn: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, MD, between 7:30 am and 4:15 pm on Federal workdays.

You may access the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function.

For information about the interactive rulemaking site, contact Ms. Carol Gallagher, (301) 415–5905; e-mail CAG@nrc.gov.

Copies of comments received may be examined or copied for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. John L. Telford, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6229, e-mail JLT@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Paducah and Portsmouth gaseous diffusion plants (GDPs) first came under NRC oversight on March 3, 1997. Since that date, as the NRC implemented the initial certification and numerous certificate amendments under the processes specified in the 1994 regulations, the staff has identified several areas to improve the renewal and amendment processes so that they are more effective and efficient. Also, in the 1994 regulations, the certificate renewal period was 1 year. However, by amendment of the Atomic Energy Act (AEA) of 1954, as amended, and implementing rulemaking, this period was recently modified to allow up to 5 years between certificate renewals. These events have caused the NRC to reexamine the part 76 certificate renewal and amendment processes. Hence, the objective of this proposed rule is to revise and improve the current regulations so that the staff can effectively and efficiently handle certificate renewals as well as the number of certificate amendments that could reasonably be expected over the recently established period of up to 5 years between certificate renewals. This proposed rulemaking would modify the process for certificate renewals, establish a process for certificate amendments comparable to the process currently used to amend a fuel cycle license, revise the appeal process for amendments, eliminate the ''significant'' designation for amendments, simplify the criteria for persons who are eligible to file a petition for review of a certificate amendment action, remove references to the initial application because the initial certificates have been issued, and lengthen the time periods associated with filing a petition for review.

Section-by-Section Analysis

Currently, § 76.37 specifies that the Director of the Office of Nuclear Material Safety and Safeguards (the Director) shall publish a **Federal Register** notice of receipt of an application for renewal. This proposed rule would replace ''shall'' with ''may, at his or her discretion,'' and insert ''for renewal'' after the first occurrence of the word ''application'' in paragraphs (a), (b), and (c). Replacing ''shall'' with ''may, at his or her discretion,'' allows the Director to determine if a **Federal Register** notice is warranted for an application for renewal, on a case-by-case basis. There are two reasons for proposing this action. First, if the application does not address any new safety issues or there have not been any major changes to the facility or its operating procedures that would substantially increase the risk associated with the facility, then the Director may decide that a **Federal Register** notice is not necessary. This flexibility would allow the agency to focus its resources on safety issues that have significant potential risk. Second, there is no requirement in the AEA to notice an application for certificate renewal. Furthermore, similar actions for 10 CFR parts 30, 40, and 70 facilities are not noticed. Also, adding ''for renewal'' clarifies that the application is specifically for renewal.

In § 76.39, the phrase ''for renewal'' would be inserted after each occurrence of the word ''application.'' This clarifies that the application being discussed in § 76.39 is specifically for renewal.

Section 76.45 would be modified in paragraph (a) to remove the responsibility for making the initial decision on an amendment application