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TITLE: PRM-036-001 - 63FR49298 - AMERICAN STANDARDS INSTITUTE N43.10 COMMITTEE; RECEIPT OF PETITION FOR RULEMAKING

CASE REFERENCE: PRM-036-001

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DOCKET NO. PRM-036-001
(63FR49298)

In the Matter of

AMERICAN STANDARDS INSTITUTE N43.10 COMMITTEE;
RECEIPT OF PETITION FOR RULEMAKING

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
06/25/98	03/24/98	LTR FM ERIC BEERS, CO-CHAIR, ANSI N43.10, ET AL. TMTG PETITION FOR RULEMAKING
09/08/98	09/08/98	FEDERAL REGISTER NOTICE - RECEIPT OF PETITION FOR RULEMAKING
01/19/99	01/07/99	COMMENT OF OHIO DEPARTMENT OF HEALTH (ROBERT E. OWEN) (1)
8/15/06	8/4/06	FRN: Denial of Petition for Rulemaking

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 36

[Docket No. PRM-36-01]

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

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (PRM-36-01) submitted by the American National Standards Institute N43.10 Committee. The petitioner requested that the NRC amend its regulations to provide relief from the requirements to have an operator present onsite whenever an irradiator is operated using an automatic product conveyor system and whenever product is moved into or out of the radiation room when an irradiator is operated in a batch mode. In addition, the petitioner requested relief from the requirement to have a person who has received training, described in the regulations, on how to respond to alarms onsite at a panoramic irradiator where static irradiations (no movement of the product) are occurring.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and NRC's letter to the petitioner may be examined at NRC Public Document Room, Public File Area Room O1F21, 11555 Rockville Pike, Rockville, MD. These documents also may be viewed and downloaded electronically via the rulemaking website.

published on 8/18/06
at 71FR 47751

The NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/reading-rm/adams.html. If you do not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC's Public Document Room Reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to: pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Thomas Young, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: (301) 415-5795, e-mail: tfy@nrc.gov.

SUPPLEMENTARY INFORMATION:

The Petition

On September 15, 1998 (63 FR 49298), the NRC published a notice of receipt of a petition for rulemaking filed by the American National Standards Institute N43.10 Committee. The petitioner requested that NRC amend 10 CFR 36.65(a) and (b). These regulations require 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 §36.51(g) must be onsite.

The petitioner suggested revisions to require that:

(1) The operator and at least one other trained individual would be present onsite whenever it is necessary to enter the radiation room;

(2) An individual trained to respond to alarms would be available and prepared to promptly attend to alarms, emergencies, or abnormal event conditions at any time the irradiator is operating;

(3) If the individual is not onsite, automatic means of communication would be provided from the irradiator control system to the individual and the irradiator control system would be secured from unauthorized access and the console key would be secured from removal from the control console when the individual is not onsite;

(4) Inspection and maintenance for operability of the automatic communication system be completed; and

(5) A definition be provided in 10 CFR 36.2 for the term, "onsite."

Currently a licensee is required to maintain adequate coverage on all shifts of a continuously operating panoramic irradiator facility. However, the petitioner believes that based on domestic and international operating experience with panoramic irradiators, there is no significant benefit to safety from having the operator and an additional trained individual onsite

as opposed to an individual being available to respond promptly from an offsite location. The petitioner believes the current cost for a licensee to employ individuals for continuous operation of the facility has a substantial impact on the expense associated with conducting business. The petitioner believes that revising the requirements as suggested above would result in cost containment without a reduction in safety.

The petitioner believes that recent improvements in communications technology support the design of automated alert systems to provide offsite warning to an individual who could then respond through technologies such as pagers, cell and land-line telephones, remote process control monitoring, etc. The petitioner believes that remote response to alarms could require only slightly longer response time than if the responder were onsite.

In its supporting information, the petitioner recognizes that during emergencies and abnormal events, human intervention is required to evaluate the situation and determine whether actions need to be taken and what specific action is required. The petitioner believes this evaluation can take place remotely, between the irradiator and an individual offsite. The petitioner also supports its position by stating that European irradiators of similar design and characteristics to those in the United States have had no incidents that can be traced to the practice of unattended operations.

Public Comments on the Petition

The notice of receipt of petition for rulemaking invited interested persons to submit comments. The NRC received one comment letter from the Manager of Technical Services, State of Ohio's Bureau of Radiation Protection. The commenter was generally in favor of granting the petition. However, the commenter noted that the problem with remote communication systems is that they are likely to fail or become overloaded under extreme

conditions, although the probability of having two remote incidents (irradiator and communication systems) occurring at one time is highly improbable for the unattended operation of a panoramic irradiator. In addition, the commenter suggested that an onsite security guard or other non-operator personnel could be trained to summon assistance as required without needing the operator. The comments were considered in the development of the NRC's decision on this petition.

Reasons for Denial

The NRC is denying the petition for the following two reasons:

1. In February 1993, the NRC amended its regulations to add 10 CFR Part 36, "Licenses and Radiation Safety Requirements for Irradiators," to specify radiation safety requirements and licensing requirements for the use of licensed radioactive materials in irradiators. After the rule became effective, the NRC received numerous licensee event reports that described failures or non-functions of source mechanisms and related systems that needed intervention by personnel who had received training described in the regulations on how to respond to alarms. The information reported to the NRC from 1990 to 2006 about events at irradiator facilities indicates no reduction in the number of events or the nature of events. The NRC determined that the data on events do not support the petitioner's request or indicate that the requirements should be revised. Rather, the NRC continues to believe that there is a need for individuals to be onsite to evaluate and respond to such emergencies, as well as to ensure day-to-day radiation safety.

2. The NRC does not believe that reliance on an automated communication system to notify a remote human operator via an electronic mechanism provides the same level of safety as currently provided by an onsite operator and/or a second individual who is trained to respond

to irradiator alarms. This issue was previously raised in comments on the proposed rule for 10 CFR Part 36. The Statements of Consideration (SOC) for the final rule (58 FR 7715; February 9, 1993) state that, for 10 CFR 36.65, "a considerable number of comments objected to the proposed requirements as excessive." A commenter suggested that an irradiator with an automatic conveyor system should be able to operate with only an operator present and an automatic telephone dialing device for responding to alarms. Another commenter suggested that the irradiator should be able to operate unattended but with an automatic telephone dialing device. The SOC state that the NRC did not accept either suggestion because the NRC believed that automatic conveyer systems have enough malfunctions to require that an operator be present at the site. In addition, the NRC believed that the operator should have some backup in case of problems.

The petitioner has not provided a sufficient basis from which to conclude that this NRC judgement is no longer correct. Specifically, no new information has been provided by the petitioner that would warrant revising the existing regulations. The existing NRC regulations provide the basis for reasonable assurance that the common defense and security and public health and safety are adequately protected.

For the reasons cited in this document, the NRC denies this petition.

Dated at Rockville, Maryland, this 4 day of August, 2006.

For the Nuclear Regulatory Commission.

Luis A. Reyes,
Executive Director
for Operations.

(1)

OHIO DEPARTMENT OF HEALTH

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GEORGE V. VOINOVICH
Governor

WILLIAM RYAN
Director of Health

January 7, 1999

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

ATTENTION: Rulemakings and Adjudications Staff

Attached are our comments on the petition for rulemaking filed by the American National Standards Institute N43.10 Committee, requesting that the NRC amend its radiation safety requirements for irradiators to allow the operation of panoramic irradiator facilities without continuous onsite attendance. The petition was docketed as PRM-36-1 on June 25, 1998.

Though comments on the above were due on November 30, 1998, I respectfully request that these comments be considered relative to revising 10 CFR 36.

Sincerely,

Robert E. Owen
Manager of Technical Services
Bureau of Radiation Protection

cf: Roger Suppes, Chief, Bureau of Radiation Protection
Marcia Howard, Administrator, Nuclear Material Safety Program
Carol Ray, Legal Counsel
Library Document File

Comments on Part 36 proposed rule change published in vol 63 Federal Register 49298, Sept 15, 1998

The petitioners response was well supported in defending the lack of incidents at panoramic irradiators during unattended operation.

Adding the of a definition of "onsite" is needed in §36.2 "Definitions" to clarify the terminology. Adding the inspection and testing of applicable automatic communications systems under §36.61(a)(17) as applicable is good and appropriate.

The current requirements of §36.65(b) for attendance refers to §36.51(g) which requires training of individuals responding to alarms. Of the sections covered under §36.51(g), as pertaining to panoramic irradiator, allow the responder to render or summon assistance. As such, an onsite security guard or other non-operator personnel could be trained to summon assistance as required without needing the operator or RSO onsite.

The heart of the petitioners request is the usage of automatic communication systems instead of a person to notify responders who will render assistance or corrective actions. The problem with remote communication systems is that they are likely to fail or become overloaded under extreme conditions. (A recent example was the misalignment of a satellite that severely disrupted phone and pager services in May 98.)

The probability of having two remote incidents (irradiator and communication systems) occurring at one time is highly improbable for the unattended operation of a panoramic irradiator. The requirements established in Part 36 for maintenance and inspection, as well as emergency procedures already cover issues that would be brought up for consideration under "what if" situations during unattended operations.

The petitioners request is acceptable.

[7590-01-P]

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.

DATE: Submit comments by (~~75 days following publication in the Federal Register~~) 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.

Pub. on 9/15/98
at 63FR49298

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 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 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 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.

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

For the Nuclear Regulatory Commission.

John C. Hoyle,
Secretary of the Commission

PRM-36-1

March 24, 1998

Attention: Rulemakings and Adjudications Staff
U.S. Nuclear Regulatory Commission
Washington, DC 2055-0001

Attached is a petition for rulemaking from the committee charged with revision of American National Standards Institute standard N43.10, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV) and Panoramic, Dry Source Storage Gamma Irradiators (Categorry II) " (revised title). The petition is for revision to the regulation at Title 10 Code of Federal Regulations, §36.65 (a) and (b) in regard to attendance during operation for panoramic irradiators.

Correspondence related to the petition should be addressed to the Eric Beers, Co-Chair of the committee at the address shown below.

Eric Beers, Co-Chair, ANSI N43.10
c/o SteriGenics International
2311 Lincoln Avenue
Hayward, CA 94545-1117

Petitioners, ANSI N43.10 Committee

Eric Beers, Co-Chair

Vincent Foerst, Co-Chair

Peter Baker

Jon Seulean

Michael Cascio

Mark Smith

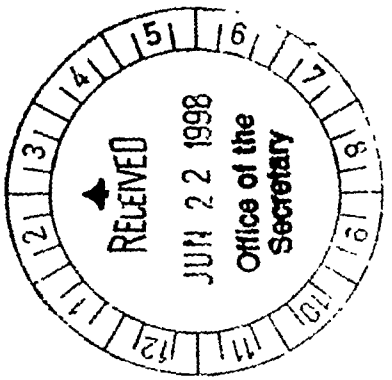
Floyd Hamiter

Michael Wynnyk

Ronald McGregor

Jonathan Young

Jack Ransohoff



Petition to Amend Regulations at 10 CFR §36.65(a) and (b)

1. Background Information

In the Nuclear Regulatory Commission regulations for Licenses and Radiation Safety Requirements for Irradiators, 10 CFR §36.65(a) and (b), "Attendance during operation" state

> "(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 §36.51(g) must be onsite."

At the time this regulation was promulgated in 1993, the intent was to ensure that appropriately trained personnel were available to provide prompt response to emergency or abnormal event conditions that could occur during operation of a panoramic irradiator. Based on case histories of accidents at panoramic irradiators and on the potential for automatic conveyor system malfunctions, (see Part 36 Statements of Consideration, February 9, 1993) the regulation was designed to ensure that the individuals responding to the abnormal event were physically located at the irradiator site to render prompt assistance.

2. Proposed Revision

Based on considerations discussed later in this petition, the following wording is suggested as a revision to 10 CFR §36.65(a) and (b), "Attendance during operation":

> "(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."

In addition, to provide an adequate level of assurance that safety will not be compromised by the actions under the proposed revision, an additional item should be incorporated into the requirements at 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)"

To clarify the meaning of these revisions, 10 CFR §36.2 should also be amended to include the following definition:

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

3. Grounds for and Interest in Action Requested

Operation of a panoramic irradiator in other than static or batch modes under the existing regulations requires that at least two individuals be onsite at any time. Static irradiation can occur with one individual on site. These requirements dictate that personnel be employed to maintain adequate coverage on all shifts of a continuously operating panoramic irradiator facility. From 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 number of personnel required to operate and safely manage an irradiator has a substantial impact on the expense associated with conducting business. Personnel expenses in salary, benefits, insurance, training, and affiliated costs must eventually be passed on to customers. 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.

4. Supporting Information

Panoramic gamma irradiators are designed to require minimal or no operator intervention with the system to continue routine operations following start-up. While the operator and other individuals are required under the current regulations to be present 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. Only during emergencies or abnormal

events is some sort of human intervention required. Controlling the response to emergencies and abnormal events, such as those listed in 10 CFR §36.53(b), 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. Therefore, the consideration as to the need to have individuals physically present onsite during operation is governed by the potential need to respond to emergencies and abnormal events.

At the time that Part 36 was promulgated, 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. Individuals responsible for responding to the alarms would be onsite and able to answer these alarms promptly.

With recent improvements of communications technology, including wireless communications, and in continuing improvement 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. 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. Provided that the offsite individual 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.

In the event of an emergency or abnormal event at an irradiator, the individual making the first response is typically the irradiator operator. Under the conditions of the current regulations, the implicit assumption is that, during evening or night shifts when the facility management or Radiation Safety Officer (RSO) are not assumed to be present, the irradiator operator would respond to the alert and assess the situation. 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.

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 emergency and abnormal event conditions for which a licensee must implement procedures to address, as identified in 10 CFR §36.53(b) 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, an 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 other phenomena as appropriate for the geographical location of the facility; and
(10) The jamming of automatic conveyor systems.

Design features of a panoramic irradiator, as required under 10 CFR 36, Subpart C, address most items from this list in terms of preventing personnel exposures and damage to the sources during an abnormal event. Specifically, the access control system as described in 10 CFR §36.23 will prevent unauthorized entry and protect against personnel exposure (item 2 on the above 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).

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. 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, sources stuck in an unshielded position (item 1 from the above 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, 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. Automated communication systems using current technology would provide for 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, it should also be noted that European nations permit unattended operation of irradiators, as requested in this petition. 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 conveyence. There have been no incidents at these irradiators that can be traced to the practice of unattended operations.

In reviewing information notices issued to irradiator operators by the NRC over the past several years, none of the events described in the notices were described as having occurred during unattended operations. However, NUREG-1345, "Review of Events at Large Pool-Type Irradiators" (1989), which summarized 45 events at Category IV irradiators, specifically mentioned three events as having occurred during unattended operations. These were:

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

   In this event, failure of the pool water purification system during unattended operations had resulted in release of uncontaminated pool water into pump room, which subsequently drained to the site sanitary sewer. A low-water alarm was activated in the irradiator control system.

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

   In this event, the product conveyance system jammed during unattended operation. Coupled with a failure of the protective interlock that was to have shut the system down in the event of a product conveyor jam, a fire resulted. The conveyor jam was recorded as occurring shortly after 2:00 PM, while the fire resulted at about 5:00 AM the following day.

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

   This event occurred during unattended pool water clean-up operations in which a water line broke, resulting in release of contaminated water to the facility floor and soil outside the facility.

Situations prompting the first two of these 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). Under the proposed regulatory revision described in this petition, both instances would require notification of the offsite individual. Note that, in the first event, there were no offsite consequences nor threat 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 shown as occurring 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.

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

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.

Events stemming from system problems are the most likely type of event in which adverse consequences from unattended operation could be postulated. 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. 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 in failure of the access control systems. 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 36. The other event involved an interlock design defect that was corrected through wiring modification.

If the irradiator access control system is designed to meet the requirements of 10 CFR 36, 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 existing regulations require that the key used to operate the irradiator be the same as the key used to open the door to the radiation room and that only one such key be in service at the facility. Under the revisions proposed in this petition, physically securing that key from removal would provide an additional layer of protection against unauthorized access to the irradiator.

Response to and mitigation of other types 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. 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 existing regulations to be onsite. The small additional delay resulting from an offsite individual being the first to respond to such abnormal event conditions would not have a discernable effect on the adequacy of response.

As another example, NUREG-1345 lists several events that resulted in fires in the irradiator, which might be considered to have important consequences for unattended operations. However, 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 listed in NUREG-1345, this 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.

Properly designed source rack protective barriers, as required under 10 CFR §36.35, minimize the probability of having a source rack become stuck from product or carrier interference. This further reduces the fire potential in irradiators designed to 10 CFR 36 criteria.

In summary, the consequences of Category IV irradiator events that described in NUREG-1345 would not be increased under the conditions proposed in this petition. Having an offsite operator with automatic communications 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.