ADAMS Template: SECY-067

DOCUMENT DATE: 12/04/1990

TITLE: PR-019,020,21,30,36,40,51,70 AND 170 - 55FR50008 - LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LARGE IRRADIATORS

CASE REFERENCE: PR-019,020,21,30,36,40,51,70 AND 170
55FR50008

KEY WORD: RULEMAKING COMMENTS

Document Sensitivity: Non-sensitive - SUNSI Review Complete

STATUS OF RULEMAKING

RECORD 1 OF 1

PROPOSED RULE: PR-019,020,21,30,36,40,51,70 AND 170   OPEN ITEM (Y/N) N

RULE NAME: LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LAR
GE IRRADIATORS

PROPOSED RULE FED REG CITE: 55FR50008

PROPOSED RULE PUBLICATION DATE: 12/04/90   NUMBER OF COMMENTS: 33

ORIGINAL DATE FOR COMMENTS: 03/04/91   EXTENSION DATE: / /

FINAL RULE FED. REG. CITE: 58FR07715 FINAL RULE PUBLICATION DATE: 02/19/93

NOTES ON: FINAL RULE PUBLISHED 2/9/93 AT 58FR7715.
STATUS : FILE LOCATED ON P-1.
OF RULE :

PRESS PAGE DOWN OR ENTER TO SEE RULE HISTORY OR STAFF CONTACT

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PAGE 2 OF 2

HISTORY OF THE RULE

PART AFFECTED: PR-019,020,21,30,36,40,51,70 AND 170

RULE TITLE: LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LAR
GE IRRADIATORS

PROPOSED RULE SECY PAPER: 90-211	PROPOSED RULE SRM DATE: 09/14/90	DATE PROPOSED RULE SIGNED BY SECRETARY: 11/27/90
FINAL RULE SECY PAPER: 92-323	FINAL RULE SRM DATE: 11/02/92	DATE FINAL RULE SIGNED BY SECRETARY: 01/28/93

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DOCKET NO. PR-019,020,21,30,36,40,51,70 AND 170
(55FR50008)

In the Matter of

LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LAR
GE IRRADIATORS

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
11/29/90	11/27/90	FEDERAL REGISTER NOTICE - PROPOSED RULE
01/25/91	01/22/91	COMMENT OF UNIVERSITY OF WISCONSIN (S. ENGELHARDT AND A. BENZIKRI) (1)
02/15/91	02/04/91	COMMENT OF ROBERT M. BOYD, DIRECTOR - OSRM (2)
02/15/91	02/01/91	COMMENT OF GEORGIA DEPARTMENT OF NATURAL RESOURCES (JOE D. TANNER, COMMISSIONER) (3)
02/21/91	02/10/91	COMMENT OF FOOD AND WATER, INC. (WALTER BURNSTEIN, M.D., PRESIDENT) (4)
02/25/91	02/01/91	COMMENT OF DANA K. MOUNT, P.E., DIRECTOR (5)
02/25/91	02/20/91	COMMENT OF ENVIRONMENTAL COALITION ON NUCLEAR POWER (JUDITH H. JOHNSRUD, PH.D., DIRECTOR) (6)
02/25/91	02/20/91	COMMENT OF COLORADO DEPARTMENT OF HEALTH (ROBERT M. QUILLIN, DIRECTOR) (7)
02/27/91	02/21/91	COMMENT OF ILLINOIS STATE DEPT. OF NUCLEAR SAFETY (THOMAS W. ORTCIGER, DIRECTOR) (8)
03/01/91	02/25/91	COMMENT OF THE BOEING COMPANY (WILLIAM E. MORGAN, MANAGER) (9)
03/04/91	03/01/91	COMMENT OF SEDA-COUNCIL OF GOVERNMENTS (THOMAS P. BRESENHAN) (10)
03/04/91	02/28/91	COMMENT OF RTI INC. (PAUL O. SHAPIRO) (11)
03/04/91	02/27/91	COMMENT OF GENERAL ATOMICS (ALLAN CHIN, CONSULTANT) (12)
03/04/91	03/02/91	COMMENT OF OHIO CITIZENS FOR RESPONSIBLE ENERGY,INC (SUSAN L. HIATT) (13)
03/05/91	12/04/90	COMMENT OF HEARTLAND OPERATION TO PROTECT THE ENVN. (DIANE A. BURTON, DIRECTOR) (14)

DOCKET NO. PR-019,020,21,30,36,40,51,70 AND 170 (55FR50008)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
03/05/91	02/28/91	COMMENT OF ALBERT RICHARDSON (15)
03/06/91	03/04/91	COMMENT OF U.S. EPA (RICHARD E. SANDERSON, DIRECTOR) (16)
03/11/91	03/04/91	COMMENT OF ARKANSAS DEPARTMENT OF HEALTH (GRETA J. DICUS) (17)
03/11/91	02/24/91	COMMENT OF SIERRA CLUB - PENNSYLVANIA CHAPTER (BARBARA D. HAYS, CHAPTER CHAIR) (18)
03/11/91	03/01/91	COMMENT OF TEXAS DEPARTMENT OF HEALTH (DAVID K. LACKER) (19)
03/13/91	03/01/91	COMMENT OF SIERRA CLUB (LAURA SPADARO) (20)
03/13/91	02/20/91	COMMENT OF MICHAEL G. UNFRIED (21)
03/18/91	03/13/91	COMMENT OF NATIONAL FIRE PROTECTION ASSOCIATION (CASEY GRANT) (22)
03/19/91	03/14/91	LTR TO B. HAYS, CHAPTER CHIEF FM STEPHEN MCGUIRE, RES/NRC RE: NRC WILL NOT FORMERLY EXTEND THE DUE DATE FOR COMMENTS BEYOND 3/4/91.
03/22/91	03/18/91	COMMENT OF ISOMEDIX, INC. (GEORGE R. DIETZ, VICE PRESIDENT) (23)
04/08/91	03/29/91	COMMENT OF 3M HEALTH PHYSICS SERVICES (DUANE C. HALL) (24)
04/09/91	04/05/91	COMMENT OF THE APPLIED RADIANT ENERGY CORPORATION (JAMES J. J. MYRON, PH.D.) (25)
04/09/91	02/21/91	COMMENT OF PERMAGRAIN PRODUCTS, INC. (A. E. WITT, PRESIDENT) (26)
04/09/91	03/21/91	COMMENT OF RADIATION STERILIZERS, INC. (BARRY P. FAIRAND, PH.D.) (27)
04/09/91	02/26/91	COMMENT OF INDIANA STATE UNIVERSITY (JOHN A. SWEZ) (28)
04/09/91	03/21/91	LTR GRETA DICUS, ARKANSAS DEPT. OF HEALTH TO S. MCGUIRE RE: APPRECIATION FOR INVITATION TO PARTICIPATE AS PANEL MEMBER
04/09/91	02/28/91	COMMENT OF DOROTHY AND RICHARD SCHOLZE (29)
04/09/91	03/05/91	COMMENT OF UNIVERSITY OF CINCINNATI MEDICAL CENTER (VICTORIA R. MORRIS) (30)

DOCKET NO. PR-019,020,21,30,36,40,51,70 AND 170 (55FR50008)

DATE DOCKETED	DATE OF DOCUMENT	TITLE OR DESCRIPTION OF DOCUMENT
04/15/91	04/12/91	COMMENT OF NATIONAL INSTITUTE OF HEALTH, HHS (WILLIAM J. WALKER, PH.D.) (31)
04/17/91	04/10/91	LTR JOHNSRUD (ECNP) TO SECY SUPPLEMENTING COMMENT #6 OF ENCP
04/24/91	04/21/91	COMMENT OF MARVIN I. LEWIS (32)
05/08/91	04/04/91	COMMENT OF ALPHA OMEGA TECHNOLOGY, INC. (MARTIN A. WELT, PH.D, CHAIRMAN) (33)
02/01/93	01/28/93	FINAL RULE PUBLISHED ON 2/9/93 AT 58 FR 7715

DSB

DOCKET NUMBER PROPOSED RULE PR 19,20,30,36,40,51,70 & 170 [7590-01]

(55FR50008)

DOCKETED USNRC

'93 FEB -1 P4:15

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, 30, 36, 40, 51, 70 and 170
RIN 3150-AC98
Licenses and Radiation Safety Requirements
for Irradiators

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations by establishing a new Part 36 to specify radiation safety requirements and licensing requirements for the use of licensed radioactive materials in irradiators. Irradiators use gamma radiation to irradiate products to change their characteristics in some way. The safety requirements apply to panoramic irradiators (those in which the material being irradiated is in air in a room that is accessible to personnel when the source is shielded) and underwater irradiators in which the source always remains shielded under water and the product is irradiated under water. The rule does not cover self-contained dry-source-storage irradiator devices, medical uses of sealed sources (such as teletherapy), or nondestructive testing (such as industrial radiography).

EFFECTIVE DATE: July 1, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-3757.

Pub. on 2/9/93 at 58 FR 7715

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I. Background

In response to the Commission's concern over irradiator use, the NRC conducted a review of its safety requirements and policies governing irradiators. Material pertinent to irradiators was contained in various sources including portions of NRC's regulations, a regulatory guide, and specific license conditions.

On December 4, 1990 (55 FR 50008), the NRC published a proposed rule that would specify the radiation safety requirements applicable to the use of licensed material in irradiators. The proposed rule was intended to enhance the efficiency of the regulatory process governing irradiators by consolidating, clarifying, and standardizing the requirements for current and future irradiators.

Irradiators use gamma radiation to irradiate products in order to change their characteristics in some way. Irradiators are used for a variety of purposes in research, industry, and other fields. The supplementary information section of the proposed rule contained a detailed discussion of the uses of irradiators, operating experience with irradiators, and the number and types of accidents involving irradiators.

The 90-day public comment period expired on March 4, 1991. The comment period was not formally extended. However, people who requested an extension were assured that comments received by April 15 would be given full consideration, and, in fact, those comments were given full consideration. The NRC also held a public meeting on February 12 and 13, 1991, to discuss the proposed rule. The meeting was held to provide interested persons an opportunity to better understand the rule and also to allow the NRC staff to hear the concerns of the public.

The transcript of the public meeting, which is available for inspection and copying in the NRC Public Document Room, and the 33 written public comments were reviewed in developing the final rule. The significant issues raised by public comment and NRC's response to these comments are discussed in Section IV of this supplementary information. Section IV presents section by section discussion of the regulation.

Because of the variety of designs, four general categories of irradiators have been defined by the American National Standards Institute (ANSI) in Standard N13.10, "Safe Design and Use Of Panoramic Wet Source Storage Gamma Irradiators (Category IV)." These categories are as follows:

Category I -- Self-contained, dry-source-storage irradiators.

This type of irradiator is built as a self-contained device. The sealed sources are completely enclosed within a shield constructed of solid materials. Human access to the sealed sources and to the space subject to irradiation is not physically possible. The physical size of the device, the space subject to irradiation, the source strength, or all three are generally not large.

This rule does not cover self-contained dry-source-storage irradiators (Category I) for several reasons. First, they are devices that the licensee usually purchases without participating in their design and manufacture. Because safety features are designed into them, self-contained irradiators present less potential hazard and they are considered to be adequately addressed by existing requirements. This type of irradiator (Category I) would continue to be licensed under the general requirements of 10 CFR 30.33. Licensees may continue to use the criteria in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Irradiators," December 1988, and the "Standard Review Plan for Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators," December 1988.

Category II -- Panoramic, dry-source-storage irradiators.

This category includes irradiators in which the sealed sources are stored in a shield constructed of solid materials and are fully shielded when not in use. Irradiations occur in air within a room accessible to personnel only while the sources are shielded. This category also includes certain beam-type irradiators in which the source remains partially shielded. Irradiators of this type are covered by the rule.

Category III -- Underwater irradiators.

This category includes irradiators in which the sealed sources are always in a storage pool and are shielded at all times. Human access to the sealed sources and the space subject to irradiation is not physically possible without entering the pool. Irradiators of this type are covered by the rule.

Category IV -- Panoramic, wet-source-storage irradiators.

This category includes irradiators in which the sealed sources are in a storage pool containing water and are fully shielded when not in use. Irradiations occur in air within a room made inaccessible to personnel by an entry control system while the sources are exposed. Irradiators of this type are covered by the rule.

The NRC's regulation uses the terms "panoramic irradiator" and "pool irradiator." "Panoramic irradiators" include Category II and IV irradiators. "Pool irradiators" include Category III and IV irradiators.

II. Need for a Rule

Before the adoption of Part 36, irradiators were licensed primarily under: (1) the general provisions of 10 CFR 30.33, which requires that "equipment and facilities are adequate" and that the "applicant is qualified by training and experience"; (2) the general requirements of Part 20; for example, dose limits and the need for "adequate" surveys; and (3) the specific requirements in 10 CFR 20.203(c)(6) and (7) (or the new 10 CFR 20.1603) that deal with access control requirements for panoramic irradiators. There was also a draft regulatory guide FC 403-

4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators," that was published in January 1985. However, the scope of the proposed guide was limited, and many subjects were not covered or were covered in a way now considered obsolete.

Although the safety requirements and policies for irradiators were generally understood and agreed upon and were incorporated on a case-by-case basis in the licenses for operating irradiators, they were not contained in a single comprehensive document. This rule consolidates, clarifies, and standardizes the requirements for the licensing and operation of current and future irradiators.

There are also some areas in which either technology is changing or NRC policy is evolving. This rule provides comprehensive and up-to-date requirements in these areas.

Several commenters misunderstood the effect of the rule. The issue in the rulemaking is not whether irradiators should be licensed or whether they should continue to be licensed. Instead, the issue is whether to license them under a formal, detailed, comprehensive set of regulations as was proposed or whether to continue licensing on a case-by-case basis with relatively few specific requirements contained in formal regulations. The NRC's decision is to adopt a comprehensive, formal set of regulations.

III. The Use of WESF Sources in Irradiators

WESF (Waste Encapsulation and Storage Facility) sources are sealed sources containing cesium-137 that were produced at the U.S. Department of Energy's Hanford facility. The Department of Energy had leased this type of source to four commercial irradiators in the United States. In June 1988, a WESF source leaked at an irradiator operated by Radiation Sterilizers, Inc., in Decatur, Georgia.

A Department of Energy board investigated the cause of the leak but has not yet identified the cause of the failure (Interim Report of the DOE Type B Investigation Group, DOE Report DOE/ORO-914, July 1990).

Subsequently, the NRC decided that the long-term use of WESF sources is unacceptable in commercial facilities licensed by NRC and that the sources currently being used should therefore be removed and returned to the Department of Energy. In February 1991, the two remaining irradiators still using WESF capsules were notified of the NRC decision. Both facilities requested that the Department of Energy remove the WESF sources as soon as it could do so. Thus, for the purposes of this rulemaking, the WESF source issue is closed.

As a consequence, this final rule was written to require that irradiators use radioactive materials that are as insoluble and nondispersible as practical (typically cobalt-60).

IV. Summary of the Requirements and the Resolution of Comments on the Requirements

This discussion summarizes by section the major requirements in the regulation and discusses the substantive comments on the requirements of the irradiator rule and how they were resolved. The bases and origins of the requirements are also explained.

Authority citation.

The authority citation was changed by moving the content of the second paragraph of the proposed citation into a new § 36.93, "Criminal penalties." This was done to be consistent with a proposed rule, "Clarification of Statutory Authority for Purposes of Criminal Enforcement," (57 FR 222, January 3, 1992).

SUBPART A - GENERAL PROVISIONS

Section 36.1 Purpose and scope.

This section describes the types of irradiators covered in the rule. The rule covers panoramic wet-source-storage, panoramic dry-source-storage, and underwater irradiators that can deliver a dose of 5 grays (500 rads) or greater in 1 hour at a distance of 1 meter, either in air or under water as appropriate for the irradiator type. The dose rate criterion is taken from the access control requirements in the new standards for protection against radiation published in the Federal Register on May 21, 1991 (56 FR 23360). See 10 CFR § 20.1003, Definitions, "Very High Radiation Area." A cobalt-60 source of approximately 1.5×10^{13} becquerels (400 curies) would deliver this dose in air if the source were small with little self-absorption. For underwater irradiators, the source activity to deliver a 5-gray (500-rad) dose at 1 meter is about 10 times larger than if the exposures were performed in air.

Some commenters suggested that small university or research irradiators should be excluded from the rule or be excluded from some of the rule's requirements because they have lower activity sources and are used less often than commercial production irradiators.

In general, this suggestion was not adopted, although in certain specific areas an attempt was made to allow more flexibility in operating a small university or research irradiator. While university and research irradiators have lower activity sources, there is still a significant potential hazard. In addition, the safety records of universities in handling radioactive materials are not substantially different from those of commercial facilities, suggesting that a similar set of regulations may be appropriate for each.

Commenters noted that some medical facilities have converted teletherapy machines from human use to the irradiation of materials and suggested it would be appropriate to allow these machines to continue to be licensed under Part 35. The NRC did not accept this suggestion. Teletherapy machines converted to irradiate materials present hazards similar in nature to other irradiators and thus should meet similar safety standards. However, a paragraph was added to § 36.17 stating that the NRC would consider certain exemptions for those devices.

Section 36.2 Definitions.

This section defines terms that are used in the new Part 36.

Section 36.5 Interpretations.

This section explains that the only interpretations of the regulations that are binding are written interpretations by NRC's General Counsel.

Section 36.8 Information collection requirements: OMB approval.

This section explains that the information collection requirements of Part 36 have been approved by the Office of Management and Budget as required by the Paperwork Reduction Act of 1980 (44 U. S. 3501 et seq.).

SUBPART B - SPECIFIC LICENSING REQUIREMENTS

Section 36.11 Application for a specific license.

This section states how to apply for a license and where the application must be sent.

Section 36.13 Specific licenses for irradiators.

This section describes information that must be included in a license application if it is to be approved by the Commission.

The applicant's proposed activities must be for a purpose authorized by the Atomic Energy Act of 1954 as amended. This is a standard requirement for all types of licenses.

The applicant's proposed equipment and facilities must be adequate to protect the health of workers and the public and minimize danger to life and property. The applicant must be qualified by training and experience to use the radioactive material for the purpose requested and in a manner that protects health and minimizes danger to life and property. These are standard requirements for all NRC licensees.

The application must describe the training for irradiator operators and the qualifications of the instructors. Some commenters recommended that the regulation specify a minimum number of hours of safety training. The NRC decided that establishing a specific number of hours for formal classroom training is not critical and represents too rigid an approach to regulation. Instead, the NRC will to review the training proposed by the applicant as part of the license application.

The application must contain an outline of the operating and emergency procedures that describes the important radiation safety aspects of the procedures. Some commenters supported the idea of submitting only the outline of the procedures while others preferred submitting complete procedures. The NRC decided to require an outline that describes the operating and emergency procedures in broad terms that specifically state the radiation safety aspects of the procedures rather than to require the complete operating and emergency procedures. In addition, if specific procedures were submitted with the license application, then minor changes that the facility might need to make from time to time (for example, improving procedures based on what is learned from operating experience) would require NRC review prior to implementation. This could unnecessarily hamper the safety of facility operation. Detailed procedures would be available to inspectors for reference during facility operation however. Procedures could be changed by the licensee under the conditions described in § 36.53. Records on changes in procedures have to be retained for 3 years for inspection by the NRC (§ 36.81(d)).

The application must describe the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. The applicant must also describe the qualifications of the radiation safety officer. These requirements are used to judge whether the applicant's personnel are qualified to handle radioactive materials safely.

Some commenters suggested that the rule contain specific requirements for the qualifications and training of the radiation safety officer, such as the amount of formal radiation safety training, the amount of on-the-job training, the length and type of previous experience, and the amount of formal education. The NRC decided not to specify minimum qualifications in the rule to allow flexibility in evaluating qualifications. Instead, it was decided that final determination of adequacy will be based on the actual qualifications of specific individuals on a case-by-case basis based on previous experience in reviewing such qualifications. This would allow the license reviewer the flexibility to consider the strengths and weaknesses of a specific individual in making the determination.

The comment was made that the rule should require that the radiation safety officer be independent from both sales and production organizations and should have the authority to cease operations. The NRC does not believe that it is necessary for the radiation safety officer to be totally independent of the sales and production organizations or that the authority to suspend operations should be rigidly fixed in the rule. The NRC believes that this suggested proposal is too rigid. The NRC believes that the authority and responsibility of the radiation safety officer is something that can and should be evaluated as part of the licensing process on a case-by-case basis based on previous NRC experience in making this type of determination.

Applications to operate panoramic irradiators must describe the access control system. Applications also must contain information on how sealed sources would be tested for leakage and contamination.

The applicant must also describe the frequency of the inspection and maintenance checks required by § 36.61. Guidelines on the frequency of checks may be included in future NRC licensing guides.

The applicant must submit information on loading and unloading sources. If the applicant intends to load and unload sources, the applicant must show that the personnel assigned to the task are qualified and trained to do so safely and that procedures are adequate to protect health and safety. The applicant may also have the loading and unloading done by another organization that the NRC or an Agreement State has specifically authorized to do loading or unloading. Most organizations that would do the loading and unloading have a license from the NRC or an Agreement State authorizing them to load and unload sources. If the qualifications of the organization have not been previously reviewed, they would then be reviewed as part of the current license application.

Section 36.15 Start of construction.

This section as proposed would have prohibited the start of construction of an irradiator before a license was issued. This proposed requirement was criticized by Agreement State regulatory agencies, who did not want to issue a license until construction was well underway or largely complete. Irradiator companies also objected because they thought the lead time would cause a severe financial burden.

Therefore, the rule was changed to require that an application and required fee be submitted before start of construction rather than requiring that the license be issued before start of construction. The object of the requirement is to allow regulatory agencies to inspect the construction of the facility as it is built. The revised wording accomplishes that objective.

Section 36.17 Applications for exemptions.

This section describes the circumstances in which the NRC may grant an exemption to a requirement in Part 36.

Some commenters stated that licensees using teletherapy machines for medical treatment should be able to change their use to irradiate materials without changing the requirements that they must meet. The NRC did not specifically adopt this comment because a teletherapy machine used to irradiate materials presents potential hazards that are the same as those from any other dry-source-storage panoramic irradiator. However, a new paragraph has been added to § 36.17 stating that the NRC is willing to consider exemptions as long as the proposed alternative provides an adequate level of safety.

Section 36.19 Request for written statements.

This section codifies a requirement (found in Section 182 of the Atomic Energy Act) that the licensee must supply any additional information required by NRC to assure that health and safety will be protected.

SUBPART C - DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

Section 36.21 Performance criteria for sealed sources.

This section lists performance criteria required for sealed sources used in irradiators. Normally the tests used to demonstrate that the criteria can be met are conducted by the source manufacturer, not the irradiator licensee. The manufacturer then applies to the NRC or an Agreement State agency for approval for use in irradiators. If this procedure has been followed, the licensee need only note the manufacturer's name and model of the sources in its license application to demonstrate that the requirement is met.

A number of commenters objected to allowing the use of cesium-137 in wet-source-storage irradiators. The requirement that the radioactive material in the sources be as insoluble (if used in wet-source-storage irradiators) and nondispersible as practical was not included in the proposed rule, although comment was sought on whether the use of cesium-137 should be permitted in irradiators in view of its solubility. The NRC has decided not to approve further use of cesium sources, although the term "as practical" would allow the NRC to make an exception where justified to the NRC. In addition, a requirement was added that source encapsulation must be of corrosion resistant materials such as 316L or 321 stainless steel or equivalent for sources to be used in pools. Since this has been a de facto requirement for meeting § 32.210, this requirement should have no impact.

The performance criteria required by the rule were taken from American National Standard N43.6-1977, "Classification of Sealed Radioactive Sources" (formerly numbered N542-1977) (Available for purchase from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.) The NRC has used this standard for many years and generally is satisfied with the performance of the sealed sources that meet the standard. Nonetheless, there is a requirement in Part 36 that sealed sources installed after July 1, 1993, also be doubly encapsulated and use radioactive material that is as insoluble and non-dispersible as practical. Double encapsulation provides additional protection in case one of the welds in the source is defective. Most of the approved sources currently in use are doubly encapsulated.

The temperature test specifies an upper temperature of 600°C. The temperature specified in American National Standard N43.6-1977 is 400°C. However, American National Standard N43.10 changed the temperature to 600°C after several fires occurred at panoramic wet-source-storage irradiators.

The rule does not specify any requirements for sealed sources installed prior to July 1, 1993. Sources previously installed were approved by NRC on a case-by-case basis under § 32.210, a review which includes consideration of the criteria in American National Standard N542-1977. Licensees may continue to use sources that were previously approved.

Several commenters stated that the performance criteria in this section by themselves are not sufficient to establish the adequacy of the performance of sealed sources in irradiators. The NRC agrees with the comment but notes that the criteria in the section are not the only criteria that the sealed sources must meet. The adequacy of sealed sources is reviewed and approved by NRC under § 32.210 of its regulations. The § 32.210 review is very extensive and considers many factors that could affect the integrity of the sealed sources, including their manufacture and conditions of use, on a case-by-case basis. Because of the large number of factors that must be considered and the special circumstances that could arise, it is not possible to establish specific criteria beyond the basic framework in § 36.21. The NRC believes that this method of sealed source review is adequate. Therefore, no additional changes in § 36.21 were necessary.

Section 36.23 Access control.

This section states requirements for systems intended to prevent entry into the radiation room of a panoramic irradiator while the source is exposed.

The requirements were taken largely from 10 CFR 20.203(c)(6) and (c)(7), but an attempt was made to simplify the wording.

For panoramic irradiators, a primary access control system and an independent backup access control system are required. In addition, operational requirements for preventing a person from being in the radiation room while the source is exposed are contained in § 36.67, "entering and leaving the radiation room."

The door or barrier that serves as the primary access control system must have controls that would (1) prevent the source from being moved out of its shielded position if the door or barrier were open and (2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

The backup access control system must be able to detect entry while the source is exposed. If entry is detected, the system must (1) automatically cause the source to return to its shielded position and (2) activate audible and visible alarms.

In addition, the rule requires a radiation monitor in the radiation room of panoramic irradiators to detect high radiation levels. The radiation monitor would have alarms and an interlock on the personnel access door. This requirement is not contained in the existing § 20.203(c). The purpose is to provide an additional level of protection in case of some failure of the source movement mechanism combined with a failure of the operator to make the required radiation survey upon entry into the radiation room.

Comments were made about how fast the sources must return to the shielded position. The phrase used in § 20.203(c)(6) concerning reduction of radiation levels upon entry is worded so that an individual could not receive "a dose in excess of 100 mrem in one hour." This requirement has been changed in § 36.23 to state that the sources must return promptly to the fully shielded position.

The requirement for a door or other physical barrier applies to each entrance of the radiation room of a panoramic irradiator whether intended for personnel access or intended only for product entrance or exit. Panoramic irradiators with a conveyor system could meet the requirement by providing such small clearances around the product carriers that a person could not squeeze through or by using barriers that would require unusual exertion to bypass. A photoelectric system cannot be considered a physical barrier. The requirement is that the door or barrier must prevent inadvertent entry, not that it need prevent a deliberate and determined effort to bypass the barrier. The purpose of this requirement is to prevent a reasonably prudent person from carelessly, inattentively, or accidentally entering the radiation room while the source is exposed.

This section also requires an independent backup access control system on panoramic irradiators. The purpose of the backup system is to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operating procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The backup system could use photo-electric cells in an entrance maze, pressure mats on the floor, or similar means to detect a person entering the radiation room while the source is exposed. The system must also alert another person of the entry. That person must be prepared to render or summon assistance. This provision prevents the operation of the panoramic irradiator without a second person being available to render or summon assistance. The proposed rule contained a statement that the irradiator could not operate if the access control requirements were not met. The statement was deleted because it is unnecessary. Operation of the facility without meeting the requirements of the section would always be a violation of the regulations.

This section also contains requirements for underwater irradiators. For example, the pool must be within an area surrounded by a personnel access barrier with an intrusion alarm when the facility is not operating.

Section 36.25 Shielding.

This section specifies maximum dose rates in normally occupied areas outside the radiation room of a panoramic irradiator. The maximum dose rate of 0.02 millisievert (2 millirems) per hour is considered practical to achieve. Areas with higher levels would have to be locked, roped off, or posted.

The comment was made that some areas that are normally not occupied, such as the equipment access area on the roof of the irradiator, normally have radiation dose rates well above 0.02 millisievert (2 millirems) per hour. Therefore, the final rule was changed to permit radiation levels outside the shield to exceed 0.02 millisievert (2 millirems) per hour in areas not normally occupied as long as the areas were locked, roped off, or posted.

For measurements to determine compliance with the requirement, the final rule specifies 30 cm as the distance from the shield to the detector. This distance is selected because at that distance the dose would be a whole-body-dose. The maximum area of 100 square centimeters for averaging dose effectively establishes a maximum detector size.

The section does not require that the NRC approve the shield design. Instead the regulations contain only a performance requirement on maximum dose rate outside the shield. The requirements apply to the completed shield.

The section also specifies maximum radiation dose levels outside the shielding of dry-source-storage irradiators. The levels are considered practical and adequate to maintain doses to workers as low as is reasonably achievable.

Section 36.27 Fire protection.

The heat generated by irradiation can cause combustible materials to catch fire. The requirements in this section are intended to prevent fires, detect fires if they occur, and allow fires to be extinguished without entry of personnel into the radiation room.

The requirements for fire detection and sprinklers or other systems to extinguish a fire at a panoramic irradiator were taken from the ANSI Category IV Standard. The fire extinguishing system does not have to be automatically activated. In response to public comments, a requirement for a shut-off valve to control flooding was added.

Overall, fires are considered to present relatively little hazard to irradiators. Radiation rooms use little combustible material in their construction, and irradiation of flammable and explosive materials is prohibited (by § 36.69) without specific NRC approval. The products being irradiated are likely to be combustible, but there is not likely to be present a sufficient quantity of combustible material to result in prolonged high-temperature fires. Thus, the temperature reached if a fire were to occur is not likely to be high enough to melt or rupture the stainless steel capsules containing the radioactive sources. Therefore, the NRC would not expect a fire to cause loss of encapsulation even if the fire were not controlled and the sources were not dropped into a source-storage pool.

The fire extinguishing system is required because a fire could disable the access control system or could prevent the sources from being shielded, thereby lowering the margin of safety. The fire extinguishing system must be operable without entry into the room. During a fire, there would be no means of assuring that the access control systems and source position indicators were operating properly. Also, no one could be sure that the mechanism that returns the source to the shielded position had operated properly.

Section 36.29 Radiation monitors.

This section requires a radiation monitor to detect radioactive sources on the exiting product. The requirement was taken from 10 CFR 20.203(c)(6)(viii). The purpose of this requirement is to detect sources that have somehow become loose from the source rack and are being carried out with the product and to stop them from being carried out of the radiation room.

This section also requires a monitor over the pool at underwater irradiators.

The comment was made that irradiated products should be routinely monitored for radioactive contamination. The NRC did not adopt this suggestion because no need for product monitoring on a routine basis was identified. The suggestion was apparently prompted by the leaking of a WESF capsule containing soluble cesium. However, even in that situation no known exposure of the public occurred. The NRC considers the monitoring required by § 36.59 to be adequate to prevent excessive radiation exposures from contaminated products in the event of a source leak.

A requirement in the proposed § 36.29 for a means to detect radioactive contamination in pool water at pool irradiators was moved to § 36.59(b) so that the subject of detection of leaking sources would be combined into a single section instead of being split up unnecessarily. This was done to improve the clarity of the rule.

Section 36.31 Control of source movement.

This section contains requirements for the control of source movement at a panoramic irradiator. Generally, the requirements are taken from the ANSI Category IV Standard.

A proposed requirement specifying a color-code system for irradiator controls was deleted. Upon reconsideration of the proposed requirement, the NRC decided that it was of minor safety significance.

Section 36.33 Irradiator pools.

For facilities licensed after July 1, 1993, the rule would require either: (1) A stainless steel pool liner (or a liner metallurgically compatible with other components in the pool) or (2) construction so there is a low likelihood of substantial leakage. The purpose of the requirement is to reduce the likelihood of pool leakage. It is desirable to control pool leakage in case the pool water should become contaminated. Backfitting is not required because modifying an existing pool would be prohibitively expensive and any gain in safety would be marginal, especially since cobalt-60 has very low solubility. Older facilities sometimes used concrete pools, sometimes lined with tiles, but usually without stainless steel liners or other ways to reduce the likelihood of leakage.

A comment was made that "substantial leakage" should be defined. The comment was not adopted. The requirement is a design standard, not an operating limit. It means the pool should be designed to prevent large leaks, which could create a radiation safety hazard.

One comment suggested that pools have a means of detecting water leakage from pools more sensitive than monitoring water loss. Examples of more sensitive systems include requiring the use of a double-lined pool or channels at welds with a means to detect water leaking from the pool. The NRC decided that it would be adequate to monitor pool water loss and unnecessary to have a more sensitive means of detecting leaks. In normal circumstances, a pool leak is not a safety concern because pool water contains little or no radioactive material. If a source leak occurred while the pool had a leak that was too small to be detected, some contaminated water could escape from the pool. Experience with cobalt-60 has shown that pool contamination levels do not increase significantly because of the very low solubility in water of cobalt-60. Therefore, the NRC does not consider that a pool leak system more sensitive than that required in the rule is necessary.

The proposed rule required both a means to replenish water that is lost and a low-water level indicator. In response to public comments, a requirement for a high water level indicator was added. The means to replenish the water does not have to be automatic. An indicator is needed even if the replenishment is automatic in case the system to replenish the water does not work. In response to a comment, a requirement for an audible alarm in the water level indicators was deleted as unnecessary. Changes in water level are expected to occur slowly and to have safety significance only after a prolonged time.

The requirement for a cover or railing to prevent workers from falling into the pool is taken from the ANSI Category IV Standard.

The rule requires a water purification system. The purposes of the purification system are to prevent the pool water from becoming cloudy and reducing visibility and from becoming corrosive and thus corroding the stainless steel sealed sources or the source rack. If the water is clear, it should be possible to visually inspect the sources and the source rack. Thus, the sources and the source rack could be inspected for damage, and the location of the sources could be checked to make sure they are in their proper positions. The criterion for design basis conductivity during normal operation is explained in the discussion on 10 CFR 36.63.

The 0.02 millisievert (2 millirems) per hour limit on the dose rates for poles and long-handled tools to be used in irradiator pools is imposed to require prevention of radiation "streaming." Hollow and low density poles and tools can have either vent holes to allow shielding water to enter or sufficient bends to prevent radiation levels at handling areas of the tools from exceeding 0.02 millisievert (2 millirems) per hour.

Section 36.35 Source rack protection.

This section requires a barrier to prevent the moving products from hitting the source rack or the mechanism that raises and lowers the sources.

Section 36.37 Power failures.

This section requires automatic source retraction for loss of power for more than 10 seconds at a panoramic irradiator. The retraction must be accomplished without offsite power. Backup power is not required as long as loss of power will cause the source to return to its shielded position, for example, the source returns to the shielded position due to gravity.

Section 36.39 Design requirements.

This section describes design requirements for irradiators constructed after July 1, 1993. Included in the section is a requirement that all irradiators must have shielding walls constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete. This provides adequate protection against moderate earthquakes, tornadoes, and other hazards. The requirement to meet generally accepted building code requirements for reinforced concrete was intentionally left general to allow licensees flexibility in complying with local building codes. Irradiator shield walls by their nature are inherently strong, stable structures so that there was no need to provide very specific requirements.

In addition, irradiators built in seismic areas must have radiation shields designed to retain their integrity in an earthquake. Seismic areas are defined in § 36.2 as any area where the probability of a horizontal acceleration in rock exceeding 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey. The NRC selected 250 years to include some areas that could have a large earthquake even if large earthquakes would seldom occur.

Maps of the United States showing these seismic areas are published by the U.S. Geological Survey (see S. T. Algermissen, et al., "Probabilistic Estimates of Maximum Acceleration and Velocity in Rock in the Contiguous United States," United States Department of the Interior, Geological Survey, Open-File Report 82-1033, 1982. This report may be purchased for $24.50 from: U.S. Geological Survey, Books and Report Sales, Box 25425, Denver, Colorado 80224. Prepayment is required). Minor updates of this report are possible as new geological information becomes available.

Studies of irradiator shield designs have shown that the shields are inherently able to withstand large earthquakes. ANSI determined that reinforced concrete shields constructed to meet generally accepted building code requirements for reinforced concrete (for example, American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," available for purchase from the American Concrete Institute, Box 19150, Redford Station, Detroit, Michigan 48219) can withstand an earthquake with an acceleration in rock of 0.3 times the acceleration of gravity plus any multiplication of acceleration that would occur due to soil. Therefore, there are no seismic requirements for irradiators located where accelerations in rock are not likely to exceed 0.3 times the acceleration of gravity.

The intent of the final rule is that shield walls in seismic areas would have to retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources. Local building codes in seismic areas are likely to specify requirements for things such as: spacing of reinforcing bars; how to tie reinforcing bars together; preferred arrangements for reinforcing bars; and requirements for joining reinforcing bars to floor slabs. If local building codes do not contain seismic requirements, "other appropriate sources" could include: American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design."

NRC also considered a comment favoring requirements for a seismic detector to automatically start the mechanism that causes the sources to return to their fully shielded position. As typically installed and as envisioned, the return mechanisms have not been designed to be fully reliable in the event of an earthquake. The NRC does not consider an automatic return necessary because shield walls must be designed to provide adequate shielding to protect workers and the public in the event of an earthquake. Thus, there would be no imminent hazard. The NRC does require that licensees have an emergency procedure for responding to earthquakes (§ 36.53(b)(9)). Therefore, NRC concluded that automatic source return is not necessary to protect public health and safety.

The NRC also considered a comment on whether there should be design requirements for shield integrity against tornadoes. The NRC decided that there was no need for special design requirements because the shielding by its very nature (about six feet thick reinforced concrete) is inherently resistant to tornadoes.

The comment was made that only wiring with insulation that is relatively resistant to radiation should be used in the radiation room. The NRC agreed with this comment and added a design requirement that electrical wiring and electrical equipment in the radiation room be selected to minimize failures due to prolonged exposure to radiation.

A comment was made concerning the location of radiation monitors to detect contamination in § 36.39(e). The comment indicated that it might not be possible to identify the exact "spot at which the highest radiation levels would be expected." The NRC agreed and revised the wording of this paragraph to allow more flexibility in locating the radiation monitor.

In § 36.39(f), a requirement was added that the design of the source holder must avoid corrosion-promoting crevices. (The word "crevices" is used in the technical sense as understood by metallurgists.) Crevices can strongly promote corrosion in even the cleanest water.

Section 36.41 Construction monitoring and acceptance testing.

This section describes checks that the licensee must make before sources are loaded to be sure the facility was constructed as designed and that alarms, controls, interlocks, and instruments operate properly.

The comment was made that the section does not address changes made in the facility after the granting of a license. That issue is dealt with in the license for the facility. It is a standard condition of licenses that facilities must be operated in accordance with the statements made in the license application. A license amendment would be necessary for any modifications making substantive changes from what was described in the license application. The NRC believes that to be the appropriate method to handle this issue.

A comment was made that the paragraph on computer controllers should explicitly address multiple simultaneous faults and also computer controllers in which a single computer controls both the process and access safety. The NRC believes that its regulations are adequate as written. The requirements include the access control system described in § 36.23 and, in particular, the independent backup system described in § 36.23(b), the acceptance testing in § 36.41(j), and the periodic operability checks in § 36.61(a)(1). A comment suggested that no modifications to software should be made without licensing Agency approval. The NRC did not adopt this suggestion. The NRC does not believe that review of software modifications would be a useful, productive, or effective use of NRC staff time. Rather, the responsibility for a proper operating computer system rests with the licensee.

SUBPART D - OPERATION OF THE IRRADIATOR

Section 36.51 Training.

This section contains safety training requirements for irradiator operators. The emphasis is on practical knowledge directly necessary for the job, rather than theoretical principles.

The subjects that an irradiator operator must be trained in are:

(1) The fundamentals of radiation protection as they apply to irradiators. The goal here is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.

(2) The requirements of Parts 19 and 36 of NRC regulations. The operator is not expected to be an expert on NRC regulations or to be able to determine whether a given procedure is adequate to meet NRC regulations. Instead, operators should be instructed on NRC requirements that are directly applicable to their responsibilities.

(3) The operation of the irradiator. The objective is to help the person understand the operating and emergency procedures, not to make the individual an engineer.

(4) Licensee operating and emergency procedures that the individual will perform. This is the most important part of the training because the safe operation of the irradiator depends on the procedures being followed correctly. The objective is that the operator be able to correctly perform the procedures that he will be expected to

perform. The training does not have to include procedures that the individual will not perform. For example, if the individual will not perform leak tests, the individual need not be trained in the procedure.

(5) Case histories of accidents and problems involving irradiators. The individual should be taught about situations that could lead to trouble. Instruction material on accidents is often difficult to obtain. However, NUREG-1345, "Review of Events at Large Pool-Type Irradiators," should provide some relevant information. Copies of NUREG 1345 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, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Also, NRC Information Notice No. 91-14, "Recent Safety-Related Incidents at Large Irradiators," can be used as a source of information.

Comments suggested that the rule should specify minimum hours of classroom training and on-the-job training for irradiator operators. In order to provide flexibility, the final rule does not specify how many hours of classroom training and on-the-job training are necessary to become an irradiator operator. This is intentional. A license applicant would describe the training program in its license application. The NRC would review the numbers of hours proposed by the applicant as part of the license application.

Comments suggested that the rule should specify the training and qualifications required for the radiation safety officer. The final rule also does not specify the training or qualifications needed by the radiation safety officer. This is also to allow flexibility. The license applicant would describe the minimum training, experience and qualifications of the radiation safety officer in its license application. A review would then be conducted on a case-by-case basis.

The NRC considered whether the regulation should include training requirements for other types of workers such as package handlers and maintenance workers. The NRC concluded that the general training requirements specified in § 19.12, "Instructions to workers," are suitable for other types of workers and, therefore, additional or more specific requirements are not necessary.

Paragraphs (f) and (g) allow oral tests following training given to certain workers (who are not operators). The comment was made that the tests should be written. The NRC did not adopt this comment. In this case the training is very minimal and could be very informal, such as a one-on-one discussion. In view of the informal and limited nature of the training, oral testing seems adequate.

Section 36.53 Operating and emergency procedures.

This section lists the specific operating and emergency procedures that a licensee must have. The section also lists requirements for changing these procedures. Operators must be instructed in a changed procedure before it may be put into use. Changes in procedures that do not reduce the safety of the facility, are consistent with the outline submitted in the license application, and have been reviewed and approved by the radiation safety officer do not have to be approved by NRC nor must changed procedures of this type be reported to NRC. However, documentation on the changes must be retained for inspection by NRC (§ 36.81(d)). In response to a public comment, a requirement was added to require an emergency procedure in case of a jam of an automatic conveyor system.

One comment suggested that there should be written emergency procedures describing how to identify an individual leaking source, how it would be isolated and removed from an irradiator, the equipment that would be used, and how the facility would be restored to a non-contaminated state. The NRC did not accept the suggestion. The final rule requires an emergency procedure for dealing with a leaking source (§ 36.53(b)). The final rule also requires monitoring of personnel, facilities, equipment, and products if a leaking source is detected (§ 36.59(c)). After the emergency, the facility would enter a decontamination phase. Decontamination procedures could be developed at that time based on the specific situation.

A comment suggested that there should be written procedures on how to repair malfunctions. The NRC did not accept this comment. There are so many possible kinds of repairs that might be needed and so many different ways that the repairs could be done that it is not feasible to have written procedures addressing each situation. The NRC believes that repairs should be done by qualified personnel using their judgment and skills to respond to each particular situation.

Section 36.55 Personnel monitoring.

This section contains the personnel monitoring requirements for irradiator operators and other people entering the radiation room of a panoramic irradiator.

A commenter argued that this section is not needed because personnel monitoring requirements in § 20.1502, "Conditions requiring individual monitoring of external and internal occupational dose," are adequate for irradiators. Section 20.1502 requires the use of individual monitoring devices for anyone likely to receive in excess of 10 percent of an applicable dose limit. At irradiators, as currently designed and operated, operators are unlikely to exceed 10 percent of a dose limit. Therefore, § 20.1502 might not require any use of personnel dosimeters at irradiators. Nevertheless, the use of dosimeters by operators ensures that there is a dose measurement in case there is an unexpected entry into the radiation room while the source is exposed.

Film badge and thermoluminescent dosimeter (TLD) processors must be accredited for high energy photons in the normal and accident dose ranges. Paragraph (c) of § 20.1501, "General," requires that film badges and TLDs must be processed by an accredited processor for the types of radiation that would be encountered. For irradiators, the radiation type is high energy photons in both the normal and accident dose ranges. In the "American National Standard for Dosimetry-Personnel Dosimetry Performance - Criteria for Testing," ANSI N13.11-1983, the normal dose range is 0.3 to 10 millisieverts (0.03 to 10 rems) and the accident dose range is 0.1 to 5 grays (10 to 500 rads).

For groups of visitors, two people who enter the radiation room would have to wear dosimeters. The people wearing the dosimeters could be employees. Two dosimeters are required rather than one because occasionally a single reading could be misleading.

Section 36.57 Radiation surveys.

Radiation surveys to verify shield adequacy must be done every 3 years. They should also be done after new sources have been added or when modifications to the facility have been made that might increase dose rates outside the shield. If a licensee has performed surveys prior to the effective date of the rule that are adequate to demonstrate compliance with the requirements in § 36.25, the next survey would not have to be done for 3 years from the previous survey or until new sources were added or the facility modified. If the previous surveys were not adequate to demonstrate compliance with § 36.25, the surveys described in § 36.57 would have to be performed when the rule became effective.

A comment suggested a semiannual survey meter calibration frequency. An annual survey instrument calibration is recommended in American National Standard N323-1978, "Radiation Protection Instrumentation Test and Calibration." The NRC considers modern survey meters reliable and stable, making more frequent calibrations unnecessary.

The accuracy requirement for survey meter calibration is ±20 percent. In the past, the NRC has specified accuracy requirements of ±10 percent for some uses and ±20 percent for other uses. Modern survey meters can fairly easily be calibrated to be accurate to ±20 percent on all scales over their entire range of dose rates. At irradiators, survey meters are most frequently used to determine whether dose rates in the entrance maze are the normally-occurring very low dose rates or are many times higher than normal. For these purposes, a survey meter accurate to ±20 percent is acceptable.

Another use of the survey meter is to verify that the dose rates outside the shielding wall and at the restricted area boundary are in compliance with NRC limits. These measurements are done infrequently. The most important purpose of these measurements is to check that the shielding contains no voids or poorly designed penetrations. Another purpose is to verify that limits on dose rates are not exceeded. A quantitative measurement is needed rather than a qualitative yes or no indication to verify that dose rate limits are not exceeded. However, at most facilities it has been found that the actual dose rates outside shield walls and at restricted area boundaries are far below the regulatory limits. Therefore, a highly accurate, quantitative measurement is not normally needed. Accuracy of ±20 percent is normally adequate to verify compliance.

It is possible that a measured dose rate might be very close to a limit. In those special situations, the licensee might need a measurement more accurate than ±20 percent. Thus, the accuracy requirement of ±20 percent in the regulations does not mean that the licensee would never need a measurement more accurate than ±20 percent. Rather, the regulation means that the ordinary, routine, periodic calibration need only be within ±20 percent.

A comment suggested that high range survey meters should be required. The NRC decided not to require high range survey meters (i.e., those that could measure dose rates in the radiation room while the source is exposed) because the NRC could not see a need for quantitative measurements of high doses. Upon entry to the maze of a radiation room, the dose rates would be relatively low if sources were exposed because of the shielding provided by the structure. The person entering should survey at a low range and exit if radiation is detected. Normal range survey meters are adequate and appropriate for that function. There is no need or use for quantitative high range measurements.

A comment on a related subject suggested required survey meters that do not saturate at high radiation dose rates. The NRC agreed with this suggestion and added a requirement to use survey meters that do not saturate.

Section 36.57 also requires that deionizing resins be monitored for radioactivity before release. A comment suggested prohibiting the return of deionizing resins to suppliers for recycling because irradiator sources could have small amounts of radioactive contamination on their surfaces due to manufacturing processes. Some of this contamination could be collected in the resins. Thus, resins could contain small amounts of radioactivity.

Instead, the rule requires an approach to monitoring very low quantities of radioactivity using survey instruments that has been used for medical waste. (See Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix R). The guide is available for inspection and copying for a fee at the Commission's Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Copies of issued guides may be purchased from the Government Printing Office at the current GPO price. Information on current GPO prices may be obtained by contacting the Superintendent of Documents, U.S.

Government Printing Office, P.O. Box 37082, Washington, DC 20013-2171. Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5825 Port Royal Road, Springfield, VA 22161.)

The requirement in the regulation is that before releasing resins, they must be monitored in an area with a background radiation level less than 0.5 microsievert (0.05 millirem) per hour. Radiation levels from the resin must not be detectable above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

Calculations show that the maximum dose rates that could go undetected correspond to concentrations of radioactivity in resins that would be below the effluent limits for water in 10 CFR Part 20, Appendix B to §§20.1001-20.2401. If the resins were regenerated, the amount of backwash solution that would remove the radioactive material from the resins would dilute the concentration of the material by at least a factor of 20, based on the volumes of water used in regeneration. If mixed with other resins, the dilution would be that much larger. Thus, concentrations in the waste stream from regeneration, if any, would be far below the water effluent concentrations in 10 CFR Part 20, Appendix B, to §20.1001-20.2401. The Commission considers this approach adequate to protect public health and safety and has therefore not adopted the commenter's recommendation.

<u>Section 36.59 Detection of leaking sources</u>.

This section describes how and when leak testing of sealed sources must be done. There are different requirements for dry-source-storage and wet-source-storage sources.

The requirements for dry-source-storage sources are similar to those contained in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source - Storage Irradiators." Although termed a "leak test," the test performed is a "contamination test." A positive indication does not necessarily indicate leakage. It could indicate surface contamination deposited during the manufacturing process.

A level of about 200 becquerels (0.005 microcurie) on a dry wipe is the level of contamination considered to indicate a leaking or contaminated source. (The value of 0.005 microcurie is represented as 200 becquerels in SI units rather than the more arithmetically precise value of 185 becquerels. The reason this value is used to represent no contamination is an order-of-magnitude value that should be stated with no more than one significant figure since a greater precision has no physical significance.)

Traditionally, the level for irradiator sources has been about 2000 becquerels (0.05 microcurie); however, previous manufacturing processes caused considerable surface contamination and irradiator sources could not be cleaned to below 2000 becquerels (0.05 microcurie). Detection of quantities below 2000 becquerels (0.05 microcurie) was difficult. Source manufacturing techniques have improved so that sources now have less surface contamination, and instruments have improved so it is possible to detect 200 becquerels (0.005 microcurie) of activity. Thus, the NRC believes it is now practical to meet a contamination level of 200 becquerels (0.005 microcurie).

The 200-becquerel (0.005-microcurie) quantity serves to alert the licensee that there might be leakage. If any leakage is discovered, the source must be removed from service.

Leak testing of sources used in pools by wipe-testing the sources is not highly sensitive or effective. The final rule requires that radioactive contamination be monitored each day the irradiator operates either by monitors on a pool water circulating system or by analysis of pool water. There are two basic methods for monitoring a pool water circulating system. One method is to use a very sensitive detector, such as a sodium iodide detector, to look at a sample of water. The other method is to use a less sensitive detector, such as a geiger-muller detector, to look at a filter/demineralizer where radioactive material would be concentrated and would build up. Both methods are acceptable.

One comment suggested that pool water should be monitored for contamination continuously. The NRC did not accept this suggestion because the monitoring frequency in the proposed rule (each day of operation) seemed adequate to avoid worker overexposures and overexposures of the public from contamination on products because significant leaks would still be discovered in time for effective protective actions.

The NRC considered whether water purification systems should be shielded. The NRC concluded that the buildup of radiation from cobalt-60 sources would be so slow that shielding would not be necessary.

One comment suggested the NRC should specify appropriate contamination levels for cleanup. The NRC did not do that in this rule. NRC's policy on this subject is being considered by NRC on a generic basis.

Section 36.61 Inspection and maintenance.

Inspection and maintenance includes the items that the licensee must periodically check to assure proper operation of the facility. The frequency of checks is not stated in the regulations because the frequency will be site-specific depending on the design of the facility. The frequency of checks must be described in the license application, as required in § 36.13(h).

A commenter suggested that the frequency of checks on the access control system, probably the most important safety feature of an irradiator, should be specified in the regulations. The NRC concluded that there is too much variation in irradiator design and operation to specify a frequency that would apply in all cases. Therefore, the NRC decided that the applicant should propose a frequency in the license application. This approach allows flexibility and at the same time allows the NRC to approve a frequency of checks that it considers adequate for a specific facility. Although not specifically stated in the regulations, the NRC expects a general check of the access control system each day the irradiator operates. The daily check, however, would not necessarily have to include a check of all components. The licensee could tailor the test to the particular facility.

Section 36.61(a)(3) requires a check of the operability of the radiation monitor on the pool water circulating system with a radiation check source. The monitor is used to detect radiation levels that are above normal, rather than to make quantitative measurements of dose. For this purpose, simple operability checks are appropriate.

The rule requires that malfunctions and defects be repaired "without undue delay." The criterion, "without undue delay," was chosen to provide the licensee with leeway in making some repairs. This provision was intentional. Sometimes it may be necessary to obtain a special part, piece of equipment, or particular skilled labor that may not be readily available. The NRC intended to allow the licensee wide latitude and flexibility in making some noncritical repairs. As long as reasonable effort had been made, the licensee would meet the requirement. Note, however, that some repairs would not be subject to this latitude given in this section. For example, 10 CFR 36.23 requires an operable access control system. Operating the irradiator with an inoperable system would immediately be a violation of 10 CFR 36.23.

Section 36.63 Pool water purity.

This section requires that the licensee run water purification systems in irradiator pools sufficiently to maintain pool water conductivity below 20 microsiemens (micromhos) per centimeter. If water conductivity exceeds 20 microsiemens (micromhos) per centimeter, the licensee must take corrective actions.

The proposed rule used a conductivity of 10 rather than 20 microsiemens per centimeter. Some commenters said that there was no need for a conductivity as low as 10 microsiemens per centimeter and that 10 was very difficult to maintain. Another commenter said that underwater irradiators should not have to maintain pool conductivity below 10 microsiemens per centimeter because (1) the sources remain under water and do not cycle thermally, (2) they do not cause impurities to concentrate on the surface when water evaporates in the air, and (3) conductivity is not a good measure of the corrosive potential because the impurities introduced are monomers and proteins, not chlorides.

The purpose of maintaining clean water is to reduce corrosion of the sources and to keep the water clear. Clear water is desirable so that the sources and source rack can be inspected visually to check their condition. The NRC considers conductivity to be a good method of checking the purity of the water in irradiator pools. Analysis of pool water for chloride ions would be a better measurement of corrosion potential, but the analysis is more difficult than conductivity measurements.

The decision to change from the proposed rule value of 10 to the final rule value of 20 microsiemens per centimeter is based in large part on recent studies conducted at Argonne National Laboratory and Savannah River Laboratory. The studies were performed to determine the cycle crack growth rate, the stress corrosion cracking resistance, and the pitting resistance of stainless steels in water environments similar to those at irradiators and in the temperature range from 50°C to 150°C. The temperature in irradiator pools is generally below 40°, which is a less corrosive condition. The experiments used 316NG (a nuclear grade version of 316L used for most irradiator sources and 316LN stainless steels. Other stabilized stainless steels occasionally used for irradiator sources, such as 321, are expected to behave similarly to the 316 grades studied.

The studies indicated that, in water environments at 50° to 150°C containing up to 3 parts per million chloride and conductivity of 20 microsiemens per centimeter, the 316L stainless steels are resistant to stress corrosion cracking and pitting corrosion and do not show enhanced cyclic crack growth rates. The studies indicate that the 316L grades of stainless steel will be resistant to corrosion even at higher chloride concentrations and conductivities. Tests currently underway at Argonne

National Laboratory will determine the threshold levels of chloride required to induce pitting corrosion.

Thus, the final rule endorses a conductivity value of 20 microsiemens per centimeter as adequate to prevent corrosion. There are likely to be unavoidable events that will occasionally cause pool conductivities to rise from time to time, but higher conductivities for limited times are not likely to initiate corrosion problems.

The final rule requires that pool water conductivity be checked frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. This can be done by taking frequent measurements such as daily or by less frequent measurements combined with commonly-used statistical process control methods. For example, control charts can be used to demonstrate that the process is in control and fluctuating within a range that is always below the limit. Similarly, trend analysis can be used to identify significant upward trends in conductivity that are likely to result in a conductivity exceeding 20 microsiemens per centimeter.

Section 36.65 Attendance during operation.

This section describes how an irradiator must be attended during operation. A considerable number of comments objected to the proposed requirements as excessive.

A suggestion was made that panoramic irradiators with automatic conveyor systems should be able to operate with only an operator present and an automatic telephone dialing device for responding to alarms. Another suggestion was made that the irradiator should be able to operate unattended but with an automatic telephone dialing device. The NRC did not accept these suggestions because automatic conveyor systems have enough malfunctions to require that an operator should be present at the site. The NRC further believes that the operator should have some type of backup in case of a problem.

The final rule requires another person onsite in addition to the operator for responding to alarms at a panoramic irradiator when product movement is involved. The term "onsite" was intended to give flexibility to the licensee. Thus, for example, for a research irradiator at a university, the person could be a guard located on campus but not in the building containing the irradiator.

A phrase in the proposed § 36.65(c) stating that static irradiations can be conducted only if the personnel access barrier is locked and all required alarms operable was deleted because it was redundant.

Section 36.67 Entering and leaving the radiation room.

This section describes the requirements for first entering the radiation room of a panoramic irradiator after an irradiation and for leaving the radiation room and locking it up before an irradiation. It also covers entry to the pool area of an underwater irradiator during a power failure.

Section 36.69 Irradiation of explosive or flammable materials.

The final rule prohibits the irradiation of explosive materials or more than small quantities of flammable materials unless the licensee has prior written authorization from the NRC. The reason for these prohibitions is that irradiation can cause chemical reactions that would cause a fire or explosion of flammable or explosive materials.

Flammable materials are those with a flash point temperature below 140°F. The flash point of 140°F was taken from the ANSI Category IV Standard. The flash point is the lowest temperature at which a substance will volatilize to yield sufficient vapor to form a flammable gaseous mixture with air, demonstrable through the production of a flash on contact with a small open flame. The flash points of common substances are tabulated in various engineering handbooks and manuals, for example, "Accident Prevention Manual for Industrial Operations," National Safety Council, Chicago, 1974, and "Handbook of Laboratory Safety," Second edition, Chemical Rubber Company, 1971. Examples of common flammable materials with a flash point below 140°F are: acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, turpentine, and any flammable gas.

SUBPART E - RECORDS

Section 36.81 Records and retention periods.

The records that a licensee must maintain and their retention periods are specified in a single section, § 36.81. Thus, the licensee has a convenient "check list" to use to make sure that all records required by Part 36 are kept.

Section 36.83 Reports.

Since the proposed rule concerning irradiators was published, an amendment of Part 30 (§ 30.50) expanded the reporting requirements for all Part 30 licensees including irradiators. (56 FR 40757, August 16, 1991). It was therefore necessary to reevaluate the section in light of the new Part 30 reporting requirements.

The proposed section listed certain irradiator-specific events to be reported that were considered to have safety significance. After comparing the events listed in the proposed section with the requirements of 10 CFR 30.50, it was concluded that 10 CFR 30.50 will require reporting of some significant events that could occur at irradiators. However, to remove any ambiguity and be sure that significant events would be reported, the NRC decided to retain the list of irradiator-specific events. However, the timing and contents of reports were made consistent with those in § 30.50 by referencing that section.

In addition, a requirement to report pool conductivity exceeding 100 microsiemens per centimeter was added. If pool conductivities approach valves at which corrosion might start to occur, the NRC wants to be informed so that it can monitor the problem.

SUBPART F - ENFORCEMENT

Section 36.91 Violations.

This section is provided to inform licensees and the public of legal actions the NRC can take against violations of the regulations. The wording of the section was changed to be consistent with a proposed rule on, "Clarification of Statutory Authority for Purposes of Criminal Enforcement" (57 FR 222, January 3, 1992).

Section 36.93 Criminal penalties.

This section was created from the last paragraph on the proposed § 36.91. The wording is consistent with that in the proposed rule on "Clarification of Statutory Authority for Purposes of Criminal Enforcement" (57 FR 222, January 3, 1992).

V. Other Issues

Certain other issues that were considered in response to public comments are discussed here.

A. Siting, zoning, land use, and building code requirements.

The NRC recognizes that many areas have zoning, land use, and building code requirements that would apply to irradiators. It is the responsibility of the applicant or licensee to assure that any proposed facility meets the zoning, land use, and building code requirements of the local and State governments having jurisdiction over the intended site. The granting of an NRC license does not override applicable local zoning, land use, or building requirements. The rule was revised to reflect this. The applicant is advised to consult with the State and local governments before starting construction to assure that the facility would meet all State and local siting, zoning, and land use requirements. The NRC may review facility siting, on a case by case basis, if a unique threat is involved which may not be addressed by State and local requirements. Some commenters were concerned with the large number of curies of radioactive material that are contained in irradiators. Some commenters compared the number of curies with the radioactive inventory at nuclear research reactors. These comparisons are not strictly relevant because the radioactive materials in irradiators are not volatile like the noble gases and iodines produced in a reactor and because irradiators do not have a driving force equivalent to the decay heat from a reactor to expel the materials from the facility.

The NRC believes that an irradiator meeting the requirements in the new Part 36 would present no greater hazard or nuisance to its neighbors than other industrial facilities, because there is little likelihood of such an irradiator causing radiation exposures offsite in excess of NRC's Part 20 limits for unrestricted areas. All irradiator experience to date indicates that irradiators do not present a threat to people outside the facility. Therefore, the NRC believes that, in general, irradiators can be located anywhere that local governments would permit an industrial facility to be built.

The NRC considered whether there should be siting requirements dealing with possible flooding of the irradiator or tidal waves. The NRC decided that no siting requirements with respect to possible flooding or tidal waves could be justified on a health and safety basis because flooding of the facility would not destroy the integrity of the shielding walls. Section 36.39 contains a requirement that shielding walls of panoramic irradiators must be constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete. With this type of construction, shielding and sources are well protected from being carried off or damaged by a flood or wave. Furthermore, the final rule includes a requirement to have emergency procedures for coping with natural phenomena, which would include floods, so that the irradiator can be safely shut down and repaired. Flooding of the facility would undoubtedly result in the need for a time-consuming and expensive repair of flood damage, but no particular radiation hazard would be involved during repair of flood damage because sources could be safely stored during the repairs. Thus, while it may be in the licensee's own economic interest to avoid siting an irradiator at a location subject to flooding, flooding would not create a health and safety hazard.

The NRC also considered whether seismic zones should be considered in siting requirements. The NRC decided that irradiators could be built in any area of the country, but that irradiators in seismic areas (as defined in § 36.2) would need shielding walls designed to withstand an earthquake.

If an irradiator were subject to a large earthquake, the potential damage of radiological significance would be to the integrity of its concrete shielding. Analyses of reinforced concrete irradiator shields designed to meet generally accepted building code requirements for reinforced concrete have shown they are inherently quite robust and resistant to damage from moderate-size earthquakes. To protect against large earthquakes, the NRC decided to include requirements that radiation shields in seismic areas be designed to retain their integrity after a large earthquake. Also, all irradiators must have an emergency procedure for earthquakes.

B. Decommissioning.

The NRC considered what design requirements were needed to facilitate decommissioning of the facility. Normally, decommissioning of facilities handling sealed sources is relatively simple, because there would be no radioactive contamination present. However, contamination could be present if leakage of the sources did occur. Thus, the NRC included requirements in the rule to facilitate decommissioning. Periodic leak tests of dry-storage sources and monitoring of the pool water are required to allow early detection of the leakage before large amounts of material have leaked out. With early detection of leakage, a leaking source could be identified and isolated. The pool walls should prevent contamination from leaking out of the pool if contamination occurred. The pool must also have a liner or a surface relatively easy to decontaminate. Thus, for an irradiator built in accordance with the rule, there should be no undue difficulty in decontamination.

The subjects of financial assurance and recordkeeping for decommissioning are dealt with in another section of the regulations (10 CFR 30.35) and thus are not included in Part 36.

Comments suggested that the rule contain a requirement for financial assurance of ability to pay for the cleanup of accidents. This subject is currently being considered by NRC on a generic basis for all NRC materials licensees. Therefore, that subject is not covered in this rulemaking.

C. Aircraft crashes.

The NRC considered whether there should be a prohibition against locating irradiators near airports because of risk of radiation overexposures caused by an airplane crash. The NRC has concluded that a prohibition against placing an irradiator where other types of occupied buildings could be placed is not justified on safety grounds. The radioactive sources in an irradiator would be relatively protected from damage because they are generally contained within 6-foot thick reinforced-concrete walls and are encapsulated in steel. Even if a source were damaged as a result of an airplane crash, large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack because the sources are not volatile. With this protection, the radiological consequences of an airplane crash at an irradiator would not substantially increase the seriousness of the accident. Therefore, NRC will allow the construction of an irradiator at any location at which local authorities would allow other occupied buildings to be built.

D. Pool water coolers.

There was a comment that pool water coolers should be required. Pool water coolers would lower water temperatures, reduce evaporation, reduce the need for makeup water, and reduce humidity in the air of the radiation room. High humidity can cause personnel discomfort or degrade cardboard packaging of the irradiated product but does not create a health and safety problem. In addition, high water temperature decreases the effectiveness of some demineralizers making it more difficult to maintain the required pool water purity. As a practical matter, irradiators with large inventories of radioactive sources are likely to have pool coolers. However, the coolers are not necessary to protect health and safety. Therefore, the NRC saw no regulatory need to require the use of pool water coolers.

E. Noxious gas control.

Irradiators can produce ozone in concentrations exceeding those permitted by regulations of the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1000, "Air Contaminants." Nitrogen oxides can also be produced, although concentrations would not be expected to exceed OSHA's limits. To control these noxious gases, irradiators with large sources are typically equipped with ventilation systems to exhaust the gases before personnel entry.

OSHA regulates exposure to ozone and other noxious gases in the workplace, and the U.S. Environmental Protection Agency regulates emissions offsite. If NRC personnel note a problem with noxious gases at an irradiator during inspection, the NRC will notify OSHA of the problem under the terms of a "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities" (53 FR 43590; October 31, 1988).

F. Use of HEPA filters.

A comment was made that the air exhaust ducts from the radiation room should be equipped with HEPA (high efficiency particulate absolute) filters to prevent the spread of contamination in case of a leaking source. The NRC has decided that HEPA filters are not necessary at irradiators to protect health and safety. The comment was made in the context of the leaking cesium-137 WESF source that occurred in Georgia in 1988. However, the NRC has decided that WESF sources should not be used in irradiators, and cobalt-60 is used in a far less dispersible form. In addition, in the Georgia accident there was little escape of cesium-137 from the building and no known dose to the public. Thus, the Georgia accident would support the view that HEPA filters are not necessary.

VI. Agreement State Compatibility

The rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency between Federal and State safety requirements. This rule is assigned a level of compatibility which would allow the Agreement States to adopt additional requirements based on local concerns or experience.

VII. 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 is not a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required. The action codifies in a rule the licensing requirements and policies on irradiators. The issue in this action is not whether to license or permit the operation of irradiators. This action concerns whether to codify the radiation safety requirements for irradiators in a regulation or whether to take no action and thus continue to license irradiators on case-by-case basis. This action is directed to improving the regulatory, licensing, inspection, and enforcement framework relating to these irradiators and will not affect the quality of the human environment. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available without charge upon written request from Distribution Section, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

VIII. Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval number 3150-0158.

Public reporting burden for this collection of information is estimated to average 750 hours per year per licensee, including the time required reviewing instructions, searching existing data sources, gathering and maintaining the data needed and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019, (3150-0158), Office of Management and Budget, Washington, DC 20503.

IX. Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the requirements in the rule. The analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained without charge upon written request from: Distribution Section, Office of Administration , USNRC, Washington, DC 20555.

X. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities.

Currently, there are roughly 70 to 80 irradiators that are covered by the rule. Of those irradiators, there are currently about 40 irradiators in the U.S. with sources greater than 9×10^{15} becquerels (250,000 curies) up to a maximum of 1.1×10^{18} becquerels (30,000,000 curies). Several additional irradiators are either under construction or proposed for construction in Agreement States. In addition, there are irradiators with sources smaller than 9×10^{15} becquerels (250,000 curies) that would be subject to the rule. Thus, the total number of facilities affected by the rule is roughly 70 to 80.

The NRC currently defines a small business as a business having less than $3.5 million in annual receipts. Some of the licensees that are affected by this rule might be small entities. However, the actual financial impacts of the rule are quite small. A survey of irradiators performed for the previously mentioned Regulatory Analysis indicated that, with minor exceptions, all surveyed licensees are in compliance with most of the requirements of the rule. The rule contains options such that the six licensees found not to be in full compliance with the requirements could limit their incremental costs to $5,000 or less, estimated as part of the previously mentioned Regulatory Analysis. These costs are not considered significant.

Thus, the rule will not impose a significant economic impact on small entities, as defined in the Regulatory Flexibility Act of 1980, because the requirements do not substantially differ from current licensing requirements.

XI. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and therefore that a backfit analysis is not required for this rule. The rule does not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 19

Criminal penalty, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalty, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 36

Byproduct material, Criminal penalty, Nuclear materials, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 40

Criminal penalty, Government contracts, Hazardous materials - transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 70

Criminal penalty, Hazardous materials - transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 170

Byproduct material, Non-payment penalty, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

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. 552 and 553, the NRC is adopting 10 CFR 36 and making the conforming amendments to 10 CFR Parts 19, 20, 30, 40, 51, 70, and 170.

1. Part 36 is added to 10 CFR Chapter I to read as follows:

Part 36 - Licenses and Radiation Safety Requirements for Irradiators

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Sec.

36.1 Purpose and scope.

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36.81 Records and retention periods.

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Subpart F - Enforcement

36.91 Violations.

36.93 Criminal penalties.

AUTHORITY: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Subpart A - General Provisions

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This part also contains radiation safety requirements for operating irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of Parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applications and licenses subject to this part. Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) The regulations in this part apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this part.

(c) The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, or open-field (agricultural) irradiations.

§ 36.2 Definitions.

Annually means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time each year (plus or minus 1 month).

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator means an individual who has successfully completed the training and testing described in § 36.51 and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 36.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-0158.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.17, 36.19, 36.21(a)(1), 36.81, and 36.83.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 36.11, NRC Form 313 is approved under control number 3150-0120.

Subpart B - Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of sealed sources in an irradiator on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from Part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application and one copy must be sent to the appropriate NRC Regional Office listed in Appendix D to Part 20 of this chapter.

§ 36.13 Specific licenses for irradiators.

The Commission will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

(a) The applicant shall satisfy the general requirements specified in § 30.33 of this chapter and the requirements contained in this part.

(b) The application must describe the training provided to irradiator operators including--

(1) Classroom training;

(2) On-the-job or simulator training;

(3) Safety reviews;

(4) Means employed by the applicant to test each operator's understanding of the Commission's regulations and licensing requirements and the irradiator operating and emergency procedures; and

(5) Minimum training and experience of personnel who may provide training.

(c) The application must include an outline of the written operating and emergency procedures listed in § 36.53 that describes the radiation safety aspects of the procedures.

(d) The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

(e) The application must include a description of the access control systems required by § 36.23, the radiation monitors required by § 36.29, the method of detecting leaking sources required by § 36.59 including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Commission. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by § 36.61.

§ 36.15 Start of construction.

The applicant may not begin construction of a new irradiator prior to the submission to NRC of both an application for a license for the irradiator and the fee required by § 170.31. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: Engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders issued under the Act.

§ 36.17 Applications for exemptions.

(a) The Commission may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(b) Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this part. The Commission will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

§ 36.19 Request for written statements.

(a) After the filing of the original application, the Commission may request further information necessary to enable the Commission to determine whether the application should be granted or denied.

(b) Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements to enable the Commission to determine whether the license should be modified, suspended, or revoked.

Subpart C - Design and Performance Requirements for Irradiators

§ 36.21 Performance criteria for sealed sources.

(a) Requirements. Sealed sources installed after July 1, 1993:

(1) Must have a certificate of registration issued under 10 CFR 32.210;

(2) Must be doubly encapsulated;

(3) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

(4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

(5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs (b) through (g) of this section.

(b) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(c) Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.

(d) Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(e) Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(f) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(g) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

§ 36.23 Access control.

(a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

(b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is onsite of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in paragraph (b) of this section. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "High radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

§ 36.25 Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in the fully shielded position.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 millirems) per hour.

§ 36.27 Fire protection.

(a) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

§ 36.29 Radiation monitors.

(a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(b) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

§ 36.31 Control of source movement.

(a) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator must be clearly marked as to its function.

§ 36.33 Irradiator pools.

(a) For licenses initially issued after July 1, 1993, irradiator pools must either:

(1) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

(2) be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(b) For licenses initially issued after July 1, 1993, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(c) A means must be provided to replenish water losses from the pool.

(d) A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(f) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

§ 36.35 Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

§ 36.37 Power failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by a power failure.

(c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

§ 36.39 Design requirements.

Irradiators whose construction begins after July 1, 1993, must meet the design requirements of this section.

(a) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of § 36.25. If the irradiator will use more than 2 x 10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(b) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(c) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of § 36.33(b), and that metal components are metallurgically compatible with other components in the pool.

(d) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of § 36.33(e). The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(e) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by § 36.29(a). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under § 36.59(b), the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(f) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(g) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of § 36.23.

(h) Fire protection. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(i) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than 10 seconds.

(j) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21, "Special Provisions for Seismic Design," or local building codes, if current.

(k) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

§ 36.41 Construction monitoring and acceptance testing.

The requirements of this section must be met for irradiators whose construction begins after July 1, 1993. The requirements must be met prior to loading sources.

(a) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(b) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of § 36.33(b).

(d) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(e) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by § 36.29(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet § 36.59(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by § 36.29(b).

(f) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in § 36.35 are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

(g) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(h) Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

(i) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(j) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

(k) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

Subpart D - Operation of Irradiators

§ 36.51 Training.

(a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamina-

tion, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

(2) The requirements of Parts 19 and 36 of NRC regulations that are relevant to the irradiator;

(3) The operation of the irradiator;

(4) Those operating and emergency procedures listed in § 36.53 that the individual is responsible for performing; and

(5) Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following--

(1) Changes in operating and emergency procedures since the last review, if any;

(2) Changes in regulations and license conditions since the last review, if any;

(3) Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(4) Relevant results of inspections of operator safety performance;

(5) Relevant results of the facility's inspection and maintenance checks; and

(6) A drill to practice an emergency or abnormal event procedure.

(e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this Part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by § 36.23(b), § 36.23(i), § 36.27(a), § 36.29(a), § 36.29(b), and § 36.59(b) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

§ 36.53 Operating and emergency procedures.

(a) The licensee shall have and follow written operating procedures for--

(1) Operation of the irradiator, including entering and leaving the radiation room;

(2) Use of personnel dosimeters;

(3) Surveying the shielding of panoramic irradiators;

(4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(5) Leak testing of sources;

(6) Inspection and maintenance checks required by § 36.61;

(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

(8) Inspection of movable shielding required by §36.23(h), if applicable.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for--

(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.

(c) The licensee may revise operating and emergency procedures without Commission approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility,

(2) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(3) The revisions have been reviewed and approved by the radiation safety officer, and

(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

§ 36.55 Personnel monitoring.

(a) Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges (see 10 CFR 20.1501(c)). Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs must be processed at least quarterly.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus 30 percent of the true radiation dose.

§ 36.57 Radiation surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed 3 years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in § 36.25 are exceeded, the facility must be modified to comply with the requirements in § 36.25.

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of ±20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR Part 20, Table 2, Column 2 or Table 3 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

(e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 millirem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 millirem) per hour.

§ 36.59 Detection of leaking sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the 6 months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the 6 months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table 2, Column 2, Appendix B to §§ 20.1001 to 20.2401 of Part 20. (See 10 CFR 30.50 for reporting requirements.)

§ 36.61 Inspection and maintenance.

(a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

(1) Operability of each aspect of the access control system required by § 36.23.

(2) Functioning of the source position indicator required by § 36.31(b).

(3) Operability of the radiation monitor for radioactive contamination in pool water required by § 36.59(b) using a radiation check source, if applicable.

(4) Operability of the over-pool radiation monitor at underwater irradiators as required by § 36.29(b).

(5) Operability of the product exit monitor required by § 36.29(a).

(6) Operability of the emergency source return control required by § 36.31(c).

(7) Leak-tightness of systems through which pool water circulates (visual inspection).

(8) Operability of the heat and smoke detectors and extinguisher system required by § 36.27 (but without turning extinguishers on).

(9) Operability of the means of pool water replenishment required by § 36.33(c).

(10) Operability of the indicators of high and low pool water levels required by § 36.33(d).

(11) Operability of the intrusion alarm required by § 36.23(i), if applicable.

(12) Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 36.35.

(14) Amount of water added to the pool to determine if the pool is leaking.

(15) Electrical wiring on required safety systems for radiation damage.

(16) Pool water conductivity measurements and analysis as required by § 36.63(b).

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

§ 36.63 Pool water purity.

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

§ 36.65 Attendance during operation.

(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.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in § 36.51(f) and (g). Static irradiations may be performed without a person present at the facility.

§ 36.67 Entering and leaving the radiation room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

(1) Visually inspect the entire radiation room to verify that no one else is in it; and

(2) Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by § 36.29(b) is operating with backup power.

§ 36.69 Irradiation of explosive or flammable materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Subpart E - Records

§ 36.81 Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified.

(a) A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Commission terminates the license for documents not superseded.

(b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of § 36.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by § 36.51(e) for 3 years after the evaluation.

(d) A copy of the current operating and emergency procedures required by § 36.53 until superseded or the Commission terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by § 36.53(c)(3) retained for 3 years from the date of the change.

(e) Film badge and TLD results required by § 36.55 until the Commission terminates the license.

(f) Records of radiation surveys required by § 36.57 for 3 years from the date of the survey.

(g) Records of radiation survey meter calibrations required by § 36.57 and pool water conductivity meter calibrations required by § 36.63(b) until 3 years from the date of calibration.

(h) Records of the results of leak tests required by § 36.59(a) and the results of contamination checks required by § 36.59(b) for 3 years from the date of each test.

(i) Records of inspection and maintenance checks required by § 36.61 for 3 years.

(j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for 3 years after repairs are completed.

(k) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by § 30.51 and § 30.41.

(l) Records on the design checks required by § 36.39 and the construction control checks as required by § 36.41 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records related to decommissioning of the irradiator as required by § 30.35(g).

§ 36.83 Reports.

(a) In addition to the reporting requirements in other parts of NRC regulations, the licensee shall report the following events if not reported under other parts of NRC regulations:

(1) Source stuck in an unshielded position.

(2) Any fire or explosion in a radiation room.

(3) Damage to the source racks.

(4) Failure of the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation source by the product exit monitor.

(7) Detection of radioactive contamination attributable to licensed radioactive material.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(10) Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in § 30.50(c)(1), and a written report within 30 days as described in § 30.50(c)(2).

Subpart F - Enforcement

§ 36.91 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of -

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act:

(1) For violations of -

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

§ 36.93 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under Sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in Part 36 are issued under one or more of Sections 161b, 161i, or 161o, except for the Sections listed in paragraph (b) of this section.

(b) The regulations in Part 36 that are not issued under Sections 161b, 161i, or 161o for the purposes of Section 223 are as follows:

§§ 36.1, 36.2, 36.5, 36.8, 36.11, 36.13, 36.17, 36.19, 36.91, and 36.93.

PART 19 - NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS AND INVESTIGATIONS

2. The authority citation for Part 19 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 19.2 [Amended]

3. Section 19.2 is amended by changing "35" to "36."

§ 19.3 [Amended]

4. In §19.3 the definition <u>License</u> is amended by changing "35" to "36" in the first sentence.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

5. The authority citation for Part 20 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 20.2 [Amended]

6. Section 20.2 is amended by changing "35" to "36."

§ 20.3 [Amended]

7. Section 20.3(a)(9) is amended by changing "35" to "36."

§ 20.203 [Amended]

8. In § 20.203, paragraphs (c)(6) and (c)(7) are removed.

§ 20.1002 [Amended]

9. Section 20.1002 is amended by changing "35" to "36."

§ 20.1003 [Amended]

10. In § 20.1003, the definition of license is amended by changing "35" to "36."

§ 20.1603 [Removed]

11. Section 20.1603 is removed.

§ 20.2109 [Removed]

12. Section 20.2109 is removed.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

13. The authority citation for Part 30 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 as amended (42 U.S.C. 5841)* * *.

§ 30.4 [Amended]

14. In § 30.4, the definition of License, is amended by changing "35" to "36."

§ 30.5 [Amended]

15. Section 30.5 is amended by changing "35" to "36."

§ 30.6 [Amended]

16. In § 30.6, paragraphs (a) and (b)(1) are amended by changing "35" to "36."

§ 30.11 [Amended]

17. In § 30.11, paragraph (a) is amended by changing "35" to "36."

§ 30.13 [Amended]

18. Section 30.13 is amended by changing "35" to "36."

§ 30.14 [Amended]

19. In § 30.14, paragraph (a) is amended by changing "35" to "36," and paragraph (c) is amended by adding ", 36" after "33, 34."

§ 30.15 [Amended]

20. In § 30.15, the introductory text of paragraph (a) is amended by changing "35" to "36."

§ 30.16 [Amended]

21. Section 30.16 is amended by changing "35" to "36."

§ 30.18 [Amended]

22. In § 30.18, paragraph (a) is amended by adding ", 36" after "30 through 34."

§ 30.19 [Amended]

23. In § 30.19, paragraph (a) is amended by changing "35" to "36."

§ 30.20 [Amended]

24. In § 30.20, paragraph (a) is amended by changing "35" to "36."

§ 30.31 [Amended]

25. Section 30.31 is amended by changing "35" to "36."

§ 30.33 [Amended]

26. Section 30.33, paragraph (a)(4) is amended by changing "35" to "36."

§ 30.34 [Amended]

27. Section 30.34, paragraphs (a) and (b) are amended by changing "35" to "36"; paragraph (c) is amended by changing "35" to "36" in the first and the second sentences; paragraphs (d) and (e) are amended by changing "35" to "36."

§ 30.39 [Amended]

28. Section 30.39 is amended by changing "35" to "36."

§ 30.51 [Amended]

29. In § 30.51, paragraphs (a), (b), and (c)(1) are amended by changing "35" to "36 and 39" and paragraph (c)(2) is amended by changing "35" to "36" in all three locations.

§ 30.53 [Amended]

30. The introductory text of § 30.53 is amended by changing "35" to "36."

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

31. The authority citation for Part 40 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438.88 Stat. 1242 as amended (42 U.S.C. 5841)* * *.

§ 40.5 [Amended]

32. In § 40.5, paragraph (b)(1) is amended by changing "35" to "36" in the first sentence.

PART 51 - ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

33. The authority citation for Part 51 continues to read, in part, as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); secs. 201 as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

§ 51.22 [Amended]

34. In § 51.22, paragraphs (c)(3), (c)(10) and (c)(14) are amended by adding "36," after "34, 35."

§ 51.60 [Amended]

35. In § 51.60, paragraph (a) is amended by adding "36," after "34, 35."

§ 51.66 [Amended]

36. In § 51.66, paragraph (a) is amended by adding "36," after "34, 35."

§ 51.68 [Amended]

37. Section 51.68 is amended by adding "36," after "34, 35,".

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

38. The authority citation for Part 70 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 70.5 [Amended]

39. In § 70.5, paragraph (b)(1) is amended by changing "35" to "36."

§ 70.20a [Amended]

40. In § 70.20a, paragraph (b) is amended by changing "35" to "36."

PART 170 - FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

41. The authority citation for Part 170 continues to read, in part, as follows:

AUTHORITY: 31 U.S.C. 9701, 96 Stat. 1051; sec. 301, Pub. L. 92-314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 170.2 [Amended]

42. In § 170.2, paragraph (a) is amended by changing "35" to "36."

Dated at Rockville, Maryland, this 28th day of January, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 & 170
(55 FR 50008)

(33)

Alpha Omega Technology, Inc.

DOCKETED
USNRC

1279 Route 46
Parsippany, N.J. 07054
United States of America

'91 MAY -8 A11:58

OFFICE OF SECRETARY
DOCKETING & SERVICE

April 4, 1991

Stephen A. McGuire, Ph.D.
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Stephen,

Enclosed you will find the comments from Craig Barnett and myself concerning the proposed 10 CFR Part 36 regulations. We would be happy to elaborate further on any of the points raised.

We appreciate your comments concerning the AOT Irradiator Simulator video that you reviewed. Everyone who has become familiar with the simulator shares your view concerning its usefulness as a training tool for operators.

Very truly yours,

Martin A. Welt, Ph.D.
Chairman

Enclosure

MAW:cwb

MAY 20 1991
Acknowledged by card ....

Tel: (201) 334-4321 Fax: (201) 334-3451

COMMENTS ON PROPOSED AMENDMENTS TO 10 CFR PART 36

Submitted by:

Martin A. Welt, Ph.D.
Chairman

and

Craig W. Barnett
Director of Engineering

Alpha Omega Technology, Inc.
1279 Route 46
Parsippany, NJ 07054

1. SECTION 36.15 - START OF CONSTRUCTION

Licensing an irradiation facility prior to initiating construction is highly undesirable for the following reasons:

1. The NRC should not need control over a company's intention to build an irradiator. Rather, the NRC is more interested in the actual radiation aspects of the facility, systems, shielding, procedures, etc., relating to the irradiator.

2. A company initiating construction of an irradiator generally has invested a lot of time, effort and money in the design of the irradiator, ensuring that it meets all applicable regulations and standards. Commencing construction implies that the company feels there will be no significant complications licensing the plant to operate with radioactive material. Should the NRC elect not to issue the company with a license once the facility is completed, that is a risk the company has elected to take.

3. We do not believe it is legal or appropriate for the NRC to set a rule making it "illegal" for a potential licensee to begin construction, at its own risk, if they so desire. We are concerned that the NRC can politicize this type of a rule, by delaying or preventing companies with all necessary qualifications from getting into the business. How, for example, could a potential licensee hope to speed up the review process, if its financing were dependant on an approval by a certain reasonable date. The NRC could prevent the plant from being built simply by delaying the review process. This is not right, and would lead to unnecessary and costly litigation.

4. For a company with past experience in the construction and operation of irradiation facilities, especially those of a standard irradiator design, for which experience exists, there is precious little the NRC review can add for a new site approval. The company must obtain land use approval from local authorities, and if the site is approved for industrial usage without a negative covenant regarding non-nuclear applications, then the risk to the company would be small if it went ahead with construction before the formal NRC approval was given.

5. Construction of an irradiator generally takes between 12 and 18 months. This, along with preplanning and design time, is a fairly long period of investment prior to seeing any return. If licensing were required before the construction begins, licensing could only be initiated following completion of the final to-build drawings. This would easily add 6 months to a year onto the construction process, making it much more costly to initiate a new project. Further, start-up companies would be adversely effected to the point where start-up capital requirements might preclude starting the company at all, thus harming the industry as a whole.

2. SECTION 36.23 ACCESS CONTROL

2.1 REQUIREMENT FOR PHYSICAL BARRIERS

It is important that personnel access and product access be treated separately. In many large irradiators, personnel access is separate from product access, especially when product is conveyed into the radiation room using some form of conveyor system.

1. Personnel Entrance Access Control

   This refers to access gates or doors used exclusively by personnel or by personnel and product. (The latter would be a common situation in a manually loaded batch irradiator.) Section 36.23(a) adequately covers the access control requirements for these access points.

2. Product Entrance Access Control

   We question the wisdom of requiring a physical barrier, i.e. a door, with a key lock for every access way into the irradiator. This makes sense for a personnel access system, but not for product portals coupled with a conveyor system. Today's irradiators process product at rates as high as one pallet per minute. To require a keyed entry for each pallet, followed by a locking of a door that does not interfere with the conveyor system, would be quite an undertaking. After 25 years of experience with 30 to 50 large commercial irradiators, the NRC has excellent statistical data to endorse other types of electro-mechanical systems that provide truly impressive access control, without encumbering a operations.

The requirement for a physical barrier at product entrances should be altered to include other access control methods. Physical barriers in a large number of facilities are the cause of many maintenance and downtime problems, and have in the past resulted in numerous regulatory infractions. AOT would endorse more appropriate methods in some irradiation facility's such as the use of a variety of redundant light screens or photo-eyes. The light screens or photo-eyes create an invisible barrier through which only pallets are allowed to pass. Any unauthorized access results in immediate shut down of the irradiator.

Fewer moving parts, especially in facilities operating 24 hours a day at high throughput rates, will result in a more secure and reliable system than a physical barrier. We are concerned that adding more "safety" features will bring on more maintenance problems, which may ultimately lead to the safety problems the additional safety features are seeking to avoid.

Further, the physical barrier at a product entrance is not as necessary as a visual deterrent against entering the irradiator as it is at a personnel entrance. Most often, the space is filled with conveyor equipment, or is of a small size, which makes the purpose of the opening evident. Finally, large hanging conveyor systems which might have a flat floor entrance (unlike roller conveyor or shuttle car conveyor systems) can use a car or tote held at the entrance to act as a barrier to deter personnel from using the product entrance for entering the irradiator.

2.2 SECTION 36.23(b) - ENTRY WARNING ALARMS

2.2.1 UNATTENDED OPERATION

We believe it is not appropriate to require that an audible alarm be heard "by at least one other person on site", who is "trained or prepared to promptly render assistance". This would required "coupled crews" for every entry. In most irradiators operating around the clock, crew size is small, especially on back shifts. If a clerical person heard the audible indicating entry, and were in a different part of the building, they would not know whether something happened to the operator. An overseas irradiator uses a mandatory remote phone dialer that is carried into the radiation room on weekends when only one person is on duty. The device requires that a button be held down to prevent dialling out. The theory being that if anything happened to an operator, the button would be let go, and the call would go through. They have used this system in Holland for years with no problems that we know of.

We favor unattended operation for approved automatic conveyor systems for the reason that if something goes wrong, a sensor would activate a telephone call to an operator who is on call. In most cases, the problem is a mechanical one, or perhaps a momentary power outage. If no one responded, the only loss would be processing time. We do not believe that any response to a shutdown signal should be made rapidly. It is better to have time to contemplate what took place, and the steps necessary to remedy the situation. If there is a source hang-up, one of the worst sorts of problems, we still believe it would be better for it to occur while the facility is operating unattended. The facility is designed to provide the shielding required. If one or two workers were present, there is always a possibility that they will try to correct the situation in an unorthodox manner. It is better for the auto-dialer to notify someone on call, who will arrive prepared to analyze the situation in a cautious manner than to charge ahead.

2.2.2 ENTRY WARNING ALARMS

In most facilities, warning lights are located adjacent the personnel gates. These lights indicate different phases of operation including when the source is in its safe storage position, when it is in motion, and when it is in the operate position. No other warning lights are generally present. Facilities also use audible warning alarms to notify personnel that the source rack is in motion, or that an emergency condition, such as a violated interlock, is occurring.

Currently, 36.23(b) calls for both a visible and audible alarm should an interlock be broken. This is vague as it does not directly state to whom that visible alarm is intended. This should be clarified.

It would be prudent that the person violating an interlock should be able to see the visible warning light. In most facilities this is currently not feasible, as once you have broken the interlock, you are already beyond the warning lights. The solution is to locate a light at the end of the first length of the maze(s) providing a clear visual warning not to proceed any further to an individual who has violated an entrance interlock. This would significantly enhance safety, and help to avoid accidental personnel radiation exposure.

3. SECTION 36.33 - IRRADIATOR POOLS AND WATER TREATMENT SYSTEMS

3.1 WATER TREATMENT SYSTEM ROOM

Any water leaking from the water treatment system room is considered contaminated until proven otherwise. Should a water pipe rupture downstream of the water pump, a large amount of source storage pool water may be pumped from the pool. This water would readily find its way down drains or out the door, possibly causing local contamination. A simple solution can be incorporated in water treatment system rooms to protect against this accidental contamination. The base of the walls around the room can be dammed providing sufficient containment for the maximum volume of water which may be lost from the top of the source storage pool and a ruptured Deionizer regeneration water settling tank. Any drains in the floor should be eliminated, and access steps provided to enter an exit the area. Thus if spilled water is contaminated, it would be contained in a small well defined area from which it can be collected and effectively disposed of.

3.2 SECTION 36.33(e) - WATER PURIFICATION SYSTEM

There is some debate as to the need to operate the water treatment system on a 24 hour basis. The paragraph in question provides an operating specification in terms of a minimal acceptable measure of water quality. This is a proper approach. Some operational specification is necessary, such that plant operators know exactly when they are able to operate the irradiator without the water treatment system in operation, and for how long.

It should be noted that if the water treatment system is not operational for a period of time, and if, as a results, the pool water quality is not up to acceptable standards, it doesn't make sense to force a facility shut-down. This only prolongs the length of time that the source rack is exposed to the low quality water. In these situations, it is preferable to maximize facility operation in order to maintain the source rack out of the pool water as much as possible. In fact, even when not operational, it is preferable to store the source rack in its exposed position to prevent damage. The irradiator's interlocks will return it to the source storage pool should any interlocks be violated.

Further, if a maximum time limit for water treatment system shut down is provided, and a facility elects to shut their water treatment system down for the duration of that maximum time, there should be a specification for the length of time that the water treatment system shall be operated at the end of the shut down time period. If at the end of this period water quality is within specification, the only purpose of operating the water treatment system is to check the system operation. It is not necessary therefore to operate the system for only 10 minutes or so, before allowing another long term shut down. We recommend 1 month between required operational checks of the water treatment system.

It should be recommended, however, that even if the water quality is better than the minimum specification, it is a good idea to operate the water treatment system on a regular basis to maintain water circulation around the source rack.

4. SECTION 36.51 - SIMULATOR TRAINING

A paragraph should be inserted into this section covering the use of control system simulators as part of an overall training program. Should an irradiation facility wish to include a simulator as part of their training program, simulator operation time should count towards the overall operation time required to become a qualified plant operator.

A control system simulator should mirror to actual control system in the plant, having the same layout and functionality. An instructor's panel can be used to simulate any alarm condition, exposing the operator to all possible operational variations. Further, a simulator is useful in allowing operators to continuously repeat critical control system operations such as the start-up procedure.

The use of a simulator in training will lessen the possibility of an "in-training" operator making a mistake during actual operations, and will thus enhancing overall operational safety.

5. OPERATING AND EMERGENCY PROCEDURES

The following requirements should be included:

1. The licensee should contact the closest hospital that is familiar with the treatment of radiation injury. The hospital name and telephone number should be clearly recorded and posted.

2. The local fire and police department should be invited to the facility annually to familiarize themselves with the layout, problems and procedures associated with a potential emergency requiring their services at the facility. This should be an annual exercise, and should be documented in the facility's QA manual. The emergency numbers should be clearly posted in strategic locations within the facility.

DS09

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55FR 50008)

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DOCKETING & SERVICE
BRANCH

55-FR-50008
12/4/90

Marvin I. Lewis
7801 Roosevelt Boulevard
Suite 62
Phila., PA 19152
(215)624-1574

In the matter of NRC Proposed Rule: Licenses and Radiation Safety Requirements for Large Irradiators(55FR50008,12-4-90.)

I respectfully and urgently request that specific concerns require that Philadelphia may not be considered as an acceptable site for an large irradiator. The specific concerns are as follows:

1. Philadelphia has a department which does inspections for safety and compliance with the various building codes.
2. This Philadelphia department has been traditionally remiss in its duties recently causing a major disaster in a high rise in the middle of the most densely populated section of this city of 2,000,000.
3. The Proposed Regulation depends upon local ordinance to provide some of the safety required. This enforcement of local regulation in Philadelphia depends upon bribery according to statements of the Fire Commissioner to Jill Porter, a reporter for the Daily News.
4. Other means to meet local regulation includes an 150.00 bribe to L&I officials alleged by local TV stations.

Since Philadelphia is alleged to operate its inspections on a system of bribes, and since this system of bribes has failed to protect this city, and since the proposed regulation depends upon local enforcement which is dubious in Philadelphia, I respectfully request that Philadelphia be specifically excluded as an acceptable site for a large irradiator in the proposed regulation.

Respectfully submitted,

Marvin I. Lewis

4-21-91.

Acknowledged by card MAY 20 1991

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 & 170
PROPOSED RULE (55 FR 50008)

ENVIRONMENTAL COALITION ON NUCLEAR POWER

Headquarters: 433 Orlando Avenue, State College, Pa. 16803

DOCKETED
USNRC

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OFFICE OF SECRETARY
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BRANCH

April 10, 1991

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

In the Matter of
55 FR 50008

Dear Madame or Sir:

Please accept the following supplemental comments for the record in the NRC's Rulemaking on Licensing and Radiation Regulatory Requirements for Large Irradiators. They are submitted on behalf of the Environmental Coalition on Nuclear Power, Food and Water, Inc., and for the Committee on Radiation and the Environment of the Pennsylvania Chapter of Sierra Club. They are meant to accompany our comments submitted in February on 55 FR 50008.

The most glaring deficiency in the Commission's Draft Rule for Large Irradiators was the total lack of detailed siting criteria for these facilities. They are expected to contain and operate with large quantities of highly radioactive source materials, either cobalt-60 or water-soluble cesium-137, with which an accident of major severity and decontamination expense has already been experienced. They are being designed and operated by companies of highly dubious character whose regulatory history is already scarred with numerous instances of violations ranging from the trivial stupid variety to those found to be criminal in nature. They are designed for uses that will cause them to be located at sites in densely populated urban areas for food irradiation and treatment of sewage sludge and garbage, as well as in food-producing and processing areas where the agricultural productivity of the land is of vital importance.

For these reasons, among many others, it is absolutely imperative that the NRC provide a full Programmatic Environment Impact Statement detailing the effects of the entire system of production and utilization and waste management for the entire industry anticipated by the Department of Energy, proponent of this commercial uses of this technology, and the NRC. The Environmental Assessment (EA) is wholly insufficient and fails to address even the issues cited above, much less all others associated with the licensing and operation of a major new nuclear industry that threatens to be pervasive in the U.S. and abroad.

<u>We request the NRC to withdraw its EA and FONSI and</u> take the time and care <u>to produce a complete PEIS on Large Irradiators</u>. Not to do so would be an act of negligence, arbitrary, capricious, and extremely contrary to the public interest and to the NRC's responsibilities under both the Atomic Energy Act, Energy Reorganization Act, and the National Environmental Policy Act, as well as Clean Air Act and Resource Conservation and Recovery Act.

Sincerely,

Judith H. Johnsrud

Judith H. Johnsrud, Ph.D.
Director, ECNP, Research Director, F&W
Co-Chair, PA Chapter CORE, Sierra Club

No member of the public interest community was listed among persons contacted, p. 11

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55FR 50008)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DOCKETED
USNRC

'91 APR 15 P4:15

OFFICE OF SECRETARY
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BRANCH

National Institutes of Health
Bethesda, Maryland 20892
Building : 21
Room : 110
(301) 496- 2254

April 12, 1991

31

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

Attention: Docketing and Service Branch

Dear Sir:

Thank you for the opportunity to comment on the proposed new 10 CFR Part 36 (Federal Register Notice dated December 4, 1990), which addresses licensing and radiation protection requirements for large gamma irradiators. The extension of the deadline to April 15, 1991 for submission of our comments is very much appreciated.

It appears that the proposed regulations have been written with large industrial irradiators in mind and are intended to prevent the specific types of accidents experienced with industrial type irradiators. As such, these proposed regulations will place unnecessary restrictions on the use of large irradiators for biomedical research by small groups of highly trained individuals. It is stated in the Federal Register Notice that it is not the intention of the NRC to "unnecessarily restrict the use and growth" of large irradiators; therefore, the NIH requests that the NRC revise the regulations in the new Part 36 with more consideration given to the type of use of the irradiator.

The NIH is licensed by the NRC for use of up to 2000 curies of cobalt-60 in an AECL Eldorado irradiator. Although this irradiator is designed for medical use, it is never used for patients at the NIH. The purpose of our irradiator facility is to irradiate *in vitro* cancer cell lines and occasionally small animals for long periods of time (hours to days) at low dose-rate radiation. The facility is used exclusively for basic science research directly related to identifying approaches/conditions that may be used to improve cancer treatment, specifically where radiation implants (brachytherapy) are used. Most of the experiments are conducted over many hours; however, experimental samples are only taken intermittently. Thus, long periods of time are devoted to simply irradiating biological samples without the need to interrupt the irradiation period by entering the room.

In 1988, the NRC granted the NIH a license amendment to allow unattended operation of our Co-60 irradiator. The facility was redesigned to include redundant warning systems (visual and audible), multiple locked barriers to prevent unauthorized entry, and an automated telephone warning device to alert an off site operator of irradiator shut-down. The NRC was obviously confident that this redesign ensured that unattended operation of the irradiator was safe.

APR 24 1991
Acknowledged by card

The facility has been inspected by the NRC on two occasions since this amendment was approved and no violations or deficiencies have been found.

A copy of our license amendment allowing unattended use is enclosed so that you may review our design. We hope that you will agree that a research facility which operates for long periods of time without interruption does not require all of the radiation protection features necessary to make an industrial irradiator safe.

In particular, the suggested regulations found in proposed Parts 36.23 (Access Control), 36.31 (Control of Source Movement) and 36.65 (Attendance During Operation) would place unnecessary restrictions on the use of research irradiators. These regulations would require the following:

- On site presence of a trained operator when the irradiator is in use. Another person, trained and prepared to render assistance if needed, must also be on site.

  The NIH and other biomedical research facilities would be particularly affected by this regulation when performing the long term irradiations previously described. Research personnel would be required to spend entire days and nights doing nothing but sitting at the irradiator console. This would be a terrible waste of valuable research time.

- A lock on the primary entry door which is operated by the same key used to move the source.
- A radiation monitor integrated to the primary entry door which would prevent entry when high radiation levels are detected or when the monitor malfunctions or is turned off.

  These two proposed regulations would require major renovations of the NIH irradiator facility. Backup access controls, such as motion detectors inside the irradiator room, redundant secondary physical barriers and multiple visible and audible warning systems should ensure that personnel do not enter the room when the source is exposed.

We would be very interested in arranging a tour of our irradiator facility for you and the NRC staff who are writing these proposed regulations. This would be an excellent (and convenient!) opportunity to observe the operation of a large research irradiator and to interview its users. Please contact me if you wish to schedule a tour or if you would like more information concerning our irradiator facility.

William J. Walker, Ph.D.
Radiation Safety Officer, NIH

Attachment

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406

SEP 0 6 1988

RECEIVED
SEP 1 2 1988
NIH, Radiation Safety

License No. 19-00296-20
Docket No. 030-17872
Control No. 109040

Department of Health and
Human Services
ATTN: R.J. Augustine, RSO
National Institutes of Health
9000 Rockville Pike Bldg. 21 R
Bethesda, Maryland 20892

Gentlemen:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

We wish you success in operating a safe and effective licensed program.

Sincerely,

John R. White, Chief
Nuclear Materials Safety Section C
Division of Radiation Safety
and Safeguards

Enclosures:
1. Amendment No. 06
2. Requirements for Materials Licensees

MATERIALS LICENSE

Amendment No. 06

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93–438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. Department of Health and Human Services National Institutes of Health	3. License number: In accordance with application dated June 8, 1988, 19-00296-20 is amended in its entirety to read as follows:
2. Radiation Safety Officer, Building 21 9000 Rockville Pike Bethesda, Maryland 20892	4. Expiration date: October 31, 1991 5. Docket or Reference No.: 030-17872

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Sealed sources (AECL Capsule Type C-151)	A. One source not to exceed 2,000 curies

9. Authorized use

A. For use in an AECL Eldorado-78 teletherapy unit to perform irradiation studies on cell cultures and small animals.

CONDITIONS

10. Licensed material shall be used only at National Institute of Health, Building 10, Room B3-B44C-1, 9000 Rockville Pike, Bethesda, Maryland.

11. A. Licensed material shall be used by individuals designated by the NIH Radiation Safety Committee.

B. The Radiation Safety Officer for this license is Robert J. Augustine, Ph.D.

12. Sealed sources containing licensed material shall not be opened by the licensee.

13. A(1) Any sealed source specified in Item 7.A shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source or detector cell is exempt from such leak tests when the source or detector cell contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

NRC Form 374A
(5-84)

U.S. NUCLEAR REGULATORY COMMISSION

License number
19-00296-20

MATERIALS LICENSE
SUPPLEMENTARY SHEET

Docket or Reference number
030-17872

Amendment No. 06

(13. continued) CONDITIONS

B. Any sealed source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.05 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the source or detector cell shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

14. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material. Removal, replacement, and disposal of sealed sources in the irradiator shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

15. Licensed material shall not be used in or on human beings.

16. After each installation of Cobalt 60 sources and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. A detailed report in duplicate of the results of the surveys shall be sent to the Nuclear Materials Safety Branch U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

NRC Form 374A (5-84)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number 19-00296-20

Docket or Reference number 030-17872

Amendment No. 06

(17. continued)

CONDITIONS

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated December 18, 1985
B. Letter dated December 11, 1986
C. Letter dated June 8, 1988
D. Letter dated August 15, 1988

For the U.S. Nuclear Regulatory Commission

Date SEP 0 6 1988

By [signature]
Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

REQUIREMENTS FOR MATERIALS LICENSEES

As a holder of an NRC material license, you must:

1. Operate in accordance with NRC regulations contained in 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Possess radioactive material only in the quantity(ies) and form(s) indicated in your license.

3. Use radioactive material only for the purpose(s) indicated in your license.

4. Notify NRC in writing of any change in mailing address (no fee required if the location of radioactive material remains the same).

5. Request and obtain appropriate amendments if you plan to change the ownership of your organization, change locations of radioactive material, or make any other changes in your facility or program which are contrary to your license conditions or representations made in your license application and any supplemental correspondence with NRC. A license fee may be charged for the amendment as specified in 10 CFR Part 170.

6. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date on your license. You should receive a reminder notice approximately 90 days before the expiration date. However, it is your responsibility to file a renewal application at the proper time. Possession of radioactive material after your license expires is a violation of NRC regulations.

7. Request termination of your license if you plan to permanently discontinue activities involving radioactive material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date September 14, 1988

From Radiation Safety Officer, NIH

Subject Amendment of NRC License No. 19-00296-20 (Eldorado 78 Teletherapy Unit)

To Dr. James Mitchell
Radiobiology Section
ROB, COP, DCT, NCI

This is to advise you that the USNRC has granted our request for amendment of the subject license to permit the unattended operation of the irradiator during long irradiation times. A copy of the amended License No. 19-00296-20, amended in its entirety as Amendment No. 6, is attached for your information and records.

Please note that this amendment was granted pursuant to the NIH commitments stated in our letter of June 8, 1988 as subsequently modified by our letter of August 15, 1988, including the revised RADIATION SAFETY PROCEDURES MANUAL FOR OPERATION OF IRRADIATOR (ELDORADO 78).

As the Authorized Custodian of this unit, please ensure that all radiation safety procedures, including the requirement to test certain alarms and safety systems prior to unattended operation and to include this testing procedure in your training programs, are adequately followed. Accomplishment of these required tests should be documented in the operating log each time prior to unattended operation.

Please contact your Area Health Physicist, Ms. Lynn Jenkins, if you have any questions regarding this amendment or the required procedures.

R.J. Augustine

R.J. Augustine, Ph.D.

Attachment

cc: Dr. Jacob Robbins, Chairman, NIH Radiation Safety Committee
Dr. Eli Glatstein, Chief, ROB, COP, DCT
Dr. Robert McKinney, Director, Division of Safety
Mr. Norman Mansfield, Acting Director, ORS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : 21
Room : 110
(301) 496- 2254

August 15, 1988

U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Section B
Division of Radiation Safety and Safeguards
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License No. 19-00296-20
Control No. 109040

Dear Sir or Ms:

This is an amendment to our request dated June 8, 1988 regarding amendment of License No. 19-00296-20 to permit unattended operation of the Eldorado 78 irradiator.

Following the suggestions of Mr. Jack Davis of your office, we have revised pages 5 and 6, IRRADIATION PROCEDURES, and page 14, TRAINING REQUIREMENTS, to specify that certain alarms and safety systems shall be tested prior to unattended operation and that such testing requirement be included in the training program for the Authorized Custodian and Designated Users.

Copies of revised pages 5,6, and 14 are enclosed. These revised pages should replace the pages in our June 8, 1988 submission.

The suggestions of Mr. Jack Davis are appreciated. I trust, with these revisions, that favorable consideration of our request for amendment can now be accomplished. If you have further questions or need additional information, please contact me at FTS 496-2254.

Sincerely,

R.J. Augustine

R.J. Augustine, Ph.D.
Radiation Safety Officer, NIH

Enclosures

cc: Dr. Jacob Robbins, Chairman, NIH Radiation Safety Committee
Dr. James Mitchell, Radiobiology Section, ROB, COP, DCT, NCI
Dr. Eli Glatstein, Chief, Radiation Oncology Branch, COP, DCT, NCI

Irradiation Procedures

The irradiator may be operated ONLY by:

- the Authorized Custodian (individual responsible for supervision of use, approved by the NIH Radiation Safety Committee)
- a Designated User; see Appendix A for sample form used to list Designated Users.

Users must be familiar with the operating instructions and adequately trained in proper operation and emergency procedures.

Continuous irradiation is allowed without a Designated User present ONLY after safety devices have been tested and when the restrictions on access and warning devices detailed in the section Description of Irradiator have been activated. The following safety devices must be tested prior to each unattended use:

- door interlock (B3-B44C-1)
- warning lights at entrance to B3-B44C and inside B3-B44C
- infrared motion detector inside B3-B44C
- telephone alert
- area radiation monitor in B3-B44C-1

1. Obtain machine operating keys from secured location. All individuals must wear personnel dosimeters before entering the irradiation room.

2. Visually check to make sure all persons are out of the irradiator room.

3. Test safety devices listed above if irradiator is to be operated unattended. If any of these devices fail to operate properly do not proceed with irradiation. Secure the area and notify Radiation Safety. If safety devices operate properly continue with irradiation procedure.

4. Place samples to be irradiated in desired geometry. Consult manufacturer's operating manual.

5. Set conditions for irradiation on control console.

6. Activate all restrictions on access and warning devices if irradiator is to be operated unattended.

7. Begin irradiation.

8. The source is returned to the "Beam Off" position:
   a. at the end of the predetermined time as set on the preset timer.
   b. by pushing the Emergency stop pushbutton on the control panel.
   c. by power interruption.

9. Deactivate keyswitch and remove key.

10. Via the TV monitor, check to see that the source rod has retracted and that the warning lights on the irradiator are no longer lit. Check warning lights outside the irradiator room. If all lights indicate source is no longer exposed, open the door to the irradiator room and check the area monitor on the ceiling to assure safe entry. If any one monitor indicates unsafe conditions, DO NOT ENTER ROOM!! Consult Emergency Procedures.

11. Record required data in use log (Appendix B).

12. Return keys to secured location.

Description of Irradiator

Safety Systems

The room housing the cobalt-60 irradiator is posted with the appropriate radiation signs according to 10 CFR 20.203. An emergency procedure sheet is posted at the control console and at the irradiator.

Several protective devices are incorporated into the unit. The source and the source drawer will remain in the "Beam Off" position or return to "Beam Off" position when:

1. Electrical power supply fails.
2. The door interlock has been activated by means of the irradiator room door being opened during irradiation or by detection of entry into the irradiation room by the infrared detector.
3. Air pressure in the pneumatic system falls below 35 psig.
4. An Emergency Stop pushbutton is depressed on the west wall of B3-B44C-1, either side of the main frame of the irradiator or on the control console outside the room.

The individual conducting the leak test shall record this in the Use Log, Appendix B.

Routine Compliance Surveys

Such surveys will be conducted at yearly intervals and consist of the following:

1. Insure proper operation of all interlocks on irradiator.
2. Measure exposure rates at all accessible points around the irradiator using a portable ionization chamber and insure that levels are within regulatory limits.
3. Checks for compliance with provisions of this manual including adherence to Irradiation Procedures and proper training of operators.
4. Inspect area radiation monitors for proper operation.
5. Document completion of survey in the Use Log (Appendix B).

Training Requirements

Training for the Authorized Custodian will include:

1. Attendance at the course, "Radiation Safety in the Laboratory", presented by the Radiation Safety Branch. A schedule for a recent course is shown on the next page.

2. Irradiator safety training provided by the Radiation Safety Branch to consist of at least the following:
   a. Contents of this manual.
   b. Demonstration of the proper operation of the irradiator. This will include instructions for testing safety devices before each unattended operation as described in the section Irradiation Procedures.
   c. Emergency procedures.

Training for Designated Users will include:

1. Designated users (operators) are required to complete the above program. The Authorized Custodian of the irradiator will be responsible for accomplishing item 2.

2. The Authorized Custodian will enter the name of Designated Users on List of Designated Users (Appendix A), note the date of training, and sign the form to certify that the Designated User is properly trained.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

Memorandum

Date July 14, 1988

From Radiation Safety Officer, NIH

Subject Additional NRC Requirements for Unattended Teletherapy Irradiator Use

To The File

Mr. Jack Davis, NRC Region I, called today to advise of additional requirements before they will grant our request for license amendment to permit unattended operation of the teletherapy irradiator.

These are as follows:

1. Commit to test all alarms prior to each unattended use.

   (I suggested to Jack that we specify which alarms or safety systems would be tested before each use of the irradiator in the unattended mode, rather than "all alarms", and he agreed with this suggestion, as long as we include all those that are critical to safety, i.e., door interlocks, warnings, remote telephone alerting system, etc.)

2. Commit to include this testing requirement in the training program for the Authorized User and the Designated Users.

Jack Davis further suggested that we initiate the written action on this, as an addition to our license amendment request, in response to his telephone call, rather than waiting for NRC to send us a letter which may take another month.

Our communication to the NRC on this matter should reference the Control Number 109040.

The appropriate HP (Lynn or ?) should discuss these new requirements with Dr. Jim Mitchell and staff and should prepare a suitable letter which specifies the "before unattended use" testing procedure and defines which alarms and/or safety systems will be tested each time. Please make sure that all those critical to safety are included. Also, we need to commit to having such testing requirement and procedures included in the required training for users of this irradiator.

Jack Davis' phone number is FTS 346-5250, in case we need to communicate directly with him.

R.J. Augustine

R.J. Augustine, Ph.D.

cc: Broseus, Fowler, Jenkins, Dr. Robbins

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
Building : 21
Room : 110
(301) 496- 2254

June 8, 1988

U.S. Nuclear Regulatory Commission
Nuclear Material Safety Section B
Division of Radiation Safety and Safeguards
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License No. 19-00296-20

Dear Sir or Ms:

This is a request to amend License No. 19-00296-20 to authorize operational procedures different from those specified in Attachment 9.1 to license renewal application dated December 18, 1985, and to provide you a copy of our revised "Radiation Safety Procedures Manual for Operation of Irradiator (Eldorado 78)" which incorporates the new operational procedures.

The specific change requested is authorization to operate this irradiator without a designated operator in constant attendance.

Long irradiation times are needed to achieve the radiation doses required for the research being done with this unit (up to 72 hours continuously with the current source activity, and longer times as the source decays). This irradiator is not used for, or authorized for patient treatment. With the system of interlocks and control methods described in the enclosed revised manual, we believe that this irradiator can be operated safely without an operator in constant attendance. We believe that unauthorized access to the irradiator room is well controlled and that the safety interlocks and warning systems will function appropriately to prevent radiation exposure if someone should gain unauthorized access.

We have verified the proper functioning of these safety systems.

Your prompt review and approval of this request will facilitate continued research using this unit. Please contact me at FTS 496-2254 if additional information is required.

Sincerely,

R.J. Augustine

R.J. Augustine, Ph.D.
Radiation Safety Officer, NIH

Enclosure

cc: Dr. Jacob Robbins, Chairman, NIH Radiation Safety Committee
Dr. James Mitchell, Radiobiology Section,
ROB, COP, DCT, NCI

This page revised: 5/88

National Institutes of Health

Division of Safety

Radiation Safety Branch

RADIATION SAFETY PROCEDURES MANUAL

FOR

OPERATION OF IRRADIATOR
(ELDORADO 78)

IN CASE OF ANY EMERGENCY INVOLVING THIS IRRADIATOR, CALL RADIATION SAFETY AT 496-5774. AFTER NORMAL WORKING HOURS, CALL 116 AND REQUEST RADIATION SAFETY ASSISTANCE.

Manufacturer of Irradiator	:	Atomic Energy of Canada Limited (AECL)
Model	:	Eldorado 78
Radionuclide	:	Cobalt 60
Rated Capacity	:	2000 Curies
Source Activity	:	553 Curies on 5/23/88
Location of Irradiator	:	Building 10 Room B3-B44C-1
Individual Responsible for Supervision of Use (Authorized Custodian)	:	Dr. James Mitchell Name
		Building 10 Room B3-B69 Address
		496-7511 Telephone

U.S. Nuclear Regulatory Commission License Number: 19-00296-20

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Certificate Of Measurement

of

TELETHERAPY SOURCE S3114

for

CUSTOMER National Institutes of Health
Bethesda, Maryland

AECL ORDER No. P&S 41299

THERAPY UNIT OUTPUT When installed in Eldorado 78 #61 (at maximum field size) the exposure rate will be 29.7 Rmm* (±5%), based on the source measurement (below), and the equipment conversion ratio described on sheet 3.

MEASUREMENT OF SOURCE Source S3114 is a 2.0 cm diameter standard source, type C-151 Co60C, containing 1426 curies of cobalt 60. The source exposure rate was 27.8 Rmm (±3%) at the one metre position of the measurement cell.

As of

DATE OF MEASUREMENT February 20, 1981

MEASUREMENT METHOD

The source exposure rate was measured in the cell described on the following sheet (Form CC 9 Sheet 2). The exposure rate was measured with an air wall cavity ionization chamber having a volume of 0.6 cm^3 and fitted with a 4.6 mm lucite equilibrium cap. The instrument is calibrated in a cobalt-60 exposure rate certified by the National Research Council of Canada.

ACCURACY

The uncertainty in the source exposure rate applies only to measurement of this source in the AECL Measurement Cell. It represents the maximum total uncertainty due to all causes including the calibration of the Council's primary exposure rate, the calibration of their instrumentation and the precision of measurement in the Measurement Cell. Additional uncertainty due to the comparative measurements involved, has been included in the statement of unit output.

EXCERPT FROM THE RECOMMENDATIONS OF THE INTERNATIONAL COMMISSION ON RADIATION UNITS & MEASUREMENTS, REPORT ICRU-13, OCTOBER 1970. "It must be emphasized the measurement of exposure rate and/or absorbed dose for treatment purposes should be made locally by the user himself. The statement of equipment conversion ratio by the manufacturer should not be regarded as a substitute for this."

ISSUED 1981 February 27

APPROVED [signature] for P.D. Lanoue
Measurement

[signature] I. Vajcovec
Quality Control

Atomic Energy of Canada Limited

Ottawa Canada

*NOTE: Rmm stands for roentgens per minute at one metre.

FORM CC 9 • SHEET 1 5/73

INTRODUCTION

The AECL Eldorado 78 cobalt-60 irradiator is a high activity sealed source machine which is capable of producing uniform radiation fields for radiobiological research. This unit is licensed by the U.S. Nuclear Regulatory Commission as an industrial type irradiator for research purposes only, even though it is designed for medical use. The Co-60 radiation sources supplied by AECL are doubly encapsulated in stainless steel and comply to ICRP Report No.18. A measurement certificate is supplied with each source. The Eldorado 78 is designed to contain a pneumatically driven sealed source which, when not in use, is contained in a heavily shielded sourcehead. The source can be brought to the "Beam On" position only when the sourcehead is directed at the floor or the west wall. This unit meets the recommendations of the International Commission on Radiological Protection, ICRP 15, paragraph 139, "Teletherapy Protective Source Housing" and National Council on Radiation Protection and Measurements Reports No. 33 and 34. The source head assembly is attached to the base and main frame and is installed in the NIH, Building 10, Room B3-B44C-1. This heavily shielded room is in the third subbasement of the Clinical Center in the Radiation Oncology Department. This is a controlled access area that is secured after normal working hours. Housekeeping, engineering and other ancillary personnel are not permitted in the area after hours. The sourcehead securely shields the cobalt-60 when the machine is not in use and requires key controlled power activation to move the source to the "Beam On" position. The key switch is mounted on the control console located in B3-B44 outside the irradiator room. Safety interlocks and other protective devices must be properly engaged in order for the machine to emit radiation. Emergency stop pushbuttons are located on the control console, the west wall of B3-B44C-1 and on either side of the main frame of the unit. Interruption of any safety device will return the source to the "Beam Off" position. Access controls and warning devices used when a designated user is not present are detailed in the section, <u>Description of Irradiator</u>. Specific details of operation are covered in the manufacturer's Operations Manual (Appendix C).

EMERGENCY Procedures

Alarm Conditions

An area radiation monitor is installed in the room housing the irradiator to indicate hazardous exposures via audible and visual alarms which will be activated if the door is opened and the cobalt-60 source retraction mechanism has malfunctioned leaving the source in the unshielded position. Also, the large warning lights at the door entrances to B3-B44C and B3-B44C-1 and inside B3-B44C-1, the red light on the control console and the red light on the irradiator itself (seen via TV monitor) will remain lit if the source remains in the "Beam On" position. See Drawing 1 for location of radiation monitor and warning lights. Should any of these conditions exist, i.e., audible alarm sounds and/or warning lights remain lit when door to B3-B44C-1 is opened, the irradiator is to be taken out of service at once and the following steps taken:

1. Do not enter the room.
   Secure door to irradiator room. Secure keys to irradiator control console. Doors to B3-B44C and B3-B44 should be locked.

2. Notify the Radiation Safety Branch at 496-5774. If after normal working hours, dial 116 to get the NIH Fire Department. The NIH Fire Department will use the Emergency Call List to obtain assistance from Radiation Safety staff.

3. Notify the Authorized Custodian shown on the cover of this manual.

4. Do not attempt to repair the irradiator.

5. Do not attempt to operate the irradiator without clearance from Radiation Safety.

6. Give a written description of the event in the user log.

Contact Radiation Safety at 496-5774 if there are any questions about the safety of the irradiator.

An emergency procedure sheet is posted at the control console and at the irradiator.

For more information on safety systems see the section of the manual entitled Description of Irradiator.

Procedures for Gaining Authorization to Use Irradiator

1. Authorized Custodians

Irradiators shall be used under the supervision of individuals so authorized by the Chairman, Radiation Safety Committee; those individuals shall be termed "Authorized Custodians".

Individuals may become Authorized by submitting a memorandum applying to be designated as an Authorized Custodian to the Chairman, Radiation Safety Committee, through the Radiation Safety Officer. In order to be approved, the memorandum must contain the following:

a. Evidence of meeting the "Training Requirements" contained in this manual.

b. A specification of the irradiator for which the individual is applying to be the Authorized Custodian including the manufacturer, model, radionuclide in sealed source contained in the irradiator and the activity, the building and room number where the irradiator is located and the individual's title, Bureau, Institute or Division (BID) and organizational subunit.

c. A statement by the applicant that he or she will be responsible for supervising the use of the irradiator in accordance with the provisions of this manual.

Upon receipt of the application, the Radiation Safety Officer shall review it to ensure compliance with applicable license conditions, NRC regulations and Radiation Safety Committee requirements. The RSO shall be responsible for making a recommendation to the Committee Chairman regarding approval/disapproval. Authority and responsibility for control of the irradiator must be in accordance with provisions of this manual and cannot be reassigned without the approval of the Radiation Safety Committee Chairman. Authorizations cannot be transferred to other individuals. See the section of the manual entitled Change of Authorized Custodian.

2. Designated Users (operators)

Individuals may become Designated Users by completing the training requirement described in this manual and by being so designated by the Authorized Custodian. This should be recorded in Appendix A, List of Designated Users.

See revised p 5 in 8/15/88 memo

Irradiation Procedures

1. The irradiator may be operated ONLY by:

   a. the Authorized Custodian (individual responsible for supervision of use, approved by the NIH Radiation Safety Committee)

   b. a Designated User; see Appendix A for sample form used to list Designated Users.

2. Continuous irradiation is allowed without a Designated User present ONLY when the restrictions on access and warning devices detailed in the section Description of Irradiator have been activated.

3. Users must be familiar with the operating instructions and adequately trained in proper operation and emergency procedures.

4. Obtain machine operating keys from secured location. All individuals must wear personnel dosimeters before entering the irradiation room.

5. Place samples to be irradiated in desired geometry. Consult manufacturer's operating manual.

6. Visually check to make sure all persons are out of the irradiator room and close the door. * Activate restrictions on access and warning devices if irradiator is to be operated unattended.

7. Set preset digital timer to desired exposure time.

8. Activate push-button marked "Treat" on timer.

9. The source is returned to the "Beam Off" position:

   a. at the end of the predetermined time as set on the preset timer.

   b. by pushing the Emergency stop pushbutton on the control panel.

   c. by power interruption.

10. Deactivate keyswitch and remove key.

See revised p. 6 in 8/15/88 memo.

11. Via the TV monitor, check to see that the source rod has retracted and that the warning lights on the irradiator are no longer lit. Check warning lights outside the irradiator room. If all lights indicate source is no longer exposed, open the door to the irradiator room and check the area monitor on the ceiling to assure safe entry. If any one monitor indicates unsafe conditions, DO NOT ENTER ROOM!! Consult Emergency Procedures.

12. Record required data in use log (Appendix B).

13. Return keys to secured location.

Description of Irradiator

Safety Systems

The room housing the cobalt-60 irradiator is posted with the appropriate radiation signs according to 10 CFR 20.203. An emergency procedure sheet is posted at the control console and at the irradiator.

Several protective devices are incorporated into the unit. The source and the source drawer will remain in the "Beam Off" position or return to "Beam Off" position when:

1. Electrical power supply fails.
2. The door interlock has been activated by means of the irradiator room door being opened during irradiation or by detection of entry into the irradiation room by the infrared detector.
3. Air pressure in the pneumatic system falls below 35 psig.
4. An Emergency Stop pushbutton is depressed on the west wall of B3-B44C-1, either side of the main frame of the irradiator or on the control console outside the room. This will retract the source and trigger one of the following audible alarm systems:
   - a buzzer on the main frame relay panel inside the irradiator room,
   - an alarm at the control console outside the irradiator room.

   There is no audible alarm with the Emergency Stop pushbutton on the west wall of B3-B44C-1.

The Emergency Stop push-buttons on the control console and the irradiator, when depressed, will, in addition to returning the source to a safe position, lock out all power to the main power supply. These push-buttons must be manually reset to restore power to the console.

5. Failure of source drawer linkage. In this event, an auxiliary source drawer retractor will return the source drawer to a safe position within 0.3 cm of the "Beam Off" position until the fault is corrected.

In addition to the protective devices described above, which are incorporated into the irradiator (some automatic), there is also a system of restrictions on access and warning devices which will allow safe operation without a Designated User in attendance. The following is a description of that system.

1. Restrictions to the Department in General

    a. After normal working hours the entire department is locked.
    b. Housekeeping functions are performed during working hours.
    c. Access to the irradiator console area (B3-B44) is restricted to personnel who are authorized to use the irradiator and to the Radiation Safety Branch. The key to this area is restricted and is not the general department key. (See Drawing 1, Position A).

2. Restrictions on Access and Warning Devices in Console Area (B3-B44)

    a. Warning lights- A three panel, four segment lighted warning sign is located next to the entrance door to room B3-B44C (see Figure 1). Each panel contains two incandescent bulbs wired in parallel. The panels are labelled as follows:
        (1) "Cobalt-60" -- Indicates power on condition, (yellow panel).
        (2) "Safe" -- Indicates source retracted, no radiation in the area, (green panel).
        (3) "Caution Radiation" -- Indicates source extended, radiation in the area, (red panel). NOTE: This segment of warning sign flashes when source is extended.

(4) Radiation Symbol -- Indicates source extended, radiation in area, (yellow panel, magenta symbol). NOTE: This segment does not flash.

b. TV monitor- A television monitor is located at the operator's console (see Figure 2). This is used to view the irradiator and surrounding area using a camera equipped with a wide-angle lens. The red warning light on the irradiator (which when lit indicates "Beam On") as well as the source rod can be seen with this monitor.

c. Door to Room B3-B44C- The Entrance to Room B3-B44C is equipped with the following warning signs and access restrictions:

(1) Key lock, same key as main entrance to console area (Drawing 1, Positions A and B.)

(2) Door has warning sign (Figure 1).

(3) Door has combination access lock. Knowledge of combination is restricted to users of the irradiator. The combination lock is programmable and the Authorized Custodian can change it if necessary. The Radiation Safety Branch will be notified of combination changes.

3. Restrictions on Access and Warning Devices in Room B3-B44C

a. Warning Lights- These warning lights are the same design as those described in Section 2.a. They are located on the west wall, directly across from the entrance door (see Figure 3). They are wired in parallel with the other warning signs.

b. Intrusion Detector- A passive infrared motion detector is mounted on the west wall, facing the room entrance. This detector is activated while the beam is on and issues a verbal warning when entry is sensed. The warning statement issued is: "WARNING, YOU ARE ENTERING A SECURE AREA. PLEASE EXIT IMMEDIATELY." This warning is issued twice, after which the detector is reset.

c. The shielded door is the only entrance to the irradiator room and is posted with a "Caution High Radiation Area" warning sign (see Figure 4). The door is equipped with an interlock switch which is in series with the circuit energizing the source to the "Beam On" position. The door must be closed (contact made between door and interlock switch) before the source can be placed in the "Beam On" position. If the door is opened while the source is in the "Beam On" position, the interlock circuit is broken and the source will retract to its shielded position. Once the door interlock is tripped, the irradiator must be manually reset at the console to resume irradiation.

4. Restrictions and Warning Devices in the Irradiation Room(B3-B44C-1)

The entrance into the irradiator room opens into a corridor that is shielded from primary radiation. The radiation levels in this corridor are substantially lower than those in the room proper. Warning indicators are arranged to be viewed while in this corridor.

a. Warning Lights- These warning lights are the same as those described in Section 2.a. These lights are on the north wall, facing the entrance (see Figure 5). They are wired in parallel with the other warning lights.
b. Independent Radiation Monitor- An area radiation monitor is mounted on the ceiling and is visible from the room entrance (see Drawing 1 and Figures 5 and 6). Power supply to the monitor is connected to the hospital emergency power system so that the monitor will continue to function in the event of a power failure. This monitor provides a visual indication of a radiation hazard, using a flashing red light, and an audible warning tone if the door is opened while the source is on. The monitor will alarm at $\geq$ 2mR/hour. This alarm is calibrated and checked annually to assure that it is functioning properly.
c. Intrusion Detector- A passive infrared sensor is mounted on the north wall facing the entrance (see Drawing 1 and Figures 5). This detector is wired in series with the door interlock circuit and will activate this interlock when entry is detected. Power to this sensor is also on the hospital emergency power supply so that it will continue to operate in the event of a power failure.

5. Alerts to the Authorized Custodian or Designated User

a. Telephone Alert System- A status monitor alarm is installed to monitor several conditions and alert the Authorized Custodian or Designated User to potential problems by a telephone message. The Authorized Custodian or Designated User is responsible for informing the Radiation Safety Branch if the telephone alert system has been activated and a radiation hazard exists. Location of this device is shown in Drawing 1 and Figures 1, 2 and 7.

The following conditions are sensed by the telephone alert system:

(1) Irradiation interrupted
(2) Temperature in irradiator room out of set limits
(3) Electrical power failure

Upon sensing any of the above conditions, a telephone alert cycle is activated. The alert can be placed to several different telephone numbers in rotary fashion. When a phone is answered, the device issues a verbal status report. The device must then be deactivated by a return phone call or the alert cycle will continue. In addition, the device can be called at any time to obtain a status report. This device is also equipped with battery back-up so that it will continue to function in the event of a power failure.

During periods of irradiation without a designated user present either the Authorized Custodian or a Designated User is required to be available to respond to a telephone alert. If a radiation hazard exists (i.e., fire) the actions outlined in the section Emergency Procedures must be taken. The Radiation Safety Branch must be notified as soon as possible.

Any changes in the above described system of restrictions on access and warning devices must have prior approval of the Chairman, Radiation Safety Committee.

All entry controls will be tested annually by the Radiation Safety Branch. If entry controls are not functioning properly the irradiator will be taken out of service immediately and the defective control repaired or replaced.

A use log is to be maintained by the Authorized Custodian and should be available for inspection by Radiation Safety staff. The use log should record the information requested in Appendix B, Use Log, along with information concerning maintenance, relocation, change of Authorized Custodian, removal and leak tests.

A copy of this document, Radiation Safety Procedures Manual For Operation of Irradiator (Eldorado 78), and the manufacturer's operations manual shall be located at the control panel for review during use of irradiator by Designated Users.

Refer to Appendix C, Specifications, Eldorado 78 Teletherapy Unit, for more description of irradiator and operating procedures.

Installation

Initial installation shall be performed by the manufacturer of the irradiator or his duly authorized representative, in accordance with provisions of a license issued to him by the U.S. Nuclear Regulatory Commission or Agreement State. This shall include transportation, rigging and source loading, if required.

Relocation

Relocation of the irradiator shall be permitted only after authorized by the NIH Radiation Safety Committee.

The Authorized Custodian shall apply to the Chairman, Radiation Safety Committee, through the RSO, for permission to relocate the irradiator. The application shall include:

1. A description of the new facilities, including an annotated sketch of the floor plan of the room and adjoining areas showing the location of the irradiator and identifying the types of activities to be conducted in adjoining areas. Adjoining areas include rooms and corridors surrounding the room and areas above and below the room.
2. Verification that the floor of the proposed facility is rated to support the irradiator. Sufficient evidence may be obtained through the Division of Engineering Services.
3. A description of the methods to be utilized to move the irradiator.

Applications shall be submitted at least 30 days prior to the intended date of relocation to allow sufficient time for review. The RSO shall be responsible for reviewing the application for compliance with applicable license conditions, NRC regulations and Radiation Safety Committee requirements and for making a recommendation to the Committee Chairman regarding approval/disapproval. Relocation shall not proceed until Radiation Safety Committee approval is received.

The RSO shall be responsible for conducting such surveys and inspections as are necessary to ensure safe relocation including supervision of safety aspects of the moving of the irradiator and a survey after reinstallation.

Relocation of the irradiator to off-campus locations is not permitted by conditions of the NRC license. If such action is contemplated, contact the RSO at least 3 months in advance to enable appropriate actions to be taken.

Relocation must be recorded in the Use Log.

See the section of the manual covering maintenance for procedures to be followed if modifications or service to the irradiator are required due to the relocation.

Change of Authorized Custodian

If transfer of responsibility for the irradiator is contemplated, the new user must apply for authorization to the Chairman, Radiation Safety Committee. The application is to be routed through the Radiation Safety Officer (RSO) who shall review it to ensure compliance with applicable license conditions, NRC regulations, and Radiation Safety Committee requirements. The RSO shall be responsible for making a recommendation to the Committee Chairman regarding approval/disapproval. Authority for and responsibility for control of the irradiator must be in accordance with provisions of this manual and cannot be reassigned without the approval of the Radiation Safety Committee Chairman. See also the section of this manual, Procedures for Gaining Authorization to Use Irradiator.

Removal

If removal or decommissioning of the irradiator is contemplated, contact the RSO. The irradiator can only be transferred to another appropriately licensed institution or individual; in the event that the sealed sources are to be disposed of, the manufacturer or others who are appropriately licensed must be involved in their removal and disposition.

Maintenance

1. In the event of malfunction of the irradiator, the Authorized Custodian shall be responsible for notifying the RSO.

2. Under no conditions shall operators or the Authorized Custodian attempt to : (a) repair or modify source positioning mechanisms or shutters, interlocks, shielding or other systems designed to maintain the irradiator in a safe condition; (b) attempt to gain access to or remove the sealed sources.

3. Source replacement shall be performed by the manufacturer or other duly licensed entity.

4. If maintenance of the above type is contemplated, the Authorized Custodian shall be responsible for notifying the RSO so that the necessary inspections and safety procedures can be performed.

Other Safety Procedures

Leak Tests

The Radiation Safety Officer will be responsible for ensuring that leak tests are performed. To insure the integrity of the sealed source, tests will be performed by Radiation Safety staff at intervals not to exceed 6 months. Test samples will be taken from appropriate accessible surfaces including sourcehead and collimators. Methods sensitive enough to detect 0.05 microcurie of activity are used. The leak tests will be performed using a calibrated gamma counter. Levels of removable contamination of less than 10 picocuries are detectable. Any smear showing 0.05 microcurie or more of removable contamination shall result in the immediate removal of the irradiator from service.

See revised p 14 in 8/15/88 memo.

The individual conducting the leak test shall record this in the Use Log, Appendix B.

Routine Compliance Surveys

Such surveys will be conducted at yearly intervals and consist of the following:

1. Insure proper operation of all interlocks on irradiator.
2. Measure exposure rates at all accessible points around the irradiator using a portable ionization chamber and insure that levels are within regulatory limits.
3. Checks for compliance with provisions of this manual including adherence to Irradiation Procedures and proper training of operators.
4. Inspect area radiation monitors for proper operation.
5. Document completion of survey in the Use Log (Appendix B).

Training Requirements

Training for the Authorized Custodian will include:

1. Attendance at the course, "Radiation Safety in the Laboratory", presented by the Radiation Safety Branch. A schedule for a recent course is shown on the next page.

2. Irradiator safety training provided by the Radiation Safety Branch to consist of at least the following:
   a. Contents of this manual.
   b. Demonstration of the proper operation of the irradiator.
   c. Emergency procedures.

Training for Designated Users will include:

1. Designated users (operators) are required to complete the above program. The Authorized Custodian of the irradiator will be responsible for accomplishing item 2.

2. The Authorized Custodian will enter the name of Designated Users on List of Designated Users (Appendix A), note the date of training, and sign the form to certify that the Designated User is properly trained.

U.S. Department of Health and Human Services
National Institutes of Health
Division of Safety
Radiation Safety Branch

RADIATION SAFETY IN THE LABORATORY
June 8, 1988

TIME	SUBJECT	LECTURER
8:30-9:35	RADIATION & RADIOACTIVITY: I origins / types of radiation interactions with matter	Mr. Doob
9:35-9:45	[break]	
9:45-10:10	RADIATION & RADIOACTIVITY: II quantities and units	Mr. Doob
10:10-10:30	SURVEY INSTRUMENTS	Mr. Doob
10:30-10:35	[break]	
10:35-12:00	EXPOSURE CONTROL internal hazards/controls decontamination/emergencies external hazards/controls	Ms. Newman
12:00-12:05	[break]	
12:05-12:30	WASTE MANAGEMENT	Mr. Austin
12:30-1:30	[lunch]	
1:30-2:30	BIOEFFECTS	Dr. Smith
2:30-2:35	[break]	
2:35-3:00	FEDERAL REQUIREMENTS legal exposure limits recommendations for fertile women rights of radiation workers	Mr. Doob
3:00-3:05	[break]	
3:05-3:30	PERSONNEL MONITORING film badge & TLD dosimeters urinalysis; thyroid & whole body	Ms Langlois
3:30-3:35	[break]	
3:35-4:00	NIH RADIATION SAFETY PROGRAM radionuclide license; accountability authorized investigator system results of NIH personnel monitoring	Dr. Broseus
4:00-4:30	EXAM	

Responsibilities

Authorized Custodian

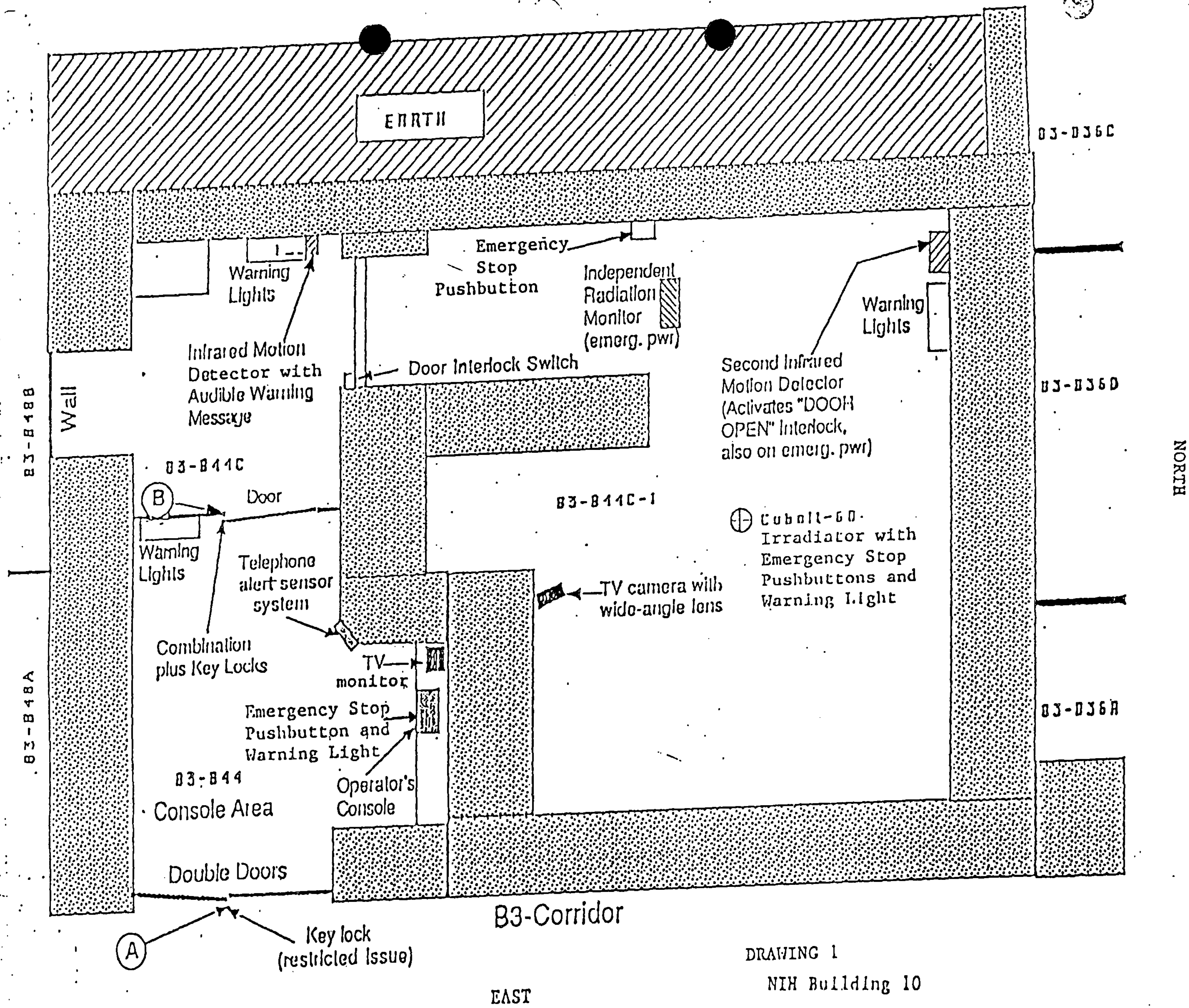
1. Maintain the irradiator in a clean and mechanically functional condition.
2. Notify the Radiation Safety Branch of any anticipated changes in configuration, location, or operation in a timely manner (see applicable sections of this manual).
3. Insure that Designated Users receive training as required and wear personnel monitoring devices when using irradiator.
4. Insure that irradiator is operated in accordance with this manual.
5. List and certify Designated Users in Appendix A to this manual.
6. Insure physical security of the key to the unit.
7. Notify Radiation Safety immediately of any malfunctions or problems with the irradiator (see Emergency Procedures section of this manual).
8. Arrange for repairs or maintenance of the unit by appropriate persons (see Maintenance section of this manual).

Designated User

1. Operate the unit in accordance with this manual at all times and wear personnel monitoring device when using irradiator.
2. Notify the Authorized Custodian immediately of any malfunctions or other problems with the irradiator.
3. Insure that the key is returned to secure storage following use of the irradiator.

Radiation Safety Branch

1. Maintain irradiator license.
2. Conduct leak tests as described in this manual.
3. Provide training as described in this manual.
4. Conduct inspections as stated in <u>Other Safety Procedures</u> section of manual.
5. Provide personnel monitoring devices to irradiator users.



DRAWING 1

NIH Building 10

DRAWING 1

NIH Building 10

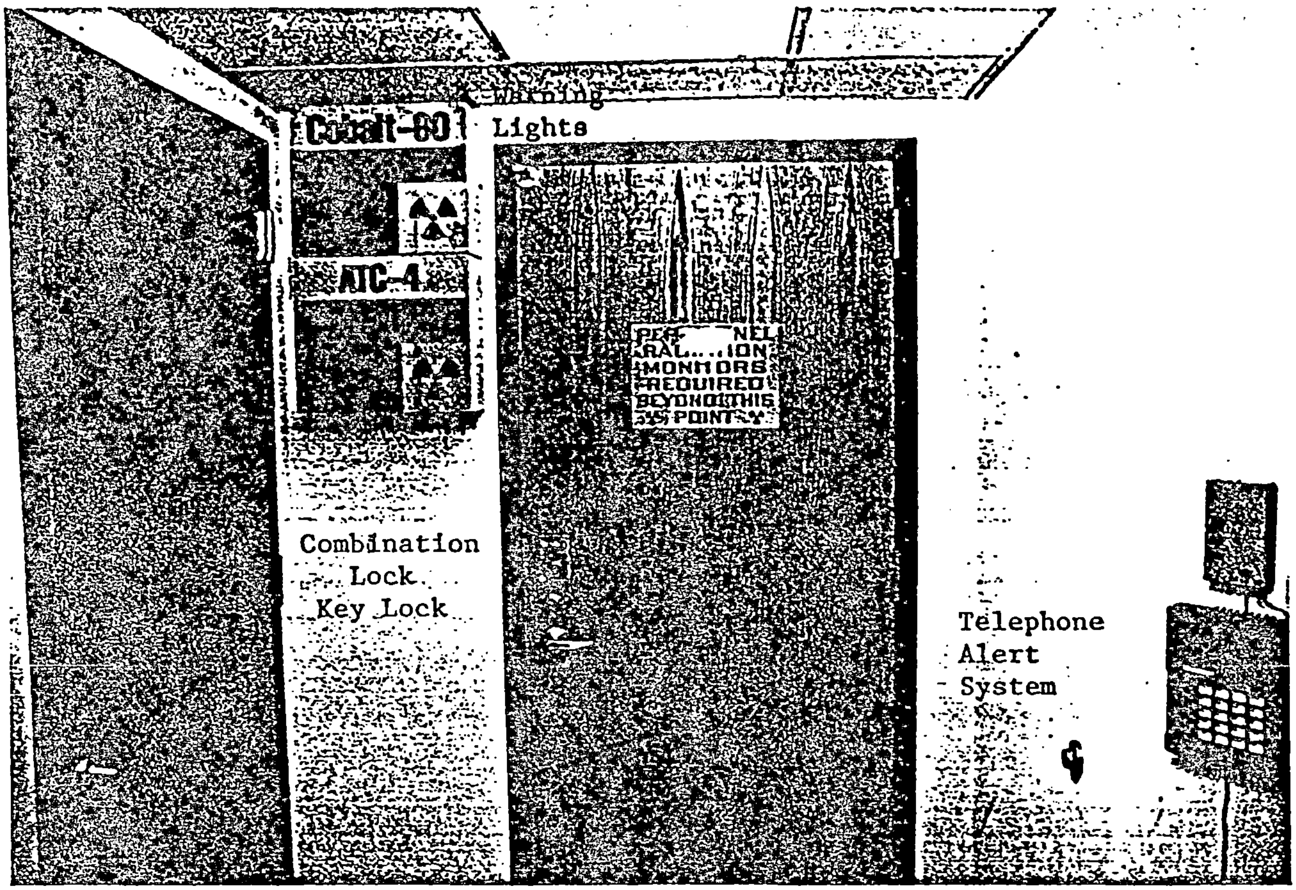


FIGURE 1 Door leading to B3-B44C

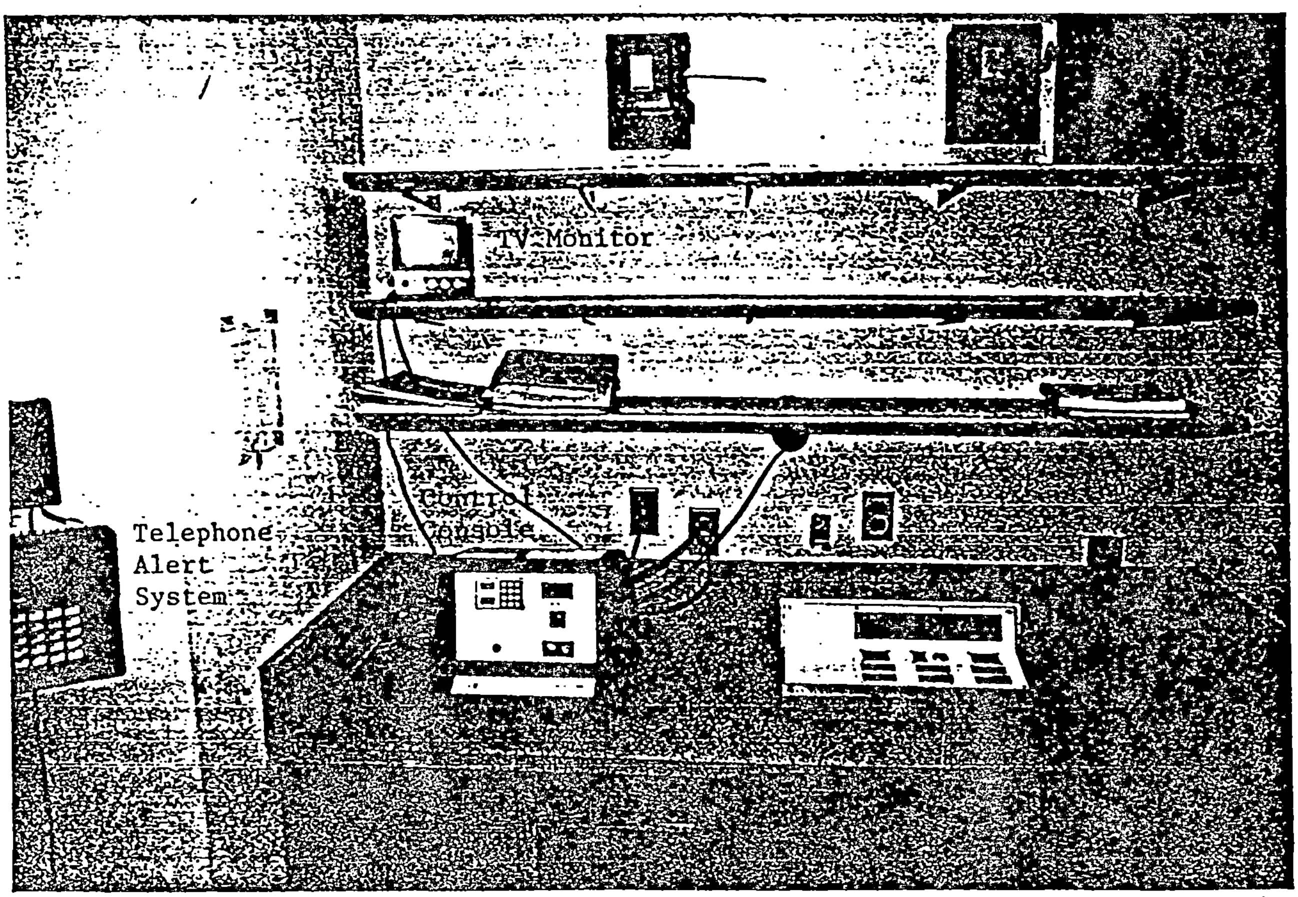


FIGURE 2 B3-B44

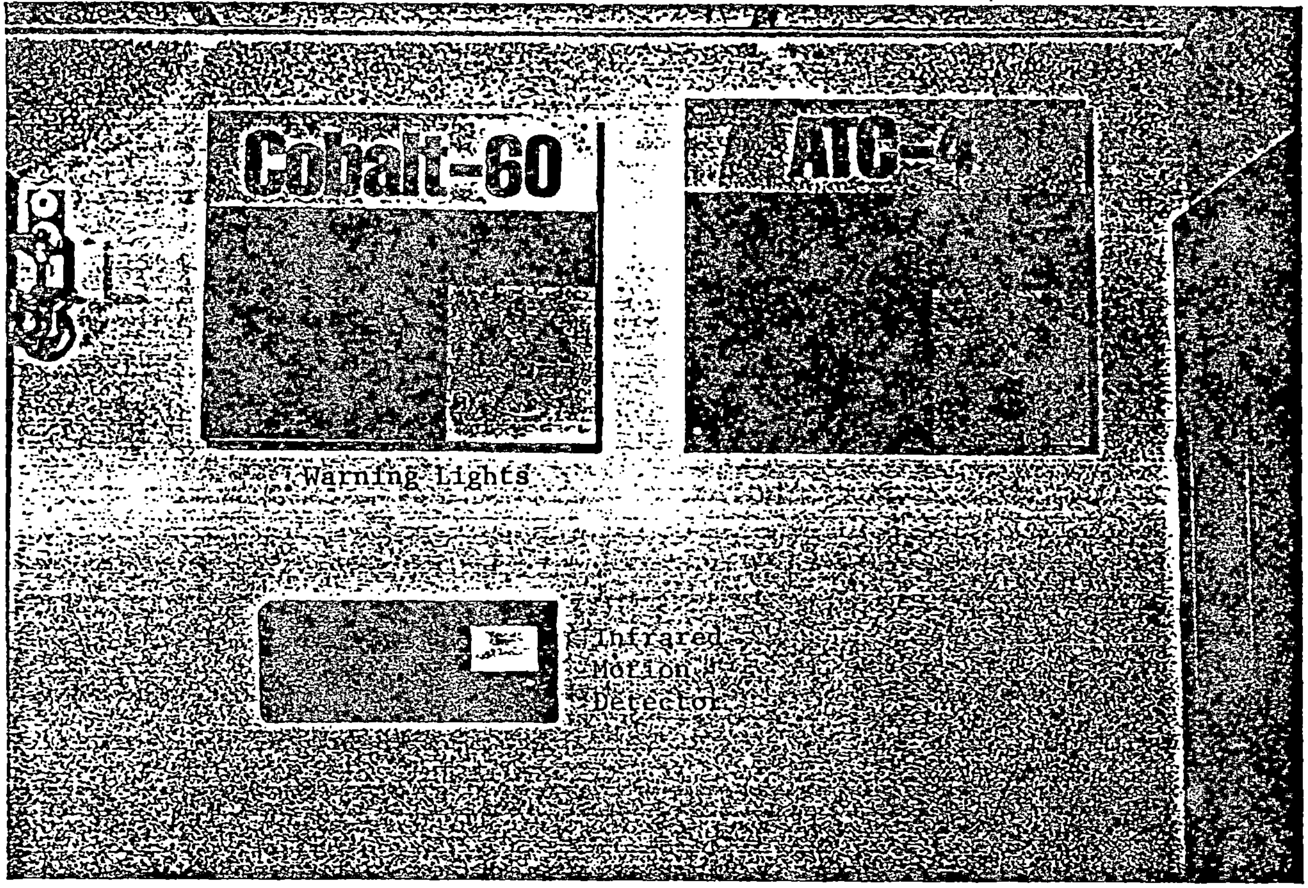


FIGURE 3 West wall of B3-B44C

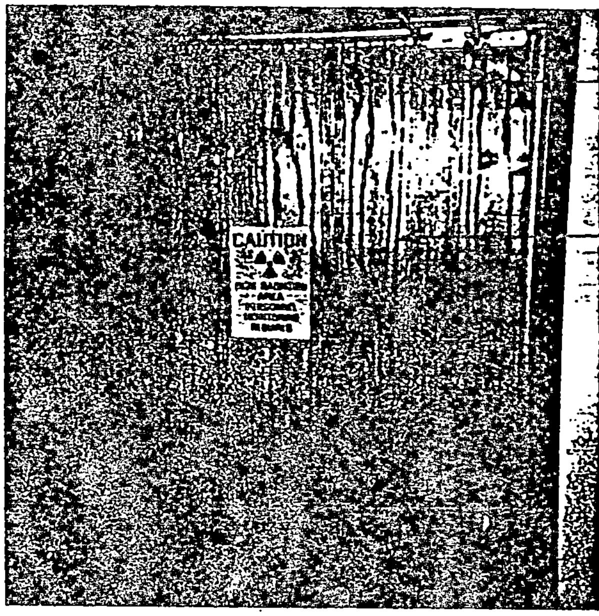


FIGURE 4   Door to B3-B44C-1

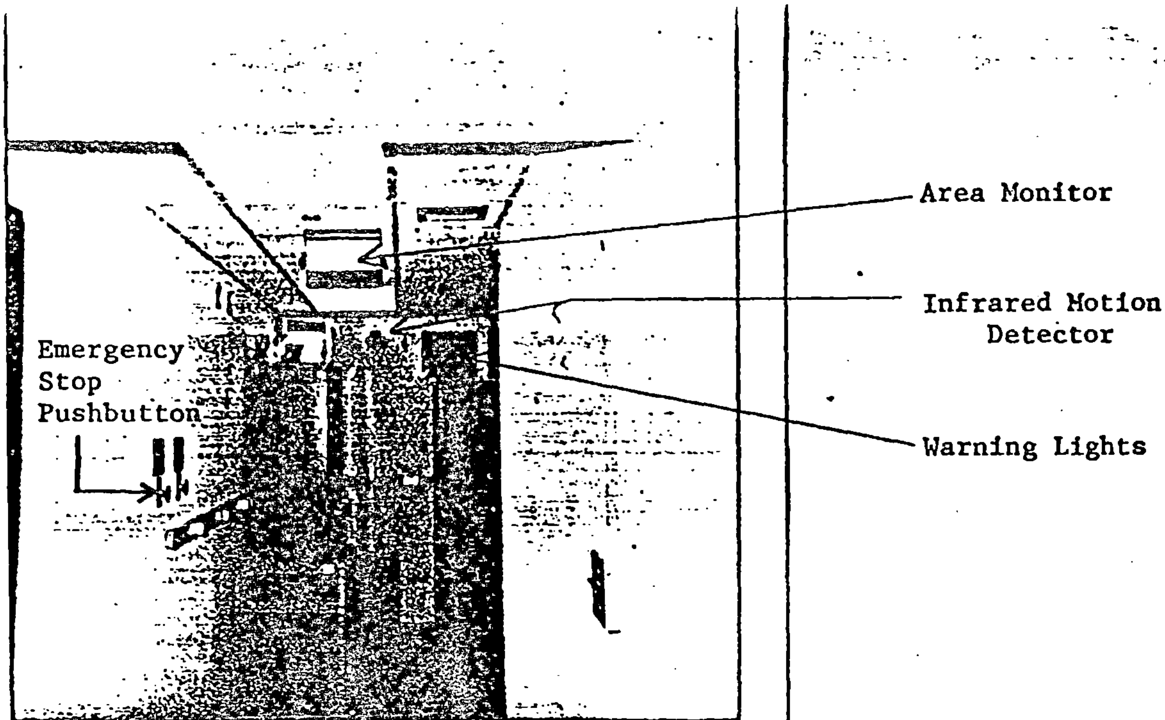
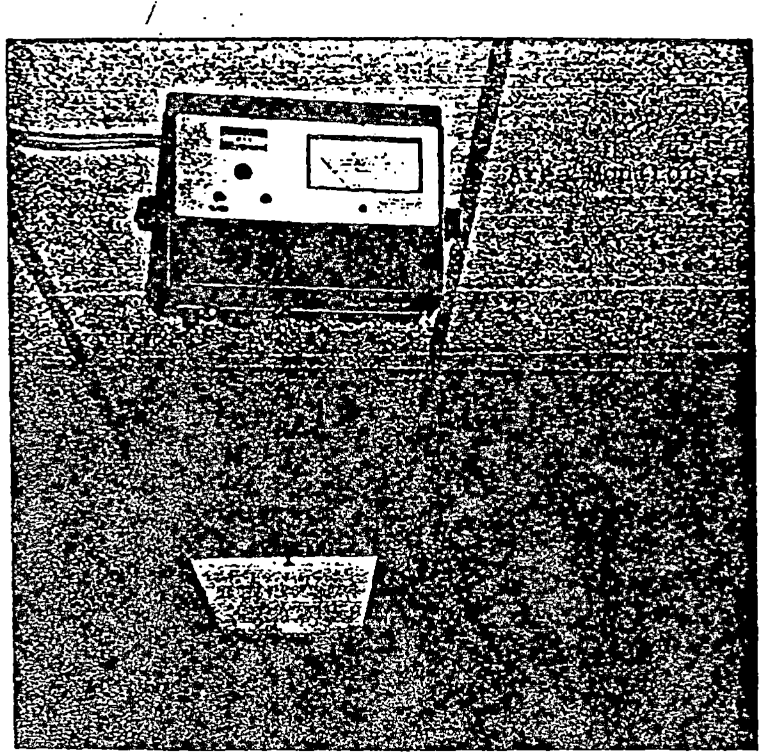


FIGURE 5 B3-B44C-1 Entrance

FIGURE 6 Ceiling of B3-B44C-1



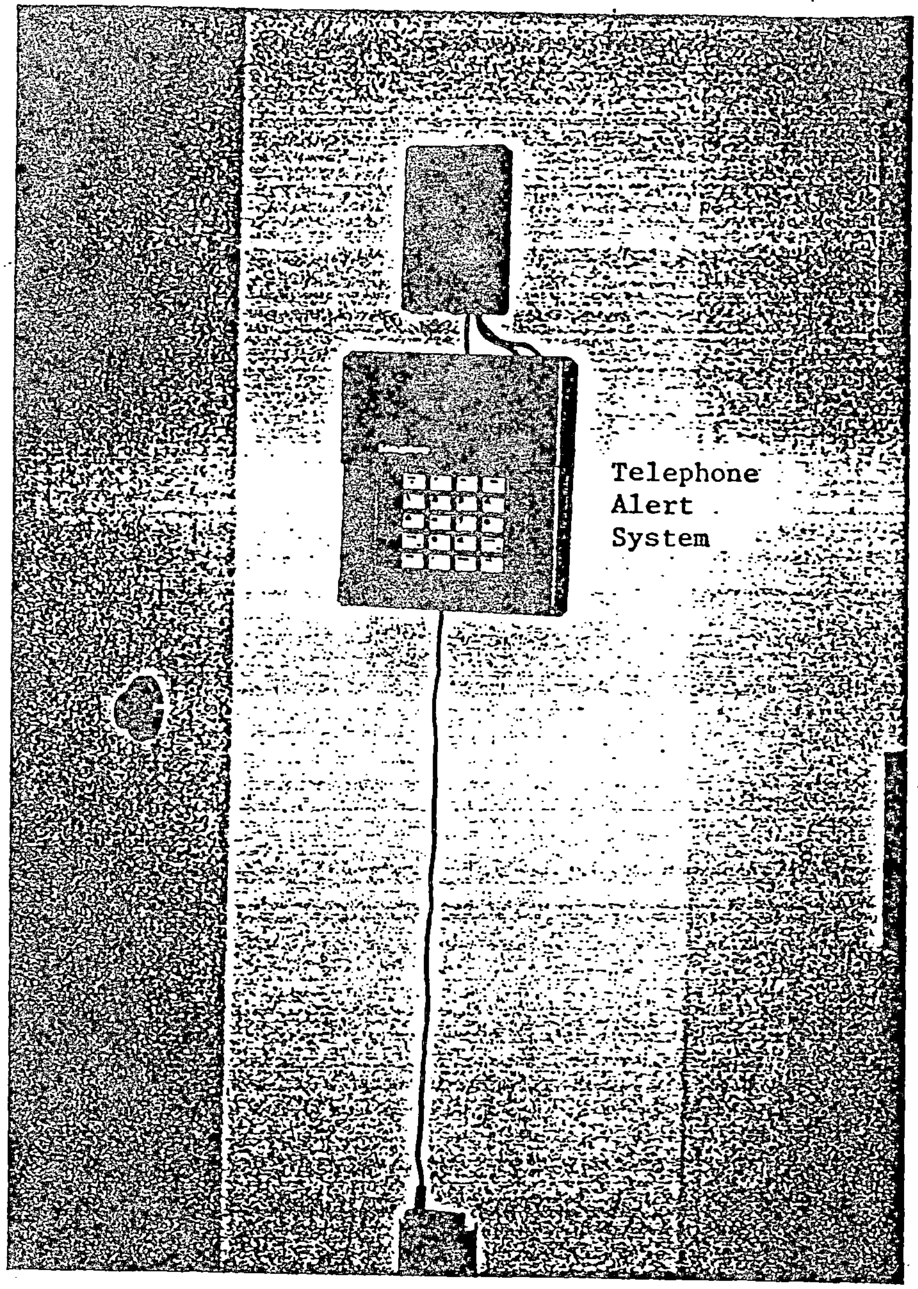


FIGURE 7 B3-B44

APPENDIX A

DESIGNATED USERS OF THIS IRRADIATOR

ONLY THE FOLLOWING INDIVIDUALS ARE PERMITTED TO OPERATE THIS UNIT

NAME OF DESIGNATED USER	DESIGNATED USER'S RADIATION SAFETY REGISTRATION NUMBER	DATE APPROVED AND CERTIFIED BY AUTHORIZED USER	SIGNATURE OF AUTHORIZED USER

APPENDIX B

IRRADIATOR USE LOG

NOTE: 1. THIS IRRADIATOR MAY BE OPERATED ONLY BY DESIGNATED USERS APPROVED BY THE AUTHORIZED USER.

2. THIS LOG MUST BE COMPLETED EACH TIME THIS IRRADIATOR IS USED.

3. WRITE ANY COMMENTS OR NOTE ANY ABNORMAL OPERATING CONDITIONS ON THE LINE FOLLOWING YOUR USE ENTRY.

NAME OF USER (PRINT NAME)	RADIATION SAFETY NUMBER	PROCEDURE CONDUCTED/ ITEM IRRADIATED	START TIME/DATE	STOP TIME/DATE

SPECIFICATIONS

NUMBER G32003
MAY 1, 1977

ELDORADO 78 TELETHERAPY UNIT

A. GENERAL

The Eldorado 78 Cobalt-60 Teletherapy Unit is designed for fixed field techniques. The sourcehead capacity of the unit is guaranteed at a minimum of 125 Rmm - ICRU* (maximum 67 Ci/Rmm - ICRU). However, for those units ordered with an AE[illegible] Cobalt-60 source with output exceeding 125 Rmm - ICRU, the unit will be provided with a guaranteed minimum capacity of 200 Rmm - ICRU, at no additional charge. The unit complies with the recommendations of ICRP-15.

*Measured according to the International Commission on Radiation Units and Measurements Report No. 18.

The unit consists of the following basic component parts:-

- Sourcehead
- Collimator Assembly
- Base and Main Frame
- Controls
- Radiation Source (see Section C - NOTE)

B. COMPONENT PARTS

B.1 Sourcehead

The sourcehead consists of a lead and depleted uranium shield encased in a cast steel shell, and a source drawer using a pneumatic drive system to move the source between the ON and OFF positions.

a) The source is mounted in a brass-encased lead source drawer. The source drawer slides within the sourcehead and is a principal part of of the Beam Control System. The source drawer also fits into the standard AECL shipping and transfer container from which it can be readily loaded into, or removed from the sourcehead. The sourcehead can also be used as a shipping container. Source drawers are interchangeable between Theratron 780/765, Eldorado 78/76, and their predecessors the Theratron 80/60 and Eldorado 8/6.

b) A compressed air driven piston moves the source drawer system between the BEAM ON and BEAM OFF positions. Accurate positioning of the source is ensured by guide pins at the BEAM ON and BEAM OFF positions.

c) The pneumatically operated system ensures that the source is moved to the BEAM OFF position at completion of the treatment period or in the event of a number of unsafe situations (see Section D).

d) Sourcehead swivel is provided through 360°. A scale which can be read from both sides of the unit indicates the angle of rotation from 0° to 359°. Travel time for 360° of swivel is approximately 2.5 minutes. When the central axis of the beam is pointing down, the scale reading is 180°.

e) A panel containing indicator lamps and illuminated switches is located on the front of the sourcehead (see Section B.4.2).

f) The face of the source may be positioned anywhere between 76 cm and 206 cm above the finished floor.

g) Provision is made on both sides of the sourcehead for mounting a Pin and Arc Localizer, a Mechanical Backpointer, or a Treatment Distance Indicator.

B.2 Collimator Assembly

Beam collimation is provided by an adjustable collimator mounted within the sourcehead. The collimator consists of a depleted uranium fixed shield; two pairs of motorized, continuously adjustable, intermeshing lead leaves called primary definers, hinged to the fixed shield; and two pairs of depleted uranium trimmer bars fixed to the primary definers at 45 cm SDD to serve as secondary definers. Additional removable trimmers are available as accessories, one set to mount at 55 cm SDD, and another to mount at 65 cm SDD.

B.2.1 Field Sizes

The continuously adjustable definers will give fields as per the table below:-

FIELD SIZE RANGE AT 80 CM SAD		
SDD	Minimum (cm)	Maximum (cm)
45	5.0	35.0
55	4.5	34.0
65	3.5	33.0

The primary definers are hinged near the source and are set so that at maximum field size, the face of the definer is on a line drawn from the edge of the source to the maximum field size at 80 cm from the source face. The hinge points are factory adjusted to suit different source diameters.

The size of the radiation field is measured on the 50% geometric pneumbra line at 80 cm from the face of the source. The field size for each SDD is displayed digitally at the front of the collimator when the SDD is selected by the Trimmer Factor Selector located near the readout.

B.2.2 Field Localizing System

The Field Localizing System consists of a high intensity, long-life, quartz-halogen light bulb, mounted on the end of the source drawer so that the light shines through the collimator when the source is in the OFF position. The radiation field set by the collimator can thus be visually confirmed. The centre of the field is marked by the projection of crosswires which are located in the collimator. The light is controlled by means of an illuminating pushbutton switch (FIELD) located on the head cover.

B.2.3 Field Accuracy

Accuracy of bulb alignment is such that the crosswires are projected to within ±1 mm at the beam centre, defined as the axis of collimator rotation at 80 cm from the source. Variation between the optical field, the radiation field, and the field size readout does not exceed ±2.5 mm at 80 cm from the source.

B.2.4 Collimator Rotation

The collimator will rotate around the central axis of the beam through an angle of ±180°. Minimum time for 360° rotation is approximately 45 seconds. With the operator facing the front of the unit the centre point of collimator rotation is 180°.

B.2.5 Optical Treatment Distance Indicator

An Optical Treatment Distance Indicator is provided with a scale range of 55 cm to 100 cm source-to-skin distance (SSD). This is controlled from the collimator control panel.

B.2.6 Collimator

The collimator is equipped with an extendable rail mechanism. These rails are equipped to accept wedge filters and beam shaping blocks at the same time. They are adjustable to allow 45 cm, 55 cm, or 65 cm wedges to be used.

B.2.7 Collimator Control Panel

A Control Panel is mounted on the front of the collimator (see Section B.4.3).

B.3 Base and Main Frame

B.3.1 Base

The unit is supplied with a welded structural steel base. The base mounts in a pit in the treatment room floor and, once aligned, can be cemented in position enabling the whole unit to be rigidly mounted. Other mounting methods are possible if the floor is too thin or weak to support the base.

B.3.2 Main Frame

The main frame, which is mounted on the base, supports the sourcehead vertical drive components, the main electrical panel, and an air compressor.

Service access to the mechanical and electrical components within the main frame is through removable panels at the rear of the main frame.

B.3.3 Carriage Assembly

The sourcehead is mounted on a carriage assembly which rides on tracks machined on the vertical main frame structure.

B.4 Control System

The Control System comprises a Set-Up Control located in the treatment room, various displays and switches on the unit, and a treatment console located outside the room.

B.4.1 Unit Mounted Controls

An EMERGENCY STOP pushbutton is located on each side of the main frame (see Section D).

B.4.2 Sourcehead Mounted Controls

On a panel mounted on the sourcehead are the following:-

a) A thumbwheel control which governs the speed and direction of collimator rotation.

b) Two lights indicating BEAM OFF and BEAM ON

c) A light to indicate if the beam is OFF SHIELD.

d) An illuminating pushbutton which controls the field light.

B.4.3 Collimator Mounted Controls

A panel on the front of the collimator contains the following:-

a) Two digital displays for indicating field size.

b) A trimmer factor selector. A three-position switch, which is used to alter both digital displays of field size to read correctly when 55 cm or 65 cm trimmers are attached.

c) Controls which govern the speed and direction of collimator leaves.

d) An Optical Distance Indicator pushbutton.

B.4.4 Set-Up Control

A portable Set-Up Control is stored on the side of the unit. It is connected to the main frame assembly by means of a flexible cable.

The Control includes the following:-

a) EMERGENCY STOP - a red pushbutton. (See Section D.)

b) HEAD SWIVEL - A pushbutton switch controlling head swivel motion.

c) HEAD VERT - A pushbutton switch controlling head vertical motion.

B.4.5 Treatment Console

The Treatment Console contains the following:-

a) A key-operated, three-position POWER switch marked OFF, ON, and START which controls electrical power to the unit.

b) A yellow RESET indicator lamp and pushbutton. This lamp will illuminate when the controls are incorrectly set or when an unsafe situation exists (see Section D). The operator must correct the situation and depress the button before treatment can be started.

c) Circuit breaker - push to reset type.

d) Indicator Lamps:-

- BEAM OFF (Green)
- BEAM ON (Red)

e) EMERGENCY STOP pushbutton (Red). (See Section D.)

f) TREATMENT TIMER - A synchronous timer having a range of 0 to 55 minutes, calibrated in minutes and hundredths of a minute, complete with a pushbutton marked TREAT and OFF.

NOTE: A spare printed circuit board Kit is included (G22-158C).

C. RADIATION SPECIFICATIONS & SOURCES

a) The Eldorado 78 meets the recommendations of the International Commission on Radiological Protection, ICRP Publication 15, paragraph 139 "Teletherapy Protective Source Housing" and National Council on Radiation Protection and Measurements Report No. 33 and No. 34 (NCRP 33 and 34).

b) The actual collimator does not exceed 1% transmission of the useful beam exposure rate, compared to the 2% maximum allowed in recommendations contained in ICRP 15.

The Cobalt-60 radiation sources supplied by AECL are doubly encapsulated in stainless steel and are measured in a measurement cell to the standards laid out in the International Commission of Radiation Units and Measurements (ICRU Report No. 18), filled to the output ordered with a filing tolerance of ±10%. A Measurement Certificate is provided with each source.

NOTE: *All references to "Rmm" contained in this specification are based on recommendations contained in ICRU 18.*

) The sources are mounted in source drawers which are interchangeable between Theratron 780/765, Eldorado 78/76, and their predecessors, the Theratron 80/60 and Eldorado 8/6.

) PROTECTIVE DEVICES

The following protective devices are incorporated in the unit:-

The radiation source and the source drawer will remain in the BEAM OFF position or return to the BEAM OFF position under the following conditions:-

a) Electrical power supply failure.

b) When the door interlock, which must be supplied by the customer, has been activated by means of the treatment room door being opened during treatment.

c) Air pressure in the pneumatic system falls below 35 psig.

d) An EMERGENCY STOP pushbutton is depressed on either side of irradiator Main Frame or on control console outside of irradiator room.
This will stop the unit, retract the source, and trigger two audible alarm systems:-

- a buzzer on the main frame relay panel inside the treatment room, and
- an alarm at the Treatment Console outside the treatment room.

The EMERGENCY STOP pushbuttons, located on the sides of the Main Frame, when depressed, will, in addition to returning the source to a safe position, LOCK OUT all power to the Main Power Supply. These pushbuttons must be manually reset to restore power to the console.

e) The source drawer linkage fails. In this event an auxiliary source drawer retractor will return the source drawer to a safe position within 0.3 cm of the BEAM OFF position at the end of treatment. The source will then remain in the BEAM OFF position until the fault is corrected.

NOTE: *In the highly unlikely event that the pneumatic system or the auxiliary source drawer retractor should fail, the source drawer may also be returned to a safe position manually. A T-bar is supplied for this purpose.*

[redacted]

E. APPEARANCE

E.1 Colour

Standard AECL colours of brown and beige.

E.2 Covers

Moulded ABS covers are provied for the sourcehead. Sheet metal covers are provided for the main frame.

F. WEIGHTS & DIMENSIONS

F.1 Basic Unit

Weight - 3,000 kg (6,600 lb) estimated.

Projected Floor Area - 2.48 sq.m (26.4 sq.ft).

Floor Loading - 1,220 kg/sq.m (250 lb/sq.ft).

F.2 Overall Unit Dimensions

Length - 240 cm (94.5 in).

Height - 270 cm (106.3 in) above the finished floor.

Width - 70 cm (27.5 in) across main frame.

F.3 Floor Pit Dimensions

Length - 259 cm (102 in).

Depth - 21.6 cm (8.5 in).

Width - 122 cm (48 in).

G. POWER REQUIREMENTS

Electrical power required is 208 or 230 Vac, three-phase, 2.5 kVA, 50 or 60 Hz. Frequency and voltage must be specified by the customer at time of order. The Unit is approved by the Canadian Standards Association (C.S.A.).

H. OPTIONS

H.1 Wedge Filter Interlock System (G22-179D)

A factory installed option which reduces the risk of a mistreatment with the wrong wedge. Treatment is not possible until a thumbwheel switch on the collimator has been set to a number which agrees with the number of the wedge inserted into the collimator rails. Each wedge is coded by the addition of a metal actuator. If the unit is used without wedges, the thumbwheel switch must be set at zero. If a coded wedge is inserted when the switch is at zero, treatment is prevented. A warning light indicates that the switch setting does not agree with the wedge coding. Wedges to be used with this option must be modified per G22-197E.

NOTE: The system can accommodate up to 27 wedges (9 at 45 cm, 9 at 55 cm, and 9 at 65 cm SSD).

I. ACCESSORIES

I.1 Accessories Provided with Unit at No Charge

~~Mechanical Treatment Distance Indicator (60 to 100 cm) (G22-[illegible])~~

~~This [illegible] is used to indicate the source to skin distance from 60 to 100 cm SSD.~~

Isodose Charts (G20-010)

The following set of approximately 140 isodose charts for fixed field techniques is supplied with each unit, provided an AECL Cobalt-60 source is purchased with the unit. Charts are provided on white opaque, shrink-proof paper.

1.00 cm diameter	(17 charts)
1.25 cm diameter	(5 charts)
1.50 cm diameter	(79 charts)
1.75 cm diameter	(8 charts)
2.00 cm diameter	(32 charts)

I.2 Beam Modifying Accessories

Trimmer Bars - 55 cm SDD (G20-092A)

A set of 4 removable trimmer bars. Material - unalloyed, depleted uranium. Weight - 8 kg per set.

Trimmer Bars - 65 cm SDD (G22-092A)

A set of 4 removable trimmer bars. Material - unalloyed depleted uranium. Weight - 9 kg per set.

BEAM SHAPING TRAY Kit (G22-097E)

The Beam Shaping tray slides into the collimator rails, and can be positioned anywhere between 54 cm and 71 cm from the source. A set of 21 lead beam shaping blocks is provided. The blocks can be mounted above or below this tray. The tray can be turned over with the blocks attached and the rails adjusted for A & P treatments. Maximum load of blocks is 14 kg. Wedge filters can be used at the same time as the blocks. The kit includes a tray with holes and a tray without.

Beam Shaping Tray (G22-150C)

An aluminum tray with an array of holes enabling the lead beam shaping blocks (G22-239) to be attached. (Part of G22-097E).

Beam Shaping Tray - Plain (G22-150B).

An acrylic tray which can be used when the unit is in the vertical position only. (Part of G22-097E).

Beam Shaping Blocks - Lead (G22-239)

An assortment of 21 lead blocks which can individually clamped to the aluminum tray (of Beam Shaping Tray Kit G22-097E).

eam Shaping Blocks (Set of 7) - Uranium (G10-149)

hese can be used with G22-097E in vertical posi-
on only, or with G21-105.

eam Shaping Tray - Mobile (G21-105)

his mobile table is used to position a set of beam
aping blocks over the patient on the stretcher.
he tray can be used above or below the stretcher
nd will support a weight of 23.0 kg. The tray can
e positioned anywhere between 137 cm and 97
n above the floor.

edge Filters

0° wedges (set of three for use at 45 cm SDD)*
G22-151)

0° wedges (set of three for use at 55 cm SDD)*
G22-174)

0° wedges (set of three for use at 65 cm SDD)*
G20-151)

wedges (set of three for use at 45 cm SDD)*
G22-152)

5° wedges (set of three for use at 55 cm SDD)*
G22-175)

5° wedges (set of three for use at 65 cm SDD)*
G20-152)

0° wedges (set of three for use at 45 cm SDD)*
G22-153)

0° wedges (set of three for use at 55 cm SDD)*
G22-176)

0° wedges (set of three for use at 65 cm SDD)*
G22-153)

In this context "45, 55, and 65 cm SDD" means that the wedges are mounted below the 45 cm defining distance or the 55 cm and 65 cm trimmers.

Each set is supplied with 12 isodose charts.

NOTE: *If the Wedge Filter Interlock System (G22-179D) is purchased, all wedges which are to be used with the system must be modified as per G22-179E.*

Modifications for Wedge Filters (G22-179E)

Modification of wedges for use with G22-179D (sets of 3 wedges).

Wedge Filter Storage Cabinet (G22-172)

This cabinet will hold up to 18 AECL wedge filters (wedges are not included).

Breast Treatment Trimmer (G22-207A)

This collimator mounted device is used in the treatment of the breast, where maximum trimming is required. The trimmer attaches to one of the lower collimator leaves and weighs only 3.6 kg. Instructions and an isodose chart are included.

Breast Treatment Set-Up Device (G22-207B)

This device attaches to one of the lower collimator leaves and provides trimming to 65 cm SDD. It includes a removable polycarbonate frame used to align the patient with the beam.

Small Field Cones (G22-167)

A set of four cones for use at 45 or 55 cm* SDD. Approximate field sizes (when cones are mounted at 55 cm) are:-

2 cm square at 80 cm SSD
3 cm square at 80 cm SSD
2 cm diameter at 80 cm SSD
3 cm diameter at 80 cm SSD

A 55 cm SDD Isodose Chart is provided for each cone.

At 55 cm SDD, 55 cm SDD trimmers (G20-092A) are required.

1.3 Beam Positioning Accessories

Mechanical Backpointer (G22-022)

This accessory is used to indicate the centre of the emergent beam after passage through the patient.

Pin & Arc Localizer - 0° to 90° (G22-024)

Based on the original Manchester design, the Pin & Arc is used to align the centre of the tumour with the beam centre line when the tumour depth is known for some angle other than the treatment angle.

Wall or Ceiling Mounted Positioning Light (G9-088)

Designed for mounting on the wall or ceiling of the treatment room, the positioning light projects a beam of light onto the patient's skin permitting the patient to be aligned with the beam axis. The Wall Lights are designed so that the light beam can be adjusted 45° from either side of centre. The lights, which are sold singly, are also equipped with their own transformer and line cord which can be connected to any convenient 110 or 230 Vac supply.

Isovigilant Laser (G22-227A)

Single IL900 laser with reflective interlock which can be used to stop treatment should the patient move.

Isovigilant Laser System (G22-240A)

Consists of three isovigilant line/spot lasers, a single sagittal plane line laser and a remote control console. Used to monitor patient movement during treatment. Can be interlocked with the unit to stop treatment if the patient moves.

1.4 Control & Patient Comfort Accessories

Teletherapy Room Monitor (G9-135)

The teletherapy room monitor is a wall-mounted radiation warning device for use in a beam therapy treatment room. (It can also be used with other types of high energy equipment.) The two-part device consists of a monitor which is wall mounted inside the treatment room and a remote warning device, also wall-mounted, outside the treatment room. When the radiation field exceeds a predetermined level of 15 mR/hr ±5 mR/hr at the monitor position, a three-way warning system is activated:-

- A red warning light on the monitor is illuminated;
- A red lamp on the remote warning device is activated at 0.5 second intervals.
- An audible alarm is electrically connected through a separate customer-supplied 12 V dc treatment room door interlock switch to the monitor unit, and functions only in the event of the door being opened while a high radiation field exists. The monitor automatically shuts itself off when the radition level returns to the predetermined level, 15 mR/hr ±5 mR/hr.

Power required is 115 V ac, 50/60 Hz, 25 W. A continuously charged battery automatically provides power for a minimum of 30 minutes under the preceding conditions in the event of a power line failure. The battery will automatically be fully recharged 16 hours after power is restored.

Patient Immobilizing Strap (G22-147C)

Consists of two straps, one 71 cm long and one 102 cm long. Straps can be joined together to wrap completely around the stretcher to restrain a patient.

The Ellis Nominal Single Dose Slide Rule (G22-224)

The Slide Rule facilitates rapid calculation of the dose per fraction using the NSD concept derived by DR. F. ELLIS, ref. BJR, Vol. 44, pg. 101-108. The Slide Rule is furnished with a detailed instruction manual containing tables and graphs which are required for its full utilization.

J. STANDARD UNIT LISTING

Cat.No.	Description
G2000A	ELDORADO 78, Vertical Stand Cobalt-60 Unit (includes a Spare Printed Circuit Board Kit G19-155C).

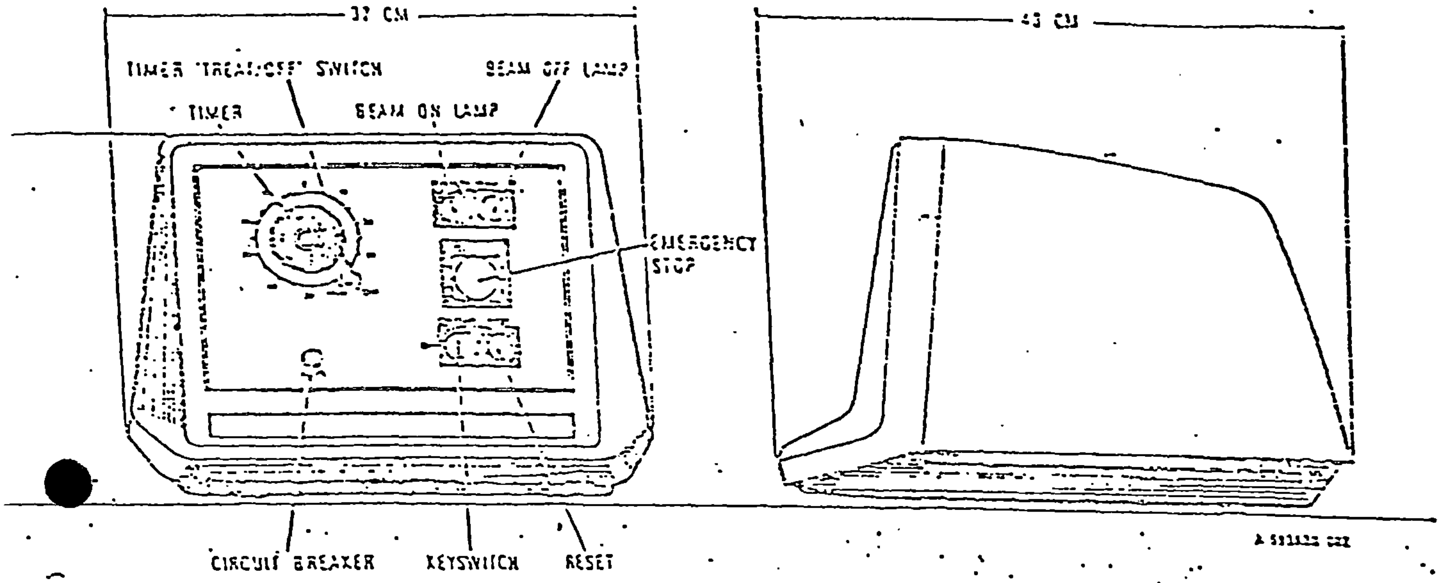
K. INSTALLATION OF COBALT-60 TELETHERAPY UNITS

The Cobalt-60 unit shall be installed in the appointed location by Atomic Energy of Canada Limited personnel, or by personnel appointed by an accredited agent or representative of Atomic Energy of Canada Limited.

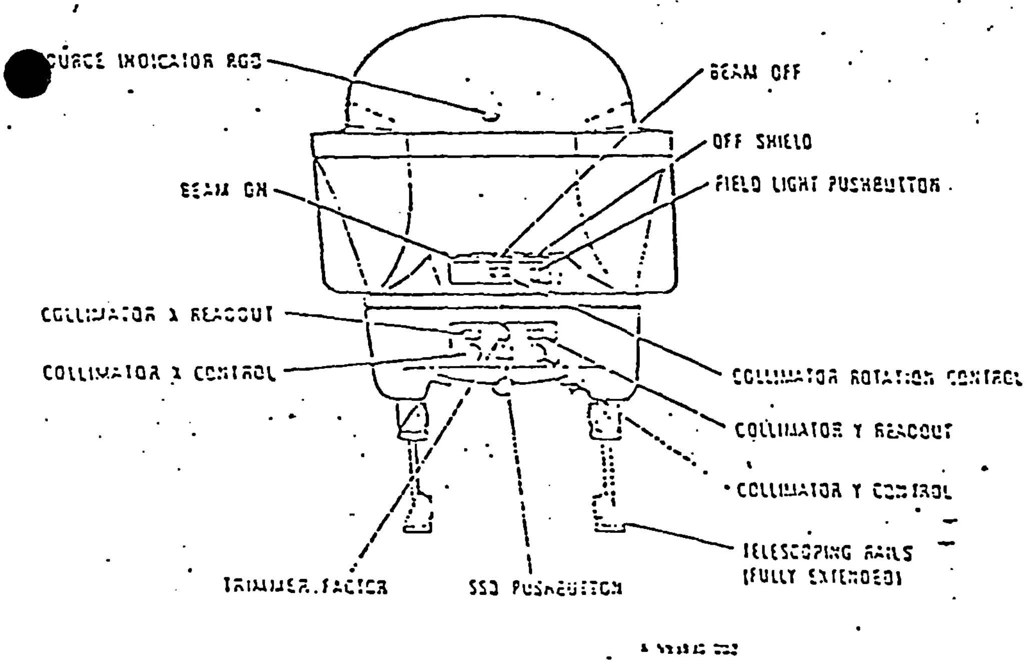
Installation of the unit shall include:-

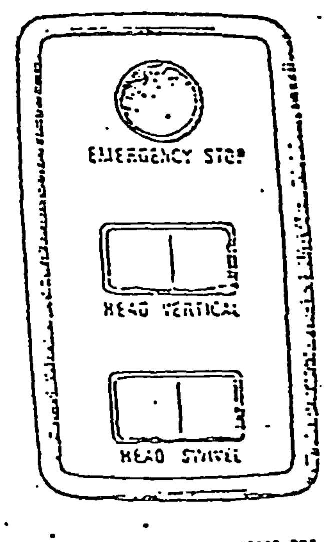
1) Erection of the unit in a suitable location provided by the purchaser, and connection of the unit and control station to a suitable source of electric power provided by the purchaser.
2) A complete operational test of the unit and control equipment.
3) Familiarization of clinic personnel with all aspects of the function and control of the unit.
4) In those instances where the source is shipped separately from the sourcehead, the installation shall include the loading of the source into the sourcehead of the unit from an approved AECL source transfer container.

The specifications contained herein were in effect at the time of printing. Atomic Energy of Canada Limited has a policy of continuing development and reserves the right to discontinue models at any time or change specifications or designs without notice and without incurring obligation.



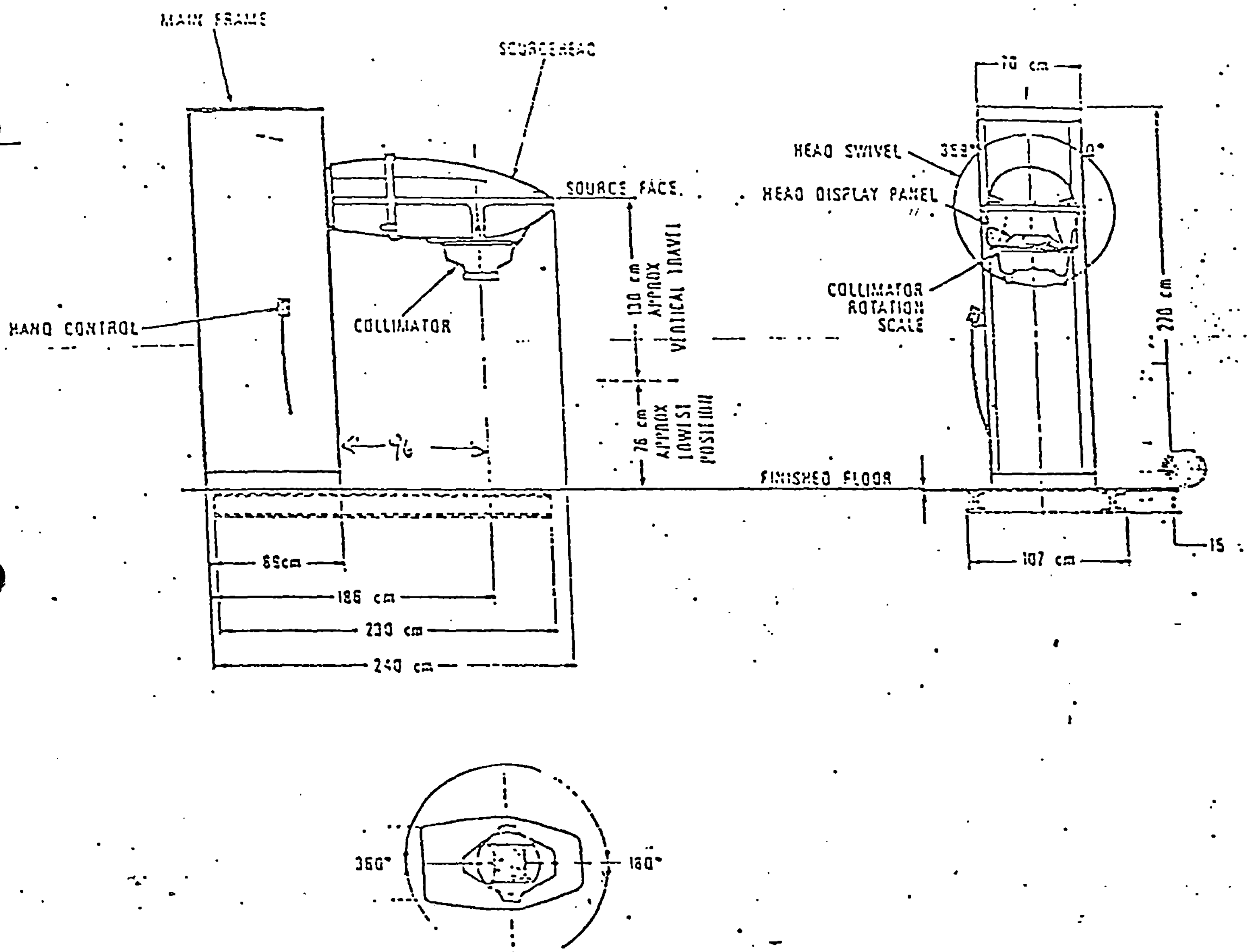
CONTROL CONSOLE PANEL



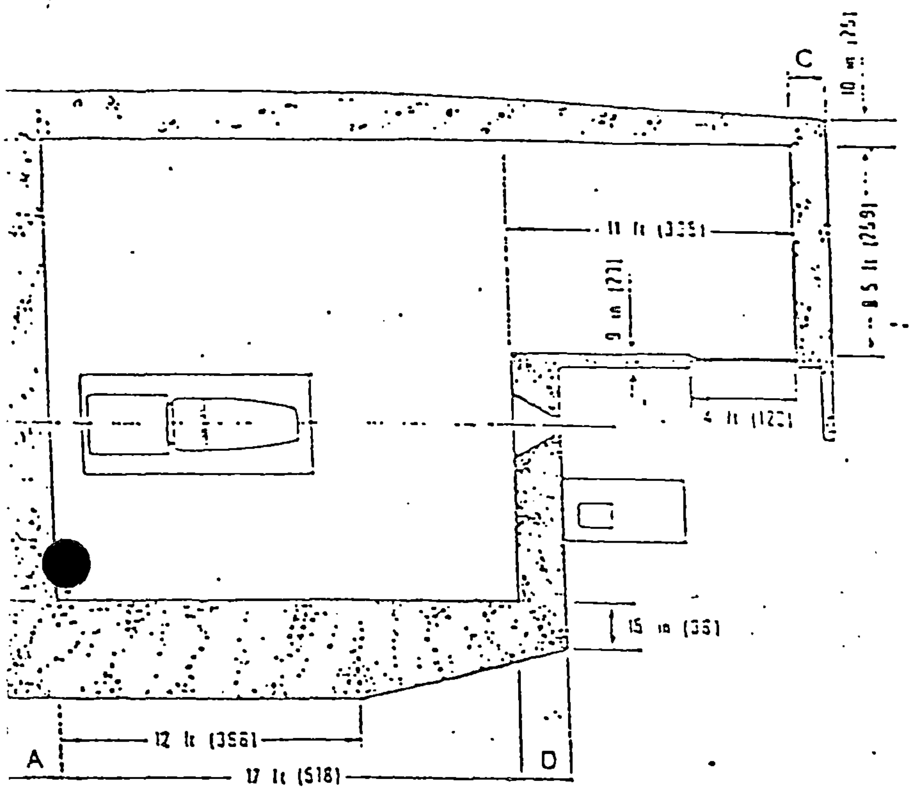


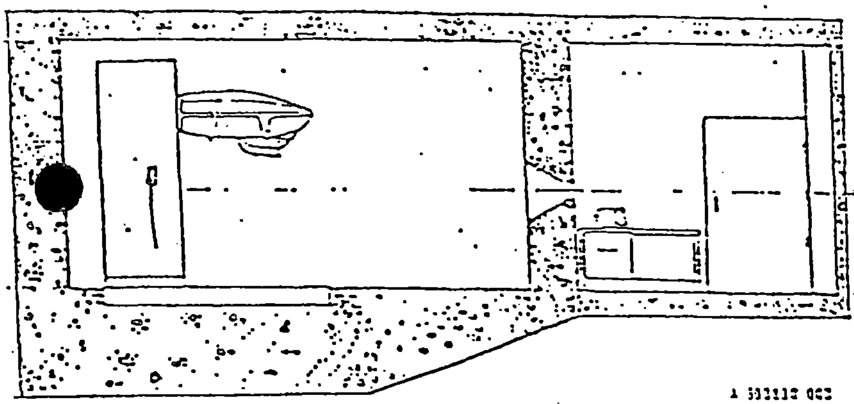
HEAD & COLLIMATOR CONTROL PANELS

SET-UP CONTROL



GENERAL DIMENSIONS





	CONCRETE THICKNESS TO REDUCE AVERAGE FIELDS TO 5 mR/hr*									CONCRETE THICKNESS TO REDUCE AVERAGE FIELD TO 0.5 mR/hr*			
	75 Rmm		100 Rmm		125 Rmm		200 Rmm		MAXIMUM DOSE RATE (mR/hr)		200 Rmm		MAXIMUM DOSE RATE (mR/hr)
SHIELD	in	cm	in	cm	in	cm	in	cm		SHIELD	in	cm	
A	14	35	15	38	16	41	17	43	10	A	22	56	1
B	16	41	17	43	18	46	19	48	10	B	27	69	1
C	11	28	12	31	13	33	14	36	10	C	20	51	1
D	14	36	15	38	16	41	17	43	10	D	22	56	1
E	35	89	36	91	37	94	39	[illegible]	50	E	47	120	5
F	12	31	13	33	14	36	15	38	25	F	23	59	2.5
G	47	120	43	109	44	112	46	116	10	G	54	137	1

* For an assumed BEAM ON time of 20 hours per week, based on NCRP Report No. 34

NOTE:-

1. Beam Limitations for Layouts Shown:- Sourcehead Swivel - 90° between floor and thickest wall (Shield E).

2. Shielding Design Criteria:-

   a) The Table below details wall thickness required to reduce average dose rates to 5 mR/hr, and to 0.5 mR/hr for 200 Rmm, for various source strengths.

   b) Concrete Density - 147 lb/cu. ft. (2.35 g/cc). If concrete density is less than 147 lb/cu. ft. (2.35 g/cc), increase wall thickness by the density factor, eg. if 16 in (41 cm) of concrete is shown and available concrete density is 138 lb/cu. ft. (2.21 g/cc), wall thickness required is:- 16(41) x 147(2.35)/138(2.21) = 17(43).

   c) Maximum dose rates will, in general, be higher than 5 mR/hr, but will only be encountered under extreme conditions of unit and patient set-up.

   d) Window Dimensions - 8 in. x 8 in. x 6 in. thick (20 cm x 20 cm x 15 cm).

   e) Window Density - 6.2 g/cc (other densities and thicknesses may be required if licensing regulations and/or source sizes dictate).

   f) Window Location - On the centre line of head swivel. (Approximately 4 ft. above the floor.)

   g) Lead Lined Door - 5 mm lead.

3. Shielding Design Approval - Final room design must be approved by qualified physicist before installation of the unit. Where licensing regulations require, room design must also be approved by the local health authority.

TYPICAL ROOM LAYOUT

DOCKET NUMBER PROPOSED RULE PR 19,20,21,30,36,40,51,70 + 170
(55 FR 50008)

DOCKETED USNRC

'91 APR -9 P12:35

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(30)

University of Cincinnati
Medical Center

University of Cincinnati
Radiation Safety Office
Old Operating Pavilion Basement, Room 9
234 Goodman Street
Cincinnati, Ohio 45267-0591
Telephone (513) 558-4110
Fax (513) 558-9905

March 5, 1991

The Secretary of the Commission
Washington, DC 20555
Attn: Docketing and Service Branch
Reference: Comments on proposed rule "Licenses and Radiation Safety Requirements for Large Irradiators"

Gentleman:

The University of Cincinnati operates an underwater irradiator for teaching and research. This facility has been operating for approximately fifteen (15) years without an incident. If all the changes outlined in the proposed rules (Federal Register/Vol 55 No. 233/Tuesday December 4, 1990) became regulation and our facility was required to abide by the regulation (i.e. not grandfathered) the modification expenses would be prohibitory and there would be a significant risk that the facility would have to be shut down.

The major concerns the University of Cincinnati has are outlined in a letter from Howard Boeing, Manager, Cobalt Sixty Facility, to Victoria Morris, Radiation Safety Officer, dated March 1, 1991. A copy of this letter is enclosed.

Sincerely,

VMorris

Victoria R. Morris
Radiation Safety Officer

cc: D. Harrison
C. Kupferberg
J. Lessard

enc.

APR 24 1991
Acknowledged by card ....

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Cincinnati, Ohio 45221-0072
Phone (513) 556-2738
FAX (513) 556-3390

To: Victoria Morris
Radiation Safety Officer

From: Howard Boeing
Manager, Cobalt Sixty Facility

Date: March 1, 1991

Re: Comments on: Large Gamma Irradiators
Proposed Rule, 10CFR Part 36

In response to the Nuclear Regulatory Commissions proposed rule changes regarding large gamma irradiators, I submit the following:

1. These new rules appear to be written for large irradiators consisting of a million curies or more, it has no consideration for the smaller research facility like ours with only 10,000 curies or less. Nor does it allow for grandfathering of current methods and procedures used successfully for a number of years, like our facility.

2. The proposed rule (36.29 & 36.63) requiring a water purity of 10 microsiemens/cm. is only a reasonable standard on purification systems that deionize the water. Systems that employ other means of purification would not be able to meet that standard. Our system is a tap water system that uses (DE) diatomaceous earth filters & small additions of chlorine. It is incapable of meeting this conductivity standard as it does not deionize the water but uses DE to filter the water and chlorine to kill algae. Our system has been in operation for 15 years and has been extremely successful in maintaining water clarity and in operational reliability. Since 1987 we have been employing chlorine monitoring procedures to ensure compliance with NRC requirements of chlorine concentrations of 1 ppm or less, see attachments.

   The purpose of this rule is to prevent pool water from becoming cloudy and reducing visibility and from becoming corrosive, thus corroding the stainless steel sources or source rack (36.33 p 50017). Our system has worked extremely well in maintaining water clarity for 15 years.

Additionally, as part of our operations, we use several different source rocks. This has allowed us to remove and inspect the source racks. We have found no corrosion nor deterioration. The source racks are made of similar material as the sources, 316 stainless steel. Additionally, due to the excellent water clarity, we have been able to see the sources and have not seen any indications of corrosion.

If we are required to meet this conductivity standard, we would have to scrap our present system and purchase a complete new system. This system would be very expensive and would be a financial hardship on us.

3. The proposed rule, 36.29 b, requires the licensee to provide a means to detect radioactive contamination in pool water each day the irradiator operates. We sample our pool water every day, irregardless of our operability. The pool water is pumped through a demineralizer cartridge to trap the Cobalt Sixty ions. We sample everyday, but are only able to analyze monthly. We need a better explanation to see if we are in compliance, if not, we would have to purchase additional expensive monitoring equipment.

The implementation of the new rules would, for the preceding cases, be a serious financial hardship on our facility. We think that grandfathering should be implemented for those smaller facilities that have had a long history of safe and successful operation.

DOCKET NUMBER PR 19,20,21,30,36,40,51,70+170
PROPOSED RULE
(55FR 50008)

DOCKETED
USNRC

(29)

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Feb. 28, 1991

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Dr. Stephen McGuire
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Sir:

These comments relate to NRC's proposed regulations for irradiation of food and sewage sludge.

For health and safety reasons, NRC should not adopt the draft regulations. Instead, NRC should shut down all irradiation plants. This technology is extremely dangerous. DOE would be able to recycle high-level radioactive waste as "source material" for food and sludge irradiators. Each irradiator may hold 10 million curies of radioactive material, primarily cobolt-60 metal or water-soluble cesium-137 (ten times more than the amount of cesium reportedly released at Chernobyl).

NRC should prohibit use of water-soluble cesium-137 in all irradiators.

The irradiation industry should not be expanded without a prior and complete Programmatic Environmental Impact Statement and without compliance with detailed siting criteria which need to be included in the regulations.

The public comment period should be extended at least three months.

Sincerely yours,

Dorothy M. Scholze
Richard Scholze

copy: Secretary of NRC
Docketing and Service Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Acknowledged by card N/A - no address

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(55FR50008)

Arkansas **DEPARTMENT OF HEALTH**

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TELEPHONE AC 501 661-2000

M. JOYCELYN ELDERS, M.D.
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OFFICE OF SECRETARY
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BRANCH

March 21, 1991

Dr. Stephen A. McGuire
Office of Nuclear Regulatory Research
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Steve,

A brief letter to again express my appreciation for the invitation to participate, as a panel member, in the public hearing on the irradiator regulations. I believe the hearing went well and I think you did a stellar job handling things. It was a learning experience for me as a State person but I believe the experience will be useful for determining how States can be more effective in participating in the overall regulatory process.

My more official comments on the regulations should be part of the public record as submitted through State Programs. I have suggested that the regulations go through one more comment period as I believe there were a enough substitutive changes suggested - if they are made - to indicate the need for another comment period.

I look forward to continuing to work with you on these regulations. Please let me know if there is anything I can do.

Sincerely,

Greta

Greta J. Dicus, Director
Division of Radiation Control
and Emergency Management

GD:lf

"An Equal Opportunity Employer"

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PROPOSED RULE (55FR 50008)

28

Indiana State University

Department of Physics

February 26, 1991

Mr. Stephen A. McGuire, Senior Health Physicist
United States Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. McGuire:

Thank you for the opportunity to discuss the proposed rule **Licenses and Radiation Safety Requirements for Large Irradiators** which took place at the Woodfin Suites, Rockville, MD on February 12-13, 1991. As invited by you and your staff, I am submitting written comments on the proposed ruling.

May I first preface my comments with a general statement pertaining to small irradiators similar to the one made at the workshop by Cindy Weber of the Texas Department of Health. I am sure that many universities share the same problems in Texas that we do in Indiana. We are in the business of educating students. Our irradiators are utilized primarily toward that means and are thus much less in magnitude than many of the commercial irradiators. Therefore, I strongly suggest that many of the comments I propose in this letter be allowed to be exempt from the stringent requirements of large commercial irradiators. I will illustrate my point more specifically later. I am suggesting, therefore, that a category of **Small Educational Irradiators** of less than 2 grays per minute and perhaps of university or college affiliation be added. The term **Large Irradiator** as defined in Part 36.2 is in reality a misnomer when constituting the class of all irradiators both large and small.

<u>Comment #1</u> Part 36.23 **Access Control**
I refer to the statement in (a) "Opening the door or barrier while the sources are exposed must cause the sources to return to their shielded position". There exist some ambiguity here, since it is not spelled out whether the door is open during the normal course of operation or during emergency procedures. During emergency procedures, almost any door can be bypassed. For example, our irradiator door is bypassed with a special large key kept only by the licensee. We do not imply that it is opened with this special key during irradiations, but that it is used to bypass the door interlocks during the time when the source is in storage in a separate environment. Perhaps the phrase "during the course of normal operation" could be added.

Terre Haute, Indiana 47809
(812) 237-2064

<u>Comment #2</u> (b) of the same part
Again, much of the same paragraph above implies. Entry while the sources are exposed at our facility cannot happen, but if it did, an alarm would occur. It can only happen with a special key which only the licensee possesses. Furthermore, only users who are trained under the licensee ever use the irradiator. Perhaps the independent backup access control referenced in (b) could be waived for **small irradiators** (as defined above) of educational nature.

<u>Comment #3</u> Part 36.29 part b
For a University operating a small irradiator of the educational variety, the addition of on-line radiation monitors just for pool and/or water purification analysis we feel is unnecessary. It would be more cost effective for the small irradiator class to simply increase the number of water analysis periods determined by the license.

<u>Comment #4</u> Part 36.53 part a
We suggest that written agreements with local hospitals be obtained to cover possible incidents of overexposure or radioactive contamination. This simple procedure will local community hospitals that such possible accidents are regionally possible.

<u>Comment #5</u> Part 36.65 part b
An on-site operator present during a panoramic irradiator at which static irradiations are being performed should not be required for educational small irradiators. This adds burdens to university operating budgets which are already constrained. We believe that for a system operating under conditions which already will lower the source in the event of an emergency and which complies with the small irradiator educational class, that this rule should be waived.

Again, thank you for the opportunity to both speak out at the proposed rule workshop and to submit these comments prior to final rule legislation.

Sincerely,

John A. Swez

John A. Swez
Chairperson of Physics and
Director, Radiation Lab

DOCKET NUMBER
~~PROPOSED~~ RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55FR 50008)

RSI
Professionals in Gamma Sterilization

DOCKETED
USNRC

27

'91 APR -9 P12:36

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

March 21, 1991

Dr. Stephen A. McGuire
U.S. Nuclear Regulatory Commission
One White Flint North
Rockville, MD 20852

Dear Dr. McGuire:

My comments on 10CFR36 are enclosed. Congratulations on an excellent workshop that was held on February 12, 13 of this year. It gave all of us an opportunity to voice our opinions.

The written comments enclosed with this letter, reinforce my thoughts on the proposed rule.

Sincerely,

Barry Fairand

Barry P. Fairand, Ph.D.
Vice President Technology & Quality

cc. L. Foster
J. Clouser

Enclosure

Acknowledged by card APR 24 1991

Radiation Sterilizers, Inc.
4020 Clipper Court
Fremont, California 94538
Telephone 415/770-9000
Fax 415/770-1499

COMMENTS ON PROPOSED RULE 10CFR36

General Comment

The CFR must not be conditioned by the possible future use of cesium chloride or other physical forms of cesium-137. Reference to cesium must be removed from the CFR. As demonstrated by the Decatur incident, cesium chloride is a virulent radioisotopic source. Even in a ceramic/glass form, the WESF salt is dirty and thermal/physical properties are controlled by the amount and type of impurities which have not been properly characterized. On the other hand, metallic cobalt has shown after more than 25 years of successful commercial use that it is a stable form of isotope.

On those rare occasions when cobalt sources were grossly abused, contamination from compromised capsules did not suddenly ramp up over time as was true for cesium. Furthermore, airborne contamination was not observed as it was for cesium. If cesium must be carried forward as a national resource for future use in the irradiator industry, a separate CFR must be structured for its use or an addendum should be added to the CFR once cesium is proven to be a safe radioisotopic source.

Section 36.15

Issuance of a license prior to initiation of construction is not warranted; however, a license to store or use radioisotopic sources must be preceded by full approval of the site as well as all radiation safety related systems. Section 36.15 must be rewritten to convey this message. Construction before issuance of a license obviously would be entirely at the risk of the applicant.

Section 36.21

Assurance by the licensee that sealed sources meet the conditions of §36.21, should not entail actual observation of the tests with confirmation of their satisfactory completion, rather a certification from the manufacturer that the sources meet the requisite conditions should be sufficient.

All sealed sources for use in irradiators within the United States must receive prior approval of the NRC and meet appropriate manufacturing specifications. The manufacturers of sources are audited by the NRC or agreement states to ensure their compliance with the regulations.

Section 36.23(c)

A fail safe interlock on the personnel access door is desirable; however, a method must be available to gain access to the cell once the RSO or designee has been notified and the situation has been assessed. For example, malfunction of the monitor may be the cause of a problem rather than lockup of the sources in a partially shielded position.

Section 36.25

It is commonplace to find regions on the roof of an irradiator cell where radiation levels exceed 2 millirem per hour. These areas are typically around source guide and drive cables. Designation of the cell roof as a controlled access area and posting of proper radiation signs provide adequate protection as long as only authorized persons are allowed on the cell roof when the sources are in an unshielded position and unauthorized persons are escorted by an authorized individual. Written approval of the radiation safety officer is not required.

Section 36.29(b)

The requirement for shut off of the water purification system, if the online monitor alarms, appears to reflect use of cesium. This type of response is not required for cobalt. With cobalt there will be ample time to assess the situation and take corrective action.

Section 36.33(a)

The last sentence in this section requires clarification. For example, does it mean construction of a separate on site storage facility for the sources until repair is completed or will removal of the sources from the facility to another site be sufficient?

Section 36.33(d)

Loss of water below the low level set should trip the safety system and lower the sources. Audible and visible indicators will accompany this action.

Section 36.39(e)

An online monitor is orders of magnitude more sensitive to radiation (contamination) than a GM probe. Therefore, the presence of a GM probe on the water purification system in addition to an online monitor is superfluous.

Section 36.41(j)

In the first sentence, the phrase, "in as many ways as possible"' must be stricken from the text, otherwise a spectrum of interpretations will ensue and a spectrum of citations, many unwarranted, also will ensue.

Section 36.53(b)(60

Momentary losses in power are not uncommon during certain months of the year, e.g., when thunderstorm activity is prevalent. These weather related losses of power will cause the system to shut down and return the sources to their fully shielded location. Return to operational status should proceed via normal procedures. The viability of the safety system to handle these events is tested periodically.

Section 36.61(a)(10)

My comments parallel those for §36.33.

Section 36.63(a)

The pool water purification system need not operate each day the irradiator operates; however; the recirculation system, to which the online monitor is attached, should be run for a sufficient time each day (at least several minutes) to check for the possible presence of contamination.

If reference to cesium is removed from the CFR, sudden ramping up of contamination in the pool water due to a compromised cobalt capsule, will not occur. Therefore, less frequent checks, e.g., weekly, would be sufficient.

The quality of the pool water can be maintained without daily operation of the water purification system. Change in conductivity is typically a slowly varying function of time. Furthermore, constant operation of the water purification system could produce ultra high purity water which has negative characteristics.

The limit of 10 microsiemens per centimeter on water conductivity is too conservative. Most metallurgists and material scientists, will agree that conductivity of water up to at least several tens of microsiemens per centimeter will not cause long term corrosion of stainless steels that are used to fabricate cobalt sources. The value of 10 microsiemens per centimeter in ANSI N43.10 may have originated from an ultra conservative position of manufacturers of sources who played a principal role in the formulation of the standard.

It is recommended that a limit of 20 microsiemens per centimeter, which is still a conservative number, be selected as an upper limit rather than 10 microsiemens per centimeter.

In addition there will be occasions when water conductivity may exceed 20 microsiemens per centimeter for short periods of time, e.g., during loading of isotope and cleaning of the pool. Allowance must be made for these occurrences.

Section 36.69(b)

From an audit standpoint, the work "traces" places an undue burden on the licensee. More definitive terminology should be added. In addition, allowance should be made for certain medical device products that may contain components, e.g., alcohol prep pads, which because of packaging and dispersal within the product unit are not highly flammable.

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
PROPOSED RULE (55 FR 50008)

PermaGrain Products, Inc.

DOCKETED
USNRC

(26)

February 21, 1991

'91 APR -9 P12:36

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Stephen A. McGuire
Senior Health Physicist
United States Nuclear Regulatory Commission
Washington, DC 20555

Subject: 10 CFR Part 36

Dear Mr. McGuire:

Thank you for the copy of the Federal Register Notice concerning the proposed irradiator licensing requirements. We are a user of a fixed source underwater cool irradiator. To us, I think the key provisions in this regulation will be proper separation from a pool storage system as compared to an underwater fixed source system. The natural activities of the source material in this system are quite different. As outlined in the Federal Register, in the pool system you have sources that are going to maintain a surface temperature that is essentially constant at around 100°F. In the pool storage system, you have a cycling situation where the source temperature in an air environment goes from 80°F to 100°F to 400°F.

Fire Protection

In the case of fire protection, the cycling source system can obviously, if contacted by the material being irradiated, be subject to starting a fire and this has been well documented in the industry. In the case of the fixed source system, the source temperature is constant and the pool water is obviously sufficient to take care of any fire requirements.

Water Quality

In the case of the moving source, water quality is extremely important because the source is cycling in an air environment from a high temperature to a low temperature. In the case of a pool system with a fixed source, the corrosive environment is not present and the cycling is not present. In the fixed storage system it would be extremely difficult to maintain a conductivity of 10 Microsiemens per centimeter. In the normal environment one is continually bringing irradiation cannisters into the pool and all of this would effect the conductivity. In addition that conductivity is also reading items that will not appreciably affect the corrosive nature of the system. In our case we are working with organic monomers which become a food for bugs and between trace amounts of monomer and protein getting into the water system, both of these items increase the conductivity of the system.

Basically, we have no problem with the remaining sections.

Very truly yours,

A. E. Witt
President

APR 24 1991
Acknowledged by card ....

AEW/jh

13 West Third Street, Media, PA 19063 (215) 565-1575 Telex 834696 FAX 215-565-1530

DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170 (55FR50008)

(25)

The Applied Radiant Energy Corporation

Manufacturers of **Gammapar**® Acrylic/Wood Flooring

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April 5, 1991

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

Attention: Docketing and Service Branch

Gentlemen:

The Applied Radiant Energy Corporation's (ARECO's) comments upon Part 36 as issued as a proposed NRC rule in the Federal Register of December 4, 1990 (pages 50008-50032) are submitted to you in this letter.

We wish to preface the comments by stating that they are directed towards pool underwater irradiators only, ANSI Category III, rather than the more general case of pool irradiators, ANSI Categories III and IV, that Part 36 addresses. This narrowing of scope is due to the fact that the company's present and proposed irradiators are of the underwater type.

By irradiating under water, the efficient use of the gamma rays provided by radioactive material is substantially compromised. This arises from the need for leak-tight containment and water gaps that develop for various reasons such as: slightly warped canister surfaces, the use of minimum force to keep the canisters in position, etc. However, the inherent safety of operating under water far outweighs the disadvantage of this loss of efficiency. This trade-off must be recognized by agencies or other groups charged with rule promulgation by concessions to underwater irradiators when addressing operational restrictions that would normally apply to panoramic irradiators.

We also wish to recognize the excellent work that Dr. McGuire and Messers. Baggett and Sjoblom have done to write the rule. The day and a half comment period meeting (which representatives of ARECO attended) of February 12-13, 1991 in Rockville, Maryland, resulted in diverse opinions by attendees on various sections of the rule and the need for some revisions was acknowledged. This informative discussion did nothing to change our very favorable opinion of the basic soundness of the rule which is a testament to the diligence of the authors, but we wish to make comments mainly in the vein of diminishing possible ambiguity of understanding and interpretation.

1) One of our main concerns is the possible confusion and imposition of unnecessary regulatory constraints that could arise

from having conditions for panoramic and underwater irradiators appearing interspersed in the same rule. The very great physical differences of the two types both require substantial differences in operational requirements and physical restraints. Thought has been given to suggesting separation of Part 36 into two divisions; one for panoramic and one for underwater irradiators. We realize this is not a novel or singular suggestion but wish to add our "vote" to others who advocate such a change.

2) Section 36.2 Definitions: Both "irradiator operator" and "operate" need further definition where underwater irradiators are concerned. The procedures necessary to perform irradiations are more modest and safer due to design simplicity. In a static plaque underwater irradiator, material handling is the only work function needed to perform an irradiation.

Wording such as "Irradiator Operator means an individual authorized by the licensee to supervise irradiation procedures so that they are carried out in a safe manner" is suggested.

This wording would not compromise the definition of a radiation safety officer.

3) Section 36.2 Definition Radiation Room: This says that "underwater irradiators are not considered to have radiation rooms."

Yet, access to underwater irradiators must be controlled by appropriate barriers at the walls of the room above the underwater irradiator.

The term Irradiation Room could be substituted for Radiation Room in the case of underwater irradiators.

4) Section 36.21(a) Design and Performance Criteria for Sealed Sources: It should be stated that a performance criteria certificate or certificate of registration from the manufacturer or supplier, as appropriate, of the sealed sources is sufficient for compliance with this requirement.

5) Section 36.33 Irradiator Pools: To accomplish safe source storage called for in (a), we propose to allow transfer of sources from one irradiator pool to another when needed. The design feature that we propose is a connection between the pools with a properly constructed transfer tube between them. As this method of source transfer or storage should be considered as a safety improvement over present commonly used methods, we fully expect this pool feature to be approved by Region II of the NRC.

This would mean that the last sentence in (b) should be followed by an exemption statement. That is: "Pipes that have intakes more than 1 foot below the normal low water level must have siphon breakers to prevent the syphoning of pool water lower than

1 foot below the normal low water level unless connected to another pool via a source transfer tube. Water transfer must be limited to levels that meet the conditions of 36.25(b)."

6) Section 36.37 Power Failures: 36.37(c) should be amended by adding the following words to the end: "unless the radiation monitoring system has a battery backed emergency power supply".

7) Section 36.39 Design Requirements (c) Pool Integrity: The statement concerning pool penetrations would still allow for source transfer tubes between pools if Comment 5's suggestion, given above, is followed.

8) Section 36.41 Construction Control (c) Pool Integrity: Again we wish to exempt source transfer tubes connecting two pools from the provisions of 36.33(b) dealing with pool penetrations.

9) Section 36.51 Training: The level of training to be qualified as an operator of a panoramic irradiator is higher than that necessary for operators of underwater irradiators where irradiation and emergency procedures are concerned. Section 36.51 needs to be rewritten, taking into account these differences. It requires clarification as to what operation in underwater irradiators constitutes.

As an example of delineation of work responsibilities that are possible, our company has personnel called Designated Users. They are designated after training by a committee of RPOs specifically named in our license. These workers are authorized to manipulate, "handle" (remotely), load and unload radioactive sources, and perform irradiator plaque movements.

A second class of workers with the job title of "technicians" insert and remove target materials to be irradiated either manually or via conveyors.

10) Section 36.53(c)(1) Operating and Emergency Procedures: In this subsection it states "The revisions do not reduce the safety of the facility." We feel that an addendum to this sentence such as "as determined by the Radiation Protection Officer" or "as determined by committee, one number of which is the Radiation Protection Officer" is in order.

11) Section 36.53(e) Operating and Emergency Procedures: Controlled storage of radioactive resins at higher than background levels should be permitted and decay before release allowed. If (e), as written, does not allow for this, it should be changed to authorize such action.

12) Sections 36.29, 36.39, and 36.59: These three sections all have references to detection of radioactivity in the pool water. Sections 36.29 and 36.59 refer to two methods of detection; daily water analysis or checking "an online radiation monitor". We consider a probe attached to a cation bed leading to an audio and

visual alarm to constitute "an online radiation monitor". Checking the radiation level on the monitor readout would satisfy the requirements of 36.59(c).

13) Section 36.67(c) Entering and Leaving the Radiation Room: (Entering or leaving the "Irradiation" Room - see Comment 3.) Subsection (c) deals with entrance and egress during power failure to and from an underwater irradiator. We urge the statement be amended to include wording such as "unless battery backed emergency power is available".

14) Section 36.83(a)(2) Reports: This subsection shows the need to differentiate more fully between panoramic and underwater irradiators. It should be rewritten (at least in part) for the case of underwater irradiators.

Underwater irradiators can comply with the first part up to "....excessive concentrations on levels of radiation".

"....Loss of one day or more of operation of the facility, or property damage in excess of $2,000 as required by 10CFR20.403 or 20.405" should not apply. Only losses of the ability to use "radioactive sources" in a safe manner should be reportable. There is no threat to personnel and public safety, no danger of radiation overexposure and no impact on the environment when mechanical failures occur in an underwater irradiator.

15) Section 36.83(d)(4) Reports: This should be changed to "Failure of the cable or drive mechanisms used to elevate or lower the source racks in panoramic irradiators".

16) Section 36.83(d)(5) Reports: This should be changed to "Inoperability of the access control system in panoramic irradiators". This is just one of many subsections where separation of two types of pool irradiators would be of benefit.

This is the extent of comments on Part 36. I apologize for our tardiness in providing them to you. A rather detailed response to an NRC letter requesting various types of information regarding our operations and a resubmittal of our license renewal application have necessarily been given priority.

Very truly yours,

THE APPLIED RADIANT ENERGY CORPORATION

James J. J. Myron/gc

James J. J. Myron, PhD
V.P. Safety and Regulatory Affairs

cc: Dr. Stephen A. McGuire
5650 Nicholson Lane
Rockville, MD 20850

glc:F38

DOCKET NUMBER
PROPOSED RULE PR 19,20,21,30,36,40,51,70+170
(55FR50008)

3M Health Physics Services

3M Center Bldg. 224-2E-06
St. Paul, MN 55144-1000
612/736 0498

DOCKETED
USNRC

'91 APR -4 P5:43

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

24

3M

March 29, 1991

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Dear Sir or Madam:

Subject: Federal Register, Volume 55, No. 233, pp 50008-50032, Proposed Rule 10CFR36,

Provided below are 3M's comments on the newly proposed 10CFR36. They are based on a review of the proposed regulations relative to 3M's gamma irradiator facility being operated at Brookings, SD under U. S. NRC License 22-00057-61, 3M's participation in the February 12 and 13, 1991 Workshop held in Rockville, MD and our knowledge of state-of-the-art safety systems and radiation detection instrumentation. Comments are provided in accordance with paragraph numbers of the proposed regulations.

Paragraph 36.15

It is unnecessary that a license be issued before construction. This will make it very cumbersome for the licensee with no obvious benefit in terms of increased safety. Any deviations from initial license commitments, common in facility construction, will require amendments and delays in the building of the irradiator. The design criteria for the actual shield and pool structures in an irradiator are straightforward and well specified in the subsequent paragraphs of 10CFR36. The need for first licensing them is not obvious, especially when the NRC does not intend to approve shield designs. Process control systems are more critical but are not installed until after the shield and pool structures are in place. As a minimum, licensing activities should be allowed to be conducted concurrently with construction of the shield and pool.

Paragraph 36.21(a)

This paragraph should be reworded to make it clear that the licensee does not have to actually perform the tests specified. Vendor certification and/or registration with the NRC in accordance with the provisions of 10CFR32.210 should be adequate.

Paragraph 36.23(a)

We question the need to specify a time for returning the source to the shielded position if the door or barrier is opened while

Acknowledged by card....APR 24 1991

the source is exposed. Assuming that the secondary backup system specified in 36.23(b) below is installed, the source return requirement of 36.23(a) is a third backup which we don't feel is necessary.

As presently worded, the criterion for specifying the source return time is ambiguous. Everyone walks at a different speed. Further, if there is really a concern about source return time, then why isn't there a concern about the person who may be in a hurry and runs to enter the irradiation room? If it is necessary to specify a time for returning the source to the shielded position, a specific time should be given.

Paragraph 36.23(b)

To our knowledge, most presently operating irradiators do not have the backup system described here. 3M's facility does not. The technology is certainly available. If the specified system will be required on all existing facilities, time for retrofitting following enactment of the regulation should be allowed and specified.

Paragraph 36.25(a)

The 2 millirems per hour dose rate criteria should be applied to areas that are accessible to nonirradiator operating personnel and/or members of the general public during operation of an irradiator. It is not necessary to prohibit properly trained operators who are provided with personnel monitoring devices and portable survey instrumentation from having access to areas where the dose rate exceeds 2 millirem per hour. Such an area might be within the penthouse where the source hoist mechanism is located.

The last sentence of this paragraph is too restrictive. Control to these areas for operators who are provided personnel monitoring devices and have proper training should be treated differently than for nonoperators. The level of control should be determined by the RSO. For example, areas near the cable penetrations in the penthouse where radiation levels exceed 2 millirem per hour do not present any real hazard to operators checking out the source hoist mechanism, etc. There is no need for the operator to get written approval from the RSO for this job. Approval from the RSO or an operator should be required for a nonoperator working in an area where the dose rate exceeds 2 millirem per hour.

Paragraph 36.25(b)

It is not necessary to specify a maximum dose rate of 2 millirem per hour 30 centimeters above the pool. During irradiation room entry, personnel are not normally at this location. Since access to the irradiator room is strictly controlled and trained operators wearing personnel monitoring devices and carrying portable survey instruments must be present during all entrees to the irradiator room, we do not understand the need to specify a maximum dose rate. What will a licensee have to do if a dose rate of 2.1 millirem per hour is experienced above the pool? Using 2 millirem per hour as a general guideline for areas normally occupied by personnel is good. However, dictating that it "must not exceed 2 millirems per hour" is not necessary.

Paragraph 36.29(a)

It is too subjective to relate operation of the radiation monitor to a possible dose of 100 millirem to an individual. All other paragraphs of the proposed regulation specify dose rate limits. Specifying a dose rate limit is also appropriate here. Possibly a dose rate of 100 millirem per hour at any accessible point external to the irradiator room, i.e., external to the product and personnel maze access points is appropriate. This will make it convenient to (2) select an appropriate radiation monitor, to (2) properly locate its radiation detector and to (3) properly calibrate the instrument and set the alarm point.

Paragraph 36.29(b)

Two types of online radiation monitors can be effectively used to detect radioactive contamination in pool water. One is a system with a detector, such as a GM probe, positioned external to the water purification system tanks. Another is a system which has a detector, such as a gamma scintillation probe, positioned in a shielded reservoir through which water being circulated through the purification system is routed. The proposed regulation needs to be reworded to allow the use of both online systems in addition to pool water sample assays.

The statement: "If a false alarm due to background radiation occurs, the alarm set-point must be increased." should be removed. It is arbitrary and serves no real purpose.

Paragraph 36.39(e)

The same comment provided in paragraph 36.29(a) above applies here for the conveyor system monitor. How do you verify a personnel dose of 100 millirem? It is possible and reasonable to verify a dose rate of, for example, 100 millirem per hour at a specified location.

How do you "verify" that the radiation monitor on the water purification system is located near the spot at which the highest radiation levels would be expected? In the absence of information on leakage of Co-60 sources and where the Co-60 will accumulate or settle out in the water purification system, it is not possible to "verify" that the radiation monitor is located near the spot at which the highest radiation level would be expected. The final sentence should be reworded to eliminate the "verification" requirement, e.g., "For pool irradiators, the licensee shall locate the radiation monitor on the water purification system near the spot at which the highest radiation levels would be expected."

Paragraph 36.51(a)(2)

The requirements of part 20 should also be included here.

Paragraph 36.51(b)

We recommend adding the phrase "that the individual is responsible for performing" to the end of the sentence in this paragraph to better define the questions to be included in the written test.

Paragraph 36.51(d)(5)

A definition of an "operational quality assurance program" is not provided in the proposed regulation. The terminology here should be "operational inspection and maintenance program" as defined in paragraph 36.61.

Paragraph 36.51(d)(6)

The general requirements of this paragraph have not been well thought out. What constitutes a drill? Is it really necessary to perform annual drills? We do not believe so.

A contingency plan and contingency type drill such as required in 10CFR30.32(i) are certainly not appropriate here because there is no real potential for significant releases of radioactive materials to the environment.

It appears that a medically oriented drill is the only practical drill that can be performed. For this drill, a medical emergency is simulated requiring the emergency squads, irradiator operators and RSO to interact with local ambulance, medical clinic and hospital personnel to test knowledge of handling a contaminated patient. We do not feel that this drill has to be performed annually. An annual review with outside medical personnel, including a verification of telephone numbers is probably appropriate with an actual drill being conducted once every three to four years.

It is difficult to simulate stuck source racks, irradiator room fires, bomb threats, etc. These can best be handled by annual training reviews followed by written exams.

Paragraph 36.53(c)

We strongly support the flexibility regarding revision of operating and emergency procedures provided in this paragraph.

Paragraph 36.57(c)

The wording in this paragraph does not apply to the use of digital readout radiation survey instruments and should be reworded to do so. For example, how do you define a "scale" on instruments that have only a digital readout? If you can't define a scale, how do you calibrate at 2 points on each scale?

Paragraph 36.61(a)(12)

The criteria to be used by the licensee to comply with this paragraph need to be specified or referenced. "Wear" is a very subjective term and needs to be defined.

Paragraph 36.69(b)

The term "trace" needs to be defined either in 10CFR36 or by reference.

Paragraph 36.81(n)

The correct reference is paragraph 30.35(g).

Paragraph 36.83(d)(4)

This item does not really have to be listed. Only failure of the cable or drive mechanism which results in sources being stuck in an unshielded position should be reportable. This is already covered by 36.83(d)(1).

Should you have questions about the above, please refer them to D. A. Loeser at 612/733-3199.

Sincerely,

Duane C. Hall

Duane C. Hall, Manager
Ionizing Radiation
Health Physics Services

DCH:ckm

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 & 170
PROPOSED RULE (55FR50008)

(23)

ISOMEDIX

DOCKETED USNRC

'91 MAR 22 A11 :38

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

March 18, 1991

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

Attention: Docketing and Service Branch

Ref: Comments on Proposed Rule Part 36

Gentlemen:

Our comments on the proposed rule follow:

Para 36.15 Start of Construction

We find the requirement to be licensed prior to start of construction to be totally unacceptable. Irradiator construction normally takes twelve to eighteen months, and prelicensing would take anywhere from six to twelve months, making total lead time unbearable. The prelicensing lag time is not warranted.

We suggest that NRC adopt a construction inspection sequence similar to that utilized in the State of Texas. In this sequence, the license application is submitted (not approved) prior to construction, and there are specific steps during construction where the State will inspect to assure that construction actions, techniques, and QA are adequate. The sequence follows through equipment and safety system checkout prior to source loading, through initial radiation surveys. The system is logical and imposes no undue delay on the licensee. Any activities undertaken by the licensee are at the licensee's risk.

Para 36.21 Sealed Sources

The licensee may not have the capabilities to perform or evaluate the sealed source criteria. Rather, the source manufacturer should submit his source integrity data to NRC and obtain a certificate of registration, which should be sufficient guarantee that the user is utilizing an approved source for the intended purpose.

APR 24 1991
Acknowledged by card ....

ISOMEDIX INC.

CORPORATE OFFICES • 11 APOLLO DRIVE, WHIPPANY, NEW JERSEY 07981 • (201) 887-4700 • FAX 887-1476 • TELEX 317361

Para 36.23(a) Access Control

In most cases involving AECL or Nordion units, a retrofit will be required to assure that the time from door opening to operator entrance will be less than the time for the source to fully descend. The time it takes an individual to walk from the entry door to the edge of the pool is primarily dependent upon the labyrinth design of the shield. Considering the four shield designs in our possession, the entry time (from door opening to pool edge) ranges from 20 to 25 seconds. We suspect that this time may be less with other designs. To comply with the requirements as written, we and others would need to increase our source rack descent rate from one foot per second to nearly two feet per second. Other designs may require even a quicker descent rate. This may be beyond the capability or design capacity of present source rack equipment thereby causing damage to the source and source rack. Therefore, we suggest that the phrase "must be less than or equal to" be changed to "should be less than or equal to". The suggestion in the preambe that "the licensee could use a time-delay me3chanism to delay opeing the door after unlocking it", is of no value since the timing sequence will begin upon intiating the source descent by opening the door.

Also, as this requirement is primarily applicable to the personnel entry door, for clarity, the first sentence of Part 20.203(c)6.(viii) should be inserted in this section. Product entry/exit portals, when physically blocked by carriers or totes, should not be subject to this redundant requirement, since they are not intended as personnel entry routes.

Para 36.23(b)

We can understand the logic for desiring a second independent system to assure that the source is down prior to personnel entry, but feel the emphasis is in the wrong place. In all incidents to date, radiation exposures have occurred because of inoperative safety systems, personnel carelessness, or gross violation of approved entry procedures. Pressure mats or electric eyes would not have helped in any case where the source rack was stuck in the exposed position (Israel, El Salvadore, Shaumberg, Illinois).

We would suggest that a better solution would be to incorporate a redundant system which, through electro or mechanical means, gives positive indication that the source is in the fully shielded position. This could be tied into both the in-cell monitor and door lock (36.23(c)), thereby denying access or continuation of the entry procedure until the proper safety signal has been received from the positive source down indicator. This positions the "back up" system before primary entry versus after entry has been achieved. Once an individual has achieved entry, the only reliable means of personnel protection is through the use of an operable hand held survey meter. (Ref. Shaumberg, Ill, 1989)

Para 36.25 Shielding

We believe that areas where radiation dose rates somewhat exceed two millirems per hour can be adequately controlled in terms of access through personnel training and appropriate temporary barriers (roped off, with radiation signs). Written approval to enter such an area on each occasion would appear to be too administratively burdensome and not really necessary.

Para 36.27(b)

For new constructions, fire marshalls and insurance companies generally require that the irradiator possess the same system as the adjoining warehouse, i.e., automatic sprinkler. Without a shut-off valve specific to the irradiator area, the only means to control flooding into unrestricted areas is by turning off the main sprinkler system water supply to the entire building, a clear fire code violation. A specific reference to require such a shut-off valve in the irradiator only would help in compliance with the code requirements set forth by both the NRC and the local fire marshall.

Para 36.39 Design Requirements (para j)

Irradiators in seismic areas should be required to have a source drop mechanism in event of an earthquake over a specified magnitude. Such mechanisms are quite inexpensive. Following a source drop caused by an earthquake, there should be a requirement for a through system check prior to start-up.

Para 36.59 Leaking Sources

Licensees should be required to maintain separate records on several activities, including pool water counts, and water added to pools. A key element of such data should be to look for unusual trends that develop, which are out of the ordinary.

Para 36.61 Operational Inspection (para (a)(8)

We suggest that reference be made to tests outlined in 29 CFR 1910.159 or NFPA 13A to assure the operability of irradiator fire extinguishing systems.

Para 36.69 Irradiation of Flammables (para b)

Considering only the flash point of flammables is not a realistic criteria for evaluation because in many cases the packaging of the component plays a key role in the components hazard classification. For instance, a bulk container of isopropyl alcohol has a flash point around 75 F. Yet alcohol pads, for disinfectant use, are packaged in sealed metal foil with little oxygen content. In this form, the final product does not possess a DOT hazard classification and is even deemed acceptable for air shipment. A better guide for designating flammable materials would be to reference the DOT hazard classification system per 49 CFR 172. Irradiation of products with a flammable or combustible label per 49 CFR 172 would, therefore, be prohibited without a specific exclusion.

Para 36.83 Reports

Para (a)(2): The damage limit should not include the inadvertent overexposure of product which renders the product unusable. The \$2,000 limit should be adjusted upward (to \$5,000) and be applicable only to the mechanism and/or sources.

Para (c) and (d)

The reportable events listed, in most cases, are almost "catastrophic" to the irradiator operation, and are among the most serious things that can happen. The notification to NRC should be immediate (verbal) followed by FAX notification so that all available resources can be brought together to control and solve the problem before it becomes worse.

We appreciate the opportunity to comment.

Very truly yours,

ISOMEDIX INC.

George R Dietz

George R. Dietz
Vice President

GRD:kl

cc: Dr. Steve McGuire
Office of Nuclear Regulatory Research
USNRC
Washington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

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USNRC

'91 MAR 19 P2:33

OFFICE OF SECRETARY
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BRANCH

Barbara D. Hays
Chapter Chief
1421 Wightman Street
Pittsburgh, PA 15217

MAR 14 1991

Dear Ms. Hays:

In response to your request to extend the public comment period beyond March 4, 1991, the NRC will not formerly extend the due date. However, the Federal Register Notice stated that comments received after that date will be considered if it is practical to do so. In this case, because of planned other work assignments, I can give full consideration to comments received by April 15, 1991.

Sincerely,

/s/

Stephen A. McGuire, Health Physicist
Radiation Protection and Health Effects Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

(22)

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National Fire Protection Association

International

'91 MAR 18 P3:59

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Fax: (703) 516-4350

March 13, 1991

The Secretary of the Commission
Nuclear Regulatory Commission
Docketing and Service Branch
Washington, D.C. 20555

Dear Sir:

The National Fire Protection Association is pleased to submit comment on the notice of proposed rulemaking, RIN 3150-AC98, concerning Licenses and Radiation Safety Requirements for Large Irradiators.

The National Fire Protection Association is an independent, voluntary membership, nonprofit organization dedicated to safeguarding people and their environment from destructing fire, using scientific and engineering techniques and education. The basic technical activity of the Association involves development, publication and dissemination of timely consensus standards intended to minimize the possibility and effects of fire in all aspects of contemporary activity. More than 4000 individuals serve on a voluntary basis on the more than 200 NFPA technical committees.

We recommend incorporation by reference of NFPA 801-1991, Recommended Fire Protection Practice for Facilities Handling Radioactive Materials. The most appropriate section of this proposed rule to reference NFPA 801 would be as part of Section 36.26 on page 50016 of the Federal Register. NFPA 801 should be a reference in addition to ANSI N43.10-1984, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)". The appropriate wording that would be added to section 36.27 would best follow item (b) as shown on page 50017. This section should be modified such that after "extinguishing system" the following is inserted: "as described in NFPA 801, Recommended Fire Protection Practice for Facilities Handling Radioactive Materials."

APR 24 1991
Acknowledged by card ....

NFPA would like to offer any assistance that may be necessary to incorporate the identified NFPA codes and standards into this proposed rulemaking. If you or your staff have any questions you may direct them to the NFPA Washington Representative, John C. Gerard, 1110 N. Glebe Road, Suite 560, Arlington, VA 22201, telephone 703/516-4346. You may also address questions or requests for assistance to Chief Engineer, Arthur Cote, NFPA, 1 Batterymarch Park, PO Box 9191, Quincy, MA 02269-9101.

Sincerely,

Casey Grant
sg

Casey Grant
Chief Systems and Applications Engineer

cc: R. J. Vondrasek
A. R. O'Neill
Jim Shannon

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 & 170
PROPOSED RULE (55 FR 50008)

(21)

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'91 MAR 13 A11:58

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BRANCH

3227 Sharon Road
Jarrettsville, MD 21084
(301) 557-9420
20 February 1991

The Secretary of the Commission
Nuclear Regulatory Commission
Washington, DC 20555
Attention: Docketing and Service Branch

Gentlemen:

My comments on your proposed rules for licenses and radiation safety requirements for large irradiators follow. If you should have any questions regarding anything I mention please feel free to contact me.

Let me begin by saying that the number and difficulty of problems which arise in the design and implementation of large irradiators and the severity of consequences should problems develop makes it impossible for me to sanction the creation of such irradiators. However, should you be dead set upon allowing the construction of more irradiators after you have looked over the difficulties I shall set forth, then at least it shall be done safely, if such can be attained at all. Please note that the following difficulties probably do not constitute a complete listing of the design problems present. They are only the significant ones I have noted.

I.
I am to understand that many if not most underwater sources are Co-60 sources. You should note that cobalt is soluble under acidic conditions. Further information regarding this fact should be collected and some form of acidity or alkalinity requirements placed upon the water in such underwater irradiators, else the result is solute cobalt source travelling wherever water moves (as moisture on irradiated materials, down pipes as water is transferred, or out into ground water should tank leaks develop due to earthquake or whatever cause).

II.
Regarding underwater irradiators, 36.39j does not require underwater pools to maintain structural integrity (or no leaks) in the event of an earthquake. Also, 36.29c allows that for such underwater irradiators there need not be any shielding construct present other than the water itself. I understand that this is the situation at two large irradiators at present. This situation allows that if a seismic disturbance were to occur and the pool be ruptured then loss of water would leave the sources potentially opened (not shielded in their casks) and without any

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shielding whatsoever. This would pose significant health risks to all people at all line of site locations, even those airborne above the site.

Corollary A.
Continuing consideration of the above situation, it was discussed that the chloride of Cs-137 encased in glass or some non-soluble substance may also be used as an underwater source. Should this be implemented, it is essential that you require the encasement to withstand thermal stress and seismic shocks (certainly including those types of shocks which may be incidental to transporting its cask). The thermal requirements evolve out of the fact that sources can reach temperatures of three to four hundred degrees Fahrenheit while surrounded by air, as would presumably be the case during cask transport. The seismic requirement, however is the critical one. At present, requirements suggest that if an earthquake were both to rupture the pool and cesium chloride encasement, then cesium source could dissolve and drain immediately out into the ground water. With a half-life of thirty years and indeterminate underground water flows this could pose an unprecedented health risk and could even make large sections of the country uninhabitable.

III.
Regarding panoramic irradiators using cesium chloride sources, there are no specifications present on how water pipes (such as may be present for sprinkler systems (36.27b) or otherwise) are to be situated relative to the CsCl source or what seismic shocks they should withstand. My reason for concern here is as follows: in the event of an earthquake, it is common that water pipes are broken. Since the source may still be exposed, should water pipes break near the CsCl source and wet it, thereby dissolving it, then the solute CsCl could travel wherever the water may flow, such as into sewer systems, should the leakage become excessive.

IV.
In reference to panoramic irradiators using cesium chloride sources, if fire occurs and sprinklers are turned on (36.27b) after the source is fully shielded (36.27a) then should there be a requirement for the sealed source (36.21) that water not be able to reach the source from sprinklers or other water sources? I realize that this may already be implied in 36.21b but believe that it should be made more explicit.

V.
It was mentioned that heat buildup within concrete shielding structures does occur. The example given was that a twelve million curie source produced an estimated temperature of 375 degrees Fahrenheit twelve inches into the solid structure. While I am not a structural engineer, I do know

that such a high internal temperature while the surfaces were close to room temperature in a continuous, uniform structure would cause tremendous internal stress and very likely significant internal structural degradation. Because this is an unusual situation (in relation to the normal applications of structural engineering) I think it unlikely that these thermal stress considerations have been applied to the ACI Standard 318-77 described in 36.39j on structural integrity of the shielding in the event of an earthquake. However, to retain shielding in any situation (whether seismic or not) the heat buildup and structural implications thereof must be studied carefully and thoroughly understood. Further study and regulation is needed here.

VI.
Two final notes on 36.39j. Your definition or interpretation of "seismic areas" needs to be elaborated upon or explained definitively, else it is likely to be overlooked. Also, it is not possible for any structure to withstand any earthquake (even the earth itself cannot withstand a great quake of magnitude about fourteen on the richter scale). Thus, you should identify the type and magnitude of seismic activity you believe the reinforced concrete radiation shields should withstand and still retain their integrity.

VII.
In your sealed source requirements (36.21) there is no requirement of maintaining a leak free sealed source after it has been dropped several feet unto a concrete surface as could relatively easily happen in a transporting error. This is especially crucial in the case that an encapsulated CsCl source in a cask is dropped in a pool so that both the pool (see 36.39c) and the source are ruptured, instantly beginning a leakage of water containing dissolved CsCl into the water table.

At this time these are the only major difficulties and clarifications I see needed in your proposed rules.

Based upon these problems and others which may appear at some later date, it seems doubtful to me that the tremendous investment and inherent risk involved in the creation of more large irradiation facilities could be worth the small returns likely in the development of the irradiating industry. Frankly, I would prefer to have a few more incinerators built to meet any possible future increases in sterilization needs.

As regards the use of irradiators for sterilizing sludge for fertilization and for preserving foodstuffs (and I know that this is FDA business) it seems as though one would have to be very careful that the irradiation at such high levels not cause significant numbers of non-inert chemical transitions, thereby creating unsafe chemicals in the foods and fertilizers.

However, should you decide to continue to allow the development of large irradiators please understand the gravity of the decisions you make regarding the difficulties I described above and others of which you may become aware. An accident of the sort which released some or much of the source into the ground water in solute form could easily develop into a catastrophe worse than the Chernobyl disaster.

Yours Truly,

Michael G. Unfried

Michael G. Unfried
Peach Bottom Alliance

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
PROPOSED RULE (55 FR 50008)

Laura Spadaro
301 Thompson Ave
Oak Hill, WV
25901

DOCKETED USNRC

'91 MAR 13 A11:57

(20)

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Secretary of the Commission
Docketing & Service Branch
US NRC
Washington, DC
20555

I am responding to the "Licences & Radiation Safety requirements for Large Irradiators". I know that the NRC should not make these regulations. We do not need any more radiation industries. The draft should be withdrawn & any existing irradiation plants should be shut down as unsafe and unhealthy. Cesium-137 should be prohibited from use in irradiators due to examples of its harmfulness — the Chernobyl accident in which Cesium 137 contaminates farm lands 200 miles away.

If ~~you~~ NRC must proceed with this idea then siting criteria must be put into the draft and a complete Programmatic Environmental Impact Statement must be done.

Please extend the public comment period beyond March 4 for at least 60 days. This is an industry which poses serious health risks for the public at large.

Laura Spadaro
Sierra Club Member

APR 24 1991
Acknowledged by card ....

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
PROPOSED RULE (55 FR 50008)

(19)

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'91 MAR 11 P4:43

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Texas Department of Health

Robert Bernstein, M.D., F.A.C.P.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3199
(512) 458-7111

Robert A. MacLean, M.D.
Deputy Commissioner

March 1, 1991

Docketing and Service Branch
The Secretary of the Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: RIN 3150-AC98

Dear Secretary:

Staff members of the Bureau of Radiation Control (BRC) have reviewed the proposed rule entitled, "Licenses and Radiation Safety Requirements for Large Irradiators," and offer the following comments for consideration:

1. The proposed rule pertains to irradiators large enough to deliver a dose exceeding 500 rads in one hour at a distance of one meter. Therefore, the rule covers irradiators containing as little as approximately 375 curies of cobalt-60. However, all of the justification and experience examples discussed in the text of the proposed rule are for irradiators with an inventory of at least 18,000 curies. Many of the proposed requirements are inappropriate for smaller irradiators.

   The BRC suggests redefining large irradiators and adding a definition of small irradiators. Since most of the overexposure incidents cited resulted in fatal doses in less than an hour, large irradiators could be defined as large enough to deliver a dose exceeding 500 rads in one <u>minute</u> at a distance of one meter and small irradiators could be defined as able to deliver a dose up to 500 rads in one minute. This would raise the minimum activity of cobalt-60 in large irradiators to approximately 22,300 curies. The small irradiators need not be required to meet as stringent rules as the large irradiators, i.e., fire protection, access control, operator attendance, etc.

2. The BRC strongly disagrees with 36.15, "Start of Construction." Upon submission and approval of facility engineering and design plans, a letter should be issued to the applicant authorizing the start of construction. During construction, the Agency will review the applicant's radiation safety and training program. Just before construction is complete and after all questions concerning the application have been satisfactorily answered, the Agency should issue a license authorizing storage only to allow the applicant to receive the initial radioactive material. During or shortly before the time the radioactive material is received, a representative of the Agency should inspect the facility to assure that all safety interlock systems are functioning properly. After the initial loading, a survey of the biological shield and a test of all safety systems should be accomplished. When adequate testing shows that the facility meets the

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engineering and design plans, the license should be amended to authorize commencement of operations. By using this mechanism, both the applicant and Agency have an opportunity to confer, consult and modify any possible deficiencies in engineering and design plans during each phase of construction, thus providing an efficient regulatory process which also fosters a cooperative working relationship with the licensee.

3. Section 36.27, "Fire Protection," is too general. Specific information and requirements should be added to insure that, if pool water is used in a sprinkler system, the piping and associated physical components of the fire protection system will not corrode between uses.

4. Section 36.39, "Design Requirements," should be more specific. The requirements for shielding should include an evaluation of heating of the shield walls. If heating is sufficient to degrade shield wall integrity, cooling of the shield wall or alternate shielding shall be included in the design. In pool type irradiators, the energy released by decay is absorbed by the product and the shield walls. Industry representatives can demonstrate that approximately 40 percent of the energy released by cobalt-60 can be absorbed by the product to produce the desired sterilization. This leaves 60 percent of the energy production to be deposited in the shield walls as heat. Irradiators with an inventory of five million curies or greater will cause heating sufficient to degrade the concrete in the shield wall, eventually causing the shield to fail.

   Also, the removal of noxious gases and ozone should be addressed in the requirements for facility design.

5. Subpart D should be expanded to specifically address emergency exercises, as in 10 CFR 30.32. Written emergency instructions, with names and addresses of safety personnel, should be required to be provided to the nearest local police and fire stations.

   The training requirements for a radiation safety officer should be expanded and specifically addressed. The RSO should have at least the same training as required of an operator and additional specific training on all safety systems, logic diagrams, etc., for the specific type of facility he/she will be responsible for.

6. In Section 36.63, "Pool Water Purity," conductivity is not always an accurate indicator of purity or clarity. The pool water should be clear enough to read the source serial numbers at a specified depth.

7. Much of the rationale for the proposed rule was appropriate in that many of the considerations for licensing and regulating large irradiators were addressed. However, the actual wording of the rule was, in most cases, too general and lacked definitive guidance and instruction.

Should you have any questions concerning these comments, please contact me.

Yours truly,

David K. Lacker

David K. Lacker, Chief
Bureau of Radiation Control

DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

(18)

SIERRA CLUB Pennsylvania Chapter

DOCKETED USNRC

Reply to:
Barbara D. Hays
1421 Wightman Street
Pittsburgh PA 15217
412 421 6560

P.O. Box 663
Harrisburg, PA 17108

'91 MAR 11 P4:28

OFFICE OF SECRETARY
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February 24, 1991

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

Sirs:

On behalf of the Pennsylvania Chapter of Sierra Club, we respectfully request an extension of the Nuclear Regulatory Commission's comment period on Large Irradiator Licensing and Regulations, for which a notice appeared in the Federal Register on in December. It is evident that this action will markedly affect our members if large-scale radiation facilities are allowed to operate for the purposes that are stated in the Federal Register notice.

We also ask that the NRC continue to receive and give consideration to comments that may be submitted beyond the formal comment expiration date, even if NRC extends that deadline. The possible distribution of large irradiators makes it very important for the regulatory agency to hear from as many people whose interests will be affected as is possible. As a public-interest environmental organization, our Chapter will try to inform our members about this proposed NRC action, but it takes time for people to obtain and absorb this kind of information and respond to it. We ask the NRC to be liberal in its acceptance of late comments.

Because we had not received any notice earlier about these new draft regulations, we have not had an opportunity to bring them before our Chapter Executive Committee for review and action. Our next Chapter meeting is scheduled for mid-March; we ask that the NRC continue to accept comments on its draft regulations for large irradiators until at least the middle of April.

Thank you for giving consideration to this request. Please notify us promptly if you will grant the extension of time.

Sincerely yours,

Barbara D Hays

Barbara D. Hays
Chapter Chair

APR 24 1991
Acknowledged by card ....

17

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cys to D. Cool
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Ark file
V. Miller
J. Lubenau

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Arkansas DEPARTMENT OF HEALTH

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TELEPHONE AC 501 661-2000

M. JOYCELYN ELDERS, M.D.
DIRECTOR

BILL CLINTON
GOVERNOR

March 4, 1991

Carlton Kammerer, Director
State Programs
Office of Governmental and Public Affairs
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Kammerer:

Attached are comments from the State of Arkansas and the CRCPD, Inc., Incident Review Team on the proposed 10 CFR Part 36 regulations.

In addition to the attached, I would like to add two other comments. We support the Texas proposal that the definition of large irradiator should be revised. The current definition takes in relatively small irradiators that need not be covered by some of the proposed regulations. We also believe that as a result of the public hearing, significant changes are made in regulations -- and same is indicated -- the regulations should be reissued for comment including the possibility of another public hearing.

I want to thank you and State programs for making it possible for me to participate in the public hearing. This type of participation approaches part of what Agreement States would like to see in terms of input into the promulgation of regulations. I believe this to be a positive step and I encourage its continuance.

Based upon my experience with this hearing, I have a recommendation that hopefully will improve state participation as a panel member. During the hearing, I had little opportunity for comment because, having not participated in the writing of the regulation, I could not explain rationales behind a regulation or provide an interpretation of its intent. Also, as a panel member it was awkward to provide comments on the proposed regulation in the same context of other commentators. There were also few comments requiring an Agreement State perspective. The State representative should be more involved in the writing of the rule to avoid this consequence or it should be understood that the individual will be both a panel member to receive comments and a commentator as well. Greater input in the writing of regulations affecting Agreement States is of course, another part of our goal relative to the promulgation of regulations.

APR 24 1991

Acknowledged by card ....

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Again, I am appreciative of the opportunity to be a part of the process.

Sincerely,

Greta J. Dicus

Greta J. Dicus, Director
Division of Radiation Control
and Emergency Management

GJD:je

PROPOSED 10 CFR PART 36 REGULATIONS COMMENTS

CRCPD, Inc. Incident Review Team

Following the RSI irradiator incident in Georgia, the Conference of Radiation Control Program Directors, Inc. (CRCPD, Inc.) established an Incident Review Team (the Team). This group was ultimately tasked with preparing a report on the role of the States in regulating irradiators. The report was developed from information supplied to the Team by Agreement States and States considering Agreement States status. The report was included in NUREG 1392, "Leakage of an Irradiator Source -- The June 1988 Georgia RSI Incident" as an Interim Report of the Team.

Briefly,

1. The States recognized that licensing an irradiator is a complex task which will involve special licensing considerations and resolution of special problems.

2. States had either a confidence in their current ability to license and regulate these facilities, or they felt that expertise could be gained if the need arose in adequate time to effectively license and regulate these facilities.

3. States were in agreement that regulation of irradiators should not be the exclusive jurisdiction of the NRC.

4. Most States did not have specific regulations for irradiators, but regulated these facilities using general radiation protection standards and special license conditions. Most States believed the earlier version of these regulations now under consideration were adequate although improvements could be considered. States, with few exceptions, believed special regulations for food irradiators were unnecessary.

5. States did not have a common position on the adequacy of guidance documents on licensing and regulation.

6. There should be advanced notice of the intent to build an irradiator and construction standards should be developed.

7. The WESF (Cs_{137}) sources should not be used in wet source storage irradiators.

From these conclusions, three recommendations were made:

1. The CRCPD develop guidance addressing licensure, regulation, and construction standards.

2. Regulations should be developed by the NRC with state participation. The regulations should address the issues raised by the States and also lessons learned from the incident in Georgia and should not be a matter of compatibility.

3. Sources used in irradiators should be manufactured for that purpose and used only after proper testing. Use should be limited to only those irradiators for which they were designed.

PROPOSED 10 CFR PART 36 REGULATIONS COMMENTS
CRCPD, Inc. Incident Review Team

The current draft of the proposed rule has successfully addressed some of the findings and recommendations, but has fallen short on others. This draft is a significantly improved document particularly with regard to the frequency of maintenance and operational checks, the attention given to access control, and the increased significance given to reports, maintenance, operation, and emergency procedures. States are having a noticeable role in development of the regulation and advanced notice of the intent to construct is addressed by the need to be licensed prior to construction. Future sources used in irradiators will have to be doubly encapsulated and meet testing standards. The effectiveness of guidance documents must be evaluated later.

However, the regulations fall short in the following areas: the States do not support the use of the Cs_{137} capsules which were responsible for the RSI incident. The proposed regulation does not remove sources from use that do not meet the new standards. There is uncertainty that the regulations are firm enough on source tests. It is also noted that the regulations will be a matter of compatibility. Several States had suggested that the siting of irradiators be addressed and the States had produced a list of siting criteria and quality assurance standards. These have not been entirely addressed.

PROPOSED 10 CFR PART 36 REGULATIONS COMMENTS

State of Arkansas

In July, 1988, the U.S. Nuclear Regulatory Commission (NRC) published the proposed rule on large irradiations. The Division of Radiation Control and Emergency Management submitted comments on the proposed rule in a letter dated October 13, 1988. In December of 1990, the NRC published a revised draft of the proposed regulation. Our comments on the 1990 version will be in three parts. We will compare the two documents relative to our comments in 1988, and second, we will provide additional comments of the second document and third, we will respond to specific requests for comment.

I. Comparison

The issue of compatibility was not addressed in the 1988 version whereas in the 1990 version the rule will be a matter of compatibility. While the Division of compatibility is not designated, Division II is implied. We had questioned the significance of a "3x background" action level for resin bed pool water monitors and now note that the 1990 document says "above normal" which suggests a specific action level will be determined on a case-by-case basis. We concur with this change. RSO training requirements were troublesome to us earlier and we still have concern that the requirements are too lax. The language in the proposed guide will be very important. We had expressed serious reservations about unattended irradiator runs. The current proposed rule requires, for in air automatic conveyor systems, two people present and at least one person present for panoramic, static irradiations. Only underwater static irradiations need not be attended under qualified conditions. We agree with the increased measure of safety provided by the new proposed regulation. We had strongly recommended regulatory oversight of the construction of irradiators so the requirement for licensure prior to construction addresses this recommendation. Licensure prior to construction may be overkill, but it will ensure the extra level of safety construction oversight provides.

Several concerns expressed in our 1988 letter are not addressed in the 1990 revision. These are: surety for accident mitigation and third party liability, survey meters that do not saturate and thus read zero, high range survey meters, an outline of operating procedures rather than the procedures, no calibration requirements for dosimeters and the need for a seismic switch in some areas. We still suggest these points be addressed. Regulations that will ultimately be developed for Arkansas under Division II compatibility will address these points.

II. Additional Comments

While we do not agree completely with the new proposed regulation, it is an improvement over the previous proposal as we noted earlier. The specified frequency of checks; the attention being given to access control, alarms, and monitoring; construction controls; and more details regarding reports, maintenance, operation and emergency procedures will increase the margin of safety for operation of these facilities.

We do not concur with the relatively long time allowed (five (5) days) to report leaking or damaged sources, contamination, and similar type events. Although the rationale for five days is reasonable, regulatory agencies should be aware that a potentially serious situation exists when that situation is discovered. The completeness of an initial report is a secondary issue. Arkansas regulation, under Division II Compatibility, will be more restrictive.

III. Requested Comments

Pool Water Purity. Conventional wisdom suggests that your approach to pool water purity is correct and should be adequate for the intent of the requirement.

Use of Cs-137 Sources. These DOE sources were not designed for irradiator use and they should not be used for irradiators. As problems have been detected with some of these sources, all should be removed and reevaluated.

Seismic Detection and Automatic Source Return. For irradiators in areas of high seismic potential, seismic switches with automatic source return should be mandatory. A severe quake during irradiation could damage source return mechanisms. This, coupled with a compromise to shielding which is also possible, could complicate recovery efforts. A seismic switch with automatic return can provide through the early warning that extra measure of safety. As this Division also has a major responsibility for Arkansas' earthquake planning for the New Madrid Fault, we are acutely aware that every effort must be made to minimize the impact of an earthquake.

+R10367/02-08-91

PROPOSED 10 CFR PART 36 REGULATIONS COMMENTS
CRCPD, Inc. Incident Review Team

The current draft of the proposed rule has successfully addressed some of the findings and recommendations, but has fallen short on others. This draft is a significantly improved document particularly with regard to the frequency of maintenance and operational checks, the attention given to access control, and the increased significance given to reports, maintenance, operation, and emergency procedures. States are having a noticeable role in development of the regulation and advanced notice of the intent to construct is addressed by the need to be licensed prior to construction. Future sources used in irradiators will have to be doubly encapsulated and meet testing standards. The effectiveness of guidance documents must be evaluated later.

However, the regulations fall short in the following areas: the States do not support the use of the Cs_{137} capsules which were responsible for the RSI incident. The proposed regulation does not remove sources from use that do not meet the new standards. There is uncertainty that the regulations are firm enough on source tests. It is also noted that the regulations will be a matter of compatibility. Several States had suggested that the siting of irradiators be addressed and the States had produced a list of siting criteria and quality assurance standards. These have not been entirely addressed.

+R10367/02-08-91

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 7, 1991

MEMORANDUM FOR: Samuel J. Chilk, Secretary

FROM: Vandy L. Miller, Assistant Director for State Agreements Program State Programs, GPA

V.L. Miller

SUBJECT: ARKANSAS' AND THE CONFERENCE OF RADIATION PROGRAM DIRECTORS, INC.'S COMMENTS ON PROPOSED 10 CFR PART 36 RULE CONCERNING IRRADIATORS

Attached in response to the Federal Register notice requesting public comments on the proposed rule concerning irradiators are comments from the State of Arkansas and the Conference of Radiation Program Directors, Inc.

Attachment:
As stated

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DOCKETED
USNRC

'91 MAR -6 P7:18

MAR 4 1991

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

OFFICE OF ENFORCEMENT

Mr. Samuel Chilk
Secretary of the Commission
Nuclear Regulatory Commission,
Attention: Docketing and Service Branch
Washington, D.C. 20555

Dear Mr. Chilk:

In accordance with Section 309 of the Clean Air Act and the National Environmental Policy Act (NEPA), the U.S. Environmental Protection Agency (EPA) has reviewed the Nuclear Regulatory Commission's (NRC) proposed rule for 10 CFR Parts 19, 20, 21, 30, 36, 40, 51, 70 and 170, licenses and radiation safety requirements for large irradiators. EPA commends the NRC for establishing licensing and safety criteria which consolidate and standardize large irradiator requirements. Our detailed comments are enclosed.

Thank you for the opportunity to review the proposed rule. Should you have any questions regarding our comments, please have your staff contact Ms. Susan Offerdal of my staff at (202) 382-5059.

Sincerely,

Richard E. Sanderson
Director
Office of Federal Activities

Enclosure

APR 24 1991
Acknowledged by card ....

Note attached: Ltr faxed 3/4/91

Detailed comments on the Nuclear Regulatory Commission (NRC) proposed rule on 10 CFR Parts 19, 20, 21, 30, 36, 40, 51, 70 and 170, Licenses and Radiation Safety Requirements for Large Irradiators

Supplementary Information, Section 1: The regulation should define the specific application(s) for the use of large irradiators. The Supplementary Information, Section 1, discusses potential uses for large irradiators, however, categories and specific uses are not identified.

Subpart C, Section 36.33: The regulation should clarify the meaning of the statement "low likelihood of a substantial leakage". The language is unquantifiable as a design guideline. To make the design specification easier, the NRC could require that all irradiator pools have a water-tight stainless steel liner.

Supplementary Information, Section VII: The NRC states, "Experience has shown that pool contamination levels did not get very high so that the escape of a small amount of pool water into the ground is not a significant concern." This statement does not consider the long-term cumulative impact that pool leaks could have on human health in the form of ground water contamination, or related environmental impacts to the soil and water caused by the possible migration of contaminants over time. The NRC should reexamine the decision "not to require a pool leak system more sensitive than the one required in the proposed rule."

Subpart C, Section 36.39 (f): The regulation should clarify the minimum and recommended requirements for the design of the mechanism that covers and uncovers the source. In the Supplementary Information, Section II, Review of Operating Experience (A and B), the operating problems discussed indicate the need for a very thorough design specification for the mechanism that protects the source.

Subpart C, Section 36.35: The text should also include specifications concerning the maximum dimensions of the product in relation to the conveyor belt, to avert product jamming on the conveyor belt system.

Subpart D, Section 36.51: The regulations should clearly identify minimum and recommended requirements for training of personnel who operate large irradiators. In the Supplementary Information, Section II, Review of Operating Experience (A and B), the operating problems discussed clearly indicate a need for better training of personnel concerning the operation of the irradiator and emergency procedures, since many of the mishaps cited were the result of human error.

Subpart D, Section 36.53: Because of the safety violations identified in the Supplementary Information, Section II, resulting from the source being stuck in the unshielded position, the regulation should specify minimum safety procedures in the regulation (in accordance with 10 CFR Part 20) that outline operator emergency procedures in the event of a shield sticking. If the irradiator has a product conveyor belt system, the regulation should specify emergency procedures in case a product jams on the conveyor while the source is in the unshielded position.

Subpart D, Section 36.61: The NRC should identify a minimum number of operational and maintenance inspections per year. Reviewing past maintenance records should provide some indication of how often specific parts of the facility need to be inspected. In the Supplementary Information, Section VII, it states that because of the variation in irradiator design, the frequency for checks on the access control system, "probably the most important safety feature of the irradiator," could not be set. We recognize that facilities vary in design, however, this variation should lead the NRC into a discussion of standardization and limitation of facility design so that a minimum number of checks can be properly defined.

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70+170
(55FR50008)

(15)

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'91 MAR -5 P7:19

OFFICE OF SECRETARY
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BRANCH

830 Washington Pl.
Erie, PA 16502
Feb. 28, 1991

Dr. Stephen McGuire
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Sir:

These comments relate to NRC's proposed regulations for irradiation of food and sewage sludge.

For health and safety reasons, NRC should not adopt the draft regulations. Instead, NRC should shut down all irradiation plants. This technology is extremely dangerous. DOE would be able to recycle high-level radioactive waste as "source material" for food and sludge irradiators. Each irradiator may hold 10 million curies of radioactive material, primarily cobolt-60 metal or water-soluble cesium-137 (ten times more than the amount of cesium reportedly released at Chernobyl).

NRC should prohibit use of water-soluble cesium-137 in all irradiators.

The irradiation industry should not be expanded without a prior and complete Programmatic Environmental Impact Statement and without compliance with detailed siting criteria which need to be included in the regulations.

The public comment period should be extended at least three months.

Sincerely yours,

Albert Richardson

Albert Richardson (814) 455-9730

copy: Secretary of NRC
Docketing and Service Branch
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Acknowledged by card 3/7/91

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55FR 50008)

(14)

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'91 MAR -5 A11:23

OFFICE OF SECRETARY
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HEARTLAND OPERATION TO PROTECT THE ENVIRONMENT

26 February 1991

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

Re: Large Irradiators
55 FR 50008
4 December 1990

Dear Mr. Chilk:

On behalf of Heartland Operation to Protect the Environment, Inc., I respectfully request that a 90 day extension of the public comment period regarding the above referenced matter be granted.

An extension is necessitated for the reason that there has not been adequate time to acquire and competently review all of the relevant material referenced in the Federal Register Notice of December 4, 1990. Further, an extension of the comment period is necessary due to the many varied and complex issues involved in the promulgation of rules, not to mention the intricate issue of large irradiators themselves.

Thank you for your consideration and attention to this matter.

Sincerely,

Diane A. Burton, Director
(402) 274-5242

1903 'N' STREET, AUBURN, NEBRASKA 68305

Acknowledged by card 3/7/91

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
PROPOSED RULE (55 FR 50008)

(13)

DOCKETED
MAR - 4 1991
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SECY-NRC

March 2, 1991

COMMENTS OF OHIO CITIZENS FOR RESPONSIBLE ENERGY, INC. ("OCRE") ON PROPOSED RULE, "LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LARGE IRRADIATORS," 55 FED. REG. 50008 (DECEMBER 4, 1990)

OCRE supports the issuance of this rule. Given the potential hazards posed by large irradiators, the tragic accidents which have already occurred at such facilities, and the anticipated growth of this industry, this regulation is extremely necessary. In fact, it is overdue. OCRE would commend the NRC for a clear, well-written rulemaking package which thoroughly explains the regulation and the need for it. The rulemaking is well-supported by the facts presented therein. The provisions for operator training, procedures and emergency plans, double-encapsulated sources, radiation monitoring, source leak testing, access control, fire protection, pool water purity, and the other design and operational requirements are all essential for the safe operation of these facilities. This rule will prevent the repeat of the unfortunate events which have resulted in personnel injury or death. It is also appropriate that the rule will be assigned a level of Agreement State compatability which would allow the Agreement States to adopt additional requirements based on local concerns or experience (55 FR 50023). This regulation should be adopted without delay. However, OCRE would recommend the following improvements to the proposed rule.

A. General Comments

1. Use of Cesium

The NRC requested comment on whether cesium-137 sources should be permitted. The problem is that cesium is encapsulated as a water-soluble salt, cesium chloride. OCRE believes that cesium chloride sources should not be permitted. The Federal Register notice states that an underlying assumption in this rulemaking is that any sealed source could leak. 55 FR 50013. Given this assumption, it is prudent to require the source to be in a form which is not conducive to the spread of contamination should a postulated leak occur. Banning the use of cesium will also minimize the potential for damage should the source rack drop. It is stated that Cs-137 sources are relatively heavy, such that damage from a drop is more likely. 55 FR 50022. Banning cesium will result in less radioactivity in use at irradiators, as the Federal Register notice indicates that 2000 curies of Cs-137 is needed to deliver the same dose as 400 curies of cobalt-60 (55 FR 50014). The fact that leakage occurred from a cesium source at the RSI irradiator also favors a ban on cesium. It has been postulated that the cause of the leak was the repeated thermal cycling of the sources which caused the

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U.S. NUCLEAR REGULATORY COMMISSION
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CsCl to expand. It has also been reported in the news media that the Department of Energy has recalled the Cs sources. Therefore, there is apparently a de facto ban. This should be made a part of the regulations. This requirement should not have a severe impact on the irradiator industry, since it is stated that only four irradiators use cesium (55 FR 50023), and apparently they won't use it any longer due to the DOE recall.

2. Need for a seismic detector and automatic source return mechanism

This should be required in the regulation. It is stated that this requirement is contained in the ANSI Category IV standard and is general practice. 55 FR 50022. Thus, including this provision in the regulation should not impose any burden on the irradiator industry. Its inclusion would reinforce this standard of safety and would make this necessary design feature enforceable. Requiring this feature would also help avoid one of the causes of the accidents which have occurred in irradiators: a jammed source. Without this feature an earthquake could result in a jammed source, which sets the stage for personnel exposure to radiation.

3. Siting Issues

Because of the large inventory of radioactive materials which an irradiator may contain, it is appropriate to apply the same siting criteria used for nuclear reactors. The Federal Register notice states that the maximum source inventory currently in use in irradiators is 30 million curies. Comparing this to the fission product inventory in a nuclear power plant gives an indication of the "equivalent" nuclear reactor size. E.g., the fission product inventory for the Perry Nuclear Power Plant, taken from NUREG-0884, the Final Environmental Statement, is 6 billion curies, assuming a power level of 3834 MWt (Table 5.6, NUREG-0884). A 30 million curie irradiator is thus equivalent to a 19 MWt reactor. A reactor of this size would be classified as a "testing facility" pursuant to 10 CFR 50.2 and thus would be subject to the siting regulations of 10 CFR Part 100. 10 CFR 100.3(e). Large irradiators should also be subject to these siting requirements.

The NRC should also prohibit siting of irradiators in at least the 100-year floodplain.

With regard to aircraft crash hazards, it is not apparent that the NRC has considered the combined effects of source damage due to aircraft impact and a resulting fire involving the burning of airplane fuel. The Federal Register notice states that "large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack because the sources are not volatile." 55 FR 50022. Would this statement be true if the aircraft crash resulted in a raging fire, as is often the case? The NRC should prohibit siting of irradiators near airports to prevent this hazard.

4. Seismic Design Requirements

With regard to the definition of a "seismic area," the background material (55 FR 50017) references a USGS report, Open File Report 82-1033. The regulation, 10 CFR 36.2, defines a "seismic area" as one designated by the USGS as having a greater than 10% probability of a horizantal acceleration exceeding 0.3g in 250 years. The specific document cited above is not referenced in the regulation. This is appropriate, as research in seismology continually produces new results. In fact, the document cited may already be outdated. See "Forecasting Damaging Earthquakes in the Central and Eastern United States," S.P. Nishenko and G.A. Bollinger, Science, Vol. 249, pp. 1412-1416, Sept. 21, 1990. In this paper the authors, both from the USGS, find that in the next 100 years, there is a 97% probability of an earthquake of magnitude 6 or greater occurring in the New England, Southeast, or New Madrid regions. There is a 33% probability of a magnitude 7 or greater earthquake occurring within the next 100 years within these regions.

This raises an interesting question: what does the phrase "as designated by the USGS" mean? Does this refer to the Open File Report 82-1033, as the legislative history of the rule might imply? Or does it mean the most current USGS position? Is the Science article an official USGS position? What if there are scientists in the USGS who hold differing professional opinions on the designation of a "seismic area"? What if there are scientists outside the USGS who disagree with the USGS designation; should not their opinions be considered as well? It is not clear how to resolve these questions. One approach might be to reference the most current official USGS position in regulatory guidance. However, this does not address the issue of differing professional opinions. Or, given the findings of the Science article, it might be simpler to designate the entire United States as a seismic area and to require irradiators to incorporate seismic design requirements in shield walls.

It is appropriate that the NRC has chosen 250 years rather than the 50 years specified in the ANSI standard, given the uncertainties of seismology.

5. Public Hearings and NEPA Analysis

As shown above, large irradiators may contain radioactivity equivalent to that in a small nuclear reactor. A nuclear reactor, being a production and utilization facility subject to the requirements of 10 CFR Part 50, cannot receive a license or an amendment thereto without a notice of proposed action being published in the Federal Register, with the opportunity for a hearing, upon the request of members of the public. 10 CFR 2.105. This notice and opportunity for hearing requirement should apply to large irradiators as well. It is incongruous that a 10 KW research reactor is subject to the notice and opportunity for hearing requirement but an irradiator using radioactivity equivalent to that in a 19 MWt reactor is not. Members of the public residing near an existing or proposed irradiator should have the right to participate in licensing decisions for these facilities.

Moreover, an evidentiary hearing is the best vehicle for resolving conflicts among experts, such as that postulated above for the seismic design issue. Such conflicts are certainly conceivable for other aspects of the irradiator design, such as the foundation (10 CFR 36.39(b)) or source rack (36.39(f)), and for issues such as the adequacy of procedures.

Irradiator licensees and license applicants should have to comply with the National Environmental Policy Act of 1969. They should be required to submit an environmental report, and the NRC should prepare an environmental impact statement. Large irradiators should be removed from the categorical exclusion list of 10 CFR 51.22(c)(14)(vii). The public should also have the right to contest, in an evidentiary hearing, the environmental impact statement prepared by the NRC, particularly with regard to the need for and alternatives to the facility.

B. Specific Comments

1. The rule mixes both metric and English units of measure. For example, 10 CFR 36.21(a) usually uses metric units, except for 36.21(a)(2) which uses psia. For units of radiation dose or radioactivity, the rule usually gives both types of units, e.g., 500 rads (5 grays). This should be done for all units for the convenience of users.

2. 10 CFR 36.21(a) sets forth testing requirements for a prototype of the sealed source. It should be clarified that the prototype must be equivalent to the production-run sources. Otherwise, licensees could use a "prototype" that has stronger and thicker capsulation than will actually be used in the irradiator. Perhaps the term "representative sample" would be better than "prototype."

10 CFR 36.21(a)(4) requires the test source to be subjected to a vibration from 25 Hz to 500 Hz at 5g for 30 minutes. Does this mean any one vibration frequency between 25 Hz and 500 Hz, or is there to be a sweep of all frequencies in this range? If it is to be a sweep, at what sweep rate?

3. 10 CFR 36.23(a) sets forth the time for the sources to

return to their shielded position after the door to the radiation room is opened. This time is given as "the time that it would take a person starting to enter the radiation room to walk to the edge of the pool or into the beam." This is too imprecise. Persons can walk at different speeds. Someone may, for whatever reason, run into the room. A minimum time, in seconds, should be specified.

4. 10 CFR 36.37 does not require backup electric power for the access control interlocks and radiation monitors. This should be required.

5. 10 CFR 36.55 only requires irradiator operators to wear either a film badge or TLD dosimeter. These dosimeters do not give instantaneous, real-time indication of dose, but rather must be processed, and need not be replaced more often than monthly (film badge) or quarterly (TLD). In addition to these dosimeters, the operators should also wear a self-reading pocket dosimeter so they can rapidly determine their dose.

6. Probable typographical errors

10 CFR 36.57(a), second sentence. Should "the area above the pool or pool irradiators" read "area above the pool for pool irradiators"?

10 CFR 36.57(e). Should "released for regeneration or an nonradioactive waste" read "released for regeneration or as nonradioactive waste"?

Respectfully submitted,

Susan L. Hiatt

Susan L. Hiatt
OCRE Representative
8275 Munson Road
Mentor, OH 44060
(216) 255-3158

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

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12

'91 MAR -4 P3:52

OFFICE OF SECRETARY
DOCKETING & SERVICE BRANCH

The Secretary of the Commision
Docketing and Service Branch
Washington, DC 20555

Re: Comments regarding the proposed 10CFR36

Dear sir:

Contained herewith are my comments regarding the proposed rule. Comments are referenced according to the rule designations.

I. Large irradiators

Consideration should be given to reviewing the definition of a large irradiator. The definition proposed, includes a large spectrum of irradiators. I feel that the proposed rule is primarily directed to large commercial irradiators, and not meant for smaller research type facilities which would be included within the current definition. Perhaps a classification according to usage might be appropriate, in terms of purpose or frequency or total curie loading.

Some consideration might be given to restrict this rule only to the use of cobalt-60, since it is highly unlikely that cesium-137 will ever be used again in a large scale commercial irradiator. The overall requirements would tend to be less demanding if only cobalt-60 were considered. It would be unfair to base the requirements of a cobalt-60 plant on the potential problems which might happen with a cesium-137 plant.

II. Need for a rule

Paragraph one - are these proposed rules consistent with the requirements set forth in 20.203 (c) (6) and (7)?

The "lessons learned" at RSI, Decatur might be considered if we are dealing with cesium-137 as a source material. They must be interpreted in that light, and not assume that everything applies equally to cobalt-60 in both potential and magnitude. It must be stated that these "lessons learned" only came about because of the use of cesium-137. In all the prior plant operating years of gamma facilities using cobalt-60 these problems were never considered to be problems of this magnitude. There is no question

Acknowledged by card 3/7/91

that cobalt-60 facilities can and should be made safer, but within reason. There is also little doubt that this revision is a result of the RSI Decatur incident

I do not believe that the regulation should prohibit the start of construction before a license has been issued. This is the right of the licensee to be able to make this decision as a normal business risk. This act does not endanger anyone but himself financially, and he should be allowed to do this if he feels that he can meet the licensing requirements established by the Regulating Agency. The Regulating Agency will always be able to protect the public by witholding issuance of the license based upon the licensee's inability to meet the regulations.

Additionally, imposing this requirement will only penalize the licensee by extending the period of time that it will take him to get into operation.

Regarding the future use of WESF capsules, I believe that the NRC has requested that the DOE recall all WESF capsules from the field. Doe has agreed to this request, and is making plans to return all WESF capsules to the DOE Hanford Operation. Also there have been statements made that Doe will not continue the failure analysis to determine the cause of failure. This action further supports my earlier statement that it is highly unlikely that WESF capsules will ever be used again in commercial irradiators, and that they should not be a subject of this regulation.

I agree with the NRC that monitoring both workers and product on a routine basis is unnecessary. Certainly the early warning provided by a sensitive on-line radiation monitor to detect leaking sources will be the best line of defense. This would then trigger the emergency response required by the regulation.

III Review of Operating Experience. (this is labeled as II and should be (III)

This whole section provides a good basis from which to improve the existing regulation. Clearly almost all of these could and should have been prevented.

IV. Radiation Protection Philosophy

It is true that the existing source requirements assure that sources will not routinely leak. However, we all know that it is possible that it could happen even though the probability is extremely low. Rather than have all of the licensed users develop the capability of being able to identify, isolate, and remove a leaky source, it might be more reasonable to require that the source supplier maintain this capability for the benefit of his customers. This would certainly be more cost effective, and place the responsibility where it most rightfully belongs.

The current state of the art in leak detection will permit the detection of 10(-7) microcuries per ml for an on-line monitor. This level should be more than adequate to provide an early warning. Certainly the first indication at this level need not trigger an emergency response, but should alert the licensee to carefully monitor the situation for a definitive trend.

VI. Public Meeting

I believe this was a good idea to solicit the face to face discussion with the regulated.

Specific comments regarding the proposed text

36.1 (b) Refer to prior comments regarding definition of a large irradiator. The use of 500 rads per hour at one meter includes more than may be intended.

36.2 Re-define large irradiator

36.13 This section states that a license will be issued if the requirements of this section are met. Therefore the licensee should be able to begin construction before being licensed if he is confident that he can meet these requirements

36.13 (c) Agree that summaries of written operating and emergency procedures need be submitted. Complete procedures are not practical nor necessary for the submission. Additionally the licensee should be able to amend the procedure if it does not compromise the summary without going through a license amendment.

36.13 (d) Describe "other management personnel". This could add significantly to the license submission.

36.15 This section should be deleted because it is irrelevant and self contradictory.

36.21 This section does not belong in this regulation, but rather in the source specification. All that is necessary here is to reference all acceptable source specifications.

Some attempt should be made to see how many sources now in use do not meet current sealed source specs. I believe that this will be a small number, and some consideration should be given to taking these sources out of use. The cost of replacement sources is relatively small compared to the cost of dealing with a leaky source.

36.23 Access control

(a) The time of source drop should not be specified, since it is a variable as defined in the proposed regulation. It is suggested that it be worded to reflect that entry can only be made after the radiation level in the radiation room has been reduced to a safe level. This item appears to be adequately covered in section (c)

(b) The qualifications of the other individual should be better defined. If the entry alarms are inadvertently triggered by the operator, is there really a need to require a second individual to be there?

(c) There is something missing in the middle of this paragraph. The monitor should be set to control and alarm at much lower levels than defined high radiation levels. Presumably before entry is permitted, the radiation level should be at or near background.

(h) In most commercial irradiators, the only moveable shielding is the roof plug. Typically, these are quite large, and weigh generally in excess of several tons. It is highly unlikely that anyone would attempt to operate one of these facilities without first replacing this plug. Requiring an interlock on the plug to assure that it is in place is unnecessary, and only introduces another item which can fail and cause unnecessary plant shutdown. This requirement of an interlock should only be applied to small port hole type plugs which can be readily be removed without the need for heavy equipment such as fork lifts or cranes. It is highly unlikely that anyone would bring in a crane to remove the roof plug at any time other than for isotope loading. Administrative controls at this time should be more than adequate.

36.25 Shielding

(a) There are generally two areas of interest in irradiators - controlled and un-controlled. Most irradiators are designed to permit un-controlled access to all areas. The controlling dosage in an un-controlled area is 0.5 rem per year. Extrapolating this to a dose rate over 40 hour weeks and 50 weeks per year, the dose rate for an un-controlled area is 0.25 mr/hr. The generally accepted dose rate for a controlled area is 2.0 mr/hr. The regulation covers the range up to 2mr/hr and the range above 2.0 mr/hr.

There appears to be the gray area between 0.2 mr/hr and 2.0 mr/hr. which the proposed regulation treats as an un-controlled area. If this is the case, the allowable annual dose has been increased to 2.0 rem/yr. Is this true?

The allowable dose rates in this whole section should be reviewed.

36.29 Radiation monitors

(a) Underwater irradiator should reference "an enclosed stationary tube" Dry tubes or containers could be attached to moving conveyors which could carry sources out. Liquids are frequently run through stationary tubes to be irradiated, and therefore the tubes would not be dry.

(b) The on-line monitor should be monitoring the re-circulation line, and therefore should be operated continuously, which is normally how the re-circulation system operates. It is entirely conceivable that the leak could be initiated during periods when the system is not operating. Continuous monitoring by the on-line unit will.detect this as soon as it occurs. It is best to monitor the re-circulating line rather than the de-ionizing line because the latter does not necessarily operate continuously.

The normal de-ionizing units are not meant for cleaning up a pool, and should not be used for this purpose except in emergency situations. Commercial shielded D.I. units should be brought in for contamination cleanup.

If analysis of pool water is used to monitor source leakage, samples should .be taken daily. If the system is shut down for a period of time, the system should not be allowed to start up without reviewing the results of a water sample taken just prior to re-starting.

(c) Underwater irradiators should comply with the same requirements for panoramic irradiators. Over pool monitors are generally of very low sensitivity, and will not provide the early warning that is desired. These irradiators really need early warning because the operators usually come in direct contact with the pool water during normal operation, and are therefore more vulnerable to being contaminated..

A detection level should be spelled out here . Both on-line and water sample testing can measure to 10(-7) microcuries/ml. G-M tube monitors will not approach this level of detection, and should not be offered as an option.

36.31 Control of source movement

(a) "operate" might be changed to "activate"

36.33 Irradiator pools

(a) Irradiators do not necessarily need to have a means of storing sources during repair of the pool. A plan for accomplishing this should be adequate.

(d) Should include alarms for exceeding the high water level. Could lead to flooding and potential spread of contamination. Most level detectors already come with low and high alarms.

(f) During normal operation of panoramic irradiators, personnel are not allowed into the irradiation chamber. As a result they cannot possibly fall into the pool.

(g) See prior comments regarding the 0.2 mr/hr level.

36.37 Power failures

(c) Applies to all irradiators.

36.39 Design requirements

(e) The location of the highest radiation levels in a D.I. column is not predictable. Also the inference is that a G-M type probe can be used as was permitted under the old regulation. Contamination monitors should be required to meet a specific sensitivity level. G-M tubes will not provide the required sensitivity

(f) Radiation overexposures for this task may be unavoidable.

36.41 Construction control

(e) G-M type radiation monitors are not sensitive enough. Refer to earlier comments on this subject.

(h) I would recommend that manually controlled water suppression systems be used where the water valve is located outside the cell. Automatic sprinkler heads tend to fail for various reasons, one of which is corrosion from the high ozone levels in the radiation room. In cold climates, the stagnant water in these systems must contain an anti-freeze additive to prevent freezing when the facility is not being used. If a sprinkler head fails, it will dump a load of corrosive water into the pool. Use of the proposed manual system will not require the anti-freeeze additive since the water supply line will be located in a heated area. Since the facility will always be operated with someone in attendance, the manual system should be preferred.

36.51 Training

This whole section should be reviewed to clarify the differences between an individual, an operator, and a supervisor. Earlier regulations got around this problem by stating that the facility should not be operated unless a responsible individual was present. It appears that items (a) through (f) could be used to define a responsible individual.

(e) "other management personnel" should be more clearly defined to identify their qualifications for doing this task.

(f) Delete the word "unescorted". If the intent is to permit maintenance or others into the radiation cell, they should only be permitted access under the supervision of the operator. Unescorted infers that they are free to enter whenever they like. This should not be allowed.

36.53 Operating and emergency procedures.

The way this is presented, the list given is all inclusive. It should be worded such that these are minimum requirements, and that other necessary procedures should be generated according to the needs of the specific facility.

36.55 Personnel monitoring

(a) It is a good idea to have all workers in a radiation facility wear a personal film badge. Also new workers should be given medical tests to establish baseline assay values.

36.57 Radiation surveys

(a) A radiation survey should be taken before and after each source loading. After the first source loading, the after after survey becomes the before survey for the subsequent loading. The survey should include the outer extremeties of the shield, as well as the area over the pool. Particular attention should be paid around any shield penetration. Of coarse, the measurements over the pool will be with the sources in the shielded position.

36.59 Detection of leaking or contaminated sources.

(c) If an on-line monitor is used, it should be used continuously whether or not the facility is operating. If water samples are used, the facility should only be permitted to operate after a successful water test.

(d) Leaking source identification and removal should only be attempted by those experienced in this area. As previously suggested, source suppliers should be required to maintain equipment and personnel available to provide these services. Decontamination efforts also should only be attempted by those skilled in these techniques. Once a leaking source has been detected, I believe that the safest plan would be to close and secure the facility, and convene a meeting with the licensee, the licensing authority, and the source supplier to discuss the situation, and to devise a plan for the clean-up. If the licensing authority is a State, the NRC should also be present. I do not think that it reasonable to expect that the licensee should be able to unilaterally deal with this magnitude of a problem. This is an industry type problem, and should be dealt with by the industry.

36.63 Pool water purity.

(a) The pool water purification system consists basically of two parts. First, the water is filtered to remove dirt and debris to maintain optical clarity of the water.for isotope loading and source inspections. Secondly, the water is de-ionized to remove soluble salts which could create a corrosive environment for the sources. Normally, the filtration of the water is carried out on a continuous basis. The de-ionization on the other hand is usually operated on demand based on a continuous monitoring of the water conductivity.

Furthermore, the de-ionization is usually not carried out on the entire flow of the re-circulation stream, but rather on only a small portion. The reason being the expense involved in sizing a de-ionization system capable of being able to handle such large flows. The build up of soluble salts in the pool water is slow, and therefore treatment of a small portion of it will be sufficient to control the conductivity within control limits even when operating on less than a continuous basis.

The regulation should only specify the value of conductivity, without trying to specify the operating conditions for attaining these values.

Based upon these comments, the in-line monitor should be monitoring the re-circulating filtration line, and not the de-ionization line for maximum safety and control.

36.65 Attendance during operation.

(b) For static operations, there is really no need to have an operator on site. The only danger is to the product, and not to personnel.

36.67 Entering and leaving the irradiation room.

(b) After visually inspecting the radiation room, the operator should activate an alarm within the radiation room to further warn that the sources are about to be raised. This is usually accomplished using a key switch which also activates a timer to control the period of time during which a second key switch must be activated at the entrance to the maze. Only then should the source raising control be activated.

(c) Should apply also to panoramic irradiators.

36.69 Irradiation of explosive or highly flammable material.

(b) The flash point should be made to refer explicitly to the packaged material, and not to any of the discrete components in their un-packaged state.

36.81 Records and retention periods.

(j) This requires a much broader definition of the types of incidences which require reporting and retention.

(m) This requires a better definition of what is required. I think the concern is a leaky pool, and therefore only excessive pool additions should be noted.

36.83 Reports.

(d) (1) should be verbally reported within 24 hours

(d) (2) ditto

(d) (3) define level of reportable damage. What if there is no safety hazard?

(d) (4) ditto

(d) (5) licensee should be allowed to fix without reporting. Report only if an extended period of time is required for repair.

(d) (6) These detectors can alarm because radiation levels are normally raised after a source addition. the normal cure is to increase the detection level as long as shielding surveys are still within regulation.. Reporting should be limited only to those confirmed cases of a source being carried out with the product.

(d) (7) Should be verbally reported within 24 hours.

(d) (8) ditto.

(d) (9) ditto

These comments have been respectfully submitted.

Sincerely,

Allan Chin

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Phone: 415 326-5912
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DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

DOCKETED USNRC

(11)

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'91 MAR -4 P2:36

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

RTI Inc.

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(201) 625-8400 • FAX (201) 625-7820

February 28, 1991

Nuclear Regulatory Commission
The Secretary of the Commission
Washington, DC 20555

Attention: Docketing and Service Branch.

Dear Sir:

We are submitting the following comments regarding the proposed rule for 10 CFR Part 36 as published in the Federal Register on December 4, 1990.

36.13.c We are in favor of submitting an outline or summary of written procedures instead of the exact procedure. The proposed wording avoids delays that might result from lengthy reviews yet maintains the desired control.

36.21.a Please clarify the use of the word "assure" Has a licensee "assured" compliance if he has a certificate of registration as required in 36.21.b?

36.23.a The use of a photoelectric barrier and an obstacle, such as a conveyor or track, in the entrance of irradiators that have a separate product entrance, should be acceptable. Currently some irradiators utilize a photoelectric barrier at the product entrance and a door or other physical barrier at the personnel entrance. The product entrance has a track or conveyor in addition to the photoelectric barrier. This track may be one to two feet high and is not readily removed as it is very heavy and secured. This is not a physical barrier but deliberate intention and effort is required for a person to enter. It should be considered the equivalent of a physical barrier. An individual has to physically climb on top of the track and walk on the rails to enter via the product entrance. In doing so the photoelectric barrier would be activated and automatically close down operations.

Acknowledged by card 3/7/91

This section also requires the sources to return to the shielded position in the time it takes to walk from the door to the pool. It does not state if that is the fully shielded position or not. It also leads to confusion and misunderstanding. What is the standard walking speed? If the inspector walks faster then we, are we in violation. If a time or exposure can not be specified this should be deleted. To accomplish the intent have each licensee specify a time for their operation. The NRC could then validate that the specified time is satisfactory and then use that as the rule.

36.23.b This requires an additional backup control independent of the primary control. It is agreed that this is required for personnel access doors but should not be required for entrances used solely for product in continuous irradiators using photoelectric barriers. For product entrances on continuous irradiators using photoelectric barriers we recommend that a second independent set of photoelectric cells should meet this requirement.

36.25.a We request this section be changed to eliminate the requirement that such areas be locked and written RSO approval be required. The areas affected by this paragraph should be controlled areas, but not locked. The requirement that areas that may on occasion have dose rates exceeding 2 millirems per hour must be locked, seems excessive. Currently ANSI Standard N43.10 specifies 2.5 mR/h over a one meter square area. The areas affected are usually small controlled areas, but have not been locked. The current system of control has effectively assured minimal exposure to personnel, at our facilities exposure is usually in the range of 0 to 10 mrem/ month. Indeed ALARA is assured and overexposure is not likely to occur at such a low dose rate. Such areas should be controlled, with limited access but the requirement for a locked area with written approval by the RSO each time is overburdensome. 36.25.c allows a does rate of 20 millirems per hour and no locks, why is this more restricted?

36.25.b The requirement that the radiation dose over a pool irradiator when the source is in the fully shielded position must not exceed 2 mR/hr should be changed. Such an area should be controlled but not prohibited. 36.23.c requires a radiation monitor to lock the door if high radiation is detected. The current ANSI standard for a controlled, but not locked area, is sufficient. If the concern is that the dose rate will be excessive if there is a loss of pool water there may be a more direct way of control. The pool low level water alarm, if activated could automatically lock the door. This could be set so that any exposure rate of 100 mR/ hr or greater would automatically lock the entrance gate and not allow normal entrance.

36.29.a The requirement for an alarm to detect loose radiation sources that automatically stop product conveyors is a good rule. However it should not be required for systems that do not have carriers that automatically enter or exit the cell. This should be changed to exclude batch systems.

36.31.d Please clarify this requirement. Is the requirement met if the labels appear on the CRT screen of a computerized system?

36.31.e Please clarify this requirement. Is the requirement met if the colors appear on the CRT screen of a computerized system?

36.33.b Irradiator pools may be so designed in pairs with a connecting channel near the bottom between the pools. This provides a safe means of transferring radioactive material from one pool to another.

36.51.d The definition of "annually" is very clear and requires exact timing. Safety reviews and emergency drills are important and should be conducted at least once a year. However the exact timing and requirements of "annually" are too restrictive. Please change "annually" to "once a year".

36.51.e The definition of "annually" is very clear and requires exact timing. Operator evaluations are important and should be conducted at least once a year. However the exact timing and requirements of "annually" are too restrictive. Please change "annually" to "once a year".

36.59.d Please clarify the requirement that "No product may be shipped until the contamination check has been done." Does that mean the check on the specific product or the entire check? The words "...on the product." added to the end of the sentence would clarify the requirement.

36.63.a We suggest this paragraph be changed to read as follows: "(a) Pool water purification systems are to be run as required to maintain the conductivity of the pool water below 10 microsiemens per centimeter. (b)Pool water must be tested at least daily for radioactive contamination. This may be accomplished by running the water purification system, if detection is done by an inline meter, or by daily water samples from the pool. (c) The conductivity meter must be calibrated at least annually."

36.83.a.2 This section could be interpreted to mean that product overdosing must be reported to the NRC. If the intention of this paragraph is to require the reporting of overexposure to people, then please have it state so.

We thank you for your consideration of these items and would appreciate being keep advised of the progress of this proposed regulation.

Sincerely,

Paul O. Shapiro

Paul O. Shapiro
VP Regulatory Affairs

SEDA COUNCIL OF GOVERNMENTS

DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 & 170 (55 FR 50008)

DOCKETED USNRC

SEDA - COUNCIL OF GOVERNMENTS

'91 MAR -4 P2:35

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OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

(10)

March 1, 1991

Secretary of the Commission
Nuclear Regulatory Commission
Washington, DC 20555

ATTN: Docketing and Service Branch

REF: PROPOSED RULES (FR55 No. 333): LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LARGE IRRADIATORS

This letter is a request to extend the comment period on the proposed rule for 60 days, in order to permit a wider dissemination of the proposed rule to potential interested parties: solid waste authorities and municipal authorities operating sewage treatment facilities, and municipalities with land use control programs.

Please note that medical waste and sewage sludges are regulated by state and federal solid waste legislation and rules. Irradiation may not be a permissible waste management practice under current rules.

It is incorrect to assume that most areas have zoning, land use, and building code requirements that would be applicable to large irradiators. The NRC should, itself, set out in these proposed rules minimum siting requirements for these facilities (beyond the assumption that they are like any other industrial neighbor).

For facilities proposed in those municipalities with land use controls, the NRC should condition any license upon the applicant obtaining necessary permits. It is simply not sufficient to state that the NRC is not responsible for checking or assuring that the requirements have been met.

Sincerely,

Thomas P. Bresenhan

Thomas P. Bresenhan
Director, Energy Programs

TPB/mw

Acknowledged by card 3/7/91

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

The Boeing Company
P.O. Box 3707
Seattle, WA 98124-2207

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DOCKETED
MAR 01 1991
DOCKETING & SERVICE BRANCH
SECY-NRC

February 25, 1991
4-1210-91R-0126

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, D.C. 20555

Subject: Comments on Proposed Rule 10 CFR 36

BOEING

Reference: (a) NRC Notice in Federal Register, 55 FR 50008, December 4, 1990

We have reviewed the proposed new part 36 to Title 10, Code of Federal Regulations, "Licenses and Radiation Safety Requirements for Large Irradiators", and wish to submit the following comments for your consideration.

In most cases, the proposed regulations are appropriate to ensure operational safety at facilities that operate large panoramic irradiators. However, the requirements of Section 36.65, "Attendance during operation", subsection (b) can be unnecessarily stringent and costly in some cases. In situations where irradiation may require several days to accomplish, it should be permissible to lock up the facility after setting up the radiation conditions in the irradiation room and leave the facility unattended. The required engineered safety features and fail-safe source exposure mechanism should be sufficient to ensure that unauthorized entry into the irradiation room is not possible without causing the radiation source to retract into a safe position.

A wording change to Section 36.65, subsection (b) can be made that would permit unattended static irradiation and still not endanger life or property. We suggest that the requirement for the on site presence of a person who has received operator training and testing be removed. Specifically, delete the words, "the operator training and testing described in 36.51(a) and (b) and" from 36.65(b). The revised section should then read as follows:

> (b) At a panoramic irradiator at which static irradiations (no movement of the product) are being performed, a person who has received the training on how to respond to alarms described in 36.51(g) must be on site.

Acknowledged by card 3/7/91

The Boeing Company has operated a panoramic irradiator for over 25 years without incident. Typically, long-term irradiations are done with the facility unattended as there is nothing for the operator to do at the facility during the irradiation. Access to the facility is controlled and the facility is located in an area that is fenced, guarded, and patrolled 24 hours a day. The presence of a person would not add to the safety or security of the facility.

BOEING

In light of the increased commercial use of radioactive materials for irradiation purposes, often by and in industries that traditionally have not been associated with radiation, the regulations in the proposed 10 CFR 36 are both timely and necessary. In some cases, however, general requirements which may be reasonable and prudent when applied to facilities that operate at high batch process rates, such as commercial sterilization plants, would not be practical for facilities which have much lower process rates, such as research facilities. We hope that NRC will take this into consideration in the course of developing its final rules for part 36.

Sincerely,

WE Morgan

William E. Morgan, Manager
Radiation Health Protection
Orgn 4-1210 M/S: 6Y-38
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WEM/PAC:ms

DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

(8)

DOCKETED USNRC

'91 FEB 27 P3:30

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, IL 62704
(217) 785-9900

THOMAS W. ORTCIGER
DIRECTOR

JIM EDGAR
GOVERNOR

February 21, 1991

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

Attention: Docketing and Service Branch

Re: Proposed Rule, "Licenses and Radiation Safety Requirements for Large Irradiators"; 10 CFR 36; 55 Federal Register 50008-50032 (December 4, 1990).

Dear Sir:

The Illinois Department of Nuclear Safety (IDNS) hereby submits its comments on the above-identified proposed rule. The rule would specify safety requirements for large panoramic irradiators and certain underwater irradiators, but specifically excludes self-contained irradiators.

The Department fully supports the concept of the proposed rule. The megacurie activities commonly used in large irradiator operations and the associated potential for safety related problems mandate strict attention to radiation safety matters. Illinois currently licenses three large pool-type irradiator facilities which are authorized to possess a total of 8,000,000 curies of cobalt-60. As your proposal describes, more irradiator facilities are anticipated due to the continued problems with ethylene oxide, the U.S. Food and Drug Administration's authorization for irradiation of fresh fruits, vegetables, and pork, and most importantly the increased demand for sterilized disposable medical commodities as a result of the AIDS crisis. Many new facilities are under construction in other parts of the nation, so the need for uniform regulations based on detailed evaluation of the safety at these facilities is long overdue. Therefore, the Department encourages the further development of these regulations.

The Department commented on the draft proposed rule on October 31, 1988. We were pleased to see that most of our comments were addressed in the proposed rule; however, we feel that further improvements are warranted. The Department continues to support the promulgation of this new rule; however, we believe that the current draft should be revised in several significant respects. The needed improvements are described below.

recyclable

Acknowledged by card 3/7/91

(1) The proposed rule addresses authorization for use of cesium-137 in pool-type irradiator facilities. As we stated in our October 31, 1988, comments, IDNS does not and will not authorize the use of soluble cesium-137 in pool-type irradiator facilities. The Texas Bureau of Radiation Control, which regulates more irradiator facilities than any other state, also refuses to authorize cesium-137 in pool-type irradiator facilities. In light of the June 1988, problems at the Radiation Sterilizers, Inc. facility in Decatur, Georgia, and the continued uncertainty of the integrity of the WESF capsules, we strongly recommend that the NRC not continue to authorize the use of soluble cesium-137 in pool-type facilities.

(2) The discussion on page 50010 references NUREG-1392 entitled <u>Leakage of an Irradiator Source-The June 1988 Georgia RSI Incident</u> describes lessons learned from the Decatur, Georgia, incident. The discussion states "One lesson learned was a need for detailed emergency plans." However, the proposed rule would allow for the submission by the applicant of an outline or a summary of the operating and emergency procedures. IDNS disagrees with the NRC in this regard. Detailed emergency procedures must be submitted and thoroughly evaluated to ensure that all emergency actions to be taken will be proper and effective. In addition, section 36.53(c) would authorize the licensee to revise operating and emergency procedures without Commission approval if the revisions would not reduce the safety of the facility. The licensee, without any regulatory review, would be allowed to determine whether or not the revision would reduce safety. If the change did, in fact, have a deleterious effect on the safety of the facility, it probably would not be noted until the next inspection or until a problem surfaced as a result of the change.

(3) The proposed rule would allow for unduly flexible training requirements for irradiator operators and the radiation safety officer. IDNS recommends a minimum amount of training, at least 40 hours, in the subjects identified in section 36.51 and a minimum amount of on-the-job training, at least one month, to be specified in the proposed regulations. Section 36.51 describes the subjects to be covered during the training, but does not require any description of the trainer qualifications. While the RSO is usually expected to perform this function, this has not always been the case. The quality of training is degraded when the RSO trains someone who subsequently trains another individual that, in turn, provides training to others. Therefore IDNS recommends that the rule include specific qualification requirements for the trainers.

Section 36.51(g) states that individuals who must be prepared to respond to alarms required by numerous sections of the proposed rule must be trained and tested on how to respond. The proposed rule goes on to say that "each individual shall be retested at least once a year. Tests may be oral." This section needs more detail as it is currently unenforcable as written. No training or testing standards are included and oral tests are difficult to document.

(4) Section 36.2 defines "Annually" by stating "means once each calendar year and at intervals not to exceed <u>one year</u>." IDNS recommends changing this definition to "means once each calendar year and at intervals not to exceed 12 consecutive months."

(5) Section 36.25(a) states that "the radiation dose rate in areas that are accessible during operation of a panoramic irradiator must not exceed 2 millirems (0.00002 sievert) per hour at 30 centimeters <u>or more</u> (emphasis added) from the wall of the room when the sources are exposed." IDNS recommends changing the above to read "... at 30 centimeters <u>and at greater distances</u> from the wall .." This would require the operators to ensure that skyshine radiation exposure levels will not exceed the 2 millirem limit.

In general, IDNS agrees with the proposed rule and supports the NRC's effort in this important endeavor. As indicated from our comments, we will adopt more stringent requirements in Illinois when we promulgate similar regulations. This is consistent with your statements regarding agreement state compatibility on page 50023 of the proposed rule. If you have any questions regarding these comments, do not hesitate to call Joe Klinger, Head of the Licensing Section, at (217) 785-9947.

Sincerely,

Thomas W. Ortciger
Director

TWO:sjk

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170 (55FR 50008)

7

DOCKETED
USNRC

STATE OF COLORADO

COLORADO DEPARTMENT OF HEALTH

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'91 FEB 25 P3:52

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Roy Romer
Governor

Thomas M. Vernon, M.D.
Executive Director

February 20, 1991

Secretary of the Nuclear Regulatory Commission
ATTN: Docketing and Service Branch
Washington, DC 20555

RE: Comments on Proposed Rules Regarding Licenses and Radiation Safety Requirements for Large Irradiators (55FR 50008 December 4, 1990)

This office concurs with the need for new part 36. Following are specific comments with regards to the proposed rules.

1. Siting, Zoning, Land Use and Building Code Requirements

   While the NRC decided not to address the above issues, an important factor is how far an irradiator facility is from residential areas, schools, child care facilities, and other general public occupied areas. While the risk to the general public is normally small with irradiators, the public perception may be otherwise. The siting of such a facility immediately adjacent to general public occupied areas should be discouraged.

2. Use of Cesium Sources

   The use of cesium sources should be prohibited until such time that the integrity of cesium capsules construction and testing can be verified through means independent of source manufacturer.

3. Seismic Detection and Resistance

   A persuasive argument was not presented as to the lack of need for seismic detection and resistance. Due to the unique characteristics of large irradiators and the ANSI criteria, this issue requires further evaluation and study.

4. Decommissioning

   If leakage were to occur, it could be expected that radioactivity should and would be concentrated on the water system ion exchange columns. Consequently, the ion exchange column resins characteristics should be known for the source radioactive materials. Also, consideration should be made of the problems presented in regeneration or removal of contaminated ion exchange resins or columns.

Acknowledged by card 3/7/91

A separate issue is the assurance that there is a disposal option available for irradiator sources. Because of the limited number of vendors for such sources, it would appear more efficient for the financial assurance for source disposal to be by the vendor rather than the licensee and the assurance to be universal to all licensees with that vendors sources. This does not preclude the need for financial assurance by licensees for site decommissioning.

5. Noxious Gas Controls

It is unclear as to what is expected of Agreement States with respect to ozone and other noxious gases. This should be clarified as the MOU referenced is between the NRC and OSHA.

6. Subpart C - Design and Performance Requirements for Large Irradiators & Subpart E - Records and Reports

It is not clear as to whether "as-built" plans are required or maintained and whether these are compared with the original "license" plans. This may be addressed in the planned Regulatory Guide. In addition, requirements for construction phase or pre-operational inspections are not addressed. These may be addressed in the NRC Inspection Manual. Both of these documents, e.g. the Guide and the Manual, should be available to Agreement States when the new Rules become final.

7. Subpart C - Design and Performance Requirements for Large Irradiators & Subpart E - Records and Reports

It is unclear as to whether interim storage of sources is permitted in the irradiator pool or adjacent storage pools during construction of a facility and whether storage pool must meet the same criteria as irradiator pools.

Robert M. Quillin, Director
Radiation Control Division

RMQ/msm

DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170 (55 FR 50008)

ENVIRONMENTAL COALITION ON NUCLEAR POWER

Headquarters: 433 Orlando Avenue, State College, Pa. 16803

6

DOCKETED USNRC

'91 FEB 25 P3:11

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

February 20, 1991

Comments on
55 FR 50008

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

Dear Sir or Madame:

The appended comments on "LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LARGE IRRADIATORS," (55 FR 50008) are submitted on behalf of the Environmental Coalition on Nuclear Power. This organization joins with Food and Water, Inc., in asking that the following requests be granted by the Commission.

1. A sixty-day extension of time for the filing of public comments on this important draft rule. Events associated with the timing of its issuance, including a plethora of major nuclear safety issues (e.g., Part 20 affirmation, Onsite LLRW Storage, LLRW Title, etc., BRC issues, DOE's PEIS for weapons facility clean-up, DOE MRS siting, etc.) and the important diversionary effect of the war in the Middle East for all Americans, have made it difficult for interested persons to learn of, obtain, review, and compose comments on this extremely significant issue.

In recent conversations with numerous people throughout the country concerning the issues listed above, I find that virtually no one in the public-interest community was even aware of these draft regulations and certainly not aware of their widespread commercial applications and implications. It should not have to fall to a few private individuals and unfunded citizens' organizations to notify the entire nation of this NRC action.

Moreover, I have just learned that not even our State regulatory agency's Director of Nuclear Safety has examined these draft regulations and had not been aware of the breadth of their potential application. He indicated that his office will need time to look at the Proposed Rule. His response to my query raised another significant reason for NRC's granting our request for an extension of comment period -- a reason that applies to our, and other, financially distressed State governments: our Department of Environmental Resources has just lost vital experienced Staff in a slashing personnel reduction that results from deep budget cuts. The workloads of those remaining have been significantly increased. So, as Pennsylvania taxpayers, we urgently ask NRC to extend the comment time. Just as State regulators at the NRC's Workshop objected to feeling pressured to issue irradiator licenses without proper review, so here multiple pressures on those who are in responsible positions may impede their ability to respond within the time allowed.

In addition, although the NRC Staff promptly provided the Draft Rule and the two NUREGs in response to my request for all major documents relating to this Rule, NRC Staff failed to provide the Environmental Assessment and FONSI cited near the end of the proposed rule. Those have been specifically requested but not yet received and will also require time to review and comment.

Acknowledged by card 3/7/91

We would echo James Setzer's observations at the February 12th NRC Workshop: this industry will face substantial public interest in siting and licensing of these facilties, and the regulations must assure that their concerns will be met. Therefore, the NRC will want to assure fully adequate opportunity for public comment at this stage of development of the Rule.

2. Retraction of the proposed rule by the Commission, a moratorium on the issuance of additional commercial irradiator licenses, and rapid phaseout of existing irradiators. We urge these actions in part because the Commission has failed, in its December 13, 1990, affirmation of the revised Title 10 CFR Part 20 regulations, to take into account the enormously significant new information which has become available during the thirteen years since the ICRP's 1977 recommendations on which the Part 20 standards are based and the new findings, since publication of the 1986 Part 20 Draft, on radiation effects, including RERF's reevaluation of Hiroshima data, BEIR V Report, and the work of Kneale and Stewart, Gardner, et al., and others. These newly realized aspects of adverse radiation effects on workers and the public must be taken into account and assessed in a full Programmatic Environmental Impact Statement (see below).

The impact of this Rule upon the quantity and activities of low-level wastes for which the States are required to be responsible could prove to be enormous, if large numbers of large irradiators are licensed for irradiation of food, sludge, medical waste, and garbage, as the NRC appears to be planning to permit. The Draft Rule does not address the disposition of damaged, degraded, spent, or otherwise used, source materials or of wastes that may be generated in consequence of accidents or facility decontamination and decommissioning. As the State of Georgia has discovered in the aftermath of the 1988 RSI accident, the costs to taxpayers (State or Federal) may be very substantial.

The active warfare in the Middle East includes reported bombing of nuclear facilities. This is a new era of nuclear facility destruction, by bombing, terrorism, and sabotage. It makes the addition of more such facilities all the more dangerous and inadvisable; it makes the prompt closure of existing facilities, in the absence of maximal safeguards which the NRC does not provide in this Rule, imperative to protect the safety of the public and environment.

If the Commission should refuse our request for withdrawal of this Part 36 Rule and instead determine to proceed with its promulgation, we strongly urge:

3. Publication of a full Programmatic Environmental Impact Statement -- not merely an Environmental Assessment and FONSI -- prior to any further consideration of these regulations. It is clear that an entire new large-scale irradiation industry for food, sludge, medical wastes, garbage -- and what all else? -- will be allowed and encouraged by these regulations.

4. An absolute prohibition of cesium-137 use as a source material for commercial irradiation. Assurances by DOE and this industry (with their unsavory safety and compliance record throughout their histories) that a mere change of encapsulation will prevent future leakage and accidents are not acceptable. There will be strong public opposition to the use of cesium for irradiation purposes; even the DOE and facility developers have bent to public objections to the use of cesium-137 capsules for DOE demonstration food irradiators.

5. The proposed Part 36 Rule appears to contain no siting criteria for irradiation plants. Whereas we in the States have been wrestling with the development of restrictive criteria for the location of low-level radioactive waste facilities that will receive a few tens of thousands of curies, the facilities that will be sited, licensed, and regulated by this Rule are proposed to contain some 10 to 12 million curies of source material. And one of the allowable sources, according to Staff's comments at the Workshop, will continue to be water-soluble cesium-137.

The vulnerability of urban areas to sabotage of these facilities (e.g., co-location of food irradiators with wholesale food distributors; sewage treatment plants in virtually every town) makes it imperative that the Commission promulgate detailed siting criteria for large irradiators -- and a level of safeguards that far exceeds anything now required under existing regulation or the Draft Rule. We would remind the Commission that residual cesium-137 contamination resulting from the Chernobyl accident is reported to be a major cause for evacuations of affected populations now at distances of two hundred miles from the Chernobyl IV reactor.

In this same vein, we underscore James Setzer's insistence that there must be far greater attention to emergency response and environmental impacts.

6. The Rule should specify NRC inspection and enforcement provisions and state the penalties for violations, including license revocation.

7. NRC must require long-term retention of all records, but especially those pertaining to accidents, equipment and personnel malfunctions, exposures, and disposition of source material; three years is not enough. Lifetime of the operation, through decommissioning for unrestricted use and final termination of license, should be required. Without records, responsibility is lost.

Additional general and detailed comments follow. The Environmental Coalition on Nuclear Power concurs with the comments of Food and Water, Inc.; the ECNP comments are very similar but not identical.

Sincerely submitted,

Judith H. Johnsrud

Judith H. Johnsrud, Ph.D.
Director, ECNP

COMMENTS ON NRC PROPOSED RULE (55 FR 50008, DECEMBER 4, 1990)
"LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LARGE IRRADIATORS" AND
PETITION FOR WITHDRAWAL OF RULE AND PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT

Prepared by Judith H. Johnsrud, Ph.D.
Research Director, Food and Water, Inc., and
Director, Environmental Coalition on Nuclear Power
February 12-13, 1991

The following comments are submitted by the Environmental Coalition on Nuclear Power in conjuction with the comments of Food and Water, Inc.

Introduction and Background:

In its Proposed Rule, 55 FR 50008, NRC proposes a new 10 CFR Part 36 to establish radiation safety and licensing requirements for large panoramic and certain underwater irradiators* that irradiate products by use of gamma radiation to "change their characteristics in some [unspecified] way." The new Part 36 Rule will not apply to self-contained dry source storage irradiator devices, instrument calibrators, teletherapy and other medical uses of sealed sources, or industrial radiography and other nondestructive testing. NRC suggests uses for this technology that include food irradiation, sewage sludge irradiation for use as fertilizer, expanded medical equipment and biomedical waste irradiation, and sterilization by irradiation of airplane and ship toilet wastes arriving from abroad. By implication, the Commission anticipates many other commercial uses of the irradiation process, as well. The consequences for public health and safety and environmental quality are, therefore, substantial.

Food and Water, Inc., incorporates with these comments (1) a request, in the cover letter, for a sixty-day extension of the public comment period on 55 FR 50008 and (2) three Petitions for Commission actions stated at page 4 below.

Summary Comments and Recommendations on (I) Large Irradiators, (II) Need for a Rule, and (III) Review of Operating Experience:

National and international experts agree that there is no "safe" threshold of exposure to ionizing radiation; all exposure, including that from naturally-occurring sources of background radiation, carries a risk of somatic or genetic injury, illness, and premature death. Numerous research findings show that adverse health effects from radiation exposures occur well within the NRC's current permissible limits. Reassessment of Hiroshima data during the previous decade showed that the cancer risk per unit of dose received is three- to fourteen-fold greater than had previously been believed (see, for example, Radiation Effects Research Foundation studies; BEIR V).

Federal and other regulatory agencies fail, at present, to assess total cumulative adverse effects of exposures of an individual to multiple sources of

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* Defined by NRC as "those large enough to deliver a dose exceeding 500 rads (5 grays) in one hour at a distance of one meter."

ionizing radiation, or potential synergistic effects of exposures to radiation plus other environmental pollutants. It is evident that any additional sources of exposure can only add to the burdens of risk, injury, and potential deprivation of life for persons who have no independent means of identifying their exposures or of assessing the risks to their personal health and safety.

It follows from these facts that it is not in the public interest; is unwise; and is an arbitrary and capricious action for the Nuclear Regulatory Commission to approve these proposed regulations that will permit or encourage establishment of additional irradiation facilities and whole new industries that will add new sources of exposure and risk from either routine permissible emissions or accident-related releases of radioactivity into the biosystem. The total impact of such multiple sources must be evaluated, in conjunction with all other sources of environmental, or other, exposures to radiation.

At the conclusion of this Federal Register Notice is a Section X, "Finding of No Significant Environmental Impact: Availability." The Environmental Assessment (EA) and FONSI referenced there were not included among the documents sent to us in response to a telephoned request for all documents pertaining to this draft rule. (Our thanks for the documents that were promptly sent.) An EA is not sufficient to address the scope of this regulatory impact. In the absence of a complete Programmatic Environmental Impact Statement, and a Comprehensive Health Impact Statement, it is improper and unacceptable for the NRC to issue these regulations that will allow and promote the construction and operation of many additional large irradiators. Given the record of such facilities as have been licensed by NRC and Agreement States and operated abroad thus far, it is clearly inadvisable for the NRC to proceed with plans for expansion of this industry as a whole. The overall environmental effects of a large scale large irradiator industry, which comprises a whole grossly expanded program, must be completely evaluated before the final regulation can be promulgated.

Moreover, the bases for approval of food irradiation (the most probable initial major use for large-scale irradiators) by the Food and Drug Administration, in 21 CFR 179.26, are highly questionable and have been challenged in the medical and public health community. In addition, the FDA, in its approvals of irradiation of foodstuffs, did not consider the environmental impacts of widespread use of this technology and potential accidents or their consequences.

The Commission, in describing food irradiation, implies, at 50009, that use of irradiation can "reduce the use of pesticides." Since irradiation is a post-harvest technique that can accomplish its disinfestation intent only if the food is prepackaged in a manner that prevents reinfestation, there is on reduction of pesticide use during food production and this statement is misleading. Similarly, extension of shelf-life by microorganism destruction is valid only if the food is not re-exposed to microorganisms post-irradiation. There is no substantiation of the claim that irradiation of sludge will kill pathogenic organisms or is needed to kill pathogens but will have no effect on heavy metals or toxic chemicals.

We find especially troubling and unacceptable NRC's statement that ensuring a high standard of radiation safety in the design and use of irradiators "should be accomplished in a way that does not unnecessarily restrict the logical use and growth of their applications." Under the Energy Reorganization Act of 1974, the NRC is charged with regulation, not promotion. Therefore, no considerations of economics or encouragement of the use of large irradiators should enter into the Commission's criteria and standards. Clearly, numerous provisions of the proposed regulations are designed so as not to inhibit the expansion of a large-scale large irradiator industry. In accordance with Section 2 (a) of that statute, the Congressional goals require this agency to protect and enhance environmental quality and to assure public health and safety. The Congressional priorities, in Section 2 (e), include "reduction of pollutants." Nuclear technology promotion is left to the Department of Energy.

The sweeping FDA approval of irradiation for fresh fruits and vegetables took place one month prior to the Chernobyl accident, which demonstrated unequivocally the real-world hazard of long-term residual radioactive contamination of vast areas of residential and agricultural lands from precisely the radioactive isotope -- cesium-137 -- that the Department of Energy has promoted for demonstration food irradiators and that NRC proposes to allow for large irradiators. Neither NRC nor FDA has given serious consideration to the costs to society of evacuation and long-term interdiction of contaminated land in the vicinity of an irradiator that is projected to contain ten times or more the amount of cesium-137 as was reportedly released in the Chernobyl accident.

The existing commercial irradiation industry is replete with occupational deaths, injuries, and overexposures, and some serious "unanticipated events," as are detailed at 55 FR 50011-13. Although the Commission may view these events as evidence of the need for more stringent regulation (and indeed they are for currently licensed facilities), they may also be interpreted as evidence that the commercial irradiator operators and industry as a whole have not proven themselves to be responsible enough to be permitted to continue to endanger populations and land by their activities.

The Commission's approach to evaluation of safety for irradiators fails to meet the necessary assurances of safety and environmental protection. It is noteworthy that significant accidents (RSI) and fatalities have occurred in facilities in operation both in and outside the United States, indicating that either irradiator designs are inadequate, or worker training and responsibility are inadequate, or operational supervision and management are inadequate, or governmental (foreign or domestic) regulation is also inadequate, or that there may be underlying flaws in the entire functional capability of commercial irradiation technology that transcend regulatory controls, posing unacceptable hazards for the public as well as workers. The kinds of events described in NUREG-1345 and 1392 lend credence to all of these possible failings.

Human factors engineering and operator training both have severe limitations in the absence of unfailing exercise of individual responsibility, both by workers and their supervisors and by top management and the regulators. The NRC appears, at 55 FR 50012 and in NUREG-1345, to minimize the importance of events that are claimed to have had only "potential safety significance" rather than "actual" impacts on health and safety of the public and of workers.

"Failure, malfunction, or degradation" of system performance indicate major failures of design, construction, operations, maintenance, management, and regulation. Access control, source movement mechanism (movement and suspension), source encapsulation, and pool or water cleanup systems are all cited as systems that failed; all have serious impacts on the safety of workers and the public and must be strictly regulated..

Licensee management deficiencies are inexcusable and should be punished by the regulator with heavy monetary fines, immediate and permanent revocation of license, and prohibition of those responsible for major infractions from future participation in this industry. The self-regulation practiced by NRC in the past is no longer societally permissible. It has been abused by both the regulated industry and the regulators.

Pending curtailments of Federal and State budgets and reductions of State regulatory personnel, as are currently being experienced in the Commonwealth of Pennsylvania and elsewhere, will lessen even more the inspection capabilities of the regulatory agencies. They, in turn, should exercise even more draconian measures for violations that might have been ignored or minimally penalized in the past.

We suggest that natural phenomena that may be beyond the control of human beings or of an unanticipated severity may constitute the limiting factor on the design and operation of any large irradiators. The full potential range of damages from such events as earthquakes, floods, and tornadoes must be accounted for in facility design and operational restrictions and emergency responses.

The conditions of war that now prevail in the Persian Gulf, including the probable intentional bombing by U.S. forces of sensitive chemical, biological, or nuclear facilities and reported Iraqi attacks on Israeli nuclear installations, and concerns about acts of domestic terrorism require a profound rethinking of the commitment in our country to yet more facilities vulnerable to sabotage that could cause widespread radiological contamination. See 56 FR 3228, January 29, 1991, Petition for Rulemaking "to revise...regulations to upgrade the design basis threat for radiological sabotage of nuclear reactors" A large irradiator that contains more than 1,000,000 curies of total activity -- in some instances more than 10,000,000 curies and possibly in the form of a soluble cesium -- and is less strictly safeguarded than a power reactor, is obviously also an attractive target for radiological sabotage.

<u>Petitions</u>:

(1) <u>The Environmental Coalition on Nuclear Power (ECNP) and Food and Water, Inc., for these reasons and others discussed below, respectfully request and here formally petition the NRC to withdraw this Proposed Rule and to disallow the licensing and operation of new large irradiators altogether, in the interests of protecting the health and safety of the public and the quality of the environment and lessening the threat of contamination resultant from terrorist action or sabotage.</u>

In the absence of a Programmatic Environmental Impact Statement for a large-scale large irradiator industry that this proposed rule will facilitate and promote, by adoption of this proposed new Part 36 the NRC would be acting in an arbitrary and capricious manner and with unlawful disregard for the health and safety of the public and of the environment, under the National Environmental Policy Act of 1969 (NEPA) and the Energy Reorganization Act of 1974 and other statutes.

(2) In the event that the NRC refuses the above petition and proceeds with this rule, the Commission must first publish a Programmatic Environmental Impact Statement on the full extent of the new irradiation industry that this rule will foster, and Food and Water, Inc., and ECNP here formally petition the Commission to do so, in accordance with the provisions of NEPA.

We note that a related precedent lies in the January 1990 decision of the Secretary of Energy to prepare a PEIS for DOE's Environmental Restoration and Waste Management Program for DOE weapons production facilities. Here, the Commission's action will facilitate major growth of new and expanded uses of irradiation technology, with impacts potentially related (in addition to NEPA) to the recently enacted Clean Air Act of 1990, the Atomic Energy Act of 1954, the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 Amendments, and the Resource Conservation and Recovery Act (RCRA) of 1976 and other surface and ground water protection laws.

(3) In the event that NRC determines to proceed with approval of this proposed rule, ECNP and Food and Water, Inc., also petition the Commission to prohibit entirely the use of cesium-137 as source material for any irradiators for which a license has been or will be issued by the NRC or Agreement States. The past accident record with cesium-137 and its solubility must disqualify this substance from use in commercial irradiation facilities. Assurances by the irradiation industry proponents and Department of Energy that satisfactory encapsulation can be devised must be disregarded by NRC.

The record clearly shows that cesium-137 has a vast potential for environmental contamination of long-lasting significance; this source material is soluble; DOE's promised improved encapsulation has not been proven and in any case cannot be relied upon to guarantee against leakage and other accidents. NRC should ban its use outright, so that there will be no repetition of the RSI sequence of events, in which a facility that was licensed for the use of one source material (cobalt-60) found it advantageous to use cesium-137 instead, resulting in an accident whose clean-up cost is currently officially estimated at $36,000,000, to be paid for by the taxpayers of the entire United States.

Additional Comments on (III) Operating Experience and (IV) Radiation Protection Philosophy:

We are troubled by NRC's treatment of source encapsulation failures and breaches of pool or water cleanup system integrity, at 55 FR 50012, as merely internal operating problems. In addition to potential dangers to workers, these and other operational failures create potential hazards for members of the public. A sufficient record exists of operational failures that resulted in offsite releases to substantiate this danger. And many of them appeared to be related to carelessness or lack of concern for strict adherence to procedures. These kinds of failures cannot be ignored or downgraded by the NRC; they typify the unpredictable and uncontrollable nature of human behavior.

Although these operational problems are mentioned in passing at 55 FR 50012-13, the NRC pays little attention to the detrimental exposure possibilities from contaminated products that may be distributed widely to the public. NRC seems to assume that, because "no contamination was found on products that had been distributed to the public" in RSI's 1988 accident, no future accidents are going to result in undetected distributions of contaminated products to the public. This is an especially important point with respect to foodstuffs. Rapid distribution of perishable foods takes place from producers to wholesalers to retailers to consumers who then may promptly consume the product.

Substantial uncertainties have been raised about the sensitivity capabilities of in-plant monitoring equipment that is supposedly designed to assure detection of contaminated products as they emerge from the highly areas of California. In the case of the tornado strike, it should be noted that the irradiation source material (cobalt-60) was indeed reportedly not adversely affected, but local news reports indicated substantial damage to the structure in which it was housed. Serious enough, these natural phenomena, to warrant NRC's close attention to design protections.

As for Inspection History, it must be remembered that NRC's present system of self-policing and self-reporting by its licensees leaves open to question the validity of the inspection records here cited. A far more rigorous monitoring and inspection and enforcement system by the regulator is essential.

The statement is made in IV Radiation Protection Philosophy that "the most important radiation protection objective at a large irradiator is preventing anyone from entering the irradiation room while the source is exposed." Preventing that sort of overexposure, or any sort of high exposure, of a worker should go without mention. The <u>most</u> important objective is preventing <u>any</u> radiation exposures to workers or the public <u>or</u> releases to the environment.

The Commission states that the second most important radiation protection objective is avoiding "excessive radiation exposure...." While we laud the recognition that sealed sources can, and do, leak, we object to the NRC's use of references to "excessive" and "over-" exposures. In light of no threshold of risk of injury, the standard must be to avoid exposures entirely, not just the excessive ones. The monitoring must be required in a manner that mandates prompt detection of <u>any</u> leak, not just "any leak of significant size." Where do the regulations codify "significance" and "excessive"? The use of these terms is tantamount to permitting a licensee to operate at the upper boundary of all regulations, and to do so is ultimately a failure of regulation.

Continuous active monitoring, not merely periodic monitoring, should be required for all irradiators. Having "procedures for dealing with accidents" is not the same as having fully developed emergency plans and procedures that have been demonstrated by both principal participants (emergency personnel) and active public participation in drills and periodic testing. The latter should be required. As this section now stands, the proposed regulations do not offer adequate assurance of a "very low likelihood that anyone inside or outside the facility would be exposed to radiation in excess of" NRC's Part 20 limits.

Supplement to Comments Submitted by Food and Water, Inc., and ECNP

VIII Other Considerations:

A. Siting, Zoning, Land Use, and Building Code Requirements:

The single most glaring deficiency of these regulations is the apparent total lack of siting criteria for irradiators that may be allowed to contain a water-soluble source material (cesium-137) in amounts of ten million curies or more. Reliance on the goodness of design and construction and management and on local building codes and industrial land use zoning is unconscionable in the extreme and clearly constitutes a capricious and arbitrary action and intent and irresponsibility on the part of the Commission.

As is pointed out elsewhere, the amount of cesium-137 that NRC proposes to permit as source material per irradiator is vastly in excess of the amount of cesium-137 reported to have been released in the course of the Chernobyl accident. The consequences of that catastrophic accident, resulting from human errors, in terms of health, interdiction of agricultural lands, and population evacuations are now said to extend to distances some two hundred miles from the reactor. Even in a lesser event than catastrophic explosion, a natural disaster, fire, sabotage, or other unanticipated situation can cause loss of pool or chamber integrity and release source material, especially cesium, to the environment with severe consequences. The NRC cannot dismiss such possibilities as "low probability events."

Especially because the proposed uses for large irradiators ("treatment" of food, sludge, medical waste, airplane and ship wastes, and garbage) are likely to require location in or very near a densely populated area it is imperative that the Commission promulgate detailed siting criteria that are fully as restrictive as those required in Parts 50 and 100. The use of Part 20 air and water concentrations for releases do not suffice. For example (but not all-inclusive), exclusionary seismic, geologic, hydrogeologic, surface water, drainage, slope, meteorological, public lands and other protected land uses, floodplains, wetlands, rare and endangered species, population, and monitorability criteria must be devised by NRC and met by a license applicant.

B. Use of Cesium Sources:

As is discussed elsewhere in these comments, the continued permission of the NRC for the use of water-soluble cesium-137 for irradiation activities at large irradiators is a serious dereliction of duty to assure protection of public health and safety and environmental quality. The RSI accident has been initially in part blamed on the type of encapsulation, the WESF capsules supplied by the DOE, that was not intended for a wet-dry facility and had been improperly prepared and tested by an enthusiastic proponent of the use of cesium for these purposes.

It is especially troubling for two reasons that NRC now proposes <u>not</u> to exclude use of cesium, apparently in the hope that DOE can develop better encapsulation. This is true because the DOE is attempting to put in place demonstration of the feasibility of recycling very large quantities of cesium to be derived from spent fuel back into the economy for the purpose of irradiating food, sludge, medical and other wastes and garbage; subsequent to such use, they may be declared to be LLRW for which the States are responsible. We didn't agree to this pass-through of the radioactive bulk of DOE's HLW. The second reason is that cesium-137, in the event of an accident that releases even a relatively small amount of the millions of curies projected per irradiator, was, and is, a major factor in the residual contamination in the USSR far distant from the Chernobyl reactor. An accident, from fire, earthquake, sabotage, etc., could have a comparably devastating effect.

C. Seismic Detection and Resistance:

ECNP and Food and Water believe that an automatic seismic detector to activate return of sources to a fully shielded position certainly should be required, especially so if this requirement exists in ANSI Category IV Standards and is general practice. NRC proposes to permit use of the cesium source known to cause a severe accident. Any safety system that could add a measure of protection for source material under seismic stress conditions should definitely be advocated and required by the NRC. Applicants must not be permitted to argue that installation of such a device is economically unwarranted. It's NRC's business to provide regulation that affords the public protection, not to adjust safety to the profit motive of those it regulates. Especially in the event that the wall shielding is damaged in a seismic event, it would be important in perhaps reducing the severity of the consequences or gaining time for correction of the problem or averting source damage in the aftermath of an earthquake for such a detector to have been operable.

D. Decommissioning:

NRC's decision to ignore decommissioning in these regulations is disheartening, to say the least. Has nothing been learned by NRC from the RSI accident? (1) The assumption that leakage would be detected quickly is wishful thinking, given the length of time before the RSI leakage was presumably found and reported. (2) The costs of the cleanup for RSI exceeded the combined 1987-88 assets and profits of the company -- costs, by the way, that we are forced to pay, rather than the company that had failed to provide constant monitoring adequate to detect leakage in time to avert that accident. (3) All back end committed costs must be accounted for at the front end; there is no mention of the costs associated with disposal of decommissioning wastes, or of the availability and costs of disposal of radioactive and mixed wastes resultant from operations at the end of the useful life of the facility. These must now be included in NRC's regulations prior to issuance of a license.

E. Drop of Source Rack:

Requirements to analyze drop accidents, including source rack and cask drops, and to design irradiators to withstand any conceivable such drops is a positive measure and we support the inclusion in regulations. Industry opposition to this regulation should be taken by NRC to imply a reluctance to comply with the highest standards of safety and hence diminish the chances that a license might issue to that kind of applicant.

F. Aircraft Crashes:

We very strongly urge the NRC to prohibit siting of an irradiator anywhere near an airport. This issue of the crash of an aircraft heavier than the plant containment was designed to withstand arose in the licensing of Three Mile Island and was litigated to the U.S. Court of Appeals, which found (in Kepford v. NRC, c.1979-80) that there was merit to the issue. The Court held final decision in abeyance because the reactor had been put out of commission by the March 28, 1979, accident but ruled that if the reactor were to be repaired and returned to service, the Court would revisit this issue.

Thus, if a reactor containment -- which had been designed with a heavier than normal containment because of its proximity to the flight path of an international airport -- was open to question with respect to ability to withstand the crash of a heavy aircraft, and given the frequency of occurrence of airplane crashes, this should be a disqualifying siting criterion. It is an example of why we are asking for siting criteria to be promulgated in this rule. We note the NRC's stated expectation that irradiators will be used to sterilize wastes from international airplane flights; thus, in the absence of a siting prohibition, there would be a better than even chance that an airport siting would actually be sought by an applicant, in turn raising the overall probability of involvement of an irradiator in this kind of accident.

G. Pool Water Coolers:

We urge NRC to reconsider its decision not to require pool water coolers. No good reason is offered for not requiring a method of reducing corrosion of irradiator operating systems; we do not believe that economic pressures from operators should be a valid reason for dispensing with a method of improving safety of the facility.

H. Noxious Gas Control:

At a time when the world is trying to reduce surface production of ozone, it is not appropriate for NRC to be encouraging a new ozone-producing nuclear utilization industry. This issue speaks, too, to the need for a Programmatic EIS. Noxious gas generation should be dealt with under both the OSHA MOU and under the new Clean Air Act.

I. Issuance of a Regulatory Guide:

If the NRC determines to reject our petition to withdraw these draft regulations and proceed to a final rule (a qualification that accompanies each of these comments throughout this endless response), we would support development of a Reg Guide and its approval by NRC prior to issuance of any license under this Part 36. We recommend that no issue of safety significance be relegated from regulation to a guidance status.

IX. Agreement State Compatibility:

The States must be able to set standards and regulatory requirements that are more restrictive than those of the NRC. This is particularly important in view of the NRC's revision of Part 20 which for some isotopes and situations actually increases permissible radiation exposures. For all purposes of assuring protection of public and worker health and safety and environmental protection, the States must be able to transcend the minimum standards and regulations of Federal agencies in the direction and interests of providing maximum protection. They should not be allowed to exercise less restrictive regulation.

X. Finding of No Significant Environmental Impact: Availability:

It is inconceivable that the development of a large-scale industry of large irradiators containing as much as 10-12 million curies of cobalt-60 or cesium-137 will have no significant environmental impacts. These sources of potential contamination of extensive areas, under the proposed regulations, could be located in the heart of great metropolitan areas. In the event of unexpected accident or act of terrorism, very large populations could be exposed to more cesium contamination than was experienced in the 1986 Chernobyl accident, now reportedly causing evacuations and interdiction of agricultural land to a distance of some 200 miles from the reactor. A full PEIS is merited and requested.

Moreover, we have had no opportunity to examine the Environmental Assessment despite having requested that all documents pertaining to this draft rule be provided to us. We repeat here our request for the EA and FONSI and our intent to supplement these comments upon its receipt and ask that the Commission give consideration to those comments, which will be submitted as promptly as is possible following receipt of the documents.

XI. Paperwork Reduction Act Statement:

We cannot resist noting for the record that the burden of 750 hours per response upon the Staff is what they are paid to do. For those in the public-interest realm, the burden of comparable hours to research and provide comments to the Commission may not be compensated at all. Where many of the recommendations contained herein are what the NRC should have included in the rule in the first place, we taxpayers are both doing the Staff's job for free and having to pay for the privilege.

XII. Regulatory Analysis:

How can a member of the public be able to exercise his or her right and ability to provide full comment on a draft rule if the information provided upon request is incomplete? Here, too, we request the Staff to provide the draft regulatory analysis to us (it should have accompanied the documents sent in response to our earlier, timely request) and sufficient time to review it and provide comments.

XIII. Regulatory Flexibility Certification:

The NRC must not utilize this mechanism, in response to the five questions posed in this section, to exempt any licensee or applicant from the regulatory provision of this Part 36 Rule (or any other regulations).

In Section I Large Irradiators, we note two inaccurate, or misleading, statements in the description of food irradiation. The statement that "Any fresh food may be irradiated...." is not strictly correct. Whole fresh and processed or prepared foods, excluding certain meats and dairy products, may be exposed to radiation. Although use of irradiation is touted to reduce pesticides and fumigants, it should be qualified to clarify that only post-harvest pesticide use could be reduced, not pesticides used in crop or meat production, and that the irradiation process could be effective only if a food were not subsequently exposed to harmful microorganisms or insects and other pests.

Comments on (VII) Summary of the Proposed Requirements and Rationale for Their Inclusion (pp. 50014-21) and on the Proposed Amendments Comprising Proposed Part 36 (pp. 50024-32):

Subpart A General Provisions:

Section 36.1 Purpose and Scope: Some commenters may object to the definition of "large irradiator" and seek a lesser degree of licensing and regulatory control. All irradiation facilities (if there are to be any, a proposition which is throughout these comments disputed to be necessary) must meet the most rigorous and comprehensive regulations. Complaint that a given facility is not able to comply and would be forced to close or that an institution can't afford to construct and operate an irradiator that meets requirements should be rejected. If the most stringent regulations cannot be met, then a facility obviously should not be operated. NRC must not yield to requests for exemption.

There is no upper curie limit of the source specified. What dose (and/or dose rate) occurs at one meter for a ten million curie source? Does the NRC expect to license even larger irradiators? If it permits any, the NRC should disallow irradiators with very large curie sources.

NRC should indicate the regulatory status of irradiators of types that are not covered in this Rule and what regulatory requirements do apply to them. If those irradiators are not regulated or if regulations for them are in development, the Commission should so state.

Section 36.2 Definitions:

Large irradiator should not be defined, as suggested by one commenter, in terms of 500 rads per minute at one meter. In our opinion, an irradiator would qualify as large if it delivered at one meter a dose exceeding the old Part 20 maximum permissible occupational dose of 3 rem per quarter in an hour. NRC should retain the definition in conformance with Part 20 requirements. However, we would caution that under the new Part 20, higher air and water concentration limits and new dose calculational methodology may apparently result in a higher radiation exposure per rem received. Permissible limits should be adjusted downward to account for the new measurement methodology.

Seismic area definition should also be described in terms commonly used to describe intensity of seismicity. What justification is offered for the definition given here? A disqualifying distance criterion should be added to limit siting to locations at some substantial distance (i.e., ten miles) from a known active fault, a capable fault, and epicenter of known or reported seismicity. See, for comparison and inspiration for this criterion and others suggested above in the third paragraph on siting criteria, Pennsylvania LLRW Rules and Regulations, Pa. Bulletin, vol. 19, number 43, Part II, October 28, 1989.

Definitions of persons, other than *Irradiator operator* and *Radiation safety officer*, who have reason to be in the irradiation chamber or elsewhere in the facility should be added to clarify all who may be authorized to enter.

Additional definitions for siting criteria should be included. Other terms in the proposed rule that may require definition will be identified under the appropriate subpart.

Subpart B Specific Licensing Requirements:

Section 36.13 Specific licenses for large irradiators: Since there may be instances in which the Commission may consider it prudent to deny a license (as, for example, to an irradiation company executive who has been convicted of and imprisoned for violations of NRC regulations), the first sentence might better begin "The Commission [will] may approve...." But keep the mandatory term "shall" in (a) and (b).

Throughout this section, the Commission must make clear what standards and requirements it is imposing, rather than leaving these to the applicant to develop and define. Otherwise, there will be no uniformity of regulations and hence an impossible burden on NRC's inspection and enforcement staff.

Subsection (b) should require submission of an applicant's full training course or curriculum, or that of an outside training firm it utilizes. At (b) (5), NRC should specify what minimum and ideal qualifications it will accept for personnel who provide training, rather than leaving it to the discretion of the applicant, who has an inherent conflict of interest in such matters.

Subsection 36.13 (c) must require submission of detailed and complete emergency response plans and procedures. If NRC fails to require all licensees to do so, then the Commission learned no lessons at all from the RSI accident. Too often, emergency plans are allowed to be ignored until very late in the process (sometimes until they are suddenly and desperately needed, by which time it's too late to develop them); they must be specific, complete, and verifiable. NRC should require submission of affidavits or other proofs that all emergency personnel and support institutions (hospitals, fire departments, police, receiving centers, etc.) are contracted and will be available. It will be most effective to require both a submission of outline for emergency response procedures and very detailed descriptions of specific plans.

At (c) the regulations should specify its requirements for changes of emergency plans and procedures, including minor ones. It is not the role of the NRC to meet applicants at some middle ground; the Commission must set rules that are as tough as need be to assure that it (the NRC) has complied with its charge in Section 2. (a) of the Energy Reorganization Act of 1974, 42 U.S.C. 5801 to protect public health and safety.

Also at (c), procedures and changes of procedures should be submitted for NRC approval for this purpose (emergency response) and all other purposes, not only in the event that safety is lessened by the procedure or change in it. With this industry, NRC need not fear that it runs a risk of over-regulating.

Since Regulatory Guides are exactly that, only guidelines, the Staff should not permit applicants to rely on Regulatory Guides with respect to matters relating to safety, health or environmental protection. Nor should the Commission allow any waiving of fees associated with license amendments. Those are necessary to enable the Staff to do its regulatory job properly and must be considered by a licensee as part of the cost of doing business.

Subsection (d) should be revised to conform with the comments for Subsection (b) above. The Commission should set the training and experience requirements for RSO personnel that would serve as a uniform minimum to which all licensees must conform, although nothing would prevent them from setting and meeting even higher standards.

Subsection (f) should specify NRC's procedures for leak testing, with which an applicant must comply. The regulator must tell the regulated what the regulations are.

Subsection (g) raises the question: if licensee personnel are <u>not</u> loading and unloading sources, who does? Why not licensee personnel? Who is liable? What are the NRC's qualifications for a source loading contractor so that a licensee will know what she/he must demand in a contract for this purpose? Requirements for frequency of operational maintenance and inspection checks should be prescribed by the Commission, not let to the discretion of a licensee. Adequate flexibility can then be permitted for an operator that wishes to check even more rigorously.

Section 36.15 Start of construction: The NRC should have reviewed completed plans for a facility prior to issuance of a construction permit. No early construction should be allowed, including all activities listed, with the exceptions of engineering and design work, purchase of a site, site surveys and soil, seismic, and hydrogeologic testing. All other earthmoving and construction activities should wait until a construction permit has been approved.

The regulator must not be subject to arguments or pressure from an applicant concerning sunk costs. Rush to decision should be actively discouraged and overtly opposed by the regulator. If an applicant is unwilling to invest time and money in assurances of safety, then no license should issue.

At the conclusion of construction, a second review and approval procedure should be completed by the Commission prior to issuance of an operating license. Both construction and operational permits must be subject to public adjudicative hearing proceedings conducted under the provisions of the Administrative Procedures Act of 1946 and must be conducted by Administrative Law personnel who are entirely independent of the Commission, with full judicial review of decisions.

Agreement States must not be preempted by the NRC in setting standards and regulations for large irradiators that are more, but not less, restrictive than these of the Commission.

Section 36.17 Applications for exemptions: This section should be deleted. The obligation of the NRC is to regulate in the interests foremost of protecting health -- not just "life" and property, as it is put here -- and if a regulation is in force, all applicants and licensees must be held to the common standard of full compliance with all regulatory requirements; no exemptions, no exceptions.

Section 36.19 Request for written statements: This section should be retained but should not be worded so as to be limited to application only to license modification, suspension, or revocation. The Commission should have full authority to require any written statements from licensees that NRC believes are needed for its regulatory purposes.

Subpart C Design and Performance Requirements for Large Irradiators:

Section 36.21 Design and performance criteria for sealed sources: In Subsection (a), all sealed sources, no matter when first installed, should be required to meet the current standards. Grandfathering is not appropriate when safety is involved. Random leak testing of sources in actual use under working and high stress conditions should be required, not merely of prototypes.

Moreover, all sources, not just sealed sources, should be subjected to leak testing. At Subsection (b), we would support double encapsulation -- although not as a substitute for other safety precautions -- and certification of registration. The adequacy of the specified measures should be clarified by additions of comparisons with the maximum potential conditions to which the sources may be subjected in practice. Testing criteria should be specified in the regulations.

The QA/QC requirements should be spelled out and strictly enforced, with clear forewarning to applicants and operators. NRC should in no way relax the requirements and criteria in this section, and should make very clear that the applicant and licensee will be held fully liable with respect to these and all other aspects of the licensed activity.

This section does not indicate that sealed sources must be solid in form, rather than liquid. Soluble cesium-137 has had its opportunity and has failed as a safe, reliable source material. The NRC should specify that cesium is not acceptable as a source. Assurances that encapsulation "can be" devised that will not leak are not acceptable. Use of cesium-137 as an irradiator source material should be unequivocally denied. NRC should not yield to pressure from the industry, for whom it might be a cheaper source (especially if subsidized by DOE), or from Agreement States for whatever reason.

Section 36.23 Access control: At Subsection (a), we urge retention of the provision requiring a physical barrier for personnel, despite arguments by licensees favoring use of only photoelectric eyes or other non-barrier devices. The "walking time" criterion is open to question and interpretation. Some people walk faster than others; it is not clear that it will be definable or enforceable. Barriers at the product exit end of the process must also be required to ensure no undetected or improper entry. Provisions should be stated for maintenance and repairs. Interlock systems have been seriously abused by management in the past; the NRC must assure defense in depth and certainty of interlock functioning.

Subsection (b) calls for independent backup, a provision we support. Visible and audible alarms should probably be separate and independent systems. At what point in the room will this (these) alarm(s) function? We would support the requirement for a second person onsite, located in or near the chamber and fully trained to respond to emergencies. The NRC should not allow licensees to use unattended automatic systems.

In Subsection (d), the NRC should specify a temporal limit for exiting; the wording "enough time to leave the room" is imprecise and open to interpretation. Licensees should not be allowed over-reliance on electronic and other powered warning systems. Redundancy is important to maintain safety.

In Subsection (j), intrusion alarms for underwater irradiators are justified to protect the facility from an intruder as well as protecting the intruder from the facility. They should be required.

Section 36.25 Shielding: This section should contain a requirement for NRC approval of shield design; no short cuts for safety measures should be allowed. NRC should not allow a buffer zone or blocked off or signed restricted area to substitute for a physical shield.

Daily and routine written entry permissions should be required, even if management finds them to be an annoyance. Small irradiators should not be exempted from these or other regulatory requirements.

We concur with the observation of William McLaughlin that terms (dose, dose rate) and units (rads, grays, rems, sieverts) should be correctly used and matched.

Section 36.27 Fire protection: This section seems very general, rather vague. Specificity is needed. Hopeful expectations instead of factual evidence seem to motivate the Staff's failure to require automatic fire extinguishing systems. This seems foolish. Both automatic and manual systems and controls should be maintained. An unanticipated event causing fire is one of the reasons for requiring irradiators to maintain a two-person staff at all times.

Section 36.29 Radiation monitors: NRC should retain and expand monitoring requirements in a Final Rule. We urge deletion of the "either-or" for online monitor and pool water analysis; defense in depth should apply to monitoring as well as other safeguards. Err in favor of redundancy. Require both. Detection systems should be designed to pick up both radioactive material and radioactive sources. This section should be expanded to require full product monitoring in a manner that is not overwhelmed by the differential in anticipated readings in and out of chamber. Product monitoring is absolutely essential; it cannot be limited to only small samplings to total throughput.

Section 36.31 Control of source movement: Control console should be "user friendly" equipped and "human factors engineered" to assist the operator in the event of an abnormality, stuck source, or other operational emergency.

Section 36.33 Irradiator pools: All facilities should be backfitted to meet the pool requirements here specified. No grandfathers. In Subsection (a), clarify safe storage requirements for sources during pool repairs. At Subsections (c and d), a means must also be provided for preventing, detecting, and alarming pool flooding and overflow.

Section 36.35 Power failures. There is no provision for required emergency backup power source. NRC should require redundant power source and independent capability for all monitoring equipment and interlocks.

Section 36.39 Design requirements: Already licensed irradiators should be included in these requirements and, if they are to continue to operate, they should be backfitted to conform with all new regulations. Dependence on local building codes to provide adequate margins of safety is insufficient. NRC must develop and rigorously apply siting criteria and design criteria that take into consideration the range of environmental factors listed above with respect to siting criteria.

At *Subsection (e) Radiation monitors*, in addition to sources being carried on the conveyor belt, the regulation should apply to any radioactive material, including radioactively contaminated product. A 100 mrem dose potential is far too high. The goal of monitoring is to detect immediately any source of radiation and any potential or actual conditions that might result in loss of pool water or loss of shielding or other accident condition that could pose a hazard to worker or public health.

For pool irradiators, the monitoring of the water purification system should not depend on the supposition of "the spot at which the highest radiation levels would be expected." It is in the nature of accidental happenings that the highest, worst, etc., is where one does not expect it to be. Random sampling should accompany sampling of the expected.

Pool wall heat removal requirements should be specified. Cask drop could breach pool integrity as well as sealed source integrity. It should be included.

At Subsection (j), irradiators should not be built in seismic areas. A substantially higher order of protection should be required than those in ordinary building codes for non-harmful contents. At any site, effects of loss of power, pool and shield cracking, source rack deformation, failure of source retraction and conveyor systems, and other earthquake damage should be carefully evaluated and mitigating measures must be required and demonstrated in the application prior to issuance of a license.

Nowhere in this section are there any requirements for design measures to protect from environmental contamination. These must be added. Nowhere is there a statement of the degrees of conservatism that the Commission should be specifying in design requirements.

Section 36.41 Construction control: The term "verify" used in this section should be explained. What evidence, data, records are required for verifications? The Commission should specify. The actual requirements are vague throughout this section and must be clarified. All systems should be subject to continuous monitoring from the start of construction through the life of the facility and decommissioning. Decommissioning should be addressed in conjunction with initial construction to ease end of facility life activities.

Subpart D Operation of Large Irradiators:

Section 36.51 Training: Complete training curriculum, testing, and experience requirements should be included in this section. In Subsection (a), the individual must be instructed <u>and demonstrate superior competence</u> in.... The trainee's knowledge and abilities should go beyond the one company's design and operations to show a broad, in-depth understanding of the technology and of the adverse health effects of exposures to radiation. RSO personnel should receive full training and demonstrate superior capabilities.

In Subsections (f and g), tests should be both written and oral and include practical demonstrations of competence.

Section 36.53 Operating and emergency procedures: The lists do not indicate any requirements for divergent thinking in terms of unimagined or unanticipated events or how to respond to the unexpected. In Subsection (c), the NRC should delete the words "without Commission approval." It should be the Commission, not the licensee, who decides if revisions reduce safety, are consistent with the license and license application. A substantial showing must be required of a licensee in each of these instances and public hearing or input must be assured, as is true for all aspects of these regulations.

All emergency personnel must be fully versed in emergency procedures, decontamination activities, and the management of radiation injuries. Agreements with all emergency personnel, agencies, and institutions must be executed in advance of license issuance.

Emergency procedures must be submitted in full detail for detection, removal and isolation of leaking sources and for facility and offsite decontamination. Somewhere in these regulations, the NRC must require an applicant to address storage and disposal of intentionally and accidentally generated radioactive wastes. Arrangements, contractual and other, for servicing, removal, and return of radiation source material to the supplier should be specified by the applicant. NRC should be informed of any service limitations or escape clauses or liability limits in any applicant subcontracting, with a statement of alternatives.

Section 36.55 Personnel monitoring: There should be provisions in the regulation for reporting film badge, TLD, or pocket dosimeter readings to all employees and visitors. All visitors should be badged or otherwise monitored.

Section 36.57 Radiation surveys: Environmental radiation surveys in the vicinity of a facility should be conducted throughout a minimum of three years prior to commencement of facility operations and continuously thereafter.

Section 36.59 Detection of leaking sources: See 36.53 comments above. Each facility should be equipped to detect leaking sources and leakage from the pool or chamber. Sealed sources should be tested for contamination immediately (no more than one week) before being sent to a licensee and more frequently than six month intervals thereafter. Pool irradiator water should be checked daily.

Section 36.61 Operational inspection and maintenance: This section is a masterpiece of directed self-regulation. The NRC must enforce rigorous and frequent unannounced inspections. Each operator must be fully subject to all requests, results, and actions imposed by NRC inspectors. Subsection (b) is vague. What's "undue delay" and who defines it?

Section 36.63 Pool water purity: The purification system should be run daily, depending on maintenance and repair activities.

Section 36.65 Attendance during operation: We strongly support the presence of more than one trained and competent person to be onsite at the irradiator at all times.

Section 36.67 Entering and leaving the radiation room: These provisions should be retained in the Final Rule, if any is to be promulgated.

Section 36.69 Irradiation of explosive or highly flammable materials: Strike the words "unless the licensee has received prior written authorization from the Commission." The prohibition on irradiation of explosive or highly flammable material should be complete and these regulations should make that clear.

Subpart E Records and Reports:

Section 36.81 Records and retention periods: All records pertaining to the testing results, operations, accidents, personnel exposures, equipment malfunctions, legal responsibilities and potential liabilities of the licensee must be retained, in printed hard copy form, for the duration of plant life and through the completion of decommissioning. All such records should be required to be made available.

Section 36.83 Reports: All thefts, losses, overexposures, excessive concentrations and levels of radiation and all accidents and malfunctions should be required to be reported to NRC or Agreement State immediately upon occurrence and in no case longer than 24 hours after the event, not five days.

Subpart F Enforcement:

Section 36.91 Violations: Provisions specifying penalties, monetary and loss of license should be included. Licensees whose violations pose a potential threat to public health and safety or possible contamination of the environment should lose their permits to operate an irradiator. The adverse consequences of allowing one who does not strictly obey all safety-related regulations to remain in business far outweigh any alleged benefits. Society cannot afford to tolerate a sloppy irradiator. Adoption of a rigid regulatory stance will only add to the NRC's reputation in a way that benefits the public NRC is supposed to serve.

# # #

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

February 21, 1991

MEMORANDUM FOR: Samuel J. Chilk, Secretary

FROM: Vandy L. Miller, Assistant Director for State Agreements Program
State Programs, GPA

SUBJECT: NORTH DAKOTA'S COMMENTS ON PROPOSED 10 CFR PART 36 RULE CONCERNING IRRADIATORS

Attached in response to the Federal Register notice requesting public comments on the proposed rule concerning irradiators are comments from the State of North Dakota.

Attachment:
As stated

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

NORTH DAKOTA
STATE DEPARTMENT OF HEALTH
AND CONSOLIDATED LABORATORIES

State Capitol
600 E. Boulevard Avenue
Bismarck, North Dakota 58505-0200

DOCKETED
USNRC

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OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

(5)

Environmental
Enforcement
701-224-3234

ENVIRONMENTAL HEALTH SECTION

1200 Missouri Avenue
P.O. Box 5520
Bismarck, North Dakota 58502-5520
Fax #701-258-0052

February 1, 1991

Mr. Vandy Miller
Director, State Agreements Program
State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Miller:

Referenced is your All Agreement State letter dated December 21, 1990 (SP-90-213) and All Agreement State letter dated January 17, 1991 (SP-91-06) regarding a proposed new rule on 10 CFR Part 36 concerning irradiators.

After reviewing the proposed new rule, it appears that the rule is well formulated and includes significant safety upgrades and upgraded leak test requirements to ensure proper evaluation of potential contamination by irradiator sources. Criteria for radiation surveys and personnel monitoring as well as attendance during operation of irradiators appears to adequately address radiation safety issues that have plagued the irradiator operations in the past.

In North Dakota, the only type of irradiator sources presently used include a blood irradiation facility and dosimeter facility which manufactures government contract dosimeters for the Department of Defense.

One concern that needs to be evaluated by the Nuclear Regulatory Commission and Agreement States is the current approval by FDA of irradiator facilities for poultry to control salmonella contamination. This may impact on many Agreement States and the NRC Licensing States for new irradiator licenses. Approval of the more stringent standards for leak testing and contamination evaluations will greatly improve current irradiator standards for irradiator facilities that are used for raw or package food products.

Acknowledged by card 3/7/91

Due to budget constraints, the State of North Dakota will not be able to fund attendance by a staff member at the Rockville, Maryland public meeting to be held on February 12-13, 1991 concerning the new 10 CFR Part 36 Rule. We appreciate the opportunity to comment on this important rule proposal.

Sincerely,

Dana K. Mount

Dana K. Mount, P.E.
Director, Division of
Environmental Engineering

DKM/TDL:dgg

DOCKET NUMBER PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

FOOD and WATER, INC.

3 Whitman Drive • Denville, NJ 07834 • (718) 783-2146 / (201) 625-3111

DOCKETED USNRC

(4)

February 10, 1991

'91 FEB 21 P4:14

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

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

In the Matter of
55 FR 50008

Dear Secretary:

Enclosed please find comments of Food and Water, Inc., on "Licenses and Radiation Safety Requirements for Large Irradiators," 55 FR 50008. Food and Water, Inc., is a non-profit public-interest consumer organization, concerned with food irradiation and other aspects of the healthfulness and safety of the food and water we consume, and of the environment in which we all live.

We ask that our comments and petitions be included in the Commission's record for this proposed rule. It is our understanding that the NRC will consider and respond to all comments filed on or before March 4, 1991. We look forward to your favorable responses to and adoption of our recommendations.

In view of the unusual importance of this action creating a new Part 36 to Title 10, CFR, and establishing the regulatory framework for entire new large-scale irradiator industries for food and sewage sludge treatments and for other purposes, <u>Food and Water, Inc., requests an extension of this public comment period for an additional sixty days</u> beyond the March 4th deadline.

We believe this extension is warranted due to, <u>inter alia</u>, (1) publication of the FR notice at the start of the holiday season when university and other libraries were closing for the seasonal vacation and people were engaged in year-end activities and travel; (2) consequent difficulty and delay in informing the many interested individuals and organizations of availability of this lengthy notice; (3) NRC's delay in sending the FR notice until well into the holiday season; (4) the Staff's failure to make available its Environmental Assessment and Finding of No Significant Impact to commenters who had requested all relevant documents pertaining to this proposed rule; (5) the almost total national focus of attention on the Middle East war since publication of this notice; and (6) the extraordinary importance of this proposed rule which may result in a vast expansion into every state of the commercial irradiator industry and the spread of commercial recycling of very large quantities of radioactive cesium and cobalt. There has been virtually no media reporting of this proposed rule to draw public attention to its significance.

No harm or undue delay would result from comment period extension. The events that spurred the NRC decision to develop these regulations had occurred at existing irradiators, as described in NUREG-1345 and NUREG-1392, in or prior to 1989; the Staff has taken more than a year to develop this draft. It is now essential for the public interest for the Commission to provide sufficient time to receive the broadest possible range of comments and recommendations for so major a new nuclear industrial program as is proposed here. We therefore strongly urge the NRC to extend the public comment period on 55 FR 50008.

Sincerely yours,

Walter Burnstein by JAH

WB/iah

Walter Burnstein, M.D., President

Acknowledged by card 3/7/91

COMMENTS ON NRC PROPOSED RULE (55 FR 50008, DECEMBER 4, 1990)
"LICENSES AND RADIATION SAFETY REQUIREMENTS FOR LARGE IRRADIATORS" AND
PETITION FOR WITHDRAWAL OF RULE AND PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT

Prepared by Judith H. Johnsrud, Ph.D.
Research Director, Food and Water, Inc., and
February 12-13, 1991

Introduction and Background:

In its Proposed Rule, 55 FR 50008, NRC proposes a new 10 CFR Part 36 to establish radiation safety and licensing requirements for large panoramic and certain underwater irradiators* that irradiate products by use of gamma radiation to "change their characteristics in some [unspecified] way." The new Part 36 Rule will not apply to self-contained dry source storage irradiator devices, instrument calibrators, teletherapy and other medical uses of sealed sources, or industrial radiography and other nondestructive testing. NRC suggests uses for this technology that include food irradiation, sewage sludge irradiation for use as fertilizer, expanded medical equipment and biomedical waste irradiation, and sterilization by irradiation of airplane and ship toilet wastes arriving from abroad. By implication, the Commission anticipates many other commercial uses of the irradiation process, as well. The consequences for public health and safety and environmental quality are, therefore, substantial.

Food and Water, Inc., incorporates with these comments (1) a request, in the cover letter, for a sixty-day extension of the public comment period on 55 FR 50008 and (2) three Petitions for Commission actions stated at page 4 below.

Summary Comments and Recommendations on (I) Large Irradiators, (II) Need for a Rule, and (III) Review of Operating Experience:

National and international experts agree that there is no "safe" threshold of exposure to ionizing radiation: all exposure, including that from naturally-occurring sources of background radiation, carries a risk of somatic or genetic injury, illness, and premature death. Numerous research findings show that adverse health effects from radiation exposures occur well within the NRC's current permissible limits. Reassessment of Hiroshima data during the previous decade showed that the cancer risk per unit of dose received is three- to fourteen-fold greater than had previously been believed (see, for example, Radiation Effects Research Foundation studies; BEIR V).

Federal and other regulatory agencies fail, at present, to assess total cumulative adverse effects of exposures of an individual to multiple sources of ionizing radiation, or potential synergistic effects of exposures to radiation

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* Defined by NRC as "those large enough to deliver a dose exceeding 500 rads (5 grays) in one hour at a distance of one meter."

plus other environmental pollutants. It is evident that any additional sources of exposure can only add to the burdens of risk, injury, and potential deprivation of life for persons who have no independent means of identifying their exposures or of assessing the risks to their personal health and safety.

It follows from these facts that it is not in the public interest; is unwise; and is an arbitrary and capricious action for the Nuclear Regulatory Commission to approve these proposed regulations that will permit or encourage establishment of additional irradiation facilities and whole new industries that will add new sources of exposure and risk from either routine permissible emissions or accident-related releases of radioactivity into the biosystem. The total impact of such multiple sources must be evaluated, in conjunction with all other sources of environmental, or other, exposures to radiation.

At the conclusion of this Federal Register Notice is a Section X, Finding of No Significant Environmental Impact: Availability. The Environmental Assessment and FONSI referenced there were not included among the documents sent to us in response to a telephoned request for all documents pertaining to this proposed rule. An Environmental Assessment is not sufficient to address the scope of this regulatory impact. In the absence of a complete Programmatic Environmental Impact Statement, and a Comprehensive Health Impact Statement, it is improper and unacceptable for the NRC to issue these regulations that will allow and promote the construction and operation of many additional large irradiators. Given the record of such facilities as have been licensed by NRC and Agreement States and operated abroad thus far, it is clearly inadvisable for the NRC to proceed with plans for expansion of this industry as a whole. The overall environmental effects of a large scale large irradiator industry, which comprises a whole grossly expanded program, must be completely evaluated before the final regulation can be promulgated.

Moreover, the bases for approval of food irradiation (the most probable initial major use for large-scale irradiators) by the Food and Drug Administration, in 21 CFR 179.26, are highly questionable and have been challenged in the medical and public health community. In addition, the FDA, in its approvals of irradiation of foodstuffs, did not consider the environmental impacts of widespread use of this technology and potential accidents or their consequences.

The Commission, in describing food irradiation, implies, at 50009, that use of irradiation can "reduce the use of pesticides." Since irradiation is a post-harvest technique that can accomplish its disinfestation intent only if the food is prepackaged in a manner that prevents reinfestation, there is on reduction of pesticide use during food production and this statement is misleading. Similarly, extension of shelf-life by microorganism destruction is valid only if the food is not re-exposed to microorganisms post-irradiation. There is no substantiation of the claim that irradiation of sludge will kill pathogenic organisms but have no effect on heavy metals or toxic chemicals.

We find especially troubling and unacceptable NRC's statement that ensuring a high standard of radiation safety in the design and use of irradiators "should be accomplished in a way that does not unnecessarily restrict the logical use and growth of their applications." Under the Energy Reorganization

Act of 1974, the NRC is charged with regulation, not promotion. Therefore, no considerations of economics or encouragement of the use of large irradiators should enter into the Commission's criteria and standards. In accordance with Section 2 (a) of that statute, the Congressional goals require this agency to protect and enhance environmental quality and to assure public health and safety, and its priorities, in Section 2 (e) include "reduction of pollutants. Nuclear technology promotion is left to the Department of Energy.

The sweeping FDA approval of irradiation for fresh fruits and vegetables took place one month prior to the Chernobyl accident, which demonstrated unequivocally the real-world hazard of long-term residual radioactive contamination of vast areas of residential and agricultural lands from precisely the radioactive isotope -- cesium-137 -- that the Department of Energy has promoted for demonstration food irradiators and that NRC proposes to allow for large irradiators. Neither NRC nor FDA has given serious consideration to the costs to society of evacuation and long-term interdiction of contaminated land in the vicinity of an irradiator that is projected to contain ten times or more the amount of cesium-137 as was reportedly released in the Chernobyl accident.

The existing commercial irradiation industry is replete with occupational deaths, injuries, and overexposures, and some serious "unanticipated events," as are detailed at 55 FR 50011-13. Although the Commission may view these events as evidence of the need for more stringent regulation (and indeed they are for currently licensed facilities), they may also be interpreted as evidence that the commercial irradiator operators and industry as a whole have not proven themselves to be responsible enough to be permitted to continue to endanger populations and land by their activities.

The Commission's approach to evaluation of safety for irradiators fails to meet the necessary assurances of safety and environmental protection. It is noteworthy that significant accidents (RSI) and fatalities have occurred in facilities in operation both in and outside the United States, indicating that either irradiator designs are inadequate, or worker training and responsibility are inadequate, or operational supervision and management are inadequate, or governmental (foreign or domestic) regulation is also inadequate, or that there may be underlying flaws in the entire functional capability of commercial irradiation technology that transcend regulatory controls, posing unacceptable hazards for the public as well as workers. The kinds of events described in NUREG-1345 and 1392 lend credence to more than one of these possible failings.

Human factors engineering and operator training both have severe limitations in the absence of unfailing exercise of individual responsibility, both by workers and their supervisors and by top management and the regulators. The NRC appears, at 55 FR 50012 and in NUREG-1345, to minimize the importance of events that are claimed to have had only "potential safety significance" rather than "actual" impacts on health and safety of the public and of workers. "Failure, malfunction, or degradation" of system performance indicate major failures of design, construction, operations, maintenance, management, and regulation. Access control, source movement mechanism (movement and suspension), source encapsulation, and pool or water cleanup systems are all cited as systems that failed; all have serious impacts on the safety of workers and the public.

Licensee management deficiencies are inexcusable and should be punished by the regulator with heavy monetary fines, immediate and permanent revocation of license, and prohibition from future participation in this industry. The self-regulation practiced by NRC in the past is no longer societally permissible. It has been abused by both the regulated industry and the regulators.

Pending curtailments of Federal and State budgets will lessen even more the inspection capabilities of the regulatory agencies. They, in turn, must exercise more draconian measures for violations that were ignored or minimally penalized in the past. Natural phenomena that may be beyond the control of human beings or of an unanticipated severity may constitute the limiting factor on the design and operation of any large irradiators.

The conditions of war that now prevail in the Persian Gulf, including the probable bombing by U.S. forces of sensitive chemical, biological, or nuclear facilities, and concerns about acts of domestic terrorism require a profound rethinking of the commitment in our country to yet more facilities vulnerable to sabotage that could cause widespread radiological contamination. See 56 FR 3228, January 29, 1991, Petition for Rulemaking "to revise...regulations to upgrade the design basis threat for radiological sabotage of nuclear reactors...." A large irradiator that contains more than 1,000,000 curies of total activity -- in some instances more than 10,000,000 curies and possibly in the form of a soluble cesium -- and is less strictly safeguarded than a power reactor, is obviously also an attractive target for radiological sabotage.

<u>Petitions</u>:

(1) <u>Food and Water, Inc., for these reasons and others discussed below, respectfully requests and formally petitions the NRC to withdraw this Proposed Rule and to disallow the licensing and operation of new large irradiators altogether, in the interests of protecting the health and safety of the public and the quality of the environment.</u>

In the absence of a Programmatic Environmental Impact Statement for a large-scale large irradiator industry that this proposed rule will facilitate and promote, by adoption of this proposed new Part 36, the NRC would be acting in an arbitrary and capricious manner and with unlawful disregard for the health and safety of the public and of the environment, under the National Environmental Policy Act of 1969 (NEPA) and the Energy Reorganization Act of 1974 and other statutes.

(2) In the event that the NRC refuses the above petition and proceeds with this rule, <u>the Commission must first publish a Programmatic Environmental Impact Statement on the full extent of the new irradiation industry that this rule will foster, and Food and Water, Inc., here formally petitions that the Commission do so, in accordance with the provisions of NEPA.</u>

We note that a related precedent lies in the January 1990 decision of the Secretary of Energy to prepare a PEIS for DOE's Environmental Restoration and Waste Management Program for DOE weapons production facilities. Here, the

Commission's action will facilitate major growth of new and expanded uses of irradiation technology, with impacts potentially related (in addition to NEPA) to the recently enacted Clean Air Act of 1990, the Atomic Energy Act of 1954, the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 Amendments, and the Resource Conservation and Recovery Act (RCRA) of 1976 and other surface and ground water protection laws.

(3) In the event that NRC determines to proceed with approval of this proposed rule, <u>Food and Water, Inc., also petitions the Commission to prohibit entirely the use of cesium-137 as source material for any irradiators for which a license has been or will be issued by the NRC or Agreement States.</u> The past accident record with cesium-137 and its solubility disqualify this substance from use in commercial irradiation facilities. Assurances by the irradiation industry proponents and Department of Energy that satisfactory encapsulation can be devised must be disregarded by NRC.

The record clearly shous that cesium-137 has a vast potential for environmental contamination of longlasting significance, and this source material is soluble. NRC should ban its use outright, so that there will be no repetition of the RSI sequence of events, with a facility licensed for the use of one source material (cobalt-60) found it advantageous to use cesium-137 instead, resulting in an accident whose clean-up cost is currently officially estimated at $36,000,000 for the taxpayers of the entire United States.

<u>Additional Comments on (III) Operating Experience and (IV) Radiation Protection Philosophy</u>:

We are troubled by NRC's treatment of source encapsulation failures and breaches of pool or water cleanup system integrity, at 55 FR 50012, as merely internal operating problems. In addition to potential dangers to workers, these and other operational failures create potential hazards for members of the public. A sufficient record exists of operational failures that resulted in offsite releases to substantiate this danger. And many of them appeared to be related to carelessness or lack of concern for strict adherence to procedures. These kinds of failures cannot be ignored or downgraded by the NRC; they typify the unpredictable and uncontrollable nature of human behavior.

Although these operational problems are mentioned in passing at 55 FR 50012-13, the NRC pays little attention to the detrimental exposure possibilities from contaminated products that may be distributed widely to the public. NRC seems to assume that, because "no contamination was found on products that had been distributed to the public" in RSI's 1988 accident, no future accidents are going to result in undetected distributions of contaminated products to the public. This is an especially important point with respect to foodstuffs. Rapid distribution of perishable foods takes place from producers to wholesalers to retailers to consumers who then may promptly consume the product.

Substantial uncertainties have been raised about the sensitivity capabilities of in-plant monitoring equipment that is supposedly designed to assure detection of contaminated products as they emerge from the highly areas of California. In the case of the tornado strike, it should be noted that the irradiation source material (cobalt-60) was indeed reportedly not adversely affected, but local news reports indicated substantial damage to the structure in which it was housed. Serious enough, these natural phenomena, to warrant NRC's close attention to design protections.

As for Inspection History, it must be remembered that NRC's present system of self-policing and self-reporting by its licensees leaves open to question the validity of the inspection records here cited. A far more rigorous monitoring and inspection and enforcement system by the regulator is essential.

The statement is made in IV Radiation Protection Philosophy that "the most important radiation protection objective at a large irradiator is preventing anyone from entering the irradiation room while the source is exposed." Preventing that sort of overexposure, or any sort of high exposure, of a worker should go without mention. The <u>most</u> important objective is preventing <u>any</u> radiation exposures to workers or the public <u>or</u> releases to the environment.

The Commission states that the second most important radiation protection objective is avoiding "excessive radiation exposure...." While we laud the recognition that sealed sources can, and do, leak, we object to the NRC's use of references to "excessive" and "over-" exposures. In light of no threshold of risk of injury, the standard must be to avoid exposures entirely, not just the excessive ones. The monitoring must be required in a manner that mandates prompt detection of <u>any</u> leak, not just "any leak of significant size."

Continuous active monitoring, not merely periodic monitoring, must be required for all irradiators. Having "procedures for dealing with accidents" is not the same as having emergency plans and procedures that have been demonstrated by active public participation in drills and periodic testing. The latter should be required. As this section now stands, the proposed regulations do not offer adequate assurance of a "very low likelihood that anyone inside or outside the facility would be exposed to radiation in excess of" NRC's Part 20 limits.

<u>Comments on (VII) Summary of the Proposed Requirements and Rationale, (VIII) Other Considerations, Part 36 Provisions, and Remainder of the Proposed Rule</u>:

(to be submitted later as a Supplement to these comments)

Georgia Department of Natural Resources

205 Butler Street, S.E., Suite 1252, Atlanta, Georgia 30334
Joe D. Tanner, Commissioner
404/656-3500

DOCKET NUMBER
PROPOSED RULE PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
(55 FR 50008)

DOCKETED
USNRC

'91 FEB 15 P4:12

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

(3)

February 1, 1991

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20472

Attention: Docketing and Services Branch

Dear Sir or Madam:

Please be advised that we have completed a review of the proposed amendments to Part 36 of Title 10 of the Code of Federal Regulations, which addresses "Licenses and Radiation Safety Requirements for Large Irradiators," as noted in the Federal Register of December 4, 1990 (55FR5008). Our specific comments relative to various sections of the proposed rule are attached. Whereas the comments, prepared by our technical staff, pertain to specific sections of the proposed rule, Georgia has also developed two very strong positions based on the lessons learned from the Radiation Sterilizers, Inc. (RSI) incident.

First, the use of soluble cesium-137 chloride as an irradiator source material led to untold complications and expenditures upon a breech of the source container walls. Therefore, Georgia strongly opposes the further use of any soluble or dispersible radioactive material as a radiation source in a pool irradiator.

Second, to date over $30,000,000 has been spent in the recovery effort at Radiation Sterilizers, Inc. in Decatur, Georgia. Although the RSI incident involved cesium-137 sources, other incidents have occurred in the past which involved cobalt-60 and had associated recovery costs of several million dollars. We have noted, with a high degree of interest, that 10CFR 30.35, "Financial assurance and record keeping for decommissioning," would require either the certification of financial assurance in the amount of $75,000 or the development of a decommissioning funding plan. This is highly inadequate and therefore unacceptable, based on past experiences. Georgia strongly urges NRC to require adequate financial assurance for the purpose of both decommissioning and decontamination of irradiator facilities.

Finally, it is apparent that the NRC rule makers have expended a considerable amount of effort in preparing this proposed rule. We recognize that the RSI incident experience has been taken into consideration by NRC in formulating the draft rules. However, there still needs to be more specificity and strength incorporated into the rule. Therefore, after review and analysis of all comments received during the comment period and the incorporation of comments into the

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rule, we recommend that NRC reissue the draft rule for additional comment prior to final adoption. On the basis of the expected future expansion of the commercial irradiator industry, it is imperative that adequate regulation be established.

Thank you for the opportunity to provide these comments and we look forward to working with NRC further on this important national issue.

Sincerely,

Joe D. Tanner
Commissioner

JDT/jss

cc: Governor Zell Miller
James L. Setser

The following comments draw heavily on over twoand one-half years of experience in recovery from the accident at the Radiation Sterilizers, Inc. (RSI) facility in Decatur, Georgia. This incident is discussed in detail in the two major publications listed below :

NUREG-1392, Leakage of an Irradiator Source - the June 1988 Georgia RSI Incident, February 1990, U.S. Nuclear Regulatory Commission, Office of Governmental and Public Affairs and the Georgia Department of Natural Resources.

DOE/ORO-914, Interim Report of the DOE Type B Investigation Group, Cs-137: A Systems Evaluation, Encapsulation to Release at Radiation Sterilizers, Inc., Decatur, Georgia, July 1990, U.S. Department of Energy, Oak Ridge Operations.

These documents are referenced in the following comments as the **NRC Report** and the **DOE Report** respectively.

Section	**Comment**
§36.13	This section includes requirements which the applicant for a license to operate an irradiator must meet. The text associated with this section (55 FR 50014) states that "[t]he applicant's proposed equipment and facilities must be adequate to protect the health of workers and the public and minimize danger to life and property."
Comments:	The source(s) to be used by the applicant will be specified, per §30.32, on Form NRC 313 "Application for Material License" (or equivalent State form in Agreement States). However, neither §30.32, §30.33 or §36.13 appear to require any information directly related to the safety of source(s) in the proposed activity. This section should require detailed information related to the safety of the source, including the testing information specified in §36.21.
	The DOE report pointed out that "[n]o formal risk assessment, safety analysis or environmental impact analysis, which should have pointed out the increased risk associated with the use of WESF capsules, was ever prepared." Among the conclusions related to licensing in the DOE report are the following:
	"All license applications for Category IV irradiators should include a safety analysis and environmental impact analysis as part of a systems analysis."

"The capsule manufacturer (and the capsule supplier, if different from the manufacturer) should be directly involved in the licensing process, particularly with respect to the evaluation of emergency response adequacy and the setting of general and special operating conditions."

"The licensing agency should verify that the recovery equipment and procedures are in place and tested and that all operating procedures are met."

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§36.13(b)

The text related to this section states that "criteria for acceptable training programs for irradiator operators are not contained in the regulations so that flexibility can be allowed". Also, the text states "it was decided not to specify minimum qualifications for a radiation safety officer because there is so much variability in qualifications among people who would be adequate to do the job".

Comments:

We feel strongly that the training for irradiator operators should include no less that 40 hours of classroom instruction and one month of on-the-job training, as specified in our comments on §36.51.

The NRC report states that " ... the upgrading of training requirements for radiation safety officers and facility operators should be a significant focus in any regulatory reform" and that " ... there needs to be a much stronger focus on health physics in the regulatory regime for commercial irradiators." We feel that our comments above, and in §36.13(d) below, address the concerns raised by the NRC in this report.

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§36.13(d)

This section states that "[t]he applicant shall describe the radiation safety responsibilities and authorities of the radiation safety officer and other management personnel."

Comments:

The rule should specify the radiation safety duties and responsibilities of the radiation safety officer, which at a minimum should include activities under §36.51, §36.53, §36.55, §36.57, §36.59, §36.61, §36.63, §36.81 and §36.83. The applicant should be required to demonstrate the qualifications of the radiation safety officer to perform the required duties.

This section should require that the radiation safety officer be independent from both sales and production organizations within the organizational structure. The radiation safety officer shall not perform duties which could detract from the radiation safety function (i.e. sales, production, etc.). The rule should clearly state that the radiation safety officer shall have the authority to cease all operations.

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§36.13(g)

The text related to this section states that "if the applicant intends to load and unload sources, the applicant must show that its personnel are qualified to do so safely and that its procedures are adequate to protect public health and safety".

Comments:

Due to the loading and unloading of sources being an infrequent operation, and the industrial and radiation safety knowledge required to perform this task, we recommend that the rule state that this function will only be performed by "approved" organizations as defined in §36.13(g).

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§36.21(a)

This section specifies that "[t]he test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds."

Comments:

This test, while severe, does not provide assurance that the source will withstand the rigors of repeated thermal cycling as experienced during the operation of Category IV irradiators. The testing for new sources designed for use in Category IV irradiators should include thermal cycling tests, in which the source is repeatedly cycled through temperatures exceeding the range of normal operations. The source should be allowed to reach thermal equilibrium after each temperature change. The number of cycles to be included in the test should exceed the number of cycles expected during the useful life of the source.

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§36.23

The text associated with this section states that operation of panoramic irradiators would require a primary access control system and an independent backup access control system. The door or barrier that serves as the primary access control system must have controls that would:

(1) prevent the source from being moved out of its shielded position if the door or barrier were open; and

(2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

The backup access control system must be able to detect entry while the source is exposed, and if entry is detected;

(1) automatically cause the source to return to its shielded position; and

(2) activate audible and visual alarms.

Comments: It is our recommendation that the primary access control system activate audible and visible alarms in the same manner as the backup access control system when entry is detected with the source in the exposed position. In addition, the rule should explicitly state that the facility shall be designed such that the only possible access to the radiation room shall be through the door or barrier which serves as the primary access control system.

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§36.23(a) This section states that the time for sources to return to the shielded position must be less than or equal to the time that it would take a person entering the radiation room to walk to the edge of the pool (wet-source storage) or into the beam (dry-source storage).

Comments: Recommend that the wording regarding wet-source storage be revised to read as follows:

> The time for the sources to return to the fully shielded position must be less than or equal to the time that it would take a person attempting to enter the radiation room to walk from the door or barrier which serves as the primary access control system, through an unobstructed path to a point where a person could receive a dose of 100 mrem.

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§36.29(a) The proposed requirement in §36.29(a) is to "detect sources that have somehow become loose from the source rack and are being carried out with the product ..."

Comments: There is no requirement for a monitoring system to detect contamination on product exiting the radiation room. Such a monitoring system should be required of all irradiators.

The NRC report states that "[t]he potential for contaminated packages is a serious matter for consideration in the operation of irradiator facilities. Public concerns can only be alleviated through strict accountability for assuring uncontaminated packages. Adequate monitoring systems must be put in place to provide such assurance. There is a precedent, experience and/or rationale for such monitoring that can be found in the kinds of monitoring systems already in place at scrap metal yards, furnaces, some landfills, and other industrial operations." The DOE report, among other requirements for the safe operation of a Category IV irradiator with cesium capsules, identifies the need for "[c]ontamination monitoring of personnel and product exiting the shielded area."

All radiation monitoring systems should be included in this section. All monitoring systems should activate both audible and visible alarms and automatically shut down the irradiator if:

(1) any monitor detects radiation levels exceeding the instrument set-point;

(2) any instrument or detector malfunctions; or

(3) any monitoring instrument is turned off.

It must be physically impossible to move the sources out of the shielded position until the cause of the alarm is both identified and corrected.

The following monitoring systems should be required for the operation of a wet-source storage panoramic irradiator:

(1) Access control, as described in §36.23;

(2) A system for detection of a loose radiation source being carried towards the product exit;

(3) A system that continuously monitors pool water concentrations (see comments on §36.29(b) below) and records the results;

(4) A system that continuously monitors exhaust air on the inlet side of the HEPA filtration system (see comments on §36.29(b) below) and records the results; and

(5) A system which monitors product packages for contamination.

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§36.29(b)

This section requires "a means to detect radioactive contamination in pool water ..." at pool irradiators, and allows the use of either continuous online monitoring or daily discrete samples to satisfy this requirement. Related requirements in §36.59 allow for analysis turnaround times of up to 24 hours for discrete samples. This section also states that if the operator uses an online monitor, that it must alarm upon the detection of "above normal" radiation levels, and that "[a]ctivation of the alarm must automatically cause the water purification system to shut off."

Comments: Daily discrete sampling will not be adequate to prevent widespread contamination from a leaking source at a pool irradiator. Such a sampling program could allow the facility to operate with an undetected leaking source for a period of up to 48 hours. The body of evidence surrounding the RSI incident indicates that a relatively large quantity of Cs-137 (on the order of 10 Curies) was released during a short period, perhaps less than 24 hours. Continuous online monitors must be required for pool irradiators. This monitoring system must be separate from the pool water purification system, as §36.63 does not require continuous operation of the purification system. The alarm on the monitor should not only disable the pool cleanup system, but should shut down the entire system and activate audible and visible alarms, much as a safety alarm (e.g. unauthorized entry) would.

In addition to monitoring of pool water, the rule should require that the exhaust air from the radiation cell at Category IV irradiators be continuously monitored and filtered with a HEPA filter installed and tested in accordance with ANSI/ASME NS10-1980, as any source leakage while sources are out of the pool would be expected to give rise to airborne activity. Replacement HEPA filters must be readily available.

The DOE report, among other requirements for the safe operation of a Category IV irradiator with cesium capsules, identifies the need for "[c]ontinuous radiation monitoring of exhaust air and pool water" and "HEPA filtering of exhaust air." As with water monitoring, the detection of elevated airborne activity should shut down the entire system and activate audible and visible alarms.

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§36.33(a) This section specifies a stainless steel (or other liner metallurgically compatible with other materials in the pool), or a liner that is constructed "so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination."

Comments: These requirements appear to be mutually exclusive, as experiences at RSI-Decatur have shown that stainless-steel surfaces are difficult to decontaminate due to the porous nature of the steel.

The terms "substantial leakage" and "low likelihood" should be defined. In determining what constitutes "substantial leakage", NRC should consider that a leaking source, particularly one which uses a water-soluble radioactive material, could give rise to radioactive materials concentrations in pool water several orders of magnitude greater that the Maximum Permissible Concentration (MPC) values in 10CFR20. The text (55 FR

50017) accompanying the proposed rule states that "[i]f a source leak occurred while the pool had a small undetected leak, some contaminated water could escape from the pool. Experience has shown that pool contamination levels do not get very high so that the escape of a small amount of pool water into the ground is not a significant safety concern." Contrary to this statement, the concentration of Cs-137 in the source storage pool at RSI-Decatur immediately after detection of the source leak in June of 1988 was 4×10^{-2} µCi/ml, a factor of 100 greater than the "occupational" MPC, and a factor of 2000 greater that the "unrestricted access" MPC. The release of such water would require a 24-hour notification, per 10 CFR 20.403(b)(2); the same notification required for a radiation overexposure between 5 and 25 rems to the whole body.

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§36.33(c)

This section states that "[a] means must be provided to replenish water losses from the pool".

Comments:

We agree that the pool water makeup capability described in §36.33(c) does not need to be automatic; it should, however, be remotely actuated, eliminating the need for personnel entry into the radiation room. However, such an automatic system shall have a manual override capability.

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§36.33(d)

This section states that "[a]n audible and a visible indicator must be provided to indicate if the pool water level falls below the normal low water level".

Comments:

The intent of this requirement, as stated in 55 FR 50017, is to determine whether a source pool is leaking. Simply monitoring pool water level is inadequate to make a conclusive determination that a pool is not leaking, due to the variability of evaporation rate as a function of water temperature, ambient air temperature and ambient relative humidity. A conclusive determination that a pool is not leaking will require more sensitive leak detection methods as described in 55 FR 50017.

In addition to a low water level indicator, a <u>high</u> water level indicator must also be provided to preclude flooding of the radiation room.

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§36.33(e)

This sections state that "[i]rradiator pools must be equipped with a purification system designed to maintain the water, under normal circumstances, at a level of conductance not to exceed 10 microsiemens per centimeter".

Comment: In addition to pool water conductivity, the licensee should be required to have automatic systems which maintain all environmental conditions within applicable limits for the particular sources being used. In addition to conductivity, the most important of these environmental conditions is temperature. The use of pool water coolers is discussed in the text.

The text (55 FR 50022) related to the use of pool water coolers tends to indicate that high humidity is the major concern related to elevated water temperatures, and that pool water chillers should not be required, since some facilities do not experience humidity problems and there are methods to avoid problems associated with high humidity. Elevated water temperature is in and by itself an operational problem for several reasons. Most pool water cleanup systems, such as demineralizers, have associated temperature limits for influent on the order of 130°F. Increased water temperature dramatically increases the rate of evaporation of pool water, and thus the requirement for makeup water. Pool water should be maintained at a temperature not to exceed 90°F (or the maximum specified in the safety analysis for the source being used, whichever is lower), which would necessitate pool water chillers for irradiators with a large radionuclide inventory.

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§36.35 This section states that "[i]f the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism".

Comments: The section should state that any barriers used in Category IV irradiators to meet the requirements of this section must be constructed in such a manner so as not to adversely affect heat transfer within the radiation room. The DOE report indicates that the close proximity of shrouds to the source capsules, which reflected heat back onto the capsules and also causes a heat build-up from bottom to top of the source rack from a "chimney" effect led to extremely high capsule temperatures which were more severe than most capsule tests.

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§36.39 This section contains specific design requirements to preclude the exposure of personnel both inside and outside the irradiator facility to gamma radiation.

Comments: These design requirements do not address the control of radioactive materials as contaminants. During normal operation of Category IV irradiators, water from the pool is splashed onto the floor of the irradiator room. In addition, steam from the evaporation of pool water from the surface of the source capsules condenses on the shielding walls. Failure of the pool water makeup system described in §36.33(c) may result in flooding of the radiation room.

Potential release points for pool water to unrestricted areas include: seams and/or expansion joints between the pool and the floor of the radiation room; seams and/or expansion joints between the floor of the radiation room and the shielding walls; piping penetrations through or underneath shielding walls; and any areas of the facility which could be affected by flooding of the radiation room. §36.57(d) requires that "water from the irradiator pool or other potentially contaminated liquids must be monitored for radioactive contamination before release to unrestricted areas." Section 36.39 should include design requirements which would preclude the release of contaminated pool water to the environment. Additionally, all components in or associated with the radiation room should be designed and constructed to facilitate decontamination.

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§36.39(e) This section states that for pool irradiators, "the licensee shall verify that the radiation monitor on the water purification system is located near the spot at which the highest radiation levels would be expected."

Comments: §36.63 states that "the purification system must continue running until the conductivity of the pool water drops below 10 microsiemens per centimeter". The purification system is not required to run continuously. As mentioned above in the comments related to §36.29(b), the pool water contamination monitor should be a separate system, and should operate continuously. Should that recommendation be accepted then this section will require revision.

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§36.39(h) This section states that "the licensee shall verify that the design and locations of the smoke and heat detectors and extinguishing system are appropriate to detect and extinguish fires."

Comments: All fire protection systems, and indeed all electrical equipment and cabling located within the radiation room, should be certified for proper operation in elevated gamma radiation fields.

§36.39(i)	This section states that "[f]or panoramic irradiators, the licensee shall verify that the source rack can be returned to the fully shielded position if offsite power is lost ..."
Comments:	This language appears inconsistent with that in §36.37(a), which states that "[i]f electrical power at a panoramic irradiator is lost for longer that 10 seconds, the sources must <u>automatically</u> return to the shielded position."

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§ 36.41	This section does not address revisions to facility design which occur <u>after</u> the granting of an operating license and during facility construction.
Comment:	This section should require the applicant to request licensing agency approval for construction changes related to the shield, foundation, pool integrity, water handling systems, ventilation systems, radiation monitors, source racks, access controls, fire protection, source return, computer systems and seismic design. The licensee must provide "as built" drawings to the licensing agency prior to final approval to commence operations.

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§ 36.41(j)	This section addresses the use of computers in access control systems at panoramic irradiators.
Comment:	Although implied, this paragraph does not require multiple simultaneous faults when demonstrating that the computer and the access control system operate as planned. Also, this section does not recognize the existence of computer-controlled production operations. This is of paramount importance, since a single computer may control both production and access. In such a system, it is conceivable that a fault or transient in the production control system may adversely affect the ability of the access control system to function as planned. Modifications to software must not be made without licensing agency approval, and with the applicant demonstrating that the access control system operates as planned.

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§36.51	This section requires the training of irradiator operators, individuals who have access to the irradiator, or individuals who may be required to respond to alarms.
Comment:	The rule should state that the radiation safety officer, or other qualified individual or organization, should conduct <u>all</u> radiation safety training. If the training is provided by an organization or individual other than the

radiation safety officer, the applicant must provide information related to the qualifications of such organization or individual to the licensing agency for approval.

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§36.51(a) This section describes initial training requirements for irradiator operators.

Comment: This section should read as follows: "Before an individual is permitted to operate an irradiator without a supervisor present the individual must have received no less than 40 hours of instruction in:"

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§36.51(c) This section describes on-the-job training requirements for irradiator operators.

Comment: This section should read as follows: "Before an individual is permitted to operate an irradiator without a supervisor present the individual must have received no less than one month of on-the-job training in the use of the irradiator as described in the license application."

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§36.51(e) This section states that "[t]he radiation safety officer or other management personnel shall evaluate the safety performance of each irradiator operator at least annually ..."

Comment: The words "or other management personnel" should be deleted from the above section, as the licensing agency would have no information regarding the qualifications of individuals other than the radiation safety officer to make such evaluations.

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§36.51(f)&(g) These sections state that "[i]ndividuals who will be permitted unescorted access to the irradiator ..." and "[i]ndividuals who must be prepared to respond to alarms ..." shall be trained and tested, and that "[t]ests may be oral".

Comments: These tests should be written, and the results of such testing should be maintained as required in §36.81(b).

§36.53

This section contains requirements for a variety of operating and emergency procedures, including detection of leaking sources and/or contamination of pool water.

Comment:

The section does not require procedures for identification of an individual leaking source, nor its removal from the facility. These emergency procedures should describe in great detail the mechanisms and equipment to be used in identification and isolation of leaking sources, and should provide assurance to the licensing agency of their availability for use. The plan should also include either an agreement from the source manufacturer to accept returned leaking sources, or an agreement from a licensed radioactive waste disposal facility to accept leaking sources for disposal. The plan should provide a description of equipment required to remove damaged or leaking sources from the facility.

The emergency response plan should also include procedures for recovery of the facility to its "pre-incident" condition following an accident. These procedures must identify either a contractor with health physics expertise or a certified health physicist with access to health physics support personnel who has formally agreed to immediately respond to and manage the recovery from an suspected radioactive materials incident at the facility.

The RSI-Decatur incident required the design and fabrication of equipment to identify and isolate the leaking source <u>after</u> the incident occurred. Shipment of the leaking source required the design and fabrication of radioactive materials packaging to be used in conjunction with Type B shipping casks. The recovery effort has required the services of a private contractor to conduct source shipments and decontaminate the facility. Review of proposed recovery activities required substantial resource commitments on the part of both federal and state agencies (i.e. review of Certificates of Compliance for Type B packages, procedure review, inspections, confirmatory surveys, laboratory services, etc.)

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§36.53(a)(6)

This section requires the development of written procedures for operational inspections and maintenance checks of a variety of equipment and systems listed in §36.61.

Comment:

The rule does not require procedures for <u>repair</u> of systems for which inspection is required. We recommend the inclusion of a new section §36.53(b)(10) to read as follows:

> "Repair of malfunctions detected during operational inspections performed pursuant to §36.61."

§36.53(b)(5)	This section requires written emergency or abnormal event procedures for "a low water level alarm, an abnormal water loss or leakage from the source storage pool".
Comment:	This section should also require development of a procedure to deal with a high water level alarm, as described in our comments on §36.33(d).

§36.55	This section would require permanent record dosimetry only for irradiator operators.
Comment:	Permanent record dosimetry <u>must</u> be required for all personnel working at an irradiator facility. Any of the employees, in particular package handlers and maintenance workers, may be required at some time to enter the irradiator. Such dosimetry would provide a radiation exposure record/history should a source leak or an inadvertent entry into the irradiator occur.

§36.57(a)	This section states that "[a] radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed condition before the facility starts to operate."
Comment:	Insert the words "and with the radiation room empty" between the words "condition" and "before".

§36.57(e)	This section states that "[r]esins to be released for regeneration or an (sic) nonradioactive waste must be monitored before release ..."
Comment:	Since the suppliers of resins also furnish regenerated resin to the food and beverage industry, educational research institutions, etc., we cannot support the release of resins for regeneration, and we would recommend that such release not be permitted. Alternately, a less desirable option would be to require the applicant to provide the licensing agency with written confirmation from the resin supplier that the supplier is aware of the potential for contaminated resins, and has agreed to accept such resins for regeneration. Regardless of whether resins are releases for regeneration or disposal as nonradioactive waste, the rule should specify that resins must be below the concentrations found in 10 CFR 20 Appendix B, Table II, Column 2 (in μCi/g) prior to release. The lower limit of detection for the measurement must be below these concentrations. Direct radiation measurements on the outside

of the demineralizer vessel could lead to release of resins having concentrations of radioactive materials much greater than these concentrations. For example, a dose rate of 0.05 millirem per hour on the outside of a 7.5 cubic foot demineralizer vessel would indicate a concentration (assuming Cs-137) of approximately $1.5x10^{-3}$ µCi/g.

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§36.59(d)

This section indicates that in the event of a leaking source, "[the] licensee shall promptly check its personnel, equipment, facilities and irradiated product for radioactive contamination. No product may be shipped until the contamination check has been done." This section also requires the licensee to "clean the pool until the contamination levels do not exceed the appropriate concentration in Table I, Column 2, Appendix B of Part 20 of this chapter."

Comment:

This section does not indicate what limits are to be used to determine whether or not "personnel, equipment, facilities and irradiated product" are contaminated, and to what level such items must be decontaminated. The distribution of irradiated product may be governed by regulations of other federal or state agencies such as the U.S. Food and Drug Administration (FDA), whose acceptable contamination levels are much lower than those contained in current NRC guidance.

This section does not address licensee actions related to product which may have already been shipped, and which may be contaminated. As mentioned above in comments related to §36.29(b), it is possible that up to 48 hours may transpire between the beginning of a source leak and its detection using daily discrete samples. It is likely that some of the product processed during this period will have been shipped to distribution centers, and perhaps to consumers, prior to detection of the leak. This possibility reinforces the need for both continuous online monitoring of pool water and continuous monitoring for product contamination.

It should be noted that the contamination level to which the licensee will be required to clean the pool is inadequate to prevent the distribution of contaminated product. For example, the cited reference (10CFR20, Appendix B, Table I, Column 2) shows a Maximum Permissible Concentration (MPC) for Cs-137 of $4x10^{-4}$ µCi/ml. A little over 1 ml of such water on the outside of a product package would exceed the limit for unrestricted use (1000 dpm/100cm^2 removeable) found in Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source or Special Nuclear Material (U.S. Nuclear Regulatory Commission, Division of Industrial and Medical Nuclear Safety, August 1987).

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§36.61(a)(5) — This section requires an inspection of the operability of the product exit monitor described in §36.29.

Comment: Our comments on §36.29 recommended including all radiation monitoring systems in that section. We recommend that §36.61(a)(5) require inspection of all of these systems. Note that this would eliminate §36.61(a)(3), as that requirement would be incorporated here.

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§36.61(a)(7) — This section requires inspection for "[l]eak-tightness of the pool purification system (visual inspection)".

Comment: This section should also require inspection for leak-tightness of the continuous pool water monitoring system, and any other system through which pool water circulates.

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§36.61(a)(10) — This section requires inspection of the "visible indicator of low pool water level ..."

Comment: This section does not require the inspection of the audible low pool water level indicator, nor does it require inspections of the high pool water level monitoring system, as recommended in our comments regarding §36.33(d).

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§36.63 — This section states that the pool water purification system must be run each day the irradiator operates or at least monthly during shutdowns.

Comment: We cannot support allowing monthly operation of the water purification system during shutdowns. The rule should require a system which continuously monitors pool water conductivity and automatically starts the purification system if the conductivity exceeds 10 microsiemens per centimeter.

§36.67(a) — This section requires the use of a survey meter upon entry to the radiation room of a panoramic irradiator to insure that the source is in the fully shielded position.

Comment: This section should require the use of an ion-chamber survey meter for entry to the radiation room. Geiger-Muller (GM) type radiation instruments may saturate or "swamp" in the presence of elevated (indeed, potentially lethal) gamma radiation fields.

§36.81 This section requires that certain records be retained, and specifies the period of retention.

Comment: For panoramic irradiators, this section should require the retention of records related to source movements (cycles) until the license is terminated.

DOCKET NUMBER PR 19, 20, 21, 30, 36, 40, 51, 70 + 170
PROPOSED RULE (55 FR 50008)

DOCKETED
USNRC

Georgia State University

Occupational Safety and Risk Management
404/651-2170

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'91 FEB 15 P3:06

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(2)

February 4, 1991

United States
Nuclear Regulatory Commission
Washington, DC 20555

Attention: Stephen H. McGuire
Senior Health Physicist

Dear Mr. McGuire:

Thank you very much for sending me information on the proposed new 10 CFR 36. As a health physicist with many years of experience around large irradiator facilities, such as hot cells, I am extremely interested in this matter.

This regulation is badly needed, as this is where real serious health physics must be practiced <u>every time</u> entry is made into hot cell or rooms where these large sources are used.

In general, I agree with the current proposed 10 CFR 36 that you sent to me. However, I have some suggestions:

1. Ref. 36.57(c) Calibration should be done every six (6) months.

2. Ref 36.67(a) The operator shall check the response of the survey meter with a radiation check source every time <u>as</u> the door of the cell or room is being slowly opened. (Hold the source on the detector all the time.) Note: Never use a GM service meter for this operation. Only use an ionization chamber dose rate meter on a low scale, so the reading comes off zero about 1/3 full scale. This is probably the most important thing that can be done to minimize a chance of walking into a cell or room where a source is still present. To check the instrument just seconds before is not safe enough.

3. The health physicist should have absolute freedom to suspend a job for safety concerns or rule infraction. As such, the health physicist should never report organizationally to the operator or manager of the irradiation cell or room. He should report to the highest company management (president, etc.) every time this is possible. He should have absolute freedom to consult with other company personnel, State, or NRC personnel, without any fear of reprisal or intimidation.

Acknowledged by card 3/7/91

4. Written and approved sequential procedures should be used (checklist method). At least 20 entry and use of procedures should be made by a new operator and health physicists on-the-job training style before performing alone.

5. A thorough contamination survey of each person or things should be made each time at the opening or door when leaving. Use a thin window G.M. pancake type counter or equivalent.

6. A smear and G.M. probe survey should be made inside the cell or room at least once a week or more often.

This is such an important issue that consideration should be given for having a roving team of NRC experts make routine detail audits of facilities. The audit should be made at least once a year.

Thank you for allowing me to make comments. Please accept these suggestions from someone who sincerely feels a need for a very strict standard regulation such as the proposed 10 CFR 36.

Robert M. Boyd

Robert M. Boyd
Director - OSRM

RMB/ct

UNIVERSITY OF
WISCONSIN
MADISON

January 22, 1991

TO: The Secretary of the Commission
Washington, DC 20555

FROM: Sue Engelhardt SE
Radiation Safety Officer

Abdul BenZikri ABZ.
Health Physicist

Re: Comments on the Licenses and Radiation Safety Requirements for Large Irradiators

The following are our comments regarding category II-panoramic,Dry-Source-Storage Irradiators.

We quote, "This category includes irradiators in which the sealed sources are stored in a shield constructed of solid materials and are fully shielded when not in use. Irradiations occur in air within a room accessible to personnel only when the sources are shielded."

From the above quote, teletherapy units which contain sources that can deliver 500 rads per hour at a distance of one meter or more, used for research, calibration of radiological instruments, and/or used at veterinary Medicine facilities, not used on humans, will be effected by this proposed rule.

Did this rule intend to include those type of sources?

If the answer is yes, we believe the proposed rule is too strict for these type of units. These type of units contain sources that remain in their shielded container at all times. When in use, the collimator allows the exposure of radiation to a defined area. These units should follow the **applicable** radiation safety requirements as those required for teletherapy units used on humans, e.g. CFR35.615 Safety Precautions. Since these units are not used for humans, full calibrations, spot checks etc. should not apply.

The second half of the same paragraph, and I again quote, "This category also includes certain beam type irradiators in which the source remains partially shielded".

It is not clear when the source is partially shielded. Is it when the source is in use, or when it is in the storage position?

We thank you for your time. Please let us know your response regarding these comments.

Safety Department

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DSIB

[7590-01]

DOCKET NUMBER PROPOSED RULE PR 19,20,21 ET AL.
(55FR50008)

DOCKETED USNRC

'90 NOV 29 A9:13

OFFICE OF SECRETARY DOCKETING & SERVICE BRANCH

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 19, 20, 21, 30, 36, 40, 51, 70 and 170
RIN 3150-AC98
Licenses and Radiation Safety Requirements
for Large Irradiators

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations by establishing a new Part 36 to specify radiation safety requirements and licensing requirements for the use of licensed radioactive materials in large irradiators. Irradiators use gamma radiation to irradiate products to change their characteristics in some way. The safety requirements would apply to large panoramic irradiators (those in which the material being irradiated is in air in a room that is accessible to personnel when the source is shielded) and certain large underwater irradiators in which the source always remains shielded under water and the product is irradiated underwater. The rule would not cover self-contained dry-source-storage irradiator devices, instrument calibrators, medical uses of sealed sources (such as teletherapy), or nondestructive testing (such as industrial radiography).

DATES: Submit comments by (ninety days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission can assure consideration only for comments received on or before this date.

pub. 12/4/90

A public meeting on the proposed rule will be held on February 12 and 13, 1991, in Rockville, Maryland.

ADDRESSES: Submit comments to: The Secretary of the Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Copies of comments received and documents referenced in this proposed rule may be examined at the NRC Public Document Room, 2120 L Street NW., Lower Level, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. Stephen A. McGuire, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-3757, or Mr. Steven L. Baggett, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-0542.

To obtain further information on and to register for the public meeting contact: Ms. Jayne McCausland, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492-3643.

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I. Large Irradiators

Irradiators use gamma radiation to irradiate products to change their characteristics in some way. Irradiators are used for a variety of purposes in research, industry, and other fields. Irradiators covered by this proposed rule are those large enough to deliver a dose exceeding 500 rads (5 grays) in one hour at a distance of one meter. The proposed rule does not cover self-contained irradiator devices in which the volume being irradiated is totally inaccessible to people.

Irradiators use either radioactive materials or electronic machines (x-ray machines or accelerators) to produce very high radiation dose levels. The NRC and Agreement States regulate irradiators using radioactive byproduct materials. Electronic machine irradiators are regulated by the Occupational Safety and Health Administration (OSHA) and States. The radioactive materials, generally cobalt-60 or cesium-137, are contained in sealed sources or capsules made of stainless steel to prevent the spread of the radioactive materials. Most often the sealed radioactive sources are stored in water pools when not in use, although some irradiators use solid shields in which to store the sources. In order to irradiate products, the sources are usually lifted out of the pool or solid shield into the air. However, in some irradiators the products to be irradiated are lowered into the pool. For large commercial production irradiators, the total activity of the sources typically exceeds 1,000,000 curies (3.7×10^{16} becquerels), and the product to be irradiated moves past the sources on an automated conveyor system.

In 1988, roughly 85 percent of the capacity of large irradiators was used to sterilize disposable medical products and supplies such as disposable rubber gloves and syringes. The past two decades have seen a slow but steady growth in the use of disposable medical products. Prior to that time, hospitals had recurring problems with biological cross-contamination (the spread of infection from one patient to another). An important cause of cross-contamination was the incomplete sterilization of certain medical products such as rubber gloves and syringes. The use of disposable products was found to greatly diminish the extent of the problem.

For years, sterilization of medical products was done primarily with heat or the chemical ethylene oxide. Ethylene oxide was used for some products that could not be satisfactorily sterilized with heat because the product would be damaged. In 1978, the EPA declared that ethylene oxide was a mutagen, possibly a carcinogen, and that its use should be carefully reviewed. Ethylene oxide residues on products thus began to be of greater concern. In 1984, OSHA established a new workplace exposure limit for ethylene oxide that lowered the acceptable level from 50 parts per million in air to 1 part per million, making its use more difficult. These changes placed the use of ethylene oxide under regulatory constraint. As a result, sterilization by gamma irradiation became the only viable alternative for sterilizing those products that would be damaged by heat.

In recent years the increasing incidence of Acquired Immune Deficiency Syndrome (AIDS) has increased the demand for disposable medical products. Combined, these factors have led to a gradually increasing use of gamma radiation in the sterilization of medical products.

Most of the remaining irradiation processing capacity is used for chemical processing, primarily the induction of polymerization in plastics. A small amount of irradiator capacity is used for research on the effects of very high doses of radiation, the production of sterile male insects for insect eradication programs, and other specialized uses.

The Food and Drug Administration has approved the use of gamma irradiation for the disinfestation and preservation of foodstuffs (21 CFR 179.26). Any food may be irradiated up to 100,000 rads (1,000 grays) for the purpose of disinfestation, such as to kill insects and parasites. Any fresh food may be irradiated up to 100,000 rads (1,000 grays) to inhibit growth or maturation, which thereby reduces spoilage. Pork may be irradiated up to 100,000 rads (1,000 grays) to kill the organisms that cause trichinosis. Dry and dehydrated foods may be irradiated up to 3,000,000 rads (30,000 grays) for microbial disinfection. Thus, irradiation is an alternative to chemical preservatives and can reduce the use of pesticides and fumigants to control insect infestation of foods.

Presently there is very little preservation of food by irradiation done in the United States. Congress, however, supports food irradiation and has appropriated money to the Department of Energy (DOE) to support the construction of six food irradiators.

There are other potential uses of irradiation. Irradiation can sterilize biomedical wastes from hospitals. Currently, potentially infectious wastes are usually incinerated. Another potential use is the sterilization of toilet wastes from airplanes and ships that arrive from abroad. Laws require that those wastes must be considered disease-bearing and that they be sterilized. Currently, the wastes are usually sterilized by incineration.

Another potential use is the sterilization of sludge from sewage plants. Sludge could be used as a fertilizer if the pathogens in it were known to be killed and if concentrations of certain heavy metals and toxic chemicals were low enough. Irradiation could kill the pathogenic organisms but would have no effect on heavy metals or toxic chemicals.

With so many different uses and potential uses, irradiator designs are varied to suit specific applications. Therefore, it is desirable to establish basic criteria to ensure a high standard of radiation safety in the design and use of irradiators. However, this should be accomplished in a way that does not unnecessarily restrict the logical use and growth of their applications.

Because of the variety of designs, four general categories of irradiators have been defined by the American National Standards Institute (ANSI). The categories are as follows:

Category I -- Self-contained, dry-source-storage irradiators.

This type of irradiator is built as a self-contained device. The sealed sources are completely enclosed within a shield constructed of solid materials. Human access to the sealed source and to the space subject to irradiation is not physically possible. The physical size of the device, the space subject to irradiation, the source strength, or all three are generally not large.

This proposed rule does not cover self-contained dry-source-storage irradiators (Category I) for several reasons. First, they are devices that the licensee usually purchases without playing any part in their design and manufacture. Also, because safety features are designed into them, self-contained irradiators present less potential hazard and they are considered to be adequately dealt with by existing requirements. This type of irradiator (Category I) would continue to be licensed under the general requirements of 10 CFR 30.33 using the criteria in Regulatory Guide 10.9, Revision 1, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source-Storage Irradiators," December 1988, and also "Standard Review Plan for Applications for Licenses for the Use of Self-Contained Dry Source-Storage Gamma Irradiators," December 1988.

Category II -- Panoramic, dry-source-storage irradiators.

This category includes irradiators in which the sealed sources are stored in a shield constructed of solid materials and are fully shielded when not in use. Irradiations occur in air within a room accessible to personnel only while the sources are shielded. This category also includes certain beam type irradiators in which the source remains partially shielded. Irradiators of this type are covered by the proposed rule.

Category III -- Underwater irradiators.

This category includes irradiators in which the sealed sources are always in a storage pool and are shielded at all times. Human access to the sealed sources and the space subject to irradiation is not physically possible. Irradiators of this type are covered by the proposed rule.

Category IV -- Panoramic, wet-source-storage irradiators.

This category includes irradiators in which the sealed sources are in a storage pool containing water and are fully shielded when not in use. Irradiations occur in air within a room made inaccessible to personnel by an entry control system while the sources are exposed. Irradiators of this type are covered by the proposed rule.

II. Need for a Rule

Large irradiators are currently licensed primarily under: (1) the general provisions of 10 CFR 30.33, which requires that "equipment and facilities are adequate" and that the "applicant is qualified by training and experience;" (2) the general requirements of Part 20, for example, dose limits and the need for "adequate" surveys; and (3) the specific requirements in 10 CFR 20.203(c)(6) and (7) that deal with access control requirements for panoramic irradiators. There is also a draft regulatory guide FC 403-4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators," that was published in January 1985. However, the scope of the guide is limited, and many subjects are not covered or are covered in a way now considered obsolete. On subjects that are not covered in the regulations or guide or for which there are no criteria on what is acceptable, the applicant has no way of knowing what will be accepted. Similarly, the license reviewer may be uncertain about what should be required. If the license reviewer considers the application incomplete or inadequate, he or she sends a "deficiency letter" to the applicant explaining what additional information is needed. Review of the application is not resumed until a written response from the applicant has been received. This can substantially delay issuance of a license.

Thus, although the safety requirements and policies are generally understood and agreed upon, they are contained in regulations, a regulatory guide, and specific licensing conditions. This rule would consolidate, clarify, and standardize the requirements for current and future irradiators.

A rule would also make the NRC's licensing reviews and inspections more efficient. If requirements are clearly stated in a rule, license applications could be shorter because there would be no need for applicants to describe what they would do in areas covered by the rule. The NRC could then issue licenses with fewer license conditions. Inspections would be more efficient because there would be a uniform set of requirements.

At present, aside from the specific requirements in § 20.203 on access control, many requirements are those committed to by the applicant in its license application. The wording of similar requirements can vary slightly from licensee to licensee. This makes the NRC inspector's job more difficult because he or she must determine precisely what each licensee is committed to doing.

There are at this time a number of new large irradiators either under construction or planned. In addition, Congress has appropriated money in support of the construction of six food irradiators. Thus, a significant expansion in irradiator operations is expected. Developers of these new facilities may not be familiar with NRC requirements. A rule would help make NRC's requirements clear to people building new irradiators.

There are also some areas in which either technology is changing (such as computer controllers) or NRC policy is evolving (such as quality assurance). A rule can provide comprehensive and up-to-date requirements in these areas that would be consistently and uniformly applied.

In addition, there were a number of lessons learned from a leaking source accident that occurred at an irradiator operated by Radiation Sterilizers, Inc. in Decatur, Georgia, in 1988. An analysis of the incident and a discussion of the lessons learned appear in the report titled "Leakage of an Irradiator Source - The June 1988 Georgia RSI Incident," NUREG-1392. One lesson learned was a need for detailed emergency plans. The NRC agrees that there is a need for plans to deal with emergencies. The proposed rule contains a detailed list of emergency and abnormal events for which the licensee must have a written emergency procedure (§ 36.53(b)). The procedures must be described in the license application (§ 36.13(c)). Operators must be trained in the procedures (§ 36.51(a)(4) and (g)) and must participate in an emergency drill annually (§ 36.51(d)).

Another lesson learned was the importance of proper training. The NRC believes in the importance of proper training for irradiator operators and the radiation safety officer. The proposed rule contains a detailed description of the training that an operator must receive (§ 36.51). The license application must describe the training program for operators and the qualifications of the radiation safety officer. These would then be evaluated by NRC on a case-by-case basis. The proposed rule also would require drills of the emergency procedures (§ 36.51(d)(6)). Specialized training in decontamination would not be required because decontamination, if extensive, should be done by specialists who are experienced in decontamination work rather than by irradiator personnel. Thus, the proposed rule would require that decontamination be done by a licensee authorized to do that type of work (§ 36.59(d)).

Included in the report was a recommendation for a "Community Relations Plan" to deal with public concerns. The NRC does not believe that a "Community Relations Plan" is necessary in order to protect public health and safety, although such a plan could be useful to a licensee for other reasons. Therefore the rule does not address the issue of the need for such a plan. The rule does, however, require operating and emergency procedures.

Another lesson learned is that the license application should be received early in the process of building an irradiator. The NRC agrees with a need for early notification. The proposed rule would prohibit the start of construction of an irradiator before a license has been issued (§ 36.15).

An issue raised in the report focused on whether WESF capsules should be used in commercial irradiators because cesium-137 chloride is highly soluble in water. The NRC believes that these questions on the "WESF" capsules cannot be resolved until the cause of the leak is better understood. However, as a practical matter, only two irradiators have used "WESF" model capsules in the frequent air-water cycling mode, and neither of these irradiators now use "WESF" capsules. One irradiator still uses the "WESF" capsules in a cycling mode, but the operation of the irradiator is such that the cycling is presently seldom done.

Also of concern was the detection of contamination on workers before they leave the facility. In the RSI accident, some contamination was carried offsite, although the radiation doses involved were low in comparison with NRC's dose limits. Monitoring of workers after a leak has been detected is important. Thus, the proposed rule would require that the licensee have a written emergency procedure for dealing with a leaking source or contamination (§ 36.53(b)) and that the licensee promptly check personnel for radioactive contamination (§ 36.59(d)). Workers would have to be trained in the procedure (§ 36.51(a)(4)).

Another issue dealt with monitoring irradiated product for contamination. In the RSI accident, there was concern that product that had been irradiated after the leak started could be contaminated. The licensee's record system allowed prompt tracking of all recently irradiated product. One shipment that had been shipped earlier in the day on which the leak was detected was found to be contaminated. It was immediately recalled and disposed of as radioactive waste. The lessons learned report recommended adequate monitoring systems for assuring uncontaminated packages, and it perhaps implied that routine monitoring of packages should be done. The NRC believes that there should be a means of promptly detecting leaking sources. The NRC believes that the most suitable way to accomplish this is with frequent monitoring of pool water, and thus the proposed rule contains that requirement (§ 36.59(c)). The NRC agrees that if a leak is detected, all recently irradiated product must promptly be tracked and monitored for contamination. Thus, the proposed rule contains a requirement to monitor irradiated product for contamination if a leak occurs (§ 36.59(d)).

III. Review of Operating Experience

To develop a basis for these proposed safety requirements, the NRC reviewed the operating experience of large irradiators. The information presented in this section is taken, in large part, from "Review of Events at Large, Pool-Type Irradiators," Eugene A. Trager, Jr., NRC Office for Analysis and Evaluation of Operating Data, NRC Report NUREG-1345, 1989. (Copies of NUREG-1345 may be purchased through the U.S. Government Printing Office by calling (202) 275-2060 or by writing to the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies may also be purchased from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.)

A. Radiation Overexposures.

Serious radiation overexposures involving irradiators occurred in the U.S. in 1974 and 1977. Fatalities were caused by radiation overexposures involving irradiators in Italy in 1975, in Norway in 1982, in El Salvador in 1989, and in Israel in 1990.

In 1974, in New Jersey, an operator at a panoramic irradiator walked into the radiation room containing an exposed source, saw it, and quickly left the room. He received a dose large enough to cause clinically observable symptoms of radiation sickness, but the dose was not large enough to be fatal. The entrance to the room lacked the modern automatic access control systems now used and an alarm system had been turned off. The operator did not follow the proper procedures for entry. It is possible the operator was not sufficiently vigilant because he was working alone at a late point in his shift. The operator made the error on the twelfth hour of the fourth straight day in which he worked 10 to 12 hours.

In 1977, a worker at another irradiator in New Jersey was overexposed to radiation after he entered a radiation room while a 500,000-curie (1.8 x 10^{16}-becquerel) cobalt-60 source was unshielded. The licensee was in the process of modifying the irradiator and was operating the irradiator while the interlocks on the door used to prevent entry into the radiation room were deactivated. In addition, construction activity caused the source-up warning light to be obscured from view. The door to the room was open, and the worker, who assumed the sources were shielded, entered the radiation room. Upon noticing that the sources were in the exposed position, the worker immediately left the room and notified his supervisor. Although not fatal, the worker's dose was calculated by the licensee to be between 150 and 300 rems to the whole body. Subsequent to the accident, the NRC adopted access control requirements (10 CFR 20.203(c)(6)) that required a backup warning system to warn anyone attempting to enter the radiation room while the source is unshielded.

In 1975 an accident occurred in Italy at a 30,000-curie (1.1 x 10^{15}-becquerel) dry-source-storage irradiator used to irradiate corn. An operator climbed onto a conveyor belt to make an adjustment and was carried under the source while it was unshielded. When the operator complained of severe pain in his head, his partner attempted to remove him from beneath the unit. However, his partner ran the conveyor forward rather than in reverse and exposed the operator's entire body to the unshielded source. The operator died 12 days later.

In 1982, an accident occurred in Norway. A maintenance man entered the radiation room of a Category IV irradiator while a 65,000-curie (2.40 x 10^{15}-becquerel), cobalt-60 source was unshielded, and received a lethal radiation exposure. The facility had two automatic locks on the door to the room to prevent it from being opened while the source was exposed. However, one lock had been previously disconnected because it was malfunctioning, and the other failed due to a broken microswitch. The facility did not meet the requirements in the NRC's current or proposed rule because (1) opening the door would not automatically cause the source to become shielded, (2) there was no backup system to automatically cause the source to become shielded upon entry if the primary door or barrier were passed, and (3) there was no alarm system to alert the person entering that the source was exposed. In addition, several NRC operational requirements were not met. In total, at least six levels of protection in NRC's current and proposed requirements were not provided. (The accident is described in more detail in "The Radiation Accident at Institute for Energy Technology, September, 1982, Some Technical Considerations," Leiv Berteig and Jon Flatby, The Journal of Industrial Irradiation Technology, Volume 2, pages 309-319, 1984.)

In 1989, a fatality resulting from an irradiator exposure occurred in El Salvador. A movable rack holding a 18,000-curie (6.60×10^{14}-becquerel) cobalt-60 source was jammed in an unshielded position. An operator bypassed safety systems and entered the irradiation chamber, along with two helpers, to free the rack and lower the source back into a storage pool. The three workers were exposed to high doses and developed acute radiation syndrome. Although prompt medical attention was effective in countering the acute effects, the legs of two of the men had to be amputated. Six months after the accident, the operator died as a result of radiation-induced lung damage which was complicated by a lung injury sustained during treatment (summarized from Croft, J., Zuniga-Bello, P., and A. Kenneke, 1989, "The Radiological Accident in

San Salvador," IAEA General Conference: Scientific Programme for Nuclear Safety, September 28, 1989).

In 1990, a fatality occurred in Israel. Product being irradiated jammed on a conveyor system. The jam also prevented the radiation sources from being lowered to the safe shielded position. To clear the jam, the operator entered the radiation room after bypassing the interlocks designed to prevent entry into the room while the sources were exposed. He received a fatal radiation dose within a minute or two.

B. Other Operating Problems.

NUREG-1345 identified forty-five events at U.S. irradiators of which forty-four had some actual or potential safety significance. Only two of the events had actual rather than potential impact on the health and safety of the employees or the public. Of the forty-four events, thirty-one involved the failure, malfunction, or degradation in the performance of some irradiator system. These systems include: access control, source movement mechanism (movement and suspension); source encapsulation; and pool or water cleanup system. An additional ten events stemmed from management deficiencies. Three events involved natural phenomena and other site problems.

1. Access control.

Two radiation overexposures involving access control were discussed in Section III.A. and will not be discussed further here. Both events occurred prior to implementation of NRC's current access control regulations in Part 20. A third event, reported in 1978, also involved the access control system. It was discovered that failure of two door interlock switches would allow the source to move from the safe storage to the exposed position even if the door to the radiation room was open.

2. Source movement.

There were thirteen events that involved interference with source movement and six other events that involved the source suspension cables.

There were insufficient data to specify a cause for five of the thirteen events in which source movement was impeded. In six of the thirteen events, the product carriers interfered with the movement of the source rack. In one of those, the interference was indirect; a box pusher cylinder created a short in a control circuit resulting in the tripping of a circuit breaker in the control circuit. The source then properly began lowering itself into the shielded position. But loss of the control circuit caused the loss of the source-down position sensor, and so the source cable drum continued to rotate and raised the source to the up position before the motor stalled. The source had to be lowered manually.

There were two source-movement events involving loss of source movement capability that had unique causes. At a research irradiator, interference between an experiment and the source impeded movement of the source. Low temperatures at another irradiator caused freezing that appears to have been responsible for preventing movement of the source.

The thirteen events involving source movement were benign in that no radiation exposures resulted. But two of the events caused fires inside the radiation room. Two events resulted in individual sources coming loose from the source rack. One event resulted in distortion of the source rack.

There were six problems with source suspension cables. In three of the events, the cable broke. In two events, the cable frayed. In one event, the cable came off its pulley. There were no radiation exposures caused by any of these events. In two of the events in which the cable broke, there are indications of some deficiencies in maintenance practices. In one, the cable was known to be frayed; in the other, the cable had not been inspected for at least three years.

3. Source encapsulation.

There have been four events in which the encapsulation of the radioactive sources appears to have failed. As a result, the storage pool was contaminated. In one case, a fire caused by a welder early in the facility life resulted in the discharge of a fire extinguisher into the pool water. Almost immediately afterwards, radioactive contamination of the pool water was detected. The source of the contamination was never established. In a second event, a source was ruptured in 1974 due to mishandling. An excessive contamination level in the pool was not noted until 1982 because the contamination stayed at the bottom of the pool.

Late in 1976, an irradiator licensee determined that the cobalt-60 concentration in the water of a research and development pool was slightly elevated (to 0.0013 microcurie/milliliter or 48 becquerels/milliliter). The licensee stated that the activity level may have been the result of surface contamination from a batch of cobalt-60 sources recently installed in the pool or activity from one source that had a loose cap. Demineralization of the pool water successfully reduced the activity of the pool to normal operational levels. The suspect source was isolated and returned to the supplier.

The previously mentioned 1988 event at RSI involved the leakage of a cesium-137 source. This resulted in the release of about 10 curies

(3.7×10^{11} becquerels) of cesium-137 to the pool. The event led to concerns that contaminated products might have been shipped from the plant. Although no contamination was found on products that had been distributed to the public, contamination was found on products that had been shipped to a warehouse and in workers' houses and a car.

4. Pool or water cleanup system integrity.

There were three events that involved pool leakage or pool cleanup system leaks. In the case of the leaking pool, the existence of a high rate of water loss from the storage pool was noted by an NRC inspector during an inspection. After discussions with the NRC, the licensee agreed to repair the leak and monitor the rate of pool leakage.

There were two events involving leaks in pool water purification systems. In one event, the piping on the discharge side of the purification system pump leaked. Contributing factors were that the piping was suitable for cold temperatures while the pool water temperature was 120°F and that the joints had recently been torqued. The leak developed when the irradiator was shut down for the weekend and there was apparently no low pool level shut-off on the purification pump. In the second event involving a pool purification system leak, a pipe broke. Contaminated water spilled into the facility and some ran out of the building. Small amounts of contamination were later found on the ground outside of the building.

5. Miscellaneous systems.

There were two events that involved miscellaneous systems. The first event involved problems with timers. The second event involved malfunction of pistons used to engage clutches in the product conveyor system.

6. Management deficiencies.

Ten events involved management deficiencies. None of the events caused radiation exposures or radioactive contamination. In one, a dose distribution study that involved the stationary irradiation of paper, a fire resulted from gamma heating of the paper. The most common management deficiency was operating an irradiator without the operable access control interlocks required by 10 CFR 20.203(c). Several events of this type occurred at the same facility.

7. Natural phenomena.

There were three events involving natural phenomena or other site problems. None had any significant impact. One irradiator was struck by a tornado, but the safety of the facility was unaffected. A second irradiator was about 120 km from the epicenter of a series of six earthquakes of about 3.6 magnitude on the Richter scale. The irradiator was inspected by state inspectors and found to be undamaged. In a third event, there was a fire at an irradiator site in a building that was separate from the irradiator building. The building was used to store sawdust. The irradiator suffered no damage.

C. Inspection History.

A review of inspection records from January 1, 1980, to December 31, 1987, for current NRC licensees indicates roughly the following types and frequencies of violations of the regulations:

Violations at NRC-Licensed Large Irradiators, 1980-1987

Radiation overexposures	none
Recordkeeping and posting violations	12
Failure to perform tests, inspections, or routine maintenance within required frequency	10
Operating without fully operable interlocks or alarms	6
Failure to calibrate radiation instruments	3
Operator not on authorized list	3
Survey instruments or personnel dosimeters not used or used improperly	3
Repairs or operation without proper authorization	2
Miscellaneous violations	5

The most significant violations are those in which the irradiator was operated without fully operable interlocks or alarms. Interlocks and alarms are an important part of the system of protection used to prevent serious overexposures.

IV. Radiation Protection Philosophy

Based on the review of operating experience, the most important radiation protection objective at a large irradiator is preventing anyone from entering the irradiation room while the source is exposed. An unshielded source at a large irradiator could deliver a lethal dose in less than a minute.

The NRC believes that its current access control requirements adequately address this problem. Since imposition of the current requirements in 1978, there have been no reported entries of personnel into an irradiator room while the source was exposed. However, this proposed rule would revise the access control requirements to increase their clarity.

The second most important radiation protection objective is avoiding excessive radiation exposure due to radioactive contamination from leaking, damaged, or contaminated sealed sources. An underlying assumption in this rulemaking is that any sealed source could leak. Therefore, the proposed rule would require means of coping with leaks so that radiation overexposures to facility employees and to the public are avoided.

The first step in avoiding radiation exposures due to contamination is to prevent leaking sources. The proposed rule has clear specific requirements on the encapsulation of sealed sources. Experience with sealed sources manufactured to the standards in the proposed rule has been good. While the proposed rule assumes that any source can leak or be damaged, leaks are rare. When leaks have occurred, the proportion of material in the source that has escaped has generally been low with the exception of a few cases in which cutting tools were mistakenly used to cut sources open.

The second step in preventing excessive radiation exposures requires that a means to detect leakage in a timely manner be provided. For pool irradiators, the proposed rule would require radiation monitoring of pool water. The monitoring should allow prompt detection of any leak of significant size. For dry-source-storage irradiators, the rule would require periodic leak tests of very high sensitivity. Although the monitoring is not as frequent as for wet-source-storage sources, the greater sensitivity should allow detection of any problem early enough.

The third step in preventing excessive radiation exposures is to require a stainless steel pool liner on all new source storage pools to act as a barrier to keep water from leaking out of the pool. The proposed rule contains this requirement.

The fourth step is to have procedures for dealing with accidents or abnormal events. The proposed rule requires the licensee to have those procedures.

Since the proposed rule contains these features, the NRC believes that the requirements in the proposed rule are adequate to assure a very low likelihood that anyone inside or outside the facility would be exposed to radiation in excess of NRC's dose limits in 10 CFR Part 20.

V. Reference Documents

The requirements in the proposed rule are based, in part, on recommendations and requirements in the documents listed below:

1. Draft Regulatory Guide FC 403-4, "Guide for the Preparation of Applications for Licenses for the Use of Panoramic Dry Source-Storage Irradiators, Self-Contained Wet Source-Storage Irradiators, and Panoramic Wet Source-Storage Irradiators," January 1985. (Hereafter called the "Irradiator Licensing Guide.") Draft Regulatory Guides may be obtained without cost by writing: Director, Division of Information Support Services, USNRC, Washington, DC 20555.

2. American National Standard N43.10-1984, "Safe Design and Use of Panoramic, Wet Source Storage Gamma Irradiators (Category IV)," National Bureau of Standards Handbook 142, 1984. (Hereafter called the "ANSI Category IV Standard.") This document may be purchased for $8 from: American National Standards Institute, 1430 Broadway, New York, NY 10018.

3. American National Standard N542-1977, "Sealed Radioactive Sources, Classification," National Bureau of Standards Handbook 126, 1978. This document may be purchased from: The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

4. Draft American National Standard N43.12 (dated October 2, 1985), "Safe Design and Use of Panoramic Dry Source Storage Gamma Irradiators," unpublished. (Hereafter called the "ANSI Category II Standard".) To obtain a copy write to: Ms. Jayne McCausland, Office of Nuclear Regulatory Research, USNRC, Washington, DC 20555.

5. NUREG-1392, "Leakage of an Irradiator Source - The June 1988 Georgia RSI Incident," February 1990. This document may be purchased from: The Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

VI. Public Meeting

Because of the length and complexity of the proposed rule, the NRC will hold a public meeting during the public comment period to discuss the rule. The meeting will be held on February 12 and 13, 1991, in Rockville, Maryland. The public meeting will provide interested persons an opportunity to question the NRC staff about the meaning, intent, logic, and Justification of the proposed rule. The meeting will also allow the NRC staff to question commenters attending the meeting about why they may object to provisions of the proposed rule and how they would suggest improving the rule. Another purpose of these exchanges is to allow commenters to improve their written public comments because, through the meeting, they might gain a better understanding of the meaning, intent, and purpose of the proposed rule. To obtain further information and to register for the public meeting, write or telephone: Ms. Jayne McCausland, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3643.

VII. Summary of the Proposed Requirements and The Rationale for Their Inclusion

The actual wording of the proposed amendments appears in the text of the proposed Part 36. The information presented in this section summarizes the major requirements by section of the regulation. The bases and origins of the major requirements are also explained.

SUBPART A - GENERAL PROVISIONS

§ 36.1 Purpose and scope.

This section describes the types of irradiators covered in the proposed Part 36. The proposed rule covers large panoramic wet-source-storage, dry-source-storage, and underwater irradiators. Large irradiators are those that can deliver a dose of 500 rads (5 grays) or greater in one hour at a distance of 1 meter, either in air or underwater as appropriate for the irradiator type. The dose rate criterion is taken from the access control requirements in the revised 10 CFR § 20.3, Definitions, "Very High Radiation Area," under consideration by the Commission. The 1-meter distance effectively excludes self-contained irradiators. A cobalt-60 source of approximately 400 curies (1.48×10^{13} becquerels) would deliver this dose in air if the source were small with little self-absorption. A cesium-137 source would need about 2,000 curies (7.4×10^{13} becquerels) to deliver the same dose. For underwater irradiators, the source activities to deliver a 500-rad (5-gray) dose at 1 meter would be about 10 times larger than if the exposures were performed in air.

§ 36.2 Definitions.

This section defines terms that are used in the proposed new Part 36.

SUBPART B - SPECIFIC LICENSING REQUIREMENTS

§ 36.11 Application for a specific license.

This section states how to apply for a license and where the application must be sent.

§ 36.13 Specific licenses for large irradiators.

This section describes information that must be included in a license application if it is to be approved by the Commission.

The applicant's proposed activities must be for a purpose authorized by the Atomic Energy Act of 1954. This is a standard requirement for all types of licenses.

The applicant's proposed equipment and facilities must be adequate to protect the health of workers and the public and minimize danger to life and property. The applicant must be qualified by training and experience to use the radioactive material for the purpose requested and in a manner that protects health and minimizes danger to life and property. These are standard requirements for all NRC licensees.

The application must describe the training program for irradiator operators. Criteria for acceptable training programs are not contained in the regulations so that flexibility can be allowed. For example, the on-the-job training of operators would be different at a new irradiator compared to an existing irradiator. Guidelines for acceptable training programs are contained in the Irradiator Licensing Guide.

The application must contain an outline of the operating and emergency procedures. The NRC prefers to review an outline that describes the operating and emergency procedures in broad terms that specifically state the radiation protection features to be included in the procedures rather than the detailed operating and emergency procedures. A step-by-step review of procedures would generally not be possible for a license reviewer without intimate knowledge of the construction, layout, and operation of the particular irradiator. In addition, if specific procedures were reviewed, then minor changes that the facility might need to make from time to time (for example, due to replaced equipment or improving procedures based on what is learned from operating experience) could require a time consuming and unnecessary license amendment. This could unnecessarily hamper the safety of facility operation. Detailed procedures would be available to inspectors for reference during facility operation, however, and documentation on changes in procedures will have to be retained for inspection by the NRC for three years (§ 36.81(d)).

The application must describe the responsibilities and authorities of the radiation safety officer and other management personnel. The applicant must also describe the qualifications of the radiation safety officer. These are standard requirements used to judge whether the applicant's personnel are qualified to handle radioactive materials safely.

Consideration was given as to whether the proposed rule should contain specific requirements for the qualifications of the radiation safety officer. Requirements could be placed on: the amount of formal radiation safety training, the amount of on-the-job training, the length and type of previous experience, and the amount of formal education. It was decided not to specify minimum qualifications in the rule because there is so much variability in qualifications among people who would be adequate to do the job. Instead, it was decided that guidance on qualifications should be included in a Regulatory Guide and that the NRC license reviewer should make the final determination of adequacy based on the actual qualifications of a specific individual. This would allow the license reviewer the flexibility to consider the strengths and weaknesses of a specific individual in making the determination.

Applications to operate panoramic irradiators must contain logic diagrams of access control systems.

Applications also must contain information on how sealed sources would be tested for leakage and contamination.

The applicant must submit information on loading and unloading sources. If the applicant intends to load and unload sources, the applicant must show that its personnel are qualified to do so safely and that its procedures are adequate to protect health and safety. The applicant may also have the loading and unloading done by another organization that the NRC or an Agreement State has approved. "Approved" means that the qualifications of the organization that would do the loading and unloading have been reviewed by the NRC or an Agreement State as part of a prior licensing action and the organization has been found qualified to safely load and unload sources. If the qualifications of the organization have not been previously reviewed, they would then be reviewed as part of the current license application and, if found qualified, added to the list of organizations approved to load and unload sources.

The applicant must also describe the frequency of the operational inspection and maintenance checks required by § 36.61. Guidelines on the frequency of checks may be included in future NRC licensing guides.

§ 36.15 Start of construction.

This section prohibits the start of construction of any portion of the permanent facility on the site before a license is issued. The section applies only to new facilities. An applicant is not prevented by this section from seeking a license to operate an irradiator that has been transferred from one owner to another or from converting an existing facility, such as a hot cell, into an irradiator.

§ 36.19 Request for written statements.

This section codifies a requirement (found in Section 182 of the Atomic Energy Act) that the licensee must supply any additional information required by NRC to assure that health and safety will be protected.

SUBPART C - DESIGN AND PERFORMANCE REQUIREMENTS FOR THE IRRADIATOR

§ 36.21 Design and performance criteria for sealed sources.

This section lists the performance criteria for sealed sources used in irradiators.

The performance criteria in the proposed rule are taken from American National Standard N542-1977, "Sealed Radioactive Sources, Classification," published by the National Bureau of Standards in 1978 as NBS Handbook 126. (Available from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.) The NRC has used this standard for many years and generally is satisfied with the performance of the sealed sources that meet the standard. Nonetheless, there is a new requirement that sealed sources installed after the effective date of the rule be doubly encapsulated. Double encapsulation provides additional protection in case one of the welds in the source is defective. The likelihood of two defective welds in one source is less than the likelihood of one weld being defective. Most of the approved sources currently in use are doubly encapsulated.

The proposed rule does not specify any requirements for sealed sources installed prior to the effective date of the rule. Current NRC staff practice is to approve sealed sources on a case-by-case basis, using the criteria in American National Standard N542-1977. Thus, all sources installed prior to that date would have been approved by the staff on a case-by-case basis, using effectively the same criteria as in the proposed rule, with the exception of the requirement for double encapsulation.

§ 36.23 Access control.

This section states requirements for systems intended to prevent entry into the radiation room of a panoramic irradiator while the source is exposed.

The proposed requirements were taken largely from the existing 10 CFR 20.203(c)(6) and (c)(7), but an attempt has been made to simplify the wording of these requirements. In addition, a requirement that the entrance to the radiation room must have a "door or other physical barrier to prevent inadvertent entry" has been added. Although the present regulation in 10 CFR 20.203(c)(6) does not require a door or barrier, the NRC licensing staff has usually required that a door or barrier be provided. The proposed rule explicitly states the requirement. As a part of the final rulemaking on the new Part 36, existing 10 CFR 20.203(c)(6) and (c)(7), which apply only to large irradiators, will be deleted from Part 20 to coincide with the effective date of the Part 36 requirements.

For panoramic irradiators, the proposed section would require a primary access control system and an independent backup access control system. In addition, operational requirements for preventing a person from being in the radiation room while the source is exposed are contained in § 36.67, "Entry into and exit from the radiation room."

The door or barrier that serves as the primary access control system must have controls that would (1) prevent the source from being moved out of its shielded position if the door or barrier were open and (2) cause the source to return to its shielded position if the door or barrier were opened while the source was exposed.

The backup access control system must be able to detect entry while the source is exposed. If entry is detected, the system must (1) automatically cause the source to return to its shielded position and (2) activate audible and visible alarms.

In addition, the proposed rule would require a radiation monitor in the radiation room of panoramic irradiators to detect radiation when the source is indicated to be in the fully shielded position. The radiation monitor would have alarms and an interlock on the personnel access door. This is a new requirement not in the existing § 20.203(c)(6). The purpose is to provide an additional level of protection in case of some failure of the source movement mechanism combined with a failure of the operator to make the required radiation survey upon entry into the radiation room.

The phrase currently used in § 20.203(c)(6) concerning reduction of radiation levels upon entry is worded so that an individual could not receive "a dose in excess of 100 mrem in one hour." This requirement has been changed in § 36.23 to state that the time for the sources to return to the shielded position must be less than or equal to the time that it would take a person entering the radiation room to walk to the edge of the pool (wet-source-storage) or into the beam (dry-source-storage). This wording more directly states the intent of the requirement. If necessary, the licensee could use a time-delay mechanism to delay opening the door after unlocking it.

The access control requirements apply to each entrance of the radiation room of a panoramic irradiator whether intended for personnel access or intended only for product entrance or exit. Panoramic irradiators with a conveyor system could meet the requirement by providing clearances around the conveyor carriers that are too small to allow someone to pass through. The requirement is that the door or barrier must prevent inadvertent entry. The purpose of this requirement is to prevent a reasonably prudent person from carelessly, inattentively, or accidentally entering the radiation room while the source is exposed.

The access control section would require an independent backup access control system on panoramic irradiators. The backup system could use photo-electric cells in an entrance maze, pressure mats on the floor, or similar means of detecting a person entering the radiation room while the source is exposed. The purpose of the backup system is to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operational procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The system must also alert another person of the entry. That person must be prepared to render or summon assistance. This provision prevents the operation of the panoramic irradiator without a second person being available to render or summon assistance.

The section explicitly states that the irradiator may not operate if the requirements of the section are not met.

This section also contains requirements for underwater irradiators. For example, the pool must be within an area surrounded by a personnel access barrier with an intrusion alarm when the facility is not operating.

§ 36.25 Shielding.

This section specifies maximum dose rates outside the radiation room of a panoramic irradiator and maximum dose rates over pools. The maximum dose rate of 2 millirems (0.00002 sievert) per hour is considered both practical to achieve and low enough to permit continuous occupancy by workers anywhere outside the shielding. The value was previously specified in the Irradiator Licensing Guide. Two millirems (0.00002 sievert) in an hour is the maximum radiation dose allowed by 10 CFR Part 20 in an unrestricted area for one-hour time periods.

For measurements to determine compliance with the requirement, the rule specifies 30 cm as the distance from the shield to the detector. This distance is selected because at that distance the dose would be a whole-body-dose and not a dose occurring in a small crevice or opening. The maximum area of 100 square centimeters for averaging dose effectively establishes a maximum detector size.

The section does not require that the NRC approve the shield design. Instead the regulations contain only a performance requirement on maximum dose rate outside the shield. The requirements apply to the completed shield.

It is possible that, in its first test, some part of the shield might fail to meet the performance requirement. If this occurs, the effect of the regulation is to require that the shielding deficiency must be corrected before operation of the facility can begin.

The section also specifies maximum radiation dose levels outside the shielding of dry-source-storage irradiators. The levels are considered practical and adequate to maintain doses to workers as low as is reasonably achievable. The levels were specified in the ANSI Category II Standard.

§ 36.27 Fire protection.

The heat generated by irradiation can cause combustible materials to catch fire. The requirements in this section are intended to prevent fires, detect fires if they occur, and allow fires to be extinguished without entry of personnel into the radiation room.

The requirements for fire detection and sprinklers or other systems to extinguish a fire at a panoramic irradiator were taken from the ANSI Category IV Standard. The fire extinguishing system does not have to be automatically activated.

Overall, fires are considered to present relatively little hazard to irradiators. Radiation rooms use little combustible material in their construction, and irradiation of highly flammable and explosive materials is prohibited (by § 36.69) without NRC specific approval. The products being irradiated are likely to be combustible, but there is not likely to be present a sufficient quantity of combustible material to result in prolonged high-temperature fires. Thus, the temperature reached is not likely to be high enough to melt or rupture the stainless steel capsules containing the radioactive sources. Therefore, the NRC would not expect a fire to cause loss of encapsulation even if the fire were not controlled and the sources were not dropped into a source-storage pool.

The fire extinguishing system is required because a fire could disable the access control system or could prevent the source from being shielded, thereby lowering the margin of safety. The fire extinguishing system must be operable without entry into the room. During a fire there would be no means of assuring that the access control systems and source position indicators are operating properly. Also, no one could be sure that the mechanism that returns the source to the shielded position had operated properly.

§ 36.29 Radiation monitors.

This section requires a radiation monitor to detect radioactive sources on the exiting product. The requirement was taken from 10 CFR 20.203(c)(6)(viii) and from the ANSI Category IV Standard. The purpose of this requirement is to detect sources that have somehow become loose from the source rack and are being carried out with the product and to stop them from being carried out of the radiation room.

This section also requires radiation measurements to detect leaking sources at pool irradiators and a monitor over the pool at underwater irradiators.

§ 36.31 Control of source movement.

This section contains the requirements for the control of source movement at a panoramic irradiator. Generally, the requirements are taken from the ANSI Category IV Standard.

§ 36.33 Irradiator pools.

This section contains requirements for irradiator pools.

For facilities licensed for the first time after the effective date of the final rule, the proposed rule would require either: (1) a stainless steel pool liner (or a liner metallurgically compatible with other components in the pool), or (2) construction so there is a low likelihood of substantial leakage, a surface designed to facilitate decontamination, and a means to safely store sources during repairs of pool walls. Backfitting is not required because modifying an existing pool would be prohibitively expensive and the gain in safety would be only marginal. Older facilities sometimes used concrete pools, sometimes lined with tiles, but usually without stainless steel liners or other ways to reduce the likelihood of leakage. The ANSI Category IV Standard does not require pool liners. However, unlined pools have leaked from time to time. The purpose of the requirement is to reduce the likelihood of pool leakage. It is desirable to control pool leakage in case the pool water becomes contaminated due to a leaking source. If the pool were leaking and a source leaked at the same time, a potential for worker and public exposure would exist, and it could be difficult and expensive to decontaminate the facility.

The NRC considered whether to require that pools have a more sensitive means of detecting water leakage from pools than monitoring water loss. Examples of more sensitive means might be a double lined pool or channels at welds with a means to detect water leaking from the pool. The NRC decided that it would be adequate to monitor pool water loss and unnecessary to have a more sensitive means of detecting leaks. There are two reasons for wanting to avoid leaks. One reason is that a substantial lowering of the pool water level would cause radiation levels at the pool surface to increase. The increased radiation levels are not a safety concern unless large volumes of water are lost. A system to monitor water loss could easily detect leaks before a safety hazard would result. The second reason to avoid leaks is to prevent the escape of radioactive material that might be in the pool water. In normal circumstances a pool leak is not a safety concern because pool water contains little or no radioactive material. If a source leak occurred while the pool had a small undetected leak, some contaminated water could escape from the pool. Experience has shown that pool contamination levels do not get very high so that the escape of a small amount of pool water into the ground is not a significant safety concern. Therefore the NRC does not consider that a pool leak system more sensitive than that required in the proposed rule is necessary.

The proposed rule would require both a means to replenish water that is lost and a low-water level indicator. The means to replenish the water does not have to be automatic. An indicator is needed even if the replenishment is automatic in case the system to replenish the water does not work. The requirement for a cover or railing to prevent workers from falling into the pool is taken from the ANSI Category IV Standard.

The proposed rule requires a water purification system. The purposes of the purification system are to prevent the pool water from becoming cloudy and reducing visibility and from becoming corrosive and thus corroding the stainless steel sealed sources or the source rack. If the water is clear, it should be possible to visually inspect the sources and the source rack. Thus, the sources and the source rack could be inspected for damage, and the location of the sources could be checked to make sure they are in their proper positions.

Requirements on the design of poles and long-handled tools to be used in irradiator pools would be imposed to prevent radiation "streaming."

Hollow and low density poles and tools must have either vent holes to allow shielding water to enter or sufficient bends to prevent radiation levels at handling areas of the tools from exceeding 2 millirems (0.00002 sievert) per hour.

§ 36.35 Source rack protection.

This section would require a barrier to prevent the moving products from hitting the source rack or the mechanism that raises and lowers the sources.

§ 36.37 Power failures.

This section would require automatic source retraction for loss of power for more than 10 seconds at a panoramic irradiator. The retraction would have to be accomplished without outside power. Backup power is not required as long as loss of power will cause the source to return to its shielded position, for example, if the source would return to the shielded position due to gravity. The requirement is taken from the ANSI Category IV Standard.

§ 36.39 Design requirements.

This section describes facility design requirements. The purpose of the requirements is to make sure the design is adequate before construction starts.

Included in the section is a requirement that all irradiators must have shielding walls constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete. This provides protection against moderate earthquakes, tornadoes, and other hazards.

In addition, irradiators built in seismic areas must have radiation shields designed to retain their integrity in an earthquake. Seismic areas are defined in § 36.2 as any area where the probability of a horizontal acceleration in rock exceeding 0.3 times the acceleration of gravity in 250 years is greater than 10 percent. The value of 0.3 comes from the ANSI Category IV Standard. The 250-year frequency is different from the frequency in the standard, which specifies a 50-year frequency. The NRC selected 250 years to include some areas that could have a large earthquake even if large earthquakes would seldom occur.

Maps of the United States showing these seismic areas are published by the U.S. Geological Survey (see S. T. Algermissen, et al., "Probabilistic Estimates of Maximum Acceleration and Velocity in Rock in the Contiguous United States," United States Department of the Interior, Geological Survey, Open-File Report 82-1033, 1982. This report may be purchased for $24.50 from: U.S. Geological Survey, Books and Report Sales, Box 25425, Denver, Colorado 80224. Prepayment is required).

Studies of irradiator shield designs have shown that the shields are inherently able to withstand large earthquakes. ANSI determined that reinforced concrete shields constructed to meet generally accepted building code requirements for reinforced concrete (for example ACI Standard 318-77, "Building Code Requirements for Reinforced Concrete," available for purchase from the American Concrete Institute, Box 19150, Redford Station, Detroit, Michigan 48219) can withstand an earthquake with an acceleration in rock of 0.3 times the acceleration of gravity plus any multiplication of acceleration that would occur due to soil. Therefore, there are no seismic requirements for irradiators located where accelerations in rock are not likely to exceed 0.3 times the acceleration of gravity.

The proposed rule would intend that shield walls in seismic areas would have to retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources. Local building codes in seismic areas are likely to specify requirements for things such as: spacing of reinforcing bars; how to tie reinforcing bars together; preferred arrangements for reinforcing bars; and requirements for joining reinforcing bars to floor slabs. If local building codes do not contain seismic requirements, "other appropriate sources" could include: American Concrete Institute Standard ACI 318, "Building Code Requirements for Reinforced Concrete, Appendix A, Special Provisions for Seismic Design," (available for purchase from the American Concrete Institute, Box 19150, Redford Station, Detroit, Michigan 48219). The NRC solicits comments, in particular, on this requirement.

The NRC also considered whether there should be design requirements for shield integrity against tornadoes. The NRC decided that there was no need for special design requirements because the shielding by its very nature (about six feet thick reinforced concrete) is inherently resistant to tornadoes.

§ 36.41 Construction control.

This section describes checks that the licensee must make before sources are loaded to be sure the facility was constructed as designed and that alarms, controls, interlocks, and instruments operate properly.

SUBPART D - OPERATION OF THE IRRADIATOR

§ 36.51 Training.

This section contains safety training requirements for irradiator operators. The emphasis is on practical knowledge directly necessary for the job rather than theoretical principles.

The subjects that an irradiator operator must be trained in are:

(1) The fundamentals of radiation protection as they apply to irradiators. The goal here is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.

(2) The requirements of Parts 19 and 36 of NRC regulations. The operator is not expected to be an expert on NRC regulations or to be able to determine whether a given procedure is adequate to meet NRC regulations. Instead, operators should be instructed on NRC requirements that are directly applicable to their responsibilities.

(3) The operation of the irradiator. The objective is not to make the individual an engineer, but to help the person understand the operating and emergency procedures.

(4) Licensee operating and emergency procedures that the individual will perform. This is the most important part of the training because the safe operation of the irradiator depends on the procedures being followed correctly. The objective is that the operator be able to correctly perform the procedures that he will be expected to perform. The training does not have to include procedures that the individual will not perform. For example, if the individual will not perform leak tests, the individual need not be trained in the procedure.

(5) Case histories of accidents and problems involving irradiators similar to those to be used by the individual. The individual should be taught about situations that could lead to trouble. Instruction material on accidents is often difficult to obtain. However, the previously mentioned NRC Report NUREG-1345, "Review of Events at Large Pool-Type Irradiators," should provide some relevant information.

In order to provide flexibility, the proposed rule intentionally does not specify how many hours of classroom training and on-the-job training are necessary to become an irradiator operator. A license applicant would describe the training program in its license application. The Irradiator Licensing Guide suggests 40 hours of classroom training and one month of on-the-job training.

The proposed rule also does not specify the training or qualifications needed by the radiation safety officer. This is also to allow flexibility. The license applicant would describe the minimum training, experience and qualifications of the radiation safety officer in its license application. A review would then be conducted on a case-by-case basis. The Irradiator Licensing Guide suggests guidelines for basic radiation protection training and on-the-job training for the radiation safety officer.

The NRC considered whether the proposed regulation should include training requirements for other types of workers such as package handlers and maintenance workers. The NRC concluded that the general training requirements specified in § 19.12, "Instructions to workers," are suitable for other types of workers, and therefore additional or more specific requirements are not necessary.

§ 36.53 Operating and emergency procedures.

This section lists the specific operating and emergency procedures that a licensee must have. The section also lists requirements for changing these procedures. Operators must be instructed in a changed procedure before it may be put into use. Changes in procedures that do not reduce the safety of the facility and are consistent with the outline submitted in the license application do not have to be approved by NRC nor must changed procedures of this type be reported to NRC. However, documentation on the changes must be retained for inspection by NRC (§ 36.81(d)).

§ 36.55 Personnel monitoring.

This section contains the personnel monitoring requirements for irradiator operators and other people entering the radiation room of a panoramic irradiator.

It could be argued that this section is not needed because the requirements in § 20.202, "Personnel monitoring," are adequate for irradiators. Section 20.202 requires personnel dosimeters for anyone likely to receive in excess of 25 percent of an applicable dose limit. At irradiators, as currently designed and operated, no operator is likely to exceed 25 percent of a dose limit. Therefore, § 20.202 does not require any use of dosimeters at irradiators. Nevertheless, the NRC wants operators to use dosimeters so that there is a dose measurement in case someone enters the radiation room while the source is exposed, even though entry is not likely. Therefore, the NRC considers it desirable to impose dosimeter requirements in excess of those in § 20.202.

Film badges and thermoluminescent dosimeters (TLDs) must be suitable for detecting high energy photons in the normal and accident dose ranges. Paragraph (c) of § 20.202, "Personnel monitoring," requires that film badges and TLDs must be processed by an accredited processor for the types of radiation that would be encountered. For irradiators, the radiation type is high energy photons in both the normal and accident dose ranges. In the "American National Standard for Dosimetry-Personnel Dosimetry Performance - Criteria for Testing," ANSI N13.11-1983, the normal dose range is 0.03 to 10 rems (0.0003 to 0.1 sievert) and the accident dose range is 10 to 500 rads (0.1 to 5 grays).

Pocket dosimeters, which could be worn by people other than operators, need not be calibrated because their purpose is primarily to indicate either no dose or a very large (but not quantitatively measured) dose.

§ 36.57 Radiation surveys.

This section lists the radiation surveys that must be done and specifies how often they must be done.

An annual survey instrument calibration is in accordance with the recommendations of American National Standard N323-1978, "Radiation Protection Instrumentation Test and Calibration." Modern survey meters are considered reliable and stable, making more frequent calibrations unnecessary.

The accuracy requirement for survey meter calibration is ±20 percent. In the past, the NRC has specified accuracy requirements of ±10 percent for some uses and ±20 percent for other uses. Modern survey meters can fairly easily be calibrated to be accurate to ±20 percent on all scales over their entire range of dose rates. On the other hand, calibrations to ±10 percent are often difficult to obtain and sometimes require the use of calibration charts for correcting the meter reading. The charts make the survey meter more complicated to use and increase the likelihood of errors in reading the meter. In determining the accuracy requirement for survey meter calibration, the key question, therefore, is when is an accuracy of ±10 percent needed, and when is an accuracy of ±20 percent adequate to accomplish the purposes of the measurement? The discussion below answers this question.

At an irradiator, the most important and frequent use of the radiation survey meter is to confirm that the source is shielded when entry into the radiation room is made. The survey meter is used to determine whether dose rates in the entrance maze are the normally-occurring very low dose rates or are many times higher than normal. For this purpose, a survey meter accurate to ±20 percent is acceptable.

Another use of the survey meter is to verify that the dose rates outside the shielding wall and at the restricted area boundary are in compliance with NRC limits. These measurements are done infrequently. The most important purpose of these measurements is to check that the shielding contains no voids or poorly designed penetrations. Another purpose is to verify that limits on dose rates are not exceeded. A quantitative measurement is needed rather than a qualitative yes/no indication to verify that dose rate limits are not exceeded. However, at most facilities it has been found that the actual dose rates outside shield walls and at restricted area boundaries are far below the regulatory limits. Therefore, a highly accurate quantitative measurement is not normally needed. Accuracy of ±20 percent is normally adequate to verify compliance.

It is possible that a measured dose rate might be very close to a limit. In those special situations, the licensee might need a measurement more accurate than ±20 percent. Thus, the accuracy requirement of ±20 percent in the regulations does not mean that the licensee would never need a measurement more accurate than ±20 percent. Rather, the regulation means that the ordinary routine periodic calibration need only be within ±20 percent. Most facilities would never need a more accurate calibration, but others at some time might.

In summary, the NRC position on survey meter calibration is that accuracy of ±20 percent is adequate for most routine measurements around irradiators and, therefore, adequate for routine gamma survey meter calibration. On the other hand, certain special measurements may require more accuracy to demonstrate compliance with regulatory limits. Thus, in special instances at specific parts of the dose rate range and for specific gamma ray energies, more accuracy may be required. Those calibrations would be done specifically for the measurement to be made (dose rate range, gamma energy, and geometry).

Very high range survey meters (those that could measure dose rates in the radiation room while the source is exposed) are not required because the NRC could not see a need for this type of measurement. Normal range survey meters are adequate to determine whether sources are fully shielded. Radiation rooms should not be entered if the sources are known to be exposed.

Section 36.57 also requires that deionizing resins be monitored for radioactivity before release to unrestricted areas. The NRC considered prohibiting the return of deionizing resins to suppliers for recycling. Irradiator sources could have small amounts of radioactive contamination on their surfaces due to manufacturing processes. Some of this contamination could be collected in the resins. Thus, even resins that have no detectable radioactivity could contain small amounts of radioactivity. If mixed with other resins, the dilution would be that much larger. Thus, concentrations in the waste stream from regeneration, if any, would be far below the 10 CFR Part 20, Appendix B, effluent limits.

An approach to monitoring very low quantities using survey instruments has been used for medical waste (see Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," Appendix R.) Calculations of dose rates show that concentrations of radioactivity in resins would have to be below a small fraction of the effluent limits for water in 10 CFR Part 20, Appendix B. If the resins were regenerated, the amount of backwash solution that would remove the radioactive material from the resins would dilute the concentration of the material by at least a factor of 20, based on the volumes of water used in regeneration. Thus, the proposed requirement, instead of prohibiting the return of resins, is that resins must be monitored before release in an area with a background radiation level less than 0.05 millirem (0.0005 millisievert) per hour. Radiation levels must not be detectable above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour. Most G.M. survey meters would be adequate. The Commission considers this approach adequate to protect public health and safety.

§ 36.59 Detection of leaking or contaminated sources.

This section describes how and when leak testing of sealed sources must be done. There are different requirements for dry-source-storage and wet-source-storage sources.

U.S. Department of Transportation regulations require that all sources, dry-storage and wet-storage, be individually leak tested in order to be shipped. Leak tests are normally done by the manufacturer. The licensee must obtain a certification from the manufacturer indicating that the leak testing has been done.

The requirements for dry-source-storage sources are similar to those contained in the second proposed Revision 1 to Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Self-Contained Dry Source - Storage Irradiators."

A level of 0.005 microcurie (185 becquerels) on a dry wipe is the level of contamination considered to indicate a leaking or contaminated source. Traditionally the level for irradiator sources has been 0.05 microcurie (1850 becquerels), and that value is used in the Irradiator Licensing Guide and the ANSI Category IV Standard. The reason for the change is that previous manufacturing processes caused considerable surface contamination and irradiator sources could not be cleaned to below 0.05 microcurie (1850 becquerels). Also, detection of quantities below 0.05 microcurie (1850 becquerels) was difficult. However, source manufacturing techniques have improved so that sources are now cleaner and have less surface contamination, and instruments have improved so it is possible to detect 0.005 microcurie (185 becquerels) of activity. Thus, the NRC believes it is now practical to meet a contamination level of 0.005 microcurie (185 becquerels).

The 0.005-microcurie (185-becquerel) quantity serves to alert the licensee that there might be a problem. Detection of 0.005 microcurie (185 becquerels) shows a need for further evaluation. The quantity is not justified on specific assumptions of risk. It is a sufficiently small quantity that it presents very low levels of risk, but it is measurable. It is not used in the regulatory program or by industry as a limit on allowable leakage rate. If any leakage is discovered, the source should be removed from service. Further, although termed a "leak test," the usual test performed by users of sealed sources is a "contamination test." A positive indication does not necessarily indicate leakage. It could indicate surface contamination deposited during the manufacturing process.

Leak testing of sources used in pools cannot be done by wipe-testing the sources. The proposed rule would require that radioactive contamination be monitored each day the irradiator operates either by on-line monitoring of a pool water circulating system or by analysis of pool water. If on-line monitoring is used, detection of above normal radiation would have to automatically cause the water purification system to shut off. The purpose of the shut off is to prevent high radiation dose rates in the water purification system.

The NRC also considered whether water purification systems should be shielded. The NRC believes that high dose rates might be a possibility if flow were not shut off, but does not believe that the normal water purification systems are always appropriate for cleaning up a leak if the leak were large. For a large leak, special equipment might be more suitable. Therefore, the rule requires a shut off of the system if a high radiation level is detected rather than requiring shielding. If emergency procedures allow the normal water purification system to be used, temporary shielding appropriate for the specific situation could be used as specified in the emergency procedures.

Section 36.61(a)(3) requires a check of the operability of the radiation monitor on the pool water purification system with a radiation check source. The monitor is used to detect radiation levels that are above normal rather than to make quantitative measurements of doses. For this purpose simple operability checks are appropriate.

§ 36.61 Operational inspection and maintenance.

Operational inspection and maintenance includes the items that the licensee must periodically check to assure proper operation of the facility. The frequency of checks is not stated in the regulations because the frequency will be site-specific depending on the design of the facility. The frequency of checks must be described in the license application, as required in § 36.13(h).

The NRC considered whether the frequency of checks on the access control system, probably the most important safety feature of an irradiator, should be specified in the regulations. The NRC concluded that there is too much variation in irradiator design and operation to specify a frequency that would apply in all cases. Therefore the NRC decided that the applicant should propose a frequency in the license application. This approach allows flexibility and at the same time allows the NRC to approve a frequency of checks that it considers adequate for a specific facility. Guidance on criteria for generally applicable frequencies for checks will be offered in a regulatory guide.

§ 36.63 Pool water purity.

This section would require that the water purification systems in irradiator pools be run each day the irradiator operates or at least monthly during shutdowns. Purification systems do not have to be run continuously and do not have to be run the entire time the irradiator operates, although many licensees may have to run the system continuously to maintain pool water conductivity near 10 microsiemens (micromhos) conductivity. If water conductivity exceeds 10 microsiemens (micromhos) per centimeter, the system must be run until the water conductivity is below

10 microsiemens (micromhos). The purpose of maintaining clean water is to reduce corrosion of the sources and to keep the water clear. Clear water is desirable so that the sources and source rack can be inspected visually to check their condition. The NRC considers conductivity to be the best method of checking the purity of the water in irradiator pools.

With regard to corrosion, the operating environment is as follows: The sealed sources used in irradiators are most commonly clad in 316L stainless steel. Sometimes 321 stainless steel is used. While in the pool, the temperatures of the sources are generally 80 to 90°F. In air the temperature of the sources can run as high as 300 to 400°F. The sources used with conveyor systems are typically cycled in and out of the water several times a day but sometimes more often. Batch irradiation sources may be cycled several dozen times a day.

Under these circumstances, generalized surface corrosion should be minimal and not of concern. The type of corrosion of potential concern might be chloride-induced stress corrosion cracking. Although inspection of sources that have been used in irradiators for long periods have revealed virtually no chloride-induced stress corrosion cracking, it is desirable as a precaution to operate the sources in a relatively low corrosion environment. Maintaining water conductivity over the long term in the vicinity of 10 microsiemens (micromhos) per centimeter should provide a low corrosion environment, although considerably higher levels could be tolerated for fairly long times with no threat to safety. Comments on this approach to water purity are specifically requested.

§ 36.65 Attendance during operation.

This section describes how an irradiator must be attended during operation.

§ 36.67 Entering and leaving the radiation room.

This section describes the requirements for first entering the radiation room of a panoramic irradiator after an irradiation and for leaving the radiation room and locking it up before an irradiation. It also covers entry to the pool area of an underwater irradiator during a power failure.

§ 36.69 Irradiation of explosive or highly flammable materials.

The proposed rule would prohibit the irradiation of explosive materials or more than traces of highly flammable materials unless the licensee has prior written authorization from the NRC. The reason for these prohibitions is that irradiation can cause chemical reactions that would cause a fire or explosion of highly flammable or explosive materials.

Highly flammable materials are those with a flash point temperature below 140°F. The flash point of 140°F was taken from the ANSI Category IV Standard. The flash point is the lowest temperature at which a substance will volatilize to yield sufficient vapor to form a flammable gaseous mixture with air, demonstrable through the production of a flash on contact with a small open flame. The flash points of common substances are tabulated in various engineering handbooks and manuals, for example, "Accident Prevention Manual for Industrial Operations," National Safety Council, Chicago, 1974, and "Handbook of Laboratory Safety," Second edition, Chemical Rubber Company, 1971. Examples of common flammable materials with a flash point below 140°F are: acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, turpentine, and any flammable gas.

SUBPART E - RECORDS AND REPORTS

§ 36.81 Records and retention periods.

The records that a licensee must maintain and their retention periods are specified in a single section, § 36.81, for ease in implementation. Thus, the licensee has a convenient "check list" to use to make sure that all records required by Part 36 are kept.

The purpose of requiring the licensee to maintain an inventory of all sources possessed is to assure that the licensee is able to account for all sources in its possession. The activity of the sources is the activity when they were received. There is no safety need to correct for radioactive decay. Decay corrections would greatly complicate record keeping without contributing to the objective of the requirement, which is that the licensee be able to account for each of the sources that it received.

§ 36.83 Reports.

This section lists all reports that are required by Part 36. All reports required by Part 36 are included in a single section for ease of use by licensees.

Paragraph (a) requires reports on lost or stolen sources, radiation overexposures, excessive levels or concentrations of radiation, and damage to or loss of the ability to operate the facility due to events involving radioactive material. The paragraph references the event reporting requirements of Part 20. The NRC is currently considering changes in the Part 20 reporting requirements. If Part 20 is amended, corresponding changes would be made in the Part 36 reporting requirements.

Paragraph (b) requires reports to individuals on radiation exposure as required by Part 19. This paragraph likewise places no new or different reporting requirements on licensees.

Paragraph (c) requires reports on leaking sources. The requirement is similar to the requirement now generally imposed under a license condition. The reporting period would be 5 days from the time of discovering the leak to allow for completeness in the reports, especially with regard to corrective actions.

Paragraph (d) requires reports within 5 days of other events with possible safety significance if not reported under paragraphs (a), (b), or (c) even though they may involve no violations of the regulations or license conditions. The purpose of the reports is to make NRC aware of problems that should be reported to other licensees because of their safety significance.

The 5-day reporting period in paragraphs (c) and (d) represents a balance between allowing sufficient time to collect, analyze, and writeup the necessary information and requiring that the report be submitted before recall of events fades.

Reports submitted generally would be subject to public disclosure in accordance with 10 CFR 2.790 and 10 CFR Part 9. The NRC was asked at a 1988 public meeting on irradiator safety whether proprietary information could be withheld from public disclosure. The NRC notes that 10 CFR 2.790 allows the NRC to withhold certain proprietary information (information of commercial value or "trade secrets") if, at the time of submittal of the report, the requirements for withholding the information are met (refer to 10 CFR 2.790(b)). Also, there are provisions in 10 CFR Part 9 for the NRC to withhold from public disclosure documents such as reports of radiation exposure to individuals and other personal records.

SUBPART F - ENFORCEMENT

§ 36.91 Violations.

This section is provided to inform licensees and the public that violations of the regulations may result in civil or criminal penalties.

VIII. Other Considerations

Certain other issues that were considered, including some that did not result in a requirement in the proposed rule, are discussed here.

A. Siting, zoning, land use, and building code requirements.

The NRC recognizes that most areas have zoning, land use, and building code requirements that would be applicable to irradiators. It is the responsibility of the applicant or licensee to assure that any proposed facility meets the zoning, land use, and building code requirements of the local and State governments having jurisdiction over the intended site. The NRC is not responsible for checking or assuring that State and local requirements have been met. The granting of an NRC license does not negate applicable local zoning, land use, or building requirements.

As a practical matter, this means that in order to meet State and local requirements, irradiators must be built in areas zoned for industrial facilities and not in residential areas. The applicant is advised to consult with the State and local governments before starting construction to assure that the facility would meet all State and local siting, zoning, and land use requirements. The NRC believes that an irradiator meeting the requirements in the new Part 36 would present no greater hazard or nuisance to its neighbors than other industrial facilities, because there is little likelihood of such an irradiator causing radiation exposures offsite in excess of NRC's Part 20 limits for unrestricted areas. Therefore, the NRC believes that, in general, irradiators can be located anywhere that local governments would permit an industrial facility to be built.

The NRC considered whether there should be siting requirements dealing with possible flooding of the irradiator or tidal waves. The NRC decided that no siting requirements with respect to possible flooding or tidal waves were necessary because flooding of the facility would not destroy the integrity of the shielding walls. Section 36.39 contains a requirement that shielding walls of panoramic irradiators must be constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete. With this type of construction, shielding and sources are well protected from being carried off in a flood or wave or damaged due to a flood or wave. Flooding of the facility would undoubtedly result in the need for a time-consuming and expensive repair of flood damage, but no particular radiation hazard would be involved during repair of flood damage because sources could be safely stored during the repairs. However, the proposed rule does include a requirement to have emergency procedures for coping with natural phenomena such as floods.

The NRC also considered whether seismic zones should be considered in siting requirements. The NRC decided that irradiators could be built in any area of the country, but that irradiators in seismic areas (as defined in § 36.2) would need shielding walls designed to withstand an earthquake.

If an irradiator were subject to a large earthquake, the potential damage of radiological significance would be to the integrity of its concrete shielding. Analyses of reinforced concrete irradiator shields designed to meet generally accepted building code requirements for reinforced concrete have shown they are inherently quite robust and resistant to damage from moderate-size earthquakes. To protect against large earthquakes, the NRC decided to include requirements that radiation shields in seismic areas be designed to retain their integrity after a large earthquake. Also, all irradiators must have an emergency procedure for earthquakes.

B. Use of cesium sources.

The two radionuclides generally used in gamma irradiators are cobalt-60 and cesium-137. Cobalt-60 is in the form of solid metal pellets that are relatively insoluble in water. Cesium-137, on the other hand, is generally encapsulated as a salt, cesium chloride, that is fairly soluble in water. Therefore, cesium-137 could be more dispersible than cobalt-60 if the sealed source leaked or was damaged. The question considered is should use of cesium-137 sources be permitted at all or permitted only with certain additional restrictions?

In 1988, a cesium-137 source at the RSI irradiator in Decatur, Georgia, leaked. No radiation exposures in excess of NRC's limits occurred, but the leak raised a question about the integrity of cesium-137 sources. As of July 1990, the cause of the leak is not known and is still being actively investigated. The NRC intends to reevaluate whether cesium-137 sources or sealed sources containing readily soluble or dispersible material are suitable for continued, long term use in irradators. The Commission specifically seeks public comment on this matter.

C. Seismic detection and resistance.

As a related issue to siting, NRC considered requirements for a seismic detector whose activation automatically causes the source to return to its fully shielded position. Such a requirement is contained in the ANSI Category IV Standard and is general practice. However, the detectors and source return mechanism would not improve the safety of large irradiators because shield walls must be designed to provide adequate shielding to protect workers and the general public in the event of a seismic event. Therefore, NRC concluded that such a requirement is not necessary to protect the public health and safety. Public comment is specifically requested on the need for a seismic detector and automatic source return mechanism.

D. Decommissioning.

The NRC considered whether special design requirements were needed to facilitate decommissioning of the facility. The NRC concluded that the requirements in the proposed rule are adequate to facilitate decommissioning. Normally, decommissioning is relatively simple, because there would be no radioactive contamination present in the facility. However, contamination could be present if leakage of the sources did occur. If leakage from sources did occur the periodic leak tests of dry-storage sources and monitoring of the pool water should allow early detection of the leakage before large amounts of material have leaked out. With early detection of leakage, a leaking source could be identified and isolated and pool cleanup would purify the water, removing contamination from the water. Thus, even if a leak occurred, there is little likelihood that contamination would reach high levels. In addition, the pool walls should prevent contamination from leaking out of the pool if contamination occurred. The pool must also have a liner or a surface relatively easy to decontaminate. Thus, an irradiator designed, licensed, and operated in accordance with the proposed rule should facilitate decontamination.

The subjects of financial assurance and recordkeeping for decommissioning are adequately dealt with in another section of the regulations (10 CFR 30.35) and thus are not included in Part 36.

E. Drop of source rack.

The NRC considered whether the drop of a source rack in the pool, caused by cable failure for example, might damage the sealed sources. Cobalt-60 sources are fairly light. Thus, in a drop the source rack would drop relatively slowly through the water and hit the pool bottom with little momentum. Cobalt-60 source racks are also generally designed with plates to slow the rate of descent. Thus, the sources are unlikely to be damaged as a result of a drop. Cesium-137 sources, on the other hand, are relatively heavy so that damage to a source as the result of a drop might be more likely.

However, in either case it was decided that it would be appropriate to analyze the consequences of a source rack drop and design the facility to prevent damage to the sources from a source rack drop. Therefore, the requirements on design include a requirement to analyze source rack drops and to design irradiators to prevent damage to the sealed sources.

F. Aircraft crashes.

The NRC considered whether there should be a prohibition from locating irradiators near airports because of risk of an irradiator release associated with an airplane crash. The NRC has concluded that a prohibition is not justified on safety grounds. The radioactive sources in an irradiator would be relatively protected from damage because they are typically contained within six-foot thick reinforced-concrete walls and are encapsulated in steel. However, if a source were damaged as a result of an airplane crash, large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack because the sources are not volatile. Since the radiological consequences of an airplane crash at an irradiator are not likely to be life-threatening, the radiological consequences are relatively unimportant compared to loss of life directly due to the crash itself. Thus, the presence of radioactive sources does not substantially change the probable consequences of an airplane crash. Therefore, NRC will allow the construction of an irradiator at any location at which local authorities would allow any type of industrial facility to be placed.

G. Pool water coolers.

The NRC considered whether pool water coolers should be required. Pool water coolers would lower water temperatures, reduce evaporation, and thus reduce humidity in the air of the radiation room. Lower humidities might result in somewhat less potential for corrosion of safety interlocks, product conveyor systems, and source raising and lowering mechanisms.

The NRC has decided not to require pool water coolers because there are many ways to avoid problems with high humidity and many smaller large irradiators do not have humidity problems. In addition, licensees would be required to maintain the facility to ensure compliance with the requirements of § 36.61 regardless of potential problems associated with high humidity.

H. Noxious gas control.

Large irradiators can produce ozone in concentrations exceeding those permitted by regulations of the Occupational Safety and Health Administration (OSHA) at 29 CFR 1910.1000, "Air Contaminants." Nitrogen oxides can also be produced although concentrations would not be expected to exceed OSHA's limits. To control these noxious gases, most radiation rooms are equipped with ventilation systems to exhaust the gases before personnel entry.

The NRC notes that OSHA regulates exposure to ozone and other noxious gases. However, if NRC personnel anticipate a problem during licensing or note a problem with ozone at an irradiator during inspection, the NRC will notify OSHA of the problem under the terms of a "Memorandum of Understanding Between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration; Worker Protection at NRC-Licensed Facilities," (53 FR 43590; October 31, 1988).

I. Issuance of a regulatory guide.

The NRC plans to develop a regulatory guide that will set forth the information that an irradiator license applicant should provide in its license application. Development of the guide will begin after public comments on the proposed rule have been reviewed. NRC intends to issue the guide in draft form for public comment before the final irradiator rule becomes effective. The guide would replace the draft irradiator licensing guide now in use.

IX. Agreement State Compatibility

The rule will be a matter of compatibility between the NRC and the Agreement States, thereby providing consistency between Federal and State safety requirements. With regard to basic radiation standards and definitions, as found in 10 CFR Part 20, which have been identified as strict matters of compatibility with respect to Agreement State regulations, in this area the Agreement States are expected to adopt essentially an identical standard. However, this rule, while being a matter of compatibility between the NRC and the Agreement States, is assigned a level of compatibility which would allow the Agreement States to adopt additional requirements based on local concerns or experience.

X. 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 action codifies in a rule the licensing requirements and policies on large irradiators. The proposed action is directed to improving the regulatory, licensing, inspection, and enforcement framework relating to these irradiators and will not affect the quality of the human environment. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies are available without charge upon written request from NRC Distribution Section, Office of Information Resources Management, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

XI. 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 these requirements.

Public reporting burden for this collection of information is estimated to average 750 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB-7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019, (3150-   ), Management and Budget, Washington, DC 20503.

XII. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis compares the costs and benefits of the requirements in the rule with current licensing requirements. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the analysis may be obtained without charge upon written request from: Distribution Section, Office of Information Resources Management, USNRC, Washington, DC 20555. Comments on the analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

XIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact upon a substantial number of small entities.

Currently, there are roughly 70 to 80 irradiators that are large irradiators, as defined by the proposed rule. Of those irradiators, there are currently 39 irradiators in the U.S. with sources greater than 250,000 curies (9×10^{15} becquerels) up to a maximum of 30,000,000 curies (1.1×10^{18} becquerels). Fifteen are licensed by NRC; 24 are licensed by Agreement States. Five additional irradiators are either under construction or proposed for construction in Agreement States. In addition, the NRC licenses 10 irradiators with sources smaller than 250,000 curies (9.25×10^{15} becquerels) that would be subject to the rule. The Agreement States probably have about twice as many of these "smaller" large irradiators. Thus, the total number of facilities that would ultimately be affected by the rule is roughly 70 to 80. All the irradiators use cobalt-60 except for four which use cesium-137. In addition to these irradiators, Congress has appropriated money to the U.S. Department of Energy to support the construction of six irradiators to be used in food processing. The food irradiators would be licensed by NRC or by Agreement States depending on their locations.

The NRC currently defines a small business as a business having less than $3.5 million in annual receipts. Some of the licensees that would be affected by this proposed rule might be small entities. However, the actual financial impacts of the proposed rule would be quite small. A survey of irradiators performed for the previously mentioned Regulatory Analysis indicated that, with minor exceptions, all surveyed licensees are in compliance with most of the requirements of the proposed rule. The proposed rule contains options such that the six licensees found not to be in full compliance with the proposed requirements could limit their incremental costs to $2,000 to $5,000, estimated as part of the previously mentioned Regulatory Analysis. These costs are not considered significant.

Thus, the proposed rule would not impose a significant economic impact on small entities, as defined in the Regulatory Flexibility Act of 1980, because the proposed requirements do not substantially differ from current licensing requirements.

Any small entity affected by 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 small entity'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 small entity as compared to that on a larger entity;

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

(d) The benefits that would be gained or the detriments that would be avoided by the licensee if the proposed regulations were modified as suggested; and

(e) How the regulation, as modified, would still adequately protect the public health and safety.

The comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTN: Docketing and Service Branch.

XIV. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and therefore that a backfit analysis is not required for this proposed rule. The proposed rule does not involve any provisions that would impose backfits as defined in 10 CFR 50.109 (a)(1).

XV. List of Subjects

10 CFR Part 19

Criminal penalty, Environmental protection, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Radiation protection, Reporting and recordkeeping requirements, Sex discrimination.

10 CFR Part 20

Byproduct material, Criminal penalty, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

10 CFR Part 30

Byproduct material, Criminal penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 36

Byproduct material, Criminal penalty, Nuclear materials, Reporting and recordkeeping requirements, Scientific equipment, Security measures.

10 CFR Part 40

Criminal penalty, Government contracts, Hazardous materials - transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 70

Criminal penalty, Hazardous materials - transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 170

Byproduct material, Non-payment penalty, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

XVI. Wording of the Proposed Amendments

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 10 CFR 36 and make the conforming amendments to 10 CFR Parts 19, 20, 21, 30, 40, 51, 70, and 170.

1. Part 36 is added to 10 CFR Chapter I to read as follows:

<u>Part 36 - Licenses and Radiation Safety Requirements for Large Irradiators</u>

<u>Subpart A - General Provisions</u>

Sec.

36.1 Purpose and scope.

36.2 Definitions.

36.5 Interpretations.

36.8 Information collection requirements: OMB approval.

<u>Subpart B - Specific Licensing Requirements</u>

36.11 Application for a specific license.

36.13 Specific licenses for large irradiators.

36.15 Start of construction.

36.17 Applications for exemptions.

36.19 Request for written statements.

Subpart C - Design and Performance Requirements for Large Irradiators

36.21 Design and performance criteria for sealed sources.

36.23 Access control.

36.25 Shielding.

36.27 Fire protection.

36.29 Radiation monitors.

36.31 Control of source movement.

36.33 Irradiator pools.

36.35 Source rack protection.

36.37 Power failures.

36.39 Design requirements.

36.41 Construction control.

Subpart D - Operation of Large Irradiators

36.51 Training.

36.53 Operating and emergency procedures.

36.55 Personnel monitoring.

36.57 Radiation surveys.

36.59 Detection of leaking or contaminated sources.

36.61 Operational inspection and maintenance.

36.63 Pool water purity.

36.65 Attendance during operation.

36.67 Entering and leaving the radiation room.

36.69 Irradiation of explosive or highly flammable materials.

Subpart E - Records and Reports

36.81 Records and retention periods.

36.83 Reports.

Subpart F - Enforcement

36.91 Violations.

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), all the provisions of this part are issued under Sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); Sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)) except the following provisions: 10 CFR §§ 36.5, 36.8, and 36.91.

Subpart A - General Provisions

§ 36.1 Purpose and scope.

(a) This part contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in large irradiators used to irradiate objects or materials. This part also contains radiation safety requirements for operating large irradiators. The requirements of this part are in addition to other requirements of this chapter. In particular, the provisions of Parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applications and licenses subject to this part.

(b) The regulations in this part apply to large panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to large underwater irradiators in which both the source and the product being irradiated are underwater. Large irradiators covered by the regulations in this part are those where radiation dose rates exceeding 500 rads (5 grays) per hour exist at one meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type.

(c) The regulations in this part do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of materials for nondestructive testing purposes), gauging, calibration of radiation detection instruments, or open-field (agricultural) irradiations.

§ 36.2 Definitions.

Annually means once each calendar year and at intervals not to exceed one year.

Doubly encapsulated sealed source means a sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator means a facility that uses radioactive sealed sources for the irradiation of objects or materials.

Irradiator operator means an individual authorized by the licensee to operate the irradiator.

Large irradiator means an irradiator where radiation dose rates exceeding 500 rads (5 grays) per hour exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Panoramic dry-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term also includes beam-type dry-source-storage irradiators in which the source remains partially shielded during irradiations.

Panoramic irradiator means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored underwater in a storage pool.

Pool irradiator means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room means a shielded room in which irradiations take place. Underwater irradiators are not considered to have radiation rooms.

Radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

Sealed source means any byproduct material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the byproduct material.

Seismic area means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.

Underwater irradiator means an irradiator in which the sources always remain shielded underwater and humans could not access the sealed sources and the space subject to irradiation without entering the pool.

§ 36.5 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission, other than a written interpretation by the General Counsel, will be recognized to be binding upon the Commission.

§ 36.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act of 1980 (44 U.S. 3501 et seq.). OMB has approved the information collection requirements contained in this part under control number 3150-____.

(b) The approved information collection requirements contained in this part appear in §§ 36.11, 36.13, 36.19, 36.21, 31.61, 36.69, 36.81, and 36.83.

(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph

(a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:

(1) In § 36.11, Form NRC-313 is approved under control number 3150-0120.

Subpart B - Specific Licensing Requirements

§ 36.11 Application for a specific license.

A person, as defined in § 30.4 of this chapter, may file an application for a specific license authorizing the use of sealed sources in a large irradiator on Form NRC 313, "Application for Material License." Each application for a license, other than a license exempted from Part 170 of this chapter, must be accompanied by the fee prescribed in § 170.31 of this chapter. The application must be sent to the appropriate NRC Regional Office listed in Appendix D to Part 20 of this chapter.

§ 36.13 Specific licenses for large irradiators.

The Commission will approve an application for a specific license for the use of licensed material in large irradiators if the applicant meets the requirements contained in this section.

(a) The applicant shall satisfy the general requirements specified in § 30.33 of this chapter and the requirements contained in this part.

(b) The applicant shall describe its training for irradiator operators that specifies the--

(1) Classroom training;

(2) On-the-job training;

(3) Safety reviews;

(4) Means the applicant will use to demonstrate the operator's knowledge and understanding of and ability to comply with the Commission's regulations and licensing requirements and the applicant's operating and emergency procedures; and

(5) Minimum qualifications of personnel who may provide training.

(c) The applicant shall submit an outline or summary of the written operating and emergency procedures listed in § 36.53. The outline or summary must include the important radiation safety aspects of the procedures.

(d) The applicant shall describe the radiation safety responsibilities and authorities of the radiation safety officer and other management personnel. The applicant shall also describe the qualifications required of the radiation safety officer.

(e) The applicant for a panoramic irradiator shall submit a description of the access control systems required by § 36.23, the radiation monitors required by § 36.29, and a diagram of the facility that shows the position of all required interlocks and radiation monitors.

(f) If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Commission. The description must include the--

(1) Instruments to be used;

(2) Methods of performing the analysis; and

(3) Pertinent experience of the individual who analyzes the samples.

(g) If licensee personnel are to load or unload sources, the applicant shall describe the qualifications of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization approved by the Commission or an Agreement State to load or unload irradiator sources.

(h) The applicant shall describe the operational inspection and maintenance program, including the frequency of the operational checks required by § 36.61.

§ 36.15 Start of construction.

The applicant shall not begin construction of a new facility prior to the issuance of a license for the facility. As used in this paragraph, the term "construction" includes the construction of any portion of the permanent facility on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse structures, and other similar tasks. Any activities undertaken prior to the issuance of a license must be entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Atomic Energy Act of 1954, as amended, and rules, regulations, and orders promulgated pursuant thereto.

§ 36.17 Applications for exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant any exemptions from the requirements in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

§ 36.19 Request for written statements.

Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Commission's request, submit written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

Subpart C - Design and Performance Requirements for Large Irradiators

§ 36.21 Design and performance criteria for sealed sources.

(a) The licensee shall assure that sealed sources installed after (effective date of rule) meet the following requirements. A prototype of the sealed source must be leak tested and found leak-free after each of the following tests:

(1) Temperature. The test source must be held at -40°C for 20 minutes, 600°C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600°C to 20°C within 15 seconds.

(2) Pressure. The test source must be subjected to an external pressure of 290 pounds per square inch absolute.

(3) Impact. A 2 kg steel weight, 2.5 cm in diameter, must be dropped from a height of 1 m onto the test source.

(4) Vibration. The test source must be subjected to a vibration from 25 Hz to 500 Hz at 5 times the acceleration of gravity for 30 minutes.

(5) Puncture. A 50 gram weight and pin, 0.3 cm pin diameter, must be dropped from a height of 1 m onto the test source.

(6) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be

subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

(b) Sealed sources installed after (effective date of rule) must be doubly encapsulated and must have a certificate of registration as required by 10 CFR § 32.210.

§ 36.23 Access control.

(a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel while the sources are exposed. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return to their shielded position. The time for the sources to return to the shielded position must be less than or equal to the time that it would take a person starting to enter the radiation room to walk to the edge of the pool or into the beam (as applicable for irradiator type). The primary entry door must have a lock that is operated by the same key used to move the sources. The doors and barriers must not prevent any individual in the radiation room from leaving.

(b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed if the primary access control fails. Entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on site of the entry. That individual shall be trained and prepared to promptly render or summon assistance.

(c) A radiation monitor must be provided to detect the presence of radiation in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when the monitor detects high radiation levels, malfunctions, or is turned off. The monitor must generate audible and visible alarms if high radiation levels are detected when personnel entry is attempted. The monitor may be located in the entrance (normally referred to as the maze), but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

(f) Each radiation room of a panoramic irradiator must contain a control that allows the sources to move from the shielded position only if the control has been activated and the door or barrier to the radiation room has been subsequently closed within a preset time.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "Caution (or danger) radioactive material." Panoramic irradiators must also have a sign stating "High radiation area," but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) Panoramic irradiators may not operate if the requirements of this section are not met.

(j) Underwater irradiators must have a personnel access barrier around the pool that can be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to keys to the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

§ 36.25 Shielding.

(a) The radiation dose rate in areas that are accessible during operation of a panoramic irradiator must not exceed 2 millirems (0.00002 sievert) per hour at 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 cm. Areas where the radiation dose rate exceeds 2 millirems (0.00002 sievert) per hour must be locked to prevent access and not entered without written approval of the radiation safety officer.

(b) The radiation dose rate at 30 centimeters over the pool of a pool irradiator when the source is in the fully shielded position must not exceed 2 millirems (0.00002 sievert) per hour.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator must not exceed 2 millirems (0.00002 sievert) per hour and at 5 centimeters from the shield must not exceed 20 millirems (0.0002 sievert) per hour.

§ 36.27 Fire protection.

(a) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator must be equipped with a fire suppression or extinguishing system capable of extinguishing a fire without the entry of personnel into the room.

§ 36.29 Radiation monitors.

(a) A radiation monitor with an audible alarm must be located to detect loose radiation sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically before radiation from the source could cause any individual to receive a radiation dose exceeding 100 mrem. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed dry tube are exempt from the requirements of this paragraph.

(b) For pool irradiators, the licensee shall provide a means to detect radioactive contamination in pool water each day the irradiator operates. The means may be either an online radiation monitor on a pool water purification system or an analysis of pool water. If the licensee uses an online radiation monitor, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. If a false alarm due to background radiation occurs, the alarm set-point must be increased. Activation of the alarm must automatically cause the water purification system to shut off. However, the licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool as specifically provided in written emergency procedures.

(c) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

§ 36.31 Control of source movement.

(a) The mechanism that moves the sources of a panoramic irradiator must require a key to operate. Only one key may be in use at any time, and only operators or facility management may possess it. The lock must be designed so that the key may not be removed if the source is in an unshielded position. The door to the radiation room must require the same key.

(b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator must be clearly labeled as to its function.

(e) Controls for a panoramic irradiator must be color-coded or illuminated as follows: red represents emergency (stop buttons or lights) or critical information (source in use or malfunction); yellow or orange represents caution (no emergency but some function taking place to be aware of); green or blue represents normal or safe functioning or information (source not in use or function safe).

§ 36.33 Irradiator pools.

(a) For licenses initially issued after (effective date of rule) irradiator pools must either: (1) have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool, or (2) be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In both cases irradiators must include a means of safely storing the sources during repairs of the pool walls.

(b) For licenses initially issued after (effective date of rule) irradiator pools must have no penetrations more than 1 foot below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 1 foot below the normal low water level must have siphon breakers to prevent the syphoning of pool water lower that 1 foot below the normal low water level.

(c) A means must be provided to replenish water losses from the pool.

(d) An audible and a visible indicator must be provided to indicate if the pool water level falls below the normal low water level.

(e) Irradiator pools must be equipped with a purification system designed to maintain the water, under normal circumstances, at a level of conductance not exceeding 10 microsiemens per centimeter.

(f) A physical barrier, such as a railing or cover, must be used around irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If hollow poles, hollow long-handled tools, or tools with a density less than that of water are to be used in irradiator pools, they must have vent holes to allow water to enter them readily and fill voids to prevent radiation streaming or they must have sufficient bends so that the radiation levels on the handling areas of the tools do not exceed 2 millirems (0.00002 sievert) per hour.

§ 36.35 Source rack protection.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

§ 36.37 Power failures.

(a) If electrical power at a panoramic irradiator is lost for longer than 10 seconds, the sources must automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator must not be deactivated by a power failure.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter.

§ 36.39 Design requirements.

Irradiators whose construction begins after (effective date of rule) must meet the design requirements of this section. The requirements must be met prior to the start of the construction of the specific component, but do not have to be met prior to submitting a license application.

(a) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of § 36.25.

(b) Foundations. For panoramic irradiators, the licensee shall design the foundation to ensure it is adequate to support the weight of the facility considering soil characteristics.

(c) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that it has no penetrations that do not meet the requirements of § 36.33(b), and that metal components are metallurgically compatible with other components in the pool.

(d) Water handling system. For pool irradiators, the licensee shall design the water purification system to meet the requirements of § 36.33(e).

(e) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by § 36.29(a). The licensee shall verify that the product conveyor would stop before a source on the product conveyor could cause a radiation dose to any person to exceed 100 mrem (0.001 sievert). For pool irradiators, the licensee shall verify that the radiation monitor on the water purification system is located near the spot at which the highest radiation levels would be expected.

(f) Source rack. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it without causing radiation overexposures of personnel.

(g) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of § 36.23.

(h) Fire protection. For panoramic irradiators, the licensee shall verify that the design and locations of the smoke and heat detectors and extinguishing system are appropriate to detect and extinguish fires.

(i) Source return. For panoramic irradiators, the licensee shall verify that the source rack can be returned to the fully shielded position if offsite power is lost or if a component of the return mechanism fails. The design must allow for accomplishing the return without causing radiation overexposures of personnel.

(j) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as ACI Standard 318-77, "Building Code Requirements for Reinforced Concrete," or local building codes, if current.

§ 36.41 Construction control.

The requirements of this section must be met for irradiators whose construction begins after (effective date of the rule). The requirements of this section must be met prior to loading sources.

(a) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(b) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that penetrations and water intakes meet the requirements of § 36.33(b).

(d) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter and the water level alarms operate properly.

(e) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on product and the related alarms and interlocks required by § 36.29(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitor on the water purification system and the related alarms and interlocks required by § 36.29(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by § 36.29(c).

(f) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss-of-power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in § 36.35 are met for protection of the source racks and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

(g) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(h) Fire protection. For panoramic irradiators, the licensee shall verify the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall also verify the operability of the fire suppression or extinguishing system.

(i) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

(j) Computer systems. For panoramic irradiators, if a computer is used to control the access control system, the licensee shall demonstrate that the computer and the access control system operate as planned by attempting to defeat the access control system in as many ways as possible. The computer must have suitable security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

Subpart D - Operation of Large Irradiators

§ 36.51 Training.

(a) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

(1) The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, NRC dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to avoid contamination, the use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

(2) The requirements of Parts 19 and 36 of NRC regulations;

(3) The operation of the irradiator;

(4) Licensee operating and emergency procedures that the individual is responsible for performing; and

(5) Case histories of accidents or problems involving irradiators similar to those to be used by the individual.

(b) Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures.

(c) Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews and emergency drills, as described below, for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following--

(1) Changes in operating and emergency procedures since the last review, if any;

(2) Changes in regulations and license conditions since the last review, if any;

(3) NRC reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

(4) Relevant results of inspections of operator safety performance;

(5) Relevant results of the facility's operational quality assurance program; and

(6) A drill to practice an emergency or abnormal event procedure.

(e) The radiation safety officer or other management personnel shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator, and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the irradiator, but who have not received the training required for operators and the radiation safety officer, shall be trained and tested in precautions they should take to avoid radiation exposure, procedures or parts of procedures in § 36.53 that they are expected to perform or comply with, and their proper response to alarms required in this Part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by § 36.23(b), § 36.23(c), § 36.23(j), § 36.27(a), § 36.29(a), § 36.29(b), § 36.29(c), and § 36.33(d) shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

§ 36.53 Operating and emergency procedures.

(a) The licensee shall have and follow written operating procedures for--

(1) Operation of the irradiator, including entering and leaving the radiation room;

(2) Use of personnel dosimeters;

(3) Surveying the shielding of panoramic irradiators;

(4) Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

(5) Leak testing of sources;

(6) Operational inspection and maintenance checks required by § 36.61; and

(7) Loading, unloading, and repositioning sources, if the operations will be performed by the licensee.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for--

(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 water level alarm, an abnormal water loss, or leakage from the source storage pool;

(6) A loss of electrical power;

(7) A fire alarm or explosion in the radiation room;

(8) An alarm indicating unauthorized entry into radiation room, area around pool, or another alarmed area; and

(9) Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility.

(c) The licensee may revise operating and emergency procedures without Commission approval only if all of the following conditions are met:

(1) The revisions do not reduce the safety of the facility,

(2) The revisions are consistent with the outline or summary of procedures submitted with the license application,

(3) The revisions have been reviewed and approved by the radiation safety officer, and

(4) The users or operators are instructed and tested on the revised procedures before they are put into use.

§ 36.55 Personnel monitoring.

(a) Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD must be suitable for high energy photons in the normal and accident dose ranges. Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be replaced at least monthly, and TLDs must be replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people are required to wear dosimeters.

§ 36.57 Radiation surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded before the facility starts to operate. If the radiation levels specified in § 36.25 are exceeded, the shielding must be repaired to comply with the dose rate requirement in § 36.25 before operation of the facility may start.

(b) An additional radiation survey of the shielding must be performed after new sources are loaded and after any modifications that might increase dose rates are made to the radiation room shielding or structure.

(c) Portable radiation survey meters used to meet the requirements of paragraphs (a) and (b) of this section or the requirements of § 36.37(c) or § 36.67(a) must be calibrated at least annually to an accuracy of ±20 percent for the gamma energy of the sources in use. The calibration must be done at two points on each scale.

(d) Water from the irradiator pool or other potentially contaminated liquids must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in 10 CFR Part 20, Table II, Column 2 of Appendix B, "Concentrations in Air and Water above Natural Background." The lower limit of detection for the measurement must be below those concentrations.

(e) Resins to be released for regeneration or as nonradioactive waste must be monitored before release in an area with a background level less than 0.05 millirem (0.0005 millisievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter must be capable of detecting radiation levels of 0.05 millirem (0.0005 millisievert) per hour.

§ 36.59 Detection of leaking or contaminated sources.

(a) The licensee shall assure that each sealed source received by the licensee after (effective date of rule) has been tested for contamination within the 6 months prior to being shipped to the licensee.

(b) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed 6 months using a leak test kit or method approved by the Commission or an Agreement State. The analysis must be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material and must be performed by a person approved by the Commission or an Agreement State to perform the analysis.

(c) For pool irradiators, the pool water must be checked for contamination each day the irradiator operates. The check must be done by using an online radiation monitor on a pool water circulating system as described in § 36.29 (b) or by analysis of pool water. If a check for contamination is done by analysis of pool water, the results of the analysis must be available within 24 hours.

(d) If a leaking source is detected, the licensee shall remove the leaking source from service and have it decontaminated, repaired, or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the contamination check has been done. If any personnel are contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or product are found, the licensee shall have them decontaminated or disposed of by an NRC or Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall clean the pool until the contamination levels do not exceed the appropriate concentration in Table I, Column 2, Appendix B of Part 20.

§ 36.61 Operational inspection and maintenance.

(a) The licensee shall establish and implement an adequate operational inspection and maintenance program as described in license application (§ 36.13(h)). This program shall include, as a minimum, inspecting or checking each of the following aspects at the frequency specified in the license or license application:

(1) Operability of each aspect of the access control system required by § 36.23.

(2) Functioning of the source position indicator required by § 36.31(b).

(3) Operability of the radiation monitor on the pool water purification system using a radiation check source if this method is chosen to detect radioactive contamination in pool water (§ 36.29(b)),

(4) Pool conductivity as required by § 36.63(a).

(5) Operability of the product exit monitor required by § 36.29.

(6) Operability of the source return control required by § 36.31(c).

(7) Leak-tightness of the pool purification system (visual inspection).

(8) Operability of the heat and smoke detectors and extinguisher system required by § 36.27.

(9) Operability of the means of pool water replenishment required by § 36.33(c).

(10) Operability of the visible indicator of low pool water level required by § 36.33(d).

(11) Operability of the intrusion alarm required by § 36.23(j), if applicable.

(12) Functioning and wear on the system, mechanisms, and cables used to raise and lower sources.

(13) Condition of the barrier to prevent products from hitting the sources or source mechanism as required by § 36.35.

(14) Amount of water added to the pool to determine if the pool is leaking.

(15) Electrical wiring on required safety systems for radiation damage.

(b) Malfunctions and defects found during operational inspection and maintenance checks must be repaired without undue delay.

§ 36.63 Pool water purity.

(a) Pool water purification systems must be run each day the irradiator operates and at least monthly during shutdowns. The purification system must continue running until the conductivity of the pool water drops below 10 microsiemens per centimeter.

(b) The conductivity meter must be calibrated at least annually.

§ 36.65 Attendance during operation.

(a) Both an operator and at least one other individual trained and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on site whenever the irradiator is operated using an automatic product conveyor system.

(b) At a panoramic irradiator at which static irradiations (no movement of the product) are being performed, a person who has received the operator training and testing described in § 36.51(a) and (b) and the training on how to respond to alarms described in § 36.51(g) must be on site.

(c) At an underwater irradiator, an operator must be present whenever product is moved into or out of the pool. Static irradiations may be performed without a person present at the facility only if the personnel access barrier around the pool is locked to prevent unauthorized entry and all required alarms are operable.

§ 36.67 Entering and leaving the radiation room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall: (1) visually inspect the entire radiation room to verify that no one else is in it and (2) activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator shall not be entered without using an operable and calibrated radiation survey meter.

§ 36.69 Irradiation of explosive or highly flammable materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate in the license application or application for amendment that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(b) Irradiation of more than traces of highly flammable material (flash point below 140°F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Commission. Authorization will not be granted unless the licensee can demonstrate in the license application or application for amendment that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

Subpart E - Records and Reports

§ 36.81 Records and retention periods.

The licensee shall maintain the following records at the irradiator for the periods specified.

(a) A copy of the license application and the license authorizing the licensee to operate the facility until a new license is issued.

(b) Records of an individual's training, tests, and safety reviews provided to meet the requirements of § 36.51(a), (b), (c), (d), (f), and (g) until 3 years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by § 36.51(e) for 3 years after the evaluation.

(d) An up-to-date copy of the operating and emergency procedures required by § 36.53. Records of changes in procedures as required by § 36.53(c)(3) retained for 3 years from the date of the change.

(e) Film badge and TLD results required by § 36.55 until the Commission terminates the license.

(f) Records of radiation surveys required by § 36.57 for 3 years from the date of the survey.

(g) Records of radiation survey meter calibrations required by § 36.57 until 3 years from the date of calibration.

(h) Records of the results of leak tests required by § 36.59 for 3 years from the date of the leak test.

(i) Records of operational inspection and maintenance checks required by § 36.61 for 3 years.

(j) Records of malfunctions, defects, operating difficulties or irregularities, and operating problems for 3 years after repairs are completed.

(k) An inventory of all licensed sealed sources until the irradiator is decommissioned. The inventory must include for each sealed source: the date received; the person from whom it was received; the model of the source; the serial number of the source, if any; the radionuclide in the source; the activity of the source as supplied by the manufacturer; an up-to-date location of the source; information on leaking or damaged sources and any actions taken to decontaminate or repair those sources; the date source was disposed of, if applicable; and the person to whom the source was transferred, if applicable.

(l) Records on the design checks required by § 36.39 and the construction control checks as required by § 36.41 until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records of water added to the pool as required by § 36.61(a)(14) for three years.

(n) Records related to decommissioning of the irradiator as required by § 30.35(g).

§ 36.83 Reports.

(a) The licensee shall report to the Commission --

(1) The theft or loss of radioactive material as required by 10 CFR § 20.402; and

(2) Events involving radioactive material possessed by the licensee that may have caused or threaten to cause radiation overexposures, excessive concentrations or levels of radiation, loss of one day or more of

operation of the facility, or property damage in excess of $2000 as required by 10 CFR §§ 20.403 or 20.405.

(b) The licensee shall notify individuals of their exposure to radiation or radioactive material as required by 10 CFR § 19.13.

(c) The licensee shall report, in writing, leaking sources, damaged sources, and pool water contaminated in excess of the concentrations in Table 1, Column 2 of Appendix B to 10 CFR Part 20 to the appropriate NRC Regional Office listed in Appendix D to Part 20 of this chapter within 5 days of discovering the contamination. The report must describe the source involved if known, the extent of the leakage or contamination, the cause or circumstances leading to the leak or contamination to the extent that they are known, and corrective actions taken up to the time the report is made.

(d) The licensee shall report within 5 days in writing to the appropriate NRC Regional Office listed in Appendix D of 10 CFR Part 20 the following events if not reported under paragraphs (a) or (c) of this section:

(1) Sources stuck in an unshielded position.

(2) Fire or explosion in a radiation room.

(3) Damage to source racks.

(4) Failure of the cable or drive mechanism used to move the source racks.

(5) Inoperability of the access control system.

(6) Detection of radiation by the product exit portal monitor.

(7) Abnormal or unusual radioactive contamination.

(8) Structural damage to the pool liner or walls.

(9) Abnormal water loss or leakage from the source storage pool.

(e) Reports must describe the event, what caused it (to the extent known), and corrective actions to prevent recurrence taken up to the time the report is made.

Subpart F - Enforcement

§ 36.91 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of this part.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed for violation of this part.

(c) Any person who willfully violates any provision of this part issued under section 161b., i., or o. of the Atomic Energy Act of 1954, as amended, or the provisions cited in the authority citation at the beginning of this part may be guilty of a crime and, upon conviction, be punished by fine or imprisonment, or both, as provided by law.

PART 19 - NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

2. The authority citation for Part 19 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 19.2 [Amended]

3. Section 19.2 is amended by changing "35" to "36."

§ 19.3 [Amended]

4. Section 19.3(d) is amended by changing "35" to "36" in the first sentence.

PART 20 - STANDARDS FOR PROTECTION AGAINST RADIATION

5. The authority citation for Part 20 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 20.2 [Amended]

6. Section 20.2 is amended by changing "35" to "36."

§ 20.3 [Amended]

7. Section 20.3(a)(9) is amended by changing "35" to "36."

§ 20.203 [Amended]

8. In § 20.203, paragraphs (c)(6) and (c)(7) are removed.

PART 30 - RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

9. The authority citation for Part 30 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 as amended (42 U.S.C. 5841)* * *.

§ 30.4 [Amended]

10. In § 30.4, the definition of "License", is amended by changing "35" to "36."

§ 30.5 [Amended]

11. Section 30.5 is amended by changing "35" to "36."

§ 30.6 [Amended]

12. In § 30.6, paragraphs (a) and (b)(1) are amended by changing "35" to "36."

§ 30.11 [Amended]

13. In § 30.11, paragraph (a) is amended by changing "35" to "36."

§ 30.13 [Amended]

14. Section 30.13 is amended by changing "35" to "36".

§ 30.14 [Amended]

15. In § 30.14, paragraph (a) is amended by changing "35" to "36," and paragraph (c) is amended by adding ",36" after "33, 34".

§ 30.15 [Amended]

16. In § 30.15, the introductory text of paragraph (a) is amended by changing "35" to "36."

§ 30.16 [Amended]

17. Section 30.16 is amended by changing "35" to "36."

§ 30.18 [Amended]

18. In § 30.18, paragraph (a) is amended by adding, "36" after "30 through 34."

§ 30.19 [Amended]

19. In § 30.19, paragraph (a) is amended by change "35" to "36."

§ 30.20 [Amended]

20. In § 30.20, paragraph (a) is amended by changing "35" to "36."

§ 30.31 [Amended]

21. Section 30.31 is amended by changing "35" to "36."

§ 30.33 [Amended]

22. Section 30.33, paragraph (a)(4) is amended by changing "35" to "36."

§ 30.34 [Amended]

23. Section 30.34, paragraphs (a) and (b) are amended by changing "35" to "36"; paragraph (c) is amended by changing "35" to "36" in the first and the second sentences; paragraphs (d) and (e) are amended by changing "35" to "36."

§ 30.39 [Amended]

24. Section 30.39 is amended by changing "35" to "36."

§ 30.51 [Amended]

25. In § 30.51, paragraphs (a), (b), (c)(1), and (c)(2) are amended by changing "35" to "36."

§ 30.53 [Amended]

26. The introductory text of § 30.53 is amended by changing "35" to "36."

PART 40 - DOMESTIC LICENSING OF SOURCE MATERIAL

27. The authority citation for Part 40 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438.88 Stat. 1242 as amended (42 U.S.C. 5841)* * *.

§ 40.5 [Amended]

28. In § 40.5, paragraph (b)(1) is amended by changing "35" to "36," in the first sentence.

PART 51 - ENVIRONMENTAL REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

29. The authority citation for Part 51 continues to read, in part, as follows:

AUTHORITY: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201 as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

§ 51.22 [Amended]

30. In § 51.22, paragraphs (c)(3), (c)(10) and (c)(14) are amended by adding "36," after "34, 35."

§ 51.60 [Amended]

31. In § 51.60, paragraph (a) is amended by adding "36," after "34, 35."

§ 51.66 [Amended]

32. In § 51.66, paragraph (a) is amended by adding "36," after "34, 35."

§ 51.68 [Amended]

33. Section 51.68 is amended by adding "36," after "34, 35,".

PART 70 - DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

34. The authority citation for Part 70 continues to read, in part, as follows:

AUTHORITY: Sec. 161, Pub. L. 83-703, 68 Stat. 948, as amended (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 70.5 [Amended]

35. In § 70.5, paragraph (b)(1) is amended by changing "35" to "36."

§ 70.20a [Amended]

36. In § 70.20a, paragraph (b) is amended by changing "35" to "36."

PART 170 - FEES FOR FACILITIES AND MATERIALS LICENSFS AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

37. The authority citation for Part 170 continues to read, in part, as follows:

AUTHORITY: 31 U.S.C. 9701, 96 Stat. 1051; Sec. 301, Pub. L. 92-314, 86 Stat. 222 (42 U.S.C. 2201w); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841)* * *.

§ 170.2 [Amended]

38. In § 170.2, paragraph (a) is amended by changing "35" to "36."

Dated at Washington, DC, this 27th day of November, 1990.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.