

Request for OMB Review

DESIGNATED ORIGINAL

Pauletto Inghel

PDR

Important

Read instructions before completing form. Do not use the same SF 83 to request both an Executive Order 12291 review and approval under the Paperwork Reduction Act.

Answer all questions in Part I. If this request is for review under E.O. 12291, complete Part II and sign the regulatory certification. If this request is for approval under the Paperwork Reduction Act and 5 CFR 1320, skip Part II, complete Part III and sign the paperwork certification.

Send three copies of this form, the material to be reviewed, and for paperwork—three copies of the supporting statement, to:

Office of Information and Regulatory Affairs
Office of Management and Budget
Attention: Docket Library, Room 3201
Washington, DC 20503

PART I.—Complete This Part for All Requests.

1. Department/agency and Bureau/office originating request:

U.S. Nuclear Regulatory Commission

2. Agency code

3 1 5 0

3. Name of person who can best answer questions regarding this request

Stephen McGuire

Telephone number

(301) 492-3757

4. Title of information collection or rulemaking

10 CFR 36, Licenses and Radiation Safety Requirements for Large Irradiators

5. Legal authority for information collection or rule (cite United States Code, Public Law, or Executive Order)

42 USC 2201(o)

6. Affected public (check all that apply)

- 1 Individuals or households
- 2 State or local governments

- 3 Farms
- 4 Businesses or other for-profit

- 5 Federal agencies or employees
- 6 Non-profit institutions
- 7 Small businesses or organizations

PART II.—Complete This Part Only if the Request is for OMB Review Under Executive Order 12291

7. Regulation Identifier Number (RIN)

or, None assigned

8. Type of submission (check one in each category)

Classification

- 1 Major
- 2 Nonmajor

Stage of development

- 1 Proposed or draft
- 2 Final or interim final, with prior proposal
- 3 Final or interim final, without prior proposal

Type of review requested

- 1 Standard
- 2 Pending
- 3 Emergency
- 4 Statutory or judicial deadline

9. CFR section affected

10 CFR

10. Does this regulation contain reporting or recordkeeping requirements that require OMB approval under the Paperwork Reduction Act and 5 CFR 1320?

Yes No

11. If a major rule, is there a regulatory impact analysis attached?

If "No," did OMB waive the analysis?

1 Yes 2 No
3 Yes 4 No

Certification for Regulatory Submissions

In submitting this request for OMB review, the authorized regulatory contact and the program official certify that the requirements of E.O. 12291 and any applicable policy directives have been complied with.

Signature of program official

Date

Signature of authorized regulatory contact

Date

12. (OMB use only)

FOZ 0/11

PART III — Complete This Part Only if the Request is for Approval of a Collection of Information Under the Paperwork Reduction Act and 5 CFR 1320.

13. Abstract—Describe needs, uses and affected public in 50 words or less: **"Radiation Safety Radioactive Materials"**
 The proposed 10 CFR 36 would adopt safety requirements for the licensing, reporting and recordkeeping for large gamma irradiators, which are for the most part a codification of current licensing policy and practices.

14. Type of information collection (check only one)

Information collections not contained in rules

- 1 Regular submission 2 Emergency submission (certification attached)

Information collections contained in rules

- 3 Existing regulation (no change proposed) 6 Final or interim final without prior NPRM 7 Enter date of expected or actual Federal Register publication at this stage of rulemaking (month, day, year): 12/90
 4 Notice of proposed rulemaking (NPRM) A Regular submission
 5 Final, NPRM was previously published B Emergency submission (certification attached)

15. Type of review requested (check only one)

- 1 New collection 4 Reinstatement of a previously approved collection for which approval has expired
 2 Revision of a currently approved collection
 3 Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection 5 Existing collection in use without an OMB control number

16. Agency report form number(s) (include standard/optional form number(s))

22. Purpose of information collection (check as many as apply)

- 1 Application for benefits
 2 Program evaluation
 3 General purpose statistics
 4 Regulatory or compliance
 5 Program planning or management
 6 Research
 7 Audit

17. Annual reporting or disclosure burden

1 Number of respondents	1
2 Number of responses per respondent	1
3 Total annual responses (line 1 times line 2)	1
4 Hours per response	1
5 Total hours (line 3 times line 4)	1

23. Frequency of recordkeeping or reporting (check all that apply)

- 1 Recordkeeping
Reporting
 2 On occasion
 3 Weekly
 4 Monthly
 5 Quarterly
 6 Semi-annually
 7 Annually
 8 Biennially
 9 Other (describe): _____

18. Annual recordkeeping burden

1 Number of recordkeepers	1
2 Annual hours per recordkeeper	1
3 Total recordkeeping hours (line 1 times line 2)	1
4 Recordkeeping retention period	1 years

19. Total annual burden

1 Requested (line 17-5 plus line 18-3)	1
2 In current OMB inventory	
3 Difference (line 1 less line 2)	
Explanation of difference	
4 Program change	
5 Adjustment	

24. Respondents' obligation to comply (check the strongest obligation that applies)

- 1 Voluntary
 2 Required to obtain or retain a benefit
 3 Mandatory

20. Current (most recent) OMB control number or comment number

21. Requested expiration date

3 years from approval

25. Are the respondents primarily educational agencies or institutions or is the primary purpose of the collection related to Federal education programs? Yes No

26. Does the agency use sampling to select respondents or does the agency recommend or prescribe the use of sampling or statistical analysis by respondents? Yes No

27. Regulatory authority for the information collection

10 CFR 36 ; or FR ; or Other (specify): _____

Paperwork Certification

In submitting this request for OMB approval, the agency head, the senior official or an authorized representative, certifies that the requirements of 5 CFR 1320, the Privacy Act, statistical standards or directives, and any other applicable information policy directives have been complied with.

Signature of program official	Date
Signature of agency head, the senior official or an authorized representative Patricia G. Norry, DSO for Information Resources Management	Date 11-27-90

OMB SUPPORTING STATEMENT FOR 10 CFR 36,
"LICENSES AND RADIATION SAFETY REQUIREMENTS
FOR LARGE IRRADIATORS"

Description of Information Collection

The reporting requirements of 10 CFR 36 would affect 25 NRC licensees. The licensees would make the required reports available at their place of business or send the reports to the appropriate NRC Regional Office (Appendix D of 10 CFR 20). Records retained for inspection onsite include the license application, training records, emergency procedures, film badge and TLD results, records of radiation surveys, radiation survey meter calibration records, results of leak tests, records of inspection and maintenance, a log book record of malfunctions, operating difficulties, and operating problems, an inventory of all sealed sources, and records of the leak tests of stainless steel pool liners. Reports are only required as occasioned by the occurrence of specific events such as the theft or loss of radioactive material, events involving over exposures, excessive concentrations or levels of radiation, loss of one day or more of operation of the facility, property damage in excess of \$2,000, leaking sources, damaged sources, and pool water contamination. Also to be reported, if not included in the aforementioned events, are sources stuck in unshielded position, fire or explosion in the radiation room, damage to source racks, abnormal water loss or leakage from the source storage pool, detection of radiation by the product exit portal monitor, abnormal or unusual radioactive contamination, and degradation of the pool liner or walls. Licensees must also notify individuals of their exposure to radiation or radioactive material. These recordkeeping and reporting requirements are currently performed by licensees in accordance with the requirements of 10 CFR Parts 19, 20, and 30. The proposed Part 36 brings together in two specified sections, §36.81 and §36.83, all of the recordkeeping and reporting requirements for licensees of large irradiators, thus providing the licensees a convenient "check list" to make sure all required records are being kept and to ensure reports are submitted as occasions require. These records and reports are necessary for the NRC to fulfill its responsibility to protect the health and safety of the

public and to enhance safe operation of the large irradiators by analyzing operational occurrences and data and communicating safety-related improvements and precautions with all licensees.

All reports submitted will be subject to public disclosure upon request. The only exception is that certain proprietary information (information of commercial value, "trade secrets") could be withheld if properly identified by the licensee at the time of submitting the report.

A. Justification

1. Need for the Information Collection

The information that will result from the recordkeeping and reports required by the proposed rule should provide timely general operation performance data and information on precursor events that may have safety significance. This information will be used to monitor the irradiator's operation to ensure safety significant events can be identified for proper corrective action and so that this operational data may be shared with other irradiator facilities to preclude their repetition. Trends may also be determined and analyzed to allow preventive action (maintenance) thus ensuring safe operation. Recordkeeping also provides a history of operation that can be utilized in assessing an abnormal occurrence in order to determine the root cause. All of the recordkeeping activities are currently required by various 10 CFR Chapter 1 regulations or by license conditions. The regulatory objective is to utilize operational data to promote safe operation of the large irradiators. Licensees of these facilities are the sole source of operational data.

The information collection requirements of the proposed 10 CFR 36 are identified below.

§36.11. Application for a specific license, and §36.13. Specific Licenses for large irradiators.

Taken together, these two sections require a licence applicant to submit an application on Form NRC 313. The purpose of the application is to permit the NRC to determine whether the applicant's equipment, procedures, and personnel

are adequate to protect public health and safety. Burden will be applied to NRC Form 313, clearance number 3150-0120 at next clearance extension.

§36.19 Request for written statements.

This section requires licensees to submit, upon request, any additional information that NRC may need to determine whether or not the license should be modified, suspended, or revoked. The purpose of the section is to allow the NRC to obtain additional information if there is a question about whether public health and safety are being adequately protected.

§36.81. Records and retention periods.

The records that a licensee must maintain and their retention period are specified in a single section. The records and their retention period are as follows:

- (a) A copy of the license application and the license authorizing the licensee to operate the facility, until a new license is issued. The purpose is so that the licensee has a record of the commitments that it has made and that it must comply with.
- (b) Records of individual's training, tests, and safety evaluations provided to meet the requirements of §36.51 (except §36.51(e)) until 3 years after the individual terminates as an irradiator operator. The records allow NRC inspectors to verify that irradiator operators have received the required training.
- (c) Records of the annual evaluations of the safety performance of irradiator operators required by §36.51(e) for 3 years after the evaluation. The records allow NRC inspectors to verify that the licensee has been evaluating the performance of its operators.
- (d) An up-to-date copy of the operating and emergency procedures required by §36.53, and records of all revisions made within the previous 3 years. The records allow the operators to have access to an up-to-date set of written operating procedures so that they can operate the

irradiator properly. The procedures may be disposed of immediately upon being replaced by a new or revised procedure.

- (e) Film badge and TLD results required by §36.55, until the license is terminated by the Commission. The records allow NRC inspectors to verify that the licensee is complying with the NRC's radiation dose limits. This requirement is a reminder to licensees and is the same as the requirement in §20.401(a) and (c)(1). Therefore it has the same retention period.
- (f) Records of radiation surveys required by §36.57(a) and (b) for 3 years. The records allow NRC inspectors to verify that required radiation surveys have been done and that radiation dose limits are being complied with.
- (g) Records of radiation survey meter calibrations required by §36.57(c) for 3 years from the date of each calibration. The records allow NRC inspectors to verify that required calibrations have been performed.
- (h) Records of the results of leak tests required by §36.59, for 3 years. The records allow NPC inspectors to verify that required leak tests to detect radioactive contamination have been done.
- (i) Records of operational quality assurance checks required by §36.61 for 3 years. The records allow NRC inspectors to verify that the licensee is making necessary safety checks to maintain the irradiator in safe working condition.
- (j) Records of malfunctions, defects, operating difficulties or irregularities, and operating problems for 3 years after the problem is corrected. These records allow NRC inspectors to verify that the irradiator is being properly maintained and repaired. The records also allow NRC to identify generic problems that may decrease safety.
- (k) An inventory of all sealed sources (but not check sources), until the irradiator is decommissioned. The inventory must include for each sealed source: date received, person from whom received, model of

the source, serial number of the source if any, radionuclide in the source, activity of the source in curies at the time of receipt, an up-to-date location of the source, date source was disposed of if applicable, and the person to whom disposed source was sent if applicable. The records allow the NRC and the licensee to account for all radioactive sources and assure that no radioactive sources have escaped effective control.

- (l) Records of the checks of quality assurance in design as required by §36.39 and in construction as required by §39.41 until the license is terminated. The quality assurance checks must be signed and dated. The title or qualification of the person signing must be included. These records allow the NRC inspector to assure that the irradiator was properly and carefully designed and constructed.
- (m) Records of water added to the pool as required by §36.1(a)(14) for three years. The records allow the NRC inspector to assure that the irradiator pool is not leaking and that an effective barrier is present to prevent leakage of radioactive contamination from the irradiator.
- (n) Records related to decommissioning of the irradiator as required by §30.35(g). This reference is added for completeness to remind the licensee that another part (Part 30) requires certain records, as specified in Part 30, that are related to decommissioning.

§36.83 Reports

- (a) The licensee shall notify the Commission of: (1) the theft or loss of radioactive material as required by §20.402, and (2) events involving radioactive material possessed by the licensee that may have caused or threatens 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 \$2,000 as required by §20.403 or §20.405. This is not a new requirement but is merely a reminder to licensees that they must follow the reporting requirements in §20.403 and §20.405.

- (b) The licensee shall notify individuals of their exposure to radiation or radioactive materials as required by §19.13. This is also not a new requirement but is merely a reminder to licensees that they must meet the reporting requirements in §19.13.
- (c) The licensee shall report leaking sources, damaged sources, and pool water contaminated in excess of the concentrations in Table 1, Column 2 of Appendix B of Part 20 in writing to the appropriate NRC Regional Office listed in Appendix D of 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 of 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. The NRC needs reports of leaking radioactive sources to be able to confirm that radioactive contamination has been properly cleaned up and to identify whether there are generic problems with certain models of sources.
- (d) The licensee shall report within 5 days in writing to the appropriate NRC Regional Office listed in Appendix D of Part 20 the following events if not reported under paragraphs (a) or (c) of this section:
- (1) Sources stuck in unshielded position.
 - (2) Fire or explosion in radiation room.
 - (3) Damage to source racks.
 - (4) Failure of the cable used to move the source racks.
 - (5) Significant major breakdown in access control systems.
 - (6) Detection of radiation by the product exit portal monitor.
 - (7) Abnormal or unusual radioactive contamination.
 - (8) Degradation of the pool liner or walls.
 - (9) Abnormal water loss or leakage from the source storage pool.

The purposes of these reports are to ensure that the licensee has properly corrected a potentially hazardous situation and to determine if any class of irradiators might have generic safety problems that should be corrected.

2. Agency Use of Information

Analysis of operational data surrounding several safety significant occurrences in the world-wide community of large irradiators has been utilized by the NRC to develop the presently used safety criteria and license conditions. These requirements have precluded a repetition of these events at facilities and have resulted in safe operation of all facilities licensed to operate in the United States. The NRC Office of Nuclear Material Safety and Safeguards (NMSS) monitors the operation of the large irradiators in conjunction with regional staff assigned to inspect and monitor these facilities. Reports containing timely operational data are essential in order to confirm and ensure safe operation. If the reports indicate the possibility of a continuing hazard at the irradiator, the NRC will take action. In many situations an emergency inspection may be carried out. Records retained by the licensee are also important and are reviewed during routine and special inspections of these facilities to assure safe operation. Accordingly, the proposed rule requires reports to be submitted to the appropriate NRC Regional office listed in Appendix D of 10 CFR Part 20.

3. Reduction of Burden Through Information Technology

There are no current information technology applications which would impact (e.g., reduce) the burden of these information collection requirements. However, the NRC encourages the use of any new technology.

4. Effort to Identify Duplication

The collection of the specified information is not a duplication of other information the affected licensee must submit for other purposes. The nature of the information being requested is unique to NRC's activities at the facilities. The Information Requirements Control Automated System (IRCAS) was searched and no duplication was found.

5. Effort to Use Similar Information

There is no other information already available that can be used to assess the safe operation of the irradiators or to identify trends and precursors that must be corrected to ensure continued safe operation.

6. Effort to Reduce Small Business Burden

While a number of the licensees are considered small businesses, under the NRC's current definitions, all licensees have the same responsibility for safe operation of their irradiators. Therefore, there is no way to reduce the burden on small businesses by less frequent or less complete records or reports while maintaining the required level of safety.

7. Consequences of Less Frequent Collection

The proposed 5 day reporting period represents a balance between allowing sufficient time to collect, analyze, and write up the necessary information and requiring that the report be submitted before memories of what happened fade. These reporting periods will provide the regulatory analyst information in a time frame that is necessary to analyze and react in a timely manner consistent with the operation of the irradiator. The reporting period is judged to be sufficiently short so that the licensee's corrective actions may be supplemented when needed to protect the health and safety of the public and the irradiator employees.

8. Circumstances Which Justify Variations From OMB Guidelines

Any report required in less than 30 days is a variation from OMB Guidelines. Reports of significant safety problems are required in less than 30 days: (1) in case emergency actions are necessary to reduce the hazard; (2) in case an emergency NRC inspection is necessary to assure the problem is being handled properly; and (3) in case the problem is important enough that other licensees should be promptly informed.

Records that must be retained longer than 3 years are contained in: §36.81(a); § 36.81(e); §36.81(k); §36.81(l); and §36.81(n). The justifications are as follows:

§36.81(a): The license must be kept for as long as it is in effect. It would be difficult to obey the conditions of a license if there were no written copy.

§36.81(e): This merely restates, as a reminder, an existing Part 20 requirement.

§36.81(k): It is important in protecting public health and safety to be able to track the receipt, possession, and disposal of all licensed radioactive sources.

§36.81(l): As long as the facility is in operation, records of the design and construction of its principal safety features are important in maintaining and demonstrating the safety of the facility.

§36.81(n): This merely restates, as a reminder, the existing requirements in §30.35(g).

9. Consultation Outside the NRC

Telephone discussions with the Agreement States having the greatest number of licensed large irradiators disclosed that the proposed rule would benefit the states from the standpoint of simplifying their effort to assure compatible recordkeeping and reporting requirements in their regulations. It should be noted the Agreement State licensees report to their states, not directly to the NRC, so there will be no duplication of effort.

10. Confidentiality of Information

Reports submitted generally would be subject to public disclosure in accordance with 10 CFR 2.790 and 10 CFR Part 9. Section 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.

11. Justification of Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Annual Cost to the Federal Government

The annual burden on the NRC to review records is estimated to be 8 hours per licensee per year, or 200 hours for all 25 licensees. The annual burden to review reports for all licensees is estimated to be an additional 200 hours per year. The total is 400 hours per year. At a cost of \$92 per hour, the total annual cost to NRC is \$36,800 per year.

13. Estimate of Burden

The total burden is estimated to be 750 hours per licensee per year, or a total of 18,750 hours per year for all 25 irradiator licensees. The details are shown in the attached Tables 1 and 2.

14. Reasons for Change in Burden

A new CFR Part dealing with the large irradiators is being added.

15. Publication for Statistical Use

There is no application to statistics in the information collected. There is no publication of this information.

Table 1. Reporting Burden of Proposed Part 36.

Section	No. of Licensees	Annual Responses per licensee	Annual hours per licensee	Total burden hours	Comment or explanation
§36.11	25	-	0	0	Covered under §36.13. Burden for §36.11 and §36.13 to be incorporated into burden for NRC 313, clearance number 3150-0120.
§36.13	25	1	100	2,500	
§36.19	25	1	1	25	Assuming 1 report/year from the 25 licensees.
§36.69	25	1	1	25	
§36.83(a)	25	-	0	0	
§36.83(b)	25	-	0	0	This is a reminder referring to 20.403.
§36.83(c)	25	1	9	225	This is a reminder referring to §19.13.
§36.83(d)	25	1	40	1,000	
Total			151	3,775	

Table 2. Recordkeeping Burden of Proposed Part 36.

Section	No. of Recordkeepers	Annual hours per licensee	Total burden hours	Comment or explanation
§36.21(b)	25	2	50	
§36.81(a)	25	1	25	
§36.81(b)	25	20	500	
§36.81(c)	25	2	50	
§36.81(d)	25	40	1,000	
§36.81(e)	25	20	500	
§36.81(f)	25	80	2,000	
§36.81(g)	25	6	150	
§36.81(h)	25	20	500	
§36.81(i)	25	200	5,000	
§36.81(j)	25	20	500	
§36.81(k)	25	20	500	
§36.81(l)	25	160	4,000	Averaged over 10 years
§36.81(m)	25	8	200	
§36.81(n)	25	0	0	Covered under 30.35(g)
Total		599	14,975	