

DRAFT OMB SUPPORTING STATEMENT FOR 10 CFR PART 36

"LICENSES AND RADIATION SAFETY REQUIREMENTS

FOR IRRADIATORS"

(3150-0158)

CLEARANCE EXTENSION WITH BURDEN REVISION

Description of the Information Collection

The Nuclear Regulatory Commission's regulations in 10 CFR Part 36 contain requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials for a variety of purposes in research, industry, and other fields. This part also contains the radiation safety requirements for operating irradiators. These regulations were issued pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended.

The regulations in 10 CFR Part 36 (as described in Subpart A) apply to panoramic, dry-source-storage irradiators; underwater irradiators; and panoramic, wet-source-storage irradiators. They do not cover self-contained dry-source-storage irradiators, medical uses of sealed sources (such as teletherapy), or nondestructive testing (such as industrial radiography). The irradiators covered by this part have dose rates that 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.

Subpart B of this part covers specific licensing requirements for obtaining a license or a license exemption. Subpart C lists the design and performance criteria for irradiators, including special requirements for sealed sources installed after, licenses issued after, and irradiator construction begun after July 1, 1993. Requirements for operating irradiators are covered in Subpart D. These include requirements for operator training, written operating and emergency procedures, personnel monitoring, radiation surveys, inspection, and maintenance. The records and reports required to ensure that the irradiator is being safely operated – so that it poses no danger to the health and safety of the general public and the irradiator employees – are listed in Subpart E.

A. Justification

1. Need for and Practical Utility of the Information Collection

The records that 10 CFR Part 36 requires the licensees to maintain will be used by NRC or Agreement State inspectors to evaluate compliance with NRC regulations to ensure that public health and safety are protected. The reports required by 10 CFR Part 36 will be used to alert NRC to any special problems that may be a threat to health and safety so that adequate protective actions can be taken.

The need for and practical utility of the specific information collection requirements of 10 CFR Part 36 are identified below.

Section 36.11 states how a person may file an application for a specific license authorizing the use of a sealed source in an irradiator on Form NRC 313, "Application for Material License," and where the application must be mailed. The information on NRC Form 313 is used by the NRC to determine whether the applicant's equipment, procedures, and personnel are adequate to protect public health and safety. NRC Form 313 has previously been cleared under OMB Clearance No. 3150-0120, which should be referred to for additional supporting information, burden and cost data.

Section 36.13 describes the information that must be included in an application for a specific license for an irradiator if it is to be approved. This information is reviewed by the NRC staff to determine if the applicant's training program, operating and emergency procedures, organizational structure, radiation safety program, personnel qualifications, and inspection procedures will provide adequate protection of the public health and safety.

Section 36.17(a) allows an applicant to apply for an exemption from the requirements in 10 CFR Part 36. This information is used by the Commission to grant exemptions from the requirements in this part as long as they are authorized by law and will not endanger life or property or the common defense and security.

Section 36.17(b) allows applicants for a license or for amendment of a license authorizing use of teletherapy-type units for irradiation of materials or objects to include proposed alternatives to the requirements in this part in their application. The Commission reviews this information to determine 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. The requests in Section 36.17 are part of the application process under Section 36.13 and, thus, the burden is covered under that section.

Section 36.19 (a) and (b) allows the Commission to request additional information. Paragraph (a) of this section allows the Commission to request any additional information that NRC may need to determine whether or not the application should be granted or denied. Paragraph (b) allows the Commission to request written statements to determine whether a license should be modified, suspended, or revoked. This section codifies a requirement (found in Section 182 of the Atomic Energy Act) that licensees must supply any additional information required by NRC to assure that health and safety will be protected.

Additional information is sometimes needed to clarify information submitted in the application, or to rectify deficiencies in proposed or existing programs for protection of the public health and safety, the common defense and security, or the environment. The additional information submitted is reviewed by various NRC organizational units to assess the adequacy of the applicant's physical plant, procedures, and plans for protection of the public health and safety. The NRC review and the findings therefrom form the basis for NRC decisions concerning the issuance, modification, or revocation of licenses authorizing the use of sealed sources containing radioactive materials in irradiators.

Section 36.21 (a)(1) requires that sealed sources installed after July 1, 1993, have a certificate of registration issued under 10 CFR 32.210. The certificate of registration demonstrates that the source design has been reviewed and approved by either the NRC or an Agreement State.

Section 36.53 (a) requires licensees to have and follow written operating procedures. Paragraph (a) lists the operating, monitoring, surveying, testing, and inspection procedures that must be addressed in the licensee's written operating procedures. The procedures ensure there is a standard way of safely operating the irradiator that can be followed by all personnel and reviewed by NRC inspectors.

Section 36.53 (b) requires licensees to have and follow emergency or abnormal event procedures, appropriate for the irradiator type. Paragraph (b) lists the types of emergency or abnormal events that must be addressed in the licensee's written emergency procedures. The purpose is to have preplanned, approved procedures for responding to emergencies.

Section 36.69 (a) prohibits the irradiation of explosive material, unless the licensee has applied for and received prior written approval. The purpose of this section is to assure that 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.

Section 36.69 (b) prohibits the irradiation of more than small quantities of flammable material (flash point below 140EF) in panoramic irradiators unless the licensee has received prior written authorization from the Commission. The application must demonstrate that the licensee can control a fire in the radiation room without damage to the sealed sources or safety systems and without radiation overexposures of personnel.

Section 36.81 states the records that a licensee must maintain and the retention periods for these records. These are as follows:

- (a) A copy of the license, license conditions, and documents incorporated into a license by reference, and amendments thereto, until superseded or until the NRC terminates the license. These documents must be maintained so that the licensee has a record of the commitments that it has made and that it must comply with.
- (b) Records of each individual's training, tests, and safety evaluations provided to meet the requirements of Section 36.51 (except Section 36.51(e)) until 3 years after the individual terminates work. 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 Section 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) A copy of the current operating and emergency procedures required by Section 36.53, until superseded or the NRC terminates the license. Records of the radiation safety officer's review and approval of changes in the procedures must be retained for 3

years from the date of the change. 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 and safely. The procedures may be disposed of immediately upon being superseded by a new or revised procedure.

- (e) Film badge and TLD results required by Section 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 in 10 CFR Part 36 is a reminder to licensees of the requirement in Section 20.2106, which is covered under OMB Clearance No. 3150-0014.
- (f) Records of radiation surveys required by Section 36.57 for 3 years from the date of the survey. 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 Section 36.57 and pool water conductivity meter calibrations required by Section 36.63(b), 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 Section 36.59(b) and the results of contamination checks required by Section 36.59(a), for 3 years from the date of each test. The records allow NRC inspectors to verify that required tests to detect radioactive contamination have been done.
- (i) Records of inspection and maintenance checks required by Section 36.61 for 3 years. The records allow NRC inspectors to verify that the licensee is making necessary checks to maintain the irradiator in safe working condition.
- (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 the repairs are completed. 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) Records of the receipt, transfer, and disposal of licensed sources, as required by Sections 30.51 and 30.41. This is a reminder that the requirements of Sections 30.51 and 30.41 must be met. (Agreement States must have requirements compatible with those of Sections 30.51 and 30.41.) For Section 30.51 recordkeeping requirements for byproduct materials, the licensee shall retain each record of receipt as long as the material is possessed and for 3 years following transfer or disposal of the material, the licensee who transfers the material shall retain each record of transfer for 3 years after each transfer unless a specific part in this chapter dictates otherwise, and the licensee who disposes of the material shall retain each record of disposal until NRC terminates that license for disposal. These records allow NRC to track the possession, use, and location of byproduct material. The collection of this information has been previously cleared under OMB Clearance No. 3150-0017.

- (l) Records of the design checks required by Section 36.39 and the construction control checks required by Section 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. These records allow NRC inspectors to assure that the irradiator was properly and carefully designed and constructed.
- (m) Records related to decommissioning of the irradiator as required by Section 30.35(g) until the license is terminated. This reference is added for completeness to remind the licensee that 10 CFR Part 30 requires certain records that are related to decommissioning. The information in these records is necessary for the safe and effective decommissioning of the facility.

Section 36.83(a) requires that, in addition to any other NRC reporting requirements, the licensee shall report the following events if not reported under other parts of NRC regulations:

- (1) Source stuck in unshielded position.
- (2) Fire or explosion in 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 a radiation source by the product exit portal 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.

Section 36.83(b) requires that the events listed in Section 36.83(a) must be reported by telephone within 24 hours as described in Section 30.50(c)(1), and in writing within 30 days as described in Section 30.50(c)(2). 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. Some of the events covered under Section 36.83 might be reportable also under Section 30.50(b), depending on the exact circumstances.

2. Agency Use of Information

Reports of operational data surrounding several significant safety occurrences at irradiators have 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 licensed facilities. The NRC's Office of Nuclear Material Safety and Safeguards (NMSS) monitors the operation of the irradiators in conjunction with regional staff assigned to inspect and monitor these facilities. Reports containing timely operational data are essential in order to 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.

The records that 10 CFR Part 36 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for irradiators.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58792), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. However, these information collections do not readily lend themselves to the use of information technology because of the varied types of information and the infrequency of submission.

4. Effort to Identify Duplication and Use Similar Information

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 reporting requirements in Section 36.83 may appear to duplicate those of Section 30.50(b) for some events, but there is no duplication because the language of Section 36.83 excludes reporting of events reported under other sections of the regulations.

There is no similar information 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.

5. 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.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Collected or is Conducted Less Frequently

If the information is not collected, NRC will have no way to assess whether this category of licensee is operating within the radiation safety requirements applicable to the use of licensed material in irradiators.

7. Circumstances Which Justify Variation From OMB Guidelines

NRC section 36.83 (b) requires licensees to submit significant safety events in a manner which varies from OMB guidelines.

Section 36.83 (b) requires the licensee to report significant safety events by telephone within 24 hours and in writing within 30 days: (1) in case emergency actions are necessary to reduce the hazard; (2) in case an emergency NRC inspection is necessary to ensure 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 Sections 36.81(a), 36.81(b), 36.81(d), 36.81(e), 36.81(k), 36.81(l), and 36.81(m). The justifications are as follows:

Section 36.81(a) requires that the licensee keep a copy of the current license, including the license conditions, documents incorporated by reference, and amendments, until license termination. It would be difficult to comply with the conditions of a license if there were no written copy of the commitments the licensee has made.

Section 36.81 (b) requires that the licensee keep 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. The record retention is necessary for assuring that individuals who are currently working, or who have recently worked, in the facility are properly trained and that the training can be reviewed in accordance with the requirements.

Section 36.81(d) requires that the licensee keep a copy of the current written operating and emergency procedures until license termination. Written procedures are considered necessary to operate the irradiator safely and to protect the health and safety of the public and irradiator employees in the event of an emergency.

Section 36.81(e) restates, as a reminder, an existing 10 CFR Part 20 requirement that film badge and TLD results be kept until license termination. This requirement is necessary for verification that irradiator operators and other individuals who have entered the radiation room have not exceeded the dose limits in 10 CFR Part 20.

Section 36.81(k) restates, as a reminder, the requirements of Sections 30.51 and 30.41 for records of receipt, transfer, and disposal of all licensed sealed sources. These records are required for tracking the location of all byproduct material licensed under the Atomic Energy Act of 1954, as amended, and under Title II of the Energy Reorganization Act of 1974.

Section 36.81(l) requires that the licensee retain the design checks required by Section 36.39 and the construction control checks required by Section 36.41 until the license for the facility is terminated. 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. In addition, they would be useful for correcting problems in the case where a vendor discovered a design flaw.

Section 36.81(m) restates, as a reminder, the existing requirements in Section 30.35(g) that the licensee keep records of information important to the safe and effective decommissioning of the facility until the license is terminated. The information in these records is necessary for the safe and effective decommissioning of the facility.

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements has been published in the Federal Register.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Reports submitted are generally 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 for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

The estimates are based on submittals to and reviews by NRC in past years. The cost to licensees and applicants is calculated for 2004 at a rate of \$156/hour for the professional staff that prepares the technical reports and records in response to the 10 CFR Part 36 information collection requirements. This rate is based on NRC's fully recoverable fee rate.

Estimated Annual Cost to RespondentsNRC Licensees:

The total annual burden is estimated to be about 8,872 hours per year for the 19 irradiator licensees covered by 10 CFR Part 36. The details are shown in the attached Tables 1 and 2. The total cost for the NRC licensees would be 8,872 hours × \$156/hour, or \$1,384,032.

Agreement State Licensees:

The recordkeeping and reporting burden on the Agreement State licensees is based on several assumptions, including:

1. The Agreement States implement 10 CFR Part 36 in exactly the same manner as the NRC.

2. The Agreement States license 4 times the number of irradiators that are covered by 10 CFR Part 36 as does the NRC.

3. The frequency of incidents requiring reports from Agreement State licensees is no different than that from the NRC licensees.

The total annual burden is estimated to be about 35,484 hours per year for approximately 76 Agreement State licensees. The details are shown in the attached Tables 3 and 4. The total cost for the Agreement State licensees would be 35,484 hours × \$156/hour, or \$5,535,504

Total Estimated Burden: 44,356 hours.

	<u>Reporting</u>	<u>Recordkeeping</u>
NRC Licensees	160	8,712
Agreement State Licensees	<u>638</u>	<u>34,846</u>
	798	43,558

Total number of respondents: 95 (19 NRC licensees and 76 Agreement State licensees).

Total number of responses: 108 {13 for reporting (3 NRC licensees and 10 Agreement States)
95 for recordkeeping (19 NRC licensees and 76 Agreement States)}

13. Estimate of Other Additional Costs

The quantity of records to be maintained is roughly proportional to the recordkeeping burden. Based on the number of pages maintained for a typical clearance, the records storage cost has been determined for 2004 to be equal to .0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is insignificant (43,558 recordkeeping hours x .0004 x \$156 = \$2,718).

14. Estimated Annualized Cost to the Federal Government

The estimated burden on the NRC to review the records and reports is based on the frequency the NRC inspects the 10 CFR Part 36 licensees.

<u>Category</u>	<u>Number of Licensees</u>	<u>Inspection Cycle</u>
Irradiators - Other, less than 10,000 Curies	7	Every 3 Years
Irradiators - Other, greater than 10,000 Curies	12	Yearly

The annual burden on the NRC to review records is estimated to be 8 hours per licensee per year, or 112 hours for the 14 NRC licensees inspected per year (12 licensees per year + 7 licensees every 3 years = 14 per year). The annual burden to review reports submitted by these licensees is estimated to be an additional 112 hours per year. The total is 224 hours per year. At a cost of \$156 per hour, the total annual cost to NRC is \$34,944 per year. The annualized cost is based on staff's best estimate. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reasons for Changes in Burden or Cost

The overall burden has increased by 7,473 hours from 36,883 to 44,356 hours because of an increase in the number of agreement state licensees from 64 to 76. Although the number of agreement state licensees increased, the number of NRC licensees decreased from 22 to 19. As a result of more recent information about the ratio of Agreement State licensees to NRC licensees, the total number of licensees subject to Part 36 has increased and the burden has increased proportionally.

On December 15, 2003 OMB approved a 908 hour burden increase related to NRC orders under § 36.19(b). These orders required licensees to submit security and safeguards information, and to update procedures to ensure safe and secure activity. Upon further review of the NRC's reporting and recordkeeping requirements, it was determined that the burden for orders given to irradiator licensees should be accounted for under Part 30 (OMB # 3510-0017), because the safeguards requirements have been extended to a variety of materials licensees licensed under Part 30. The 10 CFR Part 30 burden will be modified to incorporate this 908 burden hours.

Cost estimates have changed since the last clearance, as a result of an increase in the fee per hour from \$144 to \$156/hour.

16. Publication for Statistical Use

None.

17. Reason for Not Displaying the Expiration Date

The requirement is contained in a regulation. Amending the Code of Federal Regulations to display information that, in an annual publication, could become obsolete would be unduly burdensome and too difficult to keep current.

18. Exceptions to the Certification Statement

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

Table 1: NRC Recordkeeping Requirements for Part 36

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ \$156/Hr
36.21(a)(1)	19	0.5	10	1,560
36.53(a), (b)	19	60.0	1,140	177,840
36.81(a)	19	2.0	38	5,928
36.81(b)	19	20.0	380	59,280
36.81(c)	19	2.0	38	5,928
36.81(d)	19	40.0	760	118,560
36.81(e)	19	Addressed under OMB # 3150-0014		
36.81(f)	19	20.0	380	59,280
36.81(g)	19	4.0	76	11,856
36.81(h)	19	10.0	190	29,640
36.81(i)	19	200.0	3,800	592,800
36.81(j)	19	20.0	380	59,280
36.81(k)	19	Addressed under OMB # 3150-0017		
36.81(l)	19	80.0	1,520	237,120
36.81(m)	19	Addressed under OMB # 3150-0017		
TOTALS	19	458.5	8,712	1,359,072

Table 2: NRC Reporting Requirements for Part 36

Section	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response	Total Annual Burden (Hrs)	Cost @ \$156/Hr
36.11	19	Addressed under OMB # 3150-0120				
36.13	19	Addressed under OMB # 3150-0120				
36.17(a), (b)	19	Addressed under OMB # 3150-0120				
36.19(a)	19	Addressed under OMB # 3150-0120				
36.19(b)	19	0.05	1.0	10	10	1,560
36.19(b) orders	19	Addressed under OMB # 3150-0017				
36.69(a), (b)	19	Addressed under OMB # 3150-0120				
36.83(a), (b)	19	0.08	1.5	100	150	23,400*
TOTALS	19		2.5	110	160	24,960

Notes: * Burden calculates only those events that would not be reported under § 30.50(b).

Table 3: Agreement States Recordkeeping Requirements for Part 36

Section	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden Hours	Cost @ \$156/Hr
36.21(a)(1)	76	0.5	38	5,928
36.53(a), (b)	76	60.0	4,560	711,360
36.81(a)	76	2.0	152	23,712
36.81(b)	76	20.0	1,520	237,120
36.81(c)	76	2.0	152	23,712
36.81(d)	76	40.0	3,040	474,240
36.81(e)	76	Addressed under OMB # 3150-0014		
36.81(f)	76	20.0	1,520	237,120
36.81(g)	76	4.0	304	47,424
36.81(h)	76	10.0	760	118,560
36.81(i)	76	200.0	15,200	2,371,200
36.81(j)	76	20.0	1,520	237,120
36.81(k)	76	Addressed under OMB # 3150-0017		
36.81(l)	76	80.0	6,080	948,480
36.81(m)	76	Addressed under OMB # 3150-0017		
TOTALS	76	458.5	34,846	5,435,976

Table 4: Agreement States Reporting Requirements for Part 36

Section	Number of Respondents	Number of Responses Per Respondent	Total Annual Responses	Burden Hrs Per Response	Total Annual Burden (Hrs)	Cost @ \$156/Hr
36.11	76	Addressed under OMB # 3150-0120				
36.13	76	Addressed under OMB # 3150-0120				
36.17(a), (b)	76	Addressed under OMB # 3150-0120				
36.19(a)	76	Addressed under OMB # 3150-0120				
36.19(b)	76	0.05	3.8	10	38	5,928
36.19(b) orders	76	Addressed under OMB # 3150-0017				
36.69(a), (b)	76	Addressed under OMB # 3150-0120				
36.83(a), (b)	76	0.08	6.0	100	600	93,600*
TOTALS	76		9.8	110	638	99,528

Notes: * Burden calculates only those events that would not be reported under § 30.50(b).