

FINAL SUPPORTING STATEMENT FOR 10 CFR PART 30,
"RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF
BYPRODUCT MATERIAL"

(3150-0017)

CLEARANCE REVISION

Description of Information Collection

The Nuclear Regulatory Commission's regulations in 10 CFR Part 30 establish rules applicable to all persons in the United States governing domestic licensing of radioactive byproduct material. The regulations were issued pursuant to the Atomic Energy Act of 1954, as amended, Title II of the Energy Reorganization Act of 1974, as amended, and exemptions from the domestic licensing requirements permitted by Section 81 of the Act. Among the provisions of the licenses issued by the Nuclear Regulatory Commission are conditions which impose requirements on the licensee, including reporting and recordkeeping.

Some of the conditions imposed are specific to the particular licensee as dictated by that licensee's particular facilities, equipment, or type of use of material. Other conditions are applied more generally--some to all licensees, and some to certain types of licensees based on the category of use of radioactive material (e.g., radiography, medical human use, etc.). These are known as "standard license conditions." Standard license conditions are utilized by all NRC regions to ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in Title 10 of the Code of Federal Regulations (10 CFR) that the licensee commits to when applying for a license. Standard license conditions which contain reporting or recordkeeping requirements are described in detail below. This ongoing burden has not been previously captured in the 10 CFR Part 30 clearance. This revision to the 10 CFR Part 30 clearance extension covers only the additional requirements and burden for standard license conditions. These requirements will be incorporated into the complete Part 30 clearance extension when it is renewed in October 2002.

A. Justification

1. Need for and Practical Utility of the Collection of Information

Section 30.34(b) requires in part that licensees provide full information before transferring, assigning, or in any manner disposing of any license through transfer of control to any person. No action is required of a licensee unless and until a transfer of control is initiated.

The information required by Section 30.34(b) is necessary to verify that the licensing information that was previously submitted on Form 313, "Application for Material License," is still correct, and to permit the NRC to determine whether the proposed licensee provides adequate resources to protect public health and safety. The NRC review of the information and the findings therefrom form the basis for NRC's licensing decision. NRC Form 313, "Application for Material License," has previously been cleared under OMB Clearance No. 3150-0120 and the burden for the general licensing information has been included herein. This should be referred to for additional supporting information, burden, and cost data.

The full information that must be provided by the licensee prior to transferring, assigning or disposing through transfer of control includes the following:

- a. A complete description of the transaction (transfer of stocks or assets, or merger). The licensee must indicate whether the name has changed and include the new name, and must include the name and telephone number of a licensee contact who NRC may contact if more information is needed.
- b. A description of any changes in personnel or duties that relate to the licensed program, including training and experience for new personnel.
- c. A description of any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
- d. A description of the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
- e. A confirmation that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
- f. A confirmation that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

This information is needed to assure NRC that the transferee is qualified to gain control of an NRC-licensed operation.

Section 30.34(e)(4) permits the Commission to incorporate in any license issued pursuant to the regulations in 10 CFR Parts 30-36 and 39 additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of byproduct material. In addition, reports and the keeping of records may be required, as necessary, to fulfill the purposes of the Atomic Energy Act and regulations of the Commission.

Some of the conditions imposed are specific to the particular licensee as dictated by that licensee's particular facilities, equipment, or type of use of material. Other conditions are applied more generally--some to all licensees, and some to certain types of licensees based on the category of use of radioactive material (e.g., radiography, medical human use, etc.). These "standard license conditions" ensure that provisions for protection of public health and safety are imposed consistently among licensees. They are used in conjunction with the requirements in Title 10 of the Code of Federal Regulations, and the licensee must commit to them when applying for a license. Those standard license conditions which contain reporting or recordkeeping requirements are described in detail below.

- a. Conditions 22 and 23 Licensed material shall only be used by, or under the supervision of, individuals designated, in writing, by the Radiation Safety Committee or Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for 3 years after the individual's last use of licensed material.

The retention of records of individuals designated as users of licensed material is necessary to establish and maintain a reference that can be used by NRC and licensees of all authorized users. Not all authorized users are listed on licenses and the record of the Radiation Safety Committee's or Radiation Safety Officer's designation is the only record of individuals being recognized as authorized users.

- b. Condition 132 The licensee shall report to the U.S. Nuclear Regulatory Commission's Regional Office referenced in Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient.

The information submitted by the licensees is needed to alert NRC's regional office of the loss of contact with an individual having a pacemaker containing radioactive material so that NRC can determine what if any immediate actions are necessary.

- c. Condition 133 The licensee shall maintain records of, and written procedures for, patient follow-up and replacement of the nuclear powered pacemaker during the life of the patient. The licensee must also maintain records of, and written procedures for, recovery and authorized disposal of the nuclear powered pacemaker by returning it to the manufacturer upon the death of the patient.

The records and procedures for patient follow-up and replacement must be available for patient treatment and for recovering the nuclear pacemaker until the death of the patient. Retention of the records and procedures for recovery and authorized disposal of the nuclear pacemaker is considered information important to decommissioning and therefore must be maintained until the facility is decommissioned as required by 10 CFR 70.25(g).

- d. Condition 164 The licensee shall conduct a physical inventory every 6 months, or at other intervals approved by the U. S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

The retention of records of inventories is necessary to ensure that licensees are accountable for radioactive material authorized under their license.

- e. Condition 165(i) The licensee shall maintain records of leak tests results for 5 years.

Records of leak tests results are necessary to demonstrate that leak tests were completed as required and that the source was not leaking.

2. Agency Use of the Information

The records that 10 CFR Part 30 requires the licensees to maintain are reviewed during inspections, license renewals, and license amendment reviews to evaluate compliance with NRC radiation safety requirements for possession and use of byproduct material.

3. Reduction of Burden through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages applicants and licensees to use new automated information technology when it would be beneficial to them and they may also retain records electronically. However, the reports do not lend themselves readily to the use of automated information technology for submission because of the varied types of information and the infrequency of submission. Consequently, the current percentage of electronic submissions is zero.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System (IRCAS) was searched to determine duplication. None was found. In general, information required by NRC in applications, reports, forms, or records concerning the transfer, receipt, possession, or use of byproduct material does not duplicate other Federal information collection requirements and is not available from any source other than applicants or licensees.

There is no similar information available to the NRC that can be used to evaluate compliance with NRC requirements governing the domestic licensing of byproduct material; to ensure public health and safety from NRC-licensed activities; and to identify trends and events that must be corrected to ensure continued safe practices.

5. Effort to Reduce Small Business Burden

The majority of licensees who use byproduct material are small businesses. Since the health and safety consequences of improper handling or use of radioactive byproduct material are the same for large and small entities, it is not possible to reduce the burden on small businesses by less frequent or less complete reporting, recordkeeping, or accounting and control procedures.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted 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 possession, use, or transfer of byproduct material.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.5(d)(2),

- a. Condition 132 requires licensees to report to the U.S. Nuclear Regulatory Commission's Regional Office referenced in Appendix D of 10 CFR Part 20, within 10 days after discovery of loss of contact with a nuclear-powered pacemaker patient. This report is needed so that NRC may determine if any immediate actions are necessary.

- b. Condition 133 requires that records and procedures for patient follow-up and replacement be available for patient treatment and for recovering the nuclear pacemaker until the death of the patient.

Retention of the records and procedures for recovery and authorized disposal of the nuclear pacemaker is considered information important to decommissioning and therefore must be maintained until the facility is decommissioned as required by 10 CFR 70.25(g).

- c. Condition 164 requires that records of inventories be maintained for 5 years from the date of each inventory so that they will be available for review during inspections for materials accountability.
- d. Condition 165(i) requires that licensees maintain records of leak tests results for 5 years so that they will be available for review during inspections to demonstrate compliance with NRC radiation safety requirements.

8. Consultations with Public

Notice of opportunity for comment was published in the Federal Register on May 30, 2001 (66 FR 29346). No comments were received.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of the 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 some documents, such as reports of radiation exposure to individuals and other personal records, from public disclosure.

11. Justification for Sensitive Questions

This information collection does not involve sensitive questions.

12. Estimated Burden and Burden Hour Cost

NRC Licensees:

The estimates are based on submittals to NRC in past years. The cost to licensees and applicants is calculated at a rate of \$143 per hour for professional staff for the technical reports and records prepared in response to the 10 CFR Part 30 information collection requirements. This rate is based on NRC's fully recoverable fee rate.

The total annual burden is estimated to be about 608 hours per year for 1872 licensees. The details are shown in Tables 1 and 2. The total cost for the NRC licensees would be 608 hours x \$143/hour, giving a total cost burden of \$86,944.

Agreement State Licensees:

NRC estimates that there are approximately 2.5 times the number of Agreement State licensees as there are NRC licensees.

The total annual burden is estimated to be about 1523 hours per year for 4680 Agreement State licensees. The details are shown in Tables 3 and 4. The total cost for Agreement State Licensees would be 1523 hours x \$143/hour, giving a total cost burden of \$217,789.

The total additional burden to be added to 10 CFR Part 30 for the inclusion of license conditions is 2131 hours (608 hours for NRC licensees + 1523 hours for Agreement State licensees).

13. Estimate of Other Additional Costs

None.

14. Estimated Annualized Cost to the Federal Government

Application review activities are attributable to and reported under NRC Form 313, OMB Clearance No. 3150-0120.

The collection and review of information will require an average of 0.33 hours of NRC staff time per report. For an estimated 162 reports reviewed annually, the collection will require 54 hours per year (.33x162). Annual labor costs at \$143 per staff hour will be \$7,722.

15. Reasons for Changes in Burden or Cost

This revision to the 10 CFR Part 30 clearance adds the burden for license conditions that has not been previously captured in the clearance. The burden for license conditions will add 2131 hours to the currently approved clearance.

16. Publication for Statistical Use

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

17. Reason for Not Displaying the Expiration Date

The requirements are 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

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.

Table 1 License Condition (LC) Reporting Requirements - NRC Licensees

Section	Number of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Licensee Burden (Hours)
30.34(b)	160	2	320
30.34(e)(4) LC 132	2	.5	1
TOTAL	162		321

Table 2 - License Condition (LC) Recordkeeping Requirements - NRC Licensees

Section 30.34(e)	Number of Recordkeepers	Licensee Staff Hours Per Recordkeeper	Total Annual Recordkeeper Burden (Hours)
LCs 22 & 23	124	.5	62
LC 133	1	1	1
LC 164	1872	.06	112
LC 165(i)	1872	.06	112
TOTAL	1872		287

TOTAL ANNUAL BURDEN HOURS = 608 (321 + 287)

Table 3 - License Condition (LC) Reporting Requirements - Agreement States

Section	Number of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Licensee Burden (Hours)
30.34(b)	400	2	800
30.34(e)(4) LC 132	5	.5	3
TOTAL	405		803

Table 4 - License Condition (LC) Recordkeeping Requirements - Agreement States

Section 30.34(e)(4)	Number of Recordkeepers	Licensee Staff Hours Per Recordkeeper	Total Annual Recordkeep Burden (Hours)
LCs 22 & 23	310	.5	155
LC 133	3	1	3
LC 164	4680	.06	281
LC 165(i)	4680	.06	281
TOTAL	4680		720

TOTAL ANNUAL BURDEN HOURS = 1523 (803 + 720)

