AA73.1
PDR
M. 28

NOTICE OF OFFICE OF MANAGEMENT AND BUDGET ACTION

Rec'd 5-22-85 mlm

TO: STEPHEN SCOTT
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C., 20555

ACTION DATE

Nuclear Regulatory Commission 05/15/85

ON 04/10/85, YOU REQUESTED APPROVAL OF THE FOLLOWING INFORMATION COLLECTION:
TITLE: 10 CFR PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL
AGENCY FORM NOS.:

IN ACCORDANCE WITH THE PAPERWORK REDUCTION ACT, WE HAVE TAKEN THE FOLLOWING ACTION ON THIS INFORMATION COLLECTION:

APPROVED FOR USE THROUGH 05/31/88. OMB NO. 3150-0010.
THE OFFICE OF MANAGEMENT AND BUDGET CONTROL NUMBER MUST BE DISPLAYED IN ACCORDANCE WITH 5 CFR 1320. UNLESS OTHERWISE PROVIDED IN "REMARKS," EXPIRATION DATES MUST ALSO BE DISPLAYED AS REQUIRED BY 5 CFR 1320.

EFFECT ON BURDEN:	RESPONSES	REPORTING HOURS
PREVIOUS STATUS	469	30,343
NEW STATUS	469	30,343
DIFFERENCE	0	0

REMARKS:

OMB NO. 3150-0010

ABSTRACT:
THIS COMPLETE REVISION TO 10 CFR PART 35 CONTAINS REQUIREMENTS THAT APPLY TO APPLICANTS FOR AND HOLDERS OF NRC LICENSES AUTHORIZING THE ADMINISTRATION OF BYPRODUCT MATERIAL OR ITS RADIATION TO HUMANS FOR MEDICAL CARE.

ALLOWANCE LETTER: NO
ON PLAN: NO
NO. OF FORMS: 1
RESPONDENTS: 1
FUNCTION: ENERGY INFORMATION, POLICY, AND REGULATION
EXCEED BUDGET: NO
USE: PUBLIC
RESPONSES: 469
3504(H): N/A
REQUEST: REVISION
HOURS: 30,343
AFFECTED PUBLIC: BUS/INST
SMALL BUSINESS: YES
ACTIVITY TYPE: 806
PURPOSE: REG/COMP
FREQUENCY: ANNL & OCCAS
COLLECTION METHOD: RKP RQT
RETENTION: 5 YRS
COLLECTION AGENT: RCDKPNG RQT
CONFIDENTIALITY: NO
COMPULSORY STATUS: MANDATORY
FEDERAL COST: $1,120
PUBLIC COST:
REVIEWER: JEFFERSON B. HILL

ACTION APPROVED BY:	AUTHORIZING OFFICIAL /S/JAMES B. MACRAE FOR	TITLE: DEPUTY ADMINISTRATOR OFFICE OF INFORMATION AND REGULATORY AFFAIRS	DATE 05/15/85

IMPORTANT: BECAUSE THIS INFORMATION COLLECTION HAS BEEN APPROVED, PLEASE SEND TO THE O.M.B. AS SOON AS AVAILABLE: ONE COPY OF THE FINAL PRINTED (OR OTHERWISE REPRODUCED) REPORT FORM, OR REPORTING OR RECORDKEEPING REQUIREMENT, TRANSMITTAL LETTER, INSTRUCTIONS, AND ANY DOCUMENT BEING SENT TO EACH RESPONDENT.

rec'd 1085
mtm

Mr. James B. MacRae
Office of Management and Budget
Reports Management, Room 3201
New Executive Office Building
Washington, D.C. 20503

Dear Mr. MacRae:

In accordance with Section 3507 of Public Law 96-511 of December 11, 1980 and regulations of the Office of Management and Budget, I am enclosing for OMB review copies of Standard Form 83 and the Supporting Statement for a proposed revision of 10 CFR Part 35, "Medical Use of Byproduct Material."

In accordance with NRC's procedures, my staff has made an independent review of the practical utility and necessity for the proposed information collection and we are in concurrence with this proposal. We have also reviewed for duplication and found no similar requirement in the agency. Therefore, we are transmitting this material for OMB review and approval.

Sincerely,

Original Signed by
Patricia Norry

Patricia G. Norry, Director
Office of Administration

Enclosures:
As stated

DISTRIBUTION
NMSS r/f
FCML r/f
FCTA r/f
DMB Off File
DMB r/f
PNorry, ADM
MSpringer, ADM
JSniezek, DEDROGR
RECunningham, NMSS
VLMiller, NMSS
NMcElroy, NMSS
RLO'Connell, NMSS

FCML
NMcElroy
1/25/85

8504170024

OFFICE	NMSS-IMC	NMSS-FCML	NMSS-FC	ELD	DEDROGR	ADM	ADM
SURNAME	RLO'Connell	VLMiller	RECunningham	B Rhodes	JSniezek	MSpringer	PNorry
DATE	1/31/85	1/25/85	1/28/85	4/17/85	4/15/85	4/18/85	4/8/85

NRC FORM 318 (10 80) NRCM 0240

OFFICIAL RECORD COPY

☆ U.S. GPO 1983—400-24

Document Name:
10 CFR 35 SUPPORTING STATEMENT

Requestor's ID:
JPK

Author's Name:
MCELROY N

Document Comments:
3/14/85 - RETURN THIS SHEET WHEN SUBMITTED FOR CORRECTIONS

To Bob Ronsell

SUPPORTING STATEMENT
FOR 10 CFR PART 35
MEDICAL USE OF BYPRODUCT MATERIAL

Background

10 CFR Part 35, Medical Use of Byproduct Material, contains requirements that apply to Nuclear Regulatory Commission (NRC) licensees who are authorized to administer byproduct material or its radiation to humans for medical care. The NRC has prepared a complete revision of Part 35. The revision consolidates requirements that are scattered in the current regulation license conditions, and policy statements. It also clarifies recordkeeping and reporting requirements.

Justification

Part of NRC's function is to license and regulate the use of byproduct materials in order to assure the public health and safety. The NRC requires licensees to perform certain tasks to ensure fulfillment of their obligations. The records required in this part are the least burdensome way for licensees to demonstrate compliance. Occasionally, safety matters are of such significance that others need to be aware of information in order to perform their jobs or work in a safe manner. In these cases, reports are required.

Need for and Practical Utility of the Information Collection

Sections 35.16 (b) and (c) of 10 CFR Part 35 require that applicants submit a completed NRC Form 313. The form elicits an orderly description of the applicant's complete radiation safety program. Requests for amendments and license renewals may be submitted in letter format. This report is needed to assure NRC that the applicant is able to protect health and minimize danger to life and property before it can authorize receipt of radioactive material. NRC Form 313 has previously been cleared under OMB No. 3150-0120, which should be referred to for additional supporting information, as well as burden and cost data.

Section 35.17 of 10 CFR Part 35 requires that licensees apply for and receive a license amendment before using material not allowed by the license, before adding to or changing key individuals, before receiving more material than allowed by the license, or before changing the location of use or mailing address. The identified trigger events are critical indicators of potential for change in the licensee's ability to control radiation dose to workers and the public, or the NRC's ability to contact the licensee or conduct an inspection. The information is needed so that the staff can determine whether the licensee has the training and experience and facilities and equipment needed to assure protection of public health and safety.

Section 35.18 of 10 CFR Part 35 requires that licensees notify the NRC within 30 days if a key worker ends his association with the licensee. This prompt report is needed because if the licensee no longer has a complete staff, the collective training and experience of the remaining staff may no longer be sufficient to ensure safety. This report will trigger a check of the licensee's file to determine whether the remaining key users are qualified to receive and use material safely.

Sections 35.30 (a) and (c) of 10 CFR Part 35 require that each medical institution licensee retain a written description of a program to keep worker and public dose as low as reasonably achievable (ALARA). The record is needed so that managers and key users know what they must do to implement the program.

Section 35.30(b)(2) requires that each medical institution licensee review its radiation safety program annually. A record of the review is included in the burden estimate for Section 35.32(a)(4)(iv).

Sections 35.31(b)(2) of 10 CFR Part 35 requires that the licensee establish and implement the written policy and procedures that were submitted as part of the application. The policy and procedures are submitted as part of the application and are needed so that the staff can review them and make a determination that the applicant can meet the requirements of the Atomic Energy Act and the Commission's regulations. The procedures must be implemented in order to provide for the public health and safety. The burden is included in the burden for the application, NRC Form 313, OMB No. 3150-0120.

Section 35.32(b)(8) requires that medical institution applicants establish a table of occupational dose trigger levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer. The table is part of the ALARA program record and is included in the burden estimate for Section 35.30(c).

Sections 35.32(a)(4) and (5) of 10 CFR Part 35 require that medical institution licensees retain a copy of Radiation Safety Committee meeting minutes for the duration of the license, and prescribe the information required in the minutes. This record is needed to show continuing management oversight of the radiation safety program.

Section 35.33(b) of 10 CFR Part 35 requires that licensees provide a written statement of authority, duties, responsibilities, and radiation safety activities for the Radiation Safety Officer and Radiation Safety Committee. The record is needed so that managers and key users know their responsibilities. The final rule will require that the statement will be retained for the duration of the license.

Section 35.34(a) of 10 CFR Part 35 requires that licensees provide written permission to visiting authorized users to work under the license. Section 35.34(c) requires licensees to retain a copy of the license that identifies the visitor as an authorized user. This permission and record are needed to show that licensee management has permitted this work, and that a regulatory agency has reviewed the visitor's training and experience.

Section 35.35(b) of 10 CFR Part 35 requires that mobile nuclear medicine service licensees keep a letter of permission signed by the management of each client. This record is needed to show that client management has permitted this work.

Section 35.36(b) of 10 CFR Part 35 requires that licensees make a record of radiation safety program changes. This record is needed to show what radiation safety problems were considered before implementing the change, and also provides a record of where within the licensee's facility radioactive materials were received, used, and stored.

Section 35.37(a) of 10 CFR Part 35 requires that the licensee notify by telephone the appropriate NRC regional office in case of a therapy misadministration within 24 hours after discovering the misadministration. This prompt notification is necessary because a therapy misadministration may present a clear and present radiation hazard to a member of the public that might be mitigated by NRC assistance. The licensee is also required to notify the referring physician and the responsible relative or guardian of the patient. These reports are needed so that those individuals can provide adequate care for the patient.

Section 35.37(b) of 10 CFR Part 35 requires that a licensee file a written report to NRC within 15 days after telephoning an initial therapy misadministration report. This report is needed so that NRC can determine whether there might be generic implications in the incident which indicate a need to notify all licensees. NRC allows the licensee 15 days to submit the report so that it can review and analyze what has happened and provide NRC with a complete history of the event. NRC requires submission of the report within 15 days so that it can promptly notify other licensees if it appears the precipitating event might be generic.

Section 35.37(c) of 10 CFR Part 35 requires that licensees notify the NRC of diagnostic misadministrations. These written reports are needed to determine what kinds of actions precipitate misadministrations, and also provide a measure of the licensee's management control of the radiation safety program.

Section 35.37(d) of 10 CFR Part 35 requires licensees to retain a record of each misadministration for 10 years. The record is needed so that individual licensees can determine the causes of misadministrations within their respective facilities and take corrective action. This record must be retained for 10 years because misadministration events are infrequent and, if there is a common cause for them, it will take longer to manifest itself.

Section 35.50(b)(4) of 10 CFR Part 35 requires that licensees make a record of a geometry dependence test for the dose calibrator. This record is needed to show that the volume configuration of the radiopharmaceutical does not affect the reading given by the dose calibrator.

Section 35.50(e) of 10 CFR Part 35 requires that licensees retain a record of checks and tests of dose calibrator performance. This record is needed to show that the dose calibrator is capable of accurately measuring radiopharmaceutical dosages.

Section 35.51(b)(3) requires that the licensee note on a survey instrument the apparent exposure rate from a dedicated check source. This information is needed so the licensee can check the survey instrument for proper operation before making measurements. The burden is included in the burden estimate for Section 35.51(e).

Section 35.51(e) of 10 CFR Part 35 requires that licensees retain a record of survey instrument calibrations. This record is needed to show that survey instruments were working properly.

Section 35.53(c) of 10 CFR Part 35 requires that licensees retain a record of each radiopharmaceutical dosage measurement. This record is needed to show that licensees are maintaining control of the use of radiopharmaceuticals.

Section 35.59(a) of 10 CFR Part 35 requires that licensees maintain written instructions for the safe use of sealed sources and brachytherapy sources. These instructions are needed so that individuals who are handling sources can determine the specific safety measures appropriate for each kind of source used.

Section 35.59(d) of 10 CFR Part 35 requires that licensees retain a record of sealed source leak tests. This record is needed to show that the leak test was done at the appropriate time, and that the test showed that the source was not leaking.

Section 35.59(e)(2) requires that licensees file a report with the NRC within five days if leakage of a sealed source is detected. This report is needed so that NRC can make a determination as to whether other licensees who have similar sealed sources should take special precautions. NRC allows the licensee 5 days to submit the report so that it can review and analyze the source and the leakage measurement. NRC requires submission of the report within 5 days so that

it can promptly notify other licensees if it appears there may be a generic problem.

Section 35.59(g) of 10 CFR Part 35 requires that licensees make a record of sealed source and brachytherapy source inventory. This inventory is needed to show that possession of sealed sources did not exceed the amount authorized by the license. The five-year recordkeeping requirement will help to assure continued control over these sources that are only occasionally used.

Section 35.59(i) of 10 CFR Part 35 requires that licensees make a record of radiation surveys of areas where sealed sources and brachytherapy sources are stored. This record is needed to show that adequate radiation shielding has been provided for such sources, and that dose rates in contiguous areas are within allowed levels.

Section 35.62 of 10 CFR Part 35 requires that licensees label each syringe or syringe radiation shield as to its contents. This label is needed because review of misadministration reports has indicated that in many cases misadministrations are caused by inadvertent transposition of syringes.

Section 35.63 of 10 CFR Part 35 requires that licensees label vial radiation shields with the identity of the radiopharmaceutical contained. NRC review of several misadministration reports indicates that many misadministrations occur when technicians draw a dosage from the wrong vial of radioactive material. Labels will help to reduce the chance of this happening.

Sections 35.70(d) and (g) of 10 CFR Part 35 require that the licensee establisn action levels for radiation surveys. The action levels provide the individual who makes a radiation survey with a record of what levels are expected and what levels require investigation. The sections also require that the licensee immediately notify the Radiation Safety Officer if excessive levels are detected during a survey. This report is needed so that the Radiation Safety Officer can take appropriate remedial action. The Radiation Safety Officer is the one individual onsite who is qualified to determine what action is needed to ensure worker and public health and safety, and whether that action is needed immediately or can be delayed.

Section 35.70(h) of 10 CFR Part 35 requires that licensees retain a record of radiation surveys. The record is needed to show that the required surveys were made.

Section 35.80(f) of 10 CFR Part 35 requires that licensees make a record of radiation surveys. The record is needed to show that the required surveys were made.

Section 35.92(b) of 10 CFR Part 35 requires that licensees make a record of disposal of waste that was decayed in storage. The record is needed to show that materials were decayed for the proper length of time and that a proper survey of each waste container was made.

Section 35.204(c) of 10 CFR Part 35 requires that licensees retain a record of molybdenum-99 concentration in radiopharmaceuticals. This record is needed to show that the concentration measurement was made.

Section 35.205(e) requires that the licensee post a time period of evacuation in areas where aerosols and gases are used. In case of a spill, this provides notice to workers of how much time air handling equipment needs to reduce the air concentration to permissible limits.

Section 35.310(a) of 10 CFR Part 35 requires that licensees provide written radiation safety instruction for personnel caring for radiopharmaceutical therapy patients. This written instruction is needed so that these personnel may study and refer to it while caring for the patient.

Section 35.310(b) of 10 CFR Part 35 requires that licensees retain a record of training for personnel who care for radiopharmaceutical therapy patients. This record is needed to show that the training was given.

Sections 35.315(b) and 35.415(b) of 10 CFR Part 35 require that the licensee promptly notify the Radiation Safety Officer if the radiopharmaceutical therapy or brachytherapy patient dies or has a medical emergency. This report is needed so that the Radiation Safety Officer can take whatever actions are necessary to prevent a spread of radioactive contamination or loss of brachytherapy sources.

The Radiation Safety Officer is the one individual onsite who is qualified to determine what action is needed to ensure worker and public health and safety, and whether that action is needed immediately or can be delayed.

Sections 35.315(c) and 35.415(c) require that the licensee post radiopharmaceutical therapy and brachytherapy patient room doors with a "Radioactive Materials" sign. This provides notice to hospital workers and the public that there is radioactivity in the room. The section also requires that the licensee note in the patient's chart how long visitors may stay in the patient's room. This is the most convenient way to provide this information to nurses, who are usually responsible for enforcing visiting rules, because the patient's chart provides all the information concerning the patient.

Section 35.315(g) of 10 CFR Part 35 requires that licensees make a record of the thyroid burden measurement of each individual who helped prepare or administer a therapeutic dosage of iodine-131. This record is needed to show that workers were not exposed to excessive levels of iodine-131.

Section 35.404(b) of 10 CFR Part 35 requires that licensees retain a record of the radiation survey of each patient who was treated with temporary implant sources. The record is needed to show that the survey was made.

Section 35.406(b) of 10 CFR Part 35 requires that licensees make a record of brachytherapy source use. This record is needed so that, if a brachytherapy source is misplaced, the licensee knows where to look for it.

Section 35.406(c) of 10 CFR Part 35 requires that licensees make a record of radiation surveys of patients after implanting sources. This record is needed to show that the survey was made.

Section 35.406(d) requires that the licensee retain a record of the use of brachytherapy sources and special safety surveys. This record is needed to show that the licensee is providing adequate control for these sources. The record burden is included in the burden estimate for Sections 35.406(b) and (c).

Section 35.410(a) of 10 CFR Part 35 requires that licensees provide written radiation safety instruction for personnel caring for implant therapy patients. This written instruction is needed so that these personnel may study and refer to it while caring for the patient.

Section 35.410(b) of 10 CFR Part 35 requires that licensees retain a record of training for personnel who care for implant patients. This record is needed to show that the training was given.

Section 35.606 of 10 CFR Part 35 requires that licensees apply for and receive a license amendment before making certain changes in the teletherapy program. This license amendment process is necessary because the licensee might consider making changes that would cause radiation levels in restricted and unrestricted areas to exceed permissible levels.

Section 35.610(a) of 10 CFR Part 35 requires that licensees post written instructions for individuals who operate teletherapy units. These instructions are needed to remind workers of proper operating procedures.

Section 35.610(b) of 10 CFR Part 35 requires that licensees provide radiation safety instruction for personnel who operate teletherapy units. This instruction is needed to ensure safe operation of the unit.

Section 35.610(c) of 10 CFR Part 35 requires that licensees make a record of training for individuals who operate teletherapy units. This record is needed to show that the training was given.

Section 35.621(e) of 10 CFR Part 35 requires that licensees retain a record of the teletherapy room radiation monitoring device function check. This record is needed to show that the check was made.

Section 35.630(c) of 10 CFR Part 35 requires that licensees retain a record of each calibration, intercomparison, and comparison of teletherapy dosimetry equipment. These records are needed to show that measurements of radiation teletherapy doses were made with instruments capable of making accurate measurements.

Section 35.632(e) of 10 CFR Part 35 requires that licensees make mathematical corrections for the radioactive decay of teletherapy sources. If they did not do so, the calculated teletherapy unit output, which is used to plan patient treatments, would be different from the true output.

Section 35.632(g) of 10 CFR Part 35 requires that licensees retain a record of teletherapy unit calibration. This record is needed to show that the calibrations were done and that licensees did not inadvertently misadminister radiation doses to patients.

Section 35.633(e) of 10 CFR Part 35 requires that the qualified teletherapy calibration expert report the results of teletherapy unit spot-checks promptly to the licensee. This assures the licensee that the results of each spot-check have been reviewed by an expert. The licensee must keep a copy of each report to assure that the review has been made.

Section 35.633(j) of 10 CFR Part 35 requires that licensees retain a record of spot-checks. This record is needed to show that the required checks were made.

Section 35.641(c) of 10 CFR Part 35 requires that licensees retain a record of radiation measurements after installing a source in a teletherapy unit. These records provide assurance that the source is properly installed within the teletherapy unit, and that dose rates outside the teletherapy room are within permissible limits.

Section 35.642(c) of 10 CFR Part 35 requires that licensees retain a record of safety checks for teletherapy facilities. This record is needed to show that the checks were made.

Section 35.643(c) of 10 CFR Part 35 requires that licensees amend a report to NRC to include additional survey information if changes in an installation as approved by NRC were necessary. The additional information in the report provides assurance to NRC that dose rates in restricted and unrestricted areas are within permissible limits. The 30-day submission requirement is contained in Section 35.644.

Section 35.643(d) of 10 CFR Part 35 requires that licensees request a license amendment if radiation levels in unrestricted areas are above permitted levels. This report will trigger an indepth NRC review of safety considerations before it allows a licensee to operate the unit. The 30-day submission requirement is contained in Section 35.644.

Section 35.644 of 10 CFR Part 35 requires that licensees mail a copy of teletherapy source installation records to the NRC. This record is needed to show that dose rates in restricted and unrestricted areas are within permissible levels. The submission must be made within 30 days after the completion of the action that initiated the record requirement. The 30-day requirement is imposed because of the especially high dose rates that can be found around teletherapy units.

Section 35.645(c) of 10 CFR Part 35 requires that licensees keep a record of teletherapy unit inspection and servicing. This record is needed to show that the required work was done.

Efforts to Avoid Duplication

In general, information required by NRC in applications, reports, 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. Some of the required information might also be contained in other information submittals to NRC or other Federal agencies. However, the duplication, if any, is slight, and the collection of this information by use of specified forms and other required reports and records is the most effective and least burdensome means of obtaining the information.

Consultations Outside the Agency

Several experts in the use of radioactive material for patient care were asked to comment on the technical content, including the information collection requirements, of the proposed regulation. They were representatives of: Food

and Drug Administration, American Association of Physicists in Medicine, Health Physics Society, Society of Nuclear Medicine, and the American College of Radiology.

Description of the Information Collection

Number and Type of Respondents

These requirements will affect approximately 2500 licensees and applicants. About 2200 of the licensees are hospitals, and about 300 of the licensees are physicians in private practice.

Method of Collecting the Information, Reporting Period, and Reasonableness of Schedule

Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses or amendments may be submitted at any time. Applications for renewal of licenses are submitted every 5 years.

Information submitted in previous applications may be referenced without being resubmitted. The schedule for collecting the information is the minimum frequency which will permit NRC to assure that the public health and safety are adequately protected.

Record Retention Period

Most records must be retained for a period of 2 years. These records are needed to show that licensee radiation safety programs are being conducted in accordance with the requirements of the regulations. Sections 35.35(b), 35.50(b)(4), 35.59(a) require that licensees keep records for the duration of equipment use or service contract. This provides the licensee with a record of continued servicing and calibration of equipment, and assures NRC that the licensee is providing necessary equipment maintenance support for the byproduct materials program. Sections 35.30(c), 35.31(b)(2), 35.32(a)(4), 35.32(a)(5), 35.32(b)(8), 35.33(b), 35.36(b), 35.630(c), 35.632(g), 35.641(c), and 35.645(c) require that licensees keep records for the duration of the license. These

records provide the policy statements and management directives needed to operate a radiation safety program, or provide essential historical, site-specific information. Section 35.59(g) requires that licensees keep a record of sealed source quarterly inventories for five years. This requirement was cleared under OMB No. 3150-0010.

Copies Required to be Submitted

For most requirements only one copy need be submitted. However, applications for specific licenses and amendments are required to be submitted in duplicate to accommodate NRC's technical review and docketing requirements.

Estimate of Compliance Burden

Reporting Requirements

Section	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Licensee Burden (Hours)
35.16(b)	See OMB Clearance No. 3150-0120		
35.16(c)	See OMB Clearance No. 3150-0120		
35.17	1800	3	5400
35.18	500	0.5	250
35.34(a)(1)	2500	0.5	1250
35.34(a)(2)	2500	0.5	1250
35.37(a)	5	1	5
35.37(b)	5	10	50
35.37(c)	800	2	1600
35.59(e)	1	2	2
35.62	2200	7.5	14250
35.63	400	0.5	200
35.70(d)	26400	0.02	528
35.70(g)	26400	0.02	528
35.205(e)	400	0.1	40
35.310(a)	12000	0.5	6000
35.315(b)	1	0.1	1
35.315(c)	8400	0.2	1680
35.410(a)	4800	0.5	2400
35.415(b)	1	0.1	1
35.415(c)	4800	0.2	960
35.606	40	1	40
35.610(a)	100	0.5	50
35.610(b)	400	0.5	200
35.633(e)	4800	0.1	480
35.643(c)	1	2	2
35.643(d)	1	2	2
35.644	100	0.5	50
Total	99355		37219

Recordkeeping Requirements

Section	No. of Recordkeepers	Annual Hours per Recordkeeper	Total Recordkeeping Hours	Record Detention Period
35.30(a) and (c)		see 35.16 (b) and (c)*		license duration
35.30(b)(2)		included in 35.32 (a)(4)		
35.31(b)(2)		see 35.16 (b) and (c)*		license duration
35.32(a)(4) and (a)(5)	2200	2	4400	license duration
35.32(b)(8)		see 35.30(c)*		license duration
35.33(b)		see 35.16(b) and (c)*		license duration
35.34(c)		see 35.34(a)*		2 years after last use
35.35(b)	50	1	50	duration of service
35.36(b)	1200	1	1200	license duration
35.37(d)		see 35.37 (b) and (c)*		10 years
35.50(b)(4)		see 35.50(e)(4)		eqpt. duration
35.50(e)(1)	1900	5	9500	2 years
35.50(e)(2)	1900	0.2	380	2 years
35.50(e)(3)	1900	2	3800	2 years
35.50(e)(4)	380	1	380	eqpt. duration
35.51(e) and (b)(3)	2500	0.2	500	2 years
35.53(c)	2200	75	165000	2 years
35.59(a)	2500	0.1	250	eqpt. duration
35.59(d)	2500	2	5000	2 years
35.59(g),	2200	2	4400	5 years
35.59(i)	2200	2	4400	2 years
35.70(h)	2200	65	143000	2 years
35.80(f)	50	100	5000	2 years

Recordkeeping Requirements (Continued)

Section	No. of Record-keepers	Annual Hours per Recordkeeper	Total Record-keeping Hours	Record Detention Period
35.92(b)	2200	6	13200	2 years
35.204(c)	1900	5	9500	2 years
35.310(b)	700	1	700	2 years
35.315(g)	700	2	1400	until disposal auth'd
35.404(b)	400	1	400	2 years
35.406(b)	400	2	800	2 years
35.406(c)	400	1	400	2 years
35.406(d)	included in 35.406(b) and (c)			
35.410(b)	400	1	400	2 years
35.610(c)	400	0.1	40	2 years
35.621(e)	400	5	2000	2 years
35.630(c)	200	1	200	eqpt. duration
35.632(e)	400	1	400	1 month
35.632(g)	400	16	6400	license duration
35.633(e)	400	1	400	2 years
35.633(j)	400	12	4800	2 years
35.641(c)	100	8	800	license duration
35.642(c)	100	1	100	2 years
35.645(c)	100	0.1	10	license duration

Total Recordkeepers: 2500

Total Recordkeeping Burden: 389,210 hours

Total Burden: 426,429 hours

*These documents are prepared as a written report and must be retained by the licensee for reference. The time spent making the record is included in the noted reporting section.

Estimated Cost to Public to Respond

Section		Annual Cost to Respond
35.16(b)	See OMB Clearance No. 3150-0120	
35.16(c)	See OMB Clearance No. 3150-0120	
35.17		324,000
35.18		15,000
35.30(c)	included in 35.16(b) and (c)	
35.31(b)(2)	included in 35.16(b) and (c)	
35.32(a)(4) and (a)(5)		264,000
35.32(b)(8)	included in 35.30(c)	
35.33(b)	included in 35.16(b) and (c)	
35.34(a)(1)		75,000
35.34(a)(2)		75,000
35.34(c)	included in 35.34(a)	
35.35(b)		3,000
35.36(b)		72,000
35.37(a)		300
35.37(b)		3,000
35.37(c)		96,000
35.37(d)	included in 35.37(b) and (c)	
35.50(b)(4)	included in 35.50(e)(4)	
35.50(e)(1)		570,000
35.50(e)(2)		22,800
35.50(e)(3)		228,000
35.50(e)(4)		22,800
35.51(e)		30,000
35.53(c)		9,900,000
35.59(a)		15,000
35.59(d)		300,000
35.59(e)		120
35.59(g)		264,000
35.59(i)		264,000
35.62		855,000

Section		Annual Cost to Respond
35.63		12,000
35.70(d)		31,680
35.70(g)		31,680
35.70(h)		8,580,000
35.80(f)		300,000
35.92(b)		792,000
35.204(c)		570,000
35.205(e)		2,400
35.310(a)		360,000
35.310(b)		42,000
35.315(b)		60
35.315(c)		100,800
35.315(g)		84,000
35.404(b)		24,000
35.406(b)		48,000
35.406(c)		24,000
35.406(d)	included in 35.406(b) and (c)	
35.410(a)		144,000
35.410(b)		24,000
35.415(b)		60
35.415(c)		57,600
35.606		2,400
35.610(a)		3,000
35.610(b)		12,000
35.610(c)		2,400
35.621(e)		120,000
35.630(c)		12,000
35.632(e)		24,000
35.632(g)		384,000
35.633(e)		52,800
35.633(j)		288,000
35.641(c)		48,000
35.642(c)		6,000
35.643(c)		120

Section	Annual Cost to Respond
35.643(d)	120
35.644	3,000
35.645(c)	600
Total	$25,585,740

Source of Burden and Cost Data and Method of Estimating and Cost

The estimates are based on submittals to NRC in past years. Cost to licensees and applicants is calculated at a rate of $60.00 per hour. This figure includes both salaries and overhead.

Reason for Apparent Increase in Burden

Licensees keep the required records now in order to comply with conditions of their individual licenses. The proposed rulemaking simply codifies the usual recordkeeping requirements as part of the regulation. Therefore, licensees will not experience any real increase in recordkeeping burden; the legal requirement is simply shifted from the individual license (where burden estimates are not required) to the regulation (where burden estimates are required).

Estimate of Cost to the Federal Government

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

Annual Cost of NRC staff review for activities other than application review. (Professional effort is 640 hours @ $60.00 (hr)). = $38,400