

FINAL OMB SUPPORTING STATEMENT
FOR
10 CFR PART 31
GENERAL DOMESTIC LICENSES FOR BYPRODUCT MATERIAL
(3150-0016)

EXTENSION REQUEST WITH BURDEN REVISIONS

Description of the Information Collection

Part 31 of Title 10 of the Code of Federal Regulations establishes general licenses for certain types of activities. The terms and conditions of the general licenses require that records must be kept by the general licensees and/or the general licensees must submit reports to the NRC.

A. JUSTIFICATION

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

Section 31.2 establishes the terms and conditions of the general licenses issued pursuant to Sections 31.3, 31.5, 31.6, 31.7, 31.8, 31.9, 31.10, and 31.11 of this Part. These terms and conditions include certain requirements in 10 CFR Parts 19, 20, 21, and 30. Those requirements have previously been cleared by Office of Management and Budget (OMB) and the appropriate OMB clearance documents, listed below, should be referred to for additional supporting information, burden and cost data.

<u>10 CFR Part</u>	<u>OMB Clearance No.</u>
19	3150-0044
20	3150-0014
21	3150-0035
30	3150-0017

Section 31.5 establishes the requirements for a general license for certain measuring, gauging, or controlling devices. The devices contain radioactive byproduct material and are designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere. The devices are distributed to the general licensees by persons licensed in accordance with Section 32.51 and are manufactured under strict quality control standards and prototype testing. These controls provide reasonable assurance that under conditions of ordinary use and by persons not having training in radiation protection, the devices can be operated safely and without radiological hazard to the users and public.

Section 31.5(c)(4) requires that the general licensee maintain records showing that tests for leakage of radioactive materials, proper operation of on-off mechanism, and/or other specified tests have been performed. Many of the devices require testing for leakage, proper operation of the on-off mechanism and indicator, and installation, servicing, and removal from installation in accordance with instructions on the label or by a person holding a specific license to perform such activities. The records must contain the result of the tests, the date the tests were performed, and the names of the individuals performing testing, installing, servicing, and removing radioactive material and its shielding or containment, and records must be maintained for 3 years or until the device is transferred or disposed of. The records are used by NRC inspectors to determine that there has been compliance with the requirements of the general

license.

Section 31.5(c)(5) requires that the general licensee report, within 30 days, to the Director, Office of Nuclear Material Safety and Safeguards, the occurrence of a failure of or damage to the shielding of the radioactive material or the on-off mechanism or indicator on the generally licensed device, or upon the detection of 0.005 microcurie or more of removable radioactive material. The report must contain a brief description of the event and the remedial action taken. In addition, the licensee is required to submit a plan for ensuring that the premises and environs are acceptable for unrestricted use in the event that detection of 0.005 microcurie or more removable radioactive material, or failure of or damage to a source, is likely to result in contamination of the premises or the environs.

This reporting requirement is necessary to ensure that the NRC is notified of any problems or potential problems with devices held under a general license. It is important that the NRC receive such reports to determine if damage or failure of a device could or did constitute a radiation safety problem and to determine that the remedial action taken was appropriate. These reports also provide experience data which could assist in identifying a generic problem. The requirement for plans for ensuring that the premises and environs are acceptable for unrestricted use is to require that general licensees, who are not subject to decommissioning requirements, have adequate plans and procedures for cleaning up any contamination.

Section 31.5(c)(8) requires that general licensees transfer or dispose of devices containing byproduct material only (1) by export under NRC's import/export regulations in 10 CFR Part 110, (2) by transfer to a person authorized to receive the device by a specific license issued under Parts 30 and 32 of this chapter, or equivalent regulations of an Agreement State (distributor), (3) by transfer to a specific licensee under Part 30, or equivalent regulations of an Agreement State authorized for waste collection, (4) by transfer to another general licensee as authorized in Section 31.5(c)(9) below, or (5) by transfer to any other specific licensee with prior written approval. Upon transfer, the general licensee shall, within 30 days after such transfer, furnish to the Director of Nuclear Material Safety and Safeguards, a report containing identification of the device, the name, address, and license number of the person receiving the device, and the date of transfer.

These reports are necessary so that the NRC can make a determination that the transfer of a device was to a person authorized to receive the device. Such reports also assist in determining when devices are removed from service at a particular location and in tracking individual devices.

Section 31.5(c)(9) requires the general licensee wishing to transfer a device to another general licensee to do so only under certain circumstances and the general licensee is required to give the transferee a copy of Sections 31.5, 31.2, 30.51, 20.2201, and 20.2202 and any safety documents identified in the label of the device. In addition, the general licensee shall report within 30 days to the Director of Nuclear Material Safety and Safeguards, the manufacturer's (or initial transferor's) name, the model number and serial number of the device, the name of the transferee and the mailing address for the location of use, and the name, title and phone number of the responsible individual identified by the transferee as having the knowledge and authority for taking required actions to comply with regulatory requirements.

The transferor must provide copies of NRC regulations and safety documents to a transferee to ensure he has all necessary safety information for using the device. The required report to NRC is the only mechanism available for making the NRC aware that a particular general licensee is no longer responsible for a device at a particular location and that a different person

is responsible for the device and has the qualifications to act in that regard.

Section 31.5(c)(11) requires general licensees to respond to written requests from NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Office of Nuclear Material Safety and Safeguards and provide written justification as to why it cannot comply.

This requirement is contained in this section to clarify that the NRC may request information from the general licensee, if needed in carrying out its duties.

Section 31.5(c)(13) requires annual registration of devices for general licensees whose devices meet the registration criteria contained in this section. The general licensee is required to verify, correct, and/or add to information provided in the request for registration and submit this information to NRC within 30 days of the request. This information includes: (a) name and mailing address of the general licensee; (b) information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label); (c) the name, title, and phone number of the responsible person designated as a representative of the general licensee under Section 31.5(c)(12); (d) the address or location at which the device(s) are used and/or stored. For portable devices, the address of the primary place of storage; (e) certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information; and (f) certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

NRC Form 664, "General Licensee Registration," which is used to collect this information, has previously been cleared under OMB Clearance No. 3150-0198, which should be referred to for additional supporting information, burden, and cost data.

Section 31.5(c)(14) requires general licensees to notify NRC within 30 days of changes of address for the location of use of devices. For portable devices, the change of address reporting applies only to the device's primary place of storage.

This will allow the NRC to track general licensees for contact or inspection purposes. The quarterly reports required of distributors under Section 32.52(a) and (b) provide NRC and the Agreement State regulatory agencies with the identity of general licensees in their jurisdictions and the location of use of the generally licensed devices. If general licensees move their operations without notifying NRC or the appropriate Agreement State agency, they may be difficult to locate.

Section 31.8(c)(2) requires that persons generally licensed in accordance with Section 31.8 shall not receive, possess, use or transfer a generally licensed americium-241 calibration or reference source unless it bears a label which contains sufficient information relative to safe use and storage of the source, identification that receipt, possession, use, and transfer of the source are subject to a general license, and contain the model number and serial number. This requirement is necessary because it is the only means the Commission has to inform anyone who may come in contact with the calibration or reference source what they are and their model and serial number in the event they are lost and need to be identified.

Section 31.11(b) requires a physician receiving, possessing, using or transferring byproduct material in accordance with the general license in Section 31.8 to file NRC Form 483, "Registration Certificate--In Vitro Testing With Byproduct Material Under General License." The

physician will receive a validated copy back from NRC with a registration number assigned. This requirement is necessary because suppliers of byproduct material are required to determine that the person receiving the material is authorized to receive it. The validated registration certificate serves as evidence for the supplier that a physician is a general licensee authorized to receive the byproduct material. The certificate also contains the terms and conditions of the general license and assures that the general licensee is aware of terms and conditions prior to receipt of byproduct material. NRC Form 483 has previously been cleared under OMB No. 3150-0038, which should be referred to for additional supporting information, burden, and cost data.

Section 31.11(e) requires a physician receiving, possessing, using or transferring byproduct material in accordance with the general license in Section 31.8 to report any changes to the information furnished on NRC Form 483 within 30 days. The NRC staff uses the information submitted on the registration form to identify each physician using byproduct material under the general license. The registration information facilitates communication with the general licensee. NRC Form 483 has previously been cleared under OMB No. 3150-0038, which should be referred to for additional supporting information, burden, and cost data.

2. Agency Use of Information

The records required by Section 31.5(c)(4) are used by NRC inspectors to determine that there has been compliance with the requirements of the general license. It is important that NRC receive reports required by Section 31.5(c)(5) so that NRC may determine if damage or failure of a device could or did constitute a radiation safety problem and to determine if remedial action taken was appropriate. Other reports required by the regulation are important so that NRC can determine that the transfer of a device is to a person specifically licensed to receive the device, to assist in determining when a device is removed from a particular location, and for determining when a general licensee is no longer responsible for the device. The requirements in Section 31.8(c)(2) are necessary so that, in the event of a lost source, the NRC can provide information about the source to anyone who comes in contact with the source.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. However, because of the types of information and the infrequency of submission, the registration certificates and reports do not lend themselves readily to the use of automated information technology for submission. Consequently, the percentage of electronic submissions is zero.

4. Effort to Identify Duplication and Use Similar Information

The Information Requirements Control Automated System was searched to determine duplication. None was found. There is no similar information available to the NRC.

5. Effort to Reduce Small Business Burden

While a number of the licensees are considered small businesses, under the NRC's current definitions, the health and safety consequences of improper use of radioactive material are the same for large and small entities. Therefore, it is not possible to reduce the burden on small businesses by less frequent submission or less complete applications.

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

Required reports are collected and evaluated on a continuing basis as events occur. 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.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the Office of Management and Budget Guidelines (OMB) in 5 CFR 1320.6(b), Sections 31.5(c)(5), 31.5(c)(8), 31.5(c)(9), 31.5(c)(11), 31.5(c)(13), 31.5(c)(14), and 31.11(e) require that licensees submit a notification to NRC in less than 30 days from the date of the actions required by the respective sections. The requirement to provide notification within 30 days is necessary to ensure that NRC is made aware of any significant safety information associated with events or transfers so as to take prompt action to protect the public health and safety.

8. Consultations Outside NRC

The opportunity for public comment on the information collection requirements was published in the Federal Register on April 16, 2002 (67 FR 18639).

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

None, except for proprietary information.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

NRC Licensees

Recordkeeping Requirements

Section	No. of Recordkeepers	Annual Hrs Per Recordkeeper	Total Annual Recordkeeping Hrs	Record Retention Period	Comments
31.5(c)(4)	7,600	0.25	1,900	3 years	
31.8(c)(2)	6	0.25	2	length of license	
TOTAL	7,600		1,902		

Reporting Requirements

Section	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Reporting Burden (Hrs)	Comments
31.2				See following OMB Clearances 10 CFR Part 19 3150-0044 10 CFR Part 20 3150-0014 10 CFR Part 21 3150-0035 10 CFR Part 30 3150-0017
31.5(c)(5)	27	2.8	76	
31.5(c)(8)	13,100	0.6	7,860	
31.5(c)(9)	29	1	29	
31.5(c)(11)	1,531	0.34	516	
31.5(c)(13)				See OMB Clearance 3150-0198
31.5(c)(14)	100	0.1	10	
31.11(b)				See OMB Clearance 3150-0038
31.11(e)				See OMB Clearance 3150-0038
Total	14,787		8,491	

Total Annual Burden Hours (NRC licensees): 10,393 hours (recordkeeping and reporting)

Agreement State Licensees:

NRC estimates that Agreement States have 3 times as many licensees as does NRC. The NRC has assumed that the amount of licensee staff hours and cost will be the same as for NRC licensees.

Recordkeeping Requirements

Section	No. of Recordkeepers	Annual Hrs Per Recordkeeper	Total Annual Recordkeeping Hrs	Record Retention Period	Comments
31.5(c)(4)	22,800	0.25	5,700	3 years	
31.8(c)(2)	18	0.25	5	length of license	
TOTAL	22,800		5,705		

Reporting Requirements

Section	No. of Licensee Responses Annually	Licensee Staff Hours Per Submittal	Total Annual Reporting Burden (Hrs)	Comments
31.2				See following OMB Clearances 10 CFR Part 19 3150-0044 10 CFR Part 20 3150-0014 10 CFR Part 21 3150-0035 10 CFR Part 30 3150-0017
31.5(c)(5)	81	2.8	227	
31.5(c)(8)	39,300	0.6	23,580	
31.5(c)(9)	87	1	87	
31.5(c)(11)	4,594	0.34	1,546	
31.5(c)(13)	12,900	0.33	4,257	
31.5(c)(14)	300	0.1	30	
31.11(b)				See OMB Clearance 3150-0038
31.11(e)				See OMB Clearance 3150-0038
Total	57,262		29,727	

Total Annual Burden Hours (Agreement States): 35,432 (recordkeeping and reporting)

Total Part 31 Burden Hours: 45,825

Based on the total annual burden hours for recordkeeping and reporting, the total annual cost to NRC licensees is \$1,496,592 (1,902 recordkeeping hours + 8,491 reporting hours = 10,393 hours x \$144) and the total annual cost to Agreement State licensees is \$5,102,208 (5,705 recordkeeping hours + 29,727 reporting hours = 35,432 hours x \$144).

13. Estimate of Other Additional Costs

NRC has determined that the records storage cost is roughly proportional to the recordkeeping burden cost. Based on a typical clearance, the records storage cost has been determined to be equal to 0.04 percent of the recordkeeping burden cost. Therefore, the records storage cost for this clearance is insignificant, as shown below:

- \$438 (7,607 hours recordkeeping [1,902 NRC + 5,705 Agreement State hours] x .0004 x \$144/hr).

14. Estimated Annualized Cost to the Federal Government

The NRC staff time and associated burden for the requirements of Section 31.2 are included in the OMB clearance for the appropriate Sections of Parts 19, 20, 21, and 30. Application review activities are attributable to and reported under NRC Form 483, OMB Clearance No. 3150-0038. The estimated cost of NRC professional review and other efforts attributable to the other requirements is 1,650 hours at \$144/hr = \$237,600. This cost is fully recovered through fee assessments to NRC licensees pursuant to 10 CFR Parts 170 and/or 171.

15. Reason for Change in Burden or Cost

This clearance extension renewal incorporates the changes to Part 31 from the final amendments to 10 CFR Part 31 for the rulemakings entitled, "Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Information" that OMB approved on September 10, 1999, and "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," that OMB approved on November 20, 2000. These changes include the submittal of 7 plans at 8 hours burden each (for an additional burden of 56 hours) under 10 CFR Part 31.5(c)(5) for NRC licensees (21 plans for Agreement State licensees for an additional burden of 168 hours). In addition, Part 31.5(c)(11) in the first-stated final rule requires an estimated 1531 responses from NRC licenses with an average burden of 0.34 hours per response (burden of 516 hours) and 4594 responses for Agreement State licensees (burden of 1546 hours). Although there are minor changes in burden and number of responses included in this submittal for re-estimation of the number of responses, the principal change in the number of responses is attributable to the latter rulemaking counting revisions to the information required to be submitted in the reports required by 31.5(c)(8) and 31.5(c)(9) as additional responses (-461 responses). In addition, there is a change in cost to reflect the increase in the fee rate.

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 out of date, would confuse the public.

18. Exceptions to the Certification Statement

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.