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

REVISION

Description of the Information Collection

Part 31 of Title 10 of the *Code of Federal Regulations* (10 CFR) establishes general licenses for possession, use, and ownership of byproduct materials. The regulations governing the general licenses require that general licensees must maintain records and submit information to the U.S. Nuclear Regulatory Commission (NRC) or an Agreement State. The vast majority of general licensees are regulated under 10 CFR 31.5 and depending on the type and quantity of radioactive material in each device, may be subject to the requirement to annually register generally licensed devices with the NRC or an Agreement State. All general licensees under 10 CFR 31.5 are subject to the following requirements: (1) maintain records as applicable, for 3 years (or until the device is transferred or disposed) showing results of tests on the devices, who tested or leak tested the device, and when it occurred; (2) report to the NRC if a transfer, loss, failure, or damage to, the radioactive material device, on-off mechanism, or indicator on the device occurs, or if 0.005 microcurie or more of removable radioactive activity is detected; (3) provide regulatory and safety-related documents to the licensee receiving the device; (4) respond within 30 days to written requests from the NRC for information related to their licenses; and (5) report to the NRC on changes in the licensees name or location of use of generally licensed devices containing byproduct material.

A. JUSTIFICATION

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

Reporting requirements for 10 CFR Part 31 are generally required to ensure that the NRC or Agreement State is notified in a timely manner of any abnormal occurrences or potential problems with generally licensed devices or to assist the NRC or Agreement State in tracking the location of generally licensed devices. Recordkeeping requirements for 10 CFR Part 31 are generally required to ensure that the records may be reviewed by the NRC and Agreement States inspectors to determine that the devices are in compliance with the regulatory requirements.

For more specific information regarding why each information collection requirement is needed, see Appendix A of this document.

2. Agency Use of Information

The records required by Section 31.5(c)(4) are used by NRC inspectors to establish compliance with the requirements of the general license regulations. 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 hazard and to determine if remedial action taken was appropriate. Other reports and records required by the regulation are important so that NRC can determine that the transfer of a device for disposal 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 may provide, on request, information about the source/device to anyone who is exposed to the device source or sources.

3. Reduction of Burden Through Information Technology

The NRC has issued *Guidance for Electronic Submissions to the NRC* which provides direction for the electronic transmission and submittal of documents to the NRC. Electronic transmission and submittal of documents can be accomplished via the following avenues: the Electronic Information Exchange process, which is available from the NRC's "Electronic Submittals" Web page, by Optical Storage Media (e.g. CD-ROM, DVD), by facsimile or by e-mail. It is estimated that approximately 5 percent of the responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

No sources of similar information are available. There is no duplication of requirements.

5. Effort to Reduce Small Business Burden

While a number of the licensees are considered small businesses, 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 summary 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 the NRC to assure that the public health and safety and environment is adequately protected.

7. Circumstances Which Justify Variation from OMB Guidelines

Contrary to the OMB Guidelines 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), 31.12(c)(1), 31.12.(c)(5) and 10 CFR 20.2201 and 20.2202 require that licensees shall report immediately for the loss of certain devices and submit a report or notification to the NRC in less than 30 days from the date of the actions required by the respective sections. The requirement to provide a report or notification within 30 days is necessary to ensure that the 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

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on April 10, 2018 (83 FR 15421). Nine companies or institutions that use byproduct material under a general license were contacted by e-mail as part of the public consultation process to request comments on this clearance package. The companies and institutions contacted are: Henkel US Operations Co., Agilent Technologies, Inc., Tennessee Valley Authority, VA - St. Louis Health Care System, United States Geological Survey, Liberty Oilfield Services, Solvay Specialty Polymers, NIST, and Noble Energy, Inc. No comments were received.

9. Payment or Gifts to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, general licensees are advised and discouraged from submitting information that is proprietary, confidential or involving trade secrets.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

NRC Licensees:
See Tables 1, 2, and 3 for the estimated reporting, recordkeeping, and third-party disclosure burden for a total of approximately 18,000 NRC general licensees that will respond to and/or maintain records in accordance with 10 CFR Part 31 information collection requirements. The estimated total number of responses for each requirement listed in 10 CFR Part 31 was approximated based on past experience and staff expectations for the period of this clearance. The total annual burden for NRC licensees is estimated to be 4,926 hours (420 reporting + 4,500 recordkeeping + 6 third-party disclosure). The total cost for NRC licensees is estimated to be $1,295,538 (4,926 hours x $263/hour).

Agreement State Licensees:
See Tables 4, 5, and 6 for the estimated reporting, recordkeeping, and third-party disclosure burden for an estimated 111,600 Agreement State general licensees that will respond to and/or maintain records in accordance with Part 31 information collection requirements. The NRC estimated the number of Agreement State licensees based on the current status and knowledge of Agreement State programs. The NRC estimates that there are approximately 6.2 times the number of Agreement State licensees as there are NRC licensees. This estimate based on the estimate of 2,900 NRC specific materials licensees and 18,000 Agreement State licenses. Taking into account this ratio, the total annual burden for Agreement State general licensees is estimated to be 31,712 hours (3,779 reporting + 27,900 recordkeeping + 33 third-party disclosure) per year. The total cost for the Agreement State licensees is estimated to be $8,340,256 (31,712 hours x $263/hour).

Total:

The total burden for both NRC and Agreement State licensees is estimated to be 36,638 hours (4,926 hours for NRC licensees + 31,712 hours for Agreement State licensees). The total cost is $9,635,794 (36,638 hours x $263/hour).

The $263 hourly rate used in the burden estimates is based on the NRC's fee for hourly rates as noted in 10 CFR 170.20 "Average cost per professional staff-hour." For more information on the basis of this rate, see the *Federal Register* notice at: (82 FR 30682; June 30, 2017).

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 to be equal to 0.0004 times the recordkeeping burden cost. Therefore, the storage cost for this clearance is $3,408 (32,400 hours recordkeeping [4,500 hours for NRC licensees + 27,900 hours for Agreement State licensees] x .0004 x $263/hour).

14. Estimated Annualized Cost to the Federal Government

The staff has developed estimates of annualized costs to the Federal Government related to the conduct of this collection of information. These estimates are based on staff experience and subject matter expertise and include the burden needed to review, analyze, and process the collected information and any relevant operational expenses.

The estimated cost of NRC professional review and other efforts attributable to the 10 CFR 31 requirements addressed in this clearance is $1,293,960 (4,920 hours x $263/hour).

15. Reasons for Change in Burden or Cost

The estimated overall burden increased by 451 hours from 36,186 hours to 36,638 hours. This is primarily due to the fact that the new estimate incorporates an updated estimate of the total number of general licenses in NRC jurisdiction and in Agreement States, which led to a slight increase in the estimated number of burden hours attributable to recordkeeping. Also, burden in this supporting statement more accurately accounts for burden due to third-party disclosures.

In addition, the fee rate decreased from $279 to $263 per hour.

16. Publication for Statistical Use

This information will not be published for statistical use.

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

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.

Table 1 - Reporting Requirements for 10 CFR Part 31 NRC Licensees

Section	Description	Number of Respondents	Number of Responses	Total Annual Responses	Burden Hours Per Response (hours)	Total Annual Burden (hours)	Cost @ $263/hr
31.5(c)(5)	Event reports	2	1	2	2.8	6	1,578
31.5(c)(8)	Transfer reports	310	1	310	0.6	186	48.918
31.5(c)(9)	Transfer reports (same location)	20	1	20	1	20	5.260
31.5(c)(11)	Responses to written NRC requests	600	1	600	0.34	204	53,652
31.5(c)(13)	Annual registration	See OMB clearance 3150-0198 (NRC Form 664)					
31.5(c)(14)	Report change of mailing address	40	1	40	0.1	4	1,052
31.11(b) & (e)	In-vitro testing	See OMB clearance 3150-0038 (NRC Form 483)					
31.12(c)(1)	Report apparent damage	0	1	0	4	0	0
31.12(c)(4)	Follow Federal or State requirements	0	1	0	4	0	0
31.12(c)(5)	Responses to written NRC requests	0	1	0	4	0	0
TOTAL		972		972		420	$110,460

Table 2 - Recordkeeping Requirements for 10 CFR Part 31 NRC Licensees

Section	Description	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden (hours)	Record Retention Period	Cost @ $263/hr
31.5(c)(4)	Records related to test results and other requirements	18,000	0.25	4,500	3 years	$1,183,500
TOTAL		18,000		4,500		$1,183,500

Table 3 – Third-party Disclosure Burden for 10 CFR Part 31 NRC Licensees

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent (hours)	Total Annual Burden (hours)
31.5(c)(9)	Copy of regulations and safety documents	20	1	20	0.25	5
31.8(c)(2)	Labeling of source or container	1	1	1	0.5	0.5
TOTAL		21		21		6

Total Estimated NRC Burden: 4,926 hours (420 reporting + 4,500 recordkeeping + 6 third-party disclosure)

Table 4 - Reporting Requirements for 10 CFR Part 31 Agreement State Licensees

Section	Description	Number of Respondents	Number of Responses	Total Annual Responses	Burden Hours Per Response (hours)	Total Annual Burden (hours)	Cost @ $263/hr
31.5(c)(5)	Event reports	12	1	12	2.8	34	8,942
31.5(c)(8)	Transfer reports	1,950	1	1,950	0.6	1,170	307,710
31.5(c)(9)	Transfer reports (same location)	130	1	130	1	130	34,190
31.5(c)(11)	Responses to written NRC requests	3,720	1	3,720	0.34	1,265	332,695
31.5(c)(13)	Annual registration	3,500	1	3,500	0.33	1,155	303,765
31.5(c)(14)	Report change of mailing address	250	1	250	0.1	25	6,575
31.11(b) & (e)	In-vitro testing	See OMB clearance 3150-0038 (NRC Form 483)					
31.12(c)(1)	Report apparent damage	0	1	0	4	0	0
31.12(c)(4)	Follow Federal or State requirements	0	1	0	4	0	0
31.12(c)(5)	Responses to written NRC requests	0	1	0	4	0	0
TOTAL		9,562		9,562		3,779	$993,877

Table 5 - Recordkeeping Requirements for 10 CFR Part 31 Agreement State Licensees

Section	Description	Number of Recordkeepers	Hours Per Recordkeeper	Total Annual Burden (hours)	Record Retention Period	Cost @ $263/hr
31.5(c)(4)	Records related to test results and other requirements	111,600	0.25	27,900	3 years	$7,337,700
TOTAL		111,600		27,900		$7,337,700

Table 6 – Third-party Disclosure Burden for 10 CFR Part 31 Agreement State Licensees

Section	Description	Number of Respondents	Responses per Respondent	Total Responses	Annual Burden per Respondent (hours)	Total Annual Burden (hours)
31.5(c)(9)	Copy of regulations and safety documents	120	1	120	0.25	30
31.8(c)(2)	Labeling of source or container	6	1	6	0.5	3
TOTAL		126		126		33

Total Estimated Agreement State Burden: 31,712 hours (3,779 reporting + 27,900 recordkeeping + 33 third-party disclosure)

Total Estimated Overall Burden: 36,638 hours (4,199 reporting + 32,400 recordkeeping + 39 third-party disclosure)

Total Estimated Responses: 140,281 (10,681 responses + 129,600 recordkeepers)

Appendix A: Information Collection Requirements

Section 31.5 establishes regulatory 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 initially distributed to the general licensees by persons licensed in accordance with Section 32.51. Generally licensed devices are subjected to regulatory requirements and in-depth reviews are performed as these devices are to be used by persons requiring no radiological training. Additionally, the devices are required to have tamper-proof features.

Section 31.5(c)(4) requires that the general licensee shall maintain records showing compliance with Sections 31.5(c)(2) and 31.5(c)(3); which require the licensee to assure that prescribed periodic leak tests, proper operation of on-off mechanism, and/or other specified tests have been performed. Section 31.5(c)(4) further specifies that 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. Records must be maintained for 3 years or until the device is transferred or disposed. On an as needed basis, the test records are reviewed by the NRC and Agreement States inspectors to test their accuracy, completeness and determine that the devices are in compliance with the regulatory requirements.

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 or damage to the containment boundary or 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 of 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 in a timely manner of any abnormal occurrences or potential problems with generally licensed devices authorized by the NRC. 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 determine that the remedial action taken was appropriate. These reports also provide device performance data which could assist in identifying and characterizing 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 general licensed 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 10 CFR Parts 30 and 32 of, this chapter, or equivalent regulations of an Agreement State (manufacturer/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). Upon transfer, the general licensee shall, within 30 days after such transfer, furnish to the Director, Office of Nuclear Material Safety and Safeguards, a report containing identification of the device by manufacturers (or initial transferor's) name, model number, and serial number, the name, address, and license number of the person receiving the device (license number is not required if the device is exported), and the date of transfer.

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

Section 31.5(c)(9) requires the general licensee wishing to transfer a generally licensed device pursuant to 10 CFR Part 31.5 to another general licensee to do so only under certain circumstances and the general licensee is required to give the transferee, as a minimum, a copy of Sections 30.51, 31.2, 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, Office 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. Additionally, the name of a contact person, and the 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 must be included in the report.

The transferor must provide copies of applicable NRC regulations and safety documents to a transferee to ensure the new licensee has all necessary safety information for using the device and enable the new licensee to ensure the day-to-day compliance with regulations and requirements. The required reporting to NRC is the only mechanism available for making the regulatory authorities 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 or devices 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 for the request.

This requirement is contained in this section to clarify that the NRC may request information from the general licensee during the useful working life of a device, if needed in fulfilling its duties.

Section 31.5(c)(13) requires annual registration of certain general licensed devices which were manufactured or initially transferred and labeled in accordance with specifications contained in a specific license issued to 10 CFR 32.51. Devices for general licensees whose devices meet the annual registration criteria are contained in Section 31.5(c)(13). These general licensees are required annually to verify, correct, and/or add to information provided in the request for registration from the NRC 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. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

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 (including change of name of general licensee) of devices. For portable devices, the change of address reporting applies only to the device’s primary place of storage.

This requirement allows 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 general 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 licensed in accordance with Section 31.8 shall not receive, possess, use or transfer a general licensed americium-241 or radium-226 calibration or reference source unless it bears a label which contains sufficient information relative to safe use and storage of the source, such as identification that receipt, possession, use, and transfer of the source are subject to a general license, and contains the source model number and serial number. This requirement is necessary because it is the only means that 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 or damaged and need to be identified.

Section 31.11(b) requires a physician, veterinarian in the practice of veterinary medicine, clinical laboratory or hospital 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 contains terms and conditions of the general license that assure that the general licensee is aware of terms and conditions prior to receipt of the 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 31.11(a) 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.

Section 31.12 allows for a general license for certain items and self-luminous products containing radium-226. Section 31.12(a) states that a general license is issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the products manufactured prior to November 30, 2007.

Section 31.12(c)(1) states that any person, who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section, shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days. This reporting requirement is necessary to ensure that the NRC is notified in a timely manner of any potential problems with these generally licensed devices authorized by the NRC.

Section 31.12(c)(5) states that any person, who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section, shall respond to written requests from the 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. Furthermore, 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 providing the Director of the Office of Nuclear Material Safety and Safeguards a written justification for the request. This requirement is contained in this section to clarify that the NRC may request information from the general licensee during the useful working life of a device, if needed in fulfilling its duties.