FINAL OMB SUPPORTING STATEMENT FOR NRC FORM 664 GENERAL LICENSEE REGISTRATION (3150-0198)

EXTENSION

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) requires annual registration of certain radioactive devices issued under Title 10 *Code of Federal Regulations* (CFR). The NRC Form 664, "General Licensee Registration," is used for the collection of information pertaining to generally licensed devices that are subject to registration under 10 CFR Section 31.5. The annual registration criteria are based on radionuclide and the amount of byproduct material contained in the device at the time of purchase. If a generally licensed device contains one or more of the following isotopes, it is subject to an annual registration: 1) 370 megabecquerel (10 millicurie) cesium-137; 2) 37 megabecquerel (1 millicurie) cobalt-60; 3) 37 megabecquerel (1 millicurie) americium-241, or any other transuranic; 4) 3.7 megabecquerel (0.1 millicurie) strontium-90; or 5) 3.7 megabecquerel (0.1 millicurie) radium-226.

The NRC has developed a standard format, NRC Form 664, "General Licensee Registration," for general licensees to provide the required information. When sent to the general licensee by the NRC, the form will provide available information to the general licensee and requires the general licensee to verify and update the information as necessary. Essential information to be verified/updated on the form include 1) the name, title, and telephone number of the individual responsible for the device; 2) a mailing address and an address of use or storage for the device; and 3) information pertaining to the device such as manufacturer's name, device serial number, device model number, and the isotope and activity contained within the device. The registration Form 664 and instructions will be provided by the NRC to all affected general licensees.

A. JUSTIFICATION

1. Need for and Practical Utility of the Information Collection

In the past, general licensees were not contacted by the NRC on a regular basis for information on devices possessed, because of the relatively small radiation risk posed by these devices. However, a number of occurrences involving generally licensed devices suggest better accounting for such devices may be beneficial. For example, one or more cesium gauges were mixed in with scrap metal that was smelted to form steel, and the entire batch of steel was contaminated. There have been other types of incidents involving NRC generally licensed devices; however, lack of accountability remains the most common problem and the predominant concern.

The NRC has concluded that there is a lack of adequate awareness of applicable regulations on the part of the device user and inadequate handling and accounting for these devices. The NRC further concluded that these two problems can be addressed by more frequent and timely contact between the general licensee and NRC in the form of a registration program for the higher risk devices. The NRC Form 664 is used for the collection of information pertaining to the annual registration of certain generally licensed devices.

2. Agency Use of the Information

General licensees are required to submit information periodically, which to allow the Agency to better track general licensed devices, and so that licensees can be contacted or inspected to ensure that the devices can be identified or tracked even if lost or damaged.

3. <u>Reduction of Burden Through Information Technology</u>

The NRC has issued <u>Guidance for Electronic Submissions to the NRC</u> 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 1% of the responses are filed electronically.

Currently NRC scans the form manually or by an automatic batch scanner to upload the information into the general licensing tracking data base.

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

Because the majority of the general licensees are small businesses, care was taken to require only the minimum amount of information needed in order to assure that the health and safety of the public is protected. In an effort to simplify the process, licensees will be provided with information from the NRC database for verification and correction, rather than being required to provide all information on a blank form. It is not possible to further reduce burden on small businesses by reducing the information collection and still adequately track ownership and disposition of the devices.

6. <u>Consequences to Federal Program or Policy Activities if the Collection is not</u> <u>Conducted or is Conducted Less Frequently</u>

Periodic reporting is essential to assure that devices containing byproduct material are maintained and transferred properly. No reporting would result in a higher probability of devices being inadvertently discarded, and could lead to a diminished level of protection for the health and safety of the public, and the environment.

7. <u>Circumstances Which Justify Variation From OMB Guidelines</u>

There is no variation from OMB guidelines.

8. <u>Consultation Outside the NRC</u>

Opportunity for public comment on the information collection requirements for this clearance package was published in the Federal Register on September 7, 2018 (83 FR 45471). Four general licensees that required registration were contacted as part of the public consultation process, via email. The general licensees contacted were: Louisiana-Pacific Corporation, the Dow Chemical Company, AG Processing, Inc., Conoco Phillips Alaska, Inc. No comments were received. In addition, the NRC received two comments from members of the public. One comment is out of scope, it was not related to the information collection request. The other comment recommended removing Section 6 - Devices not subject to registration, or making sure the information is correct and up to date. The commenter also stated that making correction is difficult via mail.

NRC Response

Section 6 lists any additional devices the general licensee possesses, which are not subject to registration. It also provides general licensees with an opportunity to review their generally licensed device inventory based on the U.S. NRC's records. A review of the inventory also provides general licensees with an opportunity to inform the U.S. NRC of any changes in their inventory. The list of devices in Section 6 is generated from existing data in U.S. NRC's General License Tracking System (GLTS). Any errors contained in Section 6 may be corrected when submitting NRC Form 664 to the U.S. NRC. In general, any information contained in NRC Form 664 is retrieved from vendor guarterly reports, for newly distributed devices, and from transfer reports submitted by general licensees. Section 6 provides licensees with an annual opportunity to correct device information contained in GLTS, especially for information submitted by distributors and or manufacturers. While the devices in Section 6 may not be subject to an annual registration, the U.S. NRC notes that 10 CFR 31.5(c)(8)(ii) requires that licensees notify the U.S. NRC, in writing, of any transfers of generally licensed devices within 30 days of the transfer. These transfer reports, along with the vendor guarterly reports, are essential for maintaining an updated GLTS.

9. Payment or Gift to Respondents

Not applicable.

10. <u>Confidentiality of Information</u>

Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17 (a) and 10 CFR 2.390 (b). However, no information normally considered confidential or proprietary is requested.

11. Justification for Sensitive Questions

This information collection does not request sensitive information.

12. Estimated Burden and Burden Hour Cost

Approximately 525 general licensees are expected to respond to written registration requests from the NRC annually. The average burden per response to these written requests is 20 minutes for an overall estimated annual burden of 175 hours (525 x 1/3 hour), and a cost of approximately \$46,025 (175 x \$263/hour).

The \$263 hourly rate used in the burden estimate is based on the Nuclear Regulatory Commission'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

There are no additional costs.

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.

Based on the current estimate of affected licensees, the estimated annualized cost to the Federal Government for registration, as a result of the amendment to 10 CFR 31.5(c)(11) is as follows:

Mailing a request for verification of devices possessed by general licensees and logging the response into the computerized directory or recording that verification has been received, will take approximately 26.25 hours (525 requests @ 3 minutes per request). The annual cost would be approximately \$6,904 (26.25 hours x \$263/hour).

It is estimated that approximately 56 general licensees (10 percent) will call for technical assistance during the annual registration. Approximately 15 minutes of staff time will be required to respond to each of these requests, or 14 hours (56 x 15/60). Approximately 30 minutes of staff time will be required to respond to each of the other 40 technical requests, this number was adjusted to accommodate naturally occurring and accelerator produced radioactive material (NARM) related inquiries, or 20 hours (40 x 30/60), for a total of 34 hours (14 + 20), each year. The annual cost will be approximately \$8,942 (34 hours x 263/hour).

The total annual average registration cost to the Federal Government estimated for the next 3 years is \$47,538 (\$20,712 + \$26,826). Note that this does not include the costs associated with the scanning of the returned registrations, nor the resolutions of those registrations that require significant amount of follow-up or require NRC regional inspections.

15. Reasons for Changes in Burden or Cost

The change in the overall burden estimate for licensees to register general licensed devices containing radioisotopes on NRC Form 664 has decreased because of a re-estimate of the number of annual responses based on the actual number of responses received during the past 3 years. The number of registration responses are expected to decrease by 39 (from 564 to 525), resulting in a reduction of 13 hours (from 188 hours to 175). The decrease is based on 39 fewer licensees.

The rate has decreased from \$268 per hour to \$263 per hour in accordance with 10 CFR Part 170.

The change in annual burden overall estimate for registration of NRC authorized general licensed devices containing radionuclides on NRC Form 664 has decreased by \$4,359 (from \$50,384 to \$46,025) primarily due to a revised number of expected inquiries.

16. <u>Publication for Statistical Use</u>

None.

17. Reason for Not Displaying the Expiration Date

The expiration date will be displayed on the form.

18. Exceptions to the Certification Statement

None.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Statistical methods are not used in this collection of information.