FINAL 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 of the *Code of Federal Regulations* (10 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 with indicated minimum radioactivity thresholds, the device 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 includes (1) the name, title, email address, 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. <u>JUSTIFICATION</u>

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 subject to the registration criteria under NRC jurisdiction are required to submit information annually to allow the Agency to better track generally 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. Reduction of Burden Through Information Technology

The NRC has issued *Guidance for Electronic Submissions to the NRC*¹ 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. Since NRC has moved toward e-mailing registration forms in 2025, it is estimated that approximately 60 percent of the responses will be filed electronically.

Currently NRC scans any paper-based forms manually and staff enter updated information into the general licensing tracking database. Forms that are received via e-mail are uploaded and manually entered in the database. Additional IT-based solutions will be considered in the future to further reduce the burden.

4. Effort to Identify Duplication and Use Similar Information

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

5. <u>Effort to Reduce Small Business Burden</u>

Because most of the general licensees are small businesses, care was taken to require only the minimum amount of information needed to assure that the health and safety of the public is protected. 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 the burden on small businesses by reducing the information collection and still adequately track ownership and disposition of the devices. Approximately 30 percent of respondents are estimated to be small businesses.

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

¹ Reference Materials For Electronic Submissions | NRC.gov

Annual reporting is required and 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 Office of Management and Budget</u>
Guidelines

There is no variation from OMB guidelines.

8. Consultation Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package has been published in the *Federal Register* on June 13, 2025 (90 FR 25088). As part of the consultation process, a total of eight individual general licensees and Agreement State officials were selected and contacted directly. As a result, two anonymous sources provided public comments (Agencywide Documents Access Management System No. ML25233A031 and ML25233A032 respectively):

• The first commenter noted that the NRC and Agreement States should get together and require more from the manufacturers for the initial training and documentation on the general license documentation and necessary information collection due to changes or loss of knowledgeable staff. In addition, the individual requested that NRC keep a database of existing General License (GL) licensees who may check the box if devices are at the same location or not. Moreover, manufacturers may be able to enter information of quarterly GL distributed equipment in a web-based NRC database of GLs instead of what is done now.

NRC Response: The GL Program does routinely correspond and conducts phone calls to address manufacturer and general licensee questions or issues. NRC staff routinely interacts with Agreement States to exchange information and coordinate on matters inclusive of general licenses. NRC does have a database of existing GL licensees that is web-based and called the General License Tracking System (GLTS). The system is available to only NRC staff and portions are available to Agreement State regulators. While general licensees and manufacturers cannot access the system yet, consideration of updating forms and information via the web-based system may be planned and budgeted in the future to ensure responsible points of contact and information are up-to-date. Efforts have been underway at the NRC to increase electronic means of communication with General Licensees and manufacturers. Currently, the NRC GL Program is sending and receiving correspondence and Form 664 via the GLTS.Resource@nrc.gov inbox to enhance more timely communications. The form is being slightly revised in Section 4 to include the email address of the transferee to further facilitate electronic means of communication efficiently.

The second commenter indicated that information collection should be updated to

automated electronic forms for small business registrations and report to the Commission for compliance purposes.

NRC Response: The current Form 664 does not ask if the GL registrant is a small business. The annual fee is a flat fee and does not change if the entity is small or large. Therefore, NRC does not consider the need to collect information from the registrant whether it is a small business if there is no change in the fee or other valid reasons in the effort to reduce burden to small businesses per item 5.

9. Payment or Gift to Respondents

Not applicable.

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with NRC regulations in Paragraphs 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

Out of approximately 425 registrants, all are expected to respond to written registration requests from the NRC annually. The average burden per response to these written requests is 20 minutes (or one-third of an hour) for an overall estimated annual burden, assuming all 425 provide a response, of 142 hours (425 \times one-third of an hour), and a cost of approximately \$45,014 (142 hours \times \$317 per hour).

The \$317 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 hourly rate, see the "Revision of Fee Schedules, Fee Recovery for Fiscal Year 2024" final rule (89 FR 51789; June 20, 2024).

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 is as follows:

Mailing and/or emailing 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 71 hours (425 requests at 10 minutes per request) at a cost of \$22,507 (71 hours x \$317 per hour). The annual cost of postage for certified return receipt is approximately \$5,100 (\$12 per package x 425 packages). The total average cost ranges between \$22,507 if all packages are emailed to \$27,607 (\$22,507 + \$5,100) if all packages are mailed depending on whether valid email addresses have been obtained and successfully transmitted.

15. Reasons for Changes in Burden or Cost

The overall burden estimates for licensees to register generally licensed devices containing radioisotopes on NRC Form 664 has increased from 136 hours to 142 hours. The increase in the burden is due to an increase in the number of general licensees from 409 to 425.

The rate has increased from \$288 per hour to \$317 per hour in accordance with 10 CFR Part 170.

16. Publication for Statistical Use

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. <u>COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS</u>

Statistical methods are not used in this collection of information.