1FINAL SUPPORTING STATEMENT
FOR
DESTINATIONS OF RELEASED PATIENTS FOLLOWING TREATMENT WITH IODINE-131 AND ESTIMATION OF DOSES TO MEMBERS OF THE PUBLIC AT LOCATIONS OTHER THAN CONVENTIONAL RESIDENCES RECEIVING SUCH PATIENTS

(3150-XXXX)

NEW

Description of the Information Collection

This supporting statement provides additional information regarding the Nuclear Regulatory Commission's (NRC's or the Commission's) new request for conducting a one-time information collection supporting its project: *Destinations of Released Patients Following Treatment with Iodine-131 and Estimation of Doses to Members of the Public at Locations Other Than Conventional Residences Receiving Such Patients*. This is a voluntary information collection to assist the NRC Office of Nuclear Regulatory Research (RES) to determine where patients treated with radioactive iodine (I-131) reside after being released from licensee care; specifically, to what extent they go to locations other than their homes: for example, to hotels, nursing homes, and other institutional sites. In this case, licensees are the hospitals, medical centers outpatient facilities, or other medical facilities that provide I-131 treatment.

The prevailing practice is that patients are often released from the medical facilities following treatment with radioisotopes if they meet the release conditions specified in the Code of Federal Regulations (CFR) Title 10, Part 35.75, *Release of Individuals Containing Unsealed Byproduct Material or Implants Containing Byproduct Material*. While there is analytical information indicating that the NRC's current requirements are appropriate, there is not sufficient empirical (field measurement) data regarding the doses actually being received by members of the public that are exposed to these patients in public venues, or data regarding the prevalence of patients going to locations other than their home of record (residence) following the medical treatment. The NRC wants to identify the alternative destinations released patients may reside and what internal and external exposures members of the public might receive in order to determine how well patient release practices are working and the extent to which the NRC dose criterion is being met.

Therefore, the Commission instructed the staff to obtain analytical and empirical data collected from field measurements, which will be preceded by the surveys identifying treatment facilities that regularly send patients treated with I-131 to locations other than their homes (e.g., hotels and nursing homes), the receiving locations, and such patients themselves. As indicated in Section A.12, there will be four different groups surveyed (i.e., four separate surveys), each with its own questionnaire: treating institutions, members of the Thyroid Cancer Survivors' Association, patients identified as staying at hotels or nursing homes following treatment, and hotels and nursing homes receiving patients immediately after treatment.

A. JUSTIFICATION

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

The NRC has minimal empirical data on where patients treated with radioactive iodine (I-131) reside after being released from licensee care. This information will inform future guidance provided licensees and I-131 patients regarding management of exposure received by public from contact with the patients.

2. Agency Use of Information

The data collection will occur as part of a current NRC project, *Destinations of Released Patients Following Treatment with Iodine-131, and Estimation of Doses to Members of the Public at Locations Other Than Conventional Residences Receiving Such Patients.* The results of the data collection will be used by the NRC, as explained in more detail above, to obtain data on where patients treated with I-131 reside following treatment. This will contribute to a determination of how well the patient release criteria are working.

3. Reduction of Burden Through Information Technology

There are no legal obstacles to reducing the burden associated with this information collection. The NRC encourages respondents to use information technology when it would be beneficial to them. NRC issued a regulation on October 10, 2003 (68 FR 58791), consistent with the Government Paperwork Elimination Act, which allows its licensees, vendors, applicants, and members of the public the option to make submissions electronically via CD-ROM, e-mail, special Web-based interface, or other means. It is estimated that approximately 90% of the potential responses will be filed electronically.

4. Effort to Identify Duplication and Use of Similar Information

To the NRC's knowledge, such a data collection has not been accomplished prior to the current study.

5. Effort to Reduce Small Business Burden

None of the respondents are small businesses.

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

The NRC's mandate to monitor and reduce radiation exposures to the public would be adversely affected if the proposed, one-time data collection were not performed. As previously mentioned, the data collection will contribute to a determination of efficacy of the patient release criteria.

Circumstances Which Justify Variation from OMB Guidelines

None of the special circumstances cited in this section is applicable.

7. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements was been published in the *Federal Register* on May 15, 2015 (80 FR 28715).

The NRC consulted with its contractor for this study, SC&A, Inc., in designing the collection instruments, four questionnaires. The SC&A project team contains hospital Radiation Safety Officers, Health Physicists, a medical doctor in Nuclear Medicine, and two members of the Medical Physics faculty of a large academic institution. They are all familiar with the issues of the study and the information required for collection. In addition, the NRC staff conducted a pilot study of nine non-federal treatment facilities in order to gain experience with the use of the treatment facility questionnaire. Two commenters stated that the collecting of data was not necessary because there is enough reliable published data for exposure to the member of the public. However, this commenter believed that the information have practical utility. Five commenters stated that the proposed collection of information is necessary for the NRC to properly perform its function and the information have practical utility.

The project team consulted with representatives (e.g., the Executive Director of the Thyroid Cancer Survivors' Association) of individuals treated with I-131 when designing the simplified questionnaire for individuals.

8. Payment or Gift to Respondents

None.

9. 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). The preface to the questionnaires that will be distributed for the data collection will state that all responses will be de-identified in any reports released to the public to protect the privacy of the respondents.

In addition, in the course of performing the project of which the data collection is a part, it is expected that NRC and its contractor personnel might have occasion to view, hold, and become aware of names and phone numbers of the patients, and the workers in the hotels and nursing homes in the study which must be safeguarded from inadvertent release outside of authorized project needs according to applicable regulations (e.g., the Privacy Act). Both the NRC and its contractor have experience in safeguarding such information.

10. Justification for Sensitive Questions

The information collection instrument for institutions, such as hospitals, that administer I-131 to patients, will not solicit any information by which individual patients could be identified. The instrument for individuals was designed in consultation with their representative group to avoid any sensitive information. In addition, all collected information will be suitably de-identified to protect privacy.

12. Estimated Burden and Burden Hour Cost

Under this request, the NRC intends to send questionnaires: (1) to all non-federal medical facilities (licensed by either the NRC or Agreement States) that treat patients with I-131; (2) through patient associations, to individuals who have been treated with I-131; (3) directly to individuals who have been identified as having stayed at a hotel or nursing home immediately after I-131 treatment; and (4) to hotels or nursing homes that have received patients immediately after I-131 treatment. The four types of data collection will be discussed in turn and the burdens summarized in the following table. Note that the questionnaire for the treating institutions is more complicated than for the other categories of respondents and, therefore, should take longer to complete.

(1) *Treating Institutions*: The NRC anticipates that it will send questionnaires to about 350 institutions and estimates that it will have about a 50% response rate (Radiation Safety Officers at all these institutions are aware of the patient release issues associated with I-131 treatment). Most of the requested information should be readily available. The NRC staff estimates that it will take one hour to gather the information and fill out the questionnaire. This represents a total, one-time burden of about 175 hours and $48,825 for 175 respondents. If the institutions refer patients to NRC for this study, they will get approval from their Institutional Review Board.

(2) *Individuals*: The Thyroid Cancer Survivors' Association (ThyCa) has about 50,000 members. The simple questionnaire, designed in consultation with the Association's Executive Director, is estimated to take 15 minutes to complete. The Director estimated a response rate of about 5 – 10%, which is equivalent to 2,500 – 5,000 respondents. Taking the upper bound of the range, the information collection burden would then be 1,500 hours (0.25 x 5,000 = 1,250 hours). This represents a total, one-time burden of about 1,250 hours and $348,750 for 5,000 respondents.

(3) *Patients Staying at Hotels or Nursing Homes Following Treatment*: The NRC estimates that it will be able gather information from about 50 such patients and that it would take about 15 minutes to complete each questionnaire. Those patients will be identified and their cooperation in this study obtained by the Radiation Safety Officers (RSOs) at participating I-131 treatment facilities; then, those patients will be contacted by the NRC and/or its contractor, SC&A to complete a questionnaire. The information collection burden would then be 12.5 hours (0.25 x 50 = 12.5 hours). This represents a total, one-time burden of about 12.5 hours and $3,488 for 50 respondents.

(4) *Hotels or Nursing Homes Receiving Patients Immediately After Treatment*: The NRC estimates that it will be able to gather information from personnel at about 15 such institutions and collect data from three staff personnel at each institution for a total of 45 questionnaires at an estimated 15 minutes each to complete. The information collection burden would then be 11.25 hours (0.25 x 45 = 11.25 hours). This represents a total, one-time burden of about 11.25 hours and $3,139 for 45 respondents.

Burden Summary

Respondent Type	No. of Respondents	Responses per Respondent	Number of Responses	Burden Hours per Response	Total Annual Burden Hours	Cost $279/hr
Treating Institutions	175	1	175	1.00	175	$48,825
Individuals (ThyCa)	5,000	1	5,000	0.25	1,250	$348,750
Patients Staying at Hotels or Nursing Homes Following Treatment	50	1	50	0.25	12.5	$3,488
Hotels or Nursing Homes Receiving Patients Immediately After Treatment	45	1	45	0.25	11.25	$3,139
TOTAL			**5,270**		**1,449**	**$404,202**

13. Estimate of Other Additional Costs

There are no additional costs.

14. Estimated Annualized Cost to the Federal Government

The NRC has awarded the contract to SC&A to perform this study on behalf of this agency. The NRC estimates approximately 50hrs/yr to review the study data at a cost of $13,950 (50 hours x $279/hr.). The NRC has awarded the contract to SC&A to perform this study on behalf of this agency. The total contract amount is $681K.

15. Reasons for Change in Burden or Cost

This is a new, voluntary, one-time information collection that will result in a burden of 1,449 hours for treating institutions; patients; and hotel and nursing home staff for responding to surveys about patient destinations following treatment with iodine-131 The surveys seek to determine whether patients are going to locations other than their home, for example, hotels, nursing homes, and other institutional sites, immediately following their release from the hospital or clinic after receiving I-131 treatment.

16. Publication for Statistical Use

The results and conclusions of the study will be presented in the form of an NRC NUREG/CR report ("contractor report"), which would be made available to the public. In addition, it is possible that some of the results might be presented in other professional forums by the NRC contractor, subject to approval by the NRC. The NRC expects to publish the final report in February 2017.

17. Reason for Not Displaying the Expiration Date

Information collection instruments will display the expiration date for OMB approval.

18. Exceptions to the Certification Statement

Not applicable.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The information collection does not employ statistical methods: