DRAFT 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) new request for conducting a one-time information collection, *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. "Licensee Care" can be defined as hospitals, medical centers, or outpatient facilities. The study seeks to estimate what is the prevalence of patients 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.

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 the public venues or data regarding the prevalence of patients going to locations other than their home of record (residence) following the medical treatment. Therefore, the Commission instructed the staff to obtain a limited amount of analytical and empirical data collected from field measurements with particular interest in ensuring that any data that is acquired from patients can be obtained in a manner that avoids factors that would skew the results and the information collected will be representative of behaviors of a majority of members of the public to the maximum extent possible.

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 if the release criteria outlined in 10 CFR Part 35.75 is adequately protective of public health and safety.

A. JUSTIFICATION

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

   The NRC wants to conduct this study in order to ascertain how well the patient release criteria are working and to what extent the dose criterion in 10 CFR Part 35.75 is being met.

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 determine the extent and frequency to which patients treated with I-131 reside in locations other than their homes following treatment. This will contribute to a determination of how well the patient release criteria are working and to what extent the dose criterion in 10 CFR Part 35.75 is being met.

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, which is why the NRC is planning to undertake it at this time in support of the agency's mandate and goals.

5. Effort to Reduce Small Business Burden

   None of the institutional recipients of the information request is a small entity. Individuals (e.g., members of the Thyroid Cancer Survivors' Association), who have undergone I-131 treatment, will receive short, simplified survey instruments designed so that they will require no more than ten minutes to fill out. In all cases, response is voluntary.

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 how well the patient release criteria are working and to what extent the dose criterion in 10 CFR part 35.75 is being met.

7. Circumstances Which Justify Variation from OMB Guidelines

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

8. Consultations Outside the NRC

   Opportunity for public comment on the information collection requirements has been published in the *Federal Register.*

The NRC consulted with its contractor for this study, SC&A, Inc., in designing the institutional information collection instrument, a questionnaire. The SC&A project team contains hospital Radiation Safety Officers, Health Physicists, a medical doctor in Nuclear Medicine, and a member 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 project is conducting a Pilot Study of nine non-federal treatment facilities in order to gain experience with the use of the questionnaire.

The project team intends to consult 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.

9. Payment or Gift to Respondents

None.

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). The preface to the questionnaires that will be distributed for the data collection will state in effect 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 sensitive patient, family, and staff information, which must be safeguarded from inadvertent release outside of authorized project needs according to applicable regulations (e.g., HIPAA and the Privacy Act). Both the NRC and its contractor have experience in safeguarding such information.

11. 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 will be 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 OMB PRA 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, and (2) through patient associations, to individuals who have been treated with I-131. The two different types of data collection will be discussed in turn.

(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, so that it shouldn't take more than an estimated one hour to gather the information and fill out the questionnaire. This would then amount to a total burden of about 175 hours and the total burden is 175 hours and 175 responders. This represents a total one time burden of $48,825.

(2) *Individuals*: The Thyroid Cancer Survivors' Association has about 50,000 members. The simple questionnaire instrument will be designed in consultation with the Association's Executive Director so that it will not take more than an estimated 18 minutes to complete. The Director estimated a response rate of about 5 – 10%, which is equivalent to 2,500 – 5,000 responses. At 18 minutes (18min/60min = .30 hours) per response, the information collection burden would then be 1500 hours (.30 x 5000 = 1500 hours) and 5000 responders. This represents a total one time burden of $418,500. And a grand total of $467,325.

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	5,000	1	5,000	0.30	1500	$418,500
TOTAL			5,175		1,675	$467,325

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 total contract amount is $740K.

15. Reasons for Change in Burden or Cost

This is a new, voluntary, one-time information collection.

The data collection referred to in this OMB request is part of an 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,* which began October 1, 2014. Task 1, "Assess Where Patients Reside Immediately Following their Release," which is currently underway, is scheduled to conclude around February 1, 2016. Optional Task 3, which has not yet been awarded, would entail presentation of the results and conclusions of the study 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.

16. Publication for Statistical Use

It is not anticipated at this time that any "complex analytical techniques" will be applied.

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.