FINAL SUPPORTING STATEMENT
FOR

NRC REQUEST FOR SODIUM IODIDE I-131 TREATMENT AND PATIENT RELEASE INFORMATION
(3150-XXXX)
NEW

Description of the Information Collection

The U.S. Nuclear Regulatory Commission (NRC) is requesting a voluntary one-time information collection that will be solicited by a *Federal Register* notice (FRN). The NRC will be asking specific questions pertaining to the treatment and release of patients receiving radioactive sodium iodide I-131 (hereafter referred to as "I-131") to treat thyroid diseases. The FRN solicitation will focus on the following four topics: 1) existing Web sites that the responders believe provide access to clear and consistent patient information about I-131 treatment processes and procedures; 2) information the responders believe represent best practices used in making informed decisions on releasing I-131 patients, and stand alone or supplemental voluntary patient/licensee guidance acknowledgment forms, if available; 3) an existing set of guidelines that the responder developed or received which provides instructions to released patients; and 4) an existing guidance brochure that the responder believes would be acceptable for nationwide distribution. The responses will form the basis for patient release guidance products developed in response to the NRC's April 28, 2014, the Staff Requirements –COMAMM-14-0001/COMWDM-14-0001 – "Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance." The Commission, based on information from patients and patient advocacy groups, questioned the assumptions that patients have access to readily available clear, consistent, patient friendly, and timely information associated with their I-131 treatments and conditions for release. The Commission directed the staff to seek input on these assumptions and work with a wide variety of stakeholders (e.g., NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI), professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals). The NRC will use the FRN to solicit information from these stakeholders on existing Web sites, established best practices and existing patient/licensee acknowledgment forms, existing guidance documents, and available brochures. This information collection effort was developed to gain input from as many stakeholders as possible.

A. Justification

Part 35 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 35) contains the NRC's requirements and provisions for the medical use of byproduct material and 10 CFR 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," provides the regulatory criteria for NRC medical use licensees to release patients. This regulation permits the release of patients containing radioactive material from the licensee's control if the radiation dose to any other individual from the released individual is not likely to exceed 5 milliSieverts (mSv) (0.5 rem). If the radiation dose to any other individual is

likely to exceed 1 mSv (0.1 rem), the licensee must provide instructions to keep doses as low as reasonably achievable. When making a decision on when the patient can be released and comply with the regulation, the licensee must assess potential doses to the maximally exposed individuals and provide instructions that the patient can reasonably be expected to follow to reduce dose to others. A number of assumptions are made when making this decision and the Commission has asked the staff to verify some of these assumptions especially the clarity, consistency, and availability of information for the patient undergoing the procedure.

The NRC Commission directed the staff in Staff Requirements – COMAMM-14-0001/COMWDM-14-0001 to develop: 1) a Web site that provides access to clear and consistent patient information about I-131 treatment processes and procedures, 2) best practices guidance covering topics used in making informed decisions on releasing I-131 patients and a voluntary patient/licensee guidance acknowledgment form, 3) a standardized set of guidelines to provide instructions to released patients, and 4) an NRC or medical organization guidance brochure for nationwide distribution. The NRC has performance based rules that require licensees to develop, implement, and maintain procedures but does not require them to be submitted to NRC. The NRC usually reviews licensee procedures only when they are inadequate to meet other regulatory requirements. Therefore, NRC is seeking information from stakeholders because they deal with patient release issues on a routine basis and will be able to identify the best information available on existing Web sites, guidance documents and brochures. The information collection is the least burdensome method for NRC to obtain information that physicians, licensees and patients are using effectively in understanding I-131 medical treatment procedures, making decisions on when to release patients and how to reduce radiation exposure to others once patients are released.

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

The *Federal Register* solicitation will request information on the following four topics:

Website information collection

The NRC will develop a Web site focused on I-131 that includes both radiation-related and medical-related information about medical I-131 treatments. All stakeholders are asked to identify I-131 treatment related Web sites that address one or more of the medically-related or radiation-related topics provided in the FRN. In addition to identifying the Web site, they are asked to identify the particular topic addressed by the website and a link to the specific information. The NRC is asking I-131 patients and patient advocacy groups to not only identify I-131 treatment related websites that they find informative, but also to identify additional topics or concerns that they think should be included in NRC's Web site. This will identify the most useful and patient friendly I-131 treatment information currently available to the public and reduce the original content that the NRC will need to develop for its Web site.

Best Practices Information collection / Patient/licensee Acknowledgement Form

Physicians, licensees, medical organizations, and other interested individuals are asked to describe their best practices, or provide the procedure they use to provide them with confidence that they are releasing their patients at the appropriate time. NRC listed a number of possible topics to be discussed with patients that would lead to an informed decision on when a particular patient should be released. These topics are expected to form the basis for a

voluntary “patient/licensee acknowledgement form.” If the responder already has such a form, he/she is asked to submit it. The stakeholders are also asked when this type of discussion takes place and if it allows both patients and medical facilities to make necessary arrangements before immediate and delayed releases. They are asked to describe how their best practices are used in the decision making process. Patient, patient advocacy groups, and other interested individuals are asked if there were other topics that should be included in the discussion and what they believe is the optimal time for the discussion to take place so that they and the medical facility will have confidence that the release decision is appropriate and it allows patients enough time to make alternate arrangements. By receiving input from the medical community, patients, and other concerned individuals, the NRC will be able to ensure the contents of a voluntary form will capture best practices and help inform licensees when to best release individual patients and alleviate patient concerns that may not be currently addressed.

Guidance for Released Patient Information Collection

All stakeholders are asked to provide guidance documents that they believe provide clear instructions for released patients. They are also asked that if their guidance includes topics not addressed in the NRC’s list of possible topics, then to explain why each one should have been included, and also, to explain why they thought a particular topic should not have been included in the list. Patients, patient advocacy groups, and other interested individuals are also asked to provide topics they believe should be included in the instructions given to released patients and when they want to receive the instructions. They are also asked to comment on whether the instructions were provided in a manner that is easy to understand and follow, and what would have made the instructions better. There is concern that patients are not given consistent and clear guidance on what they should do after being released to reduce radiation exposures to others. The NRC is looking for practical information that the medical community, patients, and other interested individuals believe, through their own experiences, work effectively.

Brochure for Nationwide Use Information Collection

The NRC is asking all stakeholders if they know of one or more brochures that provides clear instruction to provide released patients that helps them keep doses as low as reasonably achievable to others. The nationwide availability of a brochure may increase the quality and consistency of information provided. If such a brochure or brochures are available the NRC intends to encourage their nationwide distribution, if not NRC may consider developing such a brochure.

2. Agency Use of Information

The NRC will use the information collected to develop products that will enhance current patient release guidance. They will help reduce the variability of instructions provided to patients and eliminate some of the uncertainty regarding the type of information that is provided to the patient. They will enhance licensee’s ability to provide clear guidance to patients on the risks associated with both their radioisotope treatments and their expected behaviors after their release.

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. The 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 percent of the potential responses are filed electronically.

4. Effort to Identify Duplication and Use Similar Information

   The NRC regulations do not require medical use licensees or applicants to submit the information being requested in this information collection effort. The NRC is taking advantage of the existence of information used on a routine basis by medical use licensees and patients to make patient release decisions inform patients of the procedures they will undergo, and inform patients how to reduce radiation exposures to others after their release. This information collection is necessary to efficiently identify existing information and reduce the need to duplicate efforts of the medical community and patients. The NRC has in place an ongoing program to examine all information collections with the goal of eliminating all duplication and/or unnecessary information collections.

5. Effort to Reduce Small Business Burden

   Approximately 40 percent of the stakeholders are considered small businesses under the NRC's current definitions. They are also the ones that have day-today experience in patient release decisions and use of patient release guidance. It is not possible to reduce the burden on small businesses and still benefit from their experience.

6. Consequences to Federal Program or Policy Activities if the Collection Is Not Conducted or Is Conducted Less Frequently

   This information collection is a one-time effort. If the information is not collected, the NRC will also not have views from the wide spectrum of stakeholders that reflect the I-131 patient treatment experience, and the NRC will not be in a position to efficiently assess and reduce the variability of patient release instructions provided to patients or eliminate some of the uncertainty regarding the type of information that is provided to the patient. Furthermore, without the information collected, patient release guidance will not be able to be updated and enhanced to reflect current patient concerns. Collection of specifically requested information on a onetime basis from concerned individuals, patients, and the medical community that administers byproduct material to patients or human research subjects is essential to protect the health and safety of workers, patients and human research subjects, and the public.

7. Circumstances Which Justify Variation from OMB Guidelines

   Not Applicable

8. Consultations Outside the NRC

Opportunity for public comment on the information collection requirements for this clearance package was published in the *Federal Register* on March 3, 2015 (80 FR 11471). Nine commenters included patients, individual physicians, large hospitals, small hospitals and professional societies responded to the 4 questions as follows:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

   Summary of Comments: One commenter stated the collection was not necessary because the commenter collected the information in 2011. However, this commenter believed the information has practical utility. The other 8 commenters affirmed the necessity of the collection and its practical utility. They stated the information collection was properly directed, appropriate and necessary, justified, long overdue, a valuable effort and extremely useful. They also stated the collection was absolutely necessary for the NRC to perform its functions and that the NRC must collect the information so things can be more standardized. They endorsed collection of information from a broad spectrum of individuals.

   Response: The NRC and most of the responders believe that the collection of information is necessary for the NRC to properly perform its functions and will have practical utility.

2. Is the burden estimate accurate?

   Summary of the comments: Eight commenters responded to this question. Three did not evaluate the burden but commented they did not have information regarding the question, believed the public could not determine the burden, or they could not verify the accuracy of the burden but believed the importance of collecting the information outweighed potential burdens. Four commenters gave positive responses with two saying the burden was accurate (but one of these said it was not needed), one said it was reasonable and the last said it was as close to accurate as you can assume.

   Response: The NRC believes its burden estimate is accurate.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

   Summary of the comments: All nine commenters responded to this question. They gave a wide spectrum of suggestions that they thought would improve the information collection. One commenter suggested that the key was to properly plan the details of the data collection. Another commenter expressed strong support for collecting data through an online Web site because of ease and timeliness in responding and perceived higher accuracy of information. The commenter further suggested a worksheet formatted with yes/no or answers multiple choice would be the easier to compile the data but it should also include a comment area for each section. One commenter addressed the importance of the NRC notifying stakeholders in professional and patient advocacy organizations who in turn can notify their associates to expand the number of responders. A different commenter focused on the importance of carefully wording the

questions so as to not bias the responses and use qualified study designers to ensure quality, utility and clarity of the information collected. Another commenter suggested that the NRC have qualified, trained professionals search available data, utilizing a process to improve the quality, utility and clarity of information collected. This commenter further suggested that the NRC advise the ACMUI to utilize an outside committee of practicing nuclear medicine physicians to provide research data to the committee, which can then be reviewed for quality, utility and clarity. One commenter wanted the collection to include identification of pertinent articles for Web sites, forms, etc. This commenter also wanted an evaluation of the burden of completing instruction forms that require individuals to enter various data. Three thought the source of the information was the most important factor. They wanted to make sure the information is collected from individuals involved in the administration of the therapy, the I-131 patient community to collect details of patients' individual experiences in seeking guidance and from Agreement States on how often I-131 is being found at landfills to determine the effectiveness of patient release instructions.

Response: The NRC will use electronic submission processes to receive the information requested. To try to reach as many stakeholders with interested in the use of I-131 in the treatment of patients, NRC plans to disseminate its proposed request for information to individuals subscribing to its medical list server, professional organizations, and patient advocacy groups so that they can in turn disseminate the request for information to their associates. Further, the NRC will hold at least one public meeting to gather more public information. The intent is to collect information on websites, processes, and procedures that the responders already have and that the responders believe is helpful to I-131 patients and their physicians. The proposed information request will be in the form of topics presented in an open way that permits the responder to address additional topics or explain why requested topics are not needed. The NRC's open format is intended to reduce bias that may be present in a work sheet/survey with yes/no answers or by using a question answer format. Because the NRC believes patient and patient advocacy input is critical for this study, the NRC does not intend to ask trained professionals to search for available data or set up a committee to provide research data. Because the NRC is asking for existing information, requesting literature references for website information that do not include such references is beyond the scope of this information collection. OMB clearances only require the NRC to determine the burden on licensees to fill out required forms, not forms the licensee voluntarily uses for non-regulatory purposes. While some commenters wanted the NRC to collect additional information on the responders such as confirmation that they were involved in the therapy administrations or personal information from patients about their treatments, the NRC does not believe this type of information is necessary for this information collection. The comment that Agreement States should be asked how often I-131 is being found at landfills to determine the effectiveness of patient release instructions is beyond the scope of this information collection.

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

Summary of comments: The six commenters that responded had a variety of suggestions. One wanted the NRC to choose a random number of submitters and sit down with them until the NRC was satisfied that the NRC was getting field tested information and actual

happenings to the patients. Most provided suggestions on having an electronic survey, using an online system to gather information, have a mechanism that includes the electronic forwarding of documents and allowing for optional written opinions. One suggestion was to provide the public with existing information and then utilized a standardized submission process so it would reduce the burden on the public to perform individual searches.

Response: The NRC intends to have at least one public meeting, but does not plan to hold sessions with individual responders. Because of the type of information the NRC is trying to collect, electronic surveys will not be used, but the NRC encourages electronic submissions through regulations.gov or e-mail. Both permit the use of attachments. The NRC is asking for stakeholders to provide information they already have and is not asking the public to perform individual searches.

9. Payment or Gift to Respondents

Not Applicable

10. Confidentiality of Information

Confidential and proprietary information is protected in accordance with the NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.39(b). However, no information normally considered confidential or proprietary is requested.

11. Justification for Sensitive Questions

No sensitive information is requested under these regulations.

12. Estimated Burden and Burden Hour Cost

The NRC will publish a *Federal Register* notice with detailed questions and anticipates approximately 620 responses from members of the medical community and 560 responses from patients or patient advocacy groups. Both groups may include responses from other interested individuals and some responders may provide information on more than one topic. Because the NRC is asking for existing information and individual opinions, responders are not expected to spend on average more than 0.25 to 0.50 hours on each response.

The following table summarizes the burden information in Table 1 for the medical community and Table 2 for patients.

	Medical Community (hrs)	Patient /Patient Advocacy groups (hrs)
Web site information collection	50	75

Patient/physician Acknowledgement Form Best Practices information collection	100	50
Guidance for released Patient information collection	100	75
Brochure for Nationwide Use Information Collection	5	2.5
Total	255	202.5
	Medical Community	255
	Patients	202.5
	BURDEN TOTAL	**457.5**

The total burden for this information collection is the estimated burden for the collection by both the medical community (physicians, licensees, professional organizations, ACMUI, Agreement States, and other interested individuals) and patients (individual patients, patient advocacy groups, and other interested individuals) 457.5 hours (255 + 202.5). The total cost is 127,642.5 (457.5 x $279/hr).

13. Estimate of Other Additional Costs

    Not Applicable

14. Estimated Annualized Cost to the Federal Government

    The NRC estimates that the annualized burden and cost to the Federal Government for the one-time requested clearance is 457 hours for the NRC staff to review the responses and $127,503 ($279 per hour x 457 hours).

15. Reasons for Change in Burden or Cost

    The Nuclear Regulatory Commission is requesting a one-time information collection solicited by a FRN that will include specific sodium iodide I-131 patient release questions associated with four topics. NRC expects responders will spend 457.5 hours responding. Information obtained from the responses will form the basis for patient release guidance products developed in response to the NRC's April 28, 2014 the Staff Requirements – COMAMM-14-0001/COMWDM-14-0001 – "Background and Proposed Direction to the NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance."

16. Publication for Statistical Use

    Not Applicable

17. Reason for Not Displaying the Expiration Date

Not Applicable

18. Exceptions to the Certification Statement

Not Applicable

Table 1 – One time burden on Medical Community

Submission Topics	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $279/hr
Website	200	1	200	0.25	50	13,950
Patient/Physician Acknowledgement Form - Best Practices in	200	1	200	0.50	100	27,900
Guidance for Released Patients	200	1	200	0.50	100	27,900
Brochure for Nationwide use	20	1	20	0.25	5	1,395
Total			**620**		**255**	**71,145**

Table 2 – One-time burden on Patients

Submission Topics	Number of Respondents	Responses Per Respondent	Total Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Cost @ $279/hr
Website	300	1	300	0.25	75	20,925
Patient/Physician Acknowledgement Form - Best Practices	100	1	100	0.50	50	13,950
Guidance for Released Patients	150	1	150	0.50	75	20,925
Brochure for Nationwide use	10	1	10	0.25	2.5	697.5
Total			**560**		**202.5**	**56,497.5**