Summary of Public Comments Regarding the Patient Release Program

Background

The U.S. Nuclear Regulatory Commission (NRC) staff published a *Federal Register* notice (82 FR 17465, April 11, 2017) to solicit comments from the public on whether additional or alternate criteria are needed with respect to patient release, and whether to clarify the NRC's current patient release requirements. The *Federal Register* notice asked six questions, which are listed below, related to issues associated with implementation of the patient release rule and to determine whether additional rulemaking is warranted. The NRC staff was directed in Staff Requirements Memorandum COMAMM-14-0001/COMWDM-14-0001, "Background and Proposed Direction to NRC Staff to Verify Assumptions made Concerning Patient Release Guidance," dated April 28, 2014 (ADAMS Accession No. ML14118A387) to ask the first four questions and the staff added two additional questions based on comments received from the *Federal Register* notice soliciting comments on best practices (80 FR 70843).

Summary of Public Responses

The NRC staff received 132 responses from the public associated with the patient release program. The comments have been consolidated for each group of commenters and can be found in the NRC's Agencywide Documents Access and Management System using the noted Accession Number. The commenters included Iodine-131 (I-131) patients (48) and patient relatives (3) (ML17310A202); professional medical and medically-related organizations (6) (ML17310A255); medical personnel (including nurses, technologists, medical physicists, and doctors) (66) and medical facilities (5) (ML17310A212); and Agreement States (4) (ML17310A250). There were 41 duplicative comments indicating agreement with another responder. Some responders provided professional and life experiences that related to the questions, but did not answer individual questions.

Development of an Activity-Based Patient Release Threshold

Question A: ***Should the NRC develop an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met?***

The staff received a total of 101 responses that contained specific responses to this question (69 respondents) or provided comments associated with this question (32 respondents). Two of the 69 commenters responding to the question did not provide a specific answer. Six of the 69 commenters recommended the NRC develop an activity-based threshold. Sixty-one of the 69 commenters do not support the NRC development of an activity-based threshold and recommended the NRC maintain its current dose-based threshold. Twenty-six of the 32 commenters that provided associated comments recommended that patients remain hospitalized or in a medically-controlled facility instead of being immediately released under the current dose-based rule. Six of these 32 commenters had good experiences being released right after treatment and supported retaining the dose-based rule.

Most of the commenters (6) that support NRC's development of an activity-based threshold stated that patients should not be allowed to go to hotels or to their homes since it allows for radiation exposure to members of the public and/or family members, but rather patients should stay in a hospital setting designed/appropriate for patients who will undergo radioiodine treatment considering the patients' individual health circumstances. Some of these commenters either suggested that the NRC adopt the pre-1997 patient release rule that required in-patient services (hospital stay) for administrations equal to or greater than 30 millicuries of I-131, or that the activity level could be determined during rulemaking. The commenters stated that in-patient care, paid for by insurance, should be an option and must be required for those patients that may pose a hazard to other individuals.

Twenty-six commenters support hospitalization of patients based on their experiences of being released immediately after treatment. These commenters are considered as supporting an activity-based rule because, under the earlier activity and radiation measurement patient release rule, they would have been hospitalized. Their basis for supporting hospitalization was the need for additional medical care after the administration, and the increased mental and emotional stress associated with concern with exposing their family members and the public to unnecessary radiation and radioactive contamination. They found it very stressful dealing with difficulties in isolating themselves at home with small children present and the disruption of their home lives, as well as not being able to focus on getting through their treatment.

Those commenters (61) who do not support the NRC's development of an activity-based threshold for patient release stated that the release requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75 should not be revised. Some stated that there is no scientific evidence to support regressing to the pre-1997 activity-based patient release threshold. Most commenters indicated that the current NRC patient release requirements are risk-informed and performance-based and they should stay as they are since it allows flexibility to accommodate patient needs. Various medical professionals expressed that the radiation exposure to other individuals from released patients can be safely controlled by the current 10 CFR 35.75 dose-based patient release criteria and by the patient following release instructions. Additionally, they commented that the current release criteria properly balance public safety with patient access to medical treatment, and raised concerns that by adopting an activity-based approach, there may be an impact on patient access to medical treatment. Several commenters highlighted that for a vast amount of patients, there is a psychological benefit from recovering at home, after I-131 treatment, since the patient can achieve a faster recovery at home rather than in the hospital (e.g., reduced anxiety, increased comfort, and closeness to loved ones/caregivers); there is a health and safety benefit (e.g., reduced risk of hospital-acquired infections); as well as a financial benefit (significantly reduced healthcare costs, and in certain scenarios, a swifter return to work). Six of the 26 individuals that provided comments associated with the question had positive experiences being allowed to go home right after treatment.

Clarification of the Time Covered by the Current Dose Limit in 10 CFR 35.75(a) for Releasing Individuals

Question B: ***Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing individuals? For example, should the regulations explicitly state that the criterion is a per year limit? If not, is there a different criterion that the NRC should consider?***

The NRC staff received 68 comments in response to this question, with 13 commenters recommending the NRC amend the regulations to clarify the time frame, and 55 recommending the NRC not amend the regulations.

The commenters (13) who recommended that the NRC amend the regulations to clarify the timeframe, emphasized that ambiguity exists in current regulations and it should be clarified by the NRC. However, they disagreed on whether the timeframe was per year or per administration. The per year criterion was seen as consistent with other public and occupational radiation dose criteria. Those supporting the per administration criterion expressed concerns with the difficulties that may arise from using a per year dose timeframe. For example, difficulties would be created with assigning doses to members of the public if the patient received treatments in more than one facility. A commenter, supporting the rulemaking change to incorporate the per year criterion, suggested specific clarifications that would reduce these concerns. The majority of commenters supporting rulemaking stated that the per administration timeframe provides a simpler approach to dose calculations.

The other commenters (55) who did not support rulemaking stated that even though the time frame in regulations is ambiguous, it has traditionally been interpreted to mean that the 5 millisievert (mSv) (0.5 rem) exposure limit is per administration, rather than a yearly limit. Further, many cited the NRC's original premise that released patients would go home exposing only family members to radiation and that it would be rare for a patient to receive more than one radioactive treatment in a year. Some commenters noted that if one applies the linear no threshold radiation risk model, there would be no difference in the theoretical risk of radiation dose from exposure to an I-131 therapy patient receiving two therapies in 1 calendar year, versus the exposure to an I-131 therapy patient receiving two therapies over 2 calendar years. They concluded that in light of this observation, there would be no difference in risk to members of the public between per year and per administration release criterion. Most commenters stated that no patient release rulemaking change is justified at this time. The majority of commenters stated that the current patient release regulations in 10 CFR 35.75 adequately protect public health and safety. A few commenters suggested the clarification should be provided through guidance and not rulemaking.

Appropriateness of Applying the Same Limit on Dose from Patient Exposure to All Members of the General Public

Question C: ***Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem) to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?***

The NRC staff received 60 comments in response to this question, with 31 commenters recommending the staff change the NRC's regulations to have different criteria for different members of the public and 24 commenters recommending that the NRC maintain a single dose criterion for all members of the public. The remaining commenters (5) provided their views and suggested alternative ideas for the NRC to consider in establishing new criteria for high risk members of the public.

Most commenters (31) who recommend the NRC change its regulations to have different criteria for different members of the public stated that the NRC should use the 5 mSv (0.5 rem) dose limit for the general public and the 1 mSv (0.1 rem) dose limit for children and pregnant women. Some commenters indicated the NRC already has a 1 mSv (0.1 rem) dose limit in 10 CFR 35.75 for children and pregnant females. Other commenters expressed that under no circumstances should children, pregnant women, nursing mothers, fetuses, embryos, or members of the public with no connection to the patient receive more than 1 mSv (0.1 rem) from a patient. Various commenters suggested that for a caretaker, 5 mSv (0.5 rem) is an appropriate limit in most cases, but that the release limit should be waivable, based on informed consent. For example, the parent who wants to assume the risk of being close to a child under treatment, for the benefit of the child, should be permitted to do so, in the hospital or out.

The majority of commenters (24) recommending that the NRC maintain a single dose criteria (0.5 mSv (0.5rem)) for all members of the general public stated that there is no evidence suggesting the current criteria are ineffective. In addition, these commenters noted that there is no evidence to support the contention that the dose level of 5 mSv (0.5 rem) has put any individual at undue risk. Other commenters suggested that while as low as reasonably achievable (ALARA) guidance exists providing ways to minimize exposure to children and pregnant women, requiring a lesser dose limit of 1 mSv (0.1 rem) for those individuals could increase patient anxiety from overly restrictive protective measures needed to comply with a lower limit. The majority of commenters expressed that the existing 5 mSv (0.5 rem) dose limit in conjunction with existing guidance and requirements for precautions to keep exposures ALARA is adequately protective and no changes to the NRC's regulations are necessary. These commenters stated that while it is desirable to maintain doses to children and pregnant women ALARA, this should be accomplished with guidance that allows physicians the flexibility to meet the needs of each patient.

Some commenters (5) suggested that the NRC should be consistent with standard dose limits for high risk individuals employed by international regulatory bodies and that a formal analysis of licensees be performed to understand if the current established dose limits are useful and adequate before proceeding with any rulemaking.

Requirements for Releasing Individuals Who Are Likely To Expose Young Children and Pregnant Women

Question D: ***Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?***

The NRC staff received 58 comments in response to this question, with 13 commenters recommending that the NRC amend its regulations to specify specific requirements for the release of a patient who is likely to expose young children or pregnant women to doses above the 10 CFR Part 20 public dose limit, and 18 commenters recommending that the NRC not amend its regulations. Although the other 27 commenters did not explicitly answer the question, they strongly felt that additional guidance is necessary.

The commenters (13) who recommended that the NRC amend its regulations stated that there should be specific regulatory requirements and in that regard, suggested the following: (1) a requirement for a standardized set of instructions to address contact by the patient with pregnant women and children; (2) all written instructions licensees provide to patients should include information on the potential risks associated with exposing pregnant women and children, and very simple instructions for the patients to avoid close proximity to those individuals for a few days following treatment; (3) a requirement that documentation be maintained by the licensee in which the patient acknowledges by signature that they have received instructions, agree to follow the instructions, and have been provided the opportunity to ask questions; (4) a requirement that would make it easier to hospitalize patients that need to be hospitalized (but not require all to be hospitalized) to provide a better chance of success in getting insurance coverage for such patients who truly need to be admitted; (5) a requirement that would set the per release limit for pregnant women and children at 1 mSv (0.1 rem) unless there is a mitigating circumstance; (6) a requirement for providing the patient with additional information on exposing young children and pregnant women, and that any licensee evaluations of potential exposure to these individuals should fully consider the patient's living situation, occupation, and ability to follow directions regarding their likelihood of exposing young children and pregnant women.

There was also a recommendation that additional detailed guidance in the form of a questionnaire (as a “model” form) that helps assess the patient's living and social situation, be provided to patients as part of the pre-procedure/treatment planning process.

These commenters who did not support the NRC amendment of its regulations (18) and those commenters who suggested that the NRC provide additional guidance (27), stated that regulatory changes were not needed but that the NRC could improve its guidance to provide simple instructions to patients. The commenters noted that guidance should highlight that the risk to other individuals associated with medical procedures involving the administration of radioactive material are estimates and viewed as potential risks. A more current methodology should be developed to include up-to-date methods of dose and risk assessment as well as more realistic consideration of special exposure pathways (such as inhalation and uptake by children. In addition, updated instructions should include information on increased risk associated with exposing young children and pregnant women and specific instructions for keeping doses to them ALARA.

Requirement for Timely Discussion with the Patient About Patient Isolation to Provide Time for Licensee and Patient Planning

Question E: ***Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?***

The NRC staff received a total of 95 comments that were either responsive to this question (69) or were related to the question (26). The 26 patients that provided comments referred to their personal isolation discussions with physicians in their response to the question. Twelve of the 69 commenters recommended that the NRC amend its regulations to specify when licensees should discuss isolation with patients, and 57 of the 69 commenters recommended that the NRC not amend its regulations. Although 22 of the 26 commenters indicated that they had isolation discussions with hospital staff in advance of their treatment, they do not believe the doctor adequately prepared them for the issues they experienced during isolation. Two of the 26 commenters stated that they did not have discussions in advance of their treatment (one had to do their own research and the other had a limited discussion after the administration), and the other 2 commenters indicated that they were given information that they thought was conflicting as they were released.

Twelve of the commenters responding to the question who recommended that the NRC amend its regulations to specify when licensees should discuss isolation with patients, all recognized that timely access to relevant patient daily living information and radiation safety information are necessary to develop instructions and restrictions necessary to meet the release criteria, reduce radiation doses, and make alternative plans if the patient cannot meet the instructions that would have been provided. As stated by one professional organization, the shared decision making with the patient and the referring and/or treating physicians allows the patient to select the best timing for I-131 treatment and to make appropriate preparations at home and at work, and further stated that it is essential that radiation safety recommendations be discussed with each patient as soon as treatment with I-131 is considered. The professional organizations expressed that by engaging early, the licensee may familiarize the patient and family members with the treatment procedure, potential complications, side effects, dietary and medication changes, and protective measures/precautions to follow before and immediately after I-131 administration. This may enable the patient and/or caregiver to ask questions to clarify any concerns ahead of time. Other commenters raised concerns that failure to allow the patient sufficient time to make the necessary arrangements at home will likely result in a delay in the patient being able to isolate himself/herself or result in no isolation practices being implemented, leading to an exceedance of the 5 mSv (0.5 rem) limit. Although those commenters disagreed on how to set a single time as the best time to have the discussion, they offered several options that they thought would be prudent and not be a burden.

The 57 commenters who did not support the NRC amending its regulations, recommended that the isolation discussion with patients be addressed in guidance. Those commenters stated that this should not be a regulatory requirement. Several commenters stated they have standard of care policies that already address the issue. These commenters stated that licensees could not comply with the existing regulations if they did not hold the isolation discussions with the patients in time for arrangements to be made, and therefore a specific requirement to that effect was not necessary. They questioned how the NRC could establish a time frame and define "sufficient time" that would meet the flexibilities needed for different treatment options. Other commenters indicated that patient isolation instructions are addressed in existing NRC guidance documents. Several commenters expressed that further guidance is needed and would be helpful to the patient and licensee.

Requirement to Ensure Patients Are Given Instructions Prior to the Procedure

Question F: ***Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?***

The NRC staff received 63 comments in response to this question, with 9 commenters recommending that the NRC amend its regulations to specify when patients should be given instructions, and 54 commenters recommending the NRC not amend its regulations.

The commenters (9) who recommended that the NRC regulations include a requirement for when licensees should provide instructions to patients, stated that providing instructions to patients in advance of the medical procedure is in the best interest of both the patient and public safety. These commenters further stated that the requirement should ensure patients and their family are fully informed and aware of the requirements prior to the procedure taking place. The commenters noted that this is especially critical for those patients who rely on others to care for them (e.g., residents of nursing homes, assisted living facilities, etc.) or who otherwise may have difficulty in adhering to the directions. These commenters indicated that the exact timing needs to be individualized and that clinical circumstances requiring urgent or emergent I-131 treatment are the exception and not the rule. The commenters who shared their life experiences with respect to I-131 treatments supported the need for instruction both early and later to allow for absorption and understanding of the information. The patient commenters expressed that they did not all experience the timely and detailed instructions described by the medical community respondents.

The commenters (54) who did not support the NRC amending its regulations stated that they do not see how the NRC could determine a specific timeframe when there is so much variability between treatment procedures and patient situations. They indicated that the decision as to when to provide the instructions is a "clinical" and "practice of medicine" issue. Several commenters from the medical community indicated that they already provide instructions and give thorough explanations for each instruction in advance of the procedure and are confident their patients are fully aware of the necessary steps they have to take. Other commenters stated that a specific timeframe should not be regulated as the timing of providing instructions to patients and their household members and/or caregivers is a clinical decision and can vary from patient to patient. The majority of commenters stated that this issue can be addressed in guidance and through collaboration with national specialty societies who develop educational materials and practice/procedure guidelines for medical professionals.