POLICY ISSUE
(Information)

January 29, 2018 SECY-18-0015

FOR: The Commissioners

FROM: Marc L. Dapas, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: STAFF EVALUATION OF THE U.S. NUCLEAR REGULATORY COMMISSION'S PROGRAM REGULATING PATIENT RELEASE AFTER RADIOISOTOPE THERAPY

PURPOSE:

The purpose of this paper is to provide the Commission with the results of the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of the NRC's program for regulating patient release after radioisotope therapy (patient release). The evaluation was conducted in response to Staff Requirements Memorandum (SRM) SRM-12-0011, "Data Collection Regarding Patient Release," dated January 25, 2012 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML121000248), and SRM-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). This paper also presents the results from revised dose modeling calculations, reviews of published literature, and extensive stakeholder engagement that included outreach to licensees, patients, Agreement States, and the Advisory Committee on Medical Uses of Isotopes (ACMUI).

SUMMARY:

As directed by the Commission, the NRC staff conducted an evaluation of whether significant regulatory changes to the patient release program are warranted. This evaluation was based on information from computational dose modeling calculations, including state of the art virtual simulations; published data, including scientific literature; and extensive stakeholder

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outreach. As part of stakeholder outreach, the NRC staff issued two *Federal Register* notices (FRNs) and held subsequent public meetings soliciting comments on patient release instructions for keeping public doses as low as reasonably achievable (ALARA) and on whether alternate criteria to clarify patient release regulations should be developed. The NRC staff also issued a licensee questionnaire on where patients reside following treatment, considered stakeholder letters to the Commission, and coordinated with Agreement States and the ACMUI. Documentation in support of these efforts is provided in the following four enclosures: (1) summary of patient release after radioiodine therapy research review, (2) summary of the draft pilot study on the assessment of where patients reside immediately following their release report, (3) summary of public comments regarding the patient release program, and (4) ACMUI comments on the draft SECY paper.

BACKGROUND:

In SRM-COMGBJ-11-0003, "Data Collection Regarding Patient Release," dated June 23, 2011 (ADAMS Accession No. ML111741188), the Commission directed the staff to evaluate whether there are gaps in the available data regarding the doses received by members of the public from released patients. The NRC staff responded to the SRM in SECY-12-0011, "Data Collection Regarding Patient Release," dated January 25, 2012 (ADAMS Accession No. ML112630115), identifying gaps related to (1) internal doses to members of the public from close physical contact with patients or radioactive contamination from bodily fluids, and (2) internal and external doses to members of the public from patients released to locations other than their primary residences (e.g., public transportation, hotels, nursing homes).

In the SRM for SECY-12-0011, the Commission directed the NRC staff to revisit patient release calculations and methods described in agency guidance and conduct additional analytical and empirical data collection. The staff coordinated with the Office of Research to analyze and collect data and perform associated evaluations. This led to the issuance of two reports: "Patient Release after Radioiodine Therapy: A Review of the Technical Literature, Dose Calculations, and Recommendations" (literature review); and "Assessment of Where Patients Reside Immediately Following Their Release." (Enclosures 1 and 2 summarize these reports).

In SRM-COMAMM-14-0001/COMWDM-14-0001, the Commission directed the NRC staff to complete four tasks associated with the consistency and usefulness of the instructions that Iodine-131 (I-131) patients are given before being released, and whether those instructions are consistently followed. The staff completed the first three tasks. The first task involved the development of a standardized set of guidelines that licensees can use to provide instructions to patients. In addressing this task, the staff published an Information Notice (IN) 2017-02, "Best Practice Concepts for Patient Release," dated May 17, 2017.

The second task involved the development of a Web page that provides information and links to relevant medical organizations and patient advocacy groups to enable patient access to accurate information. The staff launched a Web page on March 31, 2016, which provides information for patients administered I-131 that is consistent with information from professional medical organizations and patient advocacy groups. The Web page can be accessed at the following link: https://www.nrc.gov/materials/miau/patient-release.html.

With respect to the third task, the Commission directed the staff to evaluate whether significant regulatory changes to the patient release program are warranted. This paper provides the

results of that evaluation. In terms of the fourth task, the Commission directed the staff to revise Regulatory Guide (RG) 8.39 "Release of Patients Administered Radioactive Material," dated April 1997, and subsequently NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," to specify guidelines for patient information and instructions. Based on the staff's work completed in response to SRM-12-0011 and the results of the staff's evaluation pertaining to the third task, the staff determined (as discussed in this paper) that a more comprehensive update to the guidance in RG 8.39 is warranted than was directed by the Commission in connection with this fourth task. As it updates NUREG-1556, Volume 9, the staff plans to refer to RG 8.39 to remove duplicative patient release guidance and avoid inconsistencies between the two documents.

DISCUSSION:

Title 10 of the *Code of Federal Regulations* (10 CFR) 35.75, "Release of individuals containing unsealed byproduct material or implants containing byproduct material," often referred to as the "Patient Release Rule," was promulgated in 1997. The NRC developed the subject regulation because the revision of 10 CFR Part 20 in 1991, which revised the dose limits for members of the general public in 10 CFR 20.1301, did not address exposure from the release of patients. The NRC determined that while doses should be maintained ALARA, a dose limit of 1 millisievert (mSv) (0.1 rem), or a dose limit of 5 mSv (0.5 rem) in certain circumstances, provides adequate protection. The "Patient Release Rule" allows a licensee to authorize the release of a patient from its control if the total effective dose equivalent (TEDE) to any other individual, from exposure to the released patient, is not likely to exceed 5 mSv (0.5 rem).

In addition, 10 CFR 35.75 requires that a licensee provide the released individual, or the patient's family or other caregivers, with appropriate instructions, including written instructions, on recommended actions to maintain doses to other individuals ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem).

In addressing the third task in SRM-COMAMM-14-0001/COMWDM-14-0001, the NRC staff evaluated estimated radiation doses to members of the public from released patients by performing a data analysis of peer-reviewed scientific articles; evaluating models and calculations to estimate radiation doses to members of the public who are exposed through contact with released patients, such as hotel workers; and evaluating information obtained from licensee questionnaire responses to identify patient destinations after treatments.

The staff studied patients treated for hyperthyroidism and thyroid cancer and focused on exposure from I-131 given its potential for a higher external exposure to members of the public. While 10 CFR 35.75 applies to other medical radioisotope therapies such as Phosphorus-32, Strontium-89, Yttrium-90, Lutetium-177, and Radium-223, none of these radioisotopes have the high energy gamma emission and volatility of I-131, and thus, they present a lower external radiation hazard than I-131.

Based on the results of the literature review (ADAMS Accession No. ML17262A909) summarized in Enclosure 1, the staff identified that the dominant factor in determining both internal and external doses to members of the public is based on the behavior of the patient after release. Patient behavior was a more important factor than the activity, at the time of patient release, of the I-131 that had been administered to the patient. From the literature review, the staff also identified potential enhancements to the calculations, methodologies, and tables provided in RG 8.39, that are used to estimate radiation dose to members of the public

from released patients. Specifically, the existing methods could result in underestimating radiation dose in certain situations if patients do not follow the provided instructions. The literature review also indicated that radiation contamination in the home is not a significant cause of radioiodine uptake. For such uptake to occur, close contact with the released patient is necessary. The literature included reports of thyroid doses of 0.04–13.3 mSv (4–1330 mrem) to members of the public from iodine uptake. All cases involved close contact with the patient, mostly in a child-parent relationship. The results of the literature review show that the internal dose is generally small compared to the potential external dose caused by contact with patients who were administered I-131. From the literature, the staff noted that internal doses were small when the patient avoided close contact with others and followed ALARA principles and instructions. Likewise, nearly all of the recorded external doses to the family members were below the patient release limit of 5 mSv (0.5 rem). In the few instances where the dose to another individual exceeded 5 mSv (0.5 rem), not observing ALARA principles and patient instructions contributed to the higher doses to other individuals. A more detailed discussion of the internal and external exposure insights from the literature review can be found in Enclosure 1.

To evaluate exposure to members of the public, such as hotel workers and individuals exposed during public transportation, the NRC staff contracted with Oak Ridge National Laboratory to calculate the external doses received by members of the public in a variety of scenarios and geometries (hotels, nursing homes, public transportation) using a phantom model. The staff concluded that the calculations performed by licensees to determine whether the patient meets regulatory release criteria may underestimate doses to members of the public. The calculations assume hypothetical behavioral conditions by the patient and apply standard conditions for distance of 1 meter and an occupancy factor of 0.25 in the default calculations. Significant deviations from one or more of these assumptions can result in substantially different doses to members of the public than the calculated values would indicate. This highlights the importance of patient discussions and instructions by the licensee to inform the patient on how best to limit the dose to family members, hotel workers, people on buses, people in nursing homes, and others. The summary of the phantom model dose estimates are as follows:

Hotel Worker Models:

- To exceed an external dose of 1 mSv (0.1 rem), the hotel check-in staff would need to be exposed to a newly released thyroid cancer patient at 1 meter for approximately 4 hours.
- To exceed the patient release dose limit of 5 mSv (0.5 rem), the hotel check-in staff would need to be exposed to a newly released thyroid cancer patient at 1 meter for approximately 23 hours.
- The internal dose received by a hotel cleaning staff person would be approximately 1.5 microsievert (μSv) (0.15 mrem) for cleaning a newly released I-131 thyroid cancer patient's room and 0.7 μSv (0.07 mrem) for cleaning a newly released I-131 hyperthyroidism patient's room.

Consequently, the NRC staff concluded that a hotel cleaning staff person would need to clean approximately 670 rooms of newly released thyroid cancer patients to exceed 1 mSv (0.1 rem), and 3,300 rooms of newly released patients to exceed the patient release limit of 5 mSv (0.5 rem).

Public Transportation Model:

- This model, using conservative assumptions, shows that a newly released thyroid cancer patient could expose a member of the public to an external dose of greater than 5 mSv (0.5 rem) if the patient, shortly after being released, got on a public transportation system and was face-to-face with a member of the public for 3.8 hours or seated in front of someone for 13 hours.

In 2015, the staff sent a questionnaire to a limited number of licensees who administer I-131 treatments. The purpose of the questionnaire was to obtain information on where patients go immediately following treatment, and to assess the number of patients who go to locations other than their private residences. The questionnaire responses indicate that the majority of patients went home; however, about 5 to 10 percent went to other locations. A more detailed analysis and discussion of the responses to the questionnaire is provided in Enclosure 2.

The staff published a FRN (80 FR 70,843, November 16, 2015) to solicit comments from the medical community and other stakeholders on patient release instructions. The staff assessed the stakeholder responses to identify best practices, based on well-established radiation safety concepts, with respect to I-131 patient release instructions and published these best practices in IN 2017-02, “Best Practice Concepts for Patient Release,” dated May 17, 2017 (ADAMS Accession No. ML17101A560). The comments informed the staff’s evaluation of when is it best to provide the patient with instructions in meeting the 10 CFR 35.75 regulation.

In addition, to further obtain stakeholder input on the patient release matter, the staff published an FRN (82 FR 17,465, April 11, 2017) to solicit comments on whether additional or alternate criteria for patient release are needed and whether to clarify the NRC's current patient release program requirements. Specifically, the FRN asked members of the public to comment on six questions regarding the patient release program. The staff asked for comments on changing 10 CFR 35.75 to require an activity-based threshold for release; whether release limits are per year or per treatment; whether the release limit should remain above the general public limit (1 mSv (0.1 rem)); and on whether other requirements should be developed for pregnant women and children exposed to released patients. The staff also asked for comment on patient isolation and the timing of when instructions should be given to patients or caregivers. The staff held two public meetings during the public comment period. Meeting summaries are available in ADAMS at Accession Nos. ML17157B387 and ML17284A358. The full transcripts for the meetings are available in ADAMS at Accession Nos. ML17157B388 and ML17284A169. The NRC received 132 responses from 128 public stakeholders and 4 Agreement States. The specific list of questions and a summary of stakeholder comments associated with each question is contained in Enclosure 3.

The responses from medical stakeholders (including licensees, professional organizations, and medical practitioners) indicated that they strongly disagreed with any patient release rulemaking, and that the current regulations are sufficient to protect members of the public from exposure to released patients. The medical stakeholders further stated that there is no data from reputable sources that indicate that an exposure of 500 mrem causes any statistically significant increase in risk. Medical stakeholders generally supported updating NRC guidance such as RG 8.39.

Many patients responded with testimonials communicating their strong preference to have the option of being isolated in a hospital for a few days after treatment before being released. Some patients support the former activity-based rule since that rule would have required hospitalization following some I-131 treatments. Other patients who had been treated and

released under the current dose-based rule, cited their increased stress and anxiety in trying to isolate themselves from other family members, and expressed their concerns about exposing their families to radiation and contaminating their living spaces.

Patient Release Program Evaluation:

In its evaluation of the patient release program regulations, the NRC staff considered the feasibility and technical merit of rule changes and guidance updates. Specifically, the staff evaluated whether there were benefits to revisiting an activity-based limit, establishing different dose limits for different groups, clarifying a time limit for exposure, and prescribing the time frame for giving patients instructions. The staff also considered enhancements to existing guidance.

Rulemaking to change patient release criteria to an activity-based limit

Prior to the 1997 rulemaking, patient release regulations were based on retained activity in the patient and the dose rate measured at one meter from the patient. The 1997 rule changed the patient release criteria to a limit based on TEDE to any other individual regardless of the administered activity.

Benefits of returning to an activity-based rule include the use of a measurable quantity of I-131 that ensures consistent patient release practices by all licensees. An activity-based rule also would reduce reliance on assumptions about patient behavior, as well as remove the need for licensee consideration of any special circumstances associated with patient release, such as patient plans to use public transportation following treatment or to isolate themselves at locations other than at home, such as hotels.

The NRC staff determined that development of an activity-based, patient release threshold under which patients would be required to remain in a clinic-sponsored facility until the standard for release is met, is not warranted. An activity-based rule does not reduce dose to other individuals below the current dose limit, as other factors, such as biological half-life and proximity of other individuals to patients, also affect public dose. An activity-based rule could result in different exposures under seemingly identical exposure conditions for the different radionuclides, or radiopharmaceuticals with the same nuclide, because biological or radiological half-lives can be significantly different.

The broad consensus from the staff's stakeholder outreach is that the existing dose limits, and therefore the risk-informed, performance-based patient release requirements in 10 CFR 35.75, sufficiently protect public health and safety. In addition, there is no substantial benefit to using an activity-based standard instead of allowing licensees to make informed decisions based on patient circumstances. Mandatory hospitalization of otherwise healthy patients could introduce additional negative consequences, such as an increased risk of hospital-acquired infections for patients, additional patient anxiety and apprehension about the procedure, fewer healthcare facilities providing I-131 therapy, and insurance coverage and healthcare cost concerns. The staff concluded that the current dose-based release criteria provides adequate protection of the public by basing patient release decisions on the dose, directly related to the potential radiation hazard from the radiopharmaceutical administered to the patient, rather than on an activity that is at best, only indirectly related to this potential hazard.

Rulemaking to create different dose limits for different members of the public exposed to radiation from released individuals who have been administered unsealed byproduct material or implants containing byproduct material.

The provisions in 10 CFR 35.75 apply equally to all members of the public. A rulemaking to reduce the dose limit for pregnant women and children would require licensees to assume all members of the public who are not known to the patient are pregnant women or children. It is difficult for licensees to determine when and where a released patient would come into contact with a pregnant woman or child not known to the patient. This uncertainty could require licensees to hospitalize patients, which may increase the associated cost of treatment.

The 5 mSv (0.5 rem) TEDE limit for exposure from a released individual who has been administered a radiopharmaceutical, applies to any individual, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public. The 5 mSv (0.5 rem) limit is safe and reasonable under the circumstance of medical benefit. There is no evidence that the higher dose limit for those individuals exposed to the released patient, 5 mSv (0.5 rem) instead of 1 mSv (0.1 rem) for the general public, has put any individual at undue risk. The NRC staff therefore determined that changing the dose limit to members of the public who are exposed to released patients is not warranted.

The staff acknowledges that children and fetuses/embryos may be more susceptible than adults to some health effects attributable to ionizing radiation exposure, as described by the International Commission on Radiological Protection (ICRP) in Publication 94, “Release of Patients after Therapy with Unsealed Radionuclides.” However, based on the staff’s evaluation, there is no increased risk at the 5 mSv (0.5 rem) TEDE limit. The staff therefore concludes that the current regulations in 10 CFR 35.75 are adequately protective of all members of the public. In addition, 10 CFR 35.75 requires that if a patient could cause a dose to an individual in excess of 1 mSv (0.1 rem), the licensee is required to give the patient instructions on actions recommended to maintain doses to other individuals ALARA. The staff provided guidance on this topic in Regulatory Issue Summary 2008-11, “Precautions to Protect Children who may come in contact with Patients Released after Therapeutic Administration of Iodine-131.”

From the literature review, the staff noted that numerous publications discuss the radiation exposure to other individuals from I-131 patient therapy and reported that doses typically did not exceed 1 mSv (0.1 rem). Several of the publications included in the literature review contained findings that adhering to simple instructions, such as keeping an “arms-length” distance from other individuals whenever possible, is adequate to keep exposures ALARA. The consensus from the staff’s stakeholder outreach indicates the current NRC regulations, coupled with guidance, address concerns about exposures to women and children without the need for additional rulemaking. The licensee is required to provide written instructions on actions recommended to maintain doses to other individuals ALARA if the dose limit is likely to exceed 1 mSv (0.1 rem). These instructions should include information on the potential increased risks associated with exposing young children and pregnant women, including instructions to avoid close proximity to anyone for a specified period of time following treatment.

Rulemaking to change the 5 mSv (0.5 rem) limit for members of the public who are exposed by released patients from a per-release limit to a per-year limit.

The provisions in 10 CFR 35.75(a) authorize the licensee to release from its control patients who have been administered radioactive material if the TEDE to another individual from the patient does not exceed 5 mSv (0.5 rem). The Statements of Consideration for the 1997 rule

provide the clarification that the 5 mSv (0.5 rem) TEDE limit to an individual from exposure to the released patient is for each patient treatment. The broad consensus from the extensive stakeholder outreach conducted for the patient release evaluation is that the 1997 rule intended the limit to be applied on a per patient release basis. The NRC staff reaffirmed its determination that the limit for releasing patients who have been administered radioactive material applies to each individual treatment, and that based on the stakeholder feedback, rulemaking to make this clarification is not warranted. Some stakeholders suggested the limit should be an annual limit because the dose limits in 10 CFR Part 20 and the National Council on Radiation Protection and ICRP standards are annualized.

Rulemaking to require the 5 mSv (0.5 rem) limit to be a per-year limit ensures licensees track released patients throughout the year to reduce the possibility that a member of the public would receive a collective dose of more than 5 mSv (0.5 rem) per year from multiple patients, to the extent that the licensee has records that exposed individuals are common from different treatments. Rulemaking to require a per year dose limit is consistent with both occupational and public dose limits in 10 CFR Part 20 as well as national and international standards. Rulemaking would also reduce the possibility that a member of the public would receive a dose that is greater than 5 mSv (0.5 rem) in a year from a patient who receives multiple treatments or from multiple patients, to the extent that such information is available to the licensee.

However, rulemaking to require dose limits on a per-year basis could cause licensees and patients to postpone treatments that would otherwise be administered in a given year. In addition, rulemaking to require per-year limits would likely lead to inconsistencies in an otherwise standard set of patient instructions used nationwide based upon potential previous exposures to others.

Rulemaking to require licensees to conduct radiation safety discussions and provide written instructions with sufficient time prior to the administration

The provisions in 10 CFR 35.75(b) require a licensee to provide the released patient, or the patient's parent or guardian, instructions, including written instructions, on actions recommended to maintain public doses ALARA, if the dose to a member of the public is likely to exceed 1 mSv (0.1 rem). This regulation, however, does not specify that instructions need to be given before treatment.

Rulemaking to require licensees to conduct discussions with, and provide instructions to, the patient in a timely manner before the treatment could allow patients sufficient time to plan their actions following release (such as finding child care if necessary). Early discussions with the patient also allow licensees time to perform patient-specific calculations based on the patient's planned actions, and if necessary, arrange for the patient to be hospitalized. However, rulemaking to specify the timing of these discussions and when the instructions need to be provided to the patient before treatment could impede on the practice of medicine. Under the current regulations, if the licensee does not give patients adequate time to make arrangements for isolation, it will either have to wait to treat the patient until arrangements are made or make arrangements itself to hospitalize the patient; otherwise, the licensee would be in violation of the NRC's regulations.

The results of the literature review and dose calculations indicate that the dominant factor in determining both internal and external doses to members of the public from a released patient is the behavior of the patient once they have been released. This highlights the central

importance of instructions. The consensus from the stakeholder engagement indicates that a prescriptive regulatory requirement on when safety instructions must be provided to a radionuclide therapy patient or the patient's guardian is not warranted. The NRC staff determined that timely and adequate patient discussions should be addressed in guidance and not specified in regulations because there is much variability between treatment procedures and patient situations. Thus, when to provide required instructions is a "practice of medicine" decision.

Update to guidance associated with the patient release program

RG 8.39 was issued in April 1997 and provides guidance to licensees on determining when they should authorize patient release per 10 CFR 35.75(a) and when instructions to patients are required by 10 CFR 35.75(b).

The NRC staff identified that the guidance in RG 8.39 is out-of-date and could result in the underestimation of exposure if licensees use the default assumptions in the guidance when calculating the potential dose to other individuals, especially when a patient uses public transportation following release. The equations provided in RG 8.39 should not be used as an unjustified default in any particular case, but if the licensee chooses to use them, then the default assumptions need to be justified based on the licensee's assessment of the patient's likely behavior after release. The decision to release the patient should be reviewed before starting treatment to determine the conditions under which the patient is expected to be released, and whether the living arrangements, modes of transportation, and staying at a hotel are such that releasing the patient is unlikely to result in doses above 5 mSv (0.5 rem). The staff determined that the guidance in RG 8.39, as well as the equations and parameters contained/referenced in the guide, should be updated, simplified, and made more clear and explicit. A comprehensive update incorporating current scientific knowledge and patient instruction enhancements would lead to a more accurate estimate of public doses from released patients, resulting in better licensee decisions regarding when it may release patients following radioactive material administrations, as well as enhancing the patient's understanding of how their behavior, including following the provided instructions, affects the radiation exposure to other individuals.

Agreement State Coordination

The NRC staff received comments from five Agreement States and the Organization of Agreement States (OAS) board on the NRC staff's evaluation of the patient release program/regulations. The OAS board and the five Agreement States all support the staff's conclusion that updates to NRC guidance regarding calculations, methods, tables, and standard patient instructions would enhance the patient release program. In addition, the OAS board and two Agreement States are supportive of a limited rulemaking to require licensees to conduct radiation safety discussions and provide written instructions in a timely manner before radioisotope treatments.

Advisory Committee on Medical Uses of Isotopes Coordination

ACMUI agrees with the NRC staff's conclusions with respect to the patient release program. (Enclosure 4). The ACMUI also recommended specific changes in NRC guidance. The staff will consider these specific changes in updating RG 8.39.

CONCLUSION

From its evaluation, the NRC staff concluded that the current patient release regulations are protective of public health and safety, and that rulemaking to change the release criteria is not warranted. However, the staff determined that a comprehensive update to the NRC's patient release guidance, including incorporation of guidance currently provided in generic communications, as well as updates to the equations and methodologies described in the NRC guidance for calculating dose to members of the public from released patients, is warranted. Updating the NRC guidance with current scientific knowledge would lead to more accurate estimates of public doses from released patients, resulting in better licensee decisions regarding the timing, circumstances, and risks associated with patient release following byproduct material administration.

The staff is planning a phased approach to comprehensively update RG 8.39. Phase 1 would include incorporation of guidance currently provided in generic communications and patient instructions. Phase 2 would update the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients. A detailed breakdown of estimated resources for Phase 1 and Phase 2 is provided in Enclosure 5, "Resource Estimates."

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections. The Office of the Chief Financial Officer has also reviewed this paper for resource implications and has no objections.

/RA/
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Enclosures:
1. Summary of Patient Release after Radioiodine Therapy Research Review
2. Summary of Assessment of Where Patients Reside Immediately Following Their Release Report
3. Summary of Public Comments Regarding the Patient Release Program
4. Advisory Committee on the Medical Uses of Isotopes Comments on the Patient Release Draft SECY Paper Subcommittee Final Report
5. Resource Estimates (non-public)
6. NRC Form 757, "Non-Concurrence Process" (non-public)

SUBJECT: STAFF RECOMMENDATIONS FOR REVISIONS TO THE PATIENT RELEASE PROGRAM

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