POLICY ISSUE
NOTATION VOTE

January 25, 2012 SECY-12-0011

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: DATA COLLECTION REGARDING PATIENT RELEASE

PURPOSE:

The purpose of this paper is to provide to the Commission recommendations on whether data gaps exist, and whether and how such data could be collected and used regarding patient release. This paper does not address any new commitments.

SUMMARY:

The staff has concluded that there are gaps in the available empirical data regarding doses being received by members of the public as a result of the release of patients treated with medical isotopes. These gaps in the available empirical data relate 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., houses, apartments). In most cases where empirical data is lacking, analytical estimates may be used. This paper discusses possible methods that the NRC might use to collect additional data and the feasibility of collection of such data. This paper also discusses the effect of the identified gaps on the underlying assumptions and calculations used in NRC guidance to support patient release. The staff has provided four options for Commission consideration regarding both the collection of data to address the gaps and the need for revisiting the methods and assumptions involved in the dose calculations used to support patient release.

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The staff recommends that the Commission approve Option 3, whereby an evaluation would be conducted to determine if improvements are warranted in the methods and assumptions in the NRC guidance currently used to make patient release decisions. The staff anticipates that an optimum approach to undertaking this study would be via semi-empirical modeling, i.e., using models to calculate doses supported by available empirical data that may be useful in selecting the most realistic assumptions and parameters.

BACKGROUND:

The current requirements in 10 CFR 35.75, often referred to as the "Patient Release Rule," were promulgated in 1997 and establish the regulatory framework for the release of patients from licensee control who have been administered unsealed byproduct material or implants containing byproduct material. These regulations allow a licensee to authorize the release of an individual from its control if the total effective dose equivalent to any other individual, from exposure to the released individual, is not likely to exceed 5 mSv (0.5 rem). The guidance for dose calculations and calculation methods is set forth in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," and NUREG -1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Licenses," Appendix U, "Model Procedures for Release of Patients or Human Research Subjects Administered Radioactive Materials" (hereafter NUREGs-1492 and 1556).

In Staff Requirements Memorandum (SRM) - COMGBJ-11-0003, dated June 23, 2011, the Commission directed the staff to evaluate whether there are gaps in the available data on doses received by members of the public from release of patients treated with medical isotopes (hereafter Task 1). The SRM also directed the staff to consider how the agency could collect additional data, if needed, to fill these gaps. In undertaking this task, the staff was directed to consider the practicality, usefulness, and methodology of collecting this data and how it would inform and add value to regulatory decision-making. Also, the staff was directed to coordinate with the Office of Nuclear Regulatory Research (RES) in order to determine whether this type of study is feasible and, if so, the proper scope of the study and estimated resources (hereafter Task 2). With regard to this task, the Commission advised that the staff should weigh the utility of such additional data-gathering against the potential for intruding upon patient privacy protections, and assume that existing guidance provided to patients is being followed appropriately, including the additional guidance provided recently to licensees strongly discouraging the use of hotels by released patients. Finally, the SRM directed staff to include, as an alternative or additional option, a recommendation on the feasibility of revisiting the dose assessment used to support the patient release rulemaking and address the staff's recommended approach on the use of expert elicitation (hereafter Task 3).

DISCUSSION:

Staff efforts to address each of the three tasks are described in detail in Enclosures 1, 2, and 3. A summary of the staff's efforts regarding each task is provided below.

Task 1

As directed by COMGBJ-11-0003, the staff searched available technical literature on doses received by members of the public from released patients treated with medical isotopes. As described in Enclosure 1, the staff collected and reviewed literature that focused primarily on empirical (i.e., based on observation and experiments such as field studies) dose findings from exposure to patients administered medical isotopes. Almost all of the published literature addressed doses from Iodine-131 (I-131) hyperthyroid and thyroid cancer patients and focused on releases to primary residences. Analytical data (i.e., based on theoretical studies) was reviewed as well.

As a result of its review, the staff concluded that there are gaps in the empirical data on the release of patients to locations other than their primary residences, mainly with regard to exposures to other individuals at nursing homes and hotels. There are also gaps in the evaluation of internal doses delivered to members of the public from inhalation and/or ingestion of radioiodine contaminants discharged from the patient's body (i.e., perspiration, saliva, vomit, other body fluids, etc.), due to the increased activities administered in today's patient release practices.

Specifically, with regard to release of patients administered I-131, no empirical studies have been published regarding internal doses to members of the public, or for internal and external doses to members of the public for patients released to locations other than their primary residences. Where empirical data is lacking, analytical estimates are used when needed to support that radiation doses to other individuals from radioactivity in released patients can be safely controlled.

The analysis also indicated that there is a lack of available data (i.e., gaps) on the release of patients administered medical isotopes other than I-131 for hyperthyroid and thyroid cancer. However, the staff concluded that this data gap does not significantly impact patient release practices because of the lower volatility, smaller administered doses, and considerably lower external radiation dose for these other medical isotopes, as compared to I-131. In addition, these other medical isotope uses involve considerably smaller patient populations.

Task 2

For Task 2, the staff addressed: (1) how the agency could collect additional data to resolve the gaps identified during Task 1 reviews, (2) the feasibility of collecting such data and the scope of the study, and (3) the estimated resources and timeline required to conduct the study or studies. The staff also provided a discussion on the methods that NRC might use to collect additional data on doses received by members of the public due to the release of patients treated with medical isotopes to hotels and nursing homes.

The staff determined it may be beneficial to re-examine one of the assumptions in NUREGs-1492 and 1556 guidance which underlies current patient release practices, specifically that internal dose to members of the public is negligible compared with external dose. This re-examination may be warranted because current release practices permit patients to be released with much higher activity than was the case when this assumption was made in promulgating

the patient release rule. Accounting for internal dose is particularly important in the case of children and pregnant women. However, it may be difficult to collect data on internal doses to members of the public, as well as on internal and external doses at nursing homes and hotels. Additionally, there may be privacy considerations that would first have to be addressed.

As described in Enclosure 2, the staff explored the feasibility of a study to collect data related to internal dose and patients released to locations, such as nursing homes and hotels. It is anticipated that such efforts may be difficult and the number of cases examined may be too small to provide an adequate sample. If that is found to be the case, simulations using realistic dose calculations coupled with time-and-motion studies could be used to obtain reasonable dose estimates. Such a simulation would adequately fill the current data gap in this area. As explained in Enclosure 2, this proposed study/analysis would both validate and reinforce existing U.S. Nuclear Regulatory Commission (NRC) guidance and/or requirements or may demonstrate the need for further guidance and re-evaluation of existing practices.

The staff's estimated resources and timeline for completion of Task 2 are addressed in the resource section under Option 2.

Task 3

The Commission also directed that the staff include a recommendation regarding the feasibility of revisiting the dose assessment used to support the patient release rulemaking and address the staff's recommended approach on the use of expert elicitation. However, the patient release rule is not based upon dose assessments; rather, the rule provides a dose threshold for patient release. A patient may be released from licensee control if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed that threshold (i.e., 5 mSv (0.5 rem)).

NUREGs-1492 and 1556 provide the calculations and assumptions used to determine whether a patient should be released. The staff considered the feasibility of whether the calculations and assumptions underlying these calculations should be re-examined. The staff determined that re-examination of the methods and assumptions involved in the dose calculations described in the NUREGs could be accomplished by the staff with contractual support. The estimated resources and timeline for revisiting the calculations and assumptions in the NUREGs are addressed in the resource section under Option 3.

The SRM directed that the staff consider the feasibility of expert elicitation. The staff's assessment concludes that the use of expert elicitation would not be cost effective and would not be necessary because most of the methods and parameters involved in the calculations are reasonably well established and non-controversial. Once the review has started, the staff will initiate expert elicitation if it is necessary.

The staff's estimated resources and timeline for task 3 with expert elicitation are addressed in the resource section under Option 4.

Options:

In developing its recommendation regarding both the feasibility of collecting data for the identified gaps and whether the calculations and assumptions involved in determining whether a patient may be released should be re-evaluated, the staff considered the following four options:

Option 1 - Do not pursue any further research/data collection and do not revisit calculations and methods described in the NUREGs.

This option is based on the assumption that the analytical assessments performed in NUREGs-1492 and 1556 are reliable and provide reasonable assurance that the dose criterion used to release patients is in fact being met, and affirms that safety concerns are being adequately addressed. This position is supported by the few published field studies on this subject. In addition, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) has affirmed in its 2010 report that radiation doses to other individuals from radioactivity in released patients can be safely controlled by the current 10 CFR 35.75 patient release criteria (Ref. 22 in Enclosure 1). Under this option, there would be no need to expend additional agency resources. However, because existing gaps in empirical data have been identified, not pursuing additional research in this area and relying solely on analytical estimates may be viewed critically by some stakeholders.

Option 2 - Perform research/empirical data collection to fill identified gaps in available data.

Since the staff concluded that there are gaps in the data on the release of patients to locations other than their primary residences, and also in the evaluation of internal doses delivered to members of the public, this option involves collection of empirical data on external and internal doses to members of the public exposed to released patients. External dose to potentially exposed individuals could be monitored by providing the individuals most likely to come in contact with specific patients with personal dosimeters for the duration of the exposure.

It would be much more difficult to estimate internal dose. The logistics of monitoring for intake is likely to present additional problems. It would require monitoring potentially exposed people, including children, for possible intakes of I-131 using special radiation detection equipment, and the monitoring would have to be repeated several times during the exposure period to ensure that sufficient data is collected to enable calculation of the resulting internal doses.

Furthermore, the staff sees difficulties with the logistical aspects of empirical data collection in a hotel or nursing home environment due to the need for patient and hotel or nursing home staff consent, corresponding approvals from the related authorities/facilities, public perception of the facilities, and possible inaccuracies in the study's results, due to behavioral changes of participants knowing that they are being monitored. Should it be found feasible to conduct the above measurements, it is unlikely that the sample size would be large enough (due to difficulties in getting adequate numbers of participants) to make any definitive conclusions regarding the adequacy of current practices.

An alternative to monitoring exposed members of the public may be to perform semi-empirical modeling, using models to calculate doses and model parameters based on field data. Data could be obtained on levels of radiation fields around hospitalized patients, and levels of contamination measured on surfaces, walls, sheets, air, etc., in the patient's room. Using this

data, together with reasonable assumptions to allow for differences between hospital and nursing home or hotel settings, staff could obtain at least an order of magnitude estimate of the doses to members of the public. However, this approach would involve making certain assumptions, and the results would therefore have greater uncertainty than an approach based exclusively on measurements, but it would be more feasible to implement. It is anticipated that any data collection would be performed employing peer-reviewed standards by an independent entity.

Option 3 – As an alternative to collecting empirical data, revisit calculations and methods described in the NUREGs' guidance for patient release.

This option would involve a review of the methods and assumptions used in NUREGs-1492 and 1556 to determine if improvements are warranted. This evaluation would include a review of the assumptions associated with internal dose and location of release. This could result in repeating the calculations, and the generation of a new set of tables that may be used by licensees as an operational basis to release patients that the NRC would consider adequate to show compliance with the primary criterion of 5 mSv (0.5 rem) in 10 CFR Part 35. Guidance would then be updated to reflect current release practices. Any empirical data used for the revision would be obtained from published technical literature and not NRC sponsored studies.

The advantage of this option is that the NRC guidance could be enhanced by using semi-empirical data. This involves using new analytical techniques, as well as computer codes for sophisticated dose assessments, which have become available since NUREG-1492 was developed. The revised guidance would also incorporate information obtained from experience that has been gained about patient release, patient behavior after release, and issues associated with patients taking precautions to minimize dose to others. It is expected that factors will be identified that impact dose to members of the public and suggest improvements in release practices or patient instructions that could improve as low as reasonably achievable (ALARA) efforts.

Option 4 - Perform analytical and limited empirical research/data collection, and revisit calculations and methods described in the NUREGs' guidance for patient release.

This option is the same as Option 3, but supplements the formal dose assessments of Option 3 by including a limited amount of empirical data collected from field measurements. The assessments performed under Option 3 would make use of available empirical data, which would be obtained from published technical literature but would not involve staff in actual collection of data from subjects as would be undertaken under Option 2. Option 4, however, would entail supplementing the published data, which may be limited in scope and quantity, with limited analytical and empirical data collection and measurements initiated by NRC (e.g., simulations including software and tissue equivalent phantoms, using realistic dose calculations coupled with time and motion studies). This approach may reduce the uncertainty of the results considering the great variability of behaviors of released patients. However, substantial improvement would not be expected. In implementing this option, expert elicitation would be considered, although the staff's assessment indicates that this would likely not be necessary because most of the methods and parameters involved in the calculations are reasonably well established and non-controversial. Informal discussion with experts in the field, as well as with ACMUI, would be used as appropriate.

Staff's Recommendation**:**

The staff recommends Option 3. As discussed in Option 2, there are significant logistical problems with conducting empirical studies. New analytical techniques, as well as computer codes for sophisticated dose assessments, have become available since NUREG-1492 was developed and can be used in lieu of collecting empirical data to enhance the guidance for patient release.

Considerable experience has also been gained about patient release, the behavior of patients after release, and the difficulties encountered in getting patients to take precautions to minimize dose to others. Some studies have also been conducted and published that describe the radiation doses received by members of the public from released patients, and this data would also be very helpful in the re-assessments. All of these factors could be used to refine the NUREG-1492 calculations and to develop improved operational tools for licensees to use in releasing patients to meet regulatory requirements. This approach may also permit identification of the factors that have the greatest impact on dose to members of the public, and may therefore suggest improvements in release practices or patient instructions that could enhance ALARA efforts.

In addition, a frequent criticism of the guidance for patient release in NUREGs-1492 and 1556 has been that the guidance is overly conservative; i.e., if the provided calculations are strictly followed this will result in few patients being able to be released from licensee control. However, the staff considers this criticism reflects a misunderstanding of the guidance. Specifically, the provided calculations, and tables that are based upon these calculations, are intended to serve as screening tools that may be used by licensees who do not wish to perform their own calculations. As such, they must be conservative and a limiting, but plausible, scenario must be assumed. However, licensees who have specific information about an individual patient may, and in fact do, factor that information into their calculations. The staff is including in its proposed approach to revising the guidance, a more detailed discussion on the utility of this guidance which may help to correct this misunderstanding. Additionally, as part of its effort, the staff will re-evaluate the calculations and in so doing determine whether the assumptions and parameters used are overly conservative.

RESOURCES:

There is no cost to implement Option 1. Option 2 would require approximately 2 years to complete and would require 0.75 Full Time Equivalent (FTE) with an associated cost of $1.2 M in contract support. If Option 3 were implemented, the staff estimates that the work would require approximately 2 years to complete and would expend 1.0 FTE and $500K in contract support. Option 4, with expert elicitation and with limited data collection, would require 2.5 years, 1.5 FTE, and $900K in contract support. Should the Commission select Options 2, 3, or 4, the staff would need to address the resource needs through the agency Planning, Budgeting, and Performance Management process, including potential reprogramming of resources in the current fiscal year.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. This paper includes the views of the ACMUI Subcommittee on Patient Release (Enclosure 4) and the staff's review of those comments (Enclosure 5). The ACMUI Patient Release Subcommittee report reaffirms that radiation doses to other individuals from radioactivity in released patients can be safely controlled by the current 10 CFR 35.75 release criteria, licensees' use of release criteria and instructions based on individual patient circumstances, and patients' and caregivers' understanding of and adherence to the patient release instructions (Ref. 22 in Enclosure 1). The Organization of Agreement States has provided their views and comments to the proposed options in this paper (see Enclosure 6).

/RA Michael F. Weber for/

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Enclosures:
1. Summary of Staff Gap Analysis (Task 1)
2. Feasibility Analysis of Closing Gaps in Existing Data (Task 2)
3. Feasibility of Revisiting Dose Assessment Used for 1997 Patient Release Rulemaking (Task 3)
4. ACMUI Patient Release Subcommittee Comments on the Draft Commission Paper on Data Collection for Patient Release
5. NRC staff review of ACMUI Patient Release Subcommittee comments
6. Organization of Agreement States Comments on the Draft SECY Paper on Data Collection for Patient Release

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ML113530579 *via email **WITS 201100187/EDATS: SECY-2011-0393**

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