Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)
Comments on the Patient Release Draft SECY Paper Subcommittee
Final Report
September 11, 2017

Subcommittee Members

Susan Langhorst, Ph.D., Christopher Palestro, M.D., Laura Weil,
Pat Zanzonico, Ph.D. (Chair)

Charge

To review and provide recommendations for the draft SECY paper entitled, "Staff Recommendations for Revisions to the Patient Release Program."

Summary Statement

The recommendations of our Subcommittee for the draft SECY paper entitled, "Staff Recommendations for Revisions to the Patient Release Program," are consistent with those in the ACMUI's "Patient Release Report," dated December 13, 2010. The most notable of these include the following.

- The current dose-based approach for assessing patient releasability is more protective of public safety than the older activity-based approach.

- The 5-mSv (500-mrem) and the 1-mSv (100-mrem) dose limits should remain per-event, rather than annualized, limits and are appropriate for all potentially exposed cohorts, including pregnant women and children.

- The 5-mSv (500-mrem) and 1-mSv (100-mrem) dose limits are *not* radionuclide-specific but apply to all diagnostic as well as therapeutic radionuclide administrations. Importantly, the 1-mSv (100-mrem) limit for requiring patient safety instructions should not be changed for any such administration.

- The assumptions for dose calculations for patient release, which are set forth in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," are overly conservative. Application of more realistic, individualized assumptions in the assessment of patient releasability is recommended.

- The projected doses to hotel workers from released patients residing at hotels immediately post-therapy are unlikely to exceed the regulatory dose limit for the general public (i.e., 1 mSv (100 mrem)).

- Written and oral instructions must be provided to the patient far enough in advance of

treatment, without compromising patient care, to ensure that the patient has sufficient time to determine whether or not he/she can actually comply with the instructions and to make whatever arrangements may be necessary for compliance.

Introduction

The current requirements in 10 CFR 35.75, often referred to as the "Patient Release Rule," were instituted in 1997 and establish the regulatory framework for the release of individuals from licensee control who have received unsealed byproduct material or implants containing byproduct material. The current "dose-based" Patient Release Rule replaced the longstanding "activity-based" rule, namely, that such individuals could not be released from licensee control until their total-body activity was less than 30 mCi or the measured dose rate one meter away from the patient was less than 5 mrem/hour. The dose-based regulations allow 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). The guidance for dose calculations and calculation methods for patient release is set forth in Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," and in 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."

Summary of Draft SECY Paper

In COMGBJ-11-0003, dated June 23, 2011, the Commission directed the NRC staff to evaluate whether there are gaps in the available data regarding the doses received by members of the public from released patients and, if gaps in the available data were found, to provide a recommendation to the Commission on whether and how such data could be accrued. The NRC staff responded in SECY-12-0011, "Data Collection Regarding Patient Release," dated January 25, 2012, stating that gaps were identified. These gaps were specifically related to (1) internal doses to members of the public and (2) internal and external doses to members of the public from patients released to locations other than their primary residences (such as hotels and nursing homes). In SRM-12-0011, "Data Collection Regarding Patient Release," dated April 9, 2012, the Commission directed the NRC staff to revisit patient release calculations and methods and to conduct a limited amount of relevant data collection and analysis to address the identified data gaps.

In 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, the Commission directed NRC staff to complete four tasks, the first two of which have now been completed: (1) develop a standardized set of guidelines that licensees can use to provide instructions to patients to minimize their radiation exposure to other individuals; (2) develop a website that provides information and links to relevant medical organizations and patient advocacy groups to enable patients to access relevant information; (3) evaluate whether regulatory changes to the patient release program are warranted; and (4) revise Regulatory Guide 8.39, and subsequently NUREG-1556 to specify guidelines for patient information and guidance.

The draft SECY paper, which addresses task (3), evaluation of whether regulatory changes to the patient release program are warranted, is the subject of this ACMUI Subcommittee Report. With respect to task (4), NRC staff does not intend to update patient release guidance at this time, pending further direction from the Commission.

As directed in SRM-12-0011, NRC staff conducted an evaluation of guidance for patient release calculations and methods and of the adequacy of current patient release regulations. This research consisted of (1) evaluation of licensees' responses to a questionnaire to determine patients' behavior following release; (2) a literature review of peer-reviewed scientific articles; and (3) model-based calculations to estimate doses to members of the general public potentially exposed to released patients (e.g., hotel workers). The draft SECY paper is largely based on two reports which resulted from this empirical evaluation: "Assessment of Where Patients Reside Immediately Following Their Release Report" and "Patient Release Following Radioiodine Therapy: A Review of the Technical Literature, Dose Calculations, and Recommendations." These two reports were examined as part of our Subcommittee's review of the draft SECY paper. NRC staff concluded that collection "in the field" of actual dose and other pertinent data to exposed and potentially exposed cohorts was impractical, in light of relevant logistical, ethical, and cost considerations, and thus opted for the approach adopted based on a literature review and model calculations.

The options considered by NRC staff for revisions to the patient release program were: (1) propose rulemaking on the patient release program; (2) update guidance associated with the patient release program; (3) take no action.

Comments and Recommendations

Our general comments on and recommendations for the draft SECY paper are as follows.

- The literature review conducted by NRC staff was thorough and the model calculations conceptually and technically sound.

- Based on the literature review and model calculations, the current dose-based approach to assessing patient releasability has been validated as scientifically sound and more protective of public safety than the older activity-based approach (sometimes referred to as the "30-mCi rule").

- The 5-mSv (500-mrem) and 1-mSv (100-mrem) dose limits apply to each radionuclide administration or implant to a particular patient and are not a cumulative annual limit.

- The draft SECY paper states that it "…focused on exposures from patients who received I-131 administrations as I-131 is the most frequently used therapeutic radionuclide and other medical isotopes have lower volatility, are generally administered in smaller dosages, and have lower external radiation than I-131." The applicable regulations, that is, the 5-mSv (500-mrem) and 1-mSv (100-mrem) dose limits, however, are *not* radionuclide-specific. It is important, therefore, that radiation

safety guidance is generalizable, that is, applicable to all diagnostic as well as therapeutic radionuclide administrations. Furthermore, the 1-mSv (100-mrem) limit for requiring patient safety instructions should not be changed for any such administrations.

- The 5-mSv (500-mrem) dose limit applies to all potentially exposed cohorts and there is no need to establish a lower dose limit for pregnant women and children.

- The assumption, in the regulatory guidance for implementation of the dose-based approach, that the dose contribution to family members and other exposed individuals from internalized activity is negligible, has been validated by the literature review.

- Other assumptions and methods in the relevant regulatory guidance are in general excessively conservative, tending to yield overestimates of the actual doses to family members and other individuals in most cases. The guidance should be sufficiently flexible to allow incorporation of more realistic assumptions for assessing patient releasability. NRC staff is encouraged to re-visit NCRP Report No 155, entitled, "Management of Radionuclide Therapy Patients," dated December 11, 2006. This report includes a flexible, generally applicable algorithm for determining the releasability of therapy patients and the duration of post-release precautions; an EXCEL™ file for practical implementation of this algorithm is available from the NCRP.

- A patient staying at a hotel rather than their primary residence following radionuclide therapy is not a widespread practice, as documented in the report "Assessment of Where Patients Reside Immediately Following Their Release Report".

- Projected doses to hotel workers from released patients residing at hotels immediately post-therapy do not approach the regulatory dose limit for the general public, even with dose projections based on conservative assumptions and even for workers servicing hotel rooms of released patients multiple times per year. As stated in the document "Patient Release Following Radioiodine Therapy: A Review of the Technical Literature, Dose Calculations, and Recommendations," "…neither the 1 mSv (100 mrem) nor the 5 mSv (500 mrem) are exceeded in any credible hotel scenario…"

- In the past, the NRC has suggested retiring Regulatory Guide 8.39 and providing the applicable guidance exclusively in NUREG 1556, Volume 9, Appendix U. The Subcommittee recommends maintaining Regulatory Guide 8.39 or a suitable revision thereof, as it is more familiar and more accessible to the stakeholder community than Appendix U. Furthermore, any necessary updates could be implemented more readily in Regulatory Guide 8.39 than in NUREG 1556. The NRC may consider updating Appendix U to reference Regulatory Guide 8.39 rather than attempting to maintain these two separate documents. The Subcommittee noted that NRC staff is not currently considering any rulemaking related to the Patient Release. Any such rulemaking, if warranted, would therefore not be instituted for a number of years.

This reinforces the need for continuation of guidance familiar to the stakeholder community.

- The current regulation, 35.75(b), addressing instructions provided to patients released in accordance with 10 CFR 35.75 is:

> "A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem)."

In order to ensure that radiation exposure to family or other caregivers and the general public is ALARA, written and oral instructions must be provided to the patient far enough in advance, without compromising patient care, to ensure that the patient has sufficient time to determine whether or not he/she can actually comply with the instructions and to make whatever arrangements may be necessary for compliance. Giving the patient prior instructions in advance also provides the licensee with the opportunity to determine whether or not the patient is able to follow the instructions and how best to manage the radiation safety aspects of the planned treatment. The Subcommittee does not believe it is realistic to modify patient release regulations to require prescriptive timing for providing patient instructions since these regulations apply to all diagnostic and therapeutic radionuclide administrations. The applicable guidance should emphasize, however, that whenever possible patients should be provided with these instructions prior to the day of a radionuclide therapy administration. Staff is again encouraged to re-visit NCRP Report No 155, entitled, "Management of Radionuclide Therapy Patients." This Report includes a generally applicable template of written instructions for therapy patients.

Concluding Remark

With the rapid emergence of new forms of targeted radionuclide diagnostic and therapeutic procedures, it is of the utmost importance that while the Patient Release Program not compromise the safety of the public, it must be appropriately flexible and not overly conservative, so as to not encumber the development and implementation of such promising medical procedures.

The ACMUI unanimously approved this report during its public meeting on September 11, 2017.