Advisory Committee on the Medical Use of Isotopes (ACMUI)
Patient Release Subcommittee Comments on
Draft Commission Paper on Data Collection for Patient Release
December 2, 2011

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NRC Staff Request: ACMUI Patient Release Subcommittee to provide opinions and/or comments on Draft Commission Paper on Data Collection for Patient Release (Version 26, dated October 27, 2011).

Subcommittee Recommendations

The Subcommittee supports additional field measurements and improved modeling. While this encompasses certain aspects of both Option 3 and 4, the Subcommittee did not feel that either Option as stated captured the sense of the Subcommittee. Measurements of surface contamination and of activity internalized, in contrast to external-dose measurements, would more directly validate or dispute the contentious assumption that internal dose is of minimal significance in the context of release of radionuclide therapy patients, particularly with respect to patients receiving higher administered activities and released to locations other than their primary residences. The Subcommittee feels that such data could be collected through a field study done with family members and hospital, nursing home, and hotel staff willing to participate, and would provide valuable data on the conservative nature of the parameters used for patient release calculations. Additionally, external exposure measurements to cohorts not already in the literature would be useful. The Subcommittee believes the data thus collected could be reasonably applied to situations of patient release to any location. The Subcommittee further recommends that any such data gathering, analysis, and reporting be done through a fully transparent peer-reviewed process rather than internally by NRC staff.

Additional Subcommittee Discussions beyond the Scope of the Draft Commission Paper

In the course of its discussion of the Draft Commission Paper on Data Collection for Patient Release, the Subcommittee considered the following issues in light of the possibility of performing additional data collection activities related to patient release. We recognize these comments go beyond the scope of the Commission's directions to NRC staff in developing the draft commission paper, but the Subcommittee feels these comments may be helpful to future data gathering efforts related to patient release.

Explore use of existing data resources – Some existing data collection resources may be used to gather data relating to parameters impacting patient release. For example, radiation measurements done by the Transportation Security Administration (TSA) may provide or slightly adjust its data

collection protocols to provide information on numbers of released patients who travel after their radionuclide therapy administration, or numbers of non-patients who have detectable levels of contamination as a result of being associated with a released patient. Other locations where radiation scanning is routinely performed, such as nuclear power plants, national laboratories, nuclear fuel fabrication facilities, etc., may also provide comparable data collection capabilities.

Consistency of patient precautions and patient understanding of instructions – The Subcommittee believes the best ways to alleviate concerns related to patient release would be to develop reasonable and consistent precautions for patient release for various locations. Examples of recent articles focusing on this topic include:

> Greenlee, et.al. "Current Safety Practices Relating to I-131 Administration for Diseases of the Thyroid: A Survey of Physicians and Allied Practitioners." *THYROID*. 2011;21:151-160.
>
> Kloos, R.T. "Survey of Radioiodine Therapy Safety Practices Highlights the Need for User-Friendly Recommendations." *THYROID* Vol. 2011;21:97-99.
>
> The American Thyroid Association Taskforce on Radioiodine Safety. "Radiation Safety in the Treatment of Patients with Thyroid Diseases by Radioiodine ^{131}I: Practice Recommendations of the American Thyroid Association." *THYROID*. 2011;21:335-346.

The development of reasonable and consistent precautions should include evaluation of patient understanding of and/or ability to follow instructions to implement these precautions. This may also include providing instructions for individuals working at different locations likely to receive multiple released patients, such as hotels and nursing homes. The Subcommittee suggests these instructions emphasize that compliance with these precautions will ensure that the risk of health effects to others from exposure to the released patient is reduced to that comparable to the risk associated with variations in background radiation, which are too small to be observed and may be nonexistent altogether.

Subcommittee Specific Comments on the Draft Commission Paper

Given the Commission directions contained in Staff Requirements Memorandum (SRM)-COMGBJ-11-0003, the Subcommittee offers the NRC staff the following opinions and comments on the draft commission paper.

1. **Page 2, Summary, last sentence** –

   > "The staff recommends that the Commission approve Option 3, whereby an evaluation would be conducted of the methods and assumptions in NUREGs 1492 and 1556 which are used in support of releasing patients to determine if improvements are warranted."

   This sentence is not consistent with the **last sentence, Enclosure 2** –

"The staff anticipates that an optimum approach to undertaking this study would be a combination of semi-empirical modeling supported by some field measurements on a few exposed members of the public."

In discussion with NRC staff, the Subcommittee understands that the intent of NRC staff in recommending Option 3 was to also include an option to collect some field measurements if existing empirical data are not sufficient. We suggest this intent be included in the Summary section of the Draft Commission Paper.

2. **Page 3, second paragraph under Task 1, last sentence** – The Subcommittee believes this sentence is ambiguous. Is it stating that "…no studies have been published regarding internal doses to members of the public …" generally *or* only in the context of patients released to other than their primary residences? It is subsequently stated in this sentence that neither have such studies been published on "…internal and external doses to members of the public, for patients released to locations other than their primary residences and particularly for exposure scenarios at nursing homes and exposure scenarios to hotel staff (e.g. front desk clerk) and guests…" The latter statement is correct, with the exception of the Subcommittee's ACMUI Patient Release Report, which included public dose calculations for released patients going to a hotel; this Report should be cited here. However, if this sentence is meant to assert that no studies have been published on internal doses generally, that is not correct. There are at least three such studies in the peer-reviewed literature.

   Jacobsen A, Plato P, Toeroek D., "Contamination of the home environment by patients treated with iodine-131: Initial results," *Am J Publ Health*. 1978;68:228-230.

   Plato P, Jacobson A, Homann S., "In vivo thyroid monitoring for iodine-131 in the environment." *Inter J Applied Radiat Isotopes*. 1976;27:539-545.

   Toeroek D, Jacobson A, Plato P., "Radiation protection of families of radioactive patients,"*Health Phys*. 1978;35:911-912.

   In any case, the term, "studies," should be clarified to indicate that it refers to actual field measurements. We also recommend that "(e.g. front desk clerk)" be dropped here and in the **last paragraph, Enclosure 1**, since exposures to all hotel staff merit consideration.

3. **Summary of Staff Gap Analysis (Task 1)** – This section, including the list of references, should be labeled in the footer as Enclosure 1.

4. **Enclosure 1, Reference Number 6** – The Health Physics Society withdrew the referenced Position Statement from its web page soon after it was posted and is currently revising it. It therefore should not be referenced at this point.

5. **Enclosure 2** – The Subcommittee believes that various statements made in Enclosure 2 may be considered provocative in that they are not supported by reference documents or do not appear to assume that patients and licensees are appropriately following instructions/guidance as directed by the SRM. We have listed here those statements and our specific concerns we have with each.

"This task was intended to address the feasibility of closing at least some of the data gaps identified in Task 1, namely the absence of adequate field data on doses to members of the public resulting from released patients who were administered radioactive materials. To date there has been little data collected to validate the calculations and assumptions on which patient release is based. That is, it is not known whether members of the public are, in fact, receiving doses that are less than 5 mSv from the released patients."

From the Subcommittee's understanding of the gap analysis used in the Draft Commission Paper, adequacy of the field data is not judged beyond its source being a peer-reviewed publication. The Subcommittee believes this paragraph should be reworded so that it is consistent with the Draft Commission Paper. Parts of the paragraph state that doses may be exceeded, but given the constraint of the SRM that the NRC staff considers that all instructions and guidance are being followed, we believe that the wording should be modified to include that doses exceeding the limit would not be likely if instructions and guidance are followed.

"The exposed member of the public could inhale or ingest the contaminant, and as a result receive an internal dose. Radioactive material may also be transferred directly from the patient to a member of the public by sneezing, coughing, or kissing. A breast feeding patient may also transfer the radioactive material via the milk to a child through breast feeding, although breast feeding patients are provided with instructions on stopping breast feeding for a period of time after treatment."

The Subcommittee believes that the last sentence on breastfeeding and the example of kissing should be dropped as they are both examples of prohibited behavior that patients are warned against in the instructions given to them, and any recommendations involving questions about the instructions given to patients or how the patients follow the instructions runs contrary to the SRM.

"For example, per unit activity of ingested I-131, a 1-year-old child will receive both effective and thyroid doses that may be up to 10 times higher than the doses received by an adult for the same intake."

The Subcommittee believes this statement requires a cited peer-reviewed reference to in order to keep this sentence in this paragraph.

"On the other hand, the data may show doses that are higher than 5 mSv, as some available data suggests that this may be the case, and a reasonable conclusion would be that the release criteria appear inadequate and should be re-evaluated."

The Subcommittee believes the "available data" statement requires a cited peer-reviewed reference to in order to keep this sentence in this paragraph.

6. **Enclosure 3** – Concerning underlying assumptions discussed in this Enclosure, the Subcommittee believes that NRC staff should include reference to the Federal Register publication of the patient release final rule (62 FR 4120) that the 5 mSv dose limit applies to an individual's exposure from the released patient *for each patient release*. The discussion of risk (i.e., harm) in this enclosure should more explicitly reference the application of the three fundamental principles of the use of radioactive materials by recognizing the benefit of these medical procedures, the risk of harm to

the patient if these medical procedures are not available or are constrained, and that all these issues must be considered when establishing approval for radioactive material medical use, public dose limits, and the reasonable application of precautions released patients should follow.

- The Principle of Justification: Any decision that alters the radiation exposure situation should do more good than harm.

- The Principle of Optimization of Protection: The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable (ALARA), taking into account economic and societal as well as medical factors.

- The Principle of Application of Dose Limits: The total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified.

And the Subcommittee believes this discussion of harm should also reference studies or expert opinion of harm associated with aspects of patient release, such as:

Hahn, et.al. "Thyroid Cancer after Diagnostic Administration of Iodine-131 in Childhood." *Radiation Research*. 2001;156:61-70.

"Radiation Risk in Perspective," Position Statement of the Health Physics Society, PS 010-2, July 2010 [http://hps.org/documents/risk_ps010-2.pdf , last accessed December, 2, 2011].

Higashi, et.al. "Delayed Initial Radioactive Iodine Therapy Resulted in Poor Survival in Patients with Metastatic Differentiated Thyroid Carcinoma: A Retrospective Statistical Analysis of 198 Cases." *The Journal of Nuclear Medicine*. 2011;52:683-689.

Goldsmith, S.J. "The Real Cost of Theoretic Risk Avoidance: The Need to Challenge Unsubstantiated Concerns About ^{131}I Therapy." *The Journal of Nuclear Medicine*. 2011;52:681-682.

7. **Enclosure 3, page 1, paragraph 4, 2nd sentence & page 2, 1st full sentence** – The Subcommittee believes licensee responsibilities should be described identically as in the regulations, and so recommend that the words "indeed" and "are in fact" be replaced with "likely."

8. **Enclosure 3, page 1, paragraph 4, last 5 sentences** – The Subcommittee believes these sentences imply that a licensee can only determine a patient releasibility using the method and tables described in these NUREGs. A statement should be added to clarify that the NUREG tables represent a possible tool to determine patient releasibility, and that licensees are allowed to perform their own patient-specific projected-dose calculations to demonstrate compliance with the 5 mSv dose criterion.