Analysis of Feasibility of Closing Gaps in Existing Data (Task 2)

For Task 2, the Office of Nuclear Regulatory Research was requested to address the following: (1) how the agency could collect additional data to resolve the gaps identified during Task 1 reviews; and (2) the feasibility of collecting such data and the scope of the study.

This task was intended to address the feasibility of closing data gaps identified in Task 1, in particular 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.

Dose to a member of the public in proximity of the released patient may arise from two sources: external and internal exposures. External exposure refers to radiation that is emitted from the radioactive material inside the patient's body that then irradiates the exposed person. Internal exposure is more complex, referring to the radioactive material in the patient that may be released from the patient's body in several ways, such as via perspiration, saliva, vomiting, exhalation, and in excreta. This released material will contaminate surfaces, towels, sheets, eating implements, etc., with which they come in contact. A 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 and coughing.

Internal exposures are a concern especially in cases where the administered material may be volatile and is administered in large doses. Such is often the case with patients undergoing treatment with I-131, and I-131 is therefore the material of concern in this task for both external and internal doses. An important factor to consider in planning for this task is that children are at higher risk than adults when internal exposures are considered, and should therefore be included in any data collection efforts or analytical assessments. Pregnant women should also be considered due to potential higher risks to the embryo/fetus. Current patient release practices are based on the assumption that internal doses received by exposed members of the public, including family members, are likely to be a small fraction of the external doses and can therefore be neglected. This assumption was made at the time when patient release was based on activities at release not exceeding 30 mCi. Currently, with the dose-based release criterion, patients are being released immediately after administration of up to a few hundred mCi, and these increased levels of activity may invalidate the prior assumption of negligible internal doses, particularly with regard to children.

If data is collected, the staff concluded that while the external dose portion of the study would be easier to perform, the internal dose portion could be more problematic. The external dose portion could be performed by providing and monitoring the potentially exposed people with personal dosimeters. It may be difficult to find an adequate number of people willing to participate. The internal dose portion requires monitoring potentially exposed people, including children, for possible intakes of I-131 using special radiation detection equipment. This monitoring would also have to be repeated several times during the exposure period to ensure that sufficient data is collected to enable calculations of the resulting internal doses. Therefore, in addition to the difficulty of finding a sufficient number of people to participate, as in the case with external doses, the logistics of monitoring for intake is also likely to be difficult.

The staff also sees complexities with data collection either in a hotel or nursing home environment due to potential patient non-consent, corresponding approval(s) from the related authorities/facilities, public perception of the facilities (e.g., hotels or nursing homes), and possible study result inaccuracies due to behavioral changes of participants knowing that they are being monitored. If it is feasible to conduct the above measurements, it is very unlikely that the sample size would be large enough to allow reaching definitive conclusions regarding the adequacy of current practices. The best that can be expected is a qualified conclusion.

To overcome the difficulties created by the impossibility of proving the negative, namely, that doses above specified limits are not being exceeded, an alternative or supplement to monitoring exposed members of the public could be to perform a limited empirical assessment, using models to calculate doses. The staff could obtain data on levels of radiation fields around hospitalized patients, as well as levels of contamination measured on surfaces, walls, sheets, air, etc., in the patient's room. Such data is generally available from the hospital's radiation protection staff or radiation protection program. Using this data, together with reasonable assumptions to allow for differences between hospital and home or hotel settings, the staff could obtain at least an order of magnitude estimate of the doses to members of the public.

To overcome the potential insufficient patient release data sampling explained above, simulations that include software and tissue equivalent phantoms, using realistic dose calculations, coupled with time-and-motion studies, could be used to obtain reasonable dose estimates. Such a simulation may fill some of the current data gaps in this area and could allow for data extrapolation analysis. This simulation would likely be sufficient to make a determination of whether or not internal dose is a concern, and whether the external doses received support the adequacy of current patient release criteria. If staff's calculations indicate areas of concern, such as unexpectedly high internal doses, then additional effort would be devoted to refining these assessments. The staff anticipates that an optimum approach to undertaking this study would be semi-empirical modeling supported by any available empirical data that may be useful in selecting the most realistic assumptions and parameters.