Feasibility of Revisiting Calculations and Underlying Assumptions for Assessing Dose from Released Patient (Task 3)

For Task 3, the Office of Nuclear Regulatory Research was requested to address the following: (1) assess the feasibility and resources needed for revisiting the dose assessment used to support the 1997 patient release rulemaking, and (2) provide a recommendation on the feasibility and the resources and timeline needed for expert elicitation as another approach to revisiting the dose assessment.

The current patient release rule is dose-based and not based on dose assessments. However, dose assessments are needed to implement the rule. The current patient release rule and practices in the United States are radiation-dose-based, namely, patients may be released from the hospital if it is unlikely that any member of the public will receive a dose in excess of 5 mSv (0.5 rem) as a result of being in proximity to the patient. Because members of the public are not monitored to verify that this is indeed the case, calculations are used to translate the dose criterion to activity of the medical radionuclides administered to the patient, and these activities are then used by licensees as surrogates for radiation dose to determine whether the patient may be released. The calculations use simple models and conservative assumptions.

The assessments described in NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," were used in part to select among different release options, but the patient release criterion (that release may be authorized 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)) will not be re-examined. Only the calculation methods, that were subsequently used to provide guidance for licensees in NUREG-1492, and that is incorporated 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," (NUREG-1556) will be reviewed.

The 5 mSv dose criterion for patient release was a policy decision, not based on calculations. The policy decision was informed by analysis involving balancing the risk of exposure to a low dose of radiation from the patient to a member of the public against the benefits of not keeping patients for extended periods of time in the hospital following administration of byproduct material. It is the licensee's responsibility to ensure that the released patient will likely meet the dose criterion. However, because of the difficulty of ensuring that such a dose-based criterion is met, U.S. Nuclear Regulatory Commission (NRC) has performed calculations designed to derive a surrogate, measurable quantity that licensees may use as a tool or aid in showing compliance with the dose criterion. If the licensee is in compliance with the surrogate quantity, then it is acceptable to the NRC to assume that the licensee is also in compliance with the dose criterion in the regulations. Derivation of this tool is described in NUREGs-1492 and 1556. The results of the calculations in the NUREGs are presented in the form of tables of administered activities and of dose rates measured at 1 meter from the patient which, if met, may be used to release the patient. Thus, patients are being released using surrogate release criteria and not the primary dose criterion.

It should be noted, however, that the calculations and tables provided by the NRC represent guidance and suggested methods that NRC would consider acceptable in showing compliance. There is nothing in the regulations preventing licensees from doing their own calculations, using their own data and assumptions, to show compliance with the 5 mSv release criterion. The only necessity in such a case is for the licensee to be able to justify the methods, data and assumptions used in the calculations. Such an approach is likely to be less conservative than the guidance provided by NRC because it is likely to be site-specific, whereas NRC's guidance, not being based on any specific situation, serves as a generic screening tool, and hence must be conservative by its nature.

There have been complaints that the calculations used in patient release are excessively conservative and should therefore be re-examined to remove these conservatisms. A review by staff of these calculations shows that they are, indeed conservative, but that this conservatism is appropriate for the following reasons. The patient release rule is dose-based, and only requires licensees to show that they are releasing patients in a manner that complies with the rule. Licensees may use any method of calculation they wish in showing compliance, using any parameters and assumptions they deem appropriate, provided they document their calculations and support their assumptions. Therefore, conservatism is not built into the rule. The calculations performed by NRC and described in the NUREGs, and the tables that are based on these calculations, are intended to serve as screening tools for the convenience of licensees who may not wish to do their own calculations, or who do not have the technical expertise to do them. As in the case of all screening tools, they must by their nature be conservative because they assume that the patient is being released with no knowledge of what will happen following release, that is, who the patient will come in contact with, how long that contact will be, etc. Under such circumstances, conservatism is necessary because limiting, but plausible, scenarios must be assumed. Licensees who have specific information on the behavior of patients after release may use that information to adjust their calculations. Nevertheless, in reviewing dose assessments, the staff will evaluate the calculations and determine whether the models used are too basic and whether the assumptions and parameters are too conservative. This would include a review of the assumptions associated with internal dose and location of release. If that is found to be the case, staff could improve the calculations, and it can also regenerate the tables used by licensees using the improved calculations.

The staff may consider expert elicitation when reviewing dose assessments if it determines that it would be useful. Expert elicitation is widely used in formulating radiation protection recommendations and standards because many of the parameters that enter into dose and risk assessment are a matter of expert opinion, and are usually selected by a panel of experts. However, in the case of patient release dose estimates, the staff views the calculations as being fairly straightforward, and the assumptions and parameter values that are used in these calculations are few and easy to select. It is the staff's opinion that expert elicitation in this case would not be cost effective and is not likely to be needed. However, once the review is started and the details are established, the staff will initiate expert elicitation if it seems suitable. As an alternative to the formal process of elicitation, the staff will solicit opinions from many people who work in the relevant fields in order to incorporate as much of their field experience in the calculations as is feasible.