

June 23, 2011

MEMORANDUM TO: R. W. Borchardt
Executive Director for Operations

FROM: Andrew L. Bates, Acting Secretary **/RA/**

SUBJECT: STAFF REQUIREMENTS – COMGBJ-11-0003 – DATA
COLLECTION REGARDING PATIENT RELEASE

The staff should evaluate whether there are gaps in the available data regarding doses being received by members of the public due to the release of patients treated with medical isotopes, as well as how the agency could go about collecting additional data, if needed. The staff should consider the practicality, usefulness, and methodology of collecting this data, and how it would inform and whether it would add value to regulatory decisionmaking. The staff in the technical program area should coordinate with the staff from the Office of Nuclear Regulatory Research in order to determine whether this type of study is feasible and, if so, the proper scope of the study and the estimated resources. The staff should provide its recommendations to the Commission, in a notation vote paper, on whether data gaps exist and whether and how such data could be collected and used.

The staff should weigh the direct utility of any additional data-gathering exercise against the potential for intruding upon patient privacy protections.

The staff should assume that existing guidance provided to the patients is being followed appropriately, including the additional guidance provided recently to the licensees regarding the use of hotels.

Several empirical studies on dose to members of the public have been completed and the staff's analysis of the need for additional empirical data should fully utilize this previous work. The staff should also consider the various International and National Council on Radiation Protection and Measurements Reports on patient release.

The preparation of this paper should be carried out in a manner, utilizing resources from Research as appropriate, which avoids any impact to the schedule for the ongoing 10 CFR Part 35 rulemaking.

The paper should also include as an alternative or additional option, a recommendation regarding the feasibility of revisiting the dose assessment used to support the patient release rulemaking. The paper should also address the staff's recommended approach on the use of expert elicitation.

The staff should provide the Commission with its recommendations prior to the initiation of the FY 2014 budget formulation in order to assure that any resulting proposal can be considered in the budget process.

cc: Chairman Jaczko
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
CFO
OCA
OPA
Office Directors, Regions, ACRS, ASLBP (via E-Mail)
PDR