UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555

OFFICE OF THE
SECRETARY

June 5, 1997

IN RESPONSE, PLEASE
REFER TO: M970508

MEMORANDUM TO: Judith A. Stitt, Chairman
Advisory Committee on Medical Uses of Isotopes

Karen D. Cyr
General Counsel

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - MEETING WITH ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES (ACMUI), 9:00 A.M., THURSDAY, MAY 8, 1997, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

The Commission was briefed by the Advisory Committee on Medical Uses of Isotopes (ACMUI) on the Committees' discussions on DSI-7 and the revision of 10 CFR Part 35.

The Commission requested the ACMUI to take a focused look at revisions to Part 35, including test cases, as the Commission moves toward a more risk-informed, performance-based regulatory program. In providing recommendations, the Committee should address the questions posed by the Commissioners during the meeting, which include the following:

1. How should the NRC determine which industry standards, including voluntary ones, are adequate to meet the NRC's regulatory responsibility for patient, worker, and public safety? To what extent should NRC allow the licensee flexibility in interpreting or selecting an industry standard? How should the concept of "quality improvement" be incorporated into reliance on industry standards and an accreditation-type of approach to licensing and inspection?

2. What are the necessary transition steps the NRC should take in order to implement a more positive enforcement program that, in effect, encourages or rewards good performance while addressing the outlyers. What metrics should the NRC use to decide whether the approach is working?

3. In considering various events (e.g., misadministrations, equipment failures, or procedural errors), what criteria should the NRC use to determine that a particular event is

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isolated, rather than having program implications for that licensee or generic implications for other medical licensees? What is the best process for the reporting of events to ensure that the NRC is aware of potential generic issues?

4. In evaluating errors, should a threshold be established beneath which corrective action is not required? How would such a threshold be set, and how would it be implemented?

The Commission requested OGC to provide an analysis of whether the Atomic Energy Act supports ACMUI's proposal that NRC regulation should tolerate a level of risk in radiation medicine comparable to the level of risk associated with other practices of medicine.

(OGC) (SECY Suspense: 8/22/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
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