



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 5, 1997

MEMORANDUM TO: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan

FROM: L. Joseph Callan *L. Callan*
Executive Director for Operations

SUBJECT: RESPONSE TO STAFF REQUIREMENTS MEMORANDUM
SECY-97-012 - PROS AND CONS OF HAVING ADVISORY
COMMITTEE ON THE MEDICAL USE OF ISOTOPES
RECOMMENDATIONS PROVIDED DIRECTLY TO THE
COMMISSION, CONCURRENT WITH SUCH PROVISION TO
THE STAFF

Staff Requirements Memorandum - SECY-97-012, "Appointments of a Physician Practicing Nuclear Cardiology, a Patients' Rights and Care Advocate, and an Individual with State or Local Government Perspective to the Advisory Committee on the Medical Use of Isotopes" (ACMUI), directed the staff to "report back to the Commission on the pros and cons of having ACMUI's recommendations provided directly to the Commission, concurrent with such provision to the staff" (Attachment 1). Staff's understanding of the Commission's request focuses on whether or not ACMUI should communicate with the Commission following the same process as that used by the ACRS and ACNW. The ACRS and ACNW are Commission level Committees with dedicated staff to accommodate the technical and administrative issues associated with conducting the affairs of those Committees including providing their recommendations to the Commission. In contrast, ACMUI functions are supported by staff within the Division of Industrial and Medical Nuclear Safety.

The current process for providing ACMUI comments is based on direction from the Commission on April 16, 1993, in COMSECY-93-013, "Guidelines on the role, procedures, size, and composition of the Advisory Committee on the Medical Use of Isotopes" (Attachment 2). This guidance was developed in response to a review of all government advisory committees in accordance with President's general directions on the use of advisory committees. At that time, the Commission explored the role of all NRC Advisory Committees including the ACMUI and provided specific direction to staff. Some of the key points of the Commission direction were: ACMUI should provide an annual briefing to the Commission, develop bylaws governing communication between the Committee and the Commission similar to ACRS, and "the Committee should continue to interact with staff to provide such support as the staff may deem warranted to help accomplish its regulatory missions."

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As a result of this direction, substantial changes were made in the conduct of ACMUI affairs including the development of bylaws for the Committee. ACMUI now provides minutes to the Commission containing the Committees' recommendations, including dissenting opinions which was not done previously. In providing this direction, the Commission appears to have explored ACMUI as a Commission level Advisory Committee but chose to continue with the Committee as a staff level advisory Committee but "encouraged the Committee to adopt bylaws governing communications between the Committee and the Commission along the lines of the bylaws that have been adopted by the ACRS."

Recently, ACMUI raised concerns as to how its recommendations are considered with respect to the ultimate outcome of regulation and guidance development. Staff has in response, initiated two significant changes in this regard which were discussed with the ACMUI during its last meeting. First, the staff will include a line item in the Statements of Consideration for all medical use rulemakings that would address the outcome of ACMUI recommendations. Secondly, the staff now provides feedback to ACMUI, during subsequent meetings on the outcome of all Committee recommendations other than rulemaking.

The staff believes the current process is adequate to deliver ACMUI recommendations and opinions to the Commission in timely manner. Currently, the minutes are prepared by the staff in close coordination with the Chairman of the ACMUI, then reviewed and signed by the Chairman. Staff believes further movement toward an ACRS and ACNW process would add further inefficiencies and unnecessary complexity.

In light of the above, the staff does not recommend any change to the current procedures or process.

Attachments: 1. SRM - SECY-97-012
2. COMSECY-93-013

cc: SECY
OGC
OCA
OPA
CFO
CIO