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

SECRETARY

August 17, 2017

IN RESPONSE, PLEASE
REFER TO: M170817

MEMORANDUM FOR: Victor M. McCree
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary ***/RA/***

SUBJECT: STAFF REQUIREMENTS - AFFIRMATION SESSION, 10:30 A.M., THURSDAY, AUGUST 17, 2017, COMMISSIONERS' CONFERENCE ROOM, ONE WHITE FLINT NORTH, ROCKVILLE, MARYLAND (OPEN TO PUBLIC ATTENDANCE)

I. SECY-16-0080 – FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-AI63; NRC-2008-0175)

The Commission approved a final rule which amends Parts 30, 32, and 35 of Title 10 of the *Code of Federal Regulations* related to the medical use of byproduct material, with the enclosed changes. Additionally, the Commission has certified, under the Regulatory Flexibility Act that this rule will not have significant economic impact on a substantial number of small entities.

This rule amends the medical event definition for reporting and notification requirements for permanent implant brachytherapy. This rule also amends the training and experience (T&E) requirements to (1) remove the requirement to obtain a written attestation for an individual who is certified by a specialty board whose certification process has been recognized by the NRC or an Agreement State; and (2) address a request filed in a petition for rulemaking to exempt certain board-certified individuals from certain T&E requirements. Additionally, this rule (1) amends the requirements for measuring molybdenum contamination; (2) adds a new requirement for the reporting of failed technetium and rubidium generators; and (3) allows licensees to name associate radiation safety officers on a medical license.

Following incorporation of these changes, the Federal Register notice should be reviewed by the Rulemaking, Directives, and Editing Branch in the Office of Administration and forwarded to the Office of the Secretary for signature and publication.

The staff should evaluate whether it makes sense to establish tailored training and experience requirements for different categories of radiopharmaceuticals, how those categories should be determined (such as by risks posed by groups of radionuclides or by delivery method), what the appropriate training and experience requirements would be for each category, and whether those requirements should be based on hours of training and experience or focused more on competency. The staff should keep the Commission informed of its ongoing work in this area through a Commissioner Assistants Note every six months.

Enclosure:
As stated

cc: Chairman Svinicki
Commissioner Baran
Commissioner Burns
EDO
OGC
CFO
OCAA
OCA
OIG
OPA
ODs, RAs, ACRS, ASLBP (via E-Mail)
PDR