

# Medical Use of Byproduct Material: Clarifying and Minor Amendments (RIN 3150-AH08)

Dear Commisioners:

**DOCKET NUMBER**  
**PROPOSED RULE** **PR 35**  
**(68FR19321)**

The Federal Register part 35 notice should be revised to: Provide additional justification for the proposed rule changes to the "certification pathway."

This needs to be done in the context that NRC has made a determination "that, except for one board, the boards did not meet all the requirements of the current rule.

Specifically, the boards' certification programs failed to meet the requirements in the final rule regarding preceptor certification and work experience."

The single board the NRC recognizes as sufficient for RSO certification indicates that Ex-nuclear submarine non-coms and Nuclear Power generation plant employees are qualified to monitor the use of radioactive material in research and clinical settings. During 20 years at multiple Hospitals and commercial pharmaceutical companies I have seen numerous "nuclear power generating former employees" move to the medical area with unanimous failure. A RSO is required to set in of every Hospital Internal Review Board and "power generating engineers" bring very little to evaluating the safety and efficacy of the enormous list of clinical use applications. RSOs should be required to have some training in chemistry, anatomy, medicine, pharmacy, genetics, cell biology and animal research as well as physics and instrumentation.

You new revision of part 35 places impossible restrictions on physicians nuclear medicine and radiology offices, independent Radiopharmacies and PET production companies, as well as any company doing research with radioactive research material.

Respectfully,

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