



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

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August 2, 1999

MEMORANDUM TO: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: *for* James Lieberman, Director *R.W. Burchardt*
Office of Enforcement

SUBJECT: OFFICE CONCURRENCE ON FINAL RULEMAKING: REVISION
OF 10 CFR PART 35

This memorandum transmits the concurrence of the Office Of Enforcement (OE) on the final rulemaking to revise 10 CFR Part 35. OE has previously noted the following issues:

1. The guidance to accompany the new 10 CFR 35.41, "Procedures for administrations requiring a written directive," did not accompany the rule. Due to the performance-based nature of this requirement, the guidance may affect NRC's ability to bring enforcement action in cases involving medical events (misadministrations). OE may have separate comments or concurrence issues when this guidance is presented to the Offices for concurrence.
2. Section 35.70, "Surveys for ambient radiation exposure rate," is limited to the use of unsealed material *that requires a written directive*. Normally, this is not the highest activity material in a nuclear medicine laboratory, nor the most frequently used. In some cases, it is not the material with the longest physical half-life. Since the revision of Part 35 does not carry forward the current general requirements to monitor hands and clothing, and to perform daily surveys and weekly wipe tests, those are no longer enforceable requirements. It is OE's opinion that the general survey requirements in 10 CFR Part 20 do not substitute for the more specific survey requirements in 10 CFR Parts 31 through 39. If NMSS believes that Part 35 medical licensees should perform any additional *routine* surveys, the routine survey requirements should be clearly delineated within Part 35.

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