



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

AB34-1 PDR

SEP 12 1986

MEMORANDUM FOR:

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

FROM:

Donnie H. Grimsley, Director
Division of Rules and Records
Office of Administration

SUBJECT:

MANUFACTURERS' REGISTRATION OF RADIATION
SAFETY INFORMATION FOR CERTAIN DEVICES AND
SEALED SOURCES

The Division of Rules and Records, ADM, has reviewed the draft proposed rule concerning manufacturers' registration of radiation safety information for certain devices and sealed sources. We have enclosed a marked-up copy of the package that sets out our specific comments.

Additional information is required in both the Regulatory Analysis and the Regulatory Flexibility Certification statement to indicate the cost impact and potential economic effect of this proposed rule. The costs incurred by a manufacturer in developing and submitting an average information package to the NRC that is sufficient for NRC review and inclusion in the registry should be described. In addition, the analyses should indicate the number of specific license applications that use information contained in the registry and the average savings accruing to a license applicant because of the registry. Finally, the analyses should indicate the costs incurred by NRC in reviewing a manufacturer's submittal vis-a-vis the costs in reviewing multiple specific license applications.

We note that the proposed rule is silent concerning the applicability of the Commission's backfit analysis requirements. The proper approach and appropriate language concerning this matter should be coordinated with the Office of the General Counsel.

We have suggested a revision to the Summary statement that is needed to more clearly comply with the publication requirements of the Office of the Federal Register (OFR). As indicated in 3.7(c) of the NRC Regulations Handbook (NUREG/BR-0053), the Summary paragraph should succinctly indicate what the document does, why the action is necessary, and what is the intended effect of the action. In addition, we have made additional changes in the amendatory language and the presentation of the amendments that are needed to comply with OFR publication requirements.

Our comments in the regulatory text are designed to adopt the standard convention endorsed by the OFR to impose an obligation or express a prohibition. In this convention, discussed in section 13.27 of the NRC Regulations Handbook,