SUMMARY OF INFORMATION COLLECTION REQUEST

Title: 10 CFR 35, Quality Management Program and Misadministrations

Current Burden/Responses: 34,743 hours/3,194 responses

Proposed Burden/Responses: 34,743 hours/3,194 responses

Burden Attributable to Third-Party Collections: 79 hours

Freqency of Response: One time, on occasion

Reasons for Changes in Burden/Responses:
There is no change in burden. NRC is submitting the previous clearance package with minor changes to address rule considerations and the change in the fee rate only. Although there are fewer licensees, the number of licensees and subsequent burden reduction has not been revised. The clearance extension is being used merely as a place holder until the revised Part 35, which incorporates the QM provisions, is approved by OMB.

Level of Concurrence:
Information Management Coordinator
Rulemaking and Guidance Branch
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

Recordkeeping Requirements in Accordance with the Retention Periods for Records Rule:
All retentions are in accordance with standard retention periods.

Search of the Information Requirements Control Automated System (IRCAS):
IRCAS was searched on May 21, 2001. No duplication was found.

Abstract:
The NRC requires licensees to implement a quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by an authorized user physician. Records and reports to NRC are required for certain errors in the administration of limited diagnostic and therapeutic quantities of byproduct material by medical use licensees. Collection of this information enables the NRC to ascertain whether misadministrations are identified and investigated by the licensee and that corrective action is taken. The clearance renewal is being requested for a one-year extension to allow time for the complete revision to Part 35 to be implemented.

cc: B. St. Mary