

(SP-92-136, September 1992, Prog Mgmt, OMB Override)
DATED: SEPT 15, 1992

ALL AGREEMENT STATES

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION
(SP-92-136)

Your attention is invited to the attached correspondence which contains:

- INCIDENT AND EVENT INFORMATION.....
- PROGRAM MANAGEMENT INFORMATION.....XX OMB OVERRIDE
- TRAINING COURSE INFORMATION.....
- TECHNICAL INFORMATION.....
- OTHER INFORMATION.....

Supplementary information: See enclosure

If you have further questions regarding this correspondence, please contact the individual named below.

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Enclosure:
As stated

This is to inform you that the Commission, by unanimous vote, has overridden the Office of Management and Budget's (OMB) disapproval of the information collection request associated with the final amendment to 10 CFR Parts 2 and 35, entitled "Quality Management Program and Misadministrations." The NRC has certified the override to OMB in a letter dated August 14, 1992, and has requested that OMB assign a control number to the ICR for a period of three years. OMB issued a new control number on August 21, 1992. Therefore the final Quality Management and Misadministration Rule, and its information collection requirements which became effective on January 27, 1992, remain in effect.

The Commission fully supports the objectives of the Paperwork Reduction Act and strives to ensure that the private sector is requested to maintain or provide only such information as is needed to carry out regulatory responsibilities. However, the Commission continues to believe that its requirements for written quality management programs and misadministration reports, if complied with, have a reasonable likelihood of decreasing misadministrations (e.g., wrong dose or wrong patient) with a small incremental cost to licensees. Without the reporting and recordkeeping requirements, it would not be possible to implement and enforce these regulations effectively.

The Commission will continue to monitor implementation and inspection under the Quality Management and Misadministration Rule to ensure that it provides the Commission with necessary information without imposing an undue burden on the private sector. If the Commission finds this rule, in whole or in part, to be overly burdensome or ineffective, it will consider modifying or deleting portions of the rule.

Further, the NRC will hold a public workshop with the medical community and other interested parties, to ensure that there is mutual understanding as to the intent of the Quality Management and Misadministration Rule, especially its information collection requirements, and to discuss effective implementation. In particular, the NRC will discuss the extent to which the industry's self-auditing guidelines can be used. Following the workshop, the Commission will develop additional guidance on compliance with the rule, written in clear language appropriate to the medical community. Hopefully this guidance will help the Agreement States to develop a compatible rule which should be in place by January 21, 1994.