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OSP

December 5, 1996

Ms. Brenda Jo Shelton
NRC Clearance Officer
U.S. Nuclear Regulatory Commission
T-6 F33
Washington, D.C. 20555-0001

Re: 61 FR 52470-52471, Notice of pending NRC action to submit an information collection request to OMB and solicitation of public comment.

Dear Ms. Shelton:

The Illinois Department of Nuclear Safety (Department) does not support the NRC's Quality Management Plan (QMP) as specified in 10 CFR 35, and therefore we oppose any plan to continue certain information collection requirements. The Department recognizes a physician's right to practice medicine, and we also recognize the need for a regulatory agency to ensure patient and worker safety. To this end, we support the need for licensees to self-identify and correct certain actions that may result in recordable events. In addition, it is necessary for a regulatory agency to be aware of "misadministrations" to ensure the licensee has taken steps to avoid similar occurrences in the future. We are not convinced that the QMP rule, as written, achieves that goal without undue burden on licensees and regulatory agencies.

In fact, there have been no significant changes to the rule since it was disapproved by the OMB on June 26, 1992, and subsequently overridden by the Commission. There appears to be no new evidence to convince the OMB that they should not disapprove of the current regulation, also.

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1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

The Department is not convinced that the information collected under the QMP rule as written has any practical utility. In a letter to Chairman Jackson dated April 19, 1996, the Department urged the NRC to rescind the QM rule as a result of the NAS-IOM study. As written, this rule has caused frustration and animosity among the NRC, medical licensees and Agreement States.

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2. Is the burden estimate accurate?

No. The burden estimate does not take into account the amount of time individual Agreement States would spend to review and inspect licensee's QMPs in a manner similar to NRC's review and inspection program.

For example, the NRC contracted with Lawrence Livermore (at great expense) to review the QMP documents received from licensees when the rule was first implemented. As a result of that review, more than 1200 programs, out of the 1709 reviewed, received a letter from the NRC indicating that the submitted written program had flaws that needed to be corrected. There is no indication that time spent reviewing QMPs by regulatory agencies was included in the burden estimate. It is also unclear whether time licensees spent responding to NRC's deficiency letters was included in the burden estimate.

In addition, Agreement States received Temporary Instruction 2800/025 for use by the NRC field inspectors in determining compliance with the QMP rule. This instruction is extremely detailed and would be quite time-consuming (estimated at six hours per affected licensee inspection). We do not believe this level of detail is necessary to implement a "performance-based" rule, and we see no evidence of this time commitment being reflected in the burden estimate.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

The goal of the information collection is not clear. Regulatory agencies already have an understanding of how misadministrations occur, yet information collection does nothing to address the actual cause of misadministrations. For example, there are numerous "misadministrations" caused by patient intervention. How does an information collection program help the licensee to keep a patient from deciding to terminate treatment? Information collection cannot stop random human error, either. Has the NRC discovered some <u>new</u> reason for the occurrence of misadministrations based on the information collected to date?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The NRC could reduce the information collection burden by excluding certain categories of "misadministrations" such as patient intervention from the reporting requirements.

Thank you for the opportunity to comment early in the process. If you have questions about these comments, please contact either me or Kathy Allen at (217) 785-9947.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

cc: Richard Bangart, OSP ✓
Jim Lynch, R III