January 26, 1996

FOR: The Commissioners FROM: James M. Taylor,

Executive Director for Operations /s/

SUBJECT: CHANGES TO THE DELIBERATE MISCONDUCT RULE, 10 CFR PARTS 30.10, 40.10, 50.5, 60.11, 61.9B, 70.10, 72.12,

76.10, 110.7B, 150.2 AND PART 71

PURPOSE:

To inform the Commission that the EDO intends to sign the Rulemaking Plan to amend the Deliberate Misconduct Rule.

BACKGROUND:

In 1991, the Commission adopted changes to NRC regulations that established the Deliberate Misconduct Rule, which took effect September 16, 1991. This rule placed licensed and unlicensed persons on notice that they may be subject to enforcement action for deliberate misconduct that causes a licensee to be in violation of any of the Commission's requirements, or for deliberately providing to the NRC or a licensee information that is incomplete or inaccurate and in some respect material to the NRC. After this rule became effective, the NRC realized that it did not apply to applicants for NRC licenses, applicants for certificates of compliance and holders of certificates of compliance for packaging and transportation of licensed material. On May 19, 1995, the Office of Enforcement requested that the Office of Nuclear Regulatory Research initiate rulemaking to correct this weakness.

DISCUSSION:

There is a weakness in the present regulations in that the Deliberate Misconduct Rule does not apply to (1) applicants for licenses, (2) current certificate holders, and (3) applicants for certificates. The staff believes that there may be significant safety consequences from the knowing submission of false information or other deliberate wrongdoing by an applicant for a license or certificate of compliance. The attached Rulemaking Plan would modify the Deliberate Misconduct Rule in Title 10 of the Code of Federal Regulations, Chapter I, by eliminating these weaknesses.

As part of the review of this rulemaking plan, OGC noted that a related regulatory problem also needs to be addressed. This problem is to evaluate whether certificate holders and applicants for certificates should clearly be made subject to a number of Part 71 and 72 requirements, e.g., Subparts D, E, and F of Part 71 and Subpart L of Part 72 (which appear to be directed to certificate holders, but are unspecified in their application); Part 71, Subpart H; and Part 72, Subpart G (the quality assurance provisions that are explicitly directed toward licensees, but which concern requirements that ought to be followed by certificate holders as well). Notices of violation are not now issued by the NRC staff to certificate holders and applicants when they violate these provisions because the regulations are unclear regarding NRC's jurisdiction over certificate holders and applicants. The legal rationale supporting the rulemaking proposed in this rulemaking plan would also support an extension of the rulemaking to address this related regulatory problem. The staff has discussed this concern with OGC and intends to address this problem in a separate rulemaking since it will be more complex and will require a longer schedule.

COORDINATION:

The Office of the General Counsel concurs with the Rulemaking Plan.

RECOMMENDATION:

Note that it is my intention to approve the Rulemaking Plan within 10 days from the date of this paper unless otherwise directed by the Commission.

James M. Taylor Executive Director for Operations

CONTACT: Tony DiPalo, RES/DRA

415-6191

Attachment: As stated

ATTACHMENT

RULEMAKING PLAN

CHANGES TO 10 CFR 30.10, 40.10, 50.5, 60.11, 61.9b, 70.10
72.12, 76.10, 110.7b, 150.2, AND PART 71
AMENDMENTS TO THE DELIBERATE MISCONDUCT RULE

- Regulatory Issue
- · Current Rule Requirements
- · Regulatory Problem to be Resolved
- Preliminary Regulatory Analysis
- OGC's Legal Sufficiency Analysis Demonstrating that no known Basis Exists for Legal Objection
- Backfit Analysis
- Agreement State Considerations
- Supporting Documents
- Resources Required

- . Lead Office Staff and Staff From Supporting Offices
- Steering Group
- Public Participation
- Is it Recommended that the EDO Issue the Rule in Accordance with Management Directive 9.17?
- Schedule

Regulatory Issue

There is a weakness in the present regulations in that the Deliberate Misconduct Rule does not apply to (1) applicants for licenses, (2) current certificate holders, and (3) applicants for certificates. The staff believes that there may be significant safety consequences from the knowing submission of false information or other deliberate wrongdoing by an applicant for a license or certificate or holder of a certificate of compliance. Some examples that could represent a threat to public health and safety are a spent fuel cask that is certified by the NRC based on falsified test data or a quality assurance program that is submitted for NRC approval but is supported by deliberately falsified data that leads to a significant defect. A certificate holder who obtained a certificate by deliberate submission of false information would escape NRC enforcement action because the deliberate misconduct would not have put a "NRC licensee" in violation. To effectively exercise its responsibility from the point of public health and safety under the AEA, the Commission needs to be able to prevent or otherwise deter submission of false or inaccurate information.

Current Rule Requirements

In 1991, the Commission adopted changes to NRC regulations that established the Deliberate Misconduct Rule, which took effect September 16, 1991. This rule placed licensed and unlicensed persons on notice that they may be subject to enforcement actions for deliberate misconduct that causes a licensee to be in violation of any of the Commission's requirements, or for deliberately providing to the NRC, a licensee, or a contractor information that is incomplete or inaccurate in some respect that is material to the NRC. The 1991 rule established procedures to be used in issuing orders to licensed and unlicensed persons.

The requirements for an applicant or licensee to provide complete and accurate information are expressed in the Commission's regulations in Title 10 of the Code of Federal Regulations, Sections 30.9, 40.9, 50.9, 60.10, 61.9a, 70.9, 71.6a, 72.11, 76.9 and 110.7a. The Deliberate Misconduct rule is found at 10 CFR 30.10, 40.10, 50.5, 60.11, 61.9b, 70.10, 72.12, 76.10, 110.7b, and 150.2.

Regulatory Problem to be Resolved

On November 29, 1991, the NRC staff issued an Order Revoking License (Effective Immediately) to Dr. Randall C. Orem. The order was issued after the staff learned that the facility described in Dr. Orem's license application as "being finished at this time" had never been started and that the proposed place of use of the byproduct material was a private residence without adequate provisions for safe handling and use of the material. The NRC's Office of Investigations learned that the information concerning the facility was inaccurate and had been included in the license application that was prepared by a consultant for Dr. Orem. In reviewing this issue, the staff realized that the deliberate Misconduct Rule, through an apparent oversight, failed to include applicants for a license and the applicants' contractors. Thus, the regulations do not provide any deterrence to prevent these groups of people from providing false or incorrect information. In the staff's response to the Commission concerning issues raised by the Orem case, the staff discussed from an enforcement perspective the difficulty in applying the Deliberate Misconduct Rule to Dr. Orem's consultant since at the time the information was submitted, Dr. Orem was not a licensee. As a result of this case, the Commission underscored the importance that it places on the completeness and accuracy of information submitted by both applicants and licensees by stating: "We cannot overstate the importance of a licensee's or an applicant's duty to provide the Commission with accurate information." The Commission also addressed consultants, noting that: "Even if the applicant turns to a consultant to help prepare the license application, the applicant remains responsible for the contents of the application." (1)

To ensure that holders of or applicants for an NRC license or certificate, and the employees, contractors, consultants, and suppliers to these persons are subject to enforcement action for deliberate misconduct, the staff proposes to modify the Deliberate Misconduct Rule in Title 10 CFR, Chapter I.

The proposed rule would amend sections of the existing Deliberate Misconduct Rule found at 10 CFR 30.10, 40.10, 50.5, 60.11, 61.9b, 70.10, 72.12, 76.10, 110.7b, and 150.2. It would also add appropriate provisions to Part 71 which is currently not covered under the existing rule. All who are covered by this proposed rulemaking may be subject to enforcement action under the Deliberate Misconduct Rule if the information they provide to the NRC is incomplete or inaccurate and in some respect material to the NRC, or if their deliberate misconduct causes a licensee or certificate holder to be in violation of any of the Commission's requirements.

Preliminary Regulatory Analysis

The purposes of this rulemaking are to provide deterrence for deliberate misconduct including making false statements to the NRC and to provide the regulatory basis to penalize someone guilty of deliberate misconduct. Because there has been an instance in which a consultant to an applicant for a license provided inaccurate information that was included in the license application, there is a clear need for the agency to have authority to address these situations in the future. Because the persons who would be affected by this rulemaking are not NRC licensees, the conventional alternatives to rulemaking for imposing requirements (e.g. order or license condition) do not apply. In fact, the staff was unable to come up with any viable alternative to solve this problem, other than rulemaking. Accordingly, the alternative to take no action was not considered.

The proposed amendments would enable the Commission to take appropriate enforcement action against holders of or applicants for an NRC license or certificate, or a person employed by any of those persons, who deliberately violate Commission requirements or cause licensees or certificate holders to violate Commission requirements. The effect of available enforcement sanctions will help ensure the accuracy of information submitted and reduce the probability of deliberate misconduct by licensees, certificate holders, and applicants, as well as their employees and contractors.

The staff believes that no regulatory analysis is required since the benefits derived from the proposed modifications are similar to those provided by the Deliberate Misconduct Rule which became effective September 16, 1991. The proposed rule is further supported by the Atomic Energy Act, Section 186, which addresses false statements made in applications.

OGC's Legal Sufficiency Analysis Demonstrating that no known Basis Exists for Legal Objection

OGC has no legal objection to initiation of rulemaking. OGC believes that the NRC has statutory authority under the Atomic Energy Act of 1954, as amended, to bring certificate holders and applicants for licenses and certificates within the scope of its regulations. The general issue of NRC's jurisdiction over unlicensed persons was extensively addressed in the Deliberate Misconduct Rule, see 56 Fed. Reg. 40666 - 40671, and is the subject of an internal June 3, 1988, OGC memorandum. The legal rationale supporting NRC's exercise of jurisdiction over certificate holders and applicants in the proposed rulemaking is very similar to that employed in the Deliberate Misconduct Rule.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule, and therefore a backfit analysis is not required. These amendments do not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

Agreement State Considerations

No problems from the proposed amendment have been identified that would adversely affect the Agreement States.

Supporting Documents

None Required.

Resources Required

It is anticipated that 0.75 NRC FTEs will be needed to complete this action (0.35 RES, 0.2 OE, and 0.2 all other). These resources are within existing budget allocations.

Lead Office Staff and Staff From Supporting Offices

REST. DiPalo/T. Martin OGC B. Reamer/N. Jensen OEG. Cant NMSSS. Baggett/E. Easton ADM M. Lesar

Steering Group

No. These amendments are not considered significant enough to warrant a steering group.

Public Participation

This rulemaking plan will be placed on the FedWorld Bulletin Board. The proposed amendments will be published in the Federal Register as a proposed rule for public comment.

Is it Recommended that the EDO Issue the Rule in Accordance with Management Directive 9.17?

No. The proposed rule constitutes an expanded application of NRC jurisdictional authority in the existing Deliberate Misconduct Rule. Therefore, issuance of the proposed and final rule will require Commission approval.

Schedule

The schedule is expressed in terms of time from approval of Rulemaking Plan.

Proposed Rule to EDO Approval of Rulemaking Plan + 6 months
Public Comment Period Ends Approval of Rulemaking Plan + 9 months
Final Rule to EDO Approval of Rulemaking Plan + 12 months

1. In the matter of Randall C. Orem, D.O., CLI-93-14, 37 NRC 423, 430 (1993).