DSI-7

(79)

NRC STRATEGIC ASSESSMENT AND REBASELINING INITIATIVE

DIRECTION SETTING ISSUE COMMENT FORM

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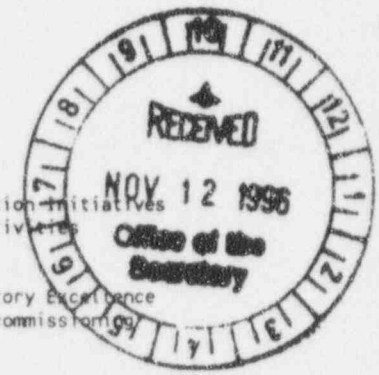

PLEASE CHECK ONLY ONE:

- ___ DSI 2 - Oversight of the Department of Energy
- ___ DSI 4 - NRC's Relationship with Agreement States
- ___ DSI 5 - Low-Level Waste
- ___ DSI 6 - High-Level Waste
- X DSI 7 - Materials/Medical Oversight
- ___ DSI 9 - Decommissioning - Non Reactor Facilities
- ___ DSI 10 - Reactor Licensing for Future Applicants
- ___ DSI 11 - Operating Rector Program Oversight
- ___ DSI 12 - Risk-Informed, Performance-Based Regulation
- ___ DSI 13 - Role of Industry
- ___ DSI 14 - Public Communication Initiatives
- ___ DSI 20 - International Activities
- ___ DSI 21 - Fees
- ___ DSI 22 - Research
- ___ DSI 23 - Enhancing Regulatory Excellence
- ___ DSI 24 - Power Reactor Decommissioning
- ___ General

COMMENT:

I am the Radiation Safety Officer at William Beaumont Hospital, which is the 6th Largest hospital in the U.S.A. William Beaumont Hospital has a broad scope medical NRC license and is located in Michigan, a non-agreement state. My comments represent the viewpoint of our hospital's administrat members of the Radiation Safety Committee, nursing staff and most of our radiation workers.

1. We commend the NRC for taking up the challenge of developing a new strategy for regulation of byproduct material in medicine, and appreciate the opportunity to present our point of view.
2. We support the IOM Report and the ACMUI recommendations that regulations of the use of radiation in medicine should uniformly affect all forms of ionizing radiation. Within our organization, all forms of ionizing radiation in our hospitals and clinics are under one uniform program: The Radiation Safety Management Program which is under the jurisdiction of our Radiation Safety Committee.
3. DSI Issue 7: The NRC should revise its oversight of the medical use of byproduct material.

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4. We strongly support Option 4 as stated in DSI 7, (a) to discontinue NRC's regulatory authority over all medical uses of byproduct material, to (b) give regulatory authority to the States, and (c) name another Federal agency to provide a leadership role (as opposed to regulatory). We also support that the Federal Agency be an authority on health care. We also agree with the impacts as stated in Option 4 ~~and~~ related to unfunded federal mandates, and the need for consistency of basic regulations. If OHHS is unwilling, then JCAHO or HICFA or Medicare.

5. At a minimum, the NRC should rescind the fundamental tenet of the Medical Program Policy Statement of 1979 which states that the NRC has a commitment to protect the patient from the use of radiation in medicine. This commitment is in conflict with goal of the use of byproduct material by physicians in Nuclear Medicine and Radiation Oncology to diagnose, treat and cure our patient. This commitment has lead to regulations that are costly to comply with, burdensome, overly prescriptive and ~~intrusive~~ intrusive into the practice of medicine. Patients should not be regulated as members of the public in relationship to NRC regulations

6. We would not oppose NRC's Preliminary Views of a combination of Option 2 and Option 3 under the following conditions: NRC rescinds the Medical Program Policy Statement of 1979; NRC rescinds parts of Title 10 CFR Part 35, Quality Management rules, definition of misadministration, training qualifications, etc.

7. We strongly support immediate action on the part of the NRC; a "show of good faith" related to this whole Strategic Assessment process. Specifically, the NRC should rescind the Quality Management rules. It has not accomplished anything substantive according to our experience, Society of Nuclear Medicine, Am. College of Radiology and ACMUI. Some agreement states have not enforced the QM rule.