

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

POSITION

Relating to: The NAS-IOM Report entitled "Radiation in Medicine - A Need for Regulatory Reform"

The members of the Conference of Radiation Control Program Directors (CRCPD) at their meeting in Albuquerque, New Mexico on May 8, 1996 directed the Chairperson of CRCPD to send the following statement to the Congress, the USNRC, the other federal agencies cited in the report referenced below, the Governors of the states and territories, affiliated national organizations and other interested parties:

The following is the position of the CRCPD regarding the recommendations presented in the National Academy of Sciences Institute of Medicine report entitled "Radiation in Medicine - A Need for Regulatory Reform". The IOM report makes 8 recommendations concerning the NRC's Medical Use Program and makes specific reference to the CRCPD in 3 of these recommendations.

CRCPD responds solely to the recommendations based on the collective experience and professional judgment of the members of the CRCPD. CRCPD did not participate in or review the recommendations of this report prior to its publication. Each recommendation presented by the IOM report is summarized and the position of the CRCPD is stated.

Recommendation A1 is that Congress eliminate all aspects of the NRC's Medical Use Program.

The CRCPD does not support this recommendation. CRCPD is concerned that elimination of the entire program, as recommended, could have immediate and undesirable consequences on citizens in non-Agreement States which cannot or will not have developed a state program consistent with the national model prior to Congressional action. In addition, the absence of federal authority in the medical use area may also have long term consequences for Agreement States as they try to maintain a nationally consistent program in the face of budget cutbacks and a changing regulatory philosophy.

Recommendation A2 is that Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage a number of activities involving regulation of all ionizing radiation in medicine including supporting the operation of CRCPD, assisting states in implementing their regulations, and assessing the effectiveness of state programs, as well as enhancing training for health care personnel and investigating significant incidents.

The CRCPD supports the notion that a single federal agency should provide a strong leadership role for all forms of ionizing radiation and therefore supports this recommendation in principle. However, CRCPD does not support the automatic selection of HHS as that agency. The lead federal agency on radiation issues needs to provide to CRCPD and its members the kinds of support suggested in this recommendation in order to ensure the continued existence of effective radiation protection programs. Regardless of the federal agency that provides this leadership role, the issue of radiation protection should be a major responsibility of the agency and not be relegated to inconsequential status. CRCPD believes that consolidation of the ionizing and non-ionizing radiation related authority currently found in several agencies, including NRC, HHS, OSHA and EPA, is highly desirable to minimize current problems related to dual regulation and that CRCPD, the affected community and the public should have considerable input into the selection of that single agency.

The CRCPD concurs with the report in that there is an important role for CRCPD to play in improving the regulation of nuclear medicine, as well as other areas of radiation exposure. Since the CRCPD is made up of state and local radiation control agencies, and closely coordinates its activities with the various federal agencies involved with radiation protection, the organization is in a unique position to promote the consistent regulation, in the United States, of, not only radioactive materials covered by the Atomic Energy Act, but Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM). NARM, especially accelerator-produced, are increasingly being used in nuclear medicine. Because of this unique position of the organization, CRCPD strongly supports the report's position that Congress direct a federal agency to support the operation of the CRCPD.

Recommendation B1 is that the NRC immediately relax enforcement of 10 CFR 35.32 (the Quality Management Program requirement) and 35.33 (the misadministration reporting requirement).

The CRCPD continues to support relaxation of the overly prescriptive and unnecessarily costly requirements in 10 CFR 35.32 and 35.33 because they do not add to radiation safety. The CRCPD also supports the elimination of overly burdensome enforcement and reporting requirements in the medical practices area and notes that state regulatory programs provide the most effective means to accomplish this.

Recommendation B2 is that the NRC revoke 10 CFR 35 in its entirety.

The CRCPD does not support this recommendation. However, CRCPD believes that a significant revision of Part 35 is warranted and will task its SR-6 committee on Suggested State Regulations in the Healing Arts to undertake this revision.

Recommendation B3 is that the NRC separate the costs of formulating regulations from the cost of administering those regulations.

The CRCPD supports this recommendation and further recommends that Congress provide general funds to support development of essential regulatory standards as a national priority not tied to user fees. It is also believed that NRC should provide improved accounting and reporting of regulatory development costs.

Recommendation C1 is that the CRCPD incorporate relevant concepts from 10 CFR 35 into its Suggested State Regulations for Control of Radiation.

The CRCPD has already accomplished this. Furthermore, the CRCPD is in the process of reviewing both the Suggested State Regulations and 10 CFR 35 to ensure that those provisions that are deemed to be overly prescriptive and burdensome provisions are eliminated and that performance based rules are adopted to the extent possible. We similarly request the USNRC to do the same through parallel rulemaking so that both sets of regulations are consistent in providing adequate protection of the public health and safety.

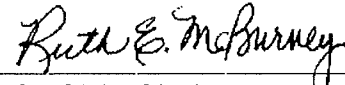
Recommendation C2 is that all state legislatures enact enabling legislation to incorporate regulation of reactor-generated byproduct material into existing state regulatory programs.

The CRCPD supports this recommendation, although it recognizes that not all states will choose to establish comprehensive programs that include reactor-generated byproduct materials. However, the CRCPD continues to support consistent application of radiation protection standards nationwide and believes that this can be best accomplished by having all radiation programs in a single state agency which can deal comprehensively with all forms of ionizing radiation within the state.

Recommendation C3 is that the CRCPD and the states continually reevaluate their regulations and procedures to ensure congruence with evolving scientific understanding and any advances in knowledge regarding benefits and risks.

The CRCPD supports this recommendation since it is fully consistent with its own principles and objectives. Furthermore, the CRCPD will require additional federal funding to support the enhanced regulatory development role suggested in this report. We believe that the CRCPD is the appropriate entity to ensure consistency in all radiation protection issues in this country, and we stand ready to assume that role.

The CRCPD supports USNRC's proposal for an enhanced review process for their medical use program. Input from, and interactive discussions between, the regulated community and the co-regulators (States and NRC) will lead to a more flexible and realistic approach to the regulation of all Atomic Energy Act materials.



CRCPD Chairperson

This position was approved by the CRCPD Membership on May 8, 1996