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FINAL REPLY:

Roy Brown
Council on Radionuclides
and Radiopharmaceuticals, Inc.

TO:

Chairman Meserve

FOR SIGNATURE OF : ** PRI ** CRC NO: 01-0201

Chairman

DESC:

Proposal to Expand Statutory Authority Over Medical Use of Naturally Occurring and Accelerator -Produced Radioactive Material (NARM)

ROUTING:

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ACTION OFFICE:	EDO		
AUTHOR:	ROY BROWN		
AFFILIATION:	CA		
ADDRESSEE:	RICHARD MESERVE		
SUBJECT:	CORAR POSITION ON THE NRC'S PROPOSAL TO EXPAND STATUROTY AUTHORITY OVER MEDICAL USE OF NATURALLY OCCURRING AND ACCELERATOR PRODUCED RADIOACTIVE MATERIAL (NARM)		
ACTION:	Signature of Chairman		
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CORAR

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Henry H. Kramer, Ph.D., FACNP
Executive Director

April 5, 2001

Richard A. Meserve, Chairman
Nuclear Regulatory Commission
One White Flint North Bldg.
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Meserve:

In 2000 the NRC initiated an effort to review the current regulation of naturally occurring and accelerator-produce radioactive material (NARM). CORAR has significant interest in NRC's consideration of this proposal. Comments were provided by CORAR at the National Materials Program Workshop in Dallas on February 21, 2000.

A number of options for national regulation of materials were discussed at the workshop, some of them with merit, and all in consideration of regulation of NARM. CORAR submits the attached comments to the NRC for additional consideration prior to NRC finalizing their proposal. CORAR would welcome an opportunity to further discuss our concerns and interest in NRC's proposals.

Sincerely,

Roy Brown

Roy Brown

cc: Mr. Francis Cameron

February, 2001

CORAR POSITION PAPER ON THE NRC PROPOSAL TO EXPAND STATUTORY AUTHORITY OVER MEDICAL USE OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL (NARM)

BACKGROUND

On October 13, 2000, Commissioner E. McGaffigan of the NRC proposed that the Commission direct staff to provide the legislative language that could be used to expand NRC statutory authority beyond the Atomic Energy Act to include medial use of NARM (COMEXM-00-0002). On December 5, 2000, the Commission stated its concurrence in this proposal and, in addition, agreed that the scope of this extension should include NARM in all applications. At the same time, the Commission provided staff requirements for this expansion of statutory authority in the form of two proposals.

The first would extend NRC's authority to include NARM when used for medical purposes. The second would extend NRC's authority to regulate NARM in all applications with the exception of sources of ionizing radiation such as that produced by accelerators or X-ray devices. With a recommendation to proceed with one of these proposals, the Commission directed the staff to consult with the States and provide an estimate of the resources needed for implementation and to provide the reasoning to the Commission if the staff recommend no extension of NRC statutory authority over NARM. The staff was also directed to consider other areas where NRC's jurisdiction might be adjusted to address risks from radioactive materials and other sources of ionizing radiation.

DISCUSSION OF ISSUES

CORAR has previously stated its position on issues relevant to this proposal. In 1998, CORAR provided comments in response to NRC's request for public input on 10 CFR Part 35. At that time we agree with the NAS-IOM report that NRC's regulation of medical use is unnecessarily burdensome and provides no benefits to patients and the public. CORAR has repeatedly stated the position that from a risk based perspective, the use of diagnostic radiopharmaceuticals did not belong within the purview of NRC regulatory jurisdiction. Furthermore, CORAR has stated in a position paper in June, 1996, that regulation of the medical community should be turned over by the NRC to the state agencies. It would be consistent for CORAR to oppose the first Commission proposal to expand NRC statutory authority over medical use of NARM.

However, CORAR support of the second proposal of NRC to expand statutory authority to include regulation of NARM in all applications would be consistent with its previously stated positions on regulation of NARM and NRC's relationship with agreement states. While CORAR has reservations on NRC's proposed approach to accelerators, sources

such as X-ray machines, and other materials and sources of radiation including technically-enhanced naturally occurring material (TNORM), the conditional expansion of NRC jurisdiction to include NARM would result in numerous benefits to the manufacture and distribution of radiopharmaceuticals and research radiochemicals in interstate commerce and would improve the overall domestic regulation of NARM. Specific benefits as well as risks are discussed as follows:

1. NRC regulation of NARM would result in a single license for both NARM and by-product material facilities in non-Agreement States. This would streamline licensee compliance programs and provide an opportunity for more efficient resource utilization. Resources could be focused on ALARA based activities rather than duplicative regulatory compliance schemes. Licenses in non-Agreement States would be required to follow one set of regulations for both NARM and by-product material concerning air borne and liquid effluent materials, exempt quantities, license conditions, reporting requirements, waste management, financial surety and decommissioning.
2. The need for improved adequacy and compatibility would be addressed in non-Agreement Sates. In addition to consistency, NRC regulation of NARM in non-Agreement States would ensure regulation of these materials that may be lacking in states with limited or nonexistent programs.
3. Specific requirements for permits or registration of NARM materials or devices could be eliminated in non-Agreement States.
4. There would be a reduced need for reciprocal agreements for the use of NARM at temporary job sites as many more licensees would be under the jurisdiction of NRC.
5. Use of NARM at federal facilities could be subject to regulation by Agreement States. This is another opportunity for enhanced compatibility and adequacy of Agreement State programs.
6. Licensing, possession and distribution of NARM would be greatly simplified for CORAR members as well as their customers. Manufactures and distributors in multi-state locations and those involved in interstate commerce would need fewer licenses themselves and would be required to verify fewer, more consistent, customer licenses. Separate NRC licenses should no longer be needed for exempt quantity distribution of by-product material by Agreement State licensees.
7. There would be an initial burden on both agencies and the regulated community in non-Agreement States to convert to NRC regulation, especially in locations where NARM is not currently regulated. CORAR companies located or doing business in these states would assume additional burden. Care would be needed in the conversion to NRC regulation of NARM to avoid disruption of business.

SPECIFIC COMMENTS

In light of the issues as discussed above, CORAR has the following comments regarding the NRC proposal to assume statutory authority over NARM:

1. Consideration of adding NARM to NRC jurisdiction should exclude medical use. The result would be no positive impact with significant cost and resource burden on licensees. Licensees would be subject to multiple licenses and regulations for essentially the same materials with no benefit.
2. NRC statutory authority should be extended to all non-medical use applications of NARM. We maintain and support the ACNP/SNM position that NRC should not be involved in the regulation of diagnostic nuclear under Part 35, regardless of whether or not the material is NARM.
3. Clarification is needed regarding how NRC would regulate the production of accelerator-produced radionuclides and the operation of the accelerators themselves. The production and distribution of PET isotopes should not be specifically categorized for regulation under Part 35.
4. The impact of the proposal on Agreement States needs to be clarified. However, we recommend that Agreement States be allowed to continue to regulate both NARM and by-product material under their current schemes.