DSI-7
(36)

# Texas Department of Health


Patti J. Patterson, M.D.
Commissioner

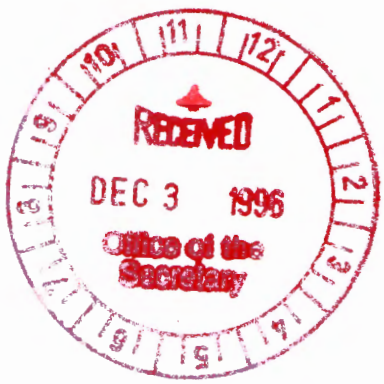
Randy P. Washington
Deputy Commissioner for Health Care Financing

1100 West 49th Street
Austin, Texas 78756-3189
(512) 458-7111

Radiation Control
(512) 834-6688

Carol S. Daniels
Deputy Commissioner for Programs

Roy L. Hogan
Deputy Commissioner for Administration


November 27, 1996

Mr. John C. Hoyle
Secretary of the Commissioner
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTN: Chief of Docketing and Services Branch

Dear Mr. Hoyle:

The Texas Department of Health's Bureau of Radiation Control has reviewed several of the Direction Setting Issues Papers (DSI's) included in the U.S. Nuclear Regulatory Commission's (NRC) strategic and rebaselining initiative. Enclosed are our comments on the following DSI's:

| | | | |
|---|---|---|---|
| DSI 2 | DSI 9 | DSI 14 | DSI 23 |
| DSI 4 | DSI 12 | DSI 20 | DSI 24 |
| DSI 5 | DSI 11 | DSI 21 | |
| DSI 7 | DSI 13 | DSI 22 | |

We appreciate the opportunity to comment on these documents and to be part of the process.

Sincerely,

Richard A. Ratliff, P.E., Chief
Bureau of Radiation Control

Enclosures



Acknowledged by card 12/3/96 DTN

# Texas Department of Health
# Bureau of Radiation Control
# Comments on

# NRC DIRECTION SETTING ISSUE PAPER 7

# MATERIALS/MEDICAL OVERSIGHT


**Summary**

This paper discusses the issue, "What should be the future role and scope of the NRC's Nuclear Materials Program, and in particular, NRC's regulation of the medical use of nuclear material?"

There is a definite need for regulatory reform in the materials area. Current regulatory schemes should be assessed for effectiveness, including appropriate risk reduction, comprehensiveness, cost, including both cost to the regulated community and the cost to regulators, and responsiveness to rapid advances in technology, both in medicine and industry. The public is protected because of the regulatory community's diligence in ensuring that individuals using radioactive material do so safely. In some cases, it is necessary to modify the regulations to be less prescriptive, but it is not necessary to relinquish all controls over the safe use of radioactive material.

Although this direction setting issue (DSI) purports to address all material oversight, the vast majority of the paper focuses on the medical area. TDH's Bureau of Radiation Control is in support of the NRC's initiatives to streamline the licensing process, eliminate duplicative or contradictory regulations, and update regulatory guidance for all categories of licensees, not just medical licensees. We recommend, however, that NRC not abandon the regulation of radioactive material altogether. As stated in the Conference of Radiation Control Program Director's position of the National Academy of Science Institute of Medicine (IOM) report on the regulation of medical radiation, we are concerned that the elimination of the entire program 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 (and all the materials area) may 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.

We are in support of establishing a consistent and unified national program to work with the states to establish basic standards for all uses of ionizing radiation, both radioactive material and machine sources. CRCPD should play a mojor role in this effort, and adequate resources should be provided to CRCPD for this coordination. This, combined with a commitment of that agency to risk-based regulations and programs, would ensure greater consistency of regulation of those sources. It makes little sense to continue dividing the issue of radiation safety according to historical distinctions. Whether the issue is misadministration, generic machine defects, computer programming errors, or radioactivity in the environment, the regulatory requirements should be based on the health risk and applied equally to all sources of radiation.

Such a program should include involving states as integrated partners, tapping in on the expertise that exists in state programs. By having federal oversight by one federal agency, combined with risk-based regulation, the establishment of radiation regulatory priorities would be more consistent and truly risk driven, rather than the current patchwork of regulatory programs whereby more resources are demanded for areas of lesser risk, due to economic or risk perception drivers or the need to meet NRC compatibility requirements in Agreement States.

**Discussion**

Considerable consultation with the state programs must be utilized in implementing any of the options under this issue. Significant risk exists that either (1) further fragmentation of radiation safety regulation will occur; or (2) the NRC will continue to mandate regulatory requirements that have no health and safety basis. The important conclusion one should draw from the IOM report is not that medical radiation should be de-regulated, but that NRC implementation of prescriptive regulations was inappropriate and heavy-handed.

It was not clear how the NRC envisions the "related issues" to be purely a Commission issue as long as NRC controls Agreement State compatibility and adequacy determinations. In addition, it would seem strange not to consider input from licensees on these issues.

Under the External Factor 4 on page 10 concerning full cost recovery, although this item contains no specific guidance, any effort to ameliorate the full cost recovery problem should not be linked to Agreement States, present or future. NRC must look to other mechanisms to solve that problem.

It was noted in the issue paper on page 14 that the definition of discrete NARM included radium sources and wastes from cyclotrons, but left out important NARM sources in the medical arena, specifically, radiopharmaceuticals used for positron emission tomography.

**Options**

Option 1

As indicated on Page 15 of DSI 7, states are in support of establishing one federal agency to work with the states to establish basic standards for all uses of sources of radiation. We recognize that this is a major departure from the current Federal approach, however, we believe it makes sense to treat all ionizing radiation equally. A rem to an individual is still a rem, whether it comes from Co-60, Ra-226 or an accelerator. It should be noted that every state, other than Wyoming, has an established program for x-ray machines, and that it is unlikely that any state wold choose to relinquish control of x-ray sources. The federal agency should work with all states to establish basic standards and minimum requirements, but the actual oversight and inspections should remain under state authority and control. The development of uniform/model standards rather than NRC taking over the program would also negotiate the need for NRC to add large #'s of staff to achieve. In fact, it may be that the states are in a better

position to oversee certain DOE operations because the state programs are more encompassing. Therefore, the NRC should seek a waiver of sovereign immunity in order for Agreement States to regulate certain activities at DOE facilities as well.

Option 2

We support the NRC's efforts to identify regulations that are obsolete, unnecessarily burdensome, duplicative or too prescriptive and the NRC's work to modify or delete these regulations. Regulatory reform in the form of risk-informed and performance based standards are needed; however, such criteria must be uniformly applied to both existing and proposed regulations.We also support the NRC's efforts to streamline the licensing process. The modifications made to-date through the BPR should benefit up to one third of the NRC's licensees (measuring system licensees). We agree that this option should continue to be pursued, but a more proactive approach is needed in addition to this option.

Option 3

Hand in hand with the proposals from Option 2, a risk-based approach should also identify areas of low risk in which NRC and the Agreement States should reduce the type and degree of regulation and other areas in which the type and degree of regulation should be increased. For example, all gas chromatography sources could probably be generally licensed and some high curie GL gauges should be SL. The identification and classification of "low-risk" activities should be done in conjunction with State programs, drawing from the experiences of both groups. A joint NRC-Agreement State Working Group on devices recently reported that problems associated with the NRC's general license program included inadequate regulatory oversight, inadequate control and accountability of devices, and improper disposal of RAM. The working group developed strawman solutions and recommendations aimed at regaining control

of the use of both generally-licensed and specifically-licensed devices. These recommendations included requirements for users, distributors and regulatory agencies.

As written, it appers that Option 3 is advocating regualtion of only "high-risk" activities. We agree that some stremlining commensurate with risk is warranted, however, we are firmly opposed to abandoning requirements for all "low-risk" activities. The regulations supposedly are written to minimize risk to workers and the public. Proper training and use of radioactive material will result in lowering any risks asociated with using radioactive material. If you remove the regualtions designed to limit the risk, you can no longer ensure that a "low-risk" activity will remain such.

Option 4

We are opposed to an across the board ramping down of all so-call "low-risk" devices. The NRC should not discontinue the regulation of all medical activities, just as it should not discontinue the regulation of all other uses of radioactive materials. It is vital that the NRC recognize the professional views of the Agreement States, physicians, physicists, pharmacists, hospitals and professional organizations regarding the unnecessarily burdensome, detailed and prescriptive requirements of Part 35, and make modifications. To assist in determining the proper course of action, the NRC, FDA and representatives from applicable boards of medicine and pharmacy should jointly develop a paper describing the jurisdictional boundaries of each entity relative to regulating the use of radioactive material and the practice of medicine. Such a document would be a great reference point to begin recalibration of the applicability of existing regulations.

As contained in the position passed by the CRCPD on May 8, 1996, we are concerned that adoption of this option would be considered an unfunded mandate for some states. The elimination of the entire program could have a detrimental impact on the users of radioactive material and the citizens of non-Agreement States which are unable to develop a state program that is not consistent with a national model. Separating medical uses of radioactive materials would add to the confusion over jurisdictional issues among federal and state agencies at a time when we need to be moving toward greater consistency in how sources of radiation are regulated.

Based upon discussion topics from DSI 2, the Department of Veterans Affairs may need to reconsider its position that legislative initiatives should ensure that federal facilities are not subject to state and local regulations (Page 21, Paragraph 2). Under some circumstances, it may be appropriate for states to regulate federal facilities, and we oppose self regulation of medical uses by federal facilities.

Option 5

We do not support this option, for similar reasons that are listed under Option 4. The NRC must not simply discontinue its oversight of the use of radioactive material. It is unreasonable to assume that individual states would regulate to the same degree. This could cause problems for facilities doing business across state borders. Additionally, one only needs to look at the problems with lack of uniformity regarding regulation of x-ray facilities, particularly in the area of mammography (reference CRCPD Publication 93-5, "Report of State Mammography Program Activities--1991") to realize the disparity that can occur without federal oversight. This disparity resulted in the enactment by Congress of the Mammography Quality Standards Act of 1992. Deregulation of radioactive material sends the message that the material is inherently safe, a sentiment that Congress is unlikely to agree with. Additionally, the public depends on regulators to assure their medical examination is safe and reduces unnecessary radiation exposure.