AGREEMENT STATES STILL CHAFING UNDER NRC COMPATIBILITY

tate regulators in charge of radiation control programs in over half the United States remain sharply at odds with the U.S. Nuclear Regulatory Commission (NRC) over what officials of these so-called "agreement states" describe as increasingly intrusive NRC policies on the state-level control of radioactive material.

State governments are able to assume regulatory authority over the radioactive materials controlled by the NRC under a formal agreement process framed by Congress in 1959. To date, 28 states have entered such agreements. The agreement states have struggled over the past two years to exert their autonomy from the NRC, especially over contentious regulatory issues such as low-level radioactive waste disposal and quality assurance in the medical use of radioactive isotopes. The NRC's most recent response to the problem was to solicit public comments in December to help the agency review its compatibility requirements for licensees in the agreement states.

The way the NRC decides the adequacy of state radiation control programs has been a long-standing source of friction between the agreement states and national regulators. State regulators say the NRC policy on compatibility has grown overly restrictive of state control and has strayed from the intent expressed in the legislation that enabled the state agreements program. What has made matters worse, officials in the agreement states say, is a series of national rules and proposed rules that the state officials vigorously oppose. The NRC policy on compatibility requires the agreement states to impose regulations comparable to the NRC's and in some cases, word for word equivalents. The NRC maintains that compatibility is needed to ensure adequate protection of the public health and safety, and also to maintain consistency in nomenclature and in reports that are added to national databases on radiation protection.

The agreement states say the NRC rules that they oppose are inflexible, financially burdensome, and overly prescriptive. "Because of their [NRC's] desire for compatibility, we will have more and more of our time and resources consumed by adopting rules that bring no benefit in health or safety," says Rita Aldrich, chief of the radioactive materials section of the New York State Bureau of Environmental Radiation Protection in Albany.

Disputed Regulations

NRC actions often criticized by officials in the agreement states include the recent final rule on quality management and medical misadministrations, and the yet-to-be-implemented "below regulatory concern," or BRC, policy that remains under a moratorium. Some agreement states want the authority to set stricter controls on disposal of low-level radioactive waste than what the NRC would set if it followed the BRC policy.

Virtually all of the agreement states have resisted the NRC's medical quality management program. State regulators argue that the rule is too prescriptive of the practice of medicine and that the record-keeping burden imposed by the rule drains the resources of regulators and physicians without bringing a demonstrable benefit of added safety.

The director of the Tennessee Division of Radiologic Health, Mike Movley characterizes the reporting requirements and other stipulations of the quality management rule as "attempting to regulate a minuscule problem down to an infinitesimal problem." The bottom line for the agreement state programs is that state budgets are strapped, leaving little money to enforce rules compatible with the NRC. The states want the authority to decide how best to allocate resources

and feel that strict compatibility with NRC requirements limits that authority.

"We regulate all sources of radiation, from accelerators to x-rays, including naturally occurring radioactive material, or NORM," says Mr. Movley. "We have to balance the magnitude of the problems we see in all of those areas," he says, not just in the areas regulated by the NRC under the Atomic Energy Act. Since last year Mr. Movley's department has had to lay-off over 13% of its professional staff, and of the professionals whose jobs were saved, many of the most experienced left in the wake of cutbacks. "When faced with dwindling resources the question is where can you have the greatest impact on the public's exposure to radiation and the real area is in medical diagnostic x-rays," says Mr. Movley.

Quality Management

Although the final quality management rule incorporated significant changes at the urging of state regulators and the nuclear medicine community, Ms. Aldrich of New York says, "We still do not think the contents of that rule should be a matter of compatibility." Mr. Movely, who is chairman of the Conference of Radiation Control Program Directors, a group representing all 50 states, says that a degree of compatibility is necessary, "but the individual states have the right to assess issues in an individual manner based on conditions in those states."

Other state officials readily agree on the need for compatibility on rules covering interstate commerce or radiation standards and definitions. But "the range of a survey meter used in a hospital does not require strict compatibility with NRC regulations," says Edgar Bailey, chief of the radiological health branch of California's Department of Health Services.

The Society of Nuclear Medicine

Newsline

(SNM) is not directly involved in the agreement states dispute, but SNM has taken legal steps against the NRC to oppose the quality management rule, which became effective in January (see under "NRC" on p. 18N.) Some SNM leaders are reluctant, however, to side whole-heartedly with state regulators on the issue of compatibility.

"The states don't really know what they want-they invoke the issue of public safety, but in some cases they want more regulations than the NRC in response to local politics, and in other cases they want less regulation for economic reasons," says the chairman of SNM's government relations committee, Stanley J. Goldsmith, MD, who practices medicine in New York, an agreement state. "Although I am opposed to the final QM rule as unnecessary, from my experience with state regulatory agencies and the NRC, I am in favor of compatibility [with national regulations]-it would be chaos for nuclear medicine if a patchwork of regulations existed across the country and it would render the national society less effective in dealing with nuclear regulators because there would be no central body for [regulators] to talk to."

Other nuclear physicians, such as Carol Marcus, MD, PhD of Harbor/ UCLA Medical Center in California, express more trust in state regulators than the NRC. Dr. Marcus says that policies and rulemakings of the NRC have been "detrimental" to the practice of nuclear medicine and that the federal nuclear regulators have proven "incompetent" compared to state health officials in overseeing the medical use of radioisotopes. "The aggreement states program should be ended as soon as possible," says Dr. Marcus. "It is preventing states from doing a good job."

Criticisms of NRC compatibility criteria first erupted at an Organization of Agreement States meeting in 1989, when state authorities raised concerns about the levels of compatibility required. G. Wayne Kerr, assistant manager of the Illinois Office of Radiation Safety says that by 1990 the states weren't satisfied

with the NRC's response. Mr. Kerr became the chairman of a task force, which was the first ever assembled by the agreement states and which produced a strongly-worded report that accused the NRC of acting arbitrarily, inconsistently, and "with little thought given" to issues of compatibility.

The report called for the NRC to involve the agreement states more in the decision-making process and cited the need for more clearly defined criteria for setting compatibility requirements. The task force requested the formation of a joint committee between the agreement states and the NRC, which has not come to pass although the NRC convened its own task force to address the problem.

The agreement states' task force specifically told the NRC not to seek public comment on compatibility determinations on the grounds that the issue was between the NRC and the agreement states and that seeking public comment on the process "gives the impression that there is a licensee type relationship between NRC and the agreement states."

The NRC did little to improve relations when it published a notice in the Federal Register last December seeking comment from the regulated community on the compatibility issue. The notice angered some state regulators because it allowed a mere 40-day comment period and because it appeared two days before Christmas. Several states filed requests for an extension of the comment period to several months. At press time the NRC had yet to decide whether to grant the extension.

Radioactive Waste

The agreement states task force also called for unfettered authority to pass tighter regulations than NRC's on low-level radioactive waste. Rules for radioactive waste disposal became a divisive issue when the NRC published its BRC policy statement in 1990. Agreement state regulators hasten to point out that they had urged the NRC and the Environmental Protection Agency to try to determine levels of radioactivity below which regulatory control would not be

necessary to protect the public. But state regulators say BRC caught them by surprise and that they had no opportunity for input. Some elected officials criticized the policy because it appeared to be a financial bail-out for utility companies running nuclear power plants. Others say the NRC failed to take into account the impact of the policy on local land fills. "Whether a state should allow low-level radioactive waste to go to municipal land fills should be a decision made in the state and not in Washington," says Mr. Bailey, the California health official.

The NRC declined to discuss with Newsline the details of forthcoming decisions on the issues raised by the agreement states, other than to say that the issues were under consideration and that they would be working "as expeditiously as possible" given the importance of the issue. About the prospects for the agreement states' request for a joint committee, Vandy L. Miller, assistant director of the NRC state agreements program says, "that's under consideration, but we feel there are other ways to address the problem."

The NRC has taken some steps to respond to the dispute over compatibility, according to Mr. Miller. "We are trying to get the states more earlier involved in the rule-making process," he says. "By doing this a lot of problems are going to go away." Mr. Kerr of Illinois acknowledges several positive steps, including a series of NRC-sponsored workshops on the medical quality management rule and the NRC request for a state regulator to join the Advisory Committee on Medical Use of Isotopes. But the core of the agreement states' grievance is the NRC policy on compatibility and until that policy is substantially altered, the agreement states have vowed to continue struggling with the NRC to maintain a measure of autonomy from federal regulations. Representatives from the agreement states stress that matters of compatibility should be judged by the effectiveness of state safety measures. Says Mr. Kerr: "Are you protecting the public health and safety?—that is the real test."

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