THE IMPACT OF A BRC POLICY ON MEDICAL BYPRODUCT AND NARM WASTE

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ABSTRACT

Disposal of very low-level or BRC waste is critically important to the medical community. The radionuclides used in most medical diagnostic and therapeutic procedures typically have very short half-lives. As a result, this waste is usually held for decay and later disposed as non-radioactive waste. This has been the practice of nuclear medicine departments in hospitals throughout the country for quite some time. With the advent of NRC's BRC Policy Statement of 1990, the future of this practice is in jeopardy. The nuclear medicine manufacturers and users support the technical basis of the NRC's Policy Statement and acknowledge the need for a nation-wide BRC policy. However the political and public relations stir that has resulted from the BRC Policy Statement will make promulgation of a standard very difficult. The medical community has and will continue to work with the NRC and Congress in an effort to arrive at a nation-wide standard based on a consensus of the affected parties, including special interest groups.

INTRODUCTION

The quality of medical care in the U.S. is among the best in the world. The advent of radioactive materials in medicine has lead to advances in biomedical research, medical diagnostic procedures, and therapeutic procedures. The use of radioactive materials in medicine offers modalities that would otherwise not be available. With advances in Nuclear Medicine, Positron Emission Tomography (PET), and monoclonal antibodies, it is clear that the use of radioactive materials in medicine will be prevalent for quite some time into the future.

Most of the radionuclides used in the nuclear medicine community are short half-life ($t_{1/2} < 60$ days). The short half-life allows physicians to collect the needed diagnostic information, or provide the dose needed in therapeutic procedures, while minimizing the dose to the patient and keeping the duration of the exposure as short as possible. The radionuclides used in nuclear medicine are both byproduct material and NARM (Naturally occurring or Accelerator-produced Radioactive Material). The byproduct radionuclides are produced in privately owned reactors, government reactor facilities, and university research reactors. The NARM radionuclides are typically produced in cyclotrons that are privately owned, or government run.

With the production and use of radioactive materials in medicine, there is, of course, the generation of low-level radioactive waste. The radwaste generated can be broken down into three main areas. The first area includes the facilities producing the radioactive material. These would include the reactor and cyclotron facilities. These facilities produce a variety of waste from the very short half-life nuclides to long half-life transuranics. The cyclotron facilities typically produce shorter half-life waste products.

The second source of radioactive waste is from the manufacture of the radiopharmaceuticals used in nuclear medicine, and radionuclides for biomedical research. This category would include the manufacturers of radiopharmaceuticals, commercial nuclear pharmacies, and the manufacturers of biomedical research radionuclides. This waste material is typically shorter half-life than that found at the reactor and cyclotron facilities. This is mainly because the waste generated by these manufacturers contains the same radionuclides used in their short half-life finished products. It is typically small quantities of short half-life radioactive materials, in low concentrations.

The third major source of radioactive waste is the end user of these medical products. This would include the physician in the hospital or clinic, and the medical researcher in a private, government, or academic setting. Radiopharmaceutical waste usually consists of short half-life nuclides in small quantities. The focus of this paper will deal with the waste generated by the end user of radiopharmaceuticals and the manufacturers of those products.

The inherently short half-life of nuclear medicine waste allows for effective decay-in-storage programs. Most hospitals and research facilities that use these medical radionuclides, store the waste they generate in-house. Manufacturers of these products all have very effective decay-in-storage programs. Most of these programs were started in response to disposal cost increases of the late 1970s. These medical facilities allow their waste to decay to background levels, then dispose of it as non-radioactive refuse. This has been done for years, regulated through license amendments and license conditions. This system has, in effect, kept this waste out of the low-level waste disposal facilities. The state of Texas has had a very effective policy of allowing licensees to dispose of similar waste for years. Disposal of both byproduct and NARM BRC waste has been occurring for years. It is a safe and effective method for disposing of this waste. This practice has also allowed the medical community to help slow the spiral of increasing health care costs.

The NRC set out to codify BRC regulations by the issuance of their BRC *Policy Statement* in June of 1990. That Policy Statement objectively presented the merits of setting up a uniform BRC program. However, since the time of the BRC Policy Statement, there has been a great deal of misunderstanding and confusion. The public meetings held by NRC and the written and oral testimonies that were made, were a clear indication of the misunderstanding.

The medical community feels very strongly that a uniform national standard for BRC waste disposal is needed. At this point in time the exposure level to which the policy is addressed is not as important as the policy itself. All interested parties should be able to arrive at some sort of consensus. The NRC's admirable effort to put together such a consensus process has not yet succeeded. The medical community has

always been, and will continue to be, in support of this consensus process for resolution of the divergent opinions. BRC is not designed to promote the disposal of radioactive material in our landfills, but is an effort to determine when a material should no longer be considered a radiological hazard.

I-123 is a radionuclide that is used extensively by physicians for diagnostic studies of the thyroid gland. It has a thirteen hour half-life. After storage of I-123 radwaste for a period of one month, it has decayed down to a level of 2E-17 of its' original value. Another popular radionuclide in nuclear medicine is Tc-99m. With its' half-life of six hours, one month of decay will yield a decay factor of 8E-37. When dealing with waste that starts with quantities on the order of fractions of microcuries, even a short decay period of one month can reduce these levels to truly negligible quantities. To bury this waste in a low-level waste in a disposal site would constitute unjustified use of this important site space. Most decay-in-storage programs have decay periods much longer than 30 days.

The practice of holding medical waste for decay has been reviewed by several of the manufacturers with regard to the NRC's proposed BRC Policy Statement. A pathway analysis was completed looking at disposal of this waste in a local landfill. Several pathways for potential exposure have been examined. The IMPACTS - BRC computer code was used in these pathway analyses. The highest pathway of exposure was the transport worker moving the waste from the site to the local landfill. Although many other pathways were reviewed, this transport worker pathway yielded the highest potential for exposure. This exposure was well below the exposure levels proposed in the NRC's BRC Policy Statement. In fact it was less than 10% of the proposed exposure level. This is further justification that the practice of BRC waste disposal in a local landfill is an acceptable alternative. Environmental groups have felt that a BRC Policy would be, in essence, a license to dump significant quantities of radioactive waste into local landfills. Potential doses to the public of less than 1 mREM per year would not be considered significant exposure.

Most of the concern over a BRC Policy is the result of a fear that the public would have the potential for significant exposure if this material were sent to a landfill. These pathway analyses show that the exposure to the public is insignificant. No one in the medical community is advocating a policy that would lead to any significant exposure to the public.

In response to the concern over so-called "deregulation" of radioactive waste, legislation was introduced in Congress to address the problem. Congressman George Miller (D-California) introduced HR.645 on January 24, 1991. Companion legislation, S.1111, was introduced by George Mitchell (D-Maine) on May 21, 1991. This legislation would affect the NRC's Policy Statement in two ways. First, the proposed legislation would require the NRC to repeal the Policy Statement. Secondly, it would allow the individual states to set their own regulations for radioactive waste disposal. The states are certainly capable of establishing workable regulations as in the case of the State of Texas. However, the medical community is afraid of the problems created by non-uniformity among the states. For example, over the last ten years, many states have tried to develop regulations with the intent of controlling the transportation of radioactive material in their state. Many of these regulations have had far reaching impacts that the regulators were not counting on. In one case, although legislation was developed with the intent of inhibiting reactor waste or fuel assemblies, in actuality it had the effect of shutting down the delivery of radiopharmaceuticals to local hospitals. We fear that if states are given the authority to regulate radioactive waste disposal we may lose our ability to dispose of this short half-life decayed waste.

The medical community is not advocating the disposal of unsafe quantities of radioactive materials in the public domain. We are merely trying to encourage the development of responsible regulations to determine when a material can be considered non-radioactive. This issue also extends to fixed facilities and the decommissioning of medical facilities with residual amounts of radioactive material. In the future there will be an increasing number of medical facilities needing to be decommissioned. Many of these facilities have residual contamination or neutron activation products as a result of years of cyclotron operation. Before a residual radioactivity standard for decommissioning can be established by NRC, an acceptable level of exposure must be established.

CONCLUSION

All parties interested in the BRC issue should be involved in the discussion and review of any rulemaking in this area. The NRC in their earlier effort to build a consensus on BRC tried to involve all interested parties. Without a consensus of all interested groups, there will be one or more groups that are not satisfied with the outcome. The NRC is to be commended for their recognition of this important point. Not all of the groups that had been extended an invitation to participate in the consensus-building process were willing to do so. As a result, the consensus-building effort for BRC was abandoned. NRC has plans to continue the development of new rulemaking on residual radioactivity. With the current moratorium on BRC implementation, some of the groups that were not willing to participate in the BRC consensus-building, may be willing to collectively discuss the residual radioactivity rule. For the good of the entire nuclear industry, we must all continue to support and foster the consensus-building type rulemaking, and push for a national standard dealing with BRC waste.