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COUNCIL ON RADIONUCLIDES AND RADIOPHARMACEUTICALS POSITION PAPER ON MIXED WASTE

INTRODUCTION

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is concerned with the slow progress in providing comprehensive viable treatment and disposal options for low level radioactive waste mixed with hazardous chemical components (mixed waste).

CORAR is comprised of representatives of the major manufacturers and distributors of radiopharmaceuticals, radioactive sources, and research radionuclides used in the U.S. for therapeutic and diagnostic medical applications and for industrial, environmental and biomedical research and quality control.

Radiopharmaceuticals and radionuclides are used world wide with immense benefit to society. Although non-radiometric methods are being sought, much essential biochemical and medical research today depends on the application of radionuclides often in the form of labelled compounds. It is interesting to note that in the past twenty-five years most Nobel prizes in medicine and physiology were awarded for research which could not have been conducted without radioactive materials. In addition to benefits accruing from research, the quality of health care is also strongly enhanced by diagnostic and treatment methods using radiopharmaceuticals and radioactive sources. Some medical treatments and diagnostics can only be done using radionuclides. Currently, when other methods are available, they are less safe, less accurate and/or are more costly than the radiometric method.

An unavoidable by-product of the manufacture and use of these essential radioactive products is the generation of mixed waste. Although manufacturers and users continue to seek methods to avoid the production of mixed waste, it is unlikely that mixed waste will be entirely eliminated and the ultimate fate of mixed waste currently held in storage is still to be determined. It is unreasonable to expect that we can eliminate mixed waste by eliminating the use of radioactive materials. Society needs the benefits from the uses of radioactive materials and will seek such uses for the foreseeable future. Since the generation of mixed waste cannot be eliminated, it is essential that provision is made for its safe handling, storage and disposal.

MIXED WASTE GENERATION

Mixed waste is generated in the manufacture of labelled compounds. This is because organic solvents must be used to mediate the necessary chemical reactions and to produce a pure product. Some of these waste forms can be complex, involving a variety of hazardous constituents, or are not always easily identifiable. In some cases it is possible to separate different components of the waste, and this technique has been widely used to minimize the generation of mixed waste. In other cases, separation is currently impossible. For example tritium, the most widely used radionuclide in biomedical research, exchanges with the hydrogen in the solvent thus forming a mixed waste which could be a single compound with both hazardous chemical and radioactive properties.

Some labelled compounds can decompose when stored. Both storage and use of labelled compounds in the biomedical community can generate other forms of mixed waste. These mixed waste forms can be complex and in many research applications it is very difficult to precisely identify and quantify the hazardous components.

The volumes of mixed waste generated by biomedical and research communities and by the manufacturers who supply the radioactive products is less than 1% of the amount of the mixed waste generated at the Department of Energy facilities. Mixed waste is only a tiny fraction of the total solid waste in the U.S.. It is less than one part in a hundred thousand of the total hazardous waste, and estimated to be 2-5% of the low level radioactive waste.

Some of the mixed waste generated by manufacturers contain relatively high concentrations of radionuclides, particularly ^{14}C and ^3H . Typically in these wastes, the dominant hazard will be the radioactivity. When radioactive products are used in the biomedical community, the resultant mixed wastes typically have low concentrations of radioactivity and the chemical components tend to be the dominant hazard.

MIXED WASTE MANAGEMENT

Mixed waste from the manufacture and use of radioactive materials in medicine and research is handled and stored safely. There have been no incidents that have resulted in injury to the public. However, recognition of potential hazards mandate that careful management of mixed waste be maintained until it is no longer hazardous. The primary management strategy for minimizing this hazard is to prevent inclusion of the hazardous components in the waste. Good practice and regulatory requirements encourage generators to seek methods to minimize mixed waste generation or ensure that it is easy to treat. Generators have had considerable successes in minimizing mixed waste but cannot completely eliminate it. ⁽¹⁾

Another waste management strategy is to determine the exact nature of the waste to allow appropriate treatments to be selected for reducing the hazardous components. Characterization of the waste may require sampling and analysis, which may be difficult to obtain for complex waste forms. When the waste is characterized adequately, opportunities may exist for treatments that either separate hazardous components or destroy the hazardous chemical. Treatments may lead to recycling separated components, to converting the mixed waste into either low level radioactive or hazardous waste form, or to preparing the mixed waste for storage or disposal.

For certain mixed waste forms, where either the radioactivity or the chemical hazard is slight, regulations may permit the waste to be treated and disposed of as simply hazardous chemical or radioactive waste. Alternatively, it is possible to develop disposal sites to contain treated or untreated mixed wastes. Generally these operations will add cost to waste disposal. In some cases the cost may be high because of the complexity of the process or because the quantities to be processed are small and do not offer economies of scale. For some waste forms, a viable process has not yet been proven which implies disproportionately large costs to research and to develop a process. Another cost factor is that any process must comply with regulatory requirements. These requirements may include costly documentation, applications for permits, the price of the permit and delays in achieving ultimate disposal. Disposal costs too may be increased by similar requirements and the application of surcharges to compensate or benefit local communities. These costs and very limited disposal options increases the financial liability for site decommissioning and results in increased cost of financial surety arrangements required by regulation for many licensees.

Actual and projected costs for ultimate disposal of mixed waste has become a significant factor in the viability of using radioactive materials. Manufacturers have to pass on this cost to the user. Users who are researchers are often funded by limited and competitive federal grants. More money spent on waste management is money lost to research. Society needs to contain costs of waste disposal to ensure that the benefits of the uses of radioactive materials are continued.⁽²⁾

REGULATORY REQUIREMENTS

Historically, regulatory developments have focused on large classes of waste with well-defined characteristics. This approach has caused mixed waste to become either neglected or subject to numerous regulations, some of which have conflicting requirements. Generators have had to contend with the absurd situation that simultaneously prohibited storage, treatment and disposal of mixed waste. Federal and State regulations are changing rapidly leading to more waste forms being classified as mixed waste. These regulatory changes have caused the costs of managing mixed waste to increase ten fold in a single year at some users' facilities.

A primary source of conflict in regulatory process is that the U.S. Nuclear Regulatory Commission (NRC) focuses on the radioactive aspect of the waste, while the U.S. Environmental Protection Agency (EPA) focuses on the hazardous chemical component. Radioactive waste is typically treated and prepared at the generator's site for transportation and final disposal. Hazardous waste, however, is normally collected and treated at the disposal site. Regulations for hazardous waste require sampling and analysis without regard for the radiation hazard to personnel carrying out the task. Another source of regulatory conflict is that the NRC regulates the performance of the entire process, including management of production, use, waste generation, treatment and disposal, while the EPA prefers prescriptive regulation of the waste only ⁽³⁾⁽⁴⁾⁽⁵⁾. Regulations have not clarified at what point in a process is the material to be considered waste.

Regulatory development has been frustrated by insufficient knowledge of the national profile of mixed waste. The punitive and no-win characteristics of regulatory requirements have removed incentives for generators to share information concerning their waste forms. For certain waste forms, no treatments are currently available. For those waste forms where treatment is possible, the need to obtain a Resource, Conservation and Recovery Act (RCRA) Class B permit ⁽⁶⁾ can cause generators to be involved in a slow, expensive process with highly uncertain outcome. In recent years regulatory agencies have been working together in an attempt to resolve these issues. In an attempt to eliminate dual and conflicting regulation of mixed waste, the EPA promulgated the Conditional Exemption Rule ⁽⁷⁾. This rule allows NRC and Agreement States licensees to manage mixed waste according to the requirements of NRC and Agreement States regulations and licensee conditions. Licensees that notify the EPA, or equivalent State agency, that they are managing mixed waste according to the conditional exemption rule, and comply with all applicable conditions, are not subject to RCRA requirements. This effectively avoids the need for costly permits and specific regulatory approval for each treatment process and enables licensees to manage the mixed waste in a manner that is both protective of the public environment and occupationally safe.

The EPA intended that State Environmental Protection Agencies would implement the Conditional Exemption Rule. However, at this time not all States have adopted the rule due primarily to the lack of staff or training resources. CORAR urges that the EPA assist these States by providing training and or financial aid.

Radiochemical Manufacturers and the research community commonly use thermal catalytic oxidation processes to synthesize radiochemicals. In 2003 and 2005 the EPA promulgated rules approving the treatment of mixed wastes consisting of tritiated solvents by catalytic oxidation ⁽⁸⁾⁽⁹⁾. This is a highly efficient method for eliminating the chemical hazard and allowing reuse or prompt disposal of the radioactive component. CORAR recommends that the EPA should allow all qualified licensees to use this treatment method for similar mixed waste forms.

RECOMMENDATIONS FOR THE SAFE MANAGEMENT OF MIXED WASTE

The definition of mixed waste needs to be clarified. In particular, the point at which a material in process is classified as waste needs to be established. The purpose of classifying waste should be revised to allow opportunities for expeditious recycling or treatments to provide a simpler, or less hazardous waste form at the generator's facility with due regard to the potential for radiation exposure.

There is a need to obtain better qualitative and quantitative information on the sources of mixed waste in the U.S.. To do this, the regulators should encourage generators to share this information, remove impossible regulatory requirements, stabilize hazardous chemical listings, provide uniform requirements from State and Federal agencies, and provide for interim storage until competitive methods are available for treatment of mixed waste forms.

The regulators need to establish comprehensive de minimis levels for the following: 1) the quantity generated, 2) quantity in storage, 3) the concentration of radioactivity and the hazardous chemical concentrations. De minimis levels should be established to permit disposal in sanitary sewers and available disposal sites. Intermediate levels should be established where the mixed waste can be treated or disposed as either radioactive or hazardous chemical waste. The Atomic Energy Act already provides for precedence over RCRA requirements, when regulations conflict, and this should be implemented when the radioactivity dominates. Similar provisions should be established when the chemical hazard dominates.

The concept of de minimis levels should also be reviewed and applied to the purity of the waste form and how accurately this needs to be known to eliminate unnecessary detailed sampling and analysis to ensure minimization of radiation exposure and potential hazards to persons conducting the analysis.

Multiple and dual regulations should be eliminated since they can lead to confusion to generators that may compromise safety, are wasteful of resources and lack justification on the basis of benefit to the public. The transfer of federal jurisdiction over mixed waste to the NRC through the Conditional Exemption Rule is a good example of beneficial change because the NRC is the only federal agency that can comprehensively regulate both the occupational and environmental protection aspects of mixed waste management.

Regulators should continue to encourage the minimization of waste. Regulators should pursue this objective by providing clear guidance and positive incentives to generators.

Mixed waste generators should be encouraged, by the dissemination of educational materials, to promote the following minimization strategies ⁽¹⁰⁾:

- include waste generation considerations early in process and product design.
- seek alternative procedure.
- substitute non-hazardous chemicals.
- optimize scale of operations.
- minimize use of materials by reducing the size of process systems.
- automate processes to improve reproducibility and reduce rework.
- recycle intermediate chemicals.
- repurify products to avoid disposal.
- segregate waste forms at the source.
- prevent the unnecessary creation of mixed waste.
- provide separate mixed waste forms that lead to appropriate specific analysis, treatment and disposal.

Provisions for the ultimate treatment and disposal of mixed waste should be comprehensive. A high priority should be given to developing a federal treatment and disposal facility at a DOE site where the majority of mixed waste is generated and stored. Alternatively a future low level radioactive waste site might have a small part of the site designed to receive mixed waste thus satisfying the state or compact's obligations while providing a national service. The ultimate goal must be to provide safe treatment and disposal, while minimizing costs, so that society may enjoy the essential benefits of radioactive materials in research and medicine with confidence in the safety of their management.

REFERENCES

1. N. Kirner, G. Faison and C. Owens, "Mixed Waste Management Options." DOE/LLW - 134, December 1991.
2. The National Academy of Sciences, "The Impact of Low-Level Radioactive Waste Management Policy on Biomedical Research in the United States." Washington, DC, 2001.
3. U.S. Nuclear Regulatory Commission, 10 CFR Parts 20, 30, 40, 61, 70.
4. U.S. Environmental Protection Agency, 40 CFR Parts 260-266, 268 and 270.
5. U.S. Environmental Protection Agency, "Low-Level Mixed Waste a RCRA Perspective for NRC Licensees." Washington, DC, 1990.
6. Resource, Conservation and Recovery Act. 1976.
7. U.S. Environmental Protection Agency, "40 CFR Part 266 Subpart N-Conditional Exemption for Low-Level Mixed Waste Storage, Treatment Transportation and Disposal." Federal Register, May 16, 2001, Volume 66, Number 95.
8. U.S. Environmental Protection Agency, "40 CFR Part 261 Hazardous Waste Management System; Exclusion for Identifying and Listing Hazardous Waste and a Determination of Equivalent Treatment; Final Exclusion." Federal Register August 17, 2003, Volume 68, Number 152.
9. U.S. Environmental Protection Agency, " Project XL Site Specific Rulemaking for the Ortho-McNeil Pharmaceutical, Inc. Facility in Spring House, PA Involving On-Site Treatment of Mixed Wastes." Federal Register June 27, 2005, Volume 70, Number 122.
10. C. Owens, "Guidelines for Mixed Waste Minimization." DOE/LLW - 144, February, 1992.