APPLYING THE "DE MINIMIS" CONCEPT TO MIXED WASTES

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ABSTRACT

In recent years, a concept of "de minimis", "below regulatory concern", "threshold", or "negligible" levels of radiation dose and risk from low level waste has begun to be accepted by standard setting and regulatory bodies throughout the world, including ICRP, NCRP, IAEA, USNRC, USDOE, USEPA, and UKNRPB. Moreover, the "de minimus" principle has long been recognized by the courts and has been applied in the area of environmental health and industrial hygiene law. This paper reviews the precidence in these areas and addresses the reasonableness of establishing BRC levels for chemical, as well as radiological constituents of mixed wastes, in order to minimize the quantity of "true" mixed wastes that must be disposed of under a duel regulatory system.

A two-tiered BRC approach is proposed, which would recognize that since waste deregulated for one of the constituents would still be strictly controlled, there could be "conditional BRC" levels established higher than those that would apply to cases where disposal of deregulated waste is essentially uncontrolled. This paper discusses some of the technical and trans-scientific concerns involved in implementing the BRC approach in the high profile world of environmental regulation.

INTRODUCTION

This paper will discuss the concept of de minimis risk in general and its application to the issue of mixed hazardous and radioactive wastes.

In the field of environmental protection, the need for defining a reasonably negligible risk level to avoid excessive control activities and expenditures to reduce individual risks has long been recognized (see e.g., Refs. 1 & 2). All organizations with risk management responsibilities use some type of de minimis approach, whether they acknowledge it or not, since risk management resources are always finite, and the supply of very small risks is virtually inexhaustible (3). Decisions based on the concept of reasonably negligible risk are made frequently in many societal and individual activities. In effect, regulatory practices have involved low exposure cutoff levels for various hazardous agents or situations, often, apparently, on the basis of triviality of the risks as compared with other natural or man-made risks. Other de facto cutoffs have been established by the computation processes available; going from slide rule to computer calculation may allow dealing with smaller and smaller numbers.

The adjective phrase "de minimis" is derived from an ancient maxim of the law: "De minimis non curat lex" The law does not care about trifles. This practical maxim has long been used by courts to justify their disregard of inconsequential matters. In recent years, interpreting statutes, courts in the United States have implied a power in regulatory agencies to refuse to regulate things that are about trifles "de minimis". The phrase de minimis, often used as a synonym for "trivial" or "of no practical importance" in a legal context, has found its way into regulatory and technical usage as well. In this paper, de minimis will be used as a generic as well as a legal term. When regulatory considerations are discussed, widely used terms include "regulatory threshold" and level "Below Regulatory Concern" (BRC). In the scientific context, NCRP has adopted the term "negligible level". Among the terms with somewhat similar meaning that have been used are: minimal, trivial, insignificant, inconsequential, immaterial, beneath regulatory concern, below a cutoff, irrelevant for regulatory purposes, and practically zero.

For the purposes of this report, a de minimis level of environmental risk is one below which any effects are so small that they need not be taken into account by the decisionmaker. Indeed, to ensure that the proper emphasis is given to nontrivial doses and risks, the de minimis approach dictates that effects at or below the de minimis level should not be taken into account.

Many experts believe it is more likely than not that there is no absolute threshold for carcinogenic and genetic risks. However, at present there is no convincing scientific evidence that such a threshold does, or does not, exist, and it may never be possible to conclusively prove or disprove the existence of such thresholds. For "conservatism" in regulatory applications, it has generally been assumed that there is no absolute threshold for such effects. However, it is also recognized that any risks associated with very low levels of carcinogens may be very small, so small, that although finite, they are close to zero.

A de minimis risk may be defined as a risk so small that its presence or absence would not influence a person's decision on whether or not to take the action to which that risk relates. Estimates of the upper limit of negligible risk generally fall into the range of E5 to E8 per year, approximately equivalent to a chance of death of one in a thousand to one in a million (E3 to E6) per lifetime. For radiation, using the linear extrapolation, the doses that

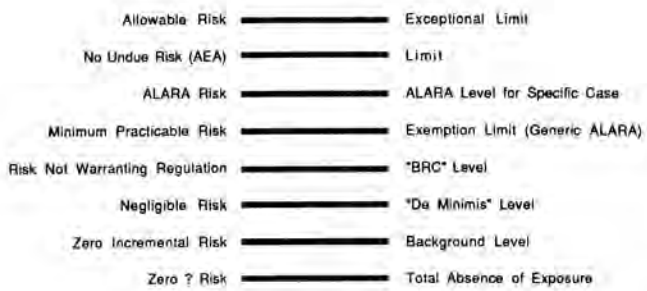

Fig. 1. Incremental Risk-Regulatory Levels.

correlate with these negligible risk levels are between about 0.1 and 1.0 mSv per year (0.1 mSv to 0.1 Sv per lifetime). This is the range within which proposed values of de minimis dose generally fall.

Figure 1 illustrates schematically the relationship of allowable and de minimis levels.

The Atomic Energy Act of 1984, as amended, gives NRC a broad mandate to protect the health and safety of the public from hazards associated with the use of nuclear energy. The standard has been interpreted as one of "reasonable assurance of no undue risk". Within these broad guidelines the agencies have discretion in establishing policy and implementing it. The Act specifically gives AEC and its successor agency, NRC, the authority to exempt certain "unimportant" quantities of material from regulation. It is likely that the statute would be interpreted as being subject to a de minimis rule in appropriate cases. Certainly there is no indication in the Act that Congress meant to impose a "zero risk" standard, and courts have made it clear that such a standard is not implied in the Act.

In late 1985, Congress amended the Low Level Waste Policy Act, to require NRC to propose the deregulation of radioactive waste that are below regulatory concern. This was the first explicit Congressional recognition of the de minimis concept in the context of radiological risk regulation. NRC activities, pursuant to this mandate, are discussed later in this paper.

The de minimis concept has formed the basis for judicial and regulatory decisions interpreting federal law in the United States. For example, in an area related to public health, under the Federal Food, Drug, and Cosmetic Act, food is deemed "adulterated" if it consists in whole or in part of any filthy, putrid, or decomposed substance. Since all food is subject to some decomposition, the Federal Courts have used the de minimis concept in considering whether a food should be considered "adulterated" (4,5).

In the environmental area, a leading case is Alabama Power Co. v. Costle (6). The federal appeals court held that EPA has authority inherent in the Clean Air Act and in "most statutory schemes ... to overlook circumstances that in context may fairly be considered de minimis." (7) The Supreme Court in a split decision in the Benzene case (AFLCIO v. API, 1980), recognized the existence of "insignificant" risks, at least under the Occupational Safety and Health Act (OSHA)(2) .

Court rulings have negated a zero risk requirement for safety regulation by the AEC/NRC. In the most recent case involving this issue, UCS v. NRC (1987), the district court stated "The level of adequate protection need not, and almost certainly will not, be the level of 'zero risk'....the adequate protection standard [of the Atomic Energy Act] permits the acceptance of some level of risk" (8).

An important case involving very low levels of environmental radioactivity is currently pending before a federal Court of Appeals; the Radionuclides case involves EPA's decision not to regulate certain classes of radionuclide emissions under the Clean Air Act. Environmental groups challenged EPA's action even though the upper limit collective risk estimate for all emissions was less than one statistical death per year.

The de minimis approach has also been tried by the Food and Drug Administration in interpreting the draconian "Delaney Clause" relating to food additives. Of all the environmental and health statutes that regulate potentially hazardous agents, the Delaney clause, because of its rigid wording and prior agency interpretation, is probably the least likely to admit a de minimis interpretation. In a 1979 case, Monsanto v. Kennedy, a federal court ruled that FDA could ignore the de minimis risk of molecules of a plastic bottle material leaching into a soft drink by thermal diffusion. However, a 1987 Circuit Court case "reluctantly" concluded otherwise for food color additives which fall directly under the Delaney "zero risk" strictures (8). It is likely that this issue will ultimately reach the Supreme Court.

A regulatory agency charged with controlling agents whose use may involve risk to the public must set priorities for its actions. The concept of a level of risk that is "Below Regulatory Concern" (BRC) is useful in helping the agency

develop such priorities on a reasonable basis by identifying risks levels that are negligible compared to the risks that must be regulated to protect people's life or health. BRC values may be set at the level of negligibility ("de minimis"); however, they need not necessarily be set there. Depending on the context, it may be reasonable to establish levels that are below regulatory concern in particular situations or on specific conditions. In this paper these are called Conditional Below Regulatory Concern (CBRC) levels to distinguish them from the more general, or generic, BRC levels.

The Concept of De Minimis or BRC levels may find a useful application in the regulation of the disposal of so called mixed waste. For the purposes of this paper, "mixed waste" is defined as waste that is both hazardous (and thus regulated by EPA) and Radioactive (and thus regulated by NRC). (Any complications arising from the fact that not all radioactive materials are regulated by the NRC are ignored in this paper. This is a reasonable simplification, since the amounts of materials involved are relatively small, and the regulators, and the states, generally follow the lead of NRC. Reference to NRC or EPA regulation includes regulations by the states under authority delegated by the federal agencies, where applicable)

TABLE I

Current Proposed BRC Levels for Radioactive Waste.

U.S.NRC	Proposed Part 20	0.01 mSv/yr
	BRC Policy Statement	0.01-0.05 mSv/yr
U.S.EPA	Draft Proposed LLW Std	0.04 mSv/yr
	NARM in LLW	74 Bq/gm
AECB (Canada)	LLW Exemptions	0.05 mSv/yr
IAEA	Generic	0.01 mSv/yr
ICRP	LLW Exemptions	0.1 mSv/yr
NCRP	Draft Recommendations-Generic	0.01 mSv/yr
NRPB (UK)	Generic	0.05 mSv/yr
RC (Japan)	LLW De-Regulation	0.01 mSv/yr

As noted above, in its 1985 amendments to the Low Level Waste Policy Act, Congress mandated that NRC develop standards and procedures to exempt specific nominally radioactive waste streams from further NRC regulation if the wastes contain activity at levels that are below regulatory concern. In response, NRC issued a policy (9), which sets forth its criteria for such exemptions. The dose criterion stated in the policy is "a few mrem (0.010.05 mSv) per year". In the accompanying staff document, a level below 0.01 mSv per year is suggested as facilitating expedited agency action. This is stated to criteria for such exemptions. In the accompanying staff document, a level below 0.01 mSv (1 mrem) per year is suggested to facilitate expedited agency action. This is stated to correspond to a risk of about 2 in ten million per year (2 E7).

Shortly after the BRC policy statement was issued, NRC published an Advance Notice of Proposed Rulemaking (10), soliciting comments on the desirability of a more generic approach to establishment of BRC levels for radioactive waste. Among the questions posed was the desirability of setting BRC levels for waste at 0.001, 0.01, or 0.1 mSv per year.

The NRC work can be viewed as part of a larger, international effort to establish lower cutoff values for the regulation of radiation dose, in general, and radioactive waste activity, in particular. Some of the actual and proposed actions in this area are presented in Table I.

The consequence of establishment of BRC levels for low level radwaste, is to essentially deregulate materials that meet BRC criteria. Thus, nuclear power plant trash that meets BRC criteria can be disposed of without regard for its radioactivity, as if it were trash from a nonnuclear facility. Generally BRC levels are set quite low because it is contemplated that the wastes involved could be released to the environment under conditions of very little control.

Under the current interpretation of applicable laws, mixed waste is subject to a complex regulatory scheme of two agencies, two statutes and two sets of regulations. The requirements are different for each type of waste, and indeed, some aspects are totally inconsistent. It is apparent that if waste that classified as both "radioactive" and "hazardous" could be re classified as one or the other only, the situation could be clarified and simplified.

Under the initial definition of mixed waste four categories of waste can be identified:

1. Waste that is neither radioactive nor hazardous.

This material is regulated, if at all, under state law or federal law other than the Atomic Energy Act or RCRA. For the purposes of this paper it is considered Unregulated.

2. Waste that is only radioactive.

This material is considered to be regulated by the Nuclear Regulatory Commission, pursuant to the Atomic Energy Act and the Low Level Waste Policy Act.

3. Waste that is only hazardous.

This material is regulated by the Environmental Protection Agency pursuant to the Resources Conservation and Recovery Act.

4. Mixed waste that is both hazardous and radioactive.

This material is regulated by both agencies under all the statutes cited above.

As NRC and EPA have recognized in their Guidance on the Definition and Identification of Commercial Mixed LowLevel Radioactive and Hazardous Waste (11), NRC's BRC concept can be applicable to mixed waste. They state that "BRC Mixed LLW may be managed without regard to its radioactivity (but it must still be managed as a hazardous waste in compliance with EPA's regulations...." Thus, applying the BRC concept, another type of waste can be defined:

5. Hazardous waste with radioactivity at or below the generic BRC level.

If such waste is deregulated insofar as its radioactivity is concerned, practically speaking it falls out of the mixed waste category (although it may legally be considered "mixed waste" for which other disposal options are permissible) and can be handled like other wastes that are only hazardous. This approach may be helpful in reducing the amounts of waste that must be handled under the difficult mixed waste rules.

A further reduction in the amount of material classified as mixed waste could be effected if a special Conditional BRC level were used for deregulating mixed waste. This reflects the fact that the disposal of waste deregulated from "mixed" to "hazardous only" status must still be done under strict controls that severely limit the release to the environment of any constituent. In a recent paper (12), Robert Augustine of NIH proposed that special BRC levels be established for certain radionuclides in mixed waste where the chemical hazard is great and the radiological hazard could be safely managed by virtue of the procedures used to manage the chemical hazard. These special BRC values could be higher than the usual BRC values which generally permit the unrestricted disposal of radioactive waste as long as the waste does not contain other hazardous components. NIH has requested NRC to amend its license to permit mixed waste to be disposed of at a RCRA permitted hazardous waste facility if the activity levels are less than 10 times the "Exempt quantities" of 10 CFR Section 30.71, Sch. B., per individual container of hazardous waste.

As Dr. Augustine notes in his paper, it is essential that NRC and EPA promulgate such a CBRC approach jointly so that RCRA permitted facilities would be allowed to take, and not be afraid to take, hazardous wastes with activity levels below some maximum acceptable (CBRC) value. Education and training about the real hazards of radiation would be needed for hazardous waste handlers, who often have a fear of radiation, but little concern for the more dangerous chemical wastes they routinely process. Coordination with the Department of Transportation would also be required.

If such a CBRC approach is adopted, another type of waste could be identified and removed from the mixed waste category:

6. Hazardous waste with radioactivity at or below the Conditional BRC level.

If such waste is deregulated insofar as its radioactivity is concerned, it, like category 5 waste, falls out of the mixed waste category and can be handled like other wastes that are hazardous only.

It may be technically possible to develop, and legally possible to apply, the BRC and CBRC concepts to the hazardous chemicals present in mixed wastes. By reasoning similar to that discussed above for radioactivity, this would enable six additional types of waste to be removed from the mixed waste category:

7. Radioactive waste with hazardous material content at or below the generic BRC level.

If this waste is deregulated insofar as its hazardous material content is concerned, it falls out of the mixed waste category and can be handled like other wastes that are radioactive only.

8. Radioactive Waste with hazardous material content at or below the Conditional BRC level.

If this waste is deregulated insofar as its hazardous material content is concerned, it falls out of the mixed waste category and can be handled like other wastes that are radioactive only.

9. Waste with the content of both radioactive and hazardous materials below the CBRC Levels but above the BRC levels.

This waste would fall out of the mixed waste category but would not be totally deregulated; it could be handled as either radioactive or hazardous.

10. Waste with hazardous material content above BRC and below the CBRC level and BRC radioactivity.

This waste would fall out of the mixed waste category but would not be totally de regulated; it can be handled like other wastes that are hazardous only.

11. Waste with radioactive material content above BRC and below the CBRC level and hazardous material content below the BRC level.

This waste would fall out of the mixed waste category but would not be totally deregulated; it can be handled like other wastes that are radioactive only.

12. Double BRC waste.

This waste would fall out of the mixed waste category into the nonradioactive, nonhazardous, unregulated area.

For completeness it should be noted that there is another way of removing wastes from the mixed waste category. NRC licensees may petition for variances from RCRA requirements when they believe that the application of one or more of these requirements would be inconsistent with the Atomic Energy Act. "Inconsistent" includes situations where satisfying both sets of regulations (RCRA and AEA) would increase the radiation hazard, would be technically infeasible, or would violate national security interests.

There are several technical, legal, and transscientific concerns involved in evaluating the feasibility of the BRC approach. Some of the important technical concerns are presented in Table II.

TABLE II
Technical Concerns

- Unexpected effects of BRC exposures
- Above BRC materials mischaracterized as BRC
- Above BRC materials inadvertently released as BRC
- Effects of multiple BRC releases or exposures

The legal concerns involve court interpretation of the statutes and regulations involved. Although some precedents exist, there are still major areas of uncertainty. Some of the Transscientific concerns of the BRC approach are indicated on Table III.

If the regulation of mixed waste continues in the current complex mode, it is essential that the amount of waste that falls into this category be minimized. The use of the de minimis or BRC concept is one way of reducing the problem by redefinition. It should be noted, however, that for this approach to proceed optimally, it should be taken in conjunction with other steps to segregate, as far as possible, the two types of constituent wastes.

TABLE III
Transscientific Concerns

- Compatability with ALARA concept and with "No Threshold"
- Use of collective exposure correlations disappearance of some "health effects"
- "Coverup" of information relating to hazards
- Public concerns about "invisible rays" and "deadly poisons" being released
- Communication with the public and decision-makers

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