THE ROLE OF RISK IN DOE ENVIRONMENTAL CLEANUP DECISION-MAKING: THE REGULATORY REQUIREMENTS

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ABSTRACT

This paper is the first in a proposed series of papers that will try to answer a question commonly directed to the Department of Energy: "How is risk used to make decisions in the Environmental Management (EM) program?" This paper summarizes the role that human health and safety risk plays in DOE cleanup decision-making under CERCLA and RCRA, two main regulatory drivers behind DOE cleanup efforts. The general conclusion is that there are some general limitations to the current use of risk in DOE CERCLA and RCRA cleanup decision-making. These limitations occur in both how risks are assessed and in how risk information is used in decision-making. DOE has made efforts at developing risk-based approaches to cleanup decision-making, and these efforts have generally been technically sound. However, in order for a more risk-informed cleanup approach to be implemented, it must either work within the current regulatory framework or DOE must negotiate exceptions to that framework. Recognizing the limited scope of this initial paper, the conclusion briefly offers an opinion on some general areas in which DOE should continue to work in order to improve the use of risk in cleanup decision-making.

INTRODUCTION

DOE's Environmental Management (EM) program faces the difficult task of cleaning up the contamination left behind as the legacy of years of nuclear weapons work as well as contamination from research activities at non-defense facilities. One DOE estimate puts the cost of this cleanup program at $227 billion over the next 75 years (DOE 1996). In order to understand how DOE uses risk, we attempt to answer the following basic, yet complicated questions:

- What role does risk play in DOE's cleanup decision-making?
- Are there general suggestions that might improve the use of risk information in DOE cleanup decision-making?

As with any paper that attempts to address an issue as large and as complex as this one, it is important to note the scope and limitations of the study. This paper is not intended to be an in-depth regulatory analysis. It is likewise not meant to be a technical analysis of the details of the types of risk assessment used in environmental cleanups. The main purpose of this paper is to provide a summary of the role that risk plays in DOE cleanup decision-making and to offer some general observations on the limitations in the current use of risk. No analysis of the costs and benefits of the use of risk information similar to the one done for non-federal sites under CERCLA (i.e., Hamilton and Viscusi 1999) has been conducted. This paper is based primarily on (1) discussions with regulators, program managers, and technical specialists within DOE, national laboratories, regulatory agencies, and stakeholder groups, (2) reviewing regulations and DOE, EPA, and state guidance documents, and (3) reviewing related technical and public policy literature. The role of risk in decontamination and decommissioning (D&D) of DOE nuclear facilities is not covered in the current discussion.

WHAT IS RISK?

The National Research Council states that risk is "a concept used to give meaning to things, forces, or circumstances that pose danger to people or to what they value" and that risk is usually stated in terms of the likelihood of losses from hazards and the magnitude of those losses (NRC 1996, 214). Most EM cleanups involve estimates of low exposures to toxic substances and radioactivity; therefore, in most environmental management situations "risk" usually refers to the estimated excess individual lifetime cancer risk (e.g., RAIS 1998). For example, a risk of $1x10^{-6}$ from exposure to a contaminant means that it is estimated that an individual exposed to the contaminant has a chance of 1 in 1,000,000 of getting cancer at some point in the future as a result of that exposure. As defined by Sutter (1993, 19) risk assessment is "a rigorous form of assessment that uses formal quantitative techniques to estimate probabilities of effects on well-defined endpoints, estimates uncertainties, and partitions analysis of risks from decision-making concerning significance of risks and choice of actions."

A term related to risk yet substantially different is "hazard." NRC (1996, 215) defines a hazard as "an act or phenomenon that has the potential to produce harm or other undesirable consequences to humans or to what they value." A hazard then can be a physical entity such as radiological groundwater contamination or a building in an earthquake zone. It can also be a person's action such as playing with matches or driving under the influence of a controlled substance, and it can even be information such as sensitive information that could harm a nation's competitive position if it were released to foreign nations. A hazard then is anything that *can* cause harm to humans or what they value.

This paper is concerned only with human health and safety risks. That is, we examine only the role that risks to public and worker health and safety play in DOE environmental cleanup decision-making. This is not to say that other forms of risk such as ecological, cultural, and programmatic risk are not important in cleanup decisions. While these risks are highly important in many situations a full discussion of the role that they play is beyond the scope of this paper.

ROLE OF RISK IN CERCLA AND RCRA CLEANUPS

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA) are two of the main driving regulations for many DOE cleanups. While other laws and regulations do play a role in cleanups, CERCLA and RCRA are the primary influences behind a large portion of DOE's cleanup efforts. This section briefly reviews the CERCLA and RCRA processes, and it discusses the role of risk in those processes. The discussion that follows assumes some familiarity with CERCLA and RCRA. More in-depth descriptions are provided in Ortolano (1997) and Wagner (1999) for those interested in additional background material.

Review of the CERCLA Process

Figure 1, an adaptation of a figure from Ehlers (1999, 323A) shows the CERCLA process and the role of risk in that process.

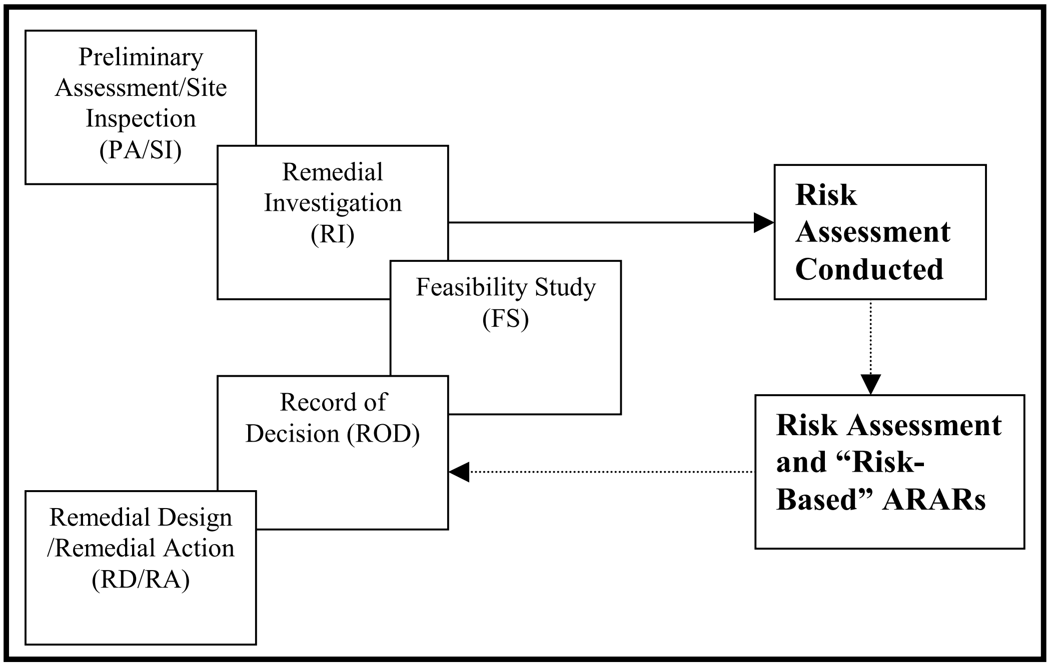

Figure 1. The Role of Risk in the CERCLA Process.

Briefly, the five steps of the CERCLA process are:

- Preliminary Assessment/Site Investigation: This step consists of a preliminary site investigation done using data that is readily available. The Hazard Ranking System is used at this stage to determine whether or not the CERCLA process should move forward.
- Remedial Investigation: This step consists of gathering the data needed to fully characterize the contamination at the site. It is at this phase that the data needed to complete a risk assessment is gathered.
- Feasibility Study: At this step alternate cleanup options are investigated in terms of their feasibility and their ability to successfully remediate the site.
- Record Of Decision: The ROD records the decision that was made regarding the selection of a cleanup plan as well as the rational for selecting that plan over the other alternatives.
- Remedial Design/Remedial Action: This step consists of designing and implementing the selected cleanup plan. It also includes monitoring the progress of the remediation to ensure that the cleanup goals are being achieved.

CERCLA specifies that in selecting cleanup options a plan shall be chosen "that is protective of human health and the environment, that is cost effective, and that utilizes permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable" (42 U.S.C. 103 §9621). While CERCLA does not establish cleanup standards per se, it does require that cleanup efforts comply with ARARs. Examples of ARARs would be the requirements of the CWA (Clean Water Act) and the CAA (Clean Air Act) for sites discharging contaminants to water and air respectively. Some of these ARAR requirements are concentration limits based on generic risk assessments conducted by the EPA when the regulations were promulgated. These limits are typically set at or below a lifetime excess cancer risk of $1x10^{-6}$ under assumptions about the exposure and the biological response to that exposure.

Risk in the CERCLA Process

While CERCLA does not explicitly call for a risk assessment, EPA requires that a quantitative human health risk assessment be conducted in conjunction with the RI stage of the CERCLA process (see Figure 1). In many cases this risk assessment is based on a number of assumptions that would tend to overestimate the risk posed by the site (e.g., Ghosh and Cox 1995; Viscusi et. al 1997), and this risk estimate is used as a screening tool. Generally, if the pre-cleanup public individual lifetime excess cancer risk is above 10^{-4} then remediation is required. If the public individual lifetime excess cancer risk estimate is below 10^{-6} remedial actions are not generally required, although other factors often lead to cleanups below this level. If the risk is in between these two endpoints remedial actions are normally determined by other site-specific factors. The first way in which risk is used in the CERCLA process then is as a screening tool to help determine whether or not a cleanup decision can be reached without further detailed assessment.

A second way in which risk enters the CERCLA decision-making process is through ARARs. As discussed above, cleanups conducted under CERCLA are required to comply with all ARARs such as the MCLs (Maximum Contaminant Limits) of the SDWA (Safe Drinking Water Act). Of the 150 Superfund sites analyzed by Hamilton and Viscusi (1999), nearly 84% of the groundwater remediation goals and approximately 33% of the soil cleanup goals were based primarily on ARARs. While Hamilton and Viscusi (1999) focused on a relatively small set of non-federal CERCLA sites, their results do suggest that ARARs play a prominent role in cleanup decisions. Some, but not all, of these ARARs were set to achieve a certain level of risk, based on generic assumptions. For example, in setting the MCLs for radionuclides in 1976, EPA set the MCL such that the estimated risk of death from beta photon emitters was $5.6x10^{-5}$ (EPA 1997). Furthermore, in revising the radionuclide MCLs EPA sought to limit the estimated risk of disease to $1x10^{-4}$ (EPA 1997). Other MCLs and ARARs are "risk-based" in a similar manner. It is important to remember, however, that these ARARs are not based on site-specific information. Among other potentially conservative assumptions, the risk estimates supporting ARARs typically assume long-term residential exposure to contaminants at the MCL. This assumption may not be logical for many DOE sites that are undesirable as residential areas and are geographically isolated.

Public policy, and DOE practice, have given little consideration of the sometimes ultra-conservative environmental limits and their impacts to the workers involved in the cleanup. In a recent article in *Risk Excellence Notes,* Bruce Church identified two case studies in which the public risk standard applied for cleanups was two orders of magnitude smaller than the risk taken by the workers on the job. Church argues that the standards applied to cleanups should be more in line with the risks associated with conducting the work (Church, 2000). In essence, Church points out that at a minimum, both cleanup levels and the age old argument of workers "acceptance" of risk must be re-evaluated.

Review of the RCRA Process

Many RCRA-driven DOE cleanups are driven by the RCRA Corrective Action process. While there is no formal regulatory program defining how the Corrective Action process works, the many policy and guidance documents released by the EPA have set the requirements for RCRA Corrective Actions (Wagner 1999, 263-264). As shown in Figure 2, the RCRA Corrective Action process is similar to the CERCLA process.

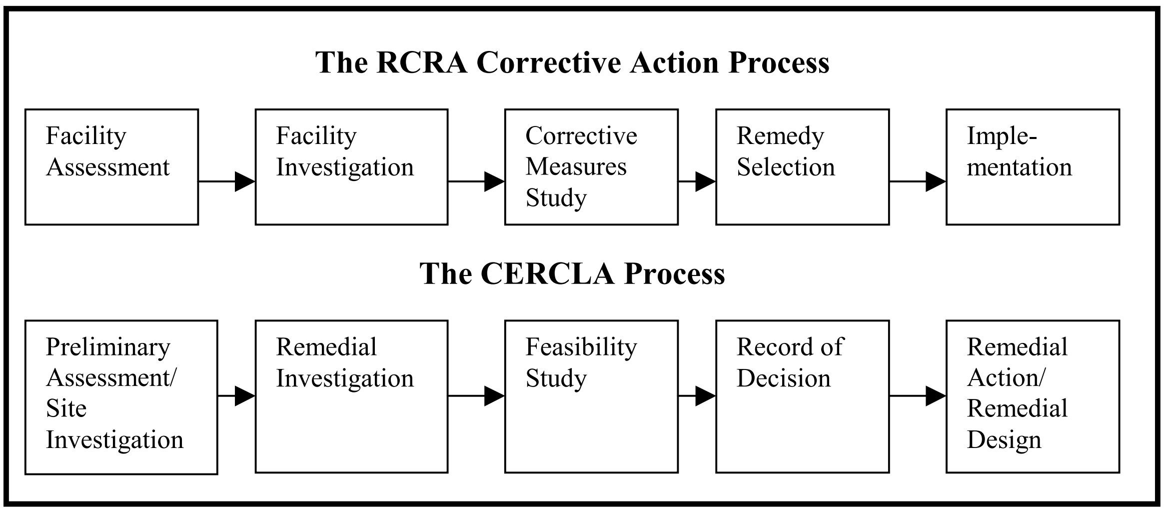

Figure 2. Comparison the RCRA Corrective Action and CERCLA Processes. (Adapted from Wagner, Figure 9.2, pp. 266)

The five steps of the RCRA process shown above are similar to the corresponding steps of the CERCLA process. One difference between RCRA and CERCLA is that RCRA and the rules that support it do not call for a risk assessment. RCRA also does not explicitly specify any uniform cleanup standards, either risk-based or concentration/dose-based (Wagner 1999, 269). However, "recommended limit factors" or "action levels" are specified as part of the RCRA Facility Investigation. These limits are often used as the cleanup goals (Wagner 1999, 269), and are health-based limitations that have undergone peer review by the EPA (Wagner 1999, 180). They currently include concentration limits from other rules and regulations such as MCLs and federal water quality criteria, reference doses, and slope factors (Wagner 1999, 178-181). Carcinogens are typically required to be reduced to a point at which the EPA-estimated risk is below $1x10^{-4}$ or $1x10^{-6}$. If there are no existing requirements for a contaminant then either natural background levels are used as the cleanup goal or the owner/operator must develop health-based limits that meet the EPA's burden of proof (Wagner 1999, 181).

Risk in the RCRA Process

As the discussion above shows, there is little explicit use of risk in the RCRA Corrective Action process. The one way that risk does enter the process is through the setting of the remediation goals. As discussed above, cleanup goals for RCRA Corrective Actions are usually based on one of two things, either existing concentration-based limits from other regulations or limits found through risk-assessments based on EPA-specified or state-specified parameters. These parameters include not only the slope factors and reference doses to be used, but also such things as the exposure duration, concentrations, and other similar parameters and they do not typically use site-specific information other than contaminant concentrations. As a number of researchers (e.g., Finley et al. 1992, Pate-Cornell 1996; Hamilton and Viscusi 1999) have discussed, this approach is likely to be overly conservative, and it has drawbacks that are significant when risk management decisions must be made in situations with limited funding.

Departures from CERCLA and RCRA Processes at DOE Sites

While the process at each DOE site is different due to unique local circumstances, there are several differences between the basic RCRA and CERCLA processes discussed above and the process that occurs at most DOE site. First, the selection of a cleanup plan at many DOE sites has been based on negotiations between DOE, EPA, and the state with input from a variety of stakeholder groups in recent years. This means that the selection of a remedy is not based exclusively on the criteria listed above. In practice other considerations, especially those related to public and political pressure, enter into the process. Some observers of the DOE cleanup efforts have gone as far as to offer the opinion that the issue of cleanup levels "has become purely political" (quote from A. Makhijani reported in Renner 1997, 136A).

Second, DOE facilities under CERCLA and RCRA are often part of a much larger DOE site that contains multiple CERCLA and RCRA cleanup efforts. These different cleanup efforts can lead to conflicting cleanup goals at a particular facility or to an unusual partitioning of a facility into different cleanup units. For example, in a recent cleanup effort at the Hanford Site in Washington, a building was considered to be subject to RCRA from the ground up, but all sub-surface contamination was considered to be subject to CERCLA. While this may work at this site, situations such as this can lead to confusion and conflicts over what the cleanup goals are at a given geographic location.

LIMITATIONS IN THE ROLE OF RISK IN DOE CLEANUP DECISION-MAKING

There are two general types of constraints in the current use of risk in DOE cleanup decision-making. The first is limitations due to the assumptions used in estimating risk, and the second is limitations due to how the results of risk assessments are used in decision-making. As will be shown below, many of the current constraints can be attributed directly to the regulatory scheme in which DOE cleanups must occur. While wholesale revision to these regulations is unlikely, it is important to note the general areas in which limitations exist. Doing so can help outline those areas in which DOE could work to improve the use of risk information in cleanup decision-making.

Limitations Due to the Type of Information Used

One area that has received a considerable amount of attention in the research literature is the use of potentially conservative exposure and dose-response assumptions in conducting both CERCLA risk assessments and risk assessments supporting contaminant-specific regulatory standards. One potential source of conservatism is the use of a residential scenario in assessing site risks. Risk assessments under CERCLA often assume that sites will be used for residential purposes (Ghosh and Cox 1995), and drinking water standards based on residential assumptions often play a large role in setting cleanup goals in remediation projects at DOE sites. Assuming residential use is often conservative at DOE sites because there is currently no residential use at most DOE sites, and some sites will need to remain under the control of the federal government well into the future because it is not possible to completely cleanup some sites using current technologies (Probst 1998). It is also arguable whether or not people would choose to live at a site that they knew to have contained contamination from a DOE facility in the past. This is not to say that residential scenarios should never be used in cleanup decision-making. There are DOE sites that can, and likely will, become residential areas. However, at those sites at which this is unlikely, the use of residential scenarios overestimates the risk from those sites.

A second source of conservatism is the contaminant concentrations, exposure rate, and exposure duration used in estimating the risk posed by contamination. EPA guidance calls for the use of either the maximum contaminant concentration detected or the 95% upper confidence limit of the arithmetic mean of the measured contaminant concentrations in estimating risk (Finley et al. 1992). EPA guidance also suggests using the 90^{th} or 95^{th} percentile of the available estimates of exposure rate and duration in computing risk (Finley et al. 1992). These requirements implicitly assume that those exposed at the site are exposed not to the level of contamination most likely to be found at the site, but to a much higher level.

A third potential source of conservatism is the dose-response functions used in assessing risks. Many of the dose-response parameters specified by the EPA for use in risk assessments are based on a linear, no-threshold response function that was extrapolated from animal exposure data for much higher doses. Much less study has been done on this potential source of conservatism than the others in part because of the difficulty and expense involved in conducting the animal or epidemiological studies on which dose-response functions are based. Because of this lack of understanding there is a high degree of uncertainty in the dose-response functions, and EPA has used assumptions that potentially introduce additional conservatism into the risk assessments used in cleanup decision-making.

Another imperfection in the current risk information that is used in cleanup decision-making is that the risk from combinations of contaminants is poorly understood. Current risk assessments typically use an additive model when dealing with multiple contaminants, but this approach does not take into account any synergistic or antagonistic interactions between the contaminants. Because nearly all sites have the potential for exposure to multiple contaminants this limitation is of great practical concern. Furthermore, it is not known what the magnitude, or even the generally the direction (i.e., whether this limitation would tend to underestimate or overestimate risk) of the impact of this limitation would be on risk estimates.

When a risk assessment containing the limitations and uncertainties discussed above is done, the uncertainty is compounded in a way that makes it difficult, in general, to determine how uncertain the risk assessment is. As Viscusi et al. (1997, 191) states, "…the degree to which conservatism is compounded is unknown, even to the analyst generating the estimate." Analyses have placed risk estimates anywhere from the 90th percentile to the 99th percentile of the 'true' risk distribution (see footnote 15, Viscusi et al. 1997, 191), but these analyses have generally not examined possible synergistic or antagonistic effects or the impacts of uncertainty in dose-response functions.

One reason commonly given for using conservative assumptions in conducting an environmental risk assessment is that there is such a high degree of uncertainty in the estimates that it is prudent to compensate for the uncertainty by using conservative, heath-protective assumptions. This may be acceptable given limited clean-up work to be done and limited funding. However, given limited funds and multiple clean-ups at different sites the conservative assumptions become a liability. Without understanding the probability distribution of risk it is at best difficult to weigh the costs and benefits of remediating to different levels at different sites. Methods exist that, in principle, would allow for the explicit assessment of the considerable uncertainty present in environmental risk assessment (e.g., Pate-Cornell, 1996). While using these methods would be difficult at many DOE sites their use would allow for a more complete assessment of the risks. Those making the clean-up decisions could then make decisions based on the best information available, and they could incorporate any level of risk-aversion that they felt was appropriate.

Limitations Due to How Risk Information is Used

In addition to restrictions that arise due to the assumptions underlying the assessment of risks, there are limitations that arise from how risk assessments are used in the cleanup decision-making process. The discussions of the CERCLA and RCRA processes in previous sections show that risk enters the cleanup decision-making process as a constraint. In the CERCLA process this occurs through the requirement that a cleanup be done if the estimated risk is above $1x10^{-4}$ and that site-specific cleanup decisions be made if the estimated risk is between $1x10^{-4}$ and $1x10^{-6}$. In both RCRA and CERCLA cleanups risk also acts as a constraint via health-based cleanup standards. As discussed above, these standards are often based on the requirements of other public health regulations that were in turn based on generic risk assessments. These requirements act to limit the risk posed by the site under the types of assumptions discussed in the previous section, but they do not give an accurate and complete picture of the risks posed by a site.

Practical Implications of the Limitations in the Use of Risk

Discussions about the limitations in current cleanup practices are not restricted to academic arguments over principles; the current limitations in the use of risk have implications for DOE cleanup decision-making. The most important implication of the limitations in the current use of risk in DOE cleanup decision-making is that the current limitations may make it impossible for DOE to allocate its resources to address the worst risks first. One reason for this is that it may not be possible to distinguish between risks of different magnitudes given the current limitations in the risk assessment methods used in environmental cleanups. For example, if most DOE sites must meet residential-based cleanup standards, does this take money away from those sites that legitimately may be used as residential areas in order to cleanup sites that are unlikely to be used as residential areas to residential standards? As Professor Bruce Ames, of the University of California, Berkeley stated:

> Society must distinguish between significant and trivial risks. Regulating trivial risks … can harm health by diverting resources from programs that could be effective in protecting the health of the public … When money and resources are wasted on trivial problems, society's wealth and hence health is harmed. (quoted in Ghosh and Cox 1995).

If the government had infinite funding to spend on remediation and other programs then arguments such as this would not matter. However, given DOE's restricted budget it is important that funds be used efficiently to address the most significant risks first.

DOE has made a number of attempts at developing methods for addressing the most significant risks first. One example is the Program Optimization System (POS) and it's later revision the Environmental Restoration Priority System (ERPS) (Merkhofer et al. 1988). The purpose of this system was to allocate DOE environmental restoration funding in a way that was based largely on the risk reduction achievable at different sites. The use of this system was discontinued after two fiscal years largely because it was based on risk reduction instead of legal compliance and, as a result, was opposed by regulators and many stakeholder groups (Jenni et al. 1995).

A second, more recent attempt at developing a more risk-informed approach to environmental cleanup was conducted at the Hanford Site. This study developed a cleanup approach for the Hanford Site that (1) protected the public, workers, and the environment, (2) was technically feasible, and (3) could be accomplished within the anticipated funding for the site. However, the recommendations of this study were not implemented, largely because they did not meet the current regulatory requirements (Messer et al. 1995).

There are undoubtedly other examples of DOE attempts to develop site-wide or complex-wide risk-based cleanup strategies, but these two examples demonstrate a critical point. DOE's environmental cleanup activities are regulation-driven, and unless a risk-based approach correlates directly with these regulations it is unlikely that it will be implemented in practice. It is because of this fundamental regulatory constraint that the current limitations in the use of risk in CERCLA and RCRA cleanups should matter to DOE. The current regulatory approach makes limited use of risk assessments that are based on potentially conservative assumptions. Unless DOE can either develop a risk-based cleanup method that fits within the current regulatory framework or obtain the "regulatory relief" needed to implement a risk-based cleanup approach it is unlikely that a fully risk-based approach to DOE cleanups will be implemented.

RECOMMENDATIONS

It is difficult to recommend any specific actions on a problem as large and complex as the effort to improve the role of risk in cleanup decision-making. However, as suggested by the discussion in the previous section, there are a few general areas that DOE should continue to pursue. The first is to quantitatively estimate the implications that changes in the assumptions underlying risk assessments would have on current DOE cleanup efforts. This could take the form of a study similar to that of Viscusi et al. (1997), and a goal could be to determine whether or not changes to the assumptions underlying risk assessments (e.g., residential vs. other land uses, exposure parameter assumptions, etc.) are worth pursuing further. A second general area would be to investigate ways in which the risk-based approaches that have already been developed could be modified to work within the current regulatory framework. The theory and concepts underlying many of these risk-based approaches are strong, and developing new approaches may be an unnecessary duplication of effort if these approaches can be modified to work within the current regulatory framework. The last general area in which DOE could continue to pursue improvements is in negotiating compliance agreements that allow DOE to better deal with the most significant risk to the public and workers first while still complying with current regulations. Most regulators show a willingness to work with DOE to address short-term immediate responses to serious risks; however, there is a sense that any negotiation, regardless of the merit, will lead to "letting DOE off the hook".

CONCLUSIONS

DOE's environmental cleanup effort is a complex activity with long-lasting implications for the nation. Risk does play a role in this effort, but DOE's cleanup decision-making makes only limited use of risk. Under CERCLA, risk enters through the explicit risk assessment and through health-based ARARs. Under RCRA, risk enters through the requirements of other regulations. However, cleanup decisions are based on criteria other than risk to perhaps too large a degree. Even when risk information is used in cleanup decision-making there are limitations in both the process used to assess the risks and in how the risk assessments are used in decision-making. Overall, DOE cleanup decisions are driven mainly by regulations that make limited use of risk assessments based on conservative assumptions. Unless either a risk-based method can be developed that works within the current regulatory framework or "regulatory relief" can be obtained through negotiation it is unlikely that DOE will be able to implement a cleanup program that makes full use of the best risk information available.

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FOOTNOTES

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