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As part of its environmental restoration (ER) program, the Department will be required to assess the impact of its wastes sites and remediation activity on both human health and the environment. The results of ecological risk assessment could play a major role in determining cleanup levels for the Department's ER sites. Environmental regulatory agencies at both the Federal and State level will play a role in establishing procedures for carrying ecological risk assessments and setting cleanup standards.

Attached, for your information, is the report, "State Trends in Ecological Risk Assessment and Standard Setting." The purposes of this report are 1) to identify key State activities and plans related to setting cleanup standards using ecological risk assessment, and 2) to discuss the impacts these actions may have on the Department of Energy's environmental restoration program. The development of State ecologically-based cleanup standards may have a significant impact on the ER program because State standards may, in some cases, be stricter than the human health-based standards that are now employed. Several States have taken initial steps to establish policies and procedures regarding the use of ecological risk assessments.

Should you have questions regarding the content of this report, please refer them to Mr. William E. Fallon, Senior Program Manager (PNL) at 202-646-7787.

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STATE TRENDS IN ECOLOGICAL RISK ASSESSMENT AND STANDARD SETTING

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Prepared for
the U.S. Department of Energy
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SUMMARY

The purposes of this paper are 1) to identify key states' activities and plans related to setting cleanup standards using the ecological risk assessment process, and 2) to discuss the impacts these actions may have on the U.S. Department of Energy's (DOE's) environmental restoration program. This report is prepared as part of a larger task, the purpose of which is to identify and assess state regulatory trends and legal developments that may impact DOE's environmental restoration program. Results of this task are intended to provide DOE with advance notice of potentially significant regulatory developments so as to enhance DOE's ability to influence these developments and to incorporate possible regulatory and policy changes into its planning process.

The development of state ecologically based cleanup standards will likely have a significant impact on DOE's environmental restoration program because state standards may, in some cases, be stricter than the human health-based standards that are now employed at either the state or the federal level. In many cases, state ecologically based cleanup standards may be considered applicable or relevant and appropriate requirements (ARARs) under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the federal facility agreement at each site. Therefore, they will be applied at many DOE environmental restoration sites.

Washington State, acknowledged to be one of the leaders in this area, has promulgated regulations under its new Model Toxics Control Act to set procedures for establishing site-specific cleanup levels. In addition, the Washington State Department of Ecology on October 30, 1991, issued a draft guidance document that describes proposed methods for setting ecologically based standards for site-specific cleanups. California, Minnesota, and New Jersey are also in the process of establishing procedures for conducting ecological risk assessments and setting standards and are actively monitoring progress in Washington for possible application in their states.

Several states indicated they will simply adopt any ecological risk program that may be developed by the U.S. Environmental Protection Agency (EPA). EPA presently is in the very early stages of developing procedures and

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1.0 INTRODUCTION

A number of states are now considering the development of site-specific cleanup standards based upon risk to natural resources and the environment, or ecological risk. These standards, in many cases, may be stricter than standards based upon risk to human health. For example, environmental contamination at many U.S. Department of Energy (DOE) sites may not pose significant threats to human health because of the remote location of these sites. Nevertheless, the same contamination could pose a substantial risk to ecological resources at the site, thereby necessitating a more stringent cleanup than would otherwise be required if human health were the sole concern. These standards are likely to be applied by individual states to DOE environmental restoration activities. If this were to occur on a large scale, the DOE cleanup program could be dramatically impacted.

When remediating hazardous waste sites under its environmental restoration program, DOE is required by the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to comply with applicable or relevant federal or state standards. These standards are known as applicable or relevant and appropriate requirements (ARARs). Traditionally, these standards have been based upon risk to human health and/or technology feasibility. It is possible that state ecological risk assessment and standard setting requirements would be applied as ARARs at many DOE environmental restoration sites that fall under CERCLA jurisdiction.

Because of the potential impact that state ecological risk requirements could have on DOE environmental restoration activities, DOE's Office of Environmental Restoration (EM-43) requested that Pacific Northwest Laboratory (PNL)[a] identify activities by individual states to establish procedures for conducting ecological risk assessments and for setting ecologically based cleanup standards. The information gathered as part of this study will be used by DOE to assist states in developing ecological risk standards.

(a) PNL is operated for the U.S. Department of Energy by Battelle Memorial Institute.

risk assessment and standard setting. Section 4.0 is a discussion of the findings and how they may impact DOE's environmental restoration program. Section 5.0 contains general conclusions and recommendations.

2.0 PRESENT STATUS OF ECOLOGICAL RISK ASSESSMENT METHODS AT THE FEDERAL LEVEL

The EPA is in the very early stages of developing procedures and guidelines for conducting ecological risk assessments. Present plans are to produce four guidance documents over the next 5 years: 1) a summary report on issues in ecological risk assessment, 2) an ecological risk framework document (presently in draft form), 3) a strategic planning document for developing ecological risk guidelines, and 4) a case studies report. Together, these four documents will provide very generic EPA guidance on the conduct of ecological risk assessments, accompanied by case studies.

The risk assessment procedures that will be the product of this process will be simply guidelines. These guidelines will not be directly enforceable by law. Their primary purpose will be to build consensus among the various implementing programs within EPA, such as CERCLA, RCRA corrective actions, the Clean Water Act, and the Safe Drinking Water Act. Accordingly, these EPA guidelines, by themselves, may not be appropriate for direct application by states or by EPA on a CERCLA site-specific basis.

3.0 ECOLOGICAL RISK ACTIVITIES IN KEY STATES

The state officials contacted as part of this study are listed in Appendix A. Although many states have the general authority under state law to set standards to prevent or minimize harm to human health and the environment, only a handful are now actively involved in developing processes for conducting ecological risk assessment and standard setting. Most states still rely strictly on human health-based standards, developed either by the state or by EPA. Many states are informally monitoring the ecological risk programs being developed in other states, such as Washington, and may consider similar actions in the future.

In addition, many state environmental officials said they will simply adopt any ecological risk program that is developed by the EPA. At the present time, however, it appears that EPA may formulate only very generic ecological risk assessment guidance that, by itself, might not be sufficient for these states. This may prove to be significant for DOE because by the time many of these states establish specific ecological risk procedures, DOE will already be many years into its environmental restoration program.

3.1 WASHINGTON STATE

Washington State is viewed as one of the leaders in pursuing a program to establish procedures for evaluating risks to the environment from hazardous waste sites and for developing a methodology for setting site-specific standards. This is especially relevant to DOE because the Hanford Site is located in Washington.

3.1.1 Statutory Basis for Standards Development

In March 1989, the Model Toxics Control Act (MTCA, RCW 1989) went into effect in Washington. This citizen-approved initiative established a comprehensive hazardous waste cleanup program that is similar to the federal CERCLA program. The MTCA mandates that site cleanups protect human health and the environment. Regulations established pursuant to the MTCA (WAC 1991) define

appropriate for the site. In addition, site managers should be able to exercise their professional judgment in applying many aspects of the guidance to site-specific conditions.

The procedures set forth in the guidance document are intended to supplement the methods for establishing site-specific cleanup standards to protect human health. The guidance document states that it is anticipated that human health-based cleanup levels will generally protect ecological receptors, but that this would not be true in all cases. Accordingly, it is expected that in some instances the ecologically based standards for specific sites may be more stringent than the human health-based standards for the same sites.

The MTCA regulation provides three options for establishing site-specific cleanup levels. These methods focus primarily on setting quantitative levels based upon risk to human health, such as cancer risk. The various methods do, however, contain qualitative goals based upon ecological risk. Method A, intended to be used for the least complex sites, utilizes levels set forth in specified tables for contaminants in ground water and soils. These values are derived primarily from human health-based concentrations included in other applicable state and federal laws.

Method B, which will be applied to most sites, utilizes site risk assessments to set cleanup levels so that individual carcinogens will not cause an estimated lifetime cancer risk in excess of 1 in 1,000,000. For non-carcinogens, the cleanup levels are set at concentrations anticipated to result in no acute or chronic toxic effects on human health and the environment. With respect to ecological risk, cleanup levels established under Method B must be no higher than concentrations that are estimated to result in no adverse effects on the protection and propagation of aquatic and terrestrial life.

Method C cleanup levels are similar to those under Method B except that the human health risk attributable to individual carcinogens is reduced to 1 in 100,000. Method C would be used 1) when Method A or B levels are below background concentrations, 2) when the attainment of Method A or B levels would create a greater overall threat to human health and the environment, 3) where it is technically impossible to obtain Method A or B levels, or

conducted to establish environmentally protective cleanup levels, 4) a comparison of these cleanup levels to other relevant criteria, and 5) an analysis of potential cleanup standards established for environmental protection.

3.1.3 Implications of Proposed Washington Guidance on Hanford

The guidance document poses several problems for the Hanford Site and for other DOE sites if adopted. First, the guidance document does not have a clear definition of a site. Although it seems clear that Washington does not intend to define the 560-square-mile Hanford Site as one "site" under the guidance, it is not certain whether a site will be an operable unit (73 at Hanford), an individual waste site (approximately 1100 at Hanford), or a new classification.

The guidance document proposes using an earthworm bioassay, daphnia (water flea) biotoxicity, and the FETAX test for amphibians as the basis for the ecological risk assessments of sites containing hazardous substances. These tests may not be appropriate for an arid site like Hanford because they are for organisms that are not natural inhabitants of the Hanford environment. However, the test organisms all have well-documented biotoxicity tests that can be easily performed in the laboratory. The guidance document also allows for in situ bioassays to be carried out at a site at the discretion of the Ecology site manager, but does not contain any criteria or methodology for determining the appropriate site-specific tests.

A major question relevant to the proposed Washington process of ecological risk assessment is what ecological resources the regulations are intended to protect. For example, is the process intended to protect all ecological resources equally (i.e., keystone species of each affected habitat, functional attributes of the potentially affected ecosystem, or threatened and endangered species)? Furthermore, as presently conceptualized, is the process sufficiently robust to protect those resources? For example, will the results of an ecological risk assessment that considers bald eagles (an endangered species) be accurate and credible given the fact that bald eagles cannot be used as test organisms? (These questions will likely be applicable to most or all of the state and federal ecological risk assessment processes developed.)

recommended bioassays were not appropriate for the ecosystem. There appeared to be a conscious effort by Ecology to consider some of the challenges involved with developing all-encompassing guidance for the different climates and ecosystems across the state. The document allowed for more flexibility, but still suggested specific bioassays for ecological risk site assessment.

In December 1991, a PNL staff member was invited to join the Ecological Advisory Subcommittee of the Washington's MTCA Science Advisory Board. This invitation appeared to address another request made in July by the Hanford representatives. The scientist that was selected was not a participant in the earlier communications with the state. It is believed that the selection was made solely because of his expertise in bioassays, not his connection with the Hanford Site.

During 1992, the Ecological Advisory Subcommittee had two meetings on revising different aspects of the guidance document. The discussions at the subcommittee meetings were not specific to the Hanford Site because the subcommittee's declared focus was how to address the more typical and less complicated hazardous waste sites across all of Washington.

Currently, there are no specific bioassays for arid regions in the guidance document. The goal of some Hanford Site representatives is to be proactive in the development of this guidance document. They would like to propose bioassays that would be appropriate for arid lands.

Ecological risk assessment standards in Washington are still being developed, but the actions taken by the Hanford representatives influenced the process. Early involvement, both formal and informal, by site representatives is important to influence the development of the risk assessment processes in a way that is most relevant for DOE sites. Concerns regarding the management of large and complicated waste sites, such as DOE sites, need to be conveyed early in the process and with as much scientific basis as is available.

ecological risk assessment section of the regulation will have three main parts: Pathway Assessment, Predictive Risk Assessment, and Ecological Impact Analysis. Pathway Assessment, a qualitative approach, and Predictive Risk Assessment, a quantitative approach, are currently very similar to the human health risk assessments. The state plans to write guidance for these two sections of the regulation first, because it wants to make them more specific to ecological risk.

The third section, Ecological Impact Analysis, may include field tests to validate the predictive risk assessment conclusion, specific toxicity studies, or any other necessary site-specific testing needed to validate the ecological risk assessment. The intention of this section is to "ground truth" the predicted ecological risk. The Ecological Impact Analysis section of the regulation is expected to consist almost completely of site-specific requirements; therefore, specific guidance will probably not be written. There is no firm schedule for action on the draft regulation or the writing of the subsequent guidance documents, but they will be subject to public review and comment when initial drafts are completed.

3.2.3 New Jersey

New Jersey is currently working to formulate procedures for developing site-specific ecological risk standards, relying in part on the documents developed by Washington. These standards will be established under the New Jersey Spill Act and will apply to hazardous waste sites if they are more stringent than existing standards. These standards were formally proposed in February 1992. The New Jersey Spill Act has been criticized by environmentalists because it sets two separate levels of cleanup for residential and industrial sites.

3.2.4 Nevada, Ohio, South Carolina, Tennessee, New Mexico, Idaho, Colorado

These states do not have specific plans to set cleanup levels for hazardous waste sites based upon ecological risk. Of the environmental officials interviewed, only those in Nevada thought their state might consider doing so in the near future. Most of the state officials cited lack of resources and expertise as the principal barriers to developing and

4.0 IMPACT ON DOE'S ENVIRONMENTAL RESTORATION PROGRAM

The adoption of requirements for conducting ecological risk assessments and setting ecologically based site-specific standards by states containing major DOE environmental restoration sites is likely to impact substantially DOE's environmental restoration activities. Because ecologically based cleanup standards may in some cases be stricter than standards based strictly on human health risk, the use of ecological standards will, in many instances, increase the cost and time needed for cleaning up specific sites.

4.1 COMPLIANCE IMPACTS

In many cases, state ecological risk assessment requirements and standards may apply to DOE environmental restoration sites primarily indirectly as ARARs under CERCLA. Federal facility agreements clearly anticipate that state standards, such as those pertaining to ecological risk assessment, will be used as ARARs. For example, the Hanford Tri-Party Agreement specifically lists Washington's MTCA as a potential ARAR. In addition, state ecological risk requirements could play a role in decisionmaking regarding RCRA corrective action sites, especially where the state has been delegated authority for this program by EPA.

The EPA is considering the development of ecological risk assessment guidelines. When developed, these guidelines may be applied in states that have not developed their own ecological risk standards or guidelines. For states that have developed their own ecological risk and standard setting process, the issue of which set of guidance to apply to a CERCLA site will likely be the subject of negotiations.

There is no guarantee that state ecological risk procedures and standards will be consistent with those promulgated at the federal level, yet both sets of procedures may be applied at DOE sites. In some cases, potential differences between state and EPA ecological risk requirements could be problematic for DOE. For example, inconsistent requirements could be imposed on

Second, in some cases the standards derived as a result of the ecological risk assessment will be stricter than the human health-based standards. In these instances, the cost of cleanup and the time required for site remediation will likely increase.

Third, many of the specific DOE operable units probably will be exempt from specific state ecological risk assessment requirements because they are industrial sites. These sites would likely be classified as Class 1 sites in Washington, or a similar classification in other states, thereby obviating the need for any intensive ecological assessment. In addition, because of their complexity, many DOE operable units may be subject to the less stringent Washington Method C cleanup levels, or levels derived using similar methods in other states. The use of these classifications may facilitate the use of the most realistic cleanup strategies and save time and money when cleaning up specific sites.

5.0 CONCLUSIONS AND RECOMMENDATIONS

DOE should not view the current relative inactivity by most states regarding ecological risk assessment as an indication that the issue will be unimportant to its environmental restoration program. Quite to the contrary, while most states have not yet taken concrete steps to formulate policies and procedures, there is an undeniable interest in pursuing this issue in the future. It appears that most of the states are now in a "wait and see" position. State action will become much more likely in the event that the current EPA guidance being considered either is delayed or is too generic to meet the needs of individual states.

DOE should actively monitor developments in relevant states regarding ecological risk assessment and standard setting. Early involvement by DOE with the states will help ensure that ecological risk assessment procedures that are most relevant to DOE sites will be developed and implemented. Among other things, DOE should attempt to ensure that any state requirements contain an equivalent of Washington's Class 1 classification and Method C procedures to guarantee maximum flexibility when addressing cleanups at industrial sites.

Especially for large complex DOE sites such as Hanford, DOE will need to recognize that specific areas of ecological concern do not necessarily conform to previously defined operable unit boundaries. For example, at Hanford, certain riparian habitats are likely to include the entire bank of the Columbia River, extending from the 100 Areas in the north to the 300 Area at the southern boundary. DOE will need to ensure that state ecological risk procedures recognize this type of complexity at many of its sites.

There will be a need to integrate the ecological risk requirements of various state and federal environmental statutes. For example, it makes little sense to utilize one ecological risk assessment and standard setting process for a RCRA corrective unit and a different process for an adjacent CERCLA operable unit. This could be a potential problem because RCRA corrective actions will fall largely under the jurisdiction of individual states, thereby directly subject to state ecological risk requirements, while CERCLA sites will be under the direct control of EPA. It is likely that the

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Revised Code of Washington (RCW). 1989. "Model Toxics Control Act." WAC-70.105D, Olympia, Washington.

Washington Administrative Code (WAC). 1991. "The Model Toxics Control Act Cleanup Regulation." WAC-173-340, Olympia, Washington.

APPENDIX A

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APPENDIX A

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