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STATUS OF EXISTING FEDERAL ENVIRONMENTAL RISK-BASED STANDARDS APPLICABLE TO DEPARTMENT OF ENERGY OPERATIONS

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[a] Pacific Northwest Laboratory is operated for the U.S. Department of Energy by Battelle Memorial Institute under Contract DE-AC06-76RLO 1830.

ABSTRACT

When conducting its environmental restoration, waste management, and decontamination and decommissioning activities, the U.S. Department of Energy (DOE) must comply with a myriad of regulatory procedures and environmental standards. An assessment of the status of existing federal standards that may be applied to chemical and radioactive substances on DOE sites found substantial gaps and inconsistencies among the existing standards, and technical issues associated with the application of those standards. Of 271 chemical and radioactive substances found to be important across environmental media at the Hanford, Savannah River, and Oak Ridge Sites, 96 (35%) are unregulated by federal regulations and are not covered by DOE guidelines, 48 (18%) are covered by single federal standards or DOE guidelines, and 127 (47%) are covered by multiple regulations or DOE guidelines. Inconsistencies and technical issues among standards include the promulgation of different standards under different regulations for a given substance in an environmental medium, the application of standards for purposes other than originally intended, and the inability to meet standards because of technical limitations. Given the lack of a complete, consistent set of standards or generic procedures for determining applicable standards, and given the existence of inconsistencies and technical issues among the existing set of standards, DOE may be faced with lengthy negotiations of standards on a case-by-case basis. Such negotiations could result in inconsistent cleanup levels, high costs, potential delays, and missed regulatory milestones. Actions that DOE could take to resolve these issues include working with the regulatory agencies to develop 1) specific risk-based standards and generic procedures for determining risk-based standards for individual contaminants and contaminant mixtures; 2) consistent, accepted methods for assessing cumulative risk to humans for contaminant mixtures; 3) consistent, accepted methods for assessing ecological risk; and 4) methods for assessing and comparing risk to the public from contamination left in place, risk to the public from transportation of contaminated materials, and risks to environmental restoration workers. DOE could also develop or adopt innovative approaches to working with regulators in determining standards, including 1) negotiated rule making among all stakeholder groups, 2) negotiated, time-phasing of activities based on relative risks and performances of existing and future technologies, and 3) reopener conditions where interim solutions are needed but cannot achieve desired levels of protection or standards.

STATUS OF EXISTING FEDERAL ENVIRONMENTAL RISK-BASED STANDARDS APPLICABLE TO DEPARTMENT OF ENERGY OPERATIONS. Bilyard, G.R. and Bischoff, R.J., Pacific Northwest Laboratory; Wallo, A. III, U.S. Department of Energy.[b]

INTRODUCTION

When conducting its environmental restoration, waste management, and decontamination and decommissioning activities, the U.S. Department of Energy (DOE) must comply with a myriad of regulatory procedures and environmental standards. This paper assesses the status of existing federal risk-based standards that may be applied to chemical and radioactive substances on DOE sites. Gaps and inconsistencies among the existing standards and the technical issues associated with the application of those standards are identified. Finally, the implications of the gaps, inconsistencies, and technical issues on DOE operations are discussed, and approaches to resolving the gaps, inconsistencies, and technical issues are identified.

BACKGROUND

DOE owns 45 sites in 26 different states where it currently operates or has operated facilities supporting national security interests. The first site, established in 1942 to support World War II efforts, has operated since 1944. Additional sites were added as the nation's security needs increased. These facilities generated, treated, stored, and disposed of hazardous, radioactive, and mixed wastes. Over 4000 active and inactive waste sites have been identified at DOE facilities nationwide.

During four decades of operations, DOE facilities released chemicals and radioactive substances into the air, surface water, ground water, and soil via trenches, landfills, pipes, and stacks. Accidental spills also occurred. As a result, many cubic miles of soils and ground water at these sites became contaminated with radioactive, hazardous, and mixed wastes. These

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contaminated media will require remediation under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 [as reauthorized in 1986 by the Superfund Amendments and Reauthorization Act (SARA)], or under the corrective action requirements of the Resource Conservation and Recovery Act (RCRA) of 1976 (as amended). DOE's sites also contain numerous old production reactors and other facilities that are no longer operable. These facilities must be decontaminated and decommissioned in accordance with RCRA and other statutes. All operating facilities must also have, and be in compliance with, RCRA operating permits from the U.S. Environmental Protection Agency (EPA) or from the state regulatory agency to which RCRA permitting responsibility has been delegated. Other environmental statutes that mandate regulations applicable to DOE's operations include the Clean Air Act (CAA); the Clean Water Act (CWA); the Safe Drinking Water Act (SDWA); the Atomic Energy Act (AEA); the Toxic Substances Control Act (TSCA); the Nuclear Waste Policy Act (NWPA); and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Several DOE Orders and Executive Orders also address environmental regulatory issues.

APPROACH

This paper identifies legally binding standards and DOE guidelines that could be applicable to important contaminants on three representative DOE sites, thereby identifying the gaps, inconsistencies, and technical issues associated with the application of those standards. This approach is not intended to identify all chemical and radioactive substances across DOE sites. Rather, it uses three major sites as representative test cases by which gaps, inconsistencies, and major technical issues associated with standards can be identified. This report does not consider non-legally-binding criteria, advisories, guidance, or proposed standards that have been developed by agencies other than DOE, although the use of such criteria and standards is often required by regulatory agencies on a case-by-case basis.

DOE's Hanford, Savannah River, and Oak Ridge Sites were chosen for review because among them, a majority of the substances important to the DOE mission should be identified. Information sources consisted of annual site

environmental reports and associated documents. Substances were considered to be important at the sites if they were present in excess of specified federal regulations or standards, if they were unregulated substances, or if large inventories of the substance exist on the site.

Potentially applicable standards were identified from DOE Orders, Executive Orders, and regulations promulgated pursuant to the CAA, CWA, CERCLA, FIFRA, AEA, NWPA, RCRA, SDWA, and TSCA. Potentially applicable quantitative standards were most often risk-based or technology-based. Risk-based standards are set based the possibility of suffering harm from a substance or action, whereas technology-based standards are set based on the performance level of the technology under consideration. Other technical bases (e.g., welfare-based) that were identified are typically combinations of risk-based and technology-based standards.

RESULTS

The types and distribution of contaminants on DOE sites are discussed briefly below. Also discussed are the gaps, inconsistencies, and technical issues associated with the standards that could potentially apply to those contaminants.

CONTAMINANT CHARACTERIZATION AND DISTRIBUTION

A total of 271 chemical and radioactive substances were determined to be important at Hanford, Savannah River, and Oak Ridge Sites. These included halogenated aromatic compounds (N = 6), halogenated aliphatic compounds (N = 16), halogenated pesticides and herbicides (N = 6), nonhalogenated nitrated compounds (N = 1), nonhalogenated simple aromatic compounds (N = 4), nonhalogenated polynuclear aromatic compounds (N = 5), nonhalogenated organic compounds with polar groups (N = 53), nonpolar aliphatic compounds (N = 4), metals and metal compounds (N = 77), inorganic nonmetals and nonmetal compounds (N = 34), and radionuclides (N = 65). Among the 206 chemical substances, 19 were detected in air, 48 in surface water, 136 in ground water, 43 in soil, 2 in flora and fauna, and 134 in tank wastes. Among the 65

radioactive substances, 21 were detected in air, 8 in surface water, 17 in ground water, 31 in soil, 14 in flora and fauna, and 35 in tank wastes.

GAPS AMONG STANDARDS

Of the 271 chemical and radioactive substances, 96 (35%) are unregulated by federal regulations and are not covered by DOE guidelines, 48 (18%) are covered by single federal standards or DOE guidelines, and 127 (47%) are covered by multiple regulations or DOE guidelines. If only chemical substances are considered, excluding radionuclides, the percentages change somewhat. Of the 206 chemical substances, 94 (45%) are unregulated, 47 (23%) are regulated by single standards, and 65 (32%) are regulated by multiple standards. No specific standards were identified for 2 (3%) of the 65 radionuclides, although the general exposure guidelines listed in DOE Order 5400.5 apply to all radionuclides. Only one radionuclide (2%) is regulated by a single standard or guideline, and the remaining 62 (95%) are regulated by multiple standards or guidelines. Most standards for radioactive substances are found in DOE Orders.

INCONSISTENCIES AND TECHNICAL ISSUES

Inconsistencies and technical issues among standards and regulations appear primarily in two forms. First, different standards may be promulgated under different regulations for a given substance in a specific environmental medium. Second, technical issues may arise during the execution of activities intended to comply with those standards. Such technical issues include the application of standards for purposes other than originally intended, and the inability to meet standards because of technical limitations.

Cross-cutting Standards Issues

The major cross-cutting issue that must be considered is the evaluation of cumulative risk. Under many of the above regulations, contaminants have been assigned standards based on their specific risk potentials. This risk value for carcinogens is typically selected in the range of 10^{-4} to 10^{-6} risk of excess cancer deaths. When organisms are exposed to mixtures of multiple

contaminants, the actual risk is determined by the degree to which the effects of those contaminants are additive, antagonistic, or synergistic. At present, however, very limited information exists regarding the types and magnitudes of interactive effects that can be expected under various contaminant mixtures, environmental conditions, and types of receptors. The available limited information precludes the development of consistent, universally accepted procedures for evaluating the cumulative risk of all substances in a sample.

A related issue is the lack of procedures for assessing risk from radioactive mixed wastes. Historically, hazardous and radioactive wastes have been regulated separately, with mixed waste being treated as one or the other type. Despite many attempts to approach the issue of combined risks of mixed waste, none have been successful.

Inconsistencies between CWA Water Quality Criteria and SDWA Maximum Contaminant Levels

In some cases, water quality criteria for water and fish ingestion promulgated pursuant to the Clean Water Act and Maximum Contaminant Levels (MCLs) promulgated pursuant to the SDWA afford different levels of protection for the same substances because of different assumptions regarding exposure and dose rates. Because these standards and criteria potentially regulate substances in the same media, the application of one or the other standards may result in different levels of protection. Inconsistencies between criteria for water and fish ingestion and MCLs exist for six halogenated aliphatic compounds, three halogenated pesticides and herbicides, and two metals and metal compounds.

Inconsistencies within Clean Water Act Standards

Water quality criteria are non-enforceable, risk-based guidelines that are intended to protect aquatic life and human health. They are used in determining appropriate limits for discharges of effluents to surface waters. Water quality criteria define acceptable pollutant concentrations in receiving water, not discharges, and are adaptable to a wide variety of circumstances. These criteria have generally been used as originally intended to regulate point source discharges of pollutants to surface waters. Occasionally, water

quality criteria are used as "applicable or relevant and appropriate requirements" (ARARs) under CERCLA remediation activities when no other standards are applicable.[1]

Inconsistencies within CERCLA Standards

A major technical feasibility problem encountered during CERCLA remediation efforts is the treatability of ground water. During CERCLA ground water remediation efforts, MCLs are usually set as the initial cleanup goals, pending a review of the feasibility of achieving those goals during the remedial action process. The remediation technology used to date consists of pumping and treating ground water. A study involving 19 sites where pumping and treating has been conducted for up to 10 years[2] found that the method removes substantial amounts of the contaminants and that the site-specific "cleanup targets" were generally achieved. However, standards that have been promulgated under the SDWA have yet to be achieved in most cases. Two major factors that influenced this inability to achieve SDWA standards are the technical limitations involved in removing all of the water and the adsorption/desorption of contaminants to the soil matrix.

Inconsistencies within Radiation Protection Standards

Two sets of standards promulgated by EPA pursuant to the AEA and the NWPA are intended as radiation protection programs for specific sources of radioactivity: 40 CFR 191 ("Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes") and 40 CFR 192 ("Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings"). Unlike many of EPA's other regulations, these two regulations set standards based on an optimized cost/benefit analysis of existing technology rather than on risk. The cost/benefit approach is inconsistent with the non-radionuclide regulations promulgated by EPA, which are at least partly risk-based.

The major inconsistency among radiation protection standards is that the older standards, 40 CFR 141, 40 CFR 190, 40 CFR 191, 40 CFR 192, 10 CFR 60, and 10 CFR 72, are based upon the dosimetry system found in ICRP Publication 2[3], published in 1959, whereas the newer standards and guidelines, 40 CFR 61,

DOE Order 5400.5, DOE Order 5480.11, and revised 10 CFR 20 are based on the dosimetry system in ICRP Publications 26 and 30.[4,5] Standards based on the old system are inconsistent with current approaches to radiation protection and are not directly comparable. For example, a 25-mrem whole body dose under the old ICRP system is an actual dose. Under the new system, a 25-mrem effective dose equivalent is a sum of the different dose terms for all radiated organs.

Inconsistencies within RCRA Standards

RCRA governs the management of solid waste. The major inconsistency within RCRA arises because solid wastes are classified within specific hazardous waste codes based on the source of the waste rather than on its chemical composition. This method of classification is not entirely consistent with the goal of treating specific wastes based on their characteristics.

Inconsistencies within SDWA Standards

The SDWA mandates the creation of primary and secondary standards to regulate the quality of water available to the public through community and non-community water systems. The primary standards, MCLs, are enforceable standards for specific contaminants that EPA has determined can adversely affect human health. They are set at levels that will protect human health, considering available technologies and cost. Because MCLs are set at levels that consider available technologies and costs, MCLs for different contaminants afford different levels of protectiveness for human health.

Although MCLs were promulgated as standards for drinking water at the tap, the EPA considers them as potential ARARs for CERCLA actions. Specifically, EPA[1] considers them to be ARARs for *in situ* cleanup of surface water or ground water that may be used for drinking water. MCLs may be conservative cleanup standards in CERCLA actions in cases where the surface waters or ground waters are treated before reaching the tap. Treatment may remove additional quantities of the target contaminants, such that levels below the MCLs are achieved. However, in cases where multiple contaminants exist in the water to be remediated, or multiple pathways for exposure result

in extraordinary risks to the human population, standards more stringent than MCLs may be needed and applied.

Inconsistencies within DOE Standards

DOE Orders provide standards that are subject-specific. In general, DOE Orders are complementary to and consistent with federal regulations. The only possible exception is DOE drinking water systems; in this instance, it is not clear whether the SDWA, DOE Orders, or both, apply.

DISCUSSION AND CONCLUSIONS

The cross-match between existing federal risk-based standards and chemical and radioactive substances on three major DOE sites demonstrates that major gaps exist among standards for substances that are important to DOE. In the absence of a complete set of standards, regulatory agencies will likely establish or negotiate applicable standards on a case-by-case basis, and in some cases elevate advisories and guidelines to legally enforceable status. Such negotiations could be lengthy and costly when contaminant mixtures are involved because of the lack of consistent, accepted approaches to deriving standards for mixtures. They are also likely to be lengthy and costly when assessments of tradeoffs among risks to the public near the site, the public along transportation corridors, and to environmental restoration workers are needed. While the case-by-case negotiation approach is feasible, it does not embody the degree of standardization that is needed to effectively streamline environmental restoration, waste management, and decontamination and decommissioning activities. Standardization and streamlining of DOE's environmental restoration and waste management activities would increase the cost-effectiveness of those activities, help ensure a consistent approach to determining "how clean is clean", and help ensure that all necessary activities are completed within the desired 30-year time frame.

The EPA is now developing additional risk-based standards that will supplement those already promulgated. However, the number of such standards now being developed will not be sufficient to generate a reasonably complete set of standards within the next few years. Hence, DOE must decide how it can

best fulfill its need for risk-based standards across its sites nationwide. Available alternatives include:

- no action, allowing standards to be decided or negotiated on a case-by-case basis between DOE and regulatory agencies

- the development of risk-based standards for individual substances in media where such standards are needed

- the establishment of generic procedures for developing standards that can be applied across DOE sites and facilities.

Combinations of these approaches are also possible.

None of these approaches will be without cost to DOE. Although the no-action approach will require minimal initial expenditures by DOE, it will require extensive negotiations with numerous regulatory agencies to determine applicable standards on a case-by-case basis. Such an approach could result in greatly varying levels of protectiveness and expenditures because DOE sites and facilities will be required to apply different standards to similar environmental restoration and waste management problems.

Past EPA experience indicates that the development of risk-based standards for individual substances in specific media requires extensive resources and long timelines. Among the three options listed above, this option is probably the most resource-intensive and probably requires the longest timeline to execute. It is likely that the time required to develop specific standards will far exceed DOE's 30-year goal for environmental restoration. Such standards are very defensible, however, because their degree of specificity (i.e., media and contaminants) is high and because they are supported by extensive research and development efforts.

The option of establishing generic procedures for developing standards that can be applied across DOE sites and facilities will require initial expenditures of research and development resources, although at much lower

levels than the second option. The greater applicability of generic procedures for developing standards is achieved at the expense of some technical defensibility. When developing generic procedures, it is difficult to anticipate all of the combinations of substances and environmental conditions under which generic procedures will be applied. Hence, it is likely that some technical difficulties will be encountered when applying generic procedures for developing standards, and that some applications of generic procedures may be inappropriate or difficult to defend.

Among the standards development needs, the estimation of risk from exposure to mixtures of contaminants is probably the most difficult. The effect of exposure to multiple contaminants can be additive, antagonistic, or synergistic, depending on the specific contaminants being considered and on the receptor (e.g., humans or species of animals or plants). In many cases, not enough is known about the types and magnitudes of the effects that are likely to occur for specific chemical mixtures under specific environmental circumstances. Hence, accepted procedures for estimating such risks are typically lacking. Because of the difficult technical problems associated with the assessment of risk from contaminant mixtures and the prevalence of chemical contaminants and radioactive mixed wastes on DOE sites, DOE should place high priority on the development of consistent methods for assessing risks to contaminant mixtures. High priority should also be placed on the development of consistent methods for assessing and comparing risks to the public from contamination left in place, risks to the public from the transportation of waste materials, and risks to environmental restoration workers. Such comparisons will be needed in the risk management decision process.

In addition to filling gaps among existing standards, DOE will also need to resolve or reach agreement on appropriate actions in cases where inconsistencies and technical issues exist. Major technical issues include the appropriateness of applying standards for purposes otner than they were originally intended, the inability (in some cases) of existing technologies to achieve regulatory compliance, and differences in the technical bases for related or similar standards. Resolution of these inconsistencies will help

ensure that levels of protectiveness are directly comparable among standards, and that non-compliance and incurring unacceptably high costs during the execution of environmental restoration, waste management, and decontamination and decommissioning activities are avoided.

An additional technical issue that does not yet greatly affect DOE's environmental restoration and waste management activities, but that may in the future, is ecological risk. Recently, the Science Advisory Board (SAB) of EPA[6] recommended that "EPA should attach as much importance to reducing ecological risk as it does to human health risk." This recommendation is based on the recognition that "productive natural ecosystems are essential to human health and to sustainable, long-term economic growth" and that "natural ecosystems are valuable in their own right." Although most federally promulgated risk-based standards protect human health, some have been promulgated to protect living resources. Because exposure scenarios for toxic substances differ between humans and living resources, and because degrees of toxicity for individual substances differ between humans and living resources, protection of human health through the application of risk-based standards cannot be assumed to afford an adequate level of protection to living resources. The EPA is presently in the initial stages of developing procedures for assessing ecological risk. Initial efforts have been focussed on the extrapolation of the single species human health risk assessment model to multispecies ecological systems. This extrapolation is proving to be a challenging task in which the DOE, through cooperative efforts with EPA, could greatly contribute to the development of ecological risk assessment procedures and standards.

In its development of risk-based standards and risk assessment procedures, DOE should establish cooperative working relationships with the major responsible regulatory agencies. If working relationships are not formed, DOE may find that the responsible agencies are reluctant to accept the standards development procedures that it establishes. Moreover, good working relationships will help ensure that DOE is not duplicating standards development activities of other agencies.

DOE may also work with other agencies to develop new and innovative approaches to setting standards and ensuring regulatory compliance, particularly where existing technologies are not capable of achieving existing standards. Such approaches could include negotiated rulemaking among all stakeholder groups, time-phasing of cleanup activities based on relative risks and the performances of existing and expected future technologies, and reopener conditions where interim solutions are needed but cannot achieve the desired cleanup or protection level. The granting of variances (especially for innovative technologies) and agreement through mediation or arbitration may also be used where no viable or expedient means of achieving compliance is, or likely will be, available in the near future.

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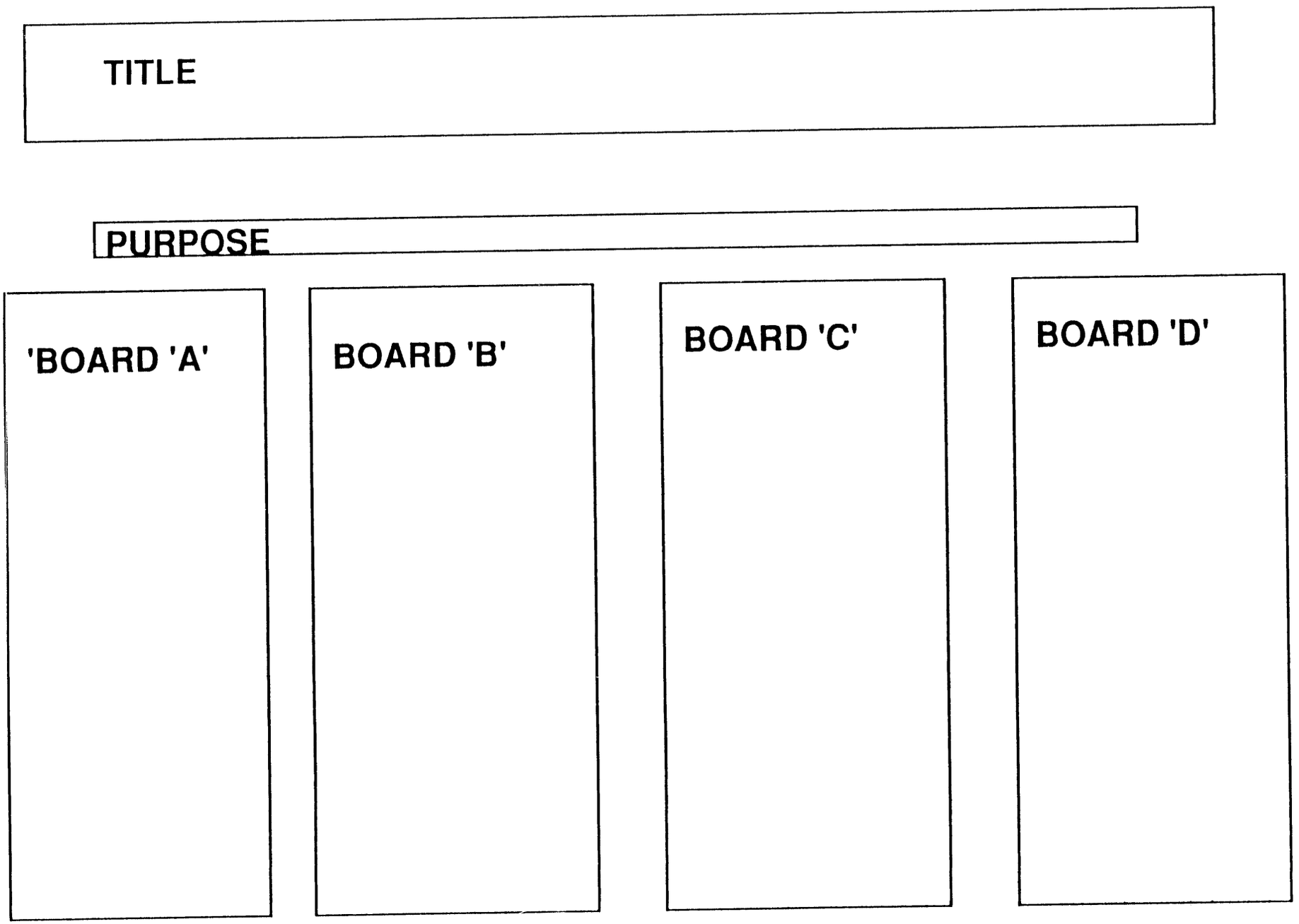
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STATUS OF EXISTING FEDERAL ENVIRONMENTAL RISK-BASED STANDARDS APPLICABLE TO DEPARTMENT OF ENERGY OPERATIONS

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Purpose: **Assess the status of federal environmental standards to provide a baseline for future standards development activities**

APPLICABLE STANDARDS

Federal environmental standards are set forth under:

- Clean Air Act
- Clean Water Act
- Comprehensive Environmental Response, Compensation, and Liability Act
- Resource Conservation and Recovery Act
- Safe Drinking Water Act
- Nuclear Waste Policy Act
- Atomic Energy Act
- Others
- DOE Orders

Various standards are applicable to environmental restoration and waste management activities.

Nearly all standards are applicable to single substances, not to mixtures of substances.

Standards may be:

- Risk-based
- Technology-based
- Combination of bases.

Most standards protect human health; some protect living resources.

U.S. Environmental Protection Agency (EPA) is increasingly emphasizing use of risk-based standards in preference to technology-based standards.

The EPA is increasingly emphasizing the protection of living resources through the management of ecological risk.

STATUS OF STANDARDS

Preliminary inventory of substances important at Hanford, Savannah River, and Oak Ridge found:

- 206 chemical substances
- 65 radioactive substances

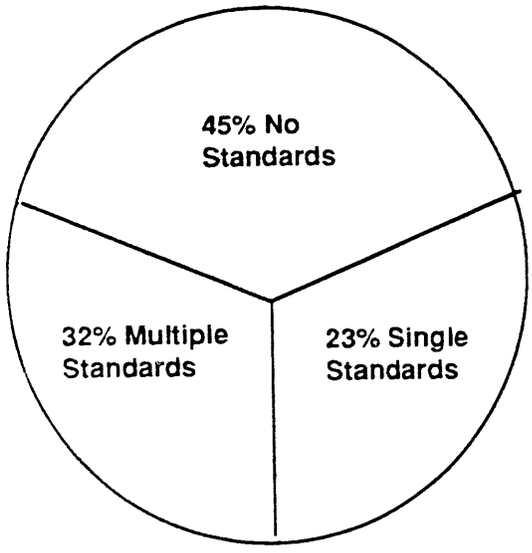
Distribution of substances by medium:

Medium	Air	Surface Water	Ground Water	Soil	Flora/ Fauna	Tank Wastes
Chemical Substances	19	48	136	43	2	134
Radioactive Substances	21	8	17	31	14	35

Gaps among existing potentially applicable or relevant standards:

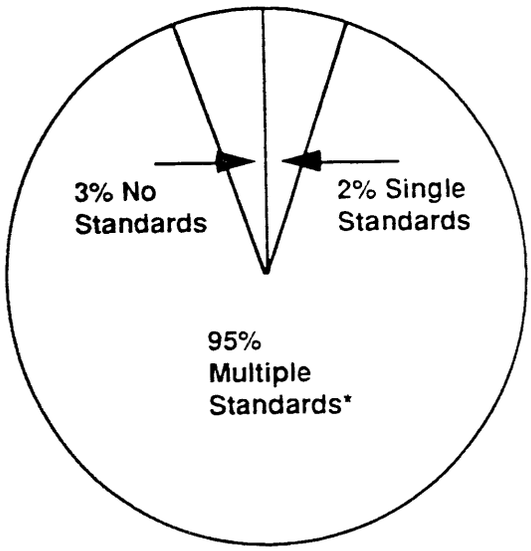
Chemical Substances

(N=206)



Radioactive Substances

(N=65)



* Primarily Standards in DOE Orders

Inconsistencies among potentially applicable or relevant standards:

- Standards for a substance may differ among regulations
- Technical bases used to set standards may also differ among regulations
- Some standards are difficult or impossible to achieve given existing technologies
- Some standards can be achieved only at unacceptably high financial costs or health risks.

IMPLICATIONS FOR DEPARTMENT OF ENERGY

The lack of a complete, consistent set of standards across all media can result in:

- Negotiations of standards on a case-by-case basis
- Potential delays and high costs
- Elevation of advisories and guidelines to legally enforceable status.

The lack of consistent, accepted approaches to deriving standards for single contaminants and contaminant mixtures can also result in:

- Negotiations of standards on a case-by-case basis
- Potential delays and higher costs.

The lack of consistent, accepted methods for assessing cumulative risk from contaminant mixtures (e.g., chemical mixtures, radioactive mixed wastes) further complicates the standards-setting process.

Inconsistencies among standards may preclude direct comparisons of levels of protectiveness.

Inconsistencies among standards may also result in non-compliance and/or unacceptably high costs.

APPROACHES TO RESOLUTION

DOE works with federal regulatory agencies to resolve inconsistencies among standards.

DOE develops specific risk-based standards to fill gaps where it has authority (e.g., radiation protection standards).

DOE works with EPA and key states to develop generic approaches for setting risk-based standards that can be applied to:

- Individual contaminants
- Mixtures of chemical contaminants
- Radioactive mixed wastes.

DOE works with other agencies in the development of consistent, accepted methods for assessing:

- Cumulative risk to humans for contaminant mixtures
- Ecological risk for individual contaminants and contaminant mixtures.

Cumulative risks associated with all environmental restoration activities (i.e., general public, occupational, transportation).

DOE develops new, innovative approaches to working with regulators in determining standards:

- Negotiated rule making among all stakeholder groups
- Negotiated, time-phasing of activities based on relative risks and performances of existing and future technologies
- Re-opener conditions where interim solutions are needed but cannot achieve desired levels of protection or standards.

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