

April 19, 1996

EPA RCRA Docket (5305W)
401 M Street, S.W.
Washington, D.C. 20460

Docket Number F-95-WHWP-FFFFF

Dear Sir or Madam:

Re: 60 FR 66344, "Hazardous Waste Management System: Identification and Listing of Hazardous Waste: Hazardous Waste Identification Rule (HWIR)"

On December 21, 1995, the Environmental Protection Agency (EPA) published a proposed rule that would amend the hazardous waste identification regulations under the Resource Conservation and Recovery Act (RCRA). This notice is referred to as the Hazardous Waste Identification Rule (HWIR), and proposes to establish constituent-specific exit levels for low-risk solid wastes that are designated as hazardous because they are listed, or have been mixed with, derived from, or contain listed hazardous wastes. The notice also proposes (among other things) to modify some of the land disposal restriction (LDR) numerical treatment standards. In addition, the notice requests comments on several options for conditional exemption from RCRA Subtitle C management.

The Department of Energy (DOE) appreciates the opportunity to raise concerns and provide input in response to the proposed HWIR. The enclosed comments refer to potential regulatory approaches and topics covered by the proposed rule, and are presented for your consideration in finalizing changes to the RCRA hazardous waste identification regulations. For your information, these comments combine the viewpoints and concerns identified by DOE Field Organizations and Program Offices.

DOE supports the Agency's efforts to establish risk-based exit levels for listed hazardous wastes regulated under Subtitle C of RCRA. Many of the enclosed Departmental comments address specific issues and concerns related to the development of HWIR exit levels and LDR minimize threat levels, the multipathway risk assessment used to establish many of the proposed exit levels, and the proposed implementation requirements.

Additionally, the enclosed comments discuss the Department's primary proposals in response to the HWIR notice, which relate to the management of certain mixed wastes. Specifically, DOE requests that EPA adopt regulations that conditionally exclude immobilized mixed waste debris and vitrified mixed waste from RCRA Subtitle C regulation. DOE forwarded two technical proposals to EPA in July and October 1995, which demonstrate that managing immobilized low-level mixed waste debris and vitrified mixed waste after treatment as non-RCRA wastes under Atomic Energy Act (AEA) requirements is protective of human health and the environment. The enclosed comments also request that EPA consider developing testing requirements

applicable for demonstrating whether mixed wastes have met HWIR exemption criteria, and express the Department's interest to work with EPA and authorized States on such a testing program.

The enclosed comments have been divided into two sections: general and specific. The general comments discuss the primary DOE proposals and positions in response to the proposed HWIR, and address broad concerns. The specific comments relate directly to potential regulatory approaches and issues raised in particular sections of the proposed HWIR. For clarity, each specific comment is preceded by a reference to the section of the proposed rule to which it applies and a brief description in bold-face type of the issue within that section to which DOE's comment is directed.

Sincerely,

Raymond P. Berube
Deputy Assistant Secretary
for Environment
Environment, Safety and Health

Enclosure

cc: M. Shapiro, EPA, OSW
D. Bussard, EPA, OSW
G. Helms, EPA, OSW

UNITED STATES DEPARTMENT OF ENERGY
Comments On HAZARDOUS WASTE MANAGEMENT SYSTEM:
IDENTIFICATION AND LISTING OF HAZARDOUS WASTE:
HAZARDOUS WASTE IDENTIFICATION RULE (HWIR)

PROPOSED RULE (60 FR 66344; December 21, 1995)

GENERAL COMMENTS

- 1. The Department of Energy (DOE) is eager to work with the Environmental Protection Agency (EPA) and the States in the development of exclusions and associated implementation mechanisms appropriate for *mixed waste*, under the Hazardous Waste Identification Rule (HWIR). DOE wishes to take this opportunity to clarify its position and discuss the Department's primary proposals in response to the proposed HWIR, which specifically pertain to mixed wastes.**

DOE is responsible for the largest universe of mixed waste in the United States, approximately 940,000 cubic meters (current inventory plus projected generation to the year 2070) according to information being developed for the 1996 Baseline Environmental Management Report (BEMR)¹. Most of DOE's mixed waste will be treated to EPA treatment standards and managed in accordance with the Site Treatment Plans and compliance orders under the Federal Facility Compliance Act (FFCA), unless it is already in compliance with the Land Disposal Restriction (LDR) program. Treatment of mixed wastes, like hazardous wastes, involves a process or a series of processes which result in the destruction of the hazardous constituents and/or the reduction of availability of the hazardous constituents to the environment. From a risk perspective, managing certain *treated* mixed wastes in Resource Conservation and Recovery Act (RCRA) storage and disposal units (specifically those mixed wastes that contain listed hazardous wastes, or that are "mixed with" or "derived from" listed hazardous wastes, and pose low risks from the hazardous component) may not provide additional protection to human health and the environment beyond that afforded by managing these wastes in storage and disposal units subject to Atomic Energy Act (AEA) control. Similarly, "*as generated*" low-risk listed mixed wastes (i.e., mixed wastes containing very low or undetectable concentrations of hazardous constituents and which meet EPA treatment standards) that are managed in AEA storage and disposal units may not realize any significant additional protection of human health and the environment through the application of RCRA requirements.

To be fiscally responsible, DOE believes it should pursue alternatives to the current compliance

¹ This total volume includes mixed wastes from operations, environmental restoration, and decontamination and decommissioning activities that is or is expected to be managed by the Department of Energy's Office of Waste Management.

regime for mixed wastes that pose low risks from the hazardous component, without compromising protection of human health and the environment. DOE believes that a contingent management approach which sets alternative exit levels for such low-risk mixed wastes should be examined. However, DOE wants to clarify that it has not forwarded to EPA or the States information to support a proposal of establishing exit levels for mixed wastes at a chemical toxicity estimated at 10^{-4} cancer risk and Hazard Quotient (HQ) of 1 (modeled at an uncontrolled site) as proposed by EPA in 60 FR 66400, December 21, 1995. DOE instead would like to explore this option and others, and work with the EPA and States to develop a contingent management option for low-risk mixed wastes on a separate schedule from the two DOE proposals which support conditional exclusions for immobilized mixed waste debris and vitrified mixed wastes from RCRA. DOE supports allowing mixed wastes which contain listed hazardous wastes (or are "mixed with" or "derived from" listed hazardous wastes) and meet exit levels and other HWIR requirements to exit RCRA, as would be allowed for other listed hazardous wastes under the HWIR final rule (as indicated by EPA in the preamble; 60 FR 66400, col. 2).

In addition to supporting the general concept of HWIR and its applicability to mixed wastes, DOE forwarded two technical proposals to EPA in July and October 1995, which demonstrate that managing immobilized low-level mixed waste debris and vitrified mixed wastes after treatment as non-RCRA wastes under AEA requirements is protective of human health and the environment. Additional information on these two proposals is offered below under General Comments 2 and 3. DOE has developed preliminary cost information relative to these proposals. This information demonstrates that managing immobilized mixed waste debris and vitrified mixed wastes in AEA disposal facilities, as opposed to RCRA disposal facilities, will provide significant cost savings and is protective of human health and the environment. These estimates are being refined and will be provided to EPA and the States. As a result of these DOE proposals, limited resources that are currently devoted to managing immobilized mixed debris and vitrified mixed wastes pursuant to RCRA Subtitle C could be diverted to activities that address higher risks to human health and the environment. In addition, low-level mixed debris and low-level vitrified mixed wastes that would potentially be excluded under these proposals could more readily be removed from storage and disposed of as low-level wastes (i.e., rather than mixed wastes) because disposal capacity is currently available for these types of wastes.

DOE is aware, as EPA has recognized in the proposed HWIR (60 FR 66400, col. 3), and from discussions with States that host DOE facilities, that several States are concerned with the potential lack of State oversight of mixed wastes after the wastes meeting specified criteria exit RCRA (under HWIR). Most of the States' concerns center around their ability to adequately regulate mixed wastes exiting HWIR under delegated RCRA programs and under the FFCA. DOE understands these concerns and also recognizes that RCRA authorized States have the option of whether or not to adopt a Federal exclusion or conditional exemption under HWIR into their authorized RCRA program. Thus, DOE believes that any regulatory approach for allowing mixed waste to exit RCRA could only be successful with State involvement. DOE is eager to work with EPA and the States on appropriate implementation mechanisms to ensure the State's

role in determining the conditions for a mixed waste exclusion. If DOE fails to meet any of the conditions established for an exclusion, State or EPA enforcement under RCRA could be triggered. Certain implementation mechanisms, such as treatment facility permits, a memorandum of agreement between DOE and the State, or regulatory requirements tied to an exclusion, could be employed to ensure that the conditions of the exclusion are being met. Finally, DOE wants to assure States that it intends to meet its obligations under the FFCA, RCRA and other applicable State laws prior to or as a component of a conditional exclusion for mixed wastes.

In a March 7, 1996 letter from the State of Nevada Office of the Attorney General, co-signed by seventeen other State Attorney Generals, to Carol M. Browner of EPA, it was expressed that the proposed rule "would have the effect of exempting most of DOE's mixed waste" from RCRA. As discussed above, DOE is only currently pursuing exclusions for immobilized mixed debris and vitrified mixed wastes. Immobilized mixed debris that would exit under these proposals is expected to account for approximately 2% of the DOE's mixed waste inventory and vitrified mixed waste is expected to account for approximately 29% (current inventory plus generation to the year 2070). These estimates were obtained from information provided by the sites for the Department's 1996 Baseline Environmental Management Report. An estimate relative to how much mixed waste would potentially exit RCRA under a contingent management approach (i.e., under alternative risk-based exit levels) is not included because the specific elements of a mixed waste contingent management option(s) and the associated technical data to support such an approach have not been developed. Therefore, DOE is not able to precisely estimate how much waste would exit under such a proposal.

In the March letter, the States referenced a DOE estimate that approximately 96% of DOE mixed waste would exit RCRA. It appears that the 96% estimate was derived by taking the sum of numbers presented by DOE to the States in October, 1995 (i.e., the sum of 66% for vitrified mixed waste, 4% for immobilized mixed debris and 26% under a contingent management approach).² These earlier estimates were very preliminary and not originally intended to be additive. More precise and detailed waste volume estimates for how much immobilized mixed debris and vitrified mixed wastes would be excluded from RCRA regulation if the two DOE proposals are implemented have been developed from information (provided by DOE sites) included in the 1996 Baseline Environmental Management Report. These updated waste volume estimates will be forwarded to EPA and the States in the near future.

In the March 7, 1996 letter, the States mention that they believe DOE's mixed waste proposals conflict with the recommendations concerning the end of DOE self regulation from the December 1995 Final Report of the Advisory Committee on External Regulation of the Department of Energy Nuclear Safety, entitled Improving Regulation of Safety at DOE Nuclear

² Note that the volumes have decreased for vitrified mixed waste from 66% (the earlier estimate) to 29% (the current estimate) mainly because the revised volume estimate consists of high-level wastes that are known to contain listed hazardous wastes and that are currently planned to be vitrified (and does not include characteristic-only high-level wastes which were contained in the previous estimate).

Facilities. DOE believes that the two proposals discussed in more detail below (under General Comments 2 and 3) could be implemented consistently with recommendations in the Final Report of the Advisory Committee, and provide opportunities for moving forward on certain recommendations. For example, such conditional exclusions could serve to integrate protections found under both the nuclear and environmental statutes, and provide flexibility for appropriate State oversight.

The States also suggest in the letter that DOE's proposals were not "sufficiently supported by available data to form a proper basis for informed decision making." DOE has provided extensive technical data to EPA and the States through the National Governors' Association to support conditional exclusions for immobilized mixed debris and vitrified mixed wastes. The technical data packages are also available to the public in the proposed HWIR rulemaking docket. In addition, briefings on the DOE's immobilized mixed debris and vitrified mixed waste proposals have been provided to EPA and State representatives in various forums. To date, the only outstanding pieces of information requested from DOE by the States is the potential cost savings information associated with the proposals, and updated information on waste volumes that would potentially exit RCRA. It is expected that EPA will publish a supplemental notice to the proposed HWIR (as indicated on 60 FR 66401, col. 1) which will address the DOE proposals in more detail, based on technical data and implementation approaches already submitted to EPA (as well as any subsequent information requested from DOE by EPA and the States).

2. **DOE requests that EPA adopt regulations excluding mixed waste debris from RCRA Subtitle C regulation, provided that: (1) such debris has been treated by immobilization; (2) the immobilized debris will be managed in disposal facilities that conform with controls and conditions put forth pursuant to the Atomic Energy Act; and (3) DOE has demonstrated to EPA or the authorized States that the above conditions and associated performance requirements have been met.**

Background

As part of the Phase I Land Disposal Restrictions (LDR) rule, EPA promulgated treatment standards for hazardous debris prohibited from land disposal (i.e., the Hazardous Debris Final Rule). Under this rule, hazardous debris treated using an extraction or destruction technology are excluded from RCRA Subtitle C control, provided the treated debris meets specified performance standards (in 40 CFR 268.45, Table 1) and does not exhibit a characteristic of hazardous waste [57 FR 37194, 37222 (08/18/92)].

At the time the Hazardous Debris Final Rule was promulgated, EPA chose not to extend the exclusion of hazardous debris from Subtitle C regulation to debris treated by an immobilization technology. The rationale for this was that insufficient data were available to demonstrate that, absent subsequent Subtitle C management, hazardous contaminants would not migrate from immobilized debris at levels that could pose a hazard to human health and the environment [57 FR 37194, 37240 (08/18/92)]. However, EPA revisited the issue in the proposed Phase II LDR rulemaking [58 FR 48092, 48135 (09/14/93)]. The proposed Phase II preamble indicated that

EPA still lacked sufficient data to propose specific exclusions for immobilized hazardous debris, and invited the regulated community to submit any available data or information demonstrating that immobilized hazardous debris (if treated properly) would not pose a substantial hazard to human health and the environment [58 FR 48092, 48136 (09/14/93)]. The preamble to the final Phase II LDR rule indicated that, in response to the proposed Phase II rule, commenters submitted claims of the protectiveness of immobilized debris and requested that immobilized debris be excluded from hazardous waste regulation. However, commenters submitted no data or other information to support their claims and requests. Therefore, EPA did not promulgate any modifications to the debris rule.³ However, the Agency further stated that exclusions for debris would be evaluated as part of the HWIR process. [59 FR 47982, 48011-48013 (09/19/94)].

DOE's Proposal for a Conditional Exclusion from RCRA Subtitle C of Immobilized Mixed Waste Debris

In response to EPA's requests for information and data demonstrating that properly treated immobilized hazardous debris would not pose a substantial threat to human health and the environment and to reform the requirements for mixed waste that pose low risks from the hazardous component, DOE submitted a technical data package (along with other related materials and information) regarding immobilized mixed waste debris to EPA on July 21, 1995.⁴ The Immobilized Mixed Waste Debris Package recommended that EPA adopt regulations excluding mixed waste debris from RCRA Subtitle C regulations provided that: (1) such debris would be treated using an immobilization treatment process subject to a permit, regulatory requirements or other environmental compliance mechanisms; (2) once immobilized, such debris would meet acceptable waste performance criteria; and (3) qualified immobilized debris would be disposed in a low-level radioactive waste (LLW) disposal facility regulated under the requirements of the AEA (e.g., a facility meeting the performance requirements of Order DOE 5820.2A, "Radioactive Waste Management"⁵). The Department believes that the integrity of the

³ Note: DOE submitted comments to EPA in response to the LDR Phase II proposed rule. These comments supported an exclusion from the hazardous waste regulations for debris treated by immobilization technologies, and addressed certain associated issues. The comments also asserted that stainless steel provides a durable encapsulant layer and provided some information in this regard. [DOE Comments on proposed rule regarding Land Disposal Restrictions for Newly Identified and Listed Hazardous Wastes and Hazardous Soil, Specific Comments IX.A, IX.B and IX.D, pp. 48-51 and Attachments 3 & 4 (Nov. 15, 1993)].

⁴ Letter to Director of EPA's Office of Solid Waste (July 21, 1995) [forwarding "Disposal of Immobilized Mixed Waste Debris in Low-Level Waste Disposal Facilities -- Technical Data Package," as well as other materials on radioactive waste management requirements and testing of mixed wastes].

⁵ Order DOE 5820.2A, "Radioactive Waste Management" (09/26/88) [Note: currently there are plans to reissue this Order as DOE Directive O 435.1], contains the policies, guidelines, and minimum requirements by which DOE manages its radioactive and mixed wastes to comply with AEA standards. It requires that radioactive and mixed wastes will be managed in a manner that assures protection of the health and safety of the public, DOE and DOE contractor employees, and the environment.

immobilized debris waste form, coupled with the protectiveness of LLW disposal facilities, is protective of human health and the environment. This proposal is supported by data presented in the technical data package. In addition, the regulatory agency would be able to assure that treatment of mixed debris using an immobilization technology in accordance with a permit, regulatory requirements or other environmental compliance mechanism produces a treated waste form that meets acceptable performance requirements.

On October 20, 1995, DOE supplemented the July 1995 Immobilized Mixed Waste Debris Package with a report entitled "Performance Evaluation for RCRA Toxic Metal Disposal in DOE Low-Level Radioactive Waste Disposal Facilities." In this supplemental report, the results of site-specific analyses for six DOE low-level waste disposal sites⁶ are described. For each site, "permissible" leachate concentrations of RCRA metals⁷ are conservatively calculated, which if present in leachate from a landfill at the site, would prevent concentrations of such metals in ground water located 100 meters from the landfill boundary from exceeding maximum contaminant levels (MCLs).⁸ The additional technical data provided in the supplemental report support that if properly immobilized mixed waste debris were disposed of in LLW disposal facilities, human health and the environment would be protected without RCRA Subtitle C regulation.

- **Proposed Encapsulants**

EPA currently recognizes polymeric organic materials or use of a jacket of inert organic materials as acceptable macroencapsulating methods, and only Portland cement and lime/pozzolans as acceptable microencapsulants [40 CFR 268.45, Table 1, "Alternative Treatment Standards for Hazardous Debris"]. Several other encapsulating agents, including hydraulic cement, sulfur polymer cement, polyethylene, phosphate ceramics, epoxies, urea formaldehyde polymer and asphalt, high integrity containers, and stainless steel containers have been developed and tested. Because the performance of some of these materials is comparable or superior to the encapsulating agents listed as Land Disposal Restriction (LDR) treatment standards for debris, DOE included these encapsulants (i.e., sulfur polymer cement, polyethylene, phosphate ceramics, specialized containers) as proposed alternative encapsulants in its proposal. The Immobilized Mixed Waste Debris Package presented data on waste form leachability and/or permeability, biodegradation, radiation stability, and long-term environmental stability.

⁶ The DOE LLW disposal sites included were Idaho National Engineering Laboratory, Nevada Test Site, Los Alamos National Laboratory, Savannah River Site, Oak Ridge Reservation and Hanford Reservation.

⁷ RCRA metals include arsenic, barium, cadmium, chromium, lead, mercury, selenium and silver. These are the metals for which concentrations in the waste (for wastewaters) or in leachate generated using the TCLP (for nonwastewaters) have been established which, if present, define wastes as characteristically hazardous.

⁸ MCLs are established by EPA as criteria for evaluating whether water is safe for human consumption.

- **Integrity of Immobilized Debris Final Waste Form**

The regulatory agency would be able to assure through a permit, regulatory requirements or other environmental compliance mechanisms that the treatment process produces immobilized debris that meets acceptable performance requirements. To ensure mixed waste debris treated by immobilization and placed in a LLW disposal facility would be sufficiently protective of human health and the environment, the Immobilized Mixed Waste Debris Package proposed that the final waste form meet or exceed established performance criteria that would be demonstrated through a two tier testing approach. Tier one would involve testing as follows:

- *Microencapsulated debris* - Toxicity Characteristic Leaching Procedure (TCLP) as per EPA Model 1311, or the Synthetic Precipitation Leaching Procedure (SPLP) as per EPA Model 1312.
- *Macroencapsulated debris* - Modified TCLP or SPLP, possibly using an encapsulated coupon of the debris, and waste form integrity testing via a non-destructive test such as real-time radiology, ultrasound, or x-ray. The standard leachability test method is not appropriate for macroencapsulated debris because it requires breaking the protective encapsulant layer and allowing the leaching solution to directly contact the debris. Since this contradicts the intent of macroencapsulation, the integrity of the final waste form should be verified using non-destructive methods.

Tier two tests would be conducted after tier one tests have been performed and passed. The tier two tests would demonstrate the integrity of the treated waste form in the disposal environment. These tests could include the following: a compressive strength test, non-destructive test, long-term immersion in water, radiation stability, biodegradation, freeze-thaw cycling, and wet-dry cycling. One or more of the tier two tests would be performed on the waste, based on the tests which are appropriate for a particular disposal facility location, to demonstrate the integrity of the final encapsulated waste form.⁹ DOE already performs some of these tests to meet waste acceptance criteria at low-level waste disposal facilities. The Immobilized Mixed Waste Debris Package recommended that these tests (both tier one and tier two) be done initially as "proof of process" tests and then periodically repeated as quality assurance checks. DOE sites would work with their respective regulator to decide which tests are appropriate for the treated mixed waste debris after considering the type of encapsulation and the characteristics (e.g., climate, depth to groundwater, etc.) of a disposal site.

- **Risk-Based Analysis of LLW Disposal Facilities**

Finally, in DOE's report, "Performance Evaluation for RCRA Toxic Metal Disposal in DOE Low-Level Radioactive Waste Disposal Facilities," a risk-based analysis evaluated the environmental transport of RCRA toxic metals from six DOE LLW disposal sites (chosen

⁹ Some tests, like freeze-thaw cycling would not be necessary if a disposal facility did not experience temperatures which would promote this phenomena.

because all are subject to the requirements of Order DOE 5820.2A and have previously disposed of LLW). The analysis focuses on the toxic metal component of the mixed waste debris and the groundwater contaminant pathway. Toxic metals are highlighted because they represent the principal RCRA hazardous contaminants in DOE's mixed waste debris. The groundwater pathway is highlighted because it is the dominant transport pathway for human exposure from land disposal facilities managing immobilized wastes. The analysis estimates permissible leachate concentrations of toxic metals by using MCL concentration values in groundwater at a receptor point along the performance boundary (100 meters from the disposal facility boundary), and attenuation factors associated with site-specific conditions. The report found that arid DOE LLW sites appear to provide a greater degree of protection of human health and the environment than humid DOE LLW sites based on higher attenuation and longer contaminant travel times. However, the report concludes that, if mixed debris are properly immobilized, even DOE disposal sites located in humid climates will be protective of human health and the environment.

Implementation

Mixed waste debris treated by immobilization would exit RCRA Subtitle C after treatment, similar to mixed debris treated by destruction or extraction technologies per the Debris Rule (57 FR 37221, August 18, 1992).

The regulatory agency would be able to assure that immobilized mixed debris treated in accordance with a permit, regulatory requirements or other environmental compliance mechanisms produces debris that meets acceptable performance requirements. Waste form performance criteria would be defined for waste immobilization by microencapsulation and macroencapsulation. Waste form performance criteria would be verified through a two-tiered testing approach discussed above. Immobilized mixed waste debris would be disposed of in a LLW disposal facility as radioactive waste.

Summary

In conclusion, DOE requests that EPA establish a conditional exclusion from RCRA Subtitle C regulation for immobilized mixed waste debris, provided that: (1) such debris would be treated using an appropriate immobilization technology, and the immobilized debris waste form would meet specified performance criteria, and (2) qualified immobilized debris would be disposed in a LLW disposal facility regulated under the requirements of the Atomic Energy Act [i.e., in a facility meeting the performance requirements of Order DOE 5820.2A (Radioactive Waste Management), or in radioactive waste disposal facilities licensed by the Nuclear Regulatory Commission]. This request is supported by the information provided in the Immobilized Mixed Waste Debris Package (submitted to EPA in July 1995) which recommends appropriate performance criteria. The supplemental information concerning metals migration from six DOE LLW disposal facilities also supports the request (submitted to EPA in October 1995). Taken together, such information demonstrates that immobilization of mixed waste debris (using appropriate technologies, along with disposal in a low-level waste disposal facility) will protect human health and the environment. Based on this information and data, DOE requests that the

proposed mixed waste debris management approach be promulgated as a part of the final HWIR.

3. **DOE requests that EPA adopt regulations excluding *vitrified* mixed wastes from RCRA Subtitle C regulation, provided that: (1) the waste is treated by a vitrification process subject to performance criteria and regulatory control; (2) the vitrified mixed waste forms will be managed in radioactive waste disposal or storage facilities that conform with controls and conditions put forth pursuant to the AEA; and (3) it has been demonstrated to EPA or the authorized State that pre-defined process control program requirements and product performance characteristics have been met.**

DOE's Proposal for a Conditional Exclusion from RCRA Subtitle C for Vitrified Mixed Wastes

DOE developed a technical data package supporting a conditional exclusion applicable to vitrified mixed waste forms for consideration during the HWIR rulemaking process. This technical data package was submitted to EPA on October 20, 1995.¹⁰ Specifically the Vitrification Technical Data Package supports a regulatory strategy allowing vitrified mixed waste forms, generated by a regulatorily controlled (e.g., through a permit, regulatory requirements or other environmental compliance mechanisms) vitrification process, to be excluded from RCRA Subtitle C regulations. Such an exclusion is justified by the inherent destruction and immobilization capabilities of the vitrification technology, as described in the technical data package. The Vitrification Technical Data Package also proposes a compliance testing strategy for vitrified waste forms that differs from the strategy EPA suggests in proposed 40 CFR 261.36(b)(1) [60 FR 66344, 66440]. Testing would primarily be intended to support a process control program that ensures consistent production of a waste form with environmentally acceptable performance characteristics. Additional testing would be performed if the waste feed composition or process was altered, instead of testing periodically, based on waste volumes. The process control program will also include a commitment that vitrified low-level mixed wastes will be disposed of either in DOE LLW disposal facilities that comply with the requirements of Order DOE 5820.2A, "Radioactive Waste Management," or in radioactive waste disposal facilities licensed by the Nuclear Regulatory Commission or an Agreement State; and vitrified high-level mixed wastes will be placed into a Federal radioactive waste repository (licensed by the Nuclear Regulatory Commission pursuant to requirements contained in 10 CFR Part 60).

- **Vitrification Concept**

Vitrification is the process of converting materials into a glass-like substance, typically through a

¹⁰ Letter to Director of EPA's Office of Solid Waste (October 20, 1995 [forwarding supplemental data regarding immobilized mixed waste debris (Enclosure 1), and a technical data package supporting the position that vitrified waste should be granted an exclusion from RCRA Subtitle C based on waste form stability and performance (Enclosure 2)].

thermal process. Vitrification has four major characteristics which make it an attractive waste treatment option:

- Vitrification produces a durable waste form which when properly formulated performs exceptionally well in leach tests.
- Vitrification destroys organic contaminants and stabilizes inorganics and metals by incorporating them into the glass structure.
- The waste glass has the ability to incorporate a wide variety of contaminants and accompanying feed material in its structure, without compromising the quality of the final waste form.
- Vitrification typically results in significant volume reductions of waste material.

Vitrification is a desirable treatment option for wastes containing long-lived radionuclides because the vitrified waste forms will resist degradation for the thousands of years necessary for radioactive decay to lessen radiation hazard to human health and the environment. During this decay period, the metals and inorganics are chemically bonded in the glass matrix. Due to these features, EPA has already specified vitrification under the land disposal restrictions program as the technology by which certain mixed high-level wastes must be treated prior to land disposal [55 FR 22520, 22627 (06/01/90)].

- **Destruction and Immobilization Capabilities of Vitrification**

Vitrification is the thermal-chemical process whereby oxides of elemental constituents are incorporated into a solid, continuous, non-crystalline, three-dimensional network or glass structure. Vitrification, which occurs in a liquid mixture at an elevated temperature (nominally 1000°C to 1500°C), chemically bonds the glass elemental constituents together using oxygen to form a solution. At the required operating temperatures, organic components are either destroyed, or volatilized and decompose in the off-gas treatment system and are not incorporated into the glass product. Therefore, DOE proposes to eliminate the HWIR testing requirements for organics. Additional data demonstrating that a properly designed vitrification system is capable of achieving organic Destruction and Removal Efficiencies (DREs) that meet the requirements of 40 CFR Parts 264 and 265, are provided as part of Attachment B.

At least one of the glass forming elemental oxides, termed "network formers," must be present in the liquid mixture in sufficient quantity to form the glass matrix as the molten solution cools. The four primary network former oxides include silicon, phosphorous, boron, and germanium. Other elements break the glass-forming bonds and can lower the melt viscosity or produce other changes in the glass physical characteristics. These oxides are "network modifiers" and include the alkali metals and alkaline earth oxides.

Most waste glasses are based on the silica network. Therefore, successful vitrification requires

most hazardous wastes to be mixed with silica to serve as the network former. The resulting waste glass can range from approximately 30 weight-percent actual waste to much higher measures when the waste itself contains substantial network formers (e.g., contaminated soils and sludges).

Like any waste treatment process, vitrification has its limitations. Although most elements can be vitrified to some extent, more volatile elements such as cesium and the halogens can be incorporated only in small concentrations. Some metals, especially chromium and the noble metals, have limited solubility within many glass melts, and high concentrations of network modifiers can have negative effects on glass properties. Most, if not all, of these limitations can be controlled by establishing vitrification process parameters and final glass cooling controls in the Process Control Program.

- **Process Control Program**

Vitrification requires a process control protocol for key operating parameters in order to yield a glass product consistently falling within a pre-defined acceptable performance envelope. This process control envelope is defined by performing treatability studies on either the actual radioactive waste or an appropriate surrogate. The treatability studies provide information on the glass formulation process and other operating variables, such as waste loading and viscosity, while ensuring the durability of the final waste form. Once the parameter values which produce a durable glass are determined, they are used to define the Process Control Program. The Process Control Program ensures both a consistent product performance as well as the key composition of liquid, air and secondary waste streams.

- **Testing**

The Process Control Program requirements include sampling and analysis to support the process acceptability envelope. To ensure the durability of the glass, DOE proposes to monitor the leach rates of several of the most leachable glass components. Two forms of leach tests, the Product Consistency Test (PCT) (ASTM-C1285-94) and TCLP have been proposed. The PCT test was developed to evaluate the performance of high-level waste glass and its durability as it relates to the release of radioactive components. The TCLP would be used to determine leach rates of hazardous components (primarily metals). Testing requirements for organic constituents identified in the vitrified waste stream are eliminated because organic components cannot survive the vitrification process (i.e., molten temperatures in excess of 1000°C), or are removed in the off-gas system.

The technical data submitted to the EPA also proposes an alternative sampling and analysis strategy for certain highly radioactive mixed waste forms. The proposed sampling strategy considers the radiological hazard associated with testing the final waste form. For wastes with low radiation hazard, sampling and analysis is performed on the final product. However, sampling and analysis of highly radioactive wastes may be performed on surrogate vitrified wastes that are chemically equivalent to the actual waste. DOE believes that this alternate

testing strategy would provide results comparable to those achieved via the testing program under proposed 40 CFR 261.36 (60 FR 66440-66442, December 21, 1996).

- **Implementation**

DOE is proposing that mixed waste, treated by vitrification would be excluded from RCRA Subtitle C at the time that treatment is complete. Vitrified mixed low-level waste would exit RCRA Subtitle C after treatment and, would be required to be disposed at a DOE low-level waste disposal facility (in accordance with DOE Orders), or in a radioactive waste disposal facility licensed by the Nuclear Regulatory Commission or an Agreement State. Vitrified high-level waste would exit RCRA Subtitle C after treatment and be disposed at a federally licensed repository.

A process control program, for the vitrification facility, would be developed that provides the description of the unit operation variables, the feed stream compositions as they relate to the end product quality and the permitted emission/effluents, and the acceptable performance envelope for unit operation. The process control program and a permit, regulatory requirements or other environmental compliance mechanisms would specify criteria that must be met to assure the characteristics and consistency of the final product result in a vitrified waste which is excluded from the RCRA hazardous waste regulations.

The EPA or authorized State would retain control over the vitrification process to assure, through a permit, regulatory requirements or other environmental compliance mechanisms, that the process produces a glass meeting environmentally acceptable performance characteristics. It is only after the production of a vitrified waste that meets these performance characteristics that DOE proposes the waste form be excluded from RCRA Subtitle C control.

Supplemental Information

Since DOE submitted the Vitrification Technical Data Package in October 1995, EPA and the National Governors' Association have requested additional documentation supporting its conclusions concerning the vitrification process and the characteristics of vitrified mixed wastes. In response to these requests, DOE has compiled two volumes of background information which are enclosed as Attachment A, "Supplemental Information for the Technical Data Package for Vitrified Wastes Forms." Volume 1 of Attachment A contains sections I and II. Section I provides information on the characteristics of vitrified glass, including the thermal destruction of organic materials. Additional information on testing and control of the process is also included. Section II contains information on TCLP testing for RCRA metals and PCT testing for selected elements. Volume 2 of Attachment A is composed of Sections III through VI. Section III provides information on the development and selection of standardized glasses with performance characteristics based on DOE Orders and Federal regulations. Section IV provides information on the range of expected glass waste forms considering the waste stream and the standard glass and the leaching characteristics of those glasses. The set of projected glasses should bound the performance of any glass produced in a mixed waste vitrification production facility. Section V

presents information on the chemical composition of the feed material and final product. Section VI contains information on the Process Control Program for the production of the vitrified waste form.

Summary

In conclusion, DOE requests that EPA adopt regulations which conditionally exclude vitrified mixed wastes from RCRA Subtitle C regulations, provided that: (1) the vitrification facility generating the treated wastes is regulated through a permit, regulatory requirements or other environmental compliance mechanisms, and is subject to an approved Process Control Program; (2) the vitrified low-level mixed waste forms will be disposed of either in DOE LLW disposal facilities that comply with the requirements of Order DOE 5820.2A (Radioactive Waste Management), or in radioactive waste disposal facilities licensed by the Nuclear Regulatory Commission or an Agreement State; and vitrified high-level mixed wastes will be stored at a DOE high-level waste storage site (operated in compliance with the requirements of Order DOE 5820.2A) pending disposal in a Federal radioactive waste repository; and (3) it has been demonstrated to EPA or the authorized State that pre-defined process control program requirements and product performance characteristics have been met. This proposal provides that waste treated using a superior treatment technology (i.e., vitrification) may be responsibly managed under the Atomic Energy Act (AEA) while reducing overall costs. Full regulatory authority by EPA or a State would be maintained until an acceptable vitrified waste form is produced.

With consideration of the Vitrification Technical Data Package (submitted to EPA in October 1995), and the supplemental information related to vitrified waste forms included with these DOE comments, the Department requests that EPA promulgate the proposed conditional exclusion for vitrified mixed waste forms as part of the final HWIR.

- 4. DOE requests that EPA consider adding regulatory provisions which define a separate testing program for evaluating whether radioactive mixed wastes qualify for the generic exemption from RCRA Subtitle C regulation proposed by the HWIR for listed wastes, or meet any conditional exemption criteria that may be established by the final HWIR.**

Under the proposed HWIR, testing would be required for two purposes: (1) to receive an exemption from RCRA Subtitle C for listed hazardous wastes, and (2) to retain the exemption. To receive an exemption, a total constituent concentration analysis (i.e., a "total" analysis of all Appendix X of 40 CFR Part 261 constituents) is proposed, except for "those constituents that the facility can document should not be present in the waste" (as discussed in section VIII.A of the preamble). To retain an exemption, EPA proposes periodic testing for constituents expected in the waste. The proposed frequency of this testing is based on waste volume for a minimum of three years, followed by annual testing thereafter. EPA also proposes that for nonwastewaters a

TCLP or a screening analysis¹¹ be performed to demonstrate that leachate concentrations will not be above nonwastewater leach exit levels. EPA did not propose specific testing requirements for mixed wastes. However, in discussions with DOE in regards to the HWIR proposed rule, EPA has expressed interest in receiving suggestions on how to tailor the HWIR testing requirements to address analytical concerns associated with mixed wastes.

DOE has been evaluating some possible alternative testing approaches for mixed wastes, and would like to work with EPA and authorized States on the development of a distinct testing program for demonstrating: (1) that a mixed waste meet the generic exemption levels (established under HWIR for all RCRA listed hazardous wastes); or (2) that a mixed waste meet other exemption criteria that may be established by the final HWIR. DOE believes that the promulgated testing program for mixed wastes should be different from the testing program that EPA proposed because sampling and analysis of these wastes often pose safety and technical challenges, as well as administrative costs, beyond those of typical non-radioactive hazardous waste. For example, many mixed wastes require special handling due to personnel radiation exposure and the potential for radioactive contamination during sampling and analysis. Also, some radionuclides interfere with the detection of hazardous constituents. For example, when a mixed waste sample containing plutonium is volatilized and analyzed as an emission spectra, the plutonium peak obscures peaks that indicate the presence of hazardous metals. This is a common analytical problem for mixed waste containing transuranic elements (atomic number greater than 92). Furthermore, certain heterogenous mixed wastes have matrices that are difficult to sample and analyze at instrument detection limits.¹² Finally, DOE would also like to perform leach rate or total constituent testing on non-radioactive surrogate waste forms that are chemically and physically equivalent to the actual process waste (i.e., in cases where the radiological component renders testing of the treated waste form of the waste impractical). The Department suggests that EPA specifically allow the use of surrogates to demonstrate that certain mixed wastes meet HWIR exit levels. DOE would also like the frequency of the testing of mixed wastes that exit under HWIR to be determined not on volume, but on the hazards associated with testing of the waste and other appropriate factors as deemed appropriate by DOE and the regulators.

As stated above, DOE is eager to work with EPA and authorized States to develop testing requirements applicable for demonstrating whether mixed wastes have met HWIR exemption criteria (and to address associated testing issues specific to mixed wastes), and requests that EPA incorporate such requirements into the final HWIR.

¹¹ In the screening analysis for a solid waste the total concentration of a listed waste constituent is divided by a factor of 20 and compared to the TCLP exit level. If the calculated value is less than the TCLP exit level the constituent is considered exempt and the TCLP need not be performed (discussed in section VIII.A.1.a.iii).

¹² The following DOE comments on prior EPA notices of proposed rulemaking address in more detail the challenges associated with sampling and analyzing certain mixed wastes: DOE Comments, Specific Comment VII.C, item 1, pp. 12-14 (03/15/94); DOE Comments, Specific Comment III.A, item 1, pp. 8-11 (11/15/93); DOE Comments, Specific Comment II.B.1, item 1, pp. 6-7 (03/04/93).

5. DOE requests that EPA pursue the development of regulations that establish conditions which, if met, would qualify mixed wastes for exemption from RCRA Subtitle C regulation (i.e., a contingent management approach for mixed waste).

The HWIR proposal requests comment on several contingent management approaches to disposal of hazardous wastes [60 FR 66344, 66395-66401]. Under such approaches, wastes that would be considered hazardous if managed in an uncontrolled manner, could be considered non-hazardous if managed in a sufficiently controlled manner. The approaches on which EPA requests comment fall into three categories: (1) establishing national exit levels that differ according to the degree of management/disposal restrictions imposed as a condition of exit [60 FR 66396]; (2) granting conditional exemptions to listed wastes managed in qualified state programs that ensure that risks are reduced to protect human health and the environment [60 FR 66398]; and (3) establishing conditions which, if met, would qualify mixed wastes for exemption from RCRA Subtitle C regulation [60 FR 66400]. Regarding the third category, EPA specifically requests comment on allowing mixed wastes meeting conditional exit levels for chemical toxicity estimated at 10^{-4} cancer risk and hazard quotient (HQ) of 1 (modeled at an uncontrolled site), to exit Subtitle C hazardous waste regulation if such mixed wastes are managed in disposal facilities meeting disposal requirements imposed pursuant to the Atomic Energy Act (AEA).

DOE has been considering possible contingent management approaches (including the options for conditional exemptions outlined by EPA in the preamble) for mixed waste, taking into account that: (1) there are certain management provisions required by the AEA to control releases of and exposure to radioactive hazards associated with mixed wastes which also provide protection from releases of and exposure to hazardous constituents in such wastes; and (2) site-specific conditions (e.g., geology, hydrology, meteorology, climate, land use) at some DOE facilities provide protection to human health and the environment beyond that which EPA assumed in developing generic exit levels for the HWIR proposal. DOE has only given preliminary consideration to the mechanisms by which such options would be implemented, and to corresponding issues or concerns.

As explained in General Comment 1 (for clarification purposes), DOE has not previously forwarded information to EPA or the States to support the proposal presented by the Agency in the preamble (60 FR 66400, col. 3) -- i.e., establishing conditional exit levels for mixed wastes at a chemical toxicity estimated at 10^{-4} cancer risk and HQ of 1 (modeled at an uncontrolled site). However, as stated earlier, the Department would like to explore this option and others, and work with the EPA and the States to develop a viable contingent management option for low-risk mixed wastes (on a *separate schedule* from the two DOE proposals which support conditional exclusions for immobilized mixed waste debris and vitrified mixed wastes from RCRA). DOE plans to pursue meetings and further communications for discussing such an option with EPA and the States in the upcoming months. [Note: also see related specific comments in response to section IX.E, item 1].

6. DOE has initiated a dialogue with EPA and the States (primarily through the

National Governors' Association (NGA)) in regards to the potential application of the HWIR to DOE mixed wastes. It is DOE's intent and desire to further discussions with these regulatory agencies and to foster continued cooperation in the context of defining acceptable exclusions from RCRA Subtitle C regulation for low-risk mixed wastes (in particular, to address the proposals and issues raised above in General Comments 1 through 5).

In July 1995, DOE provided supporting technical data and formally requested that EPA consider (in the context of the then pending HWIR proposal) excluding immobilized mixed waste debris from RCRA Subtitle C regulation when such debris were disposed of in DOE radioactive waste management facilities that comply with Order DOE 5820.2A.¹³ A second submittal was provided to EPA in October 1995 which included supplemental information regarding immobilized mixed waste debris and technical data demonstrating that vitrification produces a waste form suitable for exclusion from the RCRA Subtitle C regulations.¹⁴ More

details about these communications and the proposals they contained are presented in General Comments 2 and 3 (above), respectively.

As part of the Department's efforts to inform interested parties about the DOE proposals (and the associated supporting documentation), DOE provided briefings to the DOE/National Association of Attorneys General (NAAG) Workgroup on October 12, 1995 [Note: EPA representatives also participated in this conference] and the NGA/FFCAct group on October 20, 1995, in regards to the immobilized mixed waste debris and vitrification proposals. This was followed by a technical briefing of NGA contractors and representatives of EPA and the Nuclear Regulatory Commission (NRC) on December 14-15, 1995¹⁵. More recently (specifically March 14, 1996), NGA, States, and DOE held a conference call to discuss the key elements of the Departments' HWIR proposals (i.e., immobilized mixed waste debris and vitrified mixed waste) and potential implementation options, to discuss State concerns and comments on the technical merit of these proposals, and to identify and discuss next steps.

DOE hopes to continue the dialogue with EPA, States and the NRC that began with the communications and meetings described above. As indicated in the preceding general comments, it is the Department's hope to work closely with EPA, States, and the NRC to define

¹³ Letter to Director of EPA's Office of Solid Waste (July 21, 1995) [forwarding "Disposal of Immobilized Mixed Waste Debris in Low-Level Waste Disposal Facilities -- Technical Data Package," as well as other materials on radioactive waste management requirements and testing of mixed wastes].

¹⁴ Letter to Director of EPA's Office of Solid Waste (October 20, 1995 [forwarding supplemental data regarding immobilized mixed waste debris (Enclosure 1), and a technical data package supporting the position that vitrified waste should be granted an exclusion from RCRA Subtitle C based on waste form stability and performance (Enclosure 2)].

¹⁵ Note: Attachment B to these comments provides responses and information in regards to two issues raised by a representative of the NGA during the December 14-15, 1995 meeting.

implementing mechanisms that will provide sufficient EPA/State oversight and enforcement authority relative to the conditional exclusions for immobilized mixed waste debris and vitrified mixed wastes (as discussed in General Comments 2 and 3). Furthermore, as mentioned in General Comments 1 and 5 above, DOE would also like to work with EPA, the States and the NRC (under a separate schedule) to develop an appropriate contingent management option for low-risk mixed waste.

7. DOE is concerned that the regulations promulgated by the HWIR may be implemented by States inconsistently.

EPA states that the purpose of the HWIR is to reduce any overregulation of solid wastes (currently designated as hazardous waste) that contain constituent concentrations at levels posing low risk to human health and the environment [60 FR 66346 (col. 3), 60 FR 66347 (col. 3), and 60 FR 66349 (col. 3)]. DOE agrees with the need for and appropriateness of such changes to the RCRA hazardous waste identification program. However, the Department is concerned that the actual implementation of the regulatory approaches and requirements established under HWIR could vary significantly from State to State, and thus, complicate and potentially negate (in certain States) the intent of these amendments to the RCRA hazardous waste identification program.

Under the RCRA provisions related to authorizing States to administer and enforce hazardous waste programs, a low-risk solid waste that qualifies for exemption from RCRA Subtitle C regulation in one State might not qualify for such exemption in other States. This situation may arise because: (1) the HWIR proposal for exit levels "is considered to be less stringent than, or a reduction in the scope of, the existing Federal regulations because it would exempt certain wastes now subject to RCRA Subtitle C" (60 FR 66411, col. 3);¹⁶ and (2) the legal authority for adopting the proposed HWIR derives from non-Hazardous and Solid Waste Amendments (HSWA) authority.¹⁷

As EPA recognizes in the preamble (60 FR 66347, col. 1), one of the primary concerns raised by commenters in response to the May 20, 1992 proposed rule for revising the hazardous waste regulations (57 FR 21450) was that the proposal would result in a "patchwork" of differing State programs (because some States might not adopt the regulatory revisions). This issue was also a concern raised by the Department in response to the May 20, 1992 proposal.¹⁸ DOE asserted

¹⁶ Note: States are only required to modify their programs when EPA promulgates Federal regulations that are more stringent or broader in scope than the authorized State regulations.

¹⁷ For requirements issued under non-HSWA authority, new Federal requirements do not apply until they have been adopted by the State, and the State's authorization has been revised to incorporate the requirements.

¹⁸ See DOE Comments, Proposed Rule regarding Hazardous Waste Management System, Identification and Listing of Hazardous Waste, Crosscutting Issues, Consistent State Implementation Should Be Ensured, p. 9 (07/24/92).

that inconsistent State implementation is a key concern to generators who have operations in many States (such as the DOE complex). EPA notes in the preamble that comments regarding the potential for a "patchwork" of differing State programs contributed to the Agency's withdrawal of the initial HWIR proposed rule on October 30, 1992 (60 FR 66347, col. 1).

In the preamble to the proposed rule (60 FR 66411, col. 3), EPA asserts that the HWIR will reduce over-regulation of dilute wastes and will provide an alternative to delisting. The Agency also states that, even though States are not required to adopt most options in the proposed HWIR, it strongly encourages States to do so as quickly as possible. DOE is concerned that the differences that could exist between State hazardous waste identification programs could significantly encumber the efficiency and delay waste management (and environmental restoration) activities for owners/operators that have or utilize facilities across multiple States (e.g., the DOE complex). With this in mind, the Department urges EPA to closely coordinate the development of the final HWIR provisions with the States, and to implement criteria and approaches that will minimize the outcome of inconsistency among State programs.

8. DOE supports EPA's efforts to provide greater flexibility in managing low-risk listed hazardous wastes, but is concerned that the testing and implementation requirements may be too costly to enable many low-risk solid wastes to actually exit RCRA Subtitle C regulation.

DOE applauds EPA's efforts to establish risk-based exit levels for listed hazardous wastes regulated by RCRA Subtitle C. DOE believes that the proposed rule will provide greater flexibility for managing low-risk solid wastes that have been designated as listed hazardous wastes, or have been mixed with, derived from, or contain listed hazardous wastes. The proposed rule will also encourage pollution prevention, waste minimization, and the development of innovative waste treatment technologies because generators will have an incentive to minimize the toxic chemical concentrations in listed wastes to below the newly defined exit levels. Furthermore, since no prior government approval or review of documentation would be required before wastes are eligible to exit Subtitle C requirements, the proposed rule will facilitate exemptions for mixtures and derived-from wastes that present no significant threats to human health or the environment. DOE also believes that the adoption of minimize threat levels for constituents where the modeled risk level is higher (less stringent) than the associated technology-based treatment standard in 40 CFR 268.40 or the Universal Treatment Standard level in 40 CFR 268.48 will benefit a wide range of generators.

However, the Department is concerned that, in practice, only a limited number of waste streams may be able to utilize the proposed exemption requirements. With this result, the proposed rule would not achieve the intended goal of reducing "overregulation of low-risk wastes captured by the mixture and derived-from rule." As EPA points out, while a relatively large number of waste streams and facilities may meet the eligibility criteria for exemption, many may not gain exemption because the costs of exemption may outweigh the estimated cost savings from exemption (60 FR 66416, col. 1). Within the DOE complex, a number of listed hazardous waste streams are generated in small quantity and can be highly variable (such wastes, for instance,

may be generated from small processes or as a result of laboratory activities). EPA estimates that the start-up costs of recordkeeping and reporting during the first year will range from \$55,000 to \$235,000 per waste stream, and the annualized costs over five years will be from \$21,000 to \$170,000 (see 60 FR 66417, col. 2). It is likely that the costs to implement the proposed HWIR requirements will preclude generators of many small volume low-risk listed hazardous waste streams from pursuing an exemption. Because of the high testing and implementation costs, only large volumes of low-risk listed waste streams of fairly consistent composition would appear to be likely candidates for exemptions.

9. DOE requests that EPA clarify whether any future changes to the exit criteria would apply to wastes that have qualified for an exemption, but will be stored until treatment facilities are operational or until disposal capacity becomes available.

In the case of radioactive mixed wastes, DOE will be storing certain of these wastes until treatment facilities are operational or until disposal capacity becomes available. The Department requests that EPA clarify how, or if, any *future* changes to the listed hazardous waste exit criteria would be applied to such wastes. It is DOE's opinion that a waste stream meeting the exit criteria (i.e., a claimant has successfully demonstrated that a particular waste qualifies for exemption) and is placed in storage pending disposal should be subject to a "grandfather clause" that would allow continued exemption from Subtitle C regulation in the event that exit levels should change at some later date. DOE suggests that EPA clarify that wastes exempted under the HWIR proposal cannot be brought back under Subtitle C control, as long as the waste continues to meet the original exit criteria. EPA should not require further treatment to comply with more stringent exit criteria promulgated after initial waste treatment but before ultimate waste disposal. DOE believes that the risks associated with repeatedly treating a hazardous waste, particularly a mixed waste, to conform to a change in the exit criteria would be unwarranted when weighed against the incremental reduction in risk likely to be afforded by a more stringent exit criteria.

10. DOE requests that EPA provide clarification as to the applicability of the HWIR to wastes generated during remediation activities, and in regards to the exact interrelationship of the HWIR (for wastes) to the HWIR-Media rulemaking.

The preamble to the proposed HWIR speaks only briefly to the extent to which the HWIR-waste regulations will apply to wastes generated during remediation activities. In the background discussion (Section II.B.2), EPA states that media containing hazardous wastes with constituent concentrations below the proposed exit levels will be eligible for exemption under the procedures outlined in the HWIR proposal. In addition, the Agency mentions its plans to propose additional rules reducing regulation of contaminated media during remediation activities (i.e., the HWIR-Media proposed rule). Further discussion addressing the management of hazardous contaminated media is not provided until near the end of the preamble (under section XI.H, HWIR-Media Rule/Subtitle C Corrective Action). This later discussion explains that this HWIR proposal [for wastes] specifically applies to "listed hazardous wastes (e.g., process wastes, sludges, discarded commercial chemical products, etc.), including mixtures of one or

more listed wastes with other solid wastes, and residues derived from the treatment, storage, or disposal of one or more listed hazardous wastes." This section also reasserts that media containing listed hazardous wastes, mixtures or derived-from wastes which meet the exit criteria would be eligible for exemption.

In this discussion (section XI.H; 60 FR 66408), EPA explains that the goal of the media rule is to allow more effective cleanups at contaminated sites, and that as currently drafted, the rule will supplement the regulatory system under RCRA for the management of RCRA hazardous contaminated media applicable to sites undergoing cleanup such as RCRA corrective action sites, State cleanups, and Superfund remedial actions. These discussions could be interpreted to mean that if there is no listed "process" wastes (or other known listed wastes) generated during a remedial action, and since the subsequent [HWIR-Media] rule will be designated specifically to the management of hazardous contaminated media, the proposed HWIR (for listed wastes) would not likely apply to sites undergoing cleanup. But it appears that some portions of the proposed HWIR might impact remediation activities. DOE requests that EPA provide clarification on the specific applicability of the HWIR requirements to wastes generated from cleanup activities, and that the Agency clearly explain the intended interrelationship between the HWIR for listed wastes and the HWIR for contaminated media.

SPECIFIC COMMENTS

III Scope of Revisions to the Mixture and Derived-From Rules

III.B Revision to Derived-From Rule for Wastes Listed Because They Exhibit the Characteristics of Ignitability, Corrosivity, or Reactivity

- 1. p. 66349, cols. 1 and 2 -- EPA indicates that the proposed HWIR includes a revision to the derived-from rule (40 CFR 261.3(c)(2)(i)) providing an exemption for wastes derived from hazardous wastes that are listed solely because they exhibited one or more of the hazardous characteristics of ignitability, corrosivity and reactivity, if the derived-from wastes no longer exhibit a characteristic. EPA also explains that the exemption requires de-characterized derived-from residuals from wastes listed because they exhibit characteristics to meet LDR treatment standards. The preamble states that the proposed exemption includes clarifying language reminding the regulated community of the need to comply with Part 268 LDR requirements for all types of derived-from residues.**

DOE supports the revision to the derived-from rule which EPA describes in this section of the preamble, including the described clarifying language concerning LDR compliance. However, the actual regulatory language proposed in the HWIR notice of proposed rulemaking (i.e., the proposed amendments to the regulations beginning on 60 FR 66440) does not include language for implementing the described changes to 40 CFR 261.3(c)(2)(ii). Therefore, DOE requests

that EPA incorporate appropriate regulatory language in the final HWIR rule.

IV. Development of Exit Levels and "Minimize Threat" Levels

IV.C Selection of Constituents of Concern

IV.C.1 Development of the Master List

- 1. p. 66350, col. 3 -- EPA requests comment on whether the “master list” and Appendix VIII (of 40 CFR 261) should include the six constituents referred to in Table 1, which were not included in any of the appendices to 40 CFR 261 used by EPA to develop the master list.**

The constituents listed in Table 1 are either poisons or severe irritants. DOE believes that it would be appropriate to establish exit levels for these six constituents and to include the constituents in Appendix VIII to 40 CFR 261, Hazardous Constituents.

IV.C.2 Development of the Exit Constituent List

- 1. p. 66350, col. 1 -- EPA developed an initial “Master List” of 506 constituents to be evaluated for purposes of establishing exit criteria. It then narrowed this initial list to 376 constituents that are included in the exit constituent list.**

DOE believes that the exit constituent list should be as extensive as existing data permit. Where specific data do not exist, effort should be made to use reasonable safety factors and other methods to expand the list.

- 2. p. 66351, col. 1 -- EPA solicits comment on whether molybdenum should be included on the exit constituent list.**

DOE does not believe that molybdenum should be on the list because it does not occur free in nature and is insoluble in water.

- 3. p. 66351, col. 1 -- In the risk assessment used to develop exit levels, EPA modeled only chromium VI. However, the exit level appearing on the exit table applies to total chromium. EPA asks for comment on this approach.**

Significant differences in toxicity can exist among different ionic states of a particular constituent (e.g., chromium III and chromium VI). With respect to chromium, the proposed approach will lead to possible overregulation of wastes containing chromium III. Unless EPA can demonstrate through risk modeling for chromium III that exit levels based on chromium III

would be substantially the same as exit levels based on chromium VI, a single exit concentration based on chromium VI (which is the most hazardous ionic state) cannot represent these very toxicologically different ionic states without introducing unnecessary conservatism. DOE suggests that EPA provide alternatives [other than the delisting process or exclusion under §261.4(b)(6)] that might be used to support higher exit levels for wastes containing only, or primarily, chromium III. For example, a higher chromium exit level could be allowed if the generator demonstrated that a waste contained primarily chromium III and that the waste would be managed to preclude conversion to chromium VI. In general, when it is known that the toxicity of a constituent varies widely according to the chemical form (as in the case of chromium VI versus chromium III), DOE suggests that the exit levels reflect this. Exit levels for specific ions of key contaminants such as chromium, mercury, and others should be developed. Additionally, if generators can demonstrate that wastes contain the less toxic form, overly conservative exit criteria should not apply.

IV.C.3 Constituents of Ecological Concern

- 1. p. 66351, cols. 1 & 2 -- EPA states that it has not set benchmarks for ecological impacts for a large number of constituents under any of its programs and that establishing such benchmarks for this proposal would be a resource-intensive and time-consuming task. EPA indicates that it therefore elected to limit the list of exit constituents for which ecological receptors would be evaluated to (a) constituents that had already been targeted for analysis to protect human health, and (2) constituents that meet at least two of five criteria developed to indicate the potential for ecological risks.**

Recognizing the difficulties associated with establishing benchmarks for constituents of ecological concern, DOE nonetheless suggests that EPA continue to work toward the development of benchmarks for ecologic impacts. In addition, the Department believes that EPA should reexamine the rationale used to select constituents for which ecological receptors would be evaluated. Beginning with the 191 constituents that were targeted by human health risk and then narrowing the list based on five criteria which indicate the potential of a constituent to create ecological risk, does not seem appropriate. EPA should clarify why it is appropriate to limit the constituents evaluated for potential ecological concern to some subset of constituents that have human health concerns.

- 2. p. 66351, col. 3 -- In the last paragraph in this section, EPA explains that the ecological investigation (limited to 47 constituents), was sufficient to ensure that all 376 exit levels proposed offer reasonable protection of the environment. Also, EPA provides a concluding statement that "it is unlikely that all of the remaining constituents will present significant threats to ecological receptors at levels that would adequately protect human health."**

The statement (in the preamble) that "only 83 of 191 screened constituents showed any significant potential to pose threats to the environment at levels protective of human health" does

not support the argument that the ecological investigation was sufficient enough to offer adequate protection of the environment. Eighty-three out of 191 is not a small fraction, especially considering that a large portion of the toxicological data available for ecological risk assessment is from experiments performed on mammals as human surrogates, and the results of using these data in ecological models should be similar to human health results. EPA chose not to look at 36 constituents which met only one of the ecological risk criteria because of time and resources. Also, of the 47 constituents that were actually assessed, 6 for wastewaters (13%) and 18 for non-wastewaters (38%) required exit levels lower than those necessary to protect human health. From these findings, EPA concluded that it is unlikely that all of the remaining constituents will present significant threats to ecologic receptors at levels that would adequately protect human health. DOE questions this conclusion and the rationale for not testing other constituents for ecological risk. Even if a few of the constituents not selected for analysis are significant threats, then exit levels set for human health (or not set at all) will not be protective of the environment. DOE recommends that EPA bolster its argument or state that the extent to which the exit levels protect the environment from constituents not analyzed is not known.

IV.D Risk-Based Information

- 1. p. 66351, col. 3 - p. 66352, col. 1 -- In this section of the preamble, the Agency discusses the toxicity benchmarks chosen for non-carcinogens and carcinogens (i.e., hazard quotient of 1 and 1×10^{-6} cancer risk, respectively), and certain assumptions and parameters used for modeling the groundwater and non-groundwater pathways. EPA states that it “sought to be protective of a high percentile exposed population (at least 90th percentile).”**

DOE believes that the conservative assumptions used in the multi-pathway risk assessment model for determining exit levels from RCRA Subtitle C (which do not consider how waste will be managed) result in exit levels that are so low that the number of low-risk solid wastes able to meet such levels may be greatly diminished. Therefore, DOE suggests that the fact that the wastes eligible for exemption from RCRA Subtitle C management under the proposed rule would in fact be regulated by Subtitle D of RCRA, or perhaps under the Clean Air Act or Clean Water Act, should be reason not to make the underlying assumptions in the derivation of the exit levels so conservative. DOE suggests that EPA reconsider the following assumptions which may contribute excessive conservatism to the exit levels generated by the risk assessment.

- EPA used a 1×10^{-6} cancer risk as the toxicity benchmark. In other situations, the Agency has based proposed and final regulations on greater cancer risks. For example, EPA used a 1×10^{-5} cancer risk in establishing the toxicity characteristic (TC). The Agency indicated that such a risk level could identify broad classes of clearly hazardous wastes (55 FR 11832) as required under the characteristic program. In proposing the LDR treatment standards for solvents and dioxins (51 FR 1628), EPA suggested capping LDR treatment standards based on a risk level derived from the weight of evidence of a specific chemical's carcinogenic effects. The proposal stated that:

"Since carcinogens differ in the weight of evidence supporting the hazard assessment, EPA believes that the establishment of a single across-the-board risk level is not appropriate."

Also in that proposed rule, EPA proposed using different risk levels for Class A (human carcinogens) and Class B (probable human carcinogens) (i.e., 10^{-6}) than for Class C (possible human carcinogens) (i.e., 10^{-4} or 10^{-5}). Choice of risk level would depend on the particular scientific reasons for classifying the carcinogen as Class C.

- Although EPA has proposed doing so in prior rulemakings, it is not apparent that the Agency has considered limiting the assessment of the carcinogenic risk of compounds to specific routes of exposure in the analyses supporting the exit levels in the HWIR proposal. In proposing to cap the solvent and dioxins LDR treatment standards based on risk (51 FR 1629), EPA stated:

"Where carcinogenicity findings are available for only one route of exposure, the substance is judged to represent a cancer hazard by all routes unless it can be scientifically demonstrated that the material cannot gain access to target sites by the alternative routes of interest."

EPA indicated that for a few chemicals (notably metals), the database demonstrating that cancer is produced by one route of exposure but not by another is substantial and convincing. EPA offered as an example that chromium and some of its salts cause cancer by inhalation, but not apparently by other conventional routes of entry. EPA suggested that such substances be regulated as carcinogens only by the relevant route and as noncarcinogens by all other routes.

- EPA assumed that metals were insoluble, mobile, and in bioavailable form (see Section IV.E.2.b.3.iii). EPA could have assumed metal concentrations anticipated to result from hardness and/or pH conditions representative of the 90th percentile of wastes managed in the United States.
- EPA used high-end assumptions for two exposure values in assessing human risk (see Section IV.E.2.c.1). EPA could have based these exposure assumptions on central tendency values.

While it is difficult to determine quantitatively the net effect, the above assumptions and other aspects of EPA's methodology clearly contribute to the conservatism of the proposed exit levels. EPA should consider whether implementing less conservative assumptions in one or more of these instances would detract significantly from the rule's ability to meet the policy goal of establishing exit levels well below clearly hazardous levels. EPA's evaluation should consider the additional low-risk waste volumes eligible for exit and the associated costs savings versus Subtitle C management relative to the increment of conservatism that would be lost.

IV.D.1 Human Health Benchmarks

IV.D.1.c Consideration of MCLs

- 1. p. 66353, col. 1 -- EPA is proposing, and requests comment on, two approaches for setting human health-based levels for carcinogens and non-carcinogens in routes of exposure involving water ingestion. The two proposed approaches include: (1) using Maximum Contaminant Levels (MCLs), and (2) using only Reference Doses (RfDs) and slope factors.**

Because MCLs for carcinogens (which EPA points out "are set as close to zero as technically and economically feasible" (60 FR 66353, col.1)) do not appear to be risk-based, DOE favors using oral slope factors as the basis for calculating exit levels for all carcinogens. For non-

carcinogens, either MCLs or RfDs seem acceptable as a basis for setting human health-based levels.

IV.D.2 Ecological Benchmarks

- 1. p. 66353, col. 2 -- EPA states that "the toxicological benchmarks were established using the more conservative no effects level (or concentration) approach for ecological receptors as compared to a 20% effects level."**

DOE generally agrees with the "no effects" approach, since it is the only defensible approach for a generic model. However, if location-specific approaches are adopted as part of implementation of the rule, then provision should be made for using an upper bound on population loss as an assessment endpoint for ecological risk. This could be done when enough is known about a local population to predict reasonably the effect of losing a portion of it.

- 2. p. 66354, col. 1 -- EPA explains that the procedures used to develop benchmarks (i.e., RfDs) for protecting human health establish an acceptable daily dose for all individuals (including sensitive sub-populations) while the development of ecological benchmarks for the ecological analysis establish a level that will sustain the reproductive fitness in a local population. Consequently, benchmarks for birds and mammals were established using three key guidelines. One of these guidelines was to match the taxon of the test species to the taxon of the wildlife species to the greatest extent possible. EPA states that taxonomic similarities are generally associated with similarities in feeding habits, physiology, and chemical sensitivity at the family classification and to a lesser extent, the order classification.**

EPA's general comments on the association of taxonomic similarities and physiological similarities need to be bolstered by references. At least the example of herbivores being more resistant to toxicants than predators, needs a citation. Also, if plant toxins are bioaccumulated, this explanation may not hold.

3. **p. 66354, col. 1 -- As one of the guidelines for establishing benchmarks for birds and mammals, EPA adopted a default safety factor of 10 for extrapolating from a lowest-observed effects level (LOEL) to a no-effects level (NOEL).**

DOE agrees that a 10X safety factor for LOEL - NOEL conversion is sometimes justified. In addition, DOE recommends the use of lower factors based on familiarity with the toxicity data. For example, experiments with mice exposed to benzo(a)pyrene indicated a LOEL of 160 mg/kg/d and a NOEL of 40 mg/kg/d for a reproductive endpoint, indicating a LOEL/NOEL ratio of 4. Another benzo(a)pyrene study with a developmental endpoint had a LOEL of 10 mg/kg/d, but no reported NOEL. Although it will still result in the incorporation of a degree of uncertainty, use of the 4X factor to adjust this LOEL would be more reasonable than an arbitrary use of a 10X factor. [See Agency for Toxic Substances and Disease Registry (ATSDR), Draft Toxicity Profile for Polyaromatic Hydrocarbons; October 1993.]

4. **p. 66354, col. 1 -- For mammals and birds, differences in interspecies uncertainty were indirectly addressed through the use of a species-scaling equation.**

DOE concurs with the use of a scaling factor to adjust for the differences in metabolism of differently-sized mammals and birds. The use is reasonable, especially if it reduces or eliminates a safety factor for interspecific application of toxicity data. This would help reduce undue conservatism in the risk model. Users of the scaling factor should be aware of uncertainties due to differential thermal properties of fur and other factors.

5. **p. 66354, col. 2 -- EPA solicits comment on the inability of the risk assessment to evaluate inhalation and dermal routes of exposure for birds and mammals.**

DOE considers dermal routes of exposure to be much less important for mammals and birds than for humans. Incidental ingestion by preening seems like a more important pathway, and this is covered in the risk model. Unfortunately, there are few data to substantiate this. On the other hand, inhalation could be evaluated (at least for mammals) with the results of inhalation experiments which have been used to set occupational exposure limits in terms of concentrations in air. Because it does not estimate a dosage, a comparison with inhalation toxicity data would be a separate analysis from the approach used for the other routes. Also, the inhalation studies may be predominately designed for acute effects, so factors may be needed for conversion to chronic exposure.

IV.E Risk Assessment

IV.E.2 Detailed Overview of the Non-Groundwater Risk Assessment

IV.E.2.a Waste Management Units

1. **p. 66358, col. 1 -- EPA selected non-Subtitle C waste management units to use in the risk assessment. This selection attempted to reflect both the influence of the type of unit on pathways and those that might be commonly associated with the management of exited hazardous wastes in non-Subtitle C waste management units.**

DOE believes that while the selection of the non-Subtitle C waste management units for the risk assessment used to derive exit levels may be appropriate for most hazardous wastes that may exit under this HWIR proposal, they are not appropriate scenarios for much of DOE's mixed wastes. Most of the Department's mixed wastes will be treated, prior to disposal in a DOE or a commercial facility, in accordance with the Site Treatment Plans and compliance orders developed under the Federal Facility Compliance Act of 1992 (FFCA). In addition, DOE mixed wastes will be disposed in DOE or commercial radioactive waste disposal facilities that are managed in accordance with the requirements put forth under the Atomic Energy Act (which focus on the proper management of radioactive materials). Based on the method by which DOE wastes are and will be treated and disposed, DOE believes that, in general, the groundwater exposure pathway -- as opposed to the non-groundwater pathways -- will have the most relevance to DOE mixed wastes.

Furthermore (considering the differences in design and operation of waste management units that handle radioactive wastes), DOE suggests that mixed wastes managed in DOE radioactive waste management facilities that comply with Order DOE 5820.2A, or in commercial NRC-licensed radioactive waste management facilities, be subject to different criteria for exemption from RCRA Subtitle C than non-radioactive hazardous wastes being managed in non-Subtitle C waste management units (see DOE's General Comments 2, 3 and 5).

IV.E.2.a(2) Fate and Transport

1. **p. 66359, col. 1 -- Fate processes, particularly biodegradation and hydrolysis, were accounted for only in the land application unit. EPA requests comment on not considering biodegradation and hydrolysis in waste management units other than the land application unit.**

The fate processes of biodegradation and hydrolysis should be considered with respect to the management of wastes in treatment tanks and surface impoundments in addition to land application units. Wastes managed in these units would have a calculable residence time during which these processes could influence the availability of constituents. In addition, EPA may want to address photolysis. This process would be important in land application units and surface impoundments, and perhaps in other units where waste is exposed to light.

IV.E.2.a(5) Waste Pile

IV.E.2.a(5)(i) Waste Pile Height

1. **p. 66360, col. 2 -- EPA explains that because no data were available on waste pile height, this value is an estimate based on heights attainable by a front-end loader.**

Waste piles can often times be much higher than the height attainable by front-end loaders. Since dump trucks (not front-end loaders) typically are used for depositing wastes, the mounds can be as high as 40 feet or more. EPA may wish to consider this when modeling air dispersion from a waste pile.

IV.E.2.b Fate and Transport

IV.E.2.b(3) Specific Issues on Pathways and Equations

IV.E.2.b(3)(i) Hydrolysis

1. **p. 66362, col. 3 -- The list of inorganic salts which were not assessed because they dissociate completely includes eight cyanide salts. Cyanide ion was not assessed for human or ecological receptors; it was assigned an exit value based on "extrapolation."**

Considering that cyanide is quite toxic, and that there are considerable data available to ascertain its toxicity (e.g., ATSDR Draft Toxicity Profile, October 1991; and Quality Criteria for Water (EPA), May 1986), DOE recommends including cyanide in the risk assessment for both human and ecological receptors.

IV.E.2.b(3)(ii) Other Fate and Transport Processes

1. **p. 66363, col. 1 -- EPA solicits comments on its approach for addressing other processes (i.e., other than hydrolysis) with respect to modeling fate and transport processes throughout the exposure pathways considered in the non-groundwater analysis.**

Oversimplification of fate and transport variables into a general environmental setting can result in extreme over- or underestimation of risks at sites. Having faced this problem with DOE programmatic activities, it is suggested that, at a minimum, arid and humid climate categories be developed. Three or four categories of environmental settings would be preferable to ensure that inaccurate generalizations are not made in the development and application of the exit levels.

IV.E.2.b(3)(iii) Bioavailability

1. **p. 66363, col. 2 -- Based on a lack of data on "the speciation, solubility, or availability of the metals in the wastes in which they are disposed or how they may transform in the environment," EPA assumes for the purpose of the proposal that the metals in wastes are soluble, mobile, and bioavailable.**

EPA's assumption that metals are soluble, mobile, and bioavailable is very likely to overestimate

the risk associated with metals in many situations. DOE's research, as well as a review of the scientific literature indicates that metals in treated hazardous wastes are generally insoluble and barely mobile or bioavailable. Several factors, including sorption and interaction with soil matrices, limit the actual amount of metals which may enter the various pathways. References to this research are provided in Attachment C. These references and associated discussion are also included in DOE's July 1995 debris technical data package entitled, "Disposal of Immobilized Mixed Waste Debris in Low Level Waste Disposal Facilities"¹⁹ and in Section 2 of the October 1995 supplement, "Performance Evaluation for RCRA Toxic Metal Disposal in DOE Low-Level Radioactive Waste Disposal Facilities."²⁰ Section 2.3 of the performance evaluation report reviews chemical processes influencing transport and fate of RCRA metals in the hydrogeological environment and selection of sorption parameters.

DOE plans to use stabilization technologies for treating a large portion of the Department's mixed waste. Stabilization of these wastes will immobilize hazardous (and radioactive) constituents. Information on the leach rates associated with RCRA metals has been submitted to EPA as part of the Immobilized Debris and Vitrification Technical Data Packages (i.e., the advance input and the materials DOE submitted to EPA (in regards to proposed HWIR) on July 21, 1995 and October 20, 1995). Tables 3-1 through 3-8 of DOE's Immobilized Debris Technical Data Package contain the results of several recent studies on the leachability of RCRA metals. In addition, Tables 1 through 7 of the report entitled, "TCLP Testing of DWPF Projected Glass Compositions," WSRC-TR-94-0025, Rev. 1, contain leachability information included in the Vitrification Technical Data Package submitted to EPA in October 1995.

IV.E.2.b(3)(viii) Food-Chain Pathways

- 1. p. 66364, col. 3 - p. 66365, col. 1 -- EPA seeks comment on several issues related to the modeling of food-chain pathways. One of these issues is the use of regression equations based on K_{ow} to derive biotransfer factors for plants - The biotransfer factors are based upon empirical relationships with K_{ow} defined by studies on relatively few chemicals.**

The preamble explains that plant uptake of contaminants has been estimated by regressing biotransfer factors for plants based on K_{ow} , using studies on few chemicals. DOE believes that this approach is deficient. Plants appear to be just as likely to break organics down at the root tips as they are to accumulate them. This is the basis of some new remediation techniques. [See

¹⁹ Letter to Director of EPA's Office of Solid Waste (July 21, 1995) [transmitting DOE's technical data on the performance of immobilized debris waste forms to support EPA's assessment of this method of hazardous debris treatment].

²⁰ Letter to Director of EPA's Office of Solid Waste (October 20, 1995) [forwarding (1) supplemental data in support of an exclusion from RCRA Subtitle C requirements for immobilized mixed waste debris, and (2) a technical data package to support a proposal that certain vitrified mixed waste forms should be exempt from RCRA Subtitle C requirements after completion of the permitted treatment process].

Journal of Environmental Quality; vol. 23; p. 1113; 1994.] DOE recommends estimating uptake and breakdown only for specific chemicals, or chemical groups, which are known to be accumulated or decomposed by plants.

IV.E.2.c Receptors

IV.E.2.c(1) Human Receptors and Exposure

- 1. p. 66365, col. 2 -- EPA lists the human receptors examined in the assessment. One of the human receptors identified is an on-site worker at the waste management unit who would inhale and have dermal contact with contaminated soil during the active life of the unit.**

OSHA prescribes personal protective equipment (PPE) requirements to protect workers from both inhalation and dermal exposure. The extent to which PPE meeting OSHA standards would preclude exposure of on-site workers at the levels predicted by the model should be assessed to ensure that unrealistic occupational exposures levels were not used as the basis for the proposed exit levels.

IV.E.2.c(2) Ecological Receptors and Exposure

- 1. p. 66366, col. 3 -- EPA explains that each of the ecological receptors included in the assessment has been matched with the exposure pathways and waste management units likely to result in exposure. The Agency solicits comments on the use of a single species to represent major trophic elements.**

The use of a single species to represent "major trophic elements" is now common in ecological risk assessments. The sensitivity of this approach can be evaluated by selecting additional species from the same "trophic element" for analysis on a few constituents. DOE recommends that this analysis be performed in order to assess the uncertainty involved in selecting a single species to represent a large group of organisms.

- 2. p.66367, col. 2 -- EPA states that the key equation used to back-calculate soil concentrations as a function of dietary exposure, and the exposure inputs for ecological receptors are discussed in Section 5.3 of the Risk Assessment.**

The reference in this discussion "Section 5.3 of Risk Assessment" does not appear to correspond accurately to a section of the preamble or to a particular technical support document. Clarification or a corrected reference concerning this information should be provided.

IV.E.4 Other Risk Assessment Issues

IV.E.4.a Differences Between the Groundwater and Non-groundwater Analyses

- 1. p. 66373, col. 1 -- In a discussion regarding the evaluation of risks from groundwater and non-groundwater pathways, the preamble indicates that the approach used is consistent with "EPA's risk characterization guidance (EPA 1995)."**

In Section XV, References, of the preamble (pp. 66417-66418), there is no specific document clearly recognizable as "EPA's risk characterization guidance (EPA 1995)." It is unclear whether this citation is referring to one or more of the four EPA documents listed in Section

XV that were published in 1995 (i.e., 1995 a-d). DOE recommends that clarification be provided with respect to this reference.

IV.E.4.b Other Groundwater Pathway Analysis Issues

IV.E.4.b(1) Use of 1,000 Year Versus 10,000 Year Exposure Time Horizon

- 1. p. 66373, col. 3 - p. 66374, col. 1 -- EPA proposed concentration limits based on a 10,000 year time horizon for the groundwater pathway analysis, and requests comment on using 1,000 years as an alternative time horizon.**

DOE recommends using a 1,000 year exposure time horizon for the groundwater pathway analysis rather than a 10,000 year time horizon. The Department makes this recommendation based on three factors: (1) consistency with other EPA standards and requirements; (2) the uncertainty of modeling over a 10,000 year period and the unreliability of decisions based on risk projections extending over very long periods; and (3) the recommendations of a 1994 National Association of Public Administration workshop on intergenerational equity.

Using a 1,000 year time horizon would be more consistent with other EPA requirements, standards, and regulatory actions for near-surface disposal of hazardous and radioactive materials. In addition, EPA is considering a 1,000 year time of compliance for assessments to determine allowable levels of residual activity after decommissioning nuclear facilities (i.e., under draft 40 CFR Part 196, Environmental Protection Agency Radiation Site Cleanup Regulation). Also, EPA's standards under 40 CFR Part 192 (Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings) impose a 200 to 1,000 year horizon for control measures at uranium mill tailing processing or depository sites. A more detailed discussion regarding the use of 1,000 year time horizons in EPA regulations and guidance is provided in Attachment D to these comments. In particular, see the section on "Consistency" in the attachment.

The uncertainties are fewer and reliability is greater for modeling and decision making based on shorter time horizons. Over the past several decades, DOE has performed numerous analyses projecting possible risks from contacting, inhaling, or ingesting contaminants. Based on this experience, the validity of analyses conducted for more than a few hundred years becomes questionable, and extensive uncertainties associated with long-term predictive modeling efforts have been noted. These uncertainties are described in more detail in Attachment D to these

comments. In particular, see the section of the attachment that discusses “Reliability and Uncertainty.”

The National Academy of Public Administration (NAPA) addressed the issue of intergenerational equity at a workshop held in 1994 -- "Deciding for the Future: Balancing Risks and Benefits Fairly Across Generations." The NAPA analysis suggests that compliance or analytical periods extending beyond a few hundred years would be questionable and beyond 1,000 years would be inappropriate. A more detailed discussion of the recommendations and basis for those recommendations is provided in Attachment D to these comments. In particular, see the section that pertains to the “Recommendations from NAPA Workshop on Intergenerational Equity.”

IV.E.4.b(2) Implementation of Parameter Bounds in Monte Carlo Procedure

- p. 66374, cols. 2 & 3 -- The preamble outlines two alternative Monte Carlo procedures (i.e., in particular, parameter rejection alternatives) that could be used in the groundwater pathway analysis. EPA is soliciting comments on the Monte Carlo parameter rejection procedure used for the results presented in this subsection.**

It is not clear how the different parameter rejection methods can result in widely different results for waste piles and surface impoundments. More explanation for the bias toward larger areas for these types of units is required in order to evaluate the parameter rejection procedure employed in the Monte Carlo modeling.

IV.F Additional Eco-Receptor Considerations

- p. 66375, col. 3 - EPA chose to propose exit levels that would protect terrestrial ecological receptors located outside the boundaries of the waste management site. EPA solicits comment on an alternative of protecting ecological receptors on-site, with a rationale of protecting populations and regulating certain constituents that could result in environmental consequences extending significantly beyond the bounds of a waste management unit.**

DOE recommends that the alternative of protecting ecological receptors on-site be considered if the regulatory apparatus is flexible enough to allow exit levels to be set using local and regional data. Impacts on birds and mammals populations and other ecological receptors should be considered on a case-by-case basis because they depend on site- or region-specific criteria such as the size of contaminated area within the site, natural history of the receptors of concern, and the size and areal extent of the receptor population.

IV.G Background Concentrations in Soils and Other Issues Relating to Results

- p. 66376, col. 1 -- If the final exit levels are below typical soil levels, EPA would consider promulgating levels based on concentrations that are either typical soil**

concentrations (national mean levels) or some percentile or portion of the naturally-occurring range such as the 10th percentile. EPA asks for comments on the reasonableness of the assumptions supporting this approach.

DOE believes that the conservatism in selection of exposure parameters and safety factors is the likely reason that some of EPA's calculated exit levels for metals are lower than soil background levels. For this reason, DOE suggests that EPA re-examine potentially overly conservative assumptions in order to evaluate the validity of such low exit levels. In the absence of establishing that the calculated low exit levels are valid, DOE believes that arbitrarily selecting replacement exit levels at the 10th percentile of the natural soil background concentration range is not justified, and is itself an overly conservative assumption. Selecting national mean levels also has little justification, but seems more reasonable than the 10th percentile.

- 2. p. 66376, col. 1 -- EPA requests comment on issues related to chemical and physical form in which compounds or chemicals exist, and the possibility that a simple comparison of total concentrations in soils and in wastes might be misleading about potential ecological or human impacts.**

DOE agrees that a simple comparison between total concentrations in soils and totals in wastes is potentially misleading. It would be relevant, for instance, to compare total metals in a vitrified waste form with leachable metals in vitrified waste. However, comparing totals in soils to totals in waste would not represent accurately any threat to human health or environment if waste concentrations are not necessarily leachable.

- 3. p. 66376, col. 2 -- EPA requests comment on whether its arguments regarding background contamination in soils could be extended to site-specific determinations where information on local background constituent concentrations and form in soil are available.**

DOE believes that EPA's suggested approach to a self-implementing method for setting exit levels on a site-specific basis when the calculated exit levels are less than soil background levels would be too inflexible regarding statistical comparisons. In DOE's experience, environmental data are seldom normally distributed and many data sets do not conform to any recognizable distribution, even after transformation. Therefore, it may not be credible at some sites to establish a site-specific normal distribution for background concentrations from which the mean values can be chosen. For this reason, DOE would prefer that the final HWIR defer any background level demonstrations to an omnibus authority for the overseeing agency (see DOE comment IV.G, item 5).

- 4. p. 66376, col. 2 -- EPA states that a more simplified approach for addressing the issue of background concentrations in soils would be to establish exit levels at 1/10 of the naturally occurring background level. The rationale for using 1/10 is that these levels would not contribute appreciably to the overall risk posed by elevated levels in environmental media. EPA requests comment on this approach as well as the**

rationale.

While it is simpler, choosing 1/10 of background as an exit level is no better supported than choosing the 10th percentile of the range of background concentrations. In the absence of establishing that the calculated low exit levels are valid, DOE believes that arbitrarily selecting replacement exit levels at 1/10 of natural soil background is not justified, and is itself an overly conservative assumption. Selecting the mean background level as the exit level may also have little justification, but it seems more reasonable than 1/10.

- 5. p. 66376, col. 3 -- EPA states that another alternative for addressing exit levels that are below background levels would be to defer any background level demonstrations to an omnibus authority for the overseeing agency, and requests comment on the need for this authority.**

DOE recognizes the complexity involved in the development and evaluation of the various exposure scenarios associated with determining the proposed generic exit levels, and commends EPA for the thoroughness of its efforts. Due to the need for a model which is protective on a nationwide basis, however, the assessment assumes factors which, in many cases, may be highly conservative compared with the conditions at a specific site. As a consequence, DOE supports a provision allowing Regional Administrators or approved State programs to adjust the exit levels, when appropriate, to reflect site-specific conditions.

IV.H Constituents with Extrapolated Risk-Based Levels

- 1. p. 66377, col. 1 - EPA proposed establishing exit levels for constituents that could not be modeled by extrapolation. EPA selected the 50th percentile value from the range of risk levels for modeled constituents in the corresponding chemical class. EPA requests comment on the alternative of using the 10th percentile or some other percentile from the modeled exit levels for each chemical class, noting that such an approach would reduce the chances that the actual health benchmark for a particular level was lower than the extrapolated estimate.**

DOE agrees that the extrapolation methodology for generating for exit levels is an appropriate approach for those constituents for which risk assessments could not be conducted. DOE supports extrapolation using the 50th percentile as a balanced approach to afford wastes containing such constituents the opportunity to exit Subtitle C. DOE believes that using 10th percentile values would introduce unwarranted conservatism for these constituents given the overall level of conservatism provided by the modeled results. Use of the 50th percentile is consistent with EPA's use of central tendency values for parameters utilized in the risk assessments.

- 2. p. 66377, col. 2 -- EPA also considered using exemption quantitation criteria (EQCs) as exit levels for the unmodeled constituents (i.e., constituents for which the Agency**

was unable to conduct the risk assessment), and asked for comment on this alternative.

DOE agrees with EPA's analysis that this alternative is unreasonable because it regulates these constituents based on the analytical ability to detect them rather than on risk considerations. DOE supports the approach of extrapolating risk based levels based on the toxicity and fate and transport behavior of structurally similar chemicals, and considers it to be an appropriate risk-based methodology to establish exit levels for unmodeled constituents.

IV.I Analytical Considerations

IV.I.2 EQCs and LDR Requirements as Exit Levels

- 1. p. 66378, col. 1 -- For wastes containing constituents with a modeled or extrapolated risk-based level lower than the EQC, exit criteria include meeting the EQC along with an additional requirement that the waste meet LDR treatment standards, regardless of whether the waste is to be land disposed.**

DOE supports the use of EQCs as exit levels (i.e., when modeled or extrapolated exit levels are lower than quantitation limits). However, the benefit of requiring compliance with LDR treatment standards as well as meeting EQCs is not clear since the LDR treatment standards are technology-based standards and do not translate directly to the assessment of risks being considered in the HWIR (especially in cases that do not involve land disposal). Therefore, in some cases, treatment to LDR standards may further minimize risks, and in other cases the LDR treatment may be far more than needed -- thus, creating an unnecessary and costly level of protection. DOE recommends that EPA give further consideration to this approach and to present a more extensive supporting rationale for public review and comment before promulgating such requirements. DOE also recommends that applicability of the LDR standards be determined independent of the waste exit levels [i.e., applied only to wastes destined for land disposal as defined by §268.2(c)].

IV.I.2.a EQCs as Exit Levels

- 1. p. 66378, col. 1 -- In developing the exit levels, EPA is proposing that quantitation limits cap the modeled or extrapolated risk-based levels because a reliable, consistent measure of the constituent below the quantitation limit is not achievable.**

DOE understands that in many cases, existing analytical techniques cannot detect constituent levels at the modeled or extrapolated risk-based levels. In such cases, EPA is proposing to cap the risk-based levels using the EQCs. As stated in the comment above, DOE supports this regulatory approach. However, as EPA has stressed in the preamble (e.g., see 60 FR 66381, col. 2), more and more data and techniques are becoming available to allow confident use of risk assessment. Similarly, as analytical techniques improve, the limits of detection are also likely to improve. DOE suggests that EPA revisit the quantitation limits over time for those constituents

with exit levels capped by the EQCs. Alternatively, EPA should allow generators to petition EPA for review of the EQCs when such generators believe they have sufficient evidence to detect concentrations at the risk-based levels. In this way, EPA will continue to foster the purpose of the rule, i.e., to reduce any overregulation of low-risk wastes captured by the mixture and derived-from rule.

- 2. p. 66378, col. 1 -- EPA requests comments on whether an exemption demonstration should be considered adequate if all proper method selection and QC procedures are followed and the constituents are not detected, even though the EQC level has not been analytically attained.**

In the past, some DOE facilities have experienced difficulties in obtaining adequate analytical detection levels. DOE supports considering an exemption demonstration as adequate if all proper method selection and QC procedures are followed and the constituents are not detected, even though the EQC level has not been analytically attained. In addition, however, it is recommended that EPA develop more specific criteria relative to documenting that the proper method has been selected, and that all the appropriate QC procedures have been followed. The Department suggests that EPA use the same guidance it proposed developing in reference to defining what comprises a “good faith effort to achieve analytical sensitivity” in demonstrating compliance with LDR standards (55 FR 22541; June 1, 1990).

IV.I.2.b LDR Requirements for Constituents with EQC Exit Levels

- 1. p. 66378, col. 3 -- EPA proposed exit levels based on EQCs where the modeled or extrapolated risk-based exemption levels were lower than the levels at which the constituent could be routinely detected using existing analytical methods. In addition, EPA proposed that such wastes meet the applicable LDR treatment standards, regardless of whether the wastes were destined for land disposal. In that numerical LDR requirements for wastes subject to the universal treatment standards (UTS) are equal to or higher than the EQCs, additional treatment to meet applicable LDR standards would only be required for those wastes subject to specified technology standards under §268.40.**

DOE requests clarification concerning wastewaters being discharged under a National (or State) Pollutant Discharge Elimination System (NPDES) permit. If such wastewaters comply with NPDES discharge limitations, is compliance with EQCs and LDRs still mandated?

IV.I.3 Exemption for Constituents without EQCs

- 1. p. 66378, col. 3 -- EPA indicates that most of the 78 constituents in the category of constituents for which calculated exit levels are less than detection limits, but for which EQCs could not be developed, are found only in P and U listed wastes and are not widely prevalent in wastes.**

Given the limited circumstances under which these constituents are encountered, it may be justifiable to delete these constituents from the exit table (i.e., which is one of the alternative approaches EPA suggested), at least until EPA is able to establish EQCs. Alternatively, DOE believes that if a waste containing one or more of the 78 constituents complies with the exit levels for all other constituents (i.e., modeled, extrapolated, or EQC-based levels), there would be reasonable assurance that constituents for which EQCs cannot be set are not present at levels that warrant continued Subtitle C management. DOE recommends that compliance with the proposed exit levels for all other constituents, and compliance with the applicable LDR standards *if the waste is to be land disposed*, be considered adequate to allow wastes containing these constituents to exit.

2. **p. 66379, col. 1 - EPA proposes that wastes containing constituents for which calculated exit levels are less than detection limits, but for which EQCs could not be developed, be eligible for exemption if the wastes comply fully with applicable LDR treatment standards, regardless of whether the waste is to be land disposed. EPA asks for comments on this approach.**

As EPA pointed out in the preamble to the proposed rule, concentration-based LDR treatment standards would be equal to or higher than the EQC exit levels themselves (p. 66378, col.3). However, additional treatment might be required for wastes subject to treatment standards based on application of specified treatment methods under §268.40 (as opposed to concentration-based standards). DOE believes that requiring wastes containing constituents without EQCs to meet LDR standards when they will not be land disposed would be unnecessarily burdensome. If the concentration of the constituent in the waste is below the EQC, and the waste will not be land disposed, additional treatment is unlikely to offer a significant degree of additional protection to human health and the environment. Furthermore, application of both EQC exit levels and LDR standards to wastes that are not land disposed would be more stringent than the existing requirements imposed under Subtitle C of RCRA for the same wastes, since Subtitle C does not apply LDR standards to wastes unless they are land disposed. DOE recommends that applicability of the LDR standards be determined independently of the waste exit levels (i.e., applied only to waste destined for land disposal).

V. Presentation of Exit Levels

V.A Constituents with Modeled or Extrapolated Risk-Based Exit Levels

1. **p.66379, col. 2 -- EPA is proposing that for constituents with modeled or extrapolated risk-based exit levels [as well as those existing under EQC], nonwastewaters would require: (1) a totals analysis to show that constituents do not exist in the waste stream at levels above exemption levels; and (2) either the TCLP test or a calculational screen to show that constituents in leachate do not exceed levels above exemption levels.**

In order for a nonwastewater to be eligible for exemption from Subtitle C, every constituent in

the waste must comply with the nonwastewater total constituent exit level as well as the nonwastewater leach exit level. That is, nonwastewaters that have constituents with exemption criteria based on modeled or extrapolated exit levels (as well as those existing under EQC) would be required to conduct both a totals analysis, and the TCLP test or a calculational screen. The nonwastewater total constituent exit levels are the result of the most limiting non-groundwater exposure pathway, while the nonwastewater leach exit level are based on the most limiting groundwater pathway.

Under these proposed testing requirements, nonwastewaters treated using immobilization technologies must comply with the total constituent exit levels in order to qualify for exemption from RCRA Subtitle C regulation. As such, the proposed HWIR provides little relief for metal-bearing wastes treated via immobilization. Unlike organic constituents, metal constituents cannot be destroyed. The appropriate treatment (i.e., the only treatment options) for waste streams containing these constituents is removal or immobilization. Pursuant to the LDR program, the TCLP test has been designated as the analytical method that must be performed on immobilized waste forms to validate that the applicable treatment standards have been achieved before the waste may be land disposed.

Certain treatment residuals (e.g., certain immobilized waste forms) that would easily meet the HWIR leach exit levels (as well as the applicable LDR treatment standards) may contain *total* constituent concentrations that exceed the HWIR total constituent exit levels. As such, these treatment residuals would be ineligible for exemption from RCRA Subtitle C (under the proposed HWIR). However, the waste itself is not always the source of the hazardous constituents. Many of the media used in immobilization technologies (e.g., Portland cement, blast furnace sludge, fly ash, glass frit, vitrification additives, and so on) are based on naturally occurring minerals or raw materials that often contain trace amounts of lead, barium, selenium, or arsenic in excess of the HWIR total constituent exit levels. Additionally, some standard commercial grade filter aids, (i.e., diatomaceous earth) would not meet the HWIR total constituent exit levels for lead, copper, and zinc *prior* to treating a liquid waste stream.

One example of an immobilized waste that would not benefit from the current HWIR proposal is M-Area plating line waste at DOE's Savannah River Site. The M-Area plating line sludges contain small amounts of metallic trace constituents, such as copper, lead, and zinc, that did not result from the plating line activities, but were present as contamination in the acids, bases, and raw materials used in the plating line process. Table 1 (provided on the following page) shows totals and TCLP leach results for vitrified F006 plating line waste, and total analysis for raw materials used in the process, and compares them with the proposed HWIR exit levels. Several of the metals in the vitrified M-Area waste would not meet the total constituent exit levels, even though they would meet all of the leachate exit levels -- in most cases by orders of magnitude.

In addition to providing little or no regulatory relief, the proposed HWIR exit criteria (and associated testing requirements) may actually present a fundamental *disincentive* to treaters of metal-bearing wastes relative to improving the effectiveness of their treatment processes. With

respect to wastes containing organic constituents, the proposed HWIR exit criteria provide a distinct incentive for treatment processes to be improved (to further destroy organics) such that treatment residuals would meet the HWIR exit levels. However, since immobilization technologies do not destroy or remove metals, no benefit would be derived from improving an immobilization process for a metal-bearing waste (i.e., since the total constituent concentration of metals in the waste would remain the same, regardless of any improvement in durability or leachability of the immobilized waste form). Thus, the proposed HWIR provides no incentive for efforts to further improve upon existing immobilization technologies.

DOE also believes that EPA's proposal to require nonradioactive, hazardous nonwastewaters to conduct both totals analysis (non-groundwater dominant pathway) and TCLP analysis (groundwater dominant pathway) to demonstrate that compliance for constituents with modeled or extrapolated risk-based exit levels (and quantitation-based exit levels) could be cost-prohibitive and unnecessarily stringent. Even the option of using the calculational screen, which requires duplicate totals analyses on both the "liquid" and "solid" phases of any samples that are not considered 100 percent solids, will at least double the cost of analysis.

In the preamble to the HWIR proposal, EPA states that "it would be preferable to have one exit level, but . . . using only the leach or only the total risk level would reflect only a portion of the risks presented by the waste" (60 FR 66384, col. 2). With regard to the Department's radioactive mixed wastes, most of these wastes will be treated prior to disposal in accordance with Site Treatment Plans and compliance orders established under the Federal Facility Compliance Act (FFCA), RCRA, and applicable State laws. For these treated mixed wastes, it is likely that only one exposure pathway (i.e., the groundwater pathway) will be the dominant pathway and will drive risk at the DOE disposal facility. Therefore, with this consideration in mind, DOE requests that EPA allow treated mixed waste to qualify for exemption from RCRA Subtitle C requirements if:

- (a) the waste meets total constituent exit levels (Totals) when a non-groundwater exposure pathway is the dominant exposure pathway, i.e., disposal is in a unit other than a landfill/monofill or
- (b) the waste meets leachate exit levels (based on the TCLP or calculation screen, or possibly the Synthetic Precipitation Leaching Procedure) when groundwater is the dominant exposure pathway, i.e., when disposal is in a landfill/monofill unit.

VI Minimize Threat Levels

VI.B Risk Assessment and Minimize Threat Levels

VI.B.1 Rationale

VI.B.1.a Overview

1. **p. 66381, col. 2 -- EPA is proposing to establish risk-based LDR treatment requirements for some of the hazardous constituents for which exit levels are being proposed. These risk-based LDR requirements (or "minimize threat" levels) would have the effect of capping, or limiting, treatment of those waste constituents where the current technology-based UTS require lower concentrations.**

As DOE has commented in several previous rulemakings,²¹ the Department supports the concept of establishing risk-based "minimize threat" levels to cap RCRA section 3004(m) treatment. Furthermore, the Department supports using the HWIR risk-based exit levels to function as such "minimize threat" levels in cases where the HWIR concentrations are higher than the existing technology-based LDR standards. DOE agrees, however, that in cases where EPA is proposing HWIR exit levels not based on any analysis of risks to human health and the environment (i.e., extrapolated exit levels and exit levels based on quantitation limits), such exit levels cannot credibly serve as "minimize threat" levels for purposes of capping RCRA section 3004(m) treatment.

2. **p. 66381, col. 3 -- EPA states that it will not require compliance with LDR treatment standards for wastes that are below exit levels at the wastes's point of generation (provided the claimant meets all the requirements for filing an exit claim).**

DOE requests that EPA provide clarification as to whether this regulatory approach also applies to previously generated wastes that have been in long-term storage pending treatment (e.g., certain radioactive mixed wastes). DOE believes that wastes should be allowed to qualify for exemption (based on sufficient demonstration through testing and acceptable knowledge), not just at the point in time of initial generation, but at any time provided the claimant can show all constituents to be below the exit levels. This is particularly important for DOE legacy mixed wastes being stored (in accordance with site treatment plans prepared under the Federal Facility Compliance Act of 1992) due to the present unavailability of mixed waste disposal facilities. DOE urges EPA to consider allowing such legacy wastes to qualify for exemption, without a further requirement to meet LDR treatment standards.

VI.B.1.c Scope of the Risk Assessment

1. **p. 66383, col. 1 -- EPA states that the complexity of conducting and analyzing additivity of risk (when multiple waste constituents potentially occur in one or more waste streams that might be considered for exit) quickly becomes overwhelming. For this reason, the risk analysis does not account for additivity of risk for exposure to**

²¹ See DOE Comments, Proposed Rule regarding Land Disposal Restrictions--Phase III, Specific Comment III.B, item 1, pp. 9-10 (05/01/95); DOE Comments, Proposed Rule regarding Land Disposal Restrictions for Newly Identified and Listed Hazardous Wastes and Hazardous Soil, Specific Comment I.C., item 1, pp. 7-8 (11/15/93); DOE Comments, Interim Final Rule regarding LDR Treatment Standards for Certain Ignitable and Corrosive Wastes, Specific Comment III.F., item 1, p. 16 (07/09/93); DOE Comments, Notice of Data Availability and Request for Comments regarding Response to Court Decision, Specific Comment III.E.1, item 1, pp. 16-17 (03/04/93).

multiple constituents. EPA requests comments on the limitations of the risk assessment, such as the lack of accounting for additivity of risk for exposure to multiple constituents.

Under this proposed rule, EPA proposes to set the exit level for each chemical at a concentration which would produce a cancer risk of 1×10^{-6} . One of the reasons this "conservative risk target" was utilized, and thus, one of the contributing factors to the overly conservative results, is that the risk assessment does not account for additivity of risk for exposure to multiple constituents. Since EPA uses the upper 95 percent confidence limit in selecting these values, the associated risk is actually much less than 1×10^{-6} . However, in a practical sense, this approach is likely no more protective than one in which a summed risk of 1×10^{-4} is used as an action level (e.g., Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) response actions). EPA believes the inherent conservatism of its approach to setting HWIR exit levels without considering additivity of risk is not a problem, because individual constituents often drive determinations of whether waste streams exit, and additivity would often make little difference with respect to calculated risk levels. Nonetheless, under EPA's approach, complex mixtures with large numbers of constituents could have an associated risk comparable to 1×10^{-4} , while less complex wastes (1 or 2 constituents) would be penalized.

VI.B.2 Public Policy Considerations

- 1. p. 66383, col. 3 -- EPA states that "the Agency believes that for the initial list of constituents listed in Table 1 of 40 CFR 268.60, treatment to the UTS/LDR standards is no longer required beyond waste constituent concentrations where risks to human health and the environment are insignificant." EPA further states that the Agency is proposing "to revise [certain UTS/LDR standards (i.e., those UTS/LDR standards that are more stringent than the exit levels which are based on risk analysis)] to the risk-based [HWIR exit] levels." EPA asserts that this revision to the UTS/LDR standards "would reduce the overall number of different and distinct regulatory requirements on waste generators and treaters, [and would] ... rationalize the RCRA regulations...."**

DOE notes that the actual regulatory language which EPA proposes for 40 CFR 268.60 does not revise the existing UTS/LDR standards "to the [proposed HWIR] risk-based levels." Instead, the "Minimize Threat Levels" presented on Table 1 of proposed 40 CFR 268.60 "may be used as alternatives to waste-specific treatment standards in the table to §268.40 and to the Universal Treatment Standards in the table to §268.48." (See proposed §268.60(a); 60 FR 66465.) DOE requests that EPA clarify in the final rule the Agency's rationale for defining minimize threat levels in a separate regulatory table and then allowing them to be substituted as *alternatives* to the existing UTS/LDR treatment standards, rather than incorporating the minimize threat levels as *replacements* in the manner described by this section of the preamble. The added regulatory provisions (and corresponding table) for defining minimize threat levels seem unnecessary and somewhat confusing.

VI.C Risk-Based LDR Levels

VI.C.1 List of Constituents and Minimize Threat Concentrations

1. **p. 66383, col. 3 - p. 66384, col. 1 -- EPA states that minimize threat levels are only proposed for those constituents where the risk-based HWIR exit level is higher (less stringent) than the associated technology-based LDR treatment standard in §268.40 or the UTS level in §268.48.**

DOE agrees that minimize threat levels should only replace existing technology-based LDR treatment standards when such minimize threat levels are less stringent. Since the technology-based treatment standards are derived from the application of best demonstrated available technology (BDAT), it is unlikely that more stringent, risk-based, minimize threat levels could be met by currently available treatment technologies, even if they were substituted as LDR standards.

2. **p. 66384, col. 1 -- EPA states that it "is not proposing to set any alternative risk-based LDR standards expressed as specified technologies (rather than constituent concentrations). Consequently, the option of complying with minimize threat levels in lieu of levels specified in part 268 will be available only for wastes with treatment standards expressed as constituent concentrations."**

DOE notes that the quoted language from the preamble appears to be inconsistent with the discussion provided in Section XI.K of the preamble regarding "Hazardous Debris" (on pp.66409-66410). In this section, EPA states that hazardous debris (for which specified technologies have been established as the treatment standards) that contain one or more listed hazardous wastes is eligible for exiting Subtitle C under the HWIR proposed rule. Furthermore (in Section XI.K), EPA states that hazardous debris containing listed wastes and for which immobilization is the specified LDR treatment technology may exit Subtitle C regulation using the proposed exit criteria. DOE requests that EPA clarify in the final rule preamble this apparent inconsistency.

Similarly, the regulatory language proposed at §§268.60 and 268.70 does not preclude wastes for which a treatment method (as opposed to a concentration-based standard) is specified in the table to §268.40 from using the minimize threat levels as a basis for exemption from RCRA Subtitle C under HWIR, provided that testing and notification requirements are met. DOE requests that EPA clarify the regulatory language as necessary to make its applicability unambiguous.

3. **p. 66384, col. 1 -- EPA requests comment on whether the LDR definitions of "nonwastewater" and "wastewater" from 40 CFR 268.2(d) and (f) should be adopted for purposes of establishing minimize threat levels.**

DOE concurs with EPA's conclusion that, if minimize threat levels are to be adopted as replacements for, or alternatives to, the LDR treatment standards, it would be practical for the definitions of "nonwastewater" and "wastewater" to be the same for LDR treatment standards and minimize threat levels. It is unclear why EPA did not use the LDR definitions of "wastewater" and "nonwastewater" for developing HWIR exit levels. DOE believes this inconsistency is likely to result in confusion regarding the relationship among LDR treatment standards, minimize threat levels, and HWIR exit levels. In fact, DOE believes that there would be some clear advantages if EPA were to adopt the LDR "wastewater" and "nonwastewater" definitions for purposes of the HWIR regulations, and redevelop the HWIR exit levels based on those definitions. It appears that doing so would eliminate the need to establish "minimize threat levels" as a separate regulatory concept from HWIR exit levels. Instead, HWIR exit levels could directly correspond to the LDR treatment standards. Further, it would be unnecessary to develop new definitions for "wastewater" and "nonwastewater" (or "liquids" and "solids") that would apply only in the context of HWIR exit levels. [Note: Also see DOE comment in response to section VIII.A.1.a.ii].

VI.D Meeting LDR Requirements

VI.D.1 Wastes Below Exit Levels as Generated

- 1. p. 66384, col. 3 -- EPA proposes that if a generator samples a listed waste stream at its point of generation and analysis of the sample shows all constituents to be below exit levels, LDR requirements would not apply to the waste.**

DOE agrees with EPA's proposal that for listed waste sampled at its point of generation and shown to be below the exit levels for all constituents, the LDR requirements would not apply. As discussed by EPA, LDR's are not required under these circumstances to ensure that constituent concentration levels are reduced through compliance with the LDR treatment standards rather than dilution or other forms of inferior treatment. In addition, this approach provides incentive for pollution prevention initiatives to reduce the levels of regulated constituents within the as-generated wastes.

However, as previously stated in DOE Specific Comment VI.B.1.a, item 2, above, DOE believes a waste should be allowed to qualify for exemption from RCRA Subtitle C, not just at the point in time of initial generation, but at any time, provided the claimant can show that all the constituents in the as-generated wastes are below the exit levels. DOE urges EPA to consider allowing previously generated (e.g., certain DOE legacy wastes that have been in storage) wastes to qualify for the generic HWIR exemption, without a further requirement to meet LDR treatment standards. Since such mixed wastes must be managed following exemption from Subtitle C in disposal facilities that comply with Atomic Energy Act requirements as implemented by Order DOE 5820.2A or a license granted by the Nuclear Regulatory Commission, allowing the exemption without also requiring compliance with LDR standards would still be protective of human health and the environment.

VII Dilution

1. **p. 66385, col. 3 -- EPA states that the proposed HWIR "specifically prohibits dilution as a means of attaining the exemption levels except as provided under the LDR program under 40 CFR 268.3(b)."**

a. The actual regulatory language proposed by EPA for implementing the HWIR exemption (i.e., proposed 40 CFR 261.36) contains no specific prohibition of dilution as a means of attaining the HWIR exit levels. However, the proposed language in 40 CFR 261.36(a) indicates that 40 CFR part 268 (Land Disposal Restrictions), which includes the LDR dilution prohibition, would apply at the point of generation unless wastes meet HWIR exit levels at that point (see 60 FR 66440, cols. 1&2). DOE requests that EPA confirm whether or not the Agency intended to include a separate specific dilution prohibition applicable solely in the context of attaining HWIR exit levels.

b. DOE supports the prohibition of hazardous waste dilution to lower hazardous constituent concentrations and encourages EPA to adopt a separate dilution prohibition applicable solely in the context of treatment to meet HWIR exit levels.

c. Although DOE supports adoption of a dilution prohibition applicable solely in the context of attaining HWIR exit levels, the Department requests clarification of activities that would be considered by EPA to be "dilution." For example, DOE is concerned that adding reagents during treatment to produce physical or chemical changes in the material not be defined as dilution.

VIII Implementation

1. **p. 66385, col. 3 - 66395, col. 1 -- EPA says that the proposed rule would be self-implementing, but that claimants of an exemption would be required to meet certain testing and notification prerequisites in addition to the generic constituent concentration levels before the wastes would be considered exempt from hazardous waste regulation.**

DOE requests clarification regarding the rationale for determining that all of the testing and notification requirements are necessary or appropriate. It seems that to a large extent, the rationale stems from the potential for the public to perceive this initiative as an "exit" scheme. Nevertheless, exiting from Subtitle C has always been permissible in that characteristic wastes could exit if treated to remove all characteristics. Such exits are not subject to stringent notification and testing requirements. Moreover, wastes that "exit" at the point of generation are no different than any solid waste that is generated and determined not to be hazardous. (That is, it is improper to say that such wastes are "exiting" because they were never legitimately a part of the hazardous waste program.) Accordingly, DOE suggests that EPA minimize the implementation requirements of this rule to be consistent with the present

regulatory requirements, with only those adjustments deemed necessary to address any unique features of this proposed regulatory program.

VIII.A Implementation Requirements

1. **p. 66386, col. 1 -- EPA states that one of the requirements that must be met in order to make an effective claim is that the waste must be sampled in accordance with a comprehensive sampling and analysis plan. As guidance, EPA recommends using the basic elements of sampling and analysis plans described in “Chapters One and Nine of SW-846.”**

Pursuant to the mixture and derived-from rules, personal protective equipment (PPE) that has the *potential* of having been in contact with listed waste during its use is commonly managed as listed waste. Under current practices, this type of discarded PPE is typically managed as listed waste bearing the same hazardous codes as the original listed waste (potentially contaminating the PPE). DOE is concerned that the guidance in SW-846 (referenced in the preamble) is not readily applicable to debris such as PPE.

Due to the nonhomogeneous nature of PPE, sampling techniques likely are inadequate to verify that exit criteria have been achieved for each piece of PPE. Because the representative sampling techniques utilized may be in question and the cost of sampling each piece is prohibitive, it is unlikely that the proposed rule will allow PPE to exit Subtitle C regulations. DOE is concerned that unless the rule is modified, this low-risk waste will continue to be overregulated. To correct this overregulation, DOE suggests that EPA consider adopting as part of the HWIR one of the following approaches:

- (1) Amend 40 CFR 261.3 by adding paragraph 261.3(a)(2)(vi) to read as follows:
 - (a) ***
 - (2) ***
 - (vi) Personal protective equipment is a hazardous waste only if it exhibits the characteristics of hazardous waste identified in Subpart C; or
- (2) Amend 40 CFR 261.3 by adding paragraph 261.3 (a)(2)(vi) to read as follows:
 - (a) ***
 - (2) ***
 - (vi) Personal protective equipment worn when handling hazardous waste listed solely because of the mixture and derived from rule and that does not exhibit the characteristics of hazardous waste is not a hazardous waste.
[NOTE: This approach chooses an exit point for PPE based on the type of waste with which the PPE was associated. Specifically, PPE associated with waste that was identified as hazardous waste solely because of the mixture and derived-from rule should be exempted from Subtitle C regulations. The rationale for this exemption request is that the matrix and concentration of hazardous constituents of the “mixture and derived-from” waste are no longer the same as those of the original waste upon which EPA based its

decision to list the waste. Therefore, PPE used when handling mixture and derived-from waste has an even more remote chance of posing a threat to health or the environment than does PPE used when handling listed waste that has not been mixed with another material.]

- (3) Include a specific exclusion for radioactive PPE in the upcoming supplemental proposal on HWIR mixed waste exit criteria (referred to at 60 FR 66401, col. 1). This exclusion request is based on the low potential for significant hazardous waste contamination of PPE worn when handling hazardous waste, coupled with the added protection of management of the PPE in accordance with AEA requirements (which control the releases of and exposure to radioactive hazards).

VIII.A.1 Testing Requirements

The comments in this section pertain to particular items, issues, and concerns associated with the Testing Requirements described in this proposal. However, as included in DOE General Comment #4, DOE would like to work with EPA, in collaboration with authorized States, to develop a separate testing program for demonstrating that radioactive mixed wastes meet the final generic exemption levels or that mixed wastes meet other exemption criteria that may be established by the final HWIR. DOE believes that the testing requirements promulgated for mixed wastes should be different from the testing program that EPA outlines in the proposed rule because, the sampling and analysis of mixed wastes pose unique safety and technical challenges as well as administrative costs beyond those of typical non-radioactive hazardous wastes. As such, DOE requests that EPA address appropriate testing requirements applicable to mixed wastes in the final HWIR.

1. **p. 66386, col. 2 -- The preamble states that to be eligible for exemption from RCRA Subtitle C pursuant to the HWIR, "EPA is proposing that facilities must (1) demonstrate that each constituent of concern is not present above the specified exemption level in the waste, (2) demonstrate that the analysis could have detected the presence of the constituent at or below the specified exemption level, and, (3) where specified, comply with the LDR standards applicable to the waste." The preamble goes on to provide guidance on how item (2) can be satisfied.**

DOE notes that the summary of the requirements for qualifying for the HWIR exemption from RCRA Subtitle C (quoted above from the preamble) appears to be inconsistent with the proposed regulatory language (See proposed 40 CFR 261.36(b), p. 66440). Specifically, item (2) does not appear to be included in the proposed regulatory language. Proposed §261.36(b)(1)(ii) requires claimants to develop sampling and analysis plans for each waste, and to identify in the plans the analytical methods that will be used for determining the constituent concentrations. However, DOE could not find a specific requirement in the regulatory language for demonstrations of the capabilities of analytical methods included in sampling and analysis plans. DOE notes that the proposed regulatory language, "the claimant is required to document the basis of each determination that a constituent should not be present above the specified exemption level" (proposed 40 CFR 261.36(b)(1)(i)) may incorporate the requirement for demonstrating that the

analysis could have detected the presence of the constituent at or below the specified exemption level. However, this is not clear. DOE requests that EPA clarify the required content of sampling and analysis plans regarding analytical methods.

2. **p. 66386, col. 2 -- EPA says that the proposed rule allows that any “reliable analytical method” may be used to demonstrate that no constituent of concern is present at concentrations above the exemption levels.**

DOE requests that EPA provide a more precise definition of “reliable” and if possible, provide examples of acceptable testing methods.

3. **p. 66386, col. 3 -- The preamble indicates that EPA is proposing testing requirements for continuously generated wastes and wastes produced on an infrequent (batch) basis that would consist of an initial test to characterize waste as exempt, followed by subsequent testing as appropriate based on the volume of waste to ensure ongoing compliance. For listed wastes generated on a one-time basis, the preamble states that only initial testing requirements would apply.**

DOE is concerned that the proposed regulatory language (see proposed 40 CFR 261.36(b)(1) and (d)(2); 60 FR 66440 and 66441, respectively) does not specifically address the testing requirements for listed wastes generated on a one-time basis. DOE suggests that the final regulatory language be expanded to address the testing requirements that such wastes must meet in order to qualify for exemption under the HWIR.

DOE is also concerned that neither the preamble nor the proposed regulatory language address the testing requirements that would be applicable to wastes being held in long-term storage at the time the final HWIR becomes effective (e.g., mixed wastes for which disposal capacity is not yet available). Based on the proposed regulatory language, (see proposed 40 CFR 261.36(b)(1) and (d)(2); 60 FR 66440 and 66441, respectively), DOE believes it is possible to conclude that such wastes would require initial testing, followed by annual retesting. DOE suggests that the final regulatory language be clarified to indicate the testing frequency required for such wastes to qualify for exemption under the HWIR.

DOE is also concerned that waste analysis results for a large-volume but well-defined waste-generating process may vary less than waste analysis results for a small-volume but less well-defined waste-generating process. Yet the small-volume waste stream would require less frequent testing under the proposed testing guidelines. A revision of the proposed rule to correspond more closely with the testing requirements developed under appropriate waste analysis plans will (1) facilitate facility implementation of the rule by providing a familiar set of requirements that are compatible with existing operating practices, and (2) be more protective of human health and the environment.

VIII.A.1.a Data Evaluation

1. **pp. 66386, col. 3 - 66387, col. 3 -- EPA requests comment on three approaches to data evaluation. Under the first approach, generators would be required to evaluate their waste based on the maximum detected concentrations of the exemption constituents. Under the second approach, EPA suggests allowing analytical results to be evaluated in terms of an upper confidence limit around an average concentration. Under the third approach, facilities would be allowed to use long-term average data to demonstrate compliance without consideration of the upper confidence limit.**

DOE appreciates the issues associated with each of the approaches suggested by EPA for data evaluation, but is particularly concerned that the first proposed approach (i.e., maximum detected concentration represents the waste) may unnecessarily prevent certain wastes from meeting the exit levels. For example, a testing procedure could be faulty, leading to the occasional outlier. Hence, the first approach, while being the easiest to implement on the part of the waste generator and affording simple regulatory oversight, would compel generators to operate on average well below the exit levels to ensure that variability in wastes would not lead to transient exceedences. As a result, the first proposed approach would introduce still more conservatism relative to qualifying for exemption from RCRA Subtitle C under the HWIR. Therefore, DOE recommends that EPA not limit the data evaluation methods to the first approach.

DOE believes that characterization of a waste based on a single sampling event at an arbitrary point in space and time should not be used to determine its eligibility for exit from RCRA Subtitle C. In discussing the three approaches to data evaluation, EPA seems to argue in favor of the single composite sampling approach by raising two concerns about using average concentrations (see 60 FR 66387, col. 2): (1) waste disposal in multiple locations, with the wastes received by a particular facility exceeding the exit levels [i.e., wastes may on the average be in compliance when generated, but wastes received by a particular facility (possibly from multiple sources) may not be on the average, below the exit levels]; and (2) acute health or ecological effects due to occasional high concentrations. DOE notes that the SW-846 methodology currently used for characterizing wastes as hazardous under RCRA Subtitle C is based on exceedence of a regulatory level at the 80 percent confidence interval. Since this is an averaging method similar to the second proposed approach, it is unclear to DOE why the concerns raised by EPA, which would also be present in the existing context of waste characterization, should exist in the context of the HWIR.

Regarding the second and the third proposed data evaluation approaches, DOE recognizes that (especially for many of its facilities) the costs and practicability of conducting repeated tests may make data evaluation using such approaches unrealistic. Therefore, DOE suggests that EPA increase the flexibility of the data evaluation requirement by modifying it to allow the generator to determine whether the exit levels are met using *any* of the three approaches, as long as the approach used is documented. This would provide needed flexibility to accommodate situations where outlying test results would unnecessarily exclude a low-risk waste from exiting the

system, but would also provide a means to limit the number of tests and statistical analyses required in situations where such analyses are impractical.

The second and third approaches to data evaluation, which include averaging, are consistent with the RCRA waste characterization procedures. The second proposed approach is consistent with the data evaluation methods presented in SW-846 for use in establishing whether a waste is subject to RCRA Subtitle C management based on exceedence of a regulatory level at the 80 percent confidence interval. Hence, it is appropriate that a similar methodology be allowed to demonstrate that the waste is now below any applicable regulatory thresholds to exit Subtitle C. Similarly, the third data evaluation method requires less rigorous statistical evaluation but still allows for the waste's fate to be determined by representative sampling over space and time as set forth in the generator's sampling and analysis plan.

In the preamble (60 FR 66387, col. 2), EPA suggests addressing enforcement concerns when a generator chooses the second or third data evaluation method by allowing exit levels to be demonstrated using averages, and in addition, requiring that all samples be below some "peak" concentration. Alternatively, DOE suggests that when an average is used, the problem of an individual value being too high could be treated statistically, by setting quality control (QC) limits for individual values. This could be done in the same manner as that used in making QC charts, which have been recommended by the EPA for monitoring groundwater data (see *Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities*, Interim Final Guidance, EPA 530-SW-89-026, February 1989).

The QC chart approach would be much simpler than trying to evaluate acute risk, which would be difficult for many of the pathways used in the risk model. It should also be protective, because it would be based on significant differences from the mean. That is, a value not significantly different from the mean should not be considered a risk when the mean is below the risk threshold. This is consistent with, for example, the use of means in exposure portions of the risk model, even when it is known that there is variability associated with the mean. The QC chart approach is also valid for identifying outliers. DOE suggests the use of control charts or the setting of confidence limits for determining whether individual values are significantly above the mean.

If EPA believes it cannot provide the maximum level of flexibility that DOE suggests above, then the Department suggests that the second data evaluation method would be preferable to the other proposed approaches. With the potential variability in waste, a statistical approach with an upper confidence limit is preferred. Also, there is a real potential that the possibility of an enforcement action by EPA (or an authorized state) resulting from the collection of a single composite sample would discourage most claimants from utilizing the proposed rule if the first data evaluation approach is used. Using the upper confidence limit and an average concentration approach, EPA (or an authorized state) could still take samples and require the generator to provide historical information to show that the EPA sample analysis does not constitute an overall violation of the HWIR levels. EPA should allow for occasional exceedences as long as the average concentration meets the proposed exit levels. Given that generators will probably

limit the applicability of the exit to large-volume wastes, it is reasonable to expect occasional exceedences in the concentrations of the hazardous constituents. This approach could also save generators the additional cost of having to resample for minor exceedences that do not affect the overall characterization of the waste. The proposed exit levels are low enough not to warrant additional concerns (i.e., regarding acute health or ecological effects) relative to occasional exceedences.

- 2. p. 66387, col. 3 -- EPA notes that certain facilities may have difficulty quantifying a constituent at the exit level due to matrix interference effects, but expects that exempted wastes will have relatively clean matrices, such that exit levels should be able to be achieved. EPA states that "the exit level must be met for a waste to exit Subtitle C; therefore, waste streams that cannot meet exit levels would not exit." The Agency requests comment on this approach.**

Matrix interference effects may indeed be a consideration for certain mixed waste streams. DOE requests EPA to consider including a provision that would allow facilities the opportunity to make demonstrations regarding what, why, and how matrix interference may be involved in quantifying constituents. To deal with this and other special concerns associated with sampling and analyzing mixed wastes, General Comment #4 expresses DOE's interest in working with EPA and authorized states to develop a separate testing program for demonstrating that mixed wastes meet generic exemption criteria or some other criteria that may be established under the HWIR. As indicated by this general comment, DOE believes that the testing requirements promulgated (i.e., relative to HWIR) should separately address the unique safety and technical challenges associated with mixed wastes.

VIII.A.1.a.ii Wastewater and Nonwastewater Categories

- 1. pp. 66387, col. 3 - 66388, col. 3 -- EPA requests comment on three options for defining the two waste categories used by the Agency in developing the HWIR exit levels. The two categories are described by the preamble as (1) "solid" or "nonwastewater" typically managed in ash monofills, waste piles, and land application units, and (2) "liquid" or "wastewater" typically managed in tanks and surface impoundments. The three options suggested by EPA for defining these two categories include: (1) using percent solids; (2) using LDR definitions; and (3) using the Paint Filter Liquids Test.**

As stated in comment VI.C.1, item 3, above, DOE believes that there are some distinct advantages associated with EPA adopting the LDR "wastewater" and "nonwastewater" definitions for purposes of the HWIR regulations (i.e., Option 2), and redeveloping the HWIR exit levels based on those definitions. Considering the significant interrelationships between the HWIR and LDR programs, as outlined in the proposed rule, it would seem that utilizing the same definitions (for wastewater and nonwastewater), rather than creating new definitions solely for the purpose of HWIR, would be a practical means of ensuring consistent regulatory programs. Also, using the LDR definitions of wastewater and nonwastewater (Option 2) would

provide consistent definitions for the purpose of developing minimize threat levels. Using the LDR definitions would appear to eliminate the need to establish minimize threat levels as a separate concept from HWIR exit levels. Instead, HWIR exit levels could directly correspond to the LDR treatment standards (i.e., in cases where the risk levels are higher than the LDR treatment standards) for wastes exiting RCRA under HWIR. Further, it would be unnecessary to craft new definitions for wastewater and nonwastewater (or “liquids” and “solids”) that would apply only in the context of HWIR exit levels. In addition, using the existing LDR definitions would help prevent unnecessary confusion in the regulated community.

The Department also recognizes some favorable attributes (as well as some disadvantages) associated with Option 1 for distinguishing between the wastewater and nonwastewater categories (i.e., using percent solids). Although Option 1 would result in conflicting definitions within the RCRA hazardous waste program, this option would probably allow for the application of best management practices for the two categories of wastes that are more consistent with the treatment unit capabilities. This option also provides for a clear, concise, and easily distinguishable definition relative to the application of the proposed exit levels. Defining these terms in this manner would, in certain cases, allow generators and subsequent waste handlers to make accurate exit category determinations via a visual inspection (and thus, eliminate potential laboratory costs in these cases). Furthermore, Option 1 would be the most consistent with the assumptions made in the risk assessment used to establish the exit levels, which used 15 percent solids as the reasonable lower limit for wastes managed in land application units. If this option is implemented, DOE recommends that the column headings in Appendix X and Appendix XI be revised to use some other moniker, such as “liquid” and “nonliquid” wastes, in order to eliminate potential confusion with the LDR definitions for wastewater and nonwastewater.

If EPA does choose Option 1, consideration should be given to the merits of using the Paint Filter Liquids Test (PFLT) to separate the solid and liquid components of the waste. The PFLT is simpler and less time consuming to perform than the TCLP methodology and has been used by EPA to differentiate between the liquid and solid fractions of a hazardous waste in other RCRA regulations.

- 2. p. 66388, col. 1 -- EPA also solicits comment on whether generators should be allowed, under any of the three options, to separate in the laboratory the solid (or nonwastewater) portion of the waste from the liquid (or wastewater) portion, analyze the resultant portions, compare the results to the corresponding exit levels, and treat the waste as exempt if all exit levels are met in both portions.**

DOE encourages EPA to allow this approach. In addition, although it is not specifically discussed in this section, DOE requests that EPA clarify whether one portion of the waste would be allowed to exit Subtitle C regulatory control if only that portion were below the specified exit levels. Also, DOE requests clarification as to whether phase separation of a particular waste stream would constitute treatment, since this would be similar to other types of phase separation activities that are currently defined as treatment (such as centrifugation and decantation).

VIII.A.1.a.iii Totals and TCLP Analyses

1. **p.66389, col. 1 -- EPA proposes that for nonwastewaters to be eligible for exit, every constituent in the waste must comply with the nonwastewater total constituent exit level as well as with the nonwastewater leach exit level.**

As DOE discusses in greater detail in response to comment V.A. item 1 above, the proposed implementation (testing) requirements applicable to nonwastewaters offer little regulatory relief for metal-bearing wastes treated via immobilization, and provide no incentive to improve upon the capabilities of existing immobilization technologies. In regards to nonwastewater *mixed* wastes, DOE believes that EPA should consider the most limiting (dominant) exposure pathway (i.e., the groundwater or non-groundwater exit levels), but not both.

As stated in the earlier response (regarding section V.A), most DOE mixed wastes will be treated prior to disposal in accordance with Site Treatment Plans and compliance orders established under the FFCAct, RCRA and applicable State laws. The fate/transport models used by EPA consider solids being transported by wind and erosion which have the potential for ingestion or uptake into the food chain. In these cases, a total constituent exit level is warranted. However, applying these fate/transport parameters to many nonwastewater final forms of mixed wastes, such as grouted and vitrified waste, which are not eroded or transported by wind or water, is inappropriate and does not provide additional protection to human health or the environment. For treated mixed wastes, it is likely that only one exposure pathway (i.e., the groundwater pathway) will be the dominant pathway, and thus, will drive the risks associated with the disposal facilities. Therefore, with these considerations in mind, DOE requests that EPA allow treated mixed waste to qualify for exemption from RCRA Subtitle C requirements if:

- (a) the waste meets total constituent exit levels (Totals) when a non-groundwater exposure pathway is the dominant exposure pathway, i.e., disposal is in a unit other than a landfill/monofill or
- (b) the waste meets leachate exit levels (based on the TCLP or calculation screen, or possibly the Synthetic Precipitation Leaching Procedure²²) when groundwater is the dominant exposure pathway, i.e., when disposal is in a landfill/monofill unit.

DOE also supports the concept that a compositional (total) analysis may be used in lieu of the TCLP when the constituent of concern is absent from the waste, or is at such a low concentration that the appropriate regulatory level could not be exceeded. Use of the calculational screen will eliminate the need to conduct unnecessary tests [but as indicated in the earlier comment (i.e., in response to section V.A.), additional costs would still be incurred above those realized if there was only one (total or leach) exit level] . The text of the preamble notes that section 1.2 of the

²² The SPLP (Method 1312) is an alternative leaching procedure that may be more applicable for some waste forms than the TCLP.

TCLP, "Scope and Analysis," includes these provisions (i.e., allowing for a total analysis in lieu of the TCLP under certain situations). It should be noted, however, that the SPLP does not appear to contain the same provisions.

VIII.A.1.a.iv Oily Wastes

- 1. p. 66390, col. 1 -- EPA requests comment on how to better define oily wastes, on what testing method should be used for oily wastes, and on additional problems with oily waste leachability.**

DOE recognizes the difficulties associated with analyzing oily wastes. This is a concern for certain DOE operations and energy industry facilities. As similarly noted in the DOE consolidated comments on the 1992 proposed HWIR²³, for many compounds, currently available analytical techniques are insufficient for detecting constituents at the proposed risk-based HWIR exemption levels. Materials with an organic matrix, especially an oily matrix, may have too many interferences for many of the possible constituents to be quantified. In addition to the problems cited by EPA regarding oily waste leachability, DOE notes that extraction procedures result in samples that are not amenable to typical organic analysis (i.e., GC mass spectrometry) at the required detection limits because huge dilutions are needed to modify the matrix adequately for analysis. The result of the necessary dilutions are detection limits for organic analytes in excess of those proposed as exit criteria. DOE believes that the concept of extraction procedures for oily wastes will be inadequate because of matrix problems and high detection limits resulting from the required dilutions.

In regards to EPA's request on how to better define "oily waste," EPA may want to consider analytical testing (i.e., EPA method 418.1, Oil and Grease) as an option, in addition to visual inspection of the waste. As in proposed options for defining the categories of exit levels (i.e., as "solid" and "liquid"), a specific cutoff value (e.g., 10 percent) above which a waste would be considered an "oily waste" could be considered. Since the TCLP test (Method 1311) is not applicable to oily wastes, total analysis should be allowed.

VIII.A.1.b Initial Test

- 1. p. 66390, col. 2 - p. 66391, col. 2 -- EPA proposes to require claimants of the HWIR exemption from Subtitle C regulation to conduct initial testing of all of the 386 constituents on proposed Appendix X of 40 CFR 261, *except those that the claimant determines should not be present in the waste* [see also proposed 40 CFR 261.36(b)(1)]. EPA asks for comment on whether the absence of constituents in several specified documents could constitute sufficient justification for not analyzing all of the constituents listed in 40 CFR part 261 appendix X. EPA also asks for comment on taking the opposite approach: requiring each claimant to test only for those**

²³ DOE Comments, Notice of Proposed Rulemaking regarding Hazardous Waste Management System: Identification and Listing of Hazardous Waste, p. 11, specific comment IV.A (07/24/92).

constituents that the claimant determines “could be present” for that waste.

DOE supports limiting the constituents for which testing would be required in order to qualify wastes for exemption from RCRA Subtitle C regulation under the HWIR. However, DOE has concerns regarding the manner in which EPA proposes to limit those constituents that must be analyzed during initial testing. Under the proposed regulations for qualifying for an exemption (i.e., see proposed 40 CFR 261.36(b)(1)), testing for all the constituents on Appendix X to part 261 would be required except for those constituents that the claimant determines should not be present in the waste. In other words, the Agency is proposing that only constituents demonstrated as *not* present may be excluded from testing. DOE believes that demonstrating the *absence* of constituents is much more difficult than demonstrating the reasonable *presence* of constituents. In fact, DOE questions whether the absence of a constituent could ever be definitively demonstrated without actually testing the waste. Even then, the limitations of analytical techniques and other factors could affect the credibility of such demonstrations. For these reasons, DOE urges EPA to modify the approach to require initial testing for *all those constituents reasonably expected to be present in the wastes*. Such an approach would be similar to the way generators are required to determine the underlying hazardous constituents in their D001, D002, or D012-D043 (i.e., wastes exhibiting the characteristics of ignitability, corrosivity, or organic toxicity) under the LDR program (see §268.2(i), §268.7(a) and 59 FR 48004 (09/19/94)).

The preamble suggests that collecting documentation that indicates which constituents have previously been associated with waste streams for which exemptions are sought would be adequate to demonstrate that other constituents are absent (40 FR 66390, col.3). Certainly, such documentation would demonstrate which constituents could reasonably be expected to be present. However, demonstrating which constituents could reasonably be expected to be present in wastes does not necessarily demonstrate the absence of all other constituents. To overcome this dilemma, DOE suggests that EPA modify the proposed regulatory language to require testing for those constituents on Appendix X to 40 CFR part 261 that the claimant determines could reasonably be expected to be present in the waste. Given such a change, DOE would agree that the absence of constituents in the annotated documents listed in the preamble [60 FR 66390-66391] would adequately support and justify not analyzing for all of the constituents listed in 40 CFR part 261, Appendix X. DOE would also agree on requiring, as a minimum, testing of the following categories of constituents [60 FR 66391]:

- Constituents set out in Appendix VII to Part 261 as the basis for listing the waste stream for which exemption is sought;
- Constituents detected in any previous analysis of the same waste stream conducted by or on behalf of the claimant;
- Constituents introduced into the process which generates the waste stream; and
- Constituents which the claimant knows or has reason to believe are byproducts or side reactions to the process that generates the waste stream.

The proposed rule would also require testing of constituents that appear in the regulated

hazardous constituents column in the table to 40 CFR 268.40 (p. 66390, col.3 and p. 66391, col. 2). However, DOE does not agree that this should be required. Such an approach is overly conservative, particularly with regard to spent solvents (waste codes F001-F005). The table in 40 CFR 268.40 presents all the spent solvent constituents in the regulated hazardous constituents column for the F001-F005 entry. DOE does not believe, however, that it was EPA's intent to imply that all these constituents were present -- or needed to be analyzed for -- in every spent solvent waste. Although many spent solvents contain a mixture of several of the listed spent solvent constituents, it is inappropriate to assume that all the F001-F005 constituents would be present in every spent solvent waste. In most cases it is fairly easy to eliminate some constituents from further consideration based upon knowledge of the materials and processes involved. DOE requests that EPA give further consideration to the use of the 40 CFR 268.40 table as a basis for determining minimum testing requirements relative to certain categories of constituents (that may be present in the listed waste), at least as it pertains to the listed spent solvents.

In addition, DOE believes that in many cases, claimants may know, based on process knowledge or other information sources, that certain constituents are not present in waste streams. Requiring testing of all "constituents listed in the table to §268.40 as regulated hazardous constituents for LDR treatment" is not necessary in those cases where the claimant knows that specific hazardous constituents could not be present in a particular waste. DOE favors the use of acceptable knowledge to eliminate classes of constituents from the requirements to analyze.

The HWIR preamble requests comment on an option whereby testing would be required only for those constituents the claimant determines "could be present" in the waste. Under this option, analysis would be performed for only those constituents the claimant determines "could be present" for purposes of demonstrating that a waste meets the applicable Appendix X exit levels (see 60 FR 66391, col.2). DOE believes this "could be present" approach is similar to the approach suggested above. Therefore, DOE favors it over the approach of requiring demonstrations to show the absence of constituents. However, DOE recommends that EPA utilize consistent terminology (i.e., constituents "reasonably expected to be present" rather than "could be present") as defined in previous rules, so that any subsequent clarifications of the phrase can be used to clarify both provisions of parts 261 and 268.

- 2. p. 66390, col. 3 -- EPA requests comment on a requirement that a claimant who is not the waste generator consult with the generator prior to determining that a constituent "should not be present in the waste." This consultation would ascertain whether a constituent may be present based on its introduction to the generator's process or as a byproduct or side reaction product of that process. EPA also request comment on the type of documentation that it should require.**

DOE agrees that such consultation with the generator is warranted. However, the Department disagrees with EPA's proposal that the generator co-sign documentation setting forth the reasons a claimant need not test for a particular constituent, or that he be required to submit any supporting documentation in conjunction with the claimant's notification package. The

generator lacks control over the constituents that can be introduced during subsequent management of his waste, such as consolidation of wastes from multiple generators in the feed to a treatment process. DOE recommends that EPA simply require the claimant to certify that the consultation has occurred, maintain records of the information obtained from the waste generator, and certify that this information has been incorporated in the supporting documentation submitted to the implementing agency.

3. **p. 66391, col. 1 -- EPA solicits comment on whether the absence of constituents in any of several documents could constitute sufficient justification for not analyzing all of the constituents listed in 40 CFR part 261 Appendix X. One of the documents listed is “a certified, third party engineering analysis of the process generating that waste . . .”**

DOE suggests that EPA modify the proposed use of a certified third party engineering analysis of the process generating the waste to an engineering analysis performed and directed by a registered professional engineer. Since professional engineers are registered by State agencies and are required to meet certain ethical standards, adequate incentives are in place to insure an unbiased assessment without utilizing a third party.

4. **p. 66391, col. 2 -- EPA states that a facility would *not* be authorized to determine that the constituents in the waste meet the exemption levels based on knowledge of the waste or material.**

The proposed total exit levels for some constituents are quite high (i.e., acetone at 17,000 mg/kg, aramite at 6,900 mg/kg, butanol at 18,000 mg/kg, chlorobenzene at 2,500 mg/kg, dibenzofuran at 27,000 mg/kg, etc). Generators are likely to possess enough knowledge of their process to determine that constituents such as these, while present, would not be present in quantities above the proposed exit levels. DOE recommends that when constituents are known to be present, but the total concentration exit level is above 1,000 mg/kg, the generator be allowed to use documented process knowledge as an alternative to testing. Alternatively, EPA could allow the use of process knowledge when a constituent's concentration can be shown to be significantly below the applicable exit level [i.e., process knowledge would be acceptable if the maximum concentration of a constituent is known to be a factor of 10 (or 100) less than the applicable total exit level].

5. **p. 66391, col. 3 -- EPA requests comment on another approach for determining which constituents need to be analyzed by a claimant. The approach would be that the claimant needs to provide data on all additional constituents listed in appendix X of 40 CFR part 261 of the proposed rule for which a method used by the generator to detect other constituents which the claimant is required to test can easily determine concentrations.**

DOE opposes this approach to defining constituents for which testing would be required because, as EPA points out, even when the analytical method is the same, there may be differing

sample preparation techniques, dilutions, or other aspects of analysis. Such differences would cause problems in defining exactly which constituents would require analysis for a particular waste. It is unclear that the benefit, if any, gained from this suggested alternative approach would outweigh the resulting complications.

VIII.A.2 Notification Requirements

- 1. p. 66392, col. 2 -- After listing the specific information which would be required to be included in a notification package to the implementing authority (relative to claiming an exemption), EPA requests comment on whether certain additional information should also be required to be included as part of the notification package documentation.**

DOE opposes including the additional information listed in the preamble (i.e., name and address of the laboratory which performed the analysis, a copy of the sampling and analysis plan, etc.) as part of the required documentation in the notification package for claiming an exemption. Such information should be maintained at the claimant's facility as required records that must be available upon request for inspection by the responsible regulatory agency. However, the particular information related to waste sampling and analysis which is identified in the list of additional information does not appear necessary for demonstrating that wastes qualify for exemption. Therefore, requiring that such additional information be included in the notification package should not be necessary.

- 2. p. 66392, col. 3 -- EPA is considering whether the notification package for wastes not managed at the claimant's facility should identify the disposal facility, or if the claimant should submit documentation that he has informed the disposal facility of the waste's exempt status.**

DOE recommends that EPA not promulgate either of these requirements. Under proposed §261.36, the claimant is not restricted to specific non-Subtitle C units (e.g., Subtitle D units, CWA-regulated systems, etc.) to manage the exited wastes. It is possible for the claimant to utilize a number of disposal facilities based on their convenience, costs, or other factors considered at the time the waste is available for shipment. EPA should not restrict the claimant's ability to efficiently and cost-effectively manage exited wastes by requiring a prior commitment to utilize a particular facility via its identification in the notification package. Information regarding the facility(ies) receiving the exited wastes could be made available through the claimant's recordkeeping if the implementing authority wishes to identify these facilities in the course of its oversight of the proposed §261.36 program.

- 3. p. 66393, col. 1 -- EPA requests comment on whether the proposed certification (to accompany the notification) is sufficient assurance that the claimant has made best efforts to accurately characterize the waste, or whether additional certification language or additional certifications should be developed. As an example, EPA**

requests comment on whether certification from an analytical laboratory should be required to accompany the notification that an exemption under HWIR is being claimed.

DOE opposes requiring additional certifications or certification language from an analytical laboratory to assure that a claimant has undertaken best efforts to accurately characterize wastes in the context of exemptions under the HWIR. DOE believes the penalties associated with improper characterization are sufficient to encourage accurate and dependable waste characterization without requiring additional certifications. Further, a requirement for additional certifications would be inconsistent with the current self-implementing RCRA waste characterization requirements under 40 CFR 262.11. Under these existing regulations, waste generators are required to determine if their wastes are hazardous (i.e., subject to RCRA Subtitle C regulation). Certifications that attest to the accuracy of waste analyses conducted by analytical laboratories are not required in the process of characterizing solid wastes (i.e., to determine whether the wastes are hazardous). DOE believes that the circumstances of claiming the HWIR exemption, when compared to the process of a generator making a hazardous waste determination, are not so different that additional certifications should be required.

- 4. p. 66393, col. 1 -- EPA requests comment on whether, instead of the HWIR exemption becoming effective upon confirmation of delivery of the notification package (as proposed), there should be some brief waiting period prior to the exemption becoming effective.**

DOE supports EPA's proposal (§261.36(c)) that the exemption should take effect once the claimant receives confirmation of delivery for the notification required under §261.36 (b)(4). DOE believes that a waiting period between confirmation of delivery of the notification package and the date on which an HWIR exemption becomes effective is unnecessary *unless* the responsible regulatory agency is required to take some specified action on the notification (such as review and approval of the information submitted), or some other purpose would be served, (e.g., like providing an opportunity for public comment). However, EPA has proposed the HWIR exemption as self-implementing. If a waiting period were provided for the purpose of allowing public comment, the self-implementing aspect of the proposed rule would be eliminated (i.e., since responses to and, where appropriate, revisions to the notification package documentation to accommodate public comments would be required). Further, since action on the notification by the responsible implementing agency is proposed as being discretionary and having no binding effect, DOE believes a waiting period should not be imposed to provide time for agency action. In fact, imposing a waiting period may mislead some members of the regulated community since the waiting period could be misinterpreted as being time for review, comment and approval of the notification package by the responsible agency or the public, in spite of EPA's preamble statements to the contrary.

VIII.B Implementation Conditions

- 1. p. 66393, col. 2 - EPA states that if wastes claimed as exempt under the HWIR**

proposal are tested and found to contain constituent concentrations above exit levels at any time, that waste and subsequently generated waste would have to be managed as hazardous waste.

DOE assumes that such waste would be considered newly generated and could be managed in accordance with §262.34 requirements (i.e., accumulation time provisions applicable to generators of hazardous waste). If this is not the case, EPA should provide clarification.

VIII.B.2 Testing Conditions

- 1. pp. 66393, col. 3 - 66394, col. 1 -- EPA states that failure to test and maintain documentation of the testing in accordance with the requirements of proposed 40 CFR 261.36(d) would void the exemption. EPA describes the scope of subsequent testing.**

DOE believes that any requirements for subsequent testing should have a sound technical basis, and that automatic testing should not be required for relatively uniform waste streams. Subsequent testing requirements should reflect and address the potential variability of the waste stream and the frequency/potential for process changes only. To do otherwise would be inordinately costly and burdensome.

- 2. p. 66394, col. 1 -- EPA proposes that the scope of subsequent testing focus on those constituents from appendix X of 40 CFR part 261 that are of concern based on the initial test. In addition, the Agency proposes that the frequency with which a facility would be required to perform subsequent testing be based on the volume of waste which the facility is declaring exempt.**

DOE suggests that subsequent testing should only focus on constituents previously identified in the waste stream (and any known or expected additions).

- 3. p. 66394, col. 2 -- EPA requests comment on whether the frequency of subsequent testing should be reduced to once per year (regardless of the volume produced) if the waste has maintained exempt status for three years. EPA also requests comment on whether follow-up testing should be eliminated entirely after the first three year period.**

DOE supports the approach to eliminate the follow-up testing after the first three-year period (provided adequate data is available to support that the potential for variability in the waste is minimal). In fact after the first year, the generator should be able to rely on process knowledge as is allowable under current regulations.

VIII.B.3 Testing Frequency and Process Change

1. **p. 66394, cols. 2 & 3 -- EPA requests comment on whether it is necessary to require as a condition of maintaining the exemption that wastes be re-tested after a process change.**

DOE opposes adopting a generic requirement that exempt wastes be re-tested following a process change. DOE believes that, in many cases, a process change could be made in which the effects on hazardous constituent concentrations would be completely predictable based on process knowledge. For example, a process change might result in the addition of one or two new chemicals in very specific amounts to the process. Oftentimes, a generator will be able to calculate the impact of adding a specific amount of a constituent to the process and determine whether it will impact the exempt status of the resultant waste. It would be unnecessarily costly to require a generator to reanalyze a waste stream affected by such a process change. Under such circumstances, DOE would support EPA's suggestion of requiring the claimant to notify the implementing authority that a process change has occurred and to certify, when appropriate, that the exemption criteria continue to be met. Re-testing, however, should not be implemented as an alternative requirement for each and every process change.

2. **p. 66394, col. 3 -- EPA requests comment on how "process change" should be defined in the event that one of the following alternatives is promulgated: (a) requirements to re-test triggered by a narrative description of a process change, or (b) requirements that the claimant notify the implementing authority that a process change has occurred and certify that the exemption criteria continue to be met (if the waste still maintains the exempt status).**

This approach appears contrary to the existing RCRA general waste analysis requirements [§§ 264.13 and 265.13] which do not mandate the frequency of sampling and analysis. Instead these provisions require that the analysis be repeated, as necessary, to assure that it is accurate and up to date, including the need to repeat the analysis if the facility has reason to believe that the process or operation generating the waste has changed [§§ 264.13(a)(3)(i) and 265.13(a)(3)(i)]. These existing RCRA waste analysis regulations do not define "process change." Hence it is not apparent that a definition would need to be provided for purposes of the HWIR proposal.

VIII. C Public Participation

1. **p. 66394, col. 3 - p. 66395, col. 1 -- The Agency is proposing to require that the public be notified by the claimant that an exemption claim is being asserted, and should be accomplished by publication of a notice in a major newspaper (local to the claimant and of general circulation). EPA also requests comment on whether public notices should be placed by the claimant in a newspaper local to the claimant's facility or to the disposal facility, or both, if such facilities are located in different areas not served by the same newspaper.**

DOE notes that requiring that a notice of the exemption claim be placed in a major local

newspaper appears to be an unnecessary and unwarranted administrative burden. The public notice requirement would not augment or facilitate facility compliance, nor would it assist regulating authorities in enforcement. Considering that the proposed rule does not intend for the general public to submit written comments to the regulatory agency, or to ask for a public hearing to consider any proposed changes to the management of waste subject to an exemption claim, there does not seem to be a well grounded driver for requiring such notification -- other than establishing good public relations for issuing a public notice.

In addition, requiring such a notice seems to be inconsistent with certain other RCRA regulatory provisions. For example, EPA does not require public notification that a facility is managing waste that is exempt from Subtitle C management under the conditionally exempt small quantity generator provisions or household waste exclusions, or with respect to waste exempted under a delisting petition. The requirement for notification of claims under the proposed rule would suggest that some inherent danger of the exempted waste warranted the notification, a stigma that is unwarranted for material that satisfies the exemption criteria in the proposed rule. Public concern resulting from such notification could adversely affect the receiving facility's community relations, a situation that could lead to unwillingness on the part of non-Subtitle C facilities to manage exempted waste. With these considerations, DOE recommends that EPA not impose the proposed public notification requirement.

Furthermore, this proposed notification requirement (i.e., to require that a notice be placed in a newspaper, either local to the claimant's facility or to the disposal facility) would not appear necessary from a remediation perspective. In the case of remediation efforts, information sharing is required through the National Environmental Policy Act, CERCLA and the Emergency Planning and Community Right to Know Act. Additionally, most remediation sites are required to have public information repositories where all environmental documentation, including characterization data, is available to the public. If an exemption claim is made, it would seem sufficient to provide public access to such characterization documentation in the communities (i.e., in information repositories) where the exemption claim is being asserted.

As discussed above, the Department is opposed to the public notification requirements being proposed. However, if EPA continues towards the implementation of these requirements, DOE offers the following input. DOE recommends that claimants be required to publish notice of their exemption claims *only* in newspapers local to the claimants' facilities. If EPA decides to require a claimant to place a notice in the newspaper local to the disposal facility (when the disposal facility locale is not served by the same newspaper as is the locale surrounding the claimant's facility), then DOE suggests that EPA also require claimants to notify the disposal facility of the exempt status of the waste as suggested by preamble sections VIII.A.2 and VIII.C [60 FR 66392 and 66395].²⁴ Such notice would be most helpful if it occurred before the appearance of the newspaper notice. DOE suggests this because if a newspaper notice of the

²⁴ NOTE: However, as indicated above in response to Section VIII.A.2, DOE does not feel that it is appropriate that documentation that the disposal facility has been informed of the wastes exempt status, should be required to be part of the notification package.

exemption claim is placed in the disposal facility locale, questions from the public are likely to be directed to the disposal facility rather than the claimant or the responsible agency, unless the notice specifically directs otherwise. DOE does not generally favor requiring newspaper notices to be placed by the claimant in the vicinity of the disposal facility. Often, such disposal facilities will have permits or zoning approvals issued by State or local authorities following a process that included public comment. Even if this was not the case, exempt wastes will present no greater hazard to the community than other nonhazardous wastes disposed at the disposal facility. Therefore, it would be incongruous to require public notice for disposal of exempt wastes, but not other wastes.

2. p. 66395, col. 1 -- EPA requests comment on the need for and possible approaches to requiring that waste generators claiming the HWIR exemption notify receiving facilities that the wastes are exempt.

If EPA decides to require that claimants notify receiving facilities that wastes are exempt, DOE suggests that the method and timing of such notice be established based on whether the claimants are also required to place public notice of exemption claims in a newspaper in the locale of the disposal facility. However, as mentioned in specific comment VIII.C, item 1 above, DOE does not favor requiring claimants to publish newspaper notices. If newspaper notices are not involved, DOE suggests that claimants notify disposal facilities of the exempt status of wastes via a simple notification statement placed on shipping papers that would otherwise accompany shipped wastes.

3. p. 66395, col. 1 -- EPA requests comment on whether providing a "delay" in the effective date when the exemption attaches (e.g., 30 or 60 days) would provide a significant and meaningful opportunity for public comment prior to the waste having exited the Subtitle C system.

Specific Comment VIII.A.2, item 4 above, explains DOE's position in regard to whether a "delay" in the effective date of an exemption should be provided.

4. p. 66395, col. 1 -- EPA requests comment on whether access to claim documentation through the appropriate implementing agency will be sufficient to provide public access to documentation.

DOE believes that unless public comments are solicited as part of the public notice process concerning HWIR exemption claims, public access to claim documentation through the appropriate implementing agency should be sufficient. DOE does not favor soliciting public comment on exemption claims because, as discussed in specific comment VIII.A.2, item 4 above, doing so would annul the self-implementing nature of the exemption. Further, soliciting public comments on exemption claims would be inconsistent with other related RCRA regulations. For example, EPA does not require public comment when a waste is treated to remove characteristics, or when a waste is treated to meet LDR treatment standards. Also, current regulations do not require public comment for a determination that a waste is listed.

IX Request for Comment on Options for Conditional Exemptions

- 1. p. 66395, cols. 1 & 2 -- This section of the preamble outlines several options for establishing higher exit level tied to meeting certain management requirements. The Agency states that the options presented "are premised on the theory that a waste's risk is due not only to its chemical composition, but also the manner in which it is managed, which can greatly affect the amount of chemical constituents that ultimately reach a human or environmental receptor."**

DOE thoroughly agrees with EPA's assertion that the risks (to human health and the environment) associated with a particular waste are due not only to the chemical constituents contained in the waste, but also the manner in which the waste is managed. As such, DOE supports the Agency's efforts to develop conditional exemptions from RCRA Subtitle C regulation which are based upon the reduction in risks provided by additional waste management controls. DOE believes that the conditional exemption concept may have particular relevance to radioactive mixed wastes, in that such an approach could potentially result in more efficient management of these wastes. Certain requirements placed on mixed wastes by RCRA (for the hazardous component) and the AEA (for the radioactive component) can often be redundant, and only serve to increase the cost of compliance without any real benefit in terms of protection to human or environmental receptors.

For a number of reasons, the Agency's efforts to establish conditional exemption options appear timely. From a technical standpoint, both EPA and waste generators are now equipped with better tools for predicting the affect that different waste management scenarios will have on human health and the environment. A key to any risk-based regulatory approach obviously lies in utilizing established and accepted risk assessment methodology. The field of risk assessment has undergone significant advances and appears to be more readily accepted in recent years, as evidenced by the fact that risk assessments are being utilized nationwide to help make a variety of environmental decisions.

These advances will also support EPA's desire to shift the regulation of waste from a generic perspective to one that recognizes that all wastes are handled differently and the manner in which they are handled impacts the overall risk that the waste poses. The economics of waste management also supports the move towards this more risk-based form of waste management regulation. DOE, as is the case with any entity responsible for managing environmental protection issues, has finite resources. More flexible, cost-effective waste management regulations would allow for re-allocation of resources to address environmental issues which truly pose unacceptable risks to human health and the environment.

IX.C Overview of Options for Conditional Exemptions

IX.C.1.a Distinguish Between Disposal in Land Application Units and Other Units

- 1. p. 66396, col. 3 -- On review of the risk analysis results, EPA has determined that**

disposal in a land application unit is frequently the highest risk disposal option. With this consideration, the Agency has developed an approach to contingent management using the base case uncontrolled management scenarios, but with land application units removed from the analysis.

DOE supports distinguishing between land application and other units in terms of exit levels. Land application often has been used as a treatment method for wastes such as sewage sludges, which have relatively low hazard potential. Exposure to land-applied waste is much higher than exposure to waste placed in traditional disposal units, such as an impoundment or landfill. Treating land application as equivalent to lower risk disposal methods has the effect of lowering the exit levels for wastes that will be disposed in a landfill to levels much smaller than they need to be to protect human health and the environment.

- 2. p. 66396, col. 3 - p. 66397, col. 1 -- As conditional exemption option 1, EPA is proposing one national exit level for each constituent based on the next riskiest pathway, on condition that wastes are not disposed in land application units.**

This proposed conditional exemption option appears to be the most feasible approach in the short term. However, DOE urges EPA to continue pursuing the development of other options that would better reflect site-specific factors and circumstances.

IX.C.1.c Consideration of Additional Management Unit Design or Management Practices

- 1. p. 66397, col. 3 -- In this section, EPA has identified an issue common to all of the conditional options, which is the legal status of wastes subject to such conditioned exemptions when there is a violation of the conditions.**

DOE does not believe (as stated in the preamble) that any violation of a condition (i.e., where the waste concentration/unit requirements are conditions of an exemption) should necessarily mean that the waste generator has violated the full range of RCRA requirements and has been illegally managing a “hazardous waste” as a “nonhazardous waste.” It would be more practicable and fair to take the position that when there is a violation of the conditions, that an assessment of the violation initially focus on the particular condition that is not being met, and not broaden the non-compliant condition into a designation that the generator (or other individual managing the waste) is illegally managing a “hazardous waste” as a “nonhazardous waste.” While it is agreed that a regulatory approach must be implemented to ensure that the applicable conditions are being complied with, there is a concern that the threat of a broad violation of illegally managing waste (in the case of "any violation of a condition") would prevent generators from using the proposed exemptions.

IX.C.3 Establish Exit Levels That Consider Regional or Site-specific Factors That Might Affect Constituent Fate and Transport

1. **p. 66399, cols. 1-3 -- EPA indicates, that in addition to facility design factors, there are other location-specific factors that may substantially affect risks and the appropriate exit levels for waste management units. This section of the preamble discusses various location-specific factors that might affect constituent fate and transport. EPA requests comment on location-specific factors or combinations of factors that may be important in mitigating the risks associated with waste disposal.**

Consideration of site-specific factors for setting exit levels will require a balance of the regulated community's expectation for a reasonable approach to waste management and the volume of regulations and maze of procedures that may be required to allow such an approach. DOE recommends that the most reasonable approaches be combined with the least amount of red tape. This may be done by allowing the regulated community to do the research, set up the models, and derive the exit levels while the regulators take the roles of reviewers and advisors. This would be a cost savings for the government, it would put the burden of extra work for site-specific approaches on those most interested in doing it, and it could occur at any level of government.

2. **p. 66399, col. 3 -- Relative to groundwater modeling, EPA seeks comment on the related policy judgement as to whether the goal of more site-specific assessment should be prevention of risk based on current groundwater use, reasonably foreseeable use, or based on distances that would be more protective of the potential future use of groundwater.**

DOE recommends that groundwater use scenarios should be limited to the reasonably foreseeable future, rather than current use or any future use. This is reasonably protective and avoids implausible scenarios such as homesteading on industrial land.

IX. E Contingent Management of Mixed Waste

1. **p.66400, col. 3 -- EPA states that it is proposing and requesting public comment on allowing mixed wastes meeting conditional exit levels for chemical toxicity estimated at 10^{-4} cancer risk and HQ 1 (modeled at an uncontrolled site) to exit Subtitle C if managed in disposal facilities subject to controls under the Atomic Energy Act.**

As discussed in General Comment #5 above, the Department is interested in working with EPA and the States to develop a viable a conditional exemption approach that specifically addresses mixed wastes. As indicated in the preamble, DOE believes that certain management provisions required by the AEA to control releases of and exposure to radioactive hazards associated with mixed wastes, also provide protection from releases of and exposures to chemically hazardous constituents in these wastes. Furthermore, the Department believes that certain site-specific conditions (e.g., geology, hydrology, meteorology, climate, land use) at some DOE facilities provide protection to human health and the environment beyond that which was assumed in developing the generic exit levels for the HWIR proposal.

With these factors in mind, the Department urges EPA (in collaboration with the States) to pursue the development of conditional exemption options that specifically apply to mixed wastes and account for the manner in which these wastes are managed. Along this line, DOE generally supports the proposal to establish an adaptation of option four for the Department's mixed waste. That is, DOE generally supports the Agency's proposal to allow mixed waste meeting conditional exit levels for chemical toxicity estimated at 10^{-4} cancer risk and HQ of 1 (modeled at an uncontrolled site), to exit Subtitle C if managed in AEA disposal facilities²⁵. However, DOE believes that there are a number of implementation issues and other considerations that must be addressed before such an option could be promulgated. DOE also believes that the provisions and details of conditional exemption options that would allow mixed waste to exit Subtitle C need to be fully coordinated with EPA and affected States.

DOE has been evaluating some possible conditional exemption options for mixed waste internally, and has been considering provisions that might be necessary to implement these options. It is important to note that most of DOE's mixed waste will be treated prior to disposal in accordance with Site Treatment Plans and compliance orders established under the FFCAct, RCRA, and applicable State laws. These commitments must be met prior to, or as a component of any conditional exemption approach that may be established for mixed waste. As stated in the General Comment section (see General Comments 1 and 5), DOE would like to explore potential conditional exemption options for low-risk mixed waste, and work with EPA and the States to develop such an option (on a separate schedule from the two DOE proposals which support conditional exclusions for immobilized mixed waste debris and vitrified mixed wastes from RCRA). As also mentioned in the General Comments, DOE intends to pursue meetings and further communications with EPA and the States in regards to this subject matter.

2. p. 66400, col. 3. -- EPA requests comment on DOE's proposed conditional exclusion from RCRA requirements for mixed waste debris that is immobilized.

General Comment #2 above provides DOE's comments concerning a conditional exclusion from RCRA Subtitle C for mixed waste debris treated using immobilization. As indicated in this prior comment, the technical data and information DOE has submitted supports that immobilization of mixed waste debris can be managed safely outside RCRA Subtitle C in a low-level radioactive disposal facility (subject to and complying with AEA disposal requirements). DOE requests that the proposed mixed waste debris management approach be promulgated as part of the final HWIR.

3. p. 66400, col. 3. -- EPA requests comment on DOE's proposed approach to mixed waste management utilizing vitrification.

²⁵ As indicated in General Comments 1 and 5 (for clarification purposes), DOE has not previously forwarded information to EPA or the States to support the proposal presented by EPA in the preamble (60 FR 66400, col. 3).

As discussed above in General Comment #3, DOE requests that EPA adopt regulations excluding vitrified mixed wastes from RCRA Subtitle C regulations, provided that: (1) the vitrification facility generating the treated wastes is regulated through a permit, regulatory requirements or other environmental compliance mechanisms, and is operated in accordance with an approved Process Control Program; (2) the vitrified low-level mixed waste forms will be disposed of either in DOE LLW disposal facilities that comply with the requirements of Order DOE 5820.2A (Radioactive Waste Management), or in radioactive waste disposal facilities licensed by the Nuclear Regulatory Commission or an Agreement State; and vitrified high-level mixed wastes will be stored at a DOE high-level waste storage site (operated in compliance with the requirements of Order DOE 5820.2A) pending disposal in a Federal radioactive waste repository; and (3) it has been demonstrated to EPA or the authorized State that pre-defined process control program requirements and product performance characteristics have been met. DOE submitted a technical data package to EPA in support of this proposal on October 20, 1995 (as indicated in the preamble). As with the preceding comment (regarding DOE's proposed conditional exclusion for immobilized mixed waste debris), DOE requests that EPA promulgate the proposed conditional exclusion for vitrified mixed waste forms as part of the final HWIR.

4. p. 66401, col. 1 -- EPA says that it intends to publish a supplemental proposal on HWIR mixed waste exit criteria after initial comments have been received.

DOE requests that a supplemental notice on HWIR mixed waste exit criteria focus on the Department's primary proposals in response to the proposed HWIR. That is, DOE suggests that EPA utilize a supplemental proposal to further describe the Department's positions that: (1) disposal of immobilized mixed waste debris in a low-level radioactive waste disposal facility is protective of human health and the environment, and (2) vitrification produces a waste form suitable for exemption from the RCRA Subtitle C regulations based on the inherent destruction and immobilization capabilities of the technology. Furthermore, DOE suggests that EPA utilize the supplemental proposal to also address sampling and analysis requirements that are appropriate for mixed waste under HWIR.

As discussed earlier (General Comment #1 and #5, and Specific Comment IX.E, item 1), DOE would like to explore options for contingent management of mixed waste (i.e., the option proposed by EPA, as well as other options), and to work with EPA and the States to develop such an option. However, DOE believes that efforts to evaluate and develop a contingent management option for low-risk mixed wastes should be considered and pursued on a separate schedule from the DOE proposals discussed in the above paragraph.

X. Implementation of Conditional Exemption Option 1

X.B When Contingent Management Exemptions Become Effective

- 1. p. 66401, cols. 2&3 -- EPA proposed two options for the point at which the contingent management exemption would become effective: Option 1A under which the waste is exempt upon placement in a qualifying unit and Option 1B where the waste is exempt**

upon meeting the exit levels.

DOE supports Option 1B for the reasons described below:

- The imposition of Subtitle C management standards for candidate contingent management exempt wastes until they are placed in a qualifying unit poses several implementation problems due to the interface of these requirements with the receiving facility's non-Subtitle C regulatory status. These include hazardous waste manifest requirements for shipments to a receiving facility that is not a "designated facility" and is not subject to Subtitle C waste tracking requirements; and the need for a receiving facility to store the wastes in accordance with Subtitle C requirements until the material can be placed in the disposal unit or allowance for a limited holding period at the disposal facility (i.e., 10 days) prior to the Subtitle C storage requirements being applied. If EPA elects to go forward with Option 1A; however, the Department suggests that EPA include provisions to extend the limited period of non-Subtitle C management in the event that inclement weather, equipment failures, or other unforeseen events occur that prevent placement of the candidate contingent management exempt wastes into the applicable disposal unit within the specified timeframe.
- The creation of an alternative waste tracking system does not appear to be necessary. For universal wastes, EPA initially proposed to require the hazardous waste manifest for certain off-site shipments. In response to comments, EPA did not impose any hazardous waste manifest requirements on universal waste shipments in the final rule (see 60 FR 25530), but rather relied on the Department of Transportation (DOT) requirements applicable to shipments of hazardous materials or on standard business records (e.g., bill of lading, invoice, other shipping documents) that would normally be retained to fulfill this tracking requirement. EPA should consider whether existing tracking mechanisms already provide the necessary assurances that contingent management exempt wastes are being properly managed and an adequate paper trail documenting those activities is in place.
- Management of candidate contingent management exempt wastes under Subtitle C has significant implications for the applicability of the LDR standards. It is unwarranted for wastes that meet the applicable contingent management exemption levels at their point of generation, to be required to also meet LDR standards because the wastes were subject to an extended period of Subtitle C management control (i.e., until placement in a qualifying unit). This would be inconsistent with EPA's conclusion that as-generated wastes complying with applicable §261.36 exit levels should not incur the LDR standards.
- Option 1A would also raise several concerns with regard to EPA's proposal to allow mixed waste meeting conditional exit levels to exit Subtitle C if managed in AEA regulated disposal units (i.e., proposed adoption of Option four to DOE's special circumstances; 60 FR 66400, col. 3). DOE sites receiving waste for AEA-regulated disposal may lack RCRA storage capacity or may have RCRA permits that restrict acceptance of off-site hazardous

wastes (such permit conditions could be interpreted to preclude acceptance of candidate contingent management exempt wastes). Acquisition of a RCRA permit or modification of an existing permit solely for purposes of managing candidate contingent management wastes pending their disposal would be an unwarranted expense for both DOE and the regulatory authority.

2. **p. 66401, col. 3 Under Option 1A, EPA is considering and requesting comment on allowing off-site disposal facilities to store candidate contingent management exempt wastes for up to 10 days without becoming a Subtitle C treatment, storage, and disposal facility, prior to ultimate disposal in a monofill or landfill.**

As indicated in the preceding response (i.e., first bullet), DOE does not believe that 10 days is sufficient. The Department suggests that a minimum of 30 days would be more appropriate, to allow time for sample collection and analysis where required for confirmation relative to a waste stream, and to account for unforeseen events (such as inclement weather, equipment failures, etc.). Furthermore, EPA should consider including a provision that would allow for an extension after 30 days (possibly up to 90 days) where circumstances warrant.

X.D Implementation Conditions

X.D.2 Qualifying Unit

1. **p. 66403, col. 2 -- EPA proposed that a "qualifying unit" for the contingent management proposal (§261.37) be defined as a landfill or monofill.**

It is unclear why, in developing alternative exit levels by excluding land application units from the multipathway risk assessment, the applicability of the resulting nonwastewater exit levels (Appendix XI) has been limited to landfills and monofills. EPA solicited comment on whether wastes managed in piles should also be excluded; however, the current proposal would limit this conditional exemption to specific types of non-Subtitle C waste management units -- a situation that appears at odds with EPA's rationale for the broad applicability of the exit levels (Appendix X) under proposed §261.36.

In Section IV.E.1.b (60 FR 66356, col. 1) of the proposed rule EPA discusses the multipathway risk assessment and concludes that although the waste management units considered in the assessment (surface impoundments, aerated tanks, waste piles, monofills, and land treatment units) are not all-inclusive, the risks posed by other types of management of the exited wastes will be no greater than those from the units assessed. Accordingly, the proposed §261.36 exemptions impose no limitations on the type of non-Subtitle C waste management unit in which the exited wastes (wastewater or nonwastewater) may be managed.

EPA developed the alternative nonwastewater exit levels under conditional exemption option 1 (Section IX.C.1.a, 60 FR 66396) by again performing the multipathway risk assessment, but excluded land application units from the analysis because disposal in such units was frequently

the highest risk disposal option in both the multipathway and groundwater modeling. EPA stated that the exit concentrations derived in this analysis would be protective across a wide variety of conditions nationally, for all non-land application unit disposal. However, EPA offered conditional exemption using these revised exit levels only to wastes managed in landfills or monofills. On page 60 FR 66378, in discussing the application of the LDR standards to wastes even where such wastes are not destined for land disposal, EPA indicates that it does not know how frequently nonhazardous wastes are burned as fuel, incinerated, or otherwise managed outside of land disposal. As proposed, the §261.37 exemptions would exclude such non-land disposal management alternatives.

Based on the arguments made for the broad applicability of the exit levels (Appendix X) used in the §261.36 exemption, it would seem that the proposed §261.37 conditional exemption should only be limited to wastes meeting the alternative exit levels (Appendix XI) that are managed in non-Subtitle C units other than land application units. No rationale for restricting applicability of the conditional exemption levels to only certain non-Subtitle C management units (landfills or monofills), or restricting their applicability to disposal units was provided in the preamble. DOE requests that appropriate supporting rationale be made available for public review and comment prior to such restrictions being promulgated.

2. **p. 66404, col. 1 -- In regards to proposed conditional exemption option 1 (i.e., proposed §261.37), EPA suggests that one alternative for simplifying the claimant's burden of proving compliance with all conditions would be to set out in the rule certain documentation that, while not necessarily required of the claimant, presumptively would be sufficient evidence of satisfaction of the management condition.**

DOE would support the identification of certain documentation, which, while not necessarily required, would provide sufficient evidence that the management condition has been met. The Department does not believe that such documentation should be required of the claimant.

X.F Compliance Monitoring and Enforcement for Contingent Management Exemptions

X.F.1 Compliance Monitoring

1. **p. 66404, col. 3 -- The last paragraph of this section states that "Inspections of off-site laboratories may also be performed."**

DOE requests that EPA provide clarification as to the scope of these inspections. For instance, clarification or answers to the following questions should be provided: What is the definition of "off-site" laboratories? Would inspections be performed when analytical data submitted by a generator do not appear to meet QC criteria? Or could inspections be performed at random on any laboratory that generated data used to support an exit claim or document continued compliance with an exemption? If any discrepancy or deficiency is discovered, would the

analytical laboratory be subject to enforcement actions or fines, or would only the generator be liable? What about “on-site” laboratories owned and operated by the same parent company as the generator of the waste (which may be utilized for generating exit claim data or documentation that supports continued compliance with the exemption requirements)?

X.F.2 Enforcement

- 1. p. 66404, col. 3 -- EPA states that “failure to manage the contingent management exemption waste in accordance with the conditions [of the proposed regulations] would void the exemption and the conditionally exempt waste would be subject to full Subtitle C regulation.”**

This statement indicates that when the waste has already been disposed, the receiving facility would be subject to possible enforcement actions and permitting requirements at the mercy of the generator, who may not have properly evaluated the exit claim. EPA should limit the enforcement liability of the receiving facility that acted responsibly. If the waste can be and is removed promptly, then the receiving facility should be allowed to remain outside of RCRA Subtitle C regulation.

XI Relationship to Other RCRA Regulatory Programs

XI.B Characteristic Hazardous Waste

- 1. p. 66406, col. 1 -- EPA notes that if a waste satisfies the proposed exemption criteria, then it would not be considered a listed hazardous waste. However, the generator must still determine whether the waste exhibits any characteristics of a hazardous waste as specified in 40 CFR 261.21 through 261.24 and continue to meet hazardous waste requirements if the waste does exhibit a characteristic.**

DOE supports EPA’s proposed approach, which would allow removal of the listed hazardous waste designation (and associated regulatory requirements) for wastes which nevertheless remain within the Subtitle C regulatory framework due to exhibiting a characteristic. This raises a related issue on which DOE seeks clarification. That is, DOE requests clarification as to whether EPA would allow removal of the listed hazardous waste designation for debris and environmental media under the “contained-in” rule, even if such waste still exhibits a characteristic. In the past, the EPA provided statements which would seem to imply that the contained-in rule could be applied only for wastes which qualify for removal of the listed hazardous waste codes and exhibit no hazardous waste characteristic. Thus, it appeared that removal of a listed hazardous waste code while retaining a characteristic hazardous waste code (and hence remaining subject to Subtitle C regulation) may not be allowed. DOE believes that removal of the listed hazardous waste designation for qualifying wastes is an appropriate application of the contained-in rule, even when such wastes are characteristically hazardous.

XI.E Delisting

1. **p. 66407, col. 2 -- EPA states that delisting petitions will continue to be accepted and reviewed by the Agency (after the HWIR is promulgated) . The Agency also solicits comment on which risk models should be used to evaluate future delisting petitions.**

This statement seems to imply that EPA may be anticipating a change in the delisting process to incorporate non-groundwater pathway risk analysis data. DOE requests that EPA provide clarification in regards to this implication.

XI.G Closure

1. **p. 66407, col. 2&3 -- EPA explains that under the proposed HWIR, a hazardous waste management unit that receives wastes that are exempt under the proposed exit levels would continue to be subject to Subtitle C requirements until the unit completed a clean closure or unless all of the waste in the unit were delisted. EPA states that a unit receiving only waste that is exempt under the HWIR proposal would no longer be receiving hazardous waste upon the effective date of the exemption; such a unit would normally become subject to Subtitle C closure requirements which are triggered by the final receipt of hazardous waste by the unit. Land-based units (e.g., landfills, land treatment units, surface impoundments) could continue operation while accepting only nonhazardous wastes under the RCRA delay-of-closure regulations.**

This approach appears contrary to the delisting program whereby, when a delisting petition is approved, the unit managing the delisted wastes is no longer subject to the Subtitle C closure requirements.

"EPA's decisions to delist a waste are generally retrospective and typically remove the waste management units holding the delisted waste from control under Subtitle C of RCRA. In effect, the Agency has decided that these units have not received a hazardous waste. However, if a waste from a hazardous waste management unit is treated and subsequently delisted, the unit in which the untreated waste was managed is not necessarily removed from regulation..." (see 54 FR 41935)

DOE recommends that non-land-based waste storage units be allowed to convert from hazardous to nonhazardous waste management, when the waste managed in the unit is exempted from Subtitle C under the HWIR proposal, without completing a clean closure of the unit. Certainly for wastes that meet the exit levels at their point of generation, the storage unit in which such wastes are managed should not be subject to the clean closure requirements. This interpretation is analogous to EPA's interpretation that the LDR requirements do not apply to such wastes. Such wastes are only being protectively managed under Subtitle C requirements until characterization confirms that the constituent concentrations fall below the applicable exit levels. EPA should provide a satisfactory rationale for this seemingly contradictory approach prior to finalizing this proposal.

- 2. p. 66408, col. 1 -- EPA solicits comment on whether removal of hazardous waste residues from tanks could be accomplished by demonstrating that all waste in the tank is below the applicable exit levels, without removing the waste from the tank.**

DOE supports this closure alternative which would allow clean closure for the tank itself to be demonstrated simply by ensuring that all wastes managed in the tank comply with the proposed exit levels. DOE also supports EPA's proposal that for tank systems which also involve soil and/or groundwater contamination, the facility owner or operator may continue to use the tank for managing nonhazardous wastes (after meeting the closure standard that all wastes meet the applicable exit levels) while either removing the contamination to clean closure levels or closing the impacted area as a landfill.

XI.L Hazardous Wastes Used in Manner Constituting Disposal

- 1. p. 66410, col. 3 -- EPA proposes to eliminate the requirement that wastes to be used in a manner constituting disposal undergo a chemical reaction so as to be inseparable by physical means, since wastes will be evaluated for total constituent concentrations.**

DOE supports this proposal.

XII CERCLA Impacts

- 1. p. 66411, col. 1 -- EPA requests comments on the approach for CERCLA notification. The proposed approach is to require CERCLA notification (of releases of the waste) only if the waste or any of the constituents of the waste are CERCLA hazardous substances and are released in amounts greater than or equal to their reportable quantities.**

DOE supports this approach, since it appropriately would eliminate notification requirements under CERCLA of a release of an exempted waste.

XIII State Authority

XIII. B Effect of State Authorization

- 1. p. 66411, col. 3 -- Authorized States are only required to modify their programs when EPA promulgates Federal regulations that are more stringent or broader in scope than the authorized State regulations. EPA explains that the HWIR proposal for exit levels is considered to be less stringent than, or a reduction in scope of, the existing Federal regulations because it would exempt certain wastes now subject to RCRA Subtitle C. Therefore, authorized States are not required to adopt these regulations.**

DOE supports EPA's efforts in encouraging States to adopt the proposed HWIR regulations as quickly as possible, and agrees that the proposal will reduce the over-regulation of low-risk solid

wastes and provide an alternative to delisting. Furthermore, as discussed in General Comment #7 above, DOE urges EPA to closely coordinate the development of the final HWIR provisions with the States, and to implement criteria and approaches that will minimize the outcome of inconsistency among State programs.

XIII. C Streamlining Issues

- 1. p. 66412, col. 2 -- Currently EPA finds it unlikely that the Agency will propose a greatly streamlined authorization process for any of the contingent management options, because these options will raise novel legal, implementation and enforcement issues. Therefore EPA states that a more conventional type of approach to the review of State authorities and capabilities may be warranted. EPA also states that *if* [emphasis added] any of the options are proposed by the Agency in the future, consideration will be given to the possibility of adopting an approach to streamlining authorization that is being developed for the HWIR-Media proposal.**

DOE notes that EPA has proposed the Option 1 contingent management approach under Section X. As such, clarification should be provided in regards to the above statements. Also, inasmuch as Option 1 is in effect only a variation on the base exemption (the only difference is that land application units are removed from the risk analysis), it would seem that a streamlined authorization process would be appropriate for this option as well.

XIV Regulatory Requirements

XIV.D Assessment of Potential Costs and Benefits

XIV.D.3 Implementation Requirements

- 1. p. 66415, col. 1 -- Implementation requirements include the steps that generators (or waste managers) must take to achieve exemption of their wastes. These requirements include waste sampling and analysis, and related recordkeeping and reporting. The Agency has estimated annual sampling, analysis, recordkeeping, and reporting costs, collectively referred to as "implementation costs", that may be required under the HWIR (estimates range from \$21,000 to \$169,000).**

DOE understands that the implementation cost estimates may vary widely depending on the complexity of the waste stream and the amount of annual sampling (based on volume of waste generated). DOE requests clarification as to whether these estimates include the initial testing for the exit claim documentation. Oak Ridge National Laboratory (ORNL) estimates that it would cost approximately \$7,000 per sample to analyze one (radioactive) sample for the full Underlying Hazardous Constituents list. This cost would then need to be multiplied by the number of samples required for obtaining the statistical level of confidence needed, which could significantly increase the costs for the first year.

Comments on Proposed Amendments to the Regulatory Language

1. **p. 66440, col. 2 -- In Section III.B of the preamble (60 FR 66349, cols. 1 and 2), EPA indicates that the derived-from rule [§261.3(c)(2)(i)] would be revised to include an exemption for derivatives of wastes listed solely because they exhibit the characteristic of ignitability, corrosivity, or reactivity, if the derivatives no longer exhibit a characteristic and were treated to meet LDR requirements.**

The proposed amendments to the regulatory language do not include language which corresponds to the proposed revisions to the derived-from rule [§261.3 (c)(2)(i)] described above. EPA also states in the preamble (60 FR 66349, col. 2) that the proposed revisions to the derived-from rule would include language reminding the regulated community of the need to comply with the part 268 LDR requirements. However, the proposed regulatory language for §261.3(c)(2)(i) does not contain the LDR reminder.

2. **p. 66440, col. 3 and 66442, col. 3 -- The proposed language for §§261.36 and 261.37 indicates that wastes meeting the requirements of these sections are exempt from the requirements of parts 262-266 and part 270.**

This proposed regulatory language seems to imply that exempt wastes [except those that meet the requirements of §261.36(e) or §261.37(f)] are subject to all of the requirements of part 268. If this were the case, claimants would be required to submit notifications and certifications under both parts 261 and 268. Such dual notifications would be redundant. DOE recommends that wastes meeting the requirements of these sections only be required to meet the applicable LDR treatment standards, rather than be required to comply with part 268 in its entirety.

3. **p. 66441, col. 2 -- The regulatory language proposed for new section 40 CFR 261.36(b)(4)(vii) indicates that, among other information, the notification of the exemption claim provided to the implementing agency must include "Documentation that any waste that exits using a constituent exit level from Table B to Appendix X has met the applicable treatment standards in §268.40, unless the claimant is also claiming the exemption under §261.36(e)."**

DOE suggests that, since the proposed HWIR allows "minimize threat" levels to be substituted for the treatment standards in 40 CFR 268.40 (see proposed 40 CFR 268.60), EPA should consider expanding proposed 40 CFR 261.36(b)(4)(vii) to cover situations where minimize threat levels have been substituted.

4. **p. 66441, col. 2 -- The proposed regulatory language for new section 40 CFR 261.36(b)(4)(ix) requires the certification accompanying notification of the exemption claim provided to implementing agency to be worded as follows:**

Under penalty of criminal and civil prosecution for making or submitting false

statements, representations, or omissions, I certify that the requirements of 40 CFR 261.36(b) have been met for all waste identified in this notification. Copies of the records and information required at 40 CFR 261.36(d)(7) [sic] are available at the claimant's facility. Based upon my inquiry of the individuals immediately responsible for obtaining the information, the information is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

The above-quoted certification statement refers to "copies of the records and information required at 40 CFR 261.36(d)(7)." Since the proposed regulatory language for 40 CFR 261.36(d) contains no subsection (7), and since proposed subsection (6) discusses records that must be maintained on-site, DOE believes the citation in the certification statement should be to "40 CFR 261.36(d)(6)" rather than to "40 CFR 261.36(d)(7)."

5. **p. 66454, Appendix X, Table B -- In the preamble under Section V.B, "Constituents with Quantitation-Based Exit Levels; Table B to Appendix X. " (60 FR 66379, col. 3), EPA explains that some constituents on Table B of Appendix X of 40 CFR 261 do not have associated exit levels and that waste with these constituents may exit only after complying with the LDR treatment standards.**

Proposed Table B of Appendix X (of 40 CFR 261) includes approximately 80 constituents with a footnote identified; however, there is no footnote accompanying the table or any corresponding text provided. Language should be included in association with the Table which indicates that these constituents may exit only after complying with the LDR treatment standards.

6. **p. 66464 -- Footnote 1 to proposed Appendix XI, Table B - Quantitation-Based Conditional Exit Levels, reads "No testing required; additional LDR requirements apply."**

It is not apparent that EPA's proposal with respect to the applicability of the LDR standards to the specified constituents would be adequately conveyed by this footnote. A requirement of this significance should not be limited to a footnote where it may be overlooked. DOE recommends that EPA examine alternate language to ensure that the final regulations clearly convey the exit requirements applicable to the specified Table B constituents.

7. **p. 66465, col. 1 -- Under the proposed amendments to §268.2 (definitions applicable to the LDR program), a paragraph would be added to explain that "*land treatment means that waste is applied onto or incorporated into the soil surface.*"**

The proposed definition appears somewhat broad and could be misinterpreted to include other forms of waste placement onto a soil surface, such as landfills. It is suggested that the proposed definition be modified to encompass land application units, but not other types of land-based units, as was EPA's intention.

8. **p. 66465, col. 2 and p. 66467, col. 1 -- In the proposed language for §§268.60 and 268.70, the tables headings should indicate whether the exit levels are based on toxicity benchmarks or MCL-based numbers.**

The minimize threat levels in these Tables appear to be based on the toxicity benchmark exit levels in Part 261 Appendices X and XI. If EPA chooses the MCL-based option, the minimize threat levels in §268.60 and §268.70 should be changed to parallel the MCL-based numbers in Part 261 Appendices X and XI.

9. **p. 66465, §268.60 Table 1. - Minimize Treat Levels and p. 66467, §268.70 Table 1. - Conditional Minimize Threat Levels -- The *headings* for the columns which identify the risk-based standards representing levels at which threats to human health and the environment are minimized include: WW standard (mg/l), NWW standard (mg/kg), and NWW standard (mg/l).**

DOE believes that these tables could be made more “user-friendly” by providing additional information in the column headings. From the preamble discussion, it is understood that the proposed exit levels for nonwastewaters consist of two risk levels for each constituent. The “totals” (mg/kg) nonwastewater risk level is the result of the most limiting non-groundwater pathway, and the “leach” (mg/l) nonwastewater risk level is the result of the most limiting groundwater pathway. The results from the multipathway analysis are “totals,” and the groundwater model results are “leach,” and both levels must be met before threats to human health and the environment are considered to be “minimized.” DOE suggests that EPA make the headings in Table 1 consistent with the headings on Appendix X, Tables A and B by adding the words “Totals” and “Leach” over the appropriate columns, and include any appropriate explanatory footnotes to assist in reading these tables.