Previous versions of the Closure Plan Review Guidance contained the following documents in the appendices, but they have been removed in an effort to reduce paper use. Click on the blue links to go directly to the document.

Appendix Entitled: Clarification Concerning the Arsenic MCL

Lim, Ed. (2003) Memo to Distribution, June 4. "Clarification Concerning the Arsenic MCL"

Appendix Entitled: U.S. EPA Documentation Regarding Risk Based Closure

US EPA (1987) "Interim Standards for Owners of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final Rule". Federal Register: March 19, 1987. 52 FR 8704 pg 3-14

Cotsworth, Elizabeth (1998) Memo to RCRA Senior Policy Advisors, Regions I-X, March 16. "Risk-Based Clean Closure"

Herman, Steven A. (1996) Memo to RCRA/CERCLA National Policy Managers, Regions I-X Agency, September 24. "Coordination between RCRA Corrective Action and Closure and CERCLA Site Activities"

Appendix Entitled: Supplemental Guidance for Calculating the Concentration Term

U.S. EPA (1992) "Supplemental Guidance to RAGS: Calculating the Concentration Term" OSWER Publication 9285.7-081, May

U.S. EPA (2002) "Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites" OSWER Publication 9285.6-10

Appendix Entitled: Supplemental Guidance to RAGS: Standard Default Exposure Assumptions

U.S. EPA (1991) ""Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual, Supplemental Guidance 'Standard Default Exposure Factors'" OSWER Directive 9285.6-03, March 25

“Clarification Concerning the Arsenic MCL” Lim, Ed. (2003)

TO: Distribution

FROM: Ed Lim, ERAS, DHWM

SUBJECT: Clarifications Concerning the Arsenic MCL

DATE: June 4, 2003

As you may know, US EPA revised the Arsenic Rule a couple years ago (66 FR 6976 January 22, 2001) making the arsenic maximum contaminant level (MCL) more stringent by lowering the level from 0.05 mg/L (or 50 ppb) to 0.01 mg/L (or 10 ppb). Since that time questions slowly developed concerning the appropriate MCL value (for arsenic and other similarly situated chemicals or compounds) DHWM should apply to its ground water monitoring and response program, as well as to its decision making in the closure and corrective action context. Although DSIWM and DDAGW each have different rules involving MCLs, similar questions were also raised in those programs.

An effort was made (by management of the various divisions) in January of this year to clarify this agency's approach to the appropriate use of the new MCL. It required that if a program's rule incorporates a specific federal rule by reference and does not have statement following the federal rule citation, such as "as hereinafter amended" the cross reference to federal law will be deemed to be the federal regulation in effect at the time the Ohio rule was promulgated (or last updated). In the case of the arsenic MCL, if the DHWM rule has not been updated to account for the new MCL, the referenced ground water MCL for DHWM will be the 50 ppb standard found in the old federal rule. In terms of implementation (because the federal rule contains a provision to allow for 3 years for drinking water facilities to come into compliance with the 10 ppb standard), we were advised of the need to incorporate that delay in effectiveness into our application of the rule to ground water remediation plans.

At the February CO-DO Manager's meeting, we agreed that clarifications were needed on the agency's approach in order to accommodate specific DHWM program requirements. The managers agreed to first run the clarifications by the Director's Office for its approval prior to further advising staff on this issue. (see February 4, 2003 CO-DO Manager's Meeting Minutes). On February 12 such a memo was sent and a final response accepting our clarifications was received in mid-May. Today's clarification establishes 50 ppb as the arsenic concentration for ground water monitoring and response (until such time as OAC Rule 3745-54-94 is revised), while the 10 ppb value can be used for current closure and corrective action decision making. The following is a more detailed discussion of the approved clarifications concerning the arsenic MCL in several DHWM applications.

The Delay in Implementation Does Not Apply

Although the federal arsenic rule became effective February 22, 2002, it is not enforceable to drinking water providers until January 23, 2006. U.S. EPA acknowledges in the preamble that drinking water providers, who are mostly public entities, need considerable time to plan for (from a funding, engineering and permitting perspective) the construction of facilities needed to meet the new standard.[1] This rationale does not apply to DHWM closure and corrective action activities. Also, arsenic treatment technologies needed to effectively treat arsenic in ground water to the 10 ppb level are available today.[2] As such, the three year phase-in approach does not apply to DHWM in the remediation/cleanup context.

DHWM's Ground Water Monitoring and Response Program

In the context of ground water monitoring and response, DHWM's rule allows the agency to set hazardous constituent concentrations (during compliance monitoring) at, among other things, the levels found in Table I of the OAC Rule 3745-54-94;[3] the table is entitled "Maximum Concentration of Constituents for Ground Water Protection". Although no mention is made of "MCLs" or the National Primary Drinking Water Regulations, US EPA made clear in its 1982 preamble to the federal counterpart of the Ohio rule that it used MCLs as the basis for setting maximum concentrations. The MCLs gave them an "action level (that) is directly related to the protection of human health and the environment".[4] US EPA's intent at that time was to have Table I consist of all the MCLs for the constituents listed in Appendix IX (of 40 CFR 264).[5] Over the ensuing years EPA never updated this table even though some of the MCLs have been changed while others have been newly established.[6]

Although we know of no plans for US EPA to update Table I, US EPA, in practice, uses the expanded list of MCLs for RCRA ground water monitoring. Since 1982, DHWM's policy has been similar to that. When used as an option for defining a ground water protection concentration limit under OAC Rule 3745-54-94, it is the Division's expectation that owners/operators will use the most current federally effective MCL found in 40 CFR 141.11 for inorganic constituents and 40 CFR 141.12 for organic constituents. In light of Agency concerns discussed above however, DHWM staff are

[1] 66 FR 6976 January 22, 2001.

[2] U.S. EPA (2002) *Proven Alternative for Aboveground Treatment of Arsenic in Ground Water.* EPA 542-S-02-002.

[3] OAC Rule 3745-54-94 Concentration limits.

"The facility permit will specify the concentration limits in the ground water for hazardous constituents established under rule 3745-54-93 of the Administrative Code. The concentration of a hazardous constituent: .....
(2) For any of the constituents listed in "Table I," must not exceed the respective value given in that table...; or"

[4] 47 FR 32297 (1982) discussion of 264.94 Concentration Limits

[5] 47 FR 32297 (1982) discussion of 264.94 Concentration Limits

[6] Table I contains 14 compounds (8 metals and 6 pesticides), today the National Primary Drinking Water Regulations contain 69 compounds of interest to DHWM (16 inorganic and 53 organic compounds).

today advised to use the Table I constituent concentrations (of OAC rule 3745-54-94) in setting ground water protection standards regardless of whether there is a more recent and/or more restrictive MCL for that constituent. For ground water constituents of interest that are not listed on Table I, but for which MCLs are otherwise effective on the federal level, DHWM's current policy will be unaffected (i.e. recommend using the most current MCL). There are approximately 55 compounds that will fall into this category. Meanwhile, the DHWM will work on a rule revision to update Table I of OAC rule 3745-54-94 to add the inorganic and organic compounds found in the currently effective federal MCL rules. Thereafter, the DHWM must be vigilant to new and revised federal MCLs and be ready to revise OAC Rule 3745-54-94 accordingly.

The Arsenic MCL and DHWM's Closure Performance Standard

The Closure Performance Standard (OAC rule 3745-55-11) is an element of the DHWM program where the determination of acceptable arsenic levels in ground water is sometimes needed in order to complete the closure. The closure rule does not specify MCLs as a closure standard; instead, it sets forth a qualitative standard requiring:

> (t)he owner or operator ... close the facility in a manner that:
>
> (A) Minimizes the need for further maintenance; and
>
> (B) Controls, minimizes or eliminates, to the extent necessary to prevent threats to human health and the environment, post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere; and
>
> (C)Complies with the closure requirements of rules 3745-55-10 to 3745-55-20 of the Administrative Code, including, but not limited to, the requirements of rules 3745-55-78, 3745-55-97, 3745-56-28, 3745-56-58, 3745-56-80, 3745-57-10, 3745-57-51, and 3745-57-91 to 3745-57-93, and 3745-218-02[7] of the Administrative Code.

Generally, two types of closure are allowed - closure by removal or decontamination (referred to here as "clean closure") and closure with waste in place. The premise of clean closure is that all hazardous wastes have been removed from a given RCRA regulated unit and any releases at or from the unit have been remediated so that further regulatory control under RCRA Subtitle C is not necessary to protect human health and the environment. As part of meeting the closure performance standard referenced above, for clean closure, facility owners/operators must remove all wastes from the closing unit and remove or decontaminate all waste residues, contaminated containment system components, contaminated soils (including ground water and any other environmental media contaminated by releases from the closing unit), and structures and equipment contaminated with hazardous waste and hazardous waste leachate.

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7 Since the time of this memo, Ohio EPA has adopted revised rules as part of the Mega Set Rules. The requirements of OAC Rule 3745-218-02 can now be found under OAC Rule 3745-205-102.

The closure performance standard does not require one to completely remove all contamination, *i.e.,* to background, at or from a closing unit. Rather, some limited quantity of hazardous constituents might remain in environmental media after clean closure provided they are at concentrations below levels that may pose a risk to human health and the environment. The amount of hazardous constituents that might remain in environmental media after clean closure should be identified through appropriate application of risk information either by using available constituent-specific limits or factors that have undergone appropriate agency review (*e.g.,* MCLs or health-based limits calculated using a verified reference dose), by using background concentrations or, when such limits or factors are not available, by using toxicity information submitted by a facility owner/operator and approved by US EPA (or Ohio EPA). In establishing a clean standard, the DHWM's policy has been to select the MCL or risk based concentration number whichever is lower. For MCLs, DHWM has used the MCLs found on the currently effective federal list. Because the closure rule does not specify a particular MCL as a clean standard, DHWM's staff is advised, in clean closure situations, to continue the current practice and consider use the effective federal MCLs or the risk-based clean-up number whichever is lower as appropriate in meeting the closure performance standard.

Alternatively, a closure with waste in place will require a post-closure ground water monitoring and response program meeting the requirements of Chapter 3745-54 of the OAC. Our guidance to staff for the selection of hazardous constituent concentrations for compliance monitoring is identical to the discussion on ground water monitoring above; and staff should follow Table I for listed MCLs and encourage use of the currently effective federal list for constituents of interest not covered by Table I.

The Arsenic MCL and DHWM's Corrective Action Remediation Standard

Similar to closures, the corrective action standard is framed in qualitative terms and does not specify MCLs as a remediation standard. The corrective action rule (OAC rule 3745-55-011[8]) in part requires that:

> (A) The owner or operator of a facility seeking a permit for the treatment, storage, or disposal of hazardous waste shall institute corrective action as necessary to protect human health and the environment for all releases of hazardous waste or constituents from any waste management unit at the facility, regardless of the time at which waste was placed in such unit.

US EPA and DHWM expect final remedies to return useable ground waters to their maximum beneficial use, wherever practicable, within a reasonable time frame. The establishment of an appropriate and protective clean up standard for ground water is site specific and considers the use, vulnerability, and value of the ground water as a resource as well as all potential pathways that could result in human or ecological exposure to contaminants in or from ground water. US EPA guidance recommends that ground water clean up levels for human health be set by using drinking water standards,

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8 Since the time of this memo, Ohio EPA has adopted revised rules as part of the Mega Set Rules. The requirements of OAC Rule 3745-55-011 can now be found under OAC Rule 3745-54-101.

or by risk assessment.[9] The division has followed this guidance for some time; and application of this guidance to set arsenic concentrations in ground water to levels protective of human health would result in an MCL of 10ppb or a lower risk-based concentration. Since MCLs are not specified or required by rule as clean-up goals, we advise DHWM staff to continue to set site-specific ground water remediation standards in accordance with the objectives of OAC rule 3745-55-011[10] and in recognition of current guidance.

I appreciate your efforts in this matter and hope this provides clear guidance with respect to this important issue in our monitoring and clean-up programs.

If you would like to discuss the matter in further detail or if you have questions, please contact me.

Distribution: CO-DO Managers

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9 U.S. EPA (2002) *Handbook of Ground Water Protection and Cleanup Policies for RCRA Corrective Action*, EPA/530/R-01/015.

10 Since the time of this memo, Ohio EPA has adopted revised rules as part of the Mega Set Rules. The requirements of OAC Rule 3745-55-011 can now be found under OAC Rule 3745-54-101.

“Interim Standards for Owners of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final Rule”. Federal Register: March 19, 1987. 52 FR 8704 pg 3-14

42ND DOCUMENT of Level 1 printed in FULL format.

ENVIRONMENTAL PROTECTION AGENCY
AGENCY: Environmental Protection Agency (EPA).

40 CFR Part 265
Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final Rule

[SW-FRL-3092-1]

52 FR 8704

March 19, 1987

ACTION: Final rule.

SUMMARY: The Environmental Protection Acency is today amending the interim status regulations for closing and providing postclosure care for hazardous waste surface impoundments (40 CFR Part 265, Subpart K), under the Resource Conservation and Recovery Act (RCRA).

The Agency proposed today's modifications to the interim status standards on July 26, 1982. Today's amendments provide conformance between certain interim status requirements for surface impoundments and those requirements contained in the permitting rules of 40 CFR Part 264, that were also published on July 26, 1982. The Agency is also setting forth its interpretation of the regulatory requirements applying to closure of storage facilities regulated under both permits and interim status.

EFFECTIVE DATE: These final regulations become effective on September 15, 1987, which is six months from the date of promulgation, as RCRA section 3010(b) requires.

ADDRESS: The docket for this rulemaking (Docket No. F-87-CCF-FFFFF) is located in Room MLG100, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC and is available for viewing from 9:00 a.m. to 3:30 p.m., Monday through Friday, excluding holidays. Call Mia Zmud at 475-9327 for appointments.
FOR FURTHER INFORMATION CONTACT: RCRA hotline at (800) 424-9346 (in Washington, DC, Call 382-3000) or for technical information contact Ossi Meyn, Office of Solid Waste (WH-565E), U.S. Environmental Protection Agency, Washington, DC 20460, telephone (202) 382-4654.

TEXT: SUPPLEMENTARY INFORMATION:

I. Authority

These regulations are issued under the authority of sections 1006, 2002(a), 3004 and 3005 of the Solid Waste Disposal Act (SWDA), as amended by the Resource

Conservation and Recovery Act (RCRA) of 1976, as amended *(42 U.S.C 6905, 6912(a), 6924, and 6925)*.

II. Background

Subtitle C of RCRA creates a "cradle-to-grave" management system intended to ensure that hazardous waste is safely treated, stored, or disposed. First, Subtitle C requires the Agency to identify hazardous waste. Second, it creates a manifest system designed to track the movement of hazardous waste, and requires hazardous waste generators and transporters to employ appropriate management practices as well as procedures to ensure the effective operation of the manifest system. Third, owners and operators of treatment, storage, and disposal facilities must comply with standards the Agency established under section 3004 of RCRA that "may be necessary to protect human health and the environment." Ultimately, these standards will be implemented exclusively through permits issued to owners and operators by authorized States or the Agency. However, until these permits are issued, existing facilities are controlled under the interim status regulations of 40 CFR Part 265 that were largely promulgated on May 19, 1980. Under RCRA interim status, the owner or operator of a facility may operate without a permit if: (1) It existed on November 19, 1980, (or it existed on the effective date of statutory or regulatory changes under RCRA that render the facility subject to the requirements to have a permit under section 3005); (2) he has complied with the notification requirements of section 3010 of RCRA; (3) he applied for a permit (Part A application) in accordance with section 3005 of RCRA. Interim status is retained until the regulatory agency makes a formal decision to issue or deny the permit or until the facility loses its interim status by statute for failure to submit Part B permit application and/or certification of compliance with applicable ground-water monitoring and financial assurance requirements.

In regulations promulgated on July 26, 1982, [40 CFR Part 264, 47 FR 32274], the Agency established permitting standards in 40 CFR Part 264 covering the treatment, storage, and disposal of hazardous wastes in surface impoundments, waste piles, land treatment units, and landfills. Owners and operators of such facilities must meet these standards to receive RCRA permits. Also included in the Federal Register on that date were a series of changes to the interim status requirements of Part 265, which were promulgated to ensure consistency with the new Part 264 standards. There were, however, a few additional Part 265 conforming changes that the Agency believed should first be proposed for public comment because, in most cases, the public had not had sufficient opportunity to comment on the appropriateness of applying them during the interim status period. Many of the changes that were proposed on July 26, 1982, were promulgated in final regulations on April 23, 1985 (50 FR 16044). Today, the Agency is making final the remaining changes to the surface impoundment closure and post-closure care requirements (§ 265.228) that were proposed on July 26, 1982.

III. Discussion of Today's Amendments

The Part 264 rules issued on July 26, 1982, for surface impoundment closure and post-closure care (§§ 264.228 and 264.310) are in many ways similar to the interim status requirements (§§ 265.228 and 265.310). The Part 264 closure rules, however, contain more specific performance standards to assure adequate protection of human health and the environment. For reasons discussed below, the Agency believes the more explicit Part 264 closure rules should also be implemented during interim status. Moreover, EPA believes that the closure process is adequate to apply these closure requirements. The existing review process for interim status closure and post-closure care plans will provide an opportunity for the Agency to review the specifics of the plans for compliance with the closure performance standards. Thus, any problems with misinterpretation of the closure requirements by the owner or operator would be identified and rectified prior to actual closure. In fact, the review process for closure and post-closure care plans during interim status is similar to the review process of closure and post-closure care plans conducted during the permitting process. Therefore, the Agency believes that these closure requirements are capable of being properly implemented during interim status.

The § 265.228 closure rules proposed on July 26, 1982, and promulgated today, retain the basic format of existing regulations by allowing owners and operators to choose between removing hazardous wastes and waste residues (and terminating responsibility for the unit) or retaining wastes and managing the unit as a landfill. (An additional choice for closure is proposed elsewhere in today's Federal Register.) The requirements for both choices are made more specific in today's amendments.

If the owner or operator chooses not to remove or decontaminate the waste and waste residues, then the rules promulgated today provide that the owner or operator must: (1) Eliminate free liquids by either removing them from the impoundment or solidifying them, (2) stabilize the remaining waste and waste residues to support a final cover, (3) install a final cover to provide long-term minimization of infiltration into the closed impoundment, and (4) perform post-closure care and ground-water monitoring.

The Part 265 regulations promulgated today (like the existing Part 264 regulations for permitted units) allow owners and operators of surface impoundments to remove or decontaminate wastes to avoid capping and post-closure care requirements (§ 265.228(a)(1)). They must remove or decontaminate all wastes, waste residues, contaminated containment system components (e.g., contaminated portions of liners), contaminated subsoils, and structures and equipment contaminated with waste and leachate. All removed residues, subsoils, and equipment must be managed as hazardous waste unless there is compliance with the delisting provisions of § 261.3(d). (Similar Part 265 closure and post-closure care rules for waste piles were promulgated on July 26, 1982.)

The new requirements for closure by removal differ significantly from the previous Part 265 requirements in one respect. The previous interim status requirement in § 265.228(b) required owners or operators to remove all waste residuals and contaminated soil or to demonstrate, using the procedures in § 261.3 (c) and (d), that the materials remaining at any stage of the removal were no longer a hazardous waste. Once an owner or operator made a successful demonstration under § 261.3 (c) and (d), (s)he could discontinue removal and certify closure.

Under § 261.3 (c) and (d), materials contaminated with listed waste (as evidenced by the presence of Appendix VIII constituents) are hazardous waste by definition unless the material is delisted. Materials contaminated with characteristic wastes, however, are only hazardous wastes to the extent that the material itself exhibits a characteristic. Thus to meet the old closure by removal standard, owners or operators of characteristic waste impoundments had only to demonstrate that the remaining material did not exhibit the characteristic that first brought the impoundment under regulatory control.

This demonstration, however, arguably allowed significant and potentially harmful levels of hazardous constituents (i.e., those contained in Appendix VIII of Part 261) to remain in surface impoundment units without subjecting the units to landfill closure, post-closure care, or monitoring requirements.

For example, the previous version of the rule allowed residues from waste that originally exhibited the characteristic of extraction procedure (EP) toxicity to remain in place at "clean closure" if the residue was no longer EP toxic. This could allow an environmentally significant quantity of hazardous constituents to remain at a facility site that will receive no further monitoring or management. While EP toxic criterion would preclude only a concentration that exceeds 100 times the drinking water standard, constituents may remain at levels significantly above the drinking water standards. If such constituents are close to the saturated zone, they may contaminate ground water at levels exceeding the ground-water protection standard. Furthermore, the waste residues may contain significant and potentially harmful levels of other hazardous constituents (listed in Appendix VIII of Part 261) that are not found through EP testing. Hence, the language "or demonstrate what remains is no longer a hazardous waste" has been dropped from the interim status regulations because it is inconsistent with the overall closure performance standard requiring units to close in a manner that eliminates or minimizes the post-closure escape of Appendix VIII constituents.

Making this conforming change ensures that no Appendix VIII constituent presents any threat to human health and the environment. This is also consistent with several of the new requirements added by the Hazardous and Solid Waste Amendments of 1984. For example, new section 3004(u) of PCRA requires corrective action for releases not only of hazardous wastes, but also hazardous constituents. Similarly, section 3001(f) requires the Agency to consider, when evaluating waste delisting petitions, all hazardous constituents found in the waste, not just those for which the waste was listed as hazardous. Finally, new section 3005(i) requires owners and operators of landfills, surface impoundments, waste piles, or land treatment units that qualify for interim status and receive waste after July 26, 1982, to meet the ground-water monitoring and corrective action standards found in Subpart F to 40 CFR Part 264. These regulations also require owners and operators to monitor and clean up the full range of Appendix VIII constituents found in a waste.

The question has also arisen during the implementation of previous closures by removal whether § 265.228 requires consideration of potential ground-water contamination in addition to soil contamination. The answer to this question is yes. The closure by removal requirements in § 265.228 (a)(1) and (b) require removal or decontamination (i.e. flushing, pumping/treating the aquifer) of "underlying and surrounding contaminated soils." Since contamination of both saturated and unsaturated soils may threaten human health or the environment, the Agency interprets the term "soil" broadly to include both unsaturated soils and soils containing ground water. Thus the closure by removal standard requires consideration of both saturated and unsaturated soils. Uncontaminated ground water is, therefore, a requirement for "clean closure" under Part 265 (and Part

264) as revised today as well as under the previous regulation.

The one comment received on the proposed § 265.228 surface impoundment closure and post-closure care requirements for "clean closure" argued that clay liners should be allowed to remain in place at closure even if they are contaminated because their excavation is expensive and hazardous to workers removing the waste. EPA disagrees. While excavation may be expensive, the additional cost of removing the liner will usually be small in comparison to the cost of removing the waste. Therefore, if an owner or operator is willing to expend the resources to remove the waste, it is not unduly burdensome to go one step further and remove the liner. This burden is justified by the benefit of removing contamination from the impoundment. (See discussion below.) If extensive excavation is needed, thereby considerably increasing the cost of removal, it is generally because extensive contamination of the clay and underlying soils has occurred. In these cases, it may be cheaper to install a proper final cover and perform post-closure care rather than remove the contamination. In addition, we do not believe that removal of the liner will be any more hazardous to workers than is the removal of the waste. With proper safety procedures, removal of the waste and liner should not pose an undue hazard to workers.

EPA's Interpretation of the "Remove or Decontaminate" Standard

The sole commenter on the proposed rule also suggested that, in addition to the case where all wastes, residues, and contaminated liners and soils are removed, no final cover should be required where the type and quantity of waste in the liner can be shown to pose no public health or environmental threat. This comment touches upon an issue that has arisen in other contexts, that is: What is the necessary extent of removal or decontamination of wastes, waste residues, contaminated liners, and soils (including contaminated ground water) to avoid the landfill closure and post-closure care requirements under both Parts 264 and 265 regulations? The issue concerning how much removal or decontamination of wastes and waste residues is necessary to protect human health and the environment is relevant in a broad range of regulatory contexts currently being examined by the Agency including closure and corrective actions under RCRA and response actions under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) programs.

The removal and decontamination issue arises directly from differences in regulatory strategy between disposal and storage. A storage unit holds wastes temporarily, and the wastes are eventually removed for treatment or disposal elsewhere. The goal at closure is to leave no materials at the storage site that require further care. In contrast, a disposal unit, by definition, is closed with wastes and residues remaining at the site. The goal at closure is to assure that these remaining wastes and residues are managed in a manner that protects human health and the environment. There is no need for post-closure oversight of storage units since all potentially harmful wastes and contaminated materials are removed. This is not true for disposal units; hence, the Agency has promulgated regulations requiring post-closure care for disposal units. (For further discussions on a proposed alternative closure option, see the preamble to proposed §§ 264.310 and 265.310 elsewhere in today's Federal Register).

To assist the reader, we describe below EPA's interpretation of the "remove and decontaminate" language in §§ 264.228 and 265.228, i.e. we describe the amount of removal or decontamination that obviates the need for post-closure care for both interim status and permitted surface impoundment units. With regard to storage units regulated under both Parts 264 and 265, the Agency interprets the terms "remove" and "decontaminate" to mean removal of all wastes and liners, and the removal of leachate and materials contaminated with the waste or leachate (including ground water) that pose a substantial present or potential threat to human health or the environment. The Agency recognizes that at certain sites limited quantities of hazardous constituents might remain in the subsoil and yet present only insignificant risks to human health and the environment. Because regulations for storage facilities require no further post-closure care, the Agency must be certain that no hazardous constituents remain that could harm human health or the environment (now or in the future). To provide the necessary level of assurance, the Agency will require owners or operators to remove all wastes and contaminated liners and to demonstrate that any hazardous constituents left in the subsoils will not cause unacceptable risks to human health or the environment. The Agency will review site-specific demonstrations submitted by facility owners and operators that document that enough removal and decontamination has occurred so that no further action is necessary. Owners or operators wishing to avail themselves of the site-specific removal option must include in their closure plans specific details of how they expect to make the demonstration, including sampling protocols, schedules, and the exposure level that is intended to be used as a standard for assessing whether removal or decontamination is achieved (see discussion below). The Agency is presently developing a guidance document explaining the technical requirements for achieving a "clean closure". This guidance document should be available in draft form by January 1987. In the meantime, the following discussion presents the framework for the demonstration procedure.

The closure demonstrations submitted by facility owners and operators must document that the contaminants left in the subsoils will not impact any environmental media including ground water, surface water, or the atmosphere in excess of Agency-recommended limits or factors, and that direct contact through dermal exposure, inhalation, or ingestion will not result in a threat to human health or the environment. Agency recommended limits or factors are those that have undergone peer review by the Agency. At the present time these include water quality standards and criteria (Ambient Water Quality Criteria 45 FR 79318, November 28, 1980; 49 FR 5831, February 15, 1984; 50 FR 30784, July 29, 1985), health-based limits based on verified reference doses (RfDs) developed by the Agency's Risk Assessment Forum (Verified Reference Doses of USEPA, ECAO-CIN-475, January 1986) and Carcinogenic Potency Factors (CPF) developed by the Agency's Carcinogen Assessment Group (Table 9-11, Health Assessment Document for Tetrachloroethylene (Perchloroethylene) USEPA, OHEA/600/8-82/005F, July 1985) to be used to determine exposure at a given risk, or site-specific Agency-approved public health advisories issued by the Agency for Toxic Substance and Disease Registry of the Center for Disease Control, Department of Health and Human Services.

The Agency is currently compiling toxicity information on many of the hazardous constituents contained in Appendix VIII to Part 261. The facility owner and operators should check with the Office of Solid Waste, Characterization and Assessment Division, Technical Assessment Branch (202) 382-4761 for the latest toxicity information. However, for some hazardous constituents, formally recommended exposure limits do not yet exist. If no

Agency recommended exposure limits exist for a hazardous constituent then the owner or operator must either remove the constituent down to background levels, submit data of sufficient quality for the Agency to determine the environmental and health effects of the constituent, or follow landfill closure and post-closure requirements. Data submitted by the owner or operator on environmental and health effects of a constituent should, when possible, follow the toxicity testing guidelines of 40 CFR Parts 797 and 798 (50 FR 39252, September 27, 1985). The Agency does not believe there are many situations where developing exposure levels will be a realistic option for owners and operators because the testing required by 40 CFR Parts 797 and 798 to produce reliable toxicity estimates is expensive and time-consuming.

The Agency believes it is necessary to present policy on the appropriate point of exposure for the various pathways of exposure in order to provide some national consistency in dealing with the potential impacts of the release of hazardous constituents from closing units. The following point of exposure was chosen because the Agency believes it represents a realistic and at the same time reasonably conservative estimate of where either environmental or human receptors could be exposed to the contaminants released from the unit. For the purpose of making a closure by removal demonstration, the potential point of exposure to hazardous waste constituents is assumed to be directly at or within the unit boundary for all routes of exposure (surface-water contact, ground-water ingestion, inhalation, and direct contact). Potential exposure at or within the unit boundary must be assumed because no further oversight or monitoring of the unit is required if the unit is closed by removal. (Recall that the land overlying a unit that closes by removal may be transferred and developed freely without giving notice of its prior use.) Therefore, no attenuation of the hazardous waste constituents leaching from the waste residues can be presumed to occur before the constituents reach exposure points.

This approach differs from the existing "delisting procedure" developed in response to the requirements of §§ 261.3 (c) and (d), 260.20, and 260.22. As discussed previously, the "clean closure" approach is based on the premise that, after closure by removal is satisfied, no further management control over the waste (or unit) is necessary. In contrast, delisted solid waste remains subject to the regulatory controls promulgated by the Agency under Subtitle D of RCRA. Subtitle D contains performance criteria for the management of non-hazardous waste. Although the Agency is currently assessing whether more specific Federal regulatory requirements are needed for waste management under Subtitle D, most states have already adopted specific regulatory requirements for Subtitle D waste management. Therefore, even though a waste may be delisted its management continues to be controlled. In contrast, closure by removal will not be followed by any regulatory controls; hence, an environmentally conservative approach is needed to assure no further risk to human health and the environment. Therefore, unlike the current "delisting procedure" that is based on a generic process that only considers the ground-water route of exposure, the demonstration procedure discussed here is waste-specific and site-specific, considers all potential exposure pathways, and assumes no attenuation.

The demonstration should be conservative in the sense that it eliminates the uncertainties associated with contaminant fate and transport, focusing on the waste contaminant levels and contaminant characteristics. Therefore, arguments relying on fate and transport calculations will not be accepted. The Agency is pursuing this relatively conservative approach at this time because we are confident that it will be protective of human health and the environment. After a few years of experience with "clean closure" demonstrations, the Agency may decide that a less stringent approach is sufficiently reliable to assure that closures based on such analyses are fully protective of human health and the environment. At that time, the Agency may change its position on the use of fate and transport arguments for "clean closure" demonstrations. (Elsewhere in today's Federal Register, the Agency is proposing a third closure option that would incorporate fate and transport factors. However, unlike the closure by removal option, that option would require closure to be followed by verification monitoring to verify the fate and transport predictions and assume that the closure protects human health and the environment.)

To make the demonstration with respect to the direct contact pathway, owners or operators must demonstrate that contaminant levels in soil are less than levels established by the Agency as acceptable for ingestion or dermal contact. Total waste constituent levels in soil should be used for this analysis. Arguments based on exposure control measures such as fencing or capping will not be acceptable since the long-term future use of the property cannot be reliably controlled and hence the long-term effectiveness of these measures is uncertain.

To make the demonstration with respect to the ground-water pathway, owners or operators must remove enough contaminated soil and saturated subsoils (i.e., ground water) to demonstrate that constituent levels in ground water do not exceed Agency-established chronic health levels (based on Rfd or CPF values) and that residual contaminant levels remaining in the soil will not contribute to any future contamination of ground water. (Note: this demonstration may in some cases require constituent-specific ground water data beyond that required by §§ 265.90 through 2165.100). The demonstration related to residual soil contamination levels must show that levels of constituents found in leachate from the residual soil contamination are not above Agency-established exposure levels. Levels of constituents in leachate may be estimated based on known characteristics of the waste constituents (e.g., solubility and partitioning coefficients) or determined by the results of actual soil leaching tests. The Agency is exploring the appropriateness of using the extraction procedures (but not the acceptable contaminant levels) found in the Toxicity Characteristics Leaching Procedure (TCLP), Federal Register of January 14, 1985 (51 FR 1690). The current EP Toxicity leaching procedure is insufficient for this demonstration because it does not capture the organic constituents in the waste.

The analysis of potential air exposures should assess contaminants migrating from the soils into the atmosphere. The demonstration should include emission calculations, available monitoring data, and safe inhalation levels based on Agency-established exposure levels.

The potential surface water exposure analysis should compare Agency-established water quality standards and criteria (45 FR 79318, November 28, 1980) with the levels of constituents that may leach from the residual contaminated soil. Tests described previously should be used to estimate the level of constituents in the leachate. The surface water exposure analysis should also consider existing surface water contaminant concentrations.

IV. State Authority

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified States to administer and enforce the RCRA program within the State. (See 40 CFR Part 271 for the standards and requirements for authorization.) Following authorization, the Agency retains enforcement authority under sections 3008, 7003 and 3013 of RCRA, although authorized States have primary enforcement responsibility.

Prior to the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final authorization administered its hazardous waste program entirely in lieu of the Federal program. The Federal requirements no longer applied in the authorized State, and the Agency could not issue permits for any facilities in a State where the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obligated to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under section 3006(g) of RCRA, *42 U.S.C. 6926*(g), new requirements and prohibitions imposed by HSWA take effect in authorized States at the same time that they take effect in nonauthorized States. The Agency is directed to carry out those requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

B. Effect on State Authorization

Today's rule promulgates standards that are not effective in authorized States since the requirements are not being imposed pursuant to Hazardous and Solid Waste Amendments of 1984. Thus, the requirements will be applicable only in those States that do not have final authorization. In authorized States, the requirements will not be applicable until the State revises its program to adopt equivalent requirements under State law.

40 CFR 271.21(e)(2) requires that States that have final authorization must modify their programs to reflect Federal program changes and must subsequently submit the modification to EPA for approval. The deadline by which the State must modify its program to adopt today's rule is July 1988. These deadlines can be extended in exceptional cases (40 CFR 271.21(e)(3)). Once EPA approves the revision, the State requirements become Subtitle C RCRA requirements.

States with authorized RCRA programs may already have requirements similar to those in today's rule. These State requirements have not been assessed against the Federal regulations being promulgated today to determine whether they meet the tests for authorization. Thus, a State is not authorized to carry out these requirements in lieu of the Agency until the State requirements are approved. Of course, States with existing standards may continue to administer and enforce their standards as a matter of State law.

States that submit official applications for final authorization less than

12 months after the effective date of these standards are not required to include standards equivalent to these standards in their application. However, the State must modify its program by the deadlines set forth in § 271.21(e). States that submit official applications for final authorization 12 months after the effective date of those standards must include standards equivalent to these standards in their application. 40 CFR 271.3 sets forth the requirements a State must meet when submitting its final authorization application.

V. Effective Date

Pursuant to section 3010(b) of RCRA, today's amendments will be effective six months after promulgation.

VI. Regulatory Impact

Under Executive Order 12291, the Agency must judge whether a regulation is "major" and, therefore, subject to the requirement of a Regulatory Impact Analysis. As stated in the proposed rule on July 26, 1982, the Agency does not believe these conforming changes will result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or in domestic or export markets. In addition, the Part 265 conforming changes do not impose any requirements beyond those required for permitting facilities under Part 264. Therefore, the Agency believes that today's rule is not a major rule under Executive Order 12291.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

VII. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, *(5 U.S.C. 601* et seq.), the Agency must prepare a regulatory flexibility analysis for all regulations that may have a significant impact on a substantial number of small entities. The Agency conducted such an analysis on the land disposal regulations and published a summary of the results in the Federal Register, Vol. 48, No. 15 on January 21, 1983. Today's conforming regulation does not impose significant additional burdens. In addition, they do not impose any requirements beyond those required for permitting facilities under Part 264.

VIII. Paperwork Reduction Act

The certification requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, *44 U.S.C. 3501* et seq. and have been assigned OMB control number 2050-0008.

List of Subjects in 40 CFR Part 265

Hazardous materials, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Waste treatment and disposal, Water supply.

Dated: March 8, 1987.

Lee M. Thomas,

Administrator.

For the reasons set out in the preamble, Part 265, Subpart K of Title 40 of the Code of Federal Regulations is amended as follows:

PART 265 -- INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

1. The authority citation for Part 265 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3004, and 3005 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended *(42 U.S.C. 6905,* 6912(a), 6924, and 6925).

2. In 40 CFR Part 265, Subpart K, § 265.228 is revised to read as follows:

§ 265.228 Closure and post-closure care.

(a) At closure, the owner or operator must:

(1) Remove or decontaminate all waste residues, contaminated containment system components (liners, etc.), contaminated subsoils, and structures and equipment contaminated with waste and leachate, and manage them as hazardous waste unless § 261.3(d) of this chapter applies; or

(2) Close the impoundment and provide post-closure care for a landfill under Subpart G and § 265.310, including the following:

(i) Eliminate free liquids by removing liquid wastes or solidifying the remaining wastes and waste residues;

(ii) Stabilize remaining wastes to a bearing capacity sufficient to support the final cover; and

(iii) Cover the surface impoundment with a final cover designed and constructed to:

(A) Provide long-term minimization of the migration of liquids through the closed impoundment;

(B) Function with minimum maintenance;

(C) Promote drainage and minimize erosion or abrasion of the cover;

(D) Accommodate settling and subsidence so that the cover's integrity is maintained; and

(E) Have a permeability less than or equal to the permeability of any bottom liner system or natural subsoils present.

(b) In addition to the requirements of Subpart G, and § 265.310, during the post-closure care period, the owner or operator of a surface impoundment in which wastes, waste residues, or contaminated materials remain after closure in accordance with the provisions of paragraph (a)(2) of this section must:

(1) Maintain the integrity and effectiveness of the final cover, including making repairs to the cover as necessary to correct the effects of settling, subsidence, erosion, or other events;

(2) Maintain and monitor the ground-water monitoring system and comply with all other applicable requirements of Subpart F of this part; and

(3) Prevent run-on and run-off from eroding or otherwise damaging the final cover.

[FR Doc. 87-5575 Filed 3-18-87; 8:45 am]

BILLING CODE 6560-50-M

“Risk-Based Clean Closure”
Cotsworth, Elizabeth (1998)

MEMORANDUM – Dated March 16, 1998

SUBJECT: Risk-Based Clean Closure

FROM: Elizabeth Cotsworth, Acting Director */signed/*
Office of Solid Waste

TO: RCRA Senior Policy Advisors
Regions I - X

The purpose of this memorandum is to provide guidance on risk-based clean closure and to confirm that, under current regulations, RCRA regulated units may be clean closed to protective, risk-based media cleanup levels.

Closure Requirements and Regulations

Closure is the term used to describe taking a RCRA regulated unit out of service. During closure, facility owners/operators must comply with the closure performance standard at 40 CFR 264.111 or 40 CFR 265.111. According to 40 CFR 264.111 and 40 CFR 265.111, closure must be completed in a manner that: (a) minimizes that need for further maintenance; (b) controls, minimizes or eliminates, to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to ground or surface waters or to the atmosphere; and, (c) complies with the unit-specific closure requirements of 40 CFR Part 264 or 265. Generally, two types of closure are allowed - closure by removal or decontamination (referred to here as "clean closure") and closure with waste in place.[1]

The premise of clean closure is that all hazardous wastes have been removed from a given RCRA regulated unit and any releases at or from the unit have been remediated so that further regulatory control under RCRA Subtitle C is not necessary to protect human health and the environment. As part of meeting the closure performance standard referenced above, for clean closure, facility owners/operators must remove all wastes from the closing unit and remove or decontaminate all waste residues, contaminated containment system components, contaminated soils (including ground water and any other environmental media contaminated by releases from the closing unit), and structures and equipment contaminated with hazardous waste and hazardous waste leachate. (See, for example, 40 CFR Sections 264.178, 264.197, 264.228, 264.258 and 264.575 and corresponding interim status closure standards in 40 CFR Part 265.)

EPA's expectation is that, with the exception of landfills and most land treatment units, well designed and well operated RCRA units (*i.e.,* units that comply with the unit-specific minimum

[1] On November 8, 1994 EPA requested comment on an approach that would reduce or eliminate the regulatory distinction between cleanup of releases from closed or closing regulated units and cleanup of releases from non-regulated units under the RCRA corrective action program. 59 FR 55778. If promulgated, this approach would essentially create a third type of closure by allowing some closing units to take advantage of the additional flexibility provided by the corrective action program. The Office of Solid Waste plans to address this issue further in the final post-closure rule.

technical requirements) will generally be clean closed. Units that are not clean closed remain subject to the requirements for post-closure care, including post-closure permitting.

Reaffirming Risk-Based Clean Closure Standards

Since 1987, EPA has interpreted the regulations governing closure by removal and the term "remove or decontaminate" to require complete removal of all hazardous waste and liners and removal or decontamination of leachate and other materials contaminated with hazardous waste or hazardous constituents to the extent necessary to protect human health and the environment. (52 FR 8704, March 19, 1987.) As the Agency explained in the 1987 notice, this interpretation means that, except for hazardous waste and liners, for clean closure, the regulations do not require one to completely remove all contamination, *i.e.,* to background, at or from a closing unit. Rather, some limited quantity of hazardous constituents might remain in environmental media after clean closure provided they are at concentrations below levels that may pose a risk to human health and the environment. In the 1987 notice, EPA took the position that the amount of hazardous constituents that might remain in environmental media after clean closure should be identified through appropriate application of risk information either by using available constituent-specific limits or factors that had undergone Agency review (*e.g.,* MCLs or health-based limits calculated using a verified reference dose), or, when such limits or factors were not available, by using toxicity information submitted by a facility owner/operator and approved by EPA, or by using background concentrations.

EPA continues to interpret the regulations governing closure by removal and the "remove or decontaminate" standard as described above. In addition, EPA today is providing additional guidance on identifying the amount of hazardous constituents that might remain in environmental media after clean closure.

Since the 1987 notice, EPA and the states have gained considerable experience in making protective, risk-based cleanup decisions under the RCRA corrective action and CERCLA cleanup programs. EPA's position is that the procedures and guidance generally used to develop protective, risk-based media cleanup standards for the RCRA corrective action and CERCLA cleanup programs are also appropriate to define the amount of hazardous constituents that may remain in environmental media after clean closure. In other words, site-specific, risk-based media cleanup levels developed under the RCRA corrective action and CERCLA cleanup programs are appropriate levels at which to define clean closure.

EPA has published numerous documents offering guidance on developing site-specific, risk-based media cleanup levels. As discussed in the May 1, 1996 Advance Notice of Proposed Rulemaking for RCRA corrective action, EPA's goal continues to be to clean up sites in a manner consistent with established, protective, risk-based media cleanup levels (*e.g.,* MCLs and many state cleanup standards) or, when such levels do not exist to clean up to protective, risk-based media cleanup levels developed for the site in question (*e.g.,* through a site-specific risk assessment). Both approaches require a site-specific risk-based decision since established media cleanup levels are appropriate only when all exposure assumptions are consistent with site-specific conditions at the facility in question.

EPA generally considers protective media cleanup standards for human health to mean constituent concentrations that result in the total residual risk from any medium to an individual exposed over a lifetime falling within a range from 10^{-4} to 10^{-6}, with the cumulative carcinogenic risk not to exceed 10^{-4} and a preference for cleanup standards at the more protective end of the risk range. For non-carcinogenic effects, EPA generally interprets protective cleanup standards to mean constituent concentrations that an individual could be exposed to on a daily basis without appreciable risk of deleterious effect during a lifetime; the hazard index generally should not exceed one (1). See, *e.g.,* the National Contingency Plan (55 FR 8666, March 8, 1990) the 1990 Subpart S Proposal (55 FR 30798, July 27, 1990), and the 1996 Subpart S ANPR (61 FR 19432, May 1, 1196). Cleanup to standards that are consistent with these risk-reduction goals (*e.g.,* most Federally promulgated standards such as MCLs and many state cleanup standards) will generally be adequate to satisfy the closure performance standard and the "remove or decontaminate" standard.

In the March 19, 1987 notice, EPA also interpreted the regulations governing closure by removal and the "remove or decontaminate" standard to require consideration of the possibility of cross-media contamination so that, for example, facility owners/operators would have to show that remaining levels of hazardous constituents in soil would not migrate from the soil to air, surface, or ground water in excess of Agency-approved concentrations. EPA reaffirms that interpretation today. In addition, although not emphasized in the 1987 notice, EPA reminds program implementors and facility owners/operators that closures must protect both human health and the environment. During clean closure, ecological concerns may sometimes require more aggressive decontamination than might be necessary strictly to protect human health.

Clarification of Acceptability of Fate and Transport Modeling

In the 1987 Notice, EPA required that demonstrations of compliance with the regulations governing closure by removal and the "remove or decontaminate" standard be conservative in the sense that they eliminate the uncertainties associated with contaminant fate and transport. (50 FR 8707, March 19, 1987.) EPA recently revised its interpretation of the "remove or decontaminate" standard in a memo from Elliott Laws and Steven Herman to RCRA/CERCLA National Policy Managers (September 24, 1996) to allow limited use of fate and transport modeling during closure. This revision was based on the experience EPA has gained using fate and transport modeling since 1987. Under the new Agency interpretation, fate and transport models may be used to support clean closure determinations by modeling the potential for residual contamination in one medium to migrate to and contaminate other media. For example, under the new interpretation, fate and transport modeling might be used to model the potential for residual contamination in soil to migrate to and contaminate ground water.

Some individuals were confused by EPA's new interpretation. The Agency takes this opportunity to clarify that, when supporting demonstrations of compliance with the "remove or decontaminate" standard, fate and transport modeling is appropriate only for modeling the potential for residual contamination (not waste) to migrate from one medium to another. EPA continues to interpret the closure regulations and the remove or decontaminate standard to require removal of all hazardous waste and liners. As discussed earlier in this memo, following removal of all hazardous waste and liners, media throughout a closing unit and any areas affected by releases from the closing unit must be decontaminated. Decontamination levels must protect human health and the environment and must ensure that remaining levels of hazardous constituents in soil will not migrate from soil and contaminate air, surface, or ground water in excess of Agency-approved concentrations. It is only when identifying the appropriate level of decontamination, by, in part, considering the potential for cross media transfer, that fate and transport modeling may be used.

New Interpretation Regarding Non-Residential Exposure Assumptions

In an effort to promote redevelopment of industrial properties, many states have recently developed programs which allow them to consider reasonably expected future land use during cleanups and, in certain situations, apply non-residential exposure assumptions to development of cleanup standards. These programs primarily provide for continued maintenance of non-residential land use and any necessary additional cleanup should land use change through institutional controls such as deed restrictions.[2] EPA did not explicitly consider these types of programs when interpreting the closure regulations and the remove or decontaminate standard in the March 1987 notice.

EPA now interprets current closure regulations to allow appropriate use of non-residential exposure assumptions when identifying the amount of decontamination necessary to satisfy the "remove or decontaminate" standard. Using non-residential exposure assumptions to identify the amount of decontamination necessary to satisfy the "remove or decontaminate" standard does not affect any other closure requirement. This means, for clean closure, facility owners/operators must still remove all hazardous wastes and liners. In addition, just like for any other clean closure, a decontamination level based on non-residential exposure assumptions must be achieved throughout the closing unit and any areas affected by releases from the closing unit. It also must ensure that environmental receptors are adequately protected and that no unacceptable transfer of contamination from one medium to another (*e.g.,* soil to ground water) will occur. Issues associated with protecting environmental receptors and preventing unacceptable cross-media transfer may prohibit approval of clean closure based on non-residential exposure assumptions when such closure might otherwise be appropriate. Moreover, although some additional increment of contamination may be allowed to remain in media through application of non-residential exposure assumptions, as during any other clean closure, owners and operators may not rely on physical barriers (such as fences or slurry walls) to ensure protection of human health and the environment. When a facility is also undergoing RCRA corrective action or another type of site-wide cleanup, non-residential exposure assumptions used during clean closure must be consistent with the exposure assumptions being applied in the corrective action (or other) cleanup.

The Agency emphasizes that non-residential exposure assumptions should not be used unless there is a reasonable degree of confidence that future land use will conform to those assumptions. EPA believes this confidence would typically be based on the existence of long-term controls over land use. For example, in some cases, a local authority may have imposed zoning restrictions. In other cases a land owner may have agreed to convey an easement to another party and the easement may impose limits on how the land owner can use the property. When non-residential exposure assumptions are used, the area covered by the non-residential land use assumptions should be clearly delineated and procedures established to alert future users to the presence of contamination and risks presented and to provide for periodic evaluations of actual land use. EPA is currently developing additional guidance on land use controls and restrictions. When completed, this guidance may be used to implement the policies in this memorandum.

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2 Some states are also developing systems for ground water classification using the comprehensive state ground water protective plan (CSGWPP) process.

Program implementors and facility owners/operators should be careful to distinguish clean closures based on non-residential exposure assumptions from other clean closures, by, for example, referring to them as "non-residential clean closure"or "closure by removal and decontamination based-on non-residential exposure assumptions." Care should especially be taken to ensure that the public is aware of the exposure assumptions which are being applied and the associated land use restrictions which must be maintained in order for the assumptions to remain valid. At a minimum this information should be clearly included in public notices of tentative closure decisions. EPA's current guidance on incorporating considerations of reasonably anticipated future land use in remedial decision making is entitled, "Land Use in the CERCLA Remedy Selection Process" (OSWER Direction No. 9355.7-04, May 25, 1995).

All but a few states are currently authorized to implement the RCRA closure requirements in lieu of EPA; therefore, implementation of this policy will largely be at the discretion of state RCRA program managers. EPA does not view this change in policy to allow appropriate use of non-residential exposure assumptions during clean closures as requiring re-authorization, or re-evaluation, of authorized state programs. If EPA were asked to evaluate an individual clean closure decision made using non-residential exposure assumptions, the Agency would likely consider factors such as: the methods used to identify the reasonably expected future land use; the amount of community involvement in the land use decision; the probability that the covered property will be actively used (as opposed to abandoned) ; the enforceability of a land use control (with more weight given to programs that have a mechanism in place to review and ensure continued validity of non-residential exposure assumptions); the specific non-residential exposure assumptions which are applied; the potential for trespassers, especially children; and, the range of circumstances under which a state could compel further cleanup if land use were to change.

EPA notes that in situations where, because of a change in land use, additional cleanup is needed after clean closure, EPA would retain authority to take action, under appropriate circumstances, using RCRA Section 7003, CERCLA Section 106, and other authorities. In addition, of course, until clean closed facilities undergo final administrative disposition of a RCRA permit application (*i.e.,* through permit issuance or permit denial) they would remain subject to corrective action under RCRA Section 3008(h).

Additional Information

Reliance on risk-based approaches during clean closure will complement EPA's other ongoing efforts to encourage coordination of cleanup requirements and eliminate duplication of effort. Guidance on coordination of RCRA closure requirements with other cleanup activities was provided in the September 26, 1996 memo on RCRA/CERCLA integration, referenced above.

I encourage you to use risk-based approaches to develop site-specific clean closure requirements and to continue in your efforts to eliminate duplication of effort among cleanup programs. For additional information please contact Elizabeth McManus, of my staff, on (703) 308-8657.

cc: CERCLA Senior Policy Advisors
Barry Breen, Office of Site Remediation Enforcement
Eric Schaeffer, Office of Regulatory Enforcement
Barb Simcoe, Association of State and Territorial Solid Waste Management Officials

“Coordination between RCRA Corrective Action and Closure and CERCLA Site Activities”

Herman, Steven A. (1996)

MEMORANDUM – Dated September 24, 1996

SUBJECT: Coordination Between RCRA Corrective Action and Closure and CERCLA Site Activities

FROM: Steven A. Herman, Assistant Administrator
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

Elliott P. Laws, Assistant Administrator
Office of Solid Waste and Emergency Response
United States Environmental Protection Agency

TO: RCRA/CERCLA National Policy Managers
Regions I-X Agency

Good RCRA/CERCLA coordination has become increasingly important as our offices have reorganized and programs have assumed new organizational relationships. We believe that, in general, coordination of site cleanup activities among EPA RCRA, EPA CERCLA and state/tribal cleanup programs has improved greatly; however, we are aware of examples of some remaining coordination difficulties. In this memo, we discuss three areas: acceptance of decisions made by other remedial programs; deferral of activities and coordination among EPA RCRA, EPA CERCLA and state/tribal cleanup programs; and coordination of the specific standards and administrative requirements for closure of RCRA regulated units with other cleanup activities. We also announce a revision to the Agency's policy on the use of fate and transport calculations to meet the "clean closure" performance standard under RCRA. We hope the guidance offered here will assist in your continuing efforts to eliminate duplication of effort, streamline cleanup processes, and build effective relationships with the states and tribes.

This memorandum focuses on coordination between CERCLA and RCRA cleanup programs; however, we believe the approaches outlined here are also applicable to coordination between either of these programs and certain state or tribal cleanup programs that meet appropriate criteria. For example, over half of the states have "Superfund-like" authorities. In some cases, these state authorities are substantially equivalent in scope and effect to the federal CERCLA program and to the state or federal RCRA corrective action program. In accordance with the 1984 Indian Policy, EPA recognizes tribes as sovereign nations, and will work with them on a government-to-government basis when coordination cleanup efforts on lands under tribal jurisdiction.

In addition to the guidance provided in this memorandum, two other on-going initiatives address coordination of RCRA and CERCLA. First, EPA is currently coordinating an interagency and state "Lead Regulator Workgroup." This workgroup intends to provide guidance where overlapping cleanup authorities apply at federal facilities that identifies options for coordinating oversight and deferring cleanup from one program to another. We intend for today's memorandum and the pending guidance from the Lead Regulator Workgroup to work in concert to improve RCRA/CERCLA integration and coordination. Second, EPA has also requested comment on RCRA/CERCLA integration issues in the May 1, 1996 Advanced Notice of Proposed Rulemaking--Corrective Action for Releases From Solid Waste Management Units at

Hazardous Waste Management Facilities (61 FR 19432; commonly referred to as the RCRA "Subpart S" ANPR). We intend to coordinate all of these efforts as we develop further policy on integration issues.

Acceptance of Decisions Made by Other Remedial Programs

Generally, cleanups under RCRA corrective action or CERCLA will substantively satisfy the requirements of both programs.[1] We believe that, in most situations, EPA RCRA and CERCLA site managers can defer cleanup activities for all or part of a site from one program to another with the expectation that no further cleanup will be required under the deferring program. For example, when investigations or studies have been completed under one program, there should be no need to review or repeat those investigations or studies under another program. Similarly, a remedy that is acceptable under one program should be presumed to meet the standards of the other.

It has been our experience that, given the level of site-specific decision-making required for cleaning up sites, differences among the implementation approaches of the various remedial programs primarily reflect differences in professional judgement rather than structural inconsistencies in the programs themselves. Where there are differences in approaches among remedial programs, but not in their fundamental purposes or objectives (*e.g.,* differences in analytical QA/QC procedures), these differences should not necessarily prevent deferral. We encourage program implementers to focus on whether the end results of the remedial activities are substantively similar when making deferral decisions and to make every effort to resolve differences in professional judgement to avoid imposing two regulatory programs.

We are committed to the principle of parity between the RCRA corrective action and CERCLA programs and to the idea that the program should yield similar remedies in similar circumstances. To further this goal, we have developed and continue to develop a number of joint (RCRA/CERCLA) guidance documents. For example, the several "Presumptive Remedies," which are preferred technologies for common categories of sites, and the Guidance for Evaluating the Technical Impracticability of Groundwater Restoration (OSWER Directive 9234.2-25, September 1993), which recognizes the impracticability of achieving groundwater restoration at certain sites, are applicable to both RCRA and CERCLA cleanups. For more information on the concept of parity between the RCRA and CERCLA program see: 54 FR 41000, esp. 41006-41009 (October 4, 1989), RCRA deferral policy; 54 FR 10520 (March 13, 1989), National Priorities List for Uncontrolled Hazardous Waste Sites Listing Policy for Federal Facilities; 55 FR, 30798, esp. 30852-30853 (July 27, 1990), Proposed Rule for Corrective Action for Solid Waste Management Units at Hazardous Waste Management Facilities; 60 FR 14641 (March 20, 1995), Deletion Policy for RCRA Facilities; and, 61 FR 19432 (May 1, 1996), Corrective Action for Releases From Solid Waste Management Units at Hazardous Waste Management Facilities, Advanced Notice of Proposed Rulemaking.

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1 In a few, limited cases, program differences may be sufficiently great to prevent deferral to the other program (*e.g.,* the inability of CERCLA to address petroleum releases or RCRA to address certain radioactive materials). In these instances we encourage remedial programs to coordinate closely with each other to minimize duplication of effort, including oversight.

Program Deferral

The concept of deferral from one program to another is already in general use at EPA. For example, it has long been EPA's policy to defer facilities that may be eligible for inclusion on the National Priorities List (NPL) to the RCRA program if they are subject to RCRA corrective action (unless they fall within certain exceptions, such as federal facilities). Recently, EPA expanded on this policy by issuing criteria for deleting sites that are on the NPL and deferring their cleanup to RCRA corrective action (attached).[2] When a site is deleted from the NPL and deferred to RCRA, problems of jurisdictional overlap and duplication of effort are eliminated, because the site will be handled solely under RCRA authority. Corrective action permits or orders should address all releases at a CERCLA site being deferred to RCRA; some RCRA permits or orders may need to be modified to address all releases before a site is deleted from the NPL.

While EPA's general policy is for facilities subject to both CERCLA and RCRA to be cleaned up under RCRA, in some cases, it may be more appropriate for the federal CERCLA program or a state/tribal "Superfund-like" cleanup program to take the lead. In these cases, the RCRA permit/order should defer corrective action at all of the facility to CERCLA or a state/tribal cleanup program. For example, where program priorities differ, and a cleanup under CERCLA has already been completed or is underway at a RCRA facility, corrective action conditions in the RCRA permit/order could state that the existence of a CERCLA action makes separate RCRA action unnecessary. In this case, there would be no need for the RCRA program to revisit the remedy at some later point in time. Where the CERCLA program has already selected a remedy, the RCRA permit could cite the CERCLA decision document (*e.g.,* ROD), but would not necessarily have to incorporate that document by reference. RCRA permits/orders can also defer corrective action in a similar way for cleanups undertaken under state/tribal programs provided the state/tribal action protects human health and the environment to a degree at least equivalent to that required under the RCRA program.

Superfund policy on deferral of CERCLA sites for listing on the NPL while states and tribes oversee response actions is detailed in the May 3, 1995 OSWER Directive 9375.6-11 ("Guidance on Deferral of NPL Listing Determinations While States Oversee Response Actions"). The intent of this policy is to accelerate the rate of response actions by encouraging a greater state or tribal role, while maintaining protective cleanups and ensuring full public participation in the decision-making process. Once a deferral response is complete, EPA will remove the site from CERCLIS and will not consider the site for the NPL unless the Agency receives new information of a release or potential release that poses a significant threat to human health or the environment. The state and tribal deferral policy is available for sites not listed on the NPL; deferral of final NPL sites must be addresses under the Agency's deletion policy, as described above.

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[2] Currently, the RCRA deletion policy does not pertain to federal facilities, even if such facilities are also subject to Subtitle C of RCRA. Site Managers are encouraged to use interagency agreements to eliminate duplication of effort at federal facilities; the Lead Regulator Workgroup intends to provide additional guidance on coordinating oversight and deferring cleanup from one program to another at federal facilities.

Coordination Between Programs

While deferral from one program to another is typically the most efficient and desirable way to address overlapping cleanup requirements, in some cases, full deferral will not be appropriate and coordination between programs will be required. The goal of any approach to coordination of remedial requirements should be to avoid duplication of effort (including oversight) and second-guessing of remedial decisions. We encourage you to be creative and focus on the most efficient path to the desired environmental result as you craft strategies for coordination of cleanup requirements under RCRA and CERCLA and between federal and state/tribal cleanup programs.

Several approaches for coordination between programs at facilities subject to both RCRA and CERCLA are currently in use. It is important to note that options for coordination at federal facilities subject to CERCLA §120 may differ from those at non-federal facilities because of certain prescriptive requirements under §120. EPA anticipates issuing further guidance on coordination options specific to federal facilities through the interagency Lead Regulator Workgroup. Current approaches that are in use include:

- *Craft CERCLA or RCRA decision documents so that cleanup responsibilities are divided.* CERCLA and RCRA decision documents do not have to require that the entire facility be cleaned up under one or the other program. For example, at some facilities being cleaned up under CERCLA, the RCRA units (regulated or solid waste) are physically distinct and could be addressed under RCRA. In these cases, the CERCLA decision documents can focus CERCLA activities on certain units or areas, and designate others for action under RCRA. When units or areas are deferred from CERCLA to RCRA, the CERCLA program should include a statement (*e.g.,* in a ROD or memorandum submitted to the administrative record) that successful completion of these activities would eliminate the need for further cleanup under CERCLA at those units and minimal review would be necessary to delete the site from the NPL. Similarly, when units or areas are deferred from RCRA to CERCLA, RCRA permits or orders can reference the CERCLA cleanup process and state that complying with the terms of the CERCLA requirements would satisfy the requirements of RCRA.

- *Establish timing sequences in RCRA and CERCLA decision documents.* RCRA and CERCLA decision documents can establish schedules according to which the requirements for cleanup at all or part of a facility under one authority would be determined only after completion of an action under the other authority. For examples RCRA permits/orders can establish schedules of compliance which allow decisions as to whether corrective action is required to be made after completion of a CERCLA cleanup or a cleanup under a state/tribal authority. After the state or CERCLA response is carried out, there should be no need for further cleanup under RCRA and the RCRA permit/order could simply make that finding. Similarly, CERCLA or state/tribal cleanup program decision documents could delay review of units or areas that are being addressed under RCRA, with the expectation that no additional cleanup will need to be undertaken pending successful completion of the RCRA activities, although CERCLA would have to go through the administrative step of deleting the site from the NPL.

> A disadvantage of this approach is that it contemplates subsequent review of cleanup by the deferring program and creates uncertainty by raising the possibility that a second round of cleanup may be necessary. Therefore, we recommend that program implementers look first to approaches that divide responsibilities, as described above. A timing approach, however, may be most appropriate in certain circumstances, for example, where two different regulatory agencies are involved. Whenever a timing approach is used, the final review by the deferring program will generally be very streamlined. In conducting this review, there should be a strong presumption that the cleanup under the other program is adequate and that reconsidering the remedy should rarely be necessary.

The examples included in this memo demonstrate several possible approaches to deferring action from one cleanup program to another. For example, under RCRA, situations are described where the RCRA corrective action program would make a finding that no action is required under RCRA because the hazard is already being addressed under the CERCLA Program, which EPA believes affords equivalent protection. In other examples, the RCRA program defers not to the CERCLA program *per se*, but either defers to a particular CERCLA ROD or actually incorporates such ROD by reference into a RCRA permit or order. In addition, there are examples where the Agency commits to revisit a deferral decision once the activity to which RCRA action is being deferred is completed; in other situations, reevaluation is not contemplated. As discussed in this memorandum, no single approach is recommended, because the decision of whether to defer action under one program to another and how to structure such a deferral is highly dependent on site-specific and community circumstances. In addition, the type of deferral chosen may raise issues concerning, for example, the type of supporting documentation that should be included in the administrative record for the decision, as well as issues concerning availability and scope of administrative and judicial review.

Agreements on coordination of cleanup programs should be fashioned to prevent revisiting of decisions and should be clearly incorporated and cross-referenced into existing or new agreements, permits or orders. We recognize that this up-front coordination requires significant resources. Our expectation is that, over the long-term, duplicative Agency oversight will be reduced and cleanup efficiency will be enhanced.

RCRA Closure and Post-Closure

Some of the most significant RCRA/CERCLA integration issues are associated with coordination of requirements for closure of RCRA regulated units[3] with other cleanup activities. Currently, there are regulatory distinctions between requirements for closure of RCRA regulated units and other cleanup requirements (*e.g.,* RCRA corrective action requirements). RCRA regulated units are subject to specific standards for operation, characterization of releases, groundwater corrective action and closure. Coordination of these standards with other remedial activities can be challenging. In the November 8, 1994 proposed Post-Closure Rule (59 FR 55778), EPA requested comment on an approach that would reduce or eliminate the regulatory

3 In this document the term "regulated unit" refers to any surface impoundment, waste pile, land treatment unit or landfill that receives (or has received) hazardous waste after July 26, 1982 or that certified closure after January 26, 1983.

distinction between cleanup of releases from closed or closing regulated units and cleanup of non-regulated unit releases under RCRA corrective action. The Office of Solid Waste will address this issue further in the final Post-Closure and Subpart S rules.

At the present time, however, the dual regulatory structure for RCRA closure and other cleanup activities remains in place. There are several approaches program implementers can use to reduce inconsistency and duplication of effort when implementing RCRA closure requirements during CERCLA cleanups or RCRA corrective actions. These approaches are analogous to the options discussed above for coordination between cleanup programs. For example, a clean-up plan for a CERCLA operable unit that physically encompasses a RCRA regulated unit could be structured to provide for concurrent compliance with CERCLA and the RCRA closure and post-closure requirements. In this example, the RCRA permit/order could cite the ongoing CERCLA cleanup, and incorporate the CERCLA requirements by reference. RCRA public participation requirements would have to be met for the permit/order to be issued; however, at many sites it may be possible to use a single process to meet this need under RCRA and CERCLA.

At some sites, inconsistent cleanup levels have been applied for removal and decontamination ("clean closure") of regulated units and for site-wide remediation under CERCLA or RCRA corrective action. Where this has happened, clean closure levels have been generally set at background levels while, at the same site, cleanup levels have been at higher, risk-based concentrations. To avoid inconsistency and to better coordinate between different regulatory programs, we encourage you to use risk-based levels when developing clean closure standards. The Agency has previously presented its position on the use of background and risk-based levels as clean closure standards (52 FR 8704-8709, March 19, 1987; attached). This notice states that clean closure levels are to be based on health-based levels approved by the Agency. If no Agency-approved level exists, then background concentrations may be used or a site owner may submit sufficient data on toxicity to allow EPA to determine what the health-based level should be.

EPA continues to believe, as stated in the March 19,1987 notice, that risk-based approaches are protective and appropriate for clean closure determinations. In EPA's view, a regulatory agency could reasonably conclude that a regulated unit was clean closed under RCRA if it was cleaned up under Superfund, RCRA corrective action, or certain state/tribal cleanup programs to the performance standard for clean closure. This performance standard can be met with the use of risk-based levels. RCRA units that did not achieve the closure performance standard under a cleanup would remain subject to RCRA capping and post-closure care requirements.

The 1987 federal register notice described EPA's policy that the use of fate and transport models to establish risk levels would be inappropriate for clean closure detections. This discussion, however, also included the statement that, after additional experience with clean closures, "the Agency may decide that a less stringent approach is sufficiently reliable to assure that closures based on such analyses are fully protective of human health and the environment." After nine years of further experience, EPA believes that, consistent with the use of risk-based standards in its remedial programs, use of fate and transport models to establish risk levels can be appropriate to establish clean closure determinations. EPA today announces that it is changing its 1987 policy on evaluating clean closure under RCRA to allow use of fate and transport models to support clean closure demonstrations. EPA intends to publish this change in the Federal Register in the near future.

We encourage you to consider risk-based approaches when developing cleanup levels for RCRA regulated units and to give consideration to levels set by state/tribal programs which use risk-based approaches. EPA is developing guidance on risk-based clean closure and on the use of models to meet the clean closure performance standard.

Since almost all states oversee the closure/post-closure process and more than half implement RCRA corrective action, coordination of RCRA corrective action and closure will often be solely a state issue. However, if a state is not authorized for corrective action, or if a facility is subject to CERCLA as well as RCRA corrective action, close coordination between federal and state agencies will be necessary. As discussed above, actual approaches to coordination or deferral at any site should be developed in consideration of site-specific and community concerns.

Summary

We encourage you to continue your efforts to coordinate activities between the RCRA and CERCLA programs and between state, tribal and federal cleanup programs. We are aware that several of the EPA Regions are considering developing formal mechanisms to ensure that coordination will occur among these programs. We endorse these efforts and encourage all Regions, states and tribes to consider the adoption of mechanisms or policies to ensure coordination. If you have any questions on the issues discussed in this memorandum, or on other RCRA/CERCLA issues, please call Hugh Davis at (703)308-8633.

Attachments

cc:
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Tom Kennedy, Association of States and Territorial Solid Waste Management Officials
Robert Roberts, Environmental Council of States
John Thomasian, National Governors Association
Brian Zwit, National Association of Attorneys General

Links to Relevant *Code of Federal Regulations* (CFR)

- Vol. 60. No. 53. Monday, March 20, 1995, 40 CFR Part 300

    - The National Priorities List for Uncontrolled Hazardous Waste Sites; Deletion Policy for Resource Conservation and Recovery Act Facilities (http://www.epa.gov/docs/fedrgstr/EPA-WASTE/1995/March/Day-20/pr-174.html)

    - The National Oil and Hazardous Substances Contingency Plan; National Priorities List Update (http://www.epa.gov/docs/fedrgstr/EPA-WASTE/1995/March/Day-20/pr-175.html)

- Vol. 52. No. 53. Thursday, March 19, 1987, 40 CFR Part 265

    - Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities; Final (http://www.gpoaccess.gov/index.html)

“Supplemental Guidance to RAGS: Calculating the Concentration Term” OSWER Publication 9285.7-081

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EPA

Supplemental Guidance to RAGS: Calculating the Concentration Term

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division, OS-230

Intermittent Bulletin
Volume 1 Number 1

The overarching mandate of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances. To help meet this mandate, the U.S. Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response has developed a human health risk assessment process as part of its remedial response program. This process is described in the *Risk Assessment Guidance for Superfund: Volume I — Human Health Evaluation Manual (RAGS/HHEM).* Part A of RAGS/HHEM addresses the baseline risk assessment, and describes a general approach for estimating exposure to individuals from hazardous substance releases at Superfund sites.

This bulletin explains the concentration term in the exposure/intake equation to remedial project managers (RPMs), risk assessors, statisticians, and other personnel. This bulletin presents the general intake equation as presented in RAGS/HHEM Part A, discusses basic concepts concerning the concentration term, describes generally how to calculate the concentration term, presents examples to illustrate several important points, and lastly, identifies where to get additional help.

THE CONCENTRATION TERM

How is the concentration term used?

RAGS/HHEM Part A presents the Superfund risk assessment in four "steps": (1) data collection and evaluation; (2) exposure assessment; (3) toxicity assessment; and, (4) risk characterization. The concentration term is calculated for use in the exposure assessment step. **Highlight 1** presents the general equation Superfund uses for calculating exposure, and illustrates that the concentration term (C) is one of several parameters needed to estimate contaminant intake for an individual.

For Superfund assessments, the concentration term (C) in the intake equation is an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling results. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated.

Why use an average value for the concentration term?

An estimate of average concentration is used because:

Supplemental Guidance to RAGS is a bulletin series on risk assessment of Superfund sites. These bulletins serve as supplements to *Risk Assessment Guidance for Superfund: Volume I—Human Health Evaluation Manual.* The information presented is intended as guidance to EPA and other government employees. It does not constitute rulemaking by the Agency, and may not be relied on to create a substantive or procedural right enforceable by any other person. The Government may take action that is at variance with these bulletins.

Highlight 1
GENERAL EQUATION FOR ESTIMATING EXPOSURE TO A SITE CONTAMINANT

$$I = C \times \frac{CR \times EFD}{BW} \times \frac{1}{AT}$$

where:

I	=	Intake (i.e., the quantitative measure of exposure in RAGS/HHEM)
C	=	Contaminant Concentration
CR	=	Contact (Intake) Rate
EFD	=	Exposure Frequency and Duration
BW	=	Body Weight
AT	=	Averaging Time

(1) carcinogenic and chronic noncarcinogenic toxicity criteria[1] are based on lifetime average exposures; and,

(2) Average concentration is most representative of the concentration that would be contacted at a site, over time.

For example, if you assume that an exposed individual moves randomly across an exposure area, then the spatially-averaged soil concentration can be used to estimate the true average concentration contacted over time. In this example, the average concentration contacted over time would equal the spatially averaged concentration over the exposure area. While an individual may not actually exhibit a truly random pattern of movement across an exposure area, the assumption of equal time spent in different parts of the area is a simple but reasonable approach.

When should an average concentration be used?

The two types of exposure estimates now being required for Superfund risk assessments, a reasonable maximum exposure (RME) and an average, should both use an average concentration. To be protective, the overall estimate of intake (see **Highlight 1**) used as a basis for action at Superfund sites should be an estimate in the high-end of the intake/dose distribution. One high-end option is the RME used in the superfund program. The RME, which is defined as the highest exposure that could reasonably be expected to occur for a given exposure pathway at a site, is intended to account for both uncertainty in the contaminant concentration and variability in exposure parameters (e.g., exposure frequency, averaging time). For comparative purposes, agency guidance (U.S. EPA, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, February 26, 1992) states that an average estimate of exposure also should be presented in risk assessments. For decision-making purposes in the Superfund program, however, RME is used to estimate risk.[2]

Why use an estimate of the arithmetic mean rather than the geometric mean?

The choice of the arithmetic mean concentration as the appropriate measure for estimating exposure derives from the need to estimate an individual's long-term average exposure. Most Agency health criteria are based on the long-term average daily dose, which is simply the sum of all daily doses divided by the total number of days in the averaging period. This is the definition of an arithmetic mean. The

[1] When acute toxicity is of most concern, a long-term average concentration generally should not be used for risk assessment purposes, as the focus should be to estimate short-term, peak concentrations.

[2] For additional information on RME, see RAGS/HHEM Part A and the National Oil and Hazardous Substances Pollution contingency plan (NCP), 55 *Federal Register* 8710, March 8, 1990.

arithmetic mean is appropriate regardless of the pattern of daily exposures over time, or the type of statistical distribution that might best describe the sampling data. The geometric mean of a set of sampling results, however, bears no logical connection to the cumulative intake that would result from long-term contact with the site contaminants, and it may differ appreciably from—and be much lower than—the arithmetic mean. Although the geometric mean is a convenient parameter for describing central tendencies of lognormal distributions, it is not an appropriate basis for estimating the concentration term used in Superfund exposure assessments. The following simple example may help clarify the difference between the arithmetic and geometric mean, when used for an exposure assessment:

> Assume the daily exposure for a trespasser subject to random exposure at a site is 1.0, 0.01, 1.0, 0.01, 1.0, 0.01, 1.0, and 0.01 units/day, over an 8-day period. Given these values, the cumulative exposure is simply their summation, or 4.04 units. Dividing this by 8 days of exposure results in an arithmetic mean of 0.505 units per day. This is the value we would want to use in a risk assessment for this individual, not the geometric mean of 0.1 units per day. Viewed another way, multiplication of the geometric mean by the number of days equals 0.8 units, considerably lower than the known cumulative exposure of 4.04 units.

UCL AS AN ESTIMATE OF THE AVERAGE CONCENTRATION

What is a 95 percent UCL?

The 95 percent UCL of a mean is defined as a value that, when calculated repeatedly for randomly drawn subsets of site data, equals or exceeds the true mean 95 percent of the time. Although the 95 percent UCL of the mean provides a conservative estimate of the average (or mean) concentration, it should not be confused with a 95^{th} percentile of site concentration data (as shown in **Highlight 2**).

Why use the UCL as the average concentration?

Statistical confidence limits are the classical tool for addressing uncertainties of a distribution average. The 95 percent UCL of the arithmetic mean concentration is used as the average concentration, because it is not possible to know the true mean. The 95 percent UCL, therefore, accounts for uncertainties due to limited sampling data at Superfund sites. As sampling data become less limited at a site, uncertainties decrease, the UCL moves closer to the true mean, and exposure evaluations using either the mean or the UCL produce similar results. This concept is illustrated in **Highlight 2**.

Should a value other than the 95 percent UCL be used for the concentration?

A value other than the 95 percent UCL can be used, provided the risk assessor can document that high coverage of the true population mean occurs (i.e., the value equals or exceeds the true population mean with high probability). For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the UCL can be greater than the highest measured or modeled concentration. In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value could be used as the concentration term. Note, however, that the true mean still may be higher than this maximum value (i.e., the 95 percent UCL indicates a higher mean is possible), especially if the most contaminated portion of the site has not been sampled.

CALCULATING THE UCL

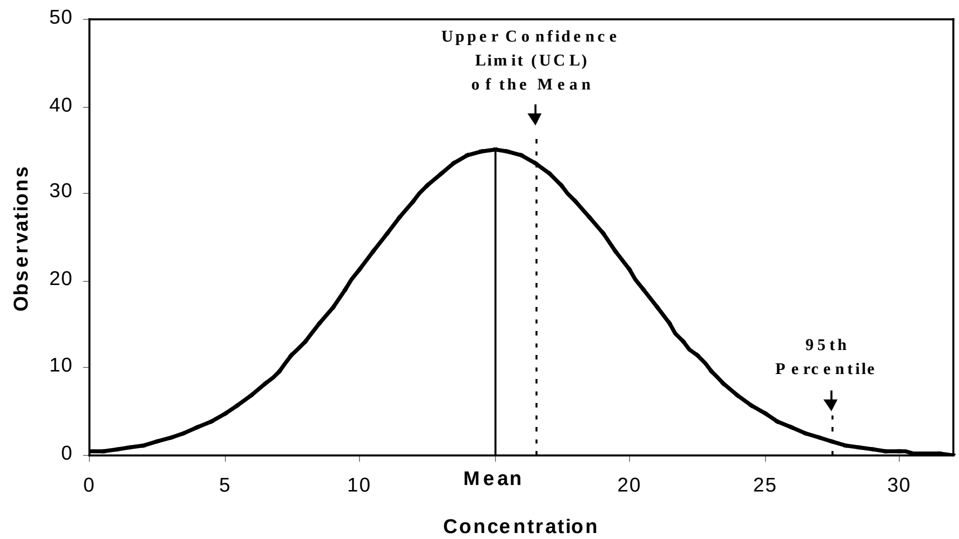
How many samples are necessary to calculate the 95 percent UCL?

Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95 percent UCL), while data sets with 10 to 20 samples per exposure are provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95 percent UCL is close to the sample mean). Remember that, in general, the UCL approaches the true mean as more samples are included in the calculation.

Should the data be transformed?

EPA's experience shows that most large or "complete" environmental contaminant data sets

Highlight 2
COMPARISON OF UCL AND 95th PERCENTILE



As sample size increases, the UCL of the mean moves closer to the true mean, while the 95th percentile of the distribution remains at the upper end of the distribution.

from soil sampling are lognormally distributed, rather than normally distributed (see **Highlights 3 and 4**, for illustrations of lognormal and normal distributions). In most cases, it is reasonable to assume that Superfund soil sampling data are lognormally distributed. Because transformation is a necessary step in calculating the UCL of the arithmetic mean for a lognormal distribution, the data should be transformed by using the natural logarithm function (i.e., calculate ln(*x*), where *x* is the value from the data set). However, in cases where there is a question about the distribution of the data set, a statistical test should be used to identify the best distributional assumption for the data set. The W-test (Gilbert, 1987) is one statistical method that can be used to determine if a data set is consistent with a normal or lognormal distribution. In all cases, it is valuable to plot the data to better understand the contaminant distribution at the site.

How do you calculate the UCL for a lognormal distribution?

To calculate the 95 percent UCL of the arithmetic mean for a lognormally-distributed data set, first transform the data using the natural logarithm function as discussed previously (i.e., calculate ln(x)). After transforming the data, determine the 95 percent UCL for the data set by completing the following four steps:

(1) Calculate the arithmetic mean of the transformed data (which is also the log of the geometric mean);

(2) Calculate the standard deviation of the transformed data;

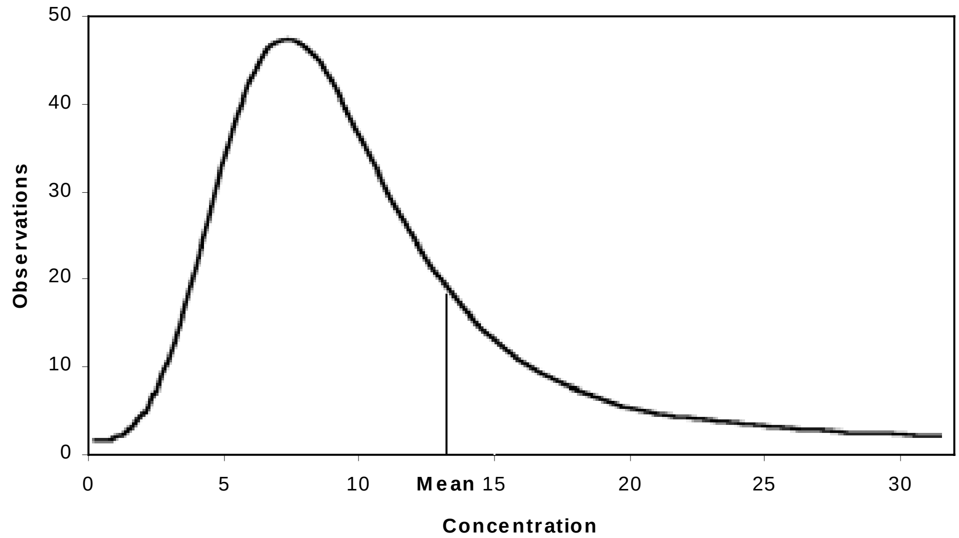
(3) Determine the H-statistic (e.g., see Gilbert, 1987); and,

(4) Calculate the UCL using the equation shown in **Highlight 5**.

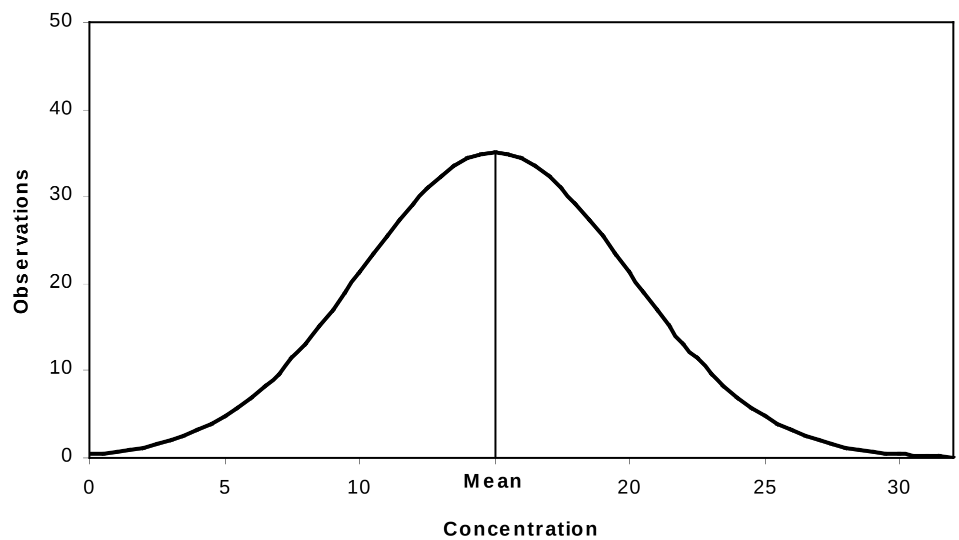
How do you calculate the UCL for a normal distribution?

If a statistical test supports the assumption that the data set is normally distributed, calculate the 95 percent UCL by completing the following four steps:

Highlight 3
EXAMPLE OF A LOGNORMAL DISTRIBUTION



Highlight 4
EXAMPLE OF A NORMAL DISTRIBUTION



Highlight 5
CALCULATING THE UCL OF THE ARITHMETIC MEAN FOR A LOGNORMAL DISTRIBUTION

$$UCL = e^{(\bar{x} + 0.5s^2 + sH / \sqrt{n-1})}$$

where:

UCL	=	upper confidence limit
e	=	constant (base of the natural log, equal to 2.718)
$\bar{x}$	=	mean of the transformed data
s	=	standard deviation of the transformed data
H	=	H-Statistic (e.g., from table published in Gilbert, 1987)
n	=	number of samples

Highlight 6
CALCULATING THE UCL OF THE ARITHMETIC MEAN FOR A NORMAL DISTRIBUTION

$$UCL = \bar{x} + t(s / \sqrt{n})$$

where:

UCL	=	upper confidence limit
$\bar{x}$	=	mean of the untransformed data
s	=	standard deviation of the untransformed data
t	=	Student-t statistic (e.g., from table published in Gilbert, 1987)
n	=	number of samples

(1) Calculate the arithmetic mean of the untransformed data;

(2) Calculate the standard deviation of the untransformed data;

(3) Determine the one-tailed t-statistic (e.g., see Gilbert, 1987); and,

(4) Calculate the UCL using the equation shown in **Highlight 6**.

Use caution when applying normal distribution calculations, if there is a possibility that heavily contaminated portions of the site have not been adequately sampled. In such cases, a UCL from normal distribution calculations could fall below the true mean, even if a limited data set at a site appears normally distributed.

EXAMPLES

The examples show in **Highlights 7 and 8** address the exposure scenario where an individual at a Superfund site has equal opportunity to contact soil in any sector of the contaminated area over time. Even though the examples address only soil exposures, the UCL approach is applicable to all exposure pathways. Guidance and examples for other exposure pathways will be presented in forthcoming bulletins.

Highlight 7 presents a simple data set and provides a stepwise demonstration of transforming the data—assuming a lognormal distribution—and calculating the UCL. **Highlight 8** uses the same data set to show the difference between the UCLs that would result from assuming normal and lognormal distribution of the data. These

Highlight 7
EXAMPLE OF DATA TRANSFORMATION AND CALCULATION OF UCL

This example shows the calculation of a 95 percent UCL of the arithmetic mean concentration for chromium in soil at a Superfund site. <u>This example is applicable only to a scenario in which a spatially random exposure pattern is assumed.</u> The concentrations of chromium obtained from random sampling in soil at this (in mg/kg) are 10, 13, 20, 36, 41, 59, 67, 110, 110, 136, 140, 160, 200, 230, and 1300. Using these data, the following steps are taken to calculate a concentration term for the intake equation:

(1) Plot the data and inspect the graph. (You may need the help of a statistician for this part, as well as other parts, of the calculation of the UCL.) The plot (not shown, but similar to **Highlight 3**) shows a skew to the right, consistent with a lognormal distribution.

(2) Transform the data by taking the natural log of the values (i.e., determine ln(x)). For this data set, the transformed values are: 2.30, 2.56, 3.00, 3.58, 3.71, 4.08, 4.20, 4.70, 4.70, 4.91, 4.94, 5.08, 5.30, 5.44, and 7.17.

(3) Apply the UCL equation in **Highlight 5**, where:

$\bar{x}$ = 4.38
s = 1.25
H = 3.163 (based on 95 percent)
n = 15

The resulting 95 percent UCL of the arithmetic mean is thus found to equal $e^{(6.218)}$, or 502 mg/kg.

Highlight 8
COMPARING UCLs OF THE ARITHMETIC MEAN ASSUMING DIFFERENT DISTRIBUTIONS

In this example, the data presented in **Highlight 7** are used to demonstrate the difference in the UCL that is seen if the normal distribution approach were inappropriately applied to this data set (i.e., if, in this example, a normal distribution is assumed).

ASSUMED DISTRIBUTION:	Normal	Lognormal
TEST STATISTIC:	Student-t	H- statistic
95 PERCENT UCL (mg/kg):	325	502

examples demonstrate the importance of using the correct assumptions.

WHERE CAN I GET MORE HELP?

Additional information on Superfund's policy and approach to calculating the concentration term and estimating exposures at waste sites can be obtained in:

- U.S. EPA, *Risk Assessment Guidance for Superfund: Volume I—Human Health Evaluation Manual (Part A)*, EPA/540/1-89/002, December 1989.

- U.S. EPA, *Guidance for Data Usability in Risk Assessment*, EPA/540/G-90/008, (OSWER Directive 9285.7-05), October 1990.

- U.S. EPA, *Risk Assessment Guidance for Superfund (Part A—Baseline Risk Assessment) Supplemental Guidance/ Standard Exposure Factors*, OSWER Directive 9285.6-03, May 1991.

Useful statistical guidance can be found in many standard textbooks, including:

- Gilbert, R.O., *Statistical Methods for Environmental Pollution Monitoring*, Van Nostrand Reinhold, New York, New York, 1987.

Questions or comments concerning the concentration term can be directed to:

- Toxics Integration Branch
  Office of Emergency and Remedial
  Response
  401 M Street, SW.
  Washington, DC 20460
  Phone: 202-260-9486

EPA staff can obtain additional copies of this bulletin by calling EPA's Superfund Document Center at 202-260-9760. Others can obtain copies by contacting NTIS at 703-487-4650.

“Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites”
OSWER Publication 9285.6-10

OSWER 9285.6-10

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CALCULATING UPPER CONFIDENCE LIMITS FOR EXPOSURE POINT CONCENTRATIONS AT HAZARDOUS WASTE SITES

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Disclaimer

This document provides guidance to EPA Regions concerning how the Agency intends to exercise its discretion in implementing one aspect of the CERCLA remedy selection process. The guidance is designed to implement national policy on these issues.

The statutory provisions and EPA regulations described in this document contain legally binding requirements. However, this document does not substitute for those provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Any decisions regarding a particular remedy selection decision will be made based on the statute and regulations, and EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. EPA may change this guidance in the future.

TABLE OF CONTENTS

1.0 INTRODUCTION

This document updates a 1992 guidance originally developed to supplement EPA's *Risk Assessment Guidance for Superfund (RAGS), Volume 1 – Human Health Evaluation Manual* (RAGS/HHEM, EPA 1989), which describes a general approach for estimating exposure of individuals to chemicals of potential concern at hazardous waste sites. It addresses a key element of the risk assessment process for hazardous waste sites: estimation of the concentration of a chemical in the environment. This concentration, commonly termed the exposure point concentration (EPC), is a conservative estimate of the average chemical concentration in an environmental medium. The EPC is determined for each individual exposure unit within a site. An exposure unit is the area throughout which a receptor moves and encounters an environmental medium for the duration of the exposure. Unless there is site-specific evidence to the contrary, an individual receptor is assumed to be equally exposed to media within all portions of the exposure unit over the time frame of the risk assessment.

EPA recommends using the average concentration to represent "a reasonable estimate of the concentration likely to be contacted over time" (EPA 1989). The guidance previously issued by EPA in 1992, *Supplemental Guidance to RAGS: Calculating the Concentration Term* (EPA 1992), states that, "because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable." The 1992 guidance addresses two kinds of data distributions: normal and lognormal. For normal data, EPA recommends an upper confidence limit (UCL) on the mean based on the Student's *t*-statistic. For lognormal data, EPA recommends the Land method using the *H*-statistic. EPA describes approaches for testing distribution assumptions in *Guidance for Data Quality Assessment: Practical Methods for Data Analysis* (EPA 2000b, section 4.2).

The 1992 guidance has been helpful for EPC calculation, but it does not address data distributions that are neither normal nor lognormal. Moreover, as has been widely acknowledged, the Land method can sometimes produce extremely high values for the UCL when the data exhibit high variance and the sample size is small (Singh et al. 1997; Schulz and Griffin 1999). EPA's 1992 guidance recognizes the problem of extremely high UCLs, and recommends that the maximum detected concentration become the default when the calculated UCL exceeds this value. Singh et al. (1997) and Schulz and Griffin (1999) suggest several alternate methods for calculating a UCL for non-normal data distributions. This guidance provides additional tools that risk assessors can use for UCL calculation, and assists in applying these methods at hazardous waste sites. It begins with a discussion of issues related to evaluating the available site data and then presents brief discussions of alternative methods for UCL calculation, with recommendations for their use at hazardous waste sites. In addition, EPA has worked with its contractor, Lockheed Martin to develop a software package, ProUCL, to perform many of the calculations described in this guidance (EPA 2001a). Both ProUCL and this guidance make recommendations for calculating UCLs, and are intended as tools to support risk assessment.

To obtain a copy of the ProUCL software or receive technical assistance in using it, risk assessors should contact:

Director of the Technical Support Center
USEPA Office of Research and Development
National Exposure Research Laboratory
Environmental Sciences Division
Las Vegas, Nevada
702-798-2270.

The ultimate responsibility for deciding how best to represent the concentration data for a site lies with the project team.[1] Simply choosing a statistical method that yields a lower UCL is not always the best representation of the concentration data at a site. The project team may elect to use a method that yields a higher (i.e., more conservative) UCL based on its understanding of site-specific conditions, including the representativeness of the data collection process, and the limits of the available statistical methods for calculating a UCL.

2.0 APPLICABILITY OF THIS GUIDANCE

This document updates 1992 guidance developed by EPA's Office of Emergency and Remedial Response; yet it can be applied to any hazardous waste site. It provides alternative methods for calculating the 95 percent upper confidence limit of the mean concentration, which can be used at sites subject to the discretion of the regulatory agencies and programs involved. The approaches described in this document are not specific to a particular medium (e.g., soil, groundwater), or receptor (e.g., human ecological), but apply to any media or receptor for which the UCL would be calculated.[2]

This document does not substitute for any statutory provisions or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulatory community, and may not apply to a particular situation based upon the circumstances. Any decision regarding cleanup of a particular site will be made based on the statutes and regulations, and EPA decisionmakers retain the discretion to adopt approaches on a case-by-case basis that differ from this guidance to a particular situation. The Agency accepts public input on this document at any time.

This guidance is based on the state of knowledge at present. The practices discussed herein may be refined, updated, or superseded by future advances in science and mathematics.

[1] The project team typically consists of a site manager (e.g., the Remedial Project Manger) and a multidisciplinary team of technical experts, including human health and ecological risk assessors, hydrogeologists, chemists, toxicologists, and quality assurance specialists.

[2] Note that this guidance does not apply to lead-contaminated sites. The Technical Review Working Group for Lead recommends that the average concentration is used in evaluating lead exposures (see http://www.epa.gov/superfund/programs/ lead/trwhome.htm).

3.0 DATA EVALUATION

In the risk assessment process, data evaluation precedes exposure assessment. Because this guidance deals with a component of exposure assessment, it therefore assumes that data have already undergone validation and evaluation and that the data have been determined to meet data quality objectives (DQOs) for the project in question. DQOs are important for any project where environmental data are used to support decision-making, as at hazardous waste sites.

One factor to consider in data evaluation is whether the number of sample measurements is sufficient to characterize the site or exposure unit. The minimum number of samples to conduct any of the statistical tests described in this document should be determined using the DQO process (EPA 2000a). Use of the methods described in this guidance is not a substitute for obtaining an adequate number of samples. Sample size is especially important when there is large variability in the underlying distribution of concentrations. However, defaulting to the maximum value of small data sets may still be the last resort when the UCL appears to exceed the range of concentrations detected.

Another important issue to consider is the method of sampling. All the statistical methods described in this guidance for calculating UCLs are based on the assumption of random sampling. At many hazardous waste sites, however, sampling is focused on areas of suspected contamination. In such cases, it is important to avoid introducing bias into statistical analyses. This can be achieved through stratified random sampling, i.e., random sampling within specified targeted areas. So long as the statistical analysis is constructed properly (i.e., there is no mixing of samples across different populations) bias can be minimized. The risk assessor should always note any potential bias in EPC estimates.

The risk assessor should also consider the duration of exposure and the time scale of the toxicity. For example, a chronic exposure may warrant the use of different concentrations or sample locations from an acute exposure. The time periods over which data were collected should also be considered. See EPA 1989, Chapters 5.1 and 6.4.2, for further details.

Once a set of data from a site has been evaluated and validated, it is appropriate to conduct exploratory analysis to determine whether there are outliers or a substantial number of non-detect values that can adversely affect the outcome of statistical analyses. The following sections describe the potential impact of outliers and non-detect values on the calculation of UCLs and approaches for addressing these types of values.

3.1 Outliers

Outliers are values in a data set that are not representative of the set as a whole, usually because they are very large relative to the rest of the data. There are a variety of statistical tests for determining whether one or more observations are outliers (EPA 2000b, section 4.4). These tests should be used judiciously, however. It is common that the distribution of concentration data at a site is strongly skewed so that it contains a few very high values corresponding to local hot spots of contamination. The receptor could be exposed to these hot spots, and to estimate the EPC correctly it is important to take account of these values. Therefore, one should be careful not to exclude values merely because they are large relative to the rest of the data set.

Extreme values in the data set may represent true spatial variation in concentrations. If an observation or group of observations is suspected to be part of a different contamination source or exposure unit, then regrouping of the data may be most appropriate. In this case, it may be necessary to evaluate these data as a separate hot spot or to resample. The behavior of the receptor and the size and location of the exposure unit will determine which sample locations to include. Such decisions depend on project-specific assessments based on the conceptual site model.

EPA guidance suggests that, when outliers are suspected of being unreliable and statistical tests show them to be unrepresentative of the underlying data set, any subsequent statistical analyses should be conducted both with and without the outlier(s) (EPA 2000b). In addition, the entire process, including identification, statistical testing and review of outliers, should be fully documented in the risk characterization.

3.2 Non-detects

Chemical analyses of contaminant concentrations often result in some samples being reported as below the sample detection limit (DL). Such values are called non-detects. Non-detects may correspond to concentrations that are actually or virtually zero, or they may correspond to values that are considerably larger than zero but which are below the laboratory's ability to provide a reliable measurement. Elevated detection limits need to be investigated, especially if there are high percentages of non-detects. It is not appropriate to simply account for elevated detection limits with statistical techniques; improvements in sampling and analysis methods may be needed to lower detection limits.

In this guidance, the term "detection limit" is used to represent the reported limit of the non-detect. In reality, this could be any of a number of detection or quantitation limits. For further discussion of detection and quantitation limits in the risk assessment, see text box and Chapter 5 of EPA 1989.

Alternative Quantitation Limits

Method Detection Limit (MDL): The lowest concentration of a hazardous substance that a method can detect reliably in either a sample or blank.

Contract-Required Quantitation Limit (CRQL): The substance-specific level that a CLP laboratory must be able to routinely and reliably detect in specific sample matrices. The CRQL is not the lowest detectable level achievable, but rather the level that a CLP laboratory must reliably quantify. The CRQL may or may not be equal to the quantitation limit of a given substance in a given sample.

Source: Superfund Glossary of Terms and Acronyms (http://www.epa.gov/superfund/resources/hrstrain/htmain/glossal.htm

In the statistical literature, data sets containing non-detects are called censored or left-censored. The detection limit achieved for a particular sample depends on the sensitivity of the measuring method used, the instrument quantitation limit, and the nature of dilutions and other preparations employed for the sample. In addition, there may be different degrees of censoring. For instance, some laboratories use the letter code "J" to indicate that a value was below the quantitation limit and the letter "U" to indicate that a value was below the detection limit. These code systems vary among laboratories, however, and it is essential to understand what the laboratory notations indicate about the reliability of its measurements.[3] Censoring can cause problems in calculating the UCL. There are several common options for handling non-detects.

Reexamining the conceptual site model may suggest that the data be partitioned. For instance, it may be clear from the spatial pattern of non-detects in the data that the region sampled can be subdivided into contaminated and non-contaminated areas. Evidence for this depends on the observed pattern of contamination, how the contamination came to be located in the medium, and how the receptors will come in contact with the medium. It may be necessary to collect more samples to obtain an adequate site characterization.

Simple Substitution methods assign a constant value or constant fraction of the detection limit (DL) to the non-detects. Three common conventions are: (1) assume non-detects are equal to zero; (2) assume non-detects are equal to the DL; or (3) assume non-detects are equal to one-half the DL. Whatever proxy value is assigned, it is then used as though it were the reliably estimated value for that measurement. Because of the complicated formulas used to compute UCLs, there is no general rule about which substitution rule will yield an appropriate UCL. The uncertainty associated with the substitution method increases, and its appropriateness decreases, as the detection limit becomes larger and as the number of non-detects in the data set increases.

Bounding methods estimate limits on the UCL in a distribution-free way. This method involves determining the lower and upper bounds of the UCL based on the full range of possible values for non-detects. If the uncertainty arising from censoring is relatively small, then the difference between the lower and upper bound estimates will be small. It is not possible to bound the UCL by using simple substitution methods such as computing the UCL once with the non-detects replaced by zeros and once with the non-detects replaced by their respective detection limits. Sometimes using all zeros will inflate the estimate of the standard deviation of the concentration values to such a degree that the resulting value for the UCL is larger than the value from using the detection limits (Ferson et al. 2002, Rowe 1988, Smith 1995). See Appendix A for an example of how to compute bounds on the UCL.

Distributional methods rely on applying an assumption that the shape of the distribution of non-detect values is similar to that of measured concentrations above the detection limit. EPA provides guidance on handling non-detects using several distributional methods, including Cohen's method (EPA 2000b, section 4.7). In addition, Helsel (1990) reviews a variety of distributional methods (see also Hass and Scheff 1990; Gleit 1985; Kushner 1976; Singh and Nocerino 2001). EnvironmentalStats for S-PLUS (Millard 1997) offers an array of methods for estimating parameters from censored data sets.

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[3] Information concerning the quantitation limits also should be incorporated into the appropriate supplemental tables in the framework for risk assessment planning, reporting, and review described in the *Risk Assessment Guidance for Superfund Volume 1: Human Health Evaluation Part D (RAGS, Part D)* (EPA 1998.)

The appropriate method to use depends on the severity of the censoring, the size of the data set, and what distributional assumptions are reasonable. There are five recommendations about how to treat censoring in the estimation of UCLs.

1) Detection limits should always be reported for non-detects. Non-detects should also be reported with observed values where possible.
2) It is inappropriate to convert non-detects into zeros without specific justification (e.g., the analyte was not detected above the detection limit in any sample at the site).
3) If a bounding analysis reveals that the quantitative effects of censoring are negligible, then no further analysis may be required.
4) If further analysis is desired, consider using a distribution-specific method.
5) If the proportion of non-detects is high ($75%) or the number of samples is small ($n<5$), no method will work well. In this case, it is reasonable to report the percentage of data below the detection limit, and resort again to a bounding approach in which non-detects are replaced by the detection limit and used to compute a UCL value that is reported as a number likely to be considerably larger than the true mean.

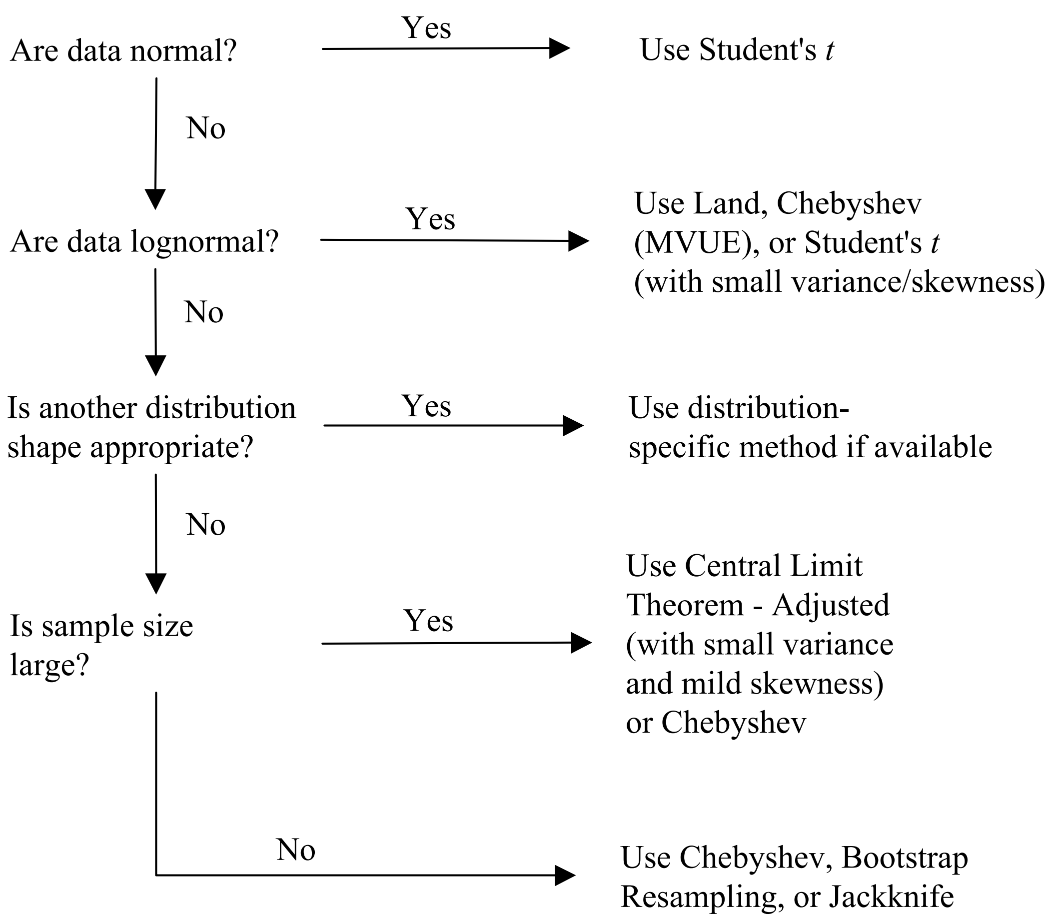
4.0 UCL CALCULATION METHODS

There are a number of different methods for calculating UCLs. Before an appropriate method can be selected the site data must be characterized through exploratory analysis. Fitting distributions to the data is a crucial part of this exploratory data analysis (Schulz and Griffin 1999). As recommended by EPA (1992), "where there is a question about the distribution of the data set, a statistical test should be used to identify the best distributional assumption for the data set." This is necessary because no single distribution type fits all environmental data sets. Risk assessors deal with some environmental data sets that appear normally distributed, and with others that appear lognormally distributed. They also encounter data sets that do not fit either normal or lognormal distributions. Distributions can be analyzed by a variety of methods, many of which are described in Gilbert (1987) and EPA (2000b). Data plotting can also help identify a useful distributional assumption. Some of these methods have been incorporated in the ProUCL software. Whatever method is used, it should be chosen in consultation with the EPA regional risk assessor and other project team members as appropriate. The assistance of a statistician may also be helpful in some cases.

The two most commonly used methods for computing UCLs are distributional methods. When the concentration distribution is normal, the classical approach based on the Student's *t*-statistic has typically been used. When the distribution is lognormal, the Land method based on the *H*-statistic has been used. Distribution-free or nonparametric methods are available if the risk assessor cannot reasonably make assumptions about the distributional type. EPA describes several methods (EPA, 2000c). For large data sets, an approach based on the Central Limit Theorem with a correction for positive skewness may be used. For data sets that are not large enough for this approach, there is more than one approach available, although none is ideal in all circumstances. General methods include an approach based on the Chebyshev inequality and an approach based on the bootstrap resampling procedure. These are described in EPA (2000c) and in Schulz and Griffin (1999). Both papers give examples and comparisons of the UCLs calculated by various methods. The flow chart shown in Figure 1 summarizes the recommendations in this guidance.

It should be noted that the "variance" in Figure 1 represents the variance of the log-transformed data. For detailed definitions of skewness, refer to the User's Guide for the ProUCL software.

Figure 1: UCL Method Flow Chart



Risk assessors are encouraged to use the most appropriate estimate for the EPC given the available data. The flow chart in Figure 1 provides general guidelines for selecting a UCL calculation method. This guidance presents descriptions of these methods, including their applicability, advantages and disadvantages. It also includes examples of how to calculate UCLs using the methods. While the methods identified in this guidance may be useful in many situations, they will probably not be appropriate for all hazardous waste sites. Moreover, other methods not specifically described in this guidance may be most appropriate for particular sites. The EPA risk assessor should be involved in the decision of which method(s) to use.

4.1 UCL Calculation with Methods for Specific Distributions

This section of the guidance presents methods for calculating UCLs when data can be shown to fit a specific distribution. Directions for using methods to calculate UCL for normal, lognormal, and other specific distributions are included, as are example calculations.

UCLs for Normal Distributions

If the data are normally distributed, then the one-sided (1-α) upper confidence limit $UCL_{1-\alpha}$ on the mean should be computed in the classical way using the Student's *t*-statistic (EPA 1992; Gilbert 1987, page 139; Student 1908). There is no change in EPA's prior recommendations for this type of data set (EPA 1992). Exhibit 1 gives the procedure for computing the UCL of the mean when the underlying distribution is normal. Exhibit 2 gives a numerical example of an application of the method.

Exhibit 1: Directions for Computing UCL for the Mean of a Normal Distribution — Student's *t*

Let $X_1, X_2, \ldots, X_n$ represent the *n* randomly sampled concentrations.

STEP 1: Compute the sample mean $\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$.

STEP 2: Compute the sample standard deviation $s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2}$.

STEP 3: Use a table of quantiles of the Student's *t* distribution to find the $(1-\alpha)^{th}$ quantile of the Student's *t* distribution with *n*-1 degrees of freedom. For example, the value at the 0.05 level with 40 degrees of freedom is 1.684. A table of Student's *t* values can be found in Gilbert (1987, page 255, where the values are indexed by p=1-α, rather than α level). The *t* value appropriate for computing the 95% UCL can be obtained in Microsoft Excel® with the formula TINV((1-0.95)*2, *n*-1).

STEP 4: Compute the one-sided (1-α) upper confidence limit on the mean

$$UCL_{1-\alpha} = \overline{X} + t_{\alpha, n-1}\, s / \sqrt{n}$$

Exhibit 2: An Example Computation of UCL for a Normal Distribution — Student's *t*

25 samples were collected at random from an exposure unit. The values observed are 228, 552, 645, 208, 755, 553, 674, 151, 251, 315, 731, 466, 261, 240, 411, 368, 492, 302, 438, 751, 304, 368, 376, 634, and 810 µg/L. It seems reasonable that the data are normally distributed, and the Shapiro-Wilk *W* test for normality fails to reject the hypothesis that they are (W = 0.937). The UCL based on Student's *t* is computed as follows.

STEP 1: The sample mean of the n=25 values is $\overline{X}$ = 451.

STEP 2: The sample standard deviation of the values is s = 198.

STEP 3: The t-value at the 0.05 level for 25-1 degrees of freedom is $t_{0.05,25-1}$ = 1.710.

STEP 4: The one-sided 95% upper confidence limit on the mean is therefore

$$UCL_{95\%} = 451 + 1.710 \times 198 / \sqrt{25} = 519$$

Testing for normality. For mildly skewed data sets, the student's t-statistic approach may be used to compute the UCL of the mean. But for moderate to highly skewed data sets, the t-statistic-based UCL can fail to provide the specific coverage for the population mean. This is especially true for small *n*. For instance, the 95% UCL based on 10 random samples from a lognormal distribution with mean 4.48 and standard deviation 5.87 will underestimate the true mean about 20% of the time, rather than the nominal rate of 5%. Therefore it is important to test the data for normality. EPA (2000b, section 4.2) gives guidance for several approaches for testing normality. The tests described therein are available in DataQUEST and ProUCL, which are convenient software tools (EPA 1997 and 2001a).

Accounting for non-detects. The use of substitution methods to account for non-detects is recommended only when a very small percentage of the data is censored (e.g., # 15%), under the presumption that the numerical consequences of censoring will be minor in this case. As the percentage of the data censored increases, substitution methods tend to alter the distribution and violate the assumption of normality. Moreover, the effect of the various substitution rules on UCL estimation is difficult to predict. Replacing non-detects with half the detection limit can underestimate the UCL, and replacing them with zeros may overestimate the UCL (because doing so inflates the estimate of the standard deviation).

When censoring is moderate (e.g., >15% and # 50%), it is preferable to account for non-detects with Cohen's method (Gilbert 1987). EPA provides guidance on the use of Cohen's method, which is a maximum likelihood method for correcting the estimates of the sample mean and the sample variance to account for the presence of non-detects among the data (EPA 2000b, beginning on page 4-43). This method requires that the detection limit be the same for all the data and that the underlying data are normally distributed.

UCLs for Lognormal Distributions

It is inappropriate to extend the methods of the previous section to lognormally distributed samples by log-transforming the data, computing a UCL and then back-transforming the results. For concentration data sets that appear to be lognormally distributed, it may instead be preferable to use one of several methods available that are specifically well-suited to this type of distribution. These methods are described in the following sections.

Land Method

In past guidance, EPA had recommended using the Land method to compute the upper confidence limit on the mean for lognormally distributed data (Land 1971, 1975; Gilbert 1987; EPA 1992; Singh et al. 1997). This method requires the use of the *H*-statistic, tables for which were published by Land (1975) and Gilbert (1987, Tables A10 and A12). Exhibit 3 gives step-by-step directions for this method and Exhibit 4 gives a numerical example of its application.

Caveats about this method. Land's approach is known to be sensitive to deviations from lognormality. The formula may commonly yield estimated UCLs substantially larger than necessary when distributions are not truly lognormal if variance or skewness is large (Gilbert 1987). When sample sizes are small (less than 30), the method can be impractical even when the underlying distribution is lognormal (Singh et al. 1997).

Exhibit 3: Directions for Computing UCL for the Mean of a Lognormal Distribution— Land Method

Let $X_1, X_2, \ldots, X_n$ represent the n randomly sampled concentrations.

STEP 1: Compute the arithmetic mean of the log-transformed data $\overline{\ln X} = \frac{1}{n}\sum_{i=1}^{n} \ln(X_i)$.

STEP 2: Compute the associated standard deviation $s_{\ln X} = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(\ln(X_i) - \overline{\ln X}\right)^2}$.

STEP 3: Look up the $H_{1-\alpha}$ statistic for sample size n and the observed standard deviation of the log-transformed data. Tables of these values are given by Gilbert (1987, Tables A-10 and A-12) and Land (1975).

STEP 4: Compute the one-sided (1-α) upper confidence limit on the mean

$$UCL_{1-\alpha} = \exp\left(\overline{\ln X} + s_{\ln X}^2 / 2 + H_{1-\alpha} s_{\ln X} / \sqrt{n-1}\right)$$

Testing for lognormality. Because the Land method assumes lognormality, it is very important to test this assumption. EPA gives guidance for several approaches to testing distribution assumptions (EPA 2000b, section 4.2). The tests are also available in the DataQUEST and ProUCL software tools (EPA 1997 and 2001a).

Exhibit 4: An Example Computation of UCL for a Lognormal Distribution — Land Method

31 samples were collected at random from an exposure unit. The observed values are 2.8, 22.9, 3.3, 4.6, 8.7, 30.4, 12.2, 2.5, 5.7, 26.3, 5.4, 6.1, 5.2, 1.8, 7.2, 3.4, 12.4, 0.8, 10.3, 11.4, 38.2, 5.6, 14.1, 12.3, 6.8, 3.3, 5.2, 2.1, 19.7, 3.9, and 2.8 mg/kg. Because of their skewness, the data may be lognormally distributed. The Shapiro-Wilk *W* test for normality rejects the hypothesis, at both the 0.05 and 0.01 levels, that the distribution is normal. The same test fails to reject at either level the hypothesis that the distribution is lognormal. The UCL on the mean based on Land's *H* statistic is computed as follows.

STEP 1: Compute the arithmetic average of the log-transformed data $\overline{\ln X} = 1.8797$.

STEP 2. Compute the standard deviation of the log-transformed data $s_{\ln X} = 0.8995$.

STEP 3. The *H* statistic for $n = 31$ and $s_{\ln X} = 0.90$ is 2.31.

STEP 4: The one-sided 95% upper confidence limit on the mean is therefore

$$UCL_{95\%} = \exp\left(1.8797 + 0.8995^2 / 2 + 2.31 \times 0.8995 / \sqrt{31-1}\right) = 14.4$$

Accounting for non-detects. Gilbert (1987, page 182) suggests extending Cohen's method to account for non-detect values in lognormally distributed concentrations. Cohen's method (EPA 2000b, page 4-43) assumes the data are normally distributed, so it must be applied to the log-transformed concentration values. If $\hat{\mu}_y$ and $\hat{\sigma}_y$ are the corrected sample mean and standard deviation, respectively, of the log-transformed concentrations, then the corrected estimates of the mean and standard deviation of the underlying lognormal distribution can be obtained from the following expressions:

$$\hat{\mu} = \exp(\hat{\mu}_y + \hat{\sigma}_y^2 / 2)$$

$$\hat{\sigma} = \hat{\mu}\sqrt{\exp(\hat{\sigma}_y^2) - 1}$$

This method requires there be a single detection level for all the data values.

Chebyshev Inequality Method

Singh et al. (1997) and EPA (2000c) suggest the use of the Chebyshev inequality to estimate UCLs which should be appropriate for a variety of distributions so long as the skewness is not very large. The one-sided version of the Chebyshev inequality (Allen 1990, page 79; Savage 1961, page 216) is appropriate in this context (cf. Singh et al. 1997, EPA 2000c). It can be applied to the sample mean to obtain a distribution-free estimate of the UCL for the population mean when the population variance or standard deviation are known. In practice, however, these values are not known and must be estimated from data. For lognormally distributed data sets, Singh et al. (1997) and EPA (2000c) suggest using the minimum-variance unbiased estimators (MVUE) for the mean and variance to obtain an UCL of the mean. (See also Gilbert 1987, for discussion of the MVUE). This approach may yield an estimated UCL that is more useful than that obtained from the Land method (when the underlying distribution of concentrations is lognormal). This alternative approach for a lognormal distribution is described in Exhibit 5 and is available in the ProUCL software tool (EPA 2001a). A numerical illustration of the Chebyshev inequality method using the sample mean and standard deviation appears in Exhibit 6. In this example the estimate of the UCL based on the Chebyshev inequality is less than that based on the Land method. The Chebyshev inequality estimate of the UCL is 1,965 mg/kg; while applying the Land method to this same data set yields a higher UCL estimate of 2,658 mg/kg.

Exhibit 5: Steps for UCL Calculation Based on the Chebyshev Inequality — MVUE Approach for Lognormal Distributions

Let $X_1, X_2, \ldots, X_n$ represent the n randomly sampled concentrations.

STEP 1: Compute the arithmetic mean of the log-transformed data $\overline{\ln X} = \frac{1}{n}\sum_{i=1}^{n} \ln(X_i)$.

STEP 2: Compute the associated variance $s_{\ln X}^2 = \frac{1}{n-1}\sum_{i=1}^{n}\left(\ln(X_i) - \bar{y}\right)^2$.

STEP 3: Compute the minimum-variance unbiased estimator (MVUE) of the population mean for a lognormal distribution $\hat{\mu}_{\mathrm{LN}} = \exp\left(\overline{\ln X}\right) g_n\left(s_{\ln X}^2/2\right)$, where g_n denotes a function for which tables are available (Aitchison and Brown 1969, Table A2; Koch and Link 1980, Table A7).

STEP 4: Compute the MVUE of the associated variance of this mean

$$\sigma_\mu^2 = \exp(2\,\overline{\ln X})\left(\left(g_n(s_{\ln X}^2/2)\right)^2 - g_n\left(\frac{n-2}{n-1}s_{\ln X}^2\right)\right)$$

STEP 5: Compute the one-sided (1-α) upper confidence limit on the mean

$$UCL_{1-\alpha} = \hat{\mu}_{\mathrm{LN}} + \sqrt{\left(\frac{1}{\alpha} - 1\right)\sigma_\mu^2}$$

Caveats about the Chebyshev method. EPA (2000c) points out that for highly skewed lognormal data with small sample size and large standard deviation, the Chebyshev 99% UCL may be more appropriate than the 95% UCL, because the Chebyshev 95% UCL may not provide adequate coverage of the mean. As skewness increases further, the Chebyshev method is not recommended. See the ProUCL User's Guide (2001a) for specific recommendations on use of these two UCL estimates.

Exhibit 6: An Example Computation of UCL Based on the Chebyshev Inequality

29 samples were collected at random from an exposure unit. The observed values are 107, 175, 1796, 2002, 109, 30, 273, 83, 127, 254, 466, 12, 403, 31, 1042, 923, 24, 537, 5667, 59, 158, 59, 353, 10, 8, 33, 1129, 3 and 279 mg/kg. The observed skewness of this data set is 3.8, and these data may be lognormally distributed. The assumption of normality is rejected at the 0.05 level by a Shapiro-Wilk W test, but the same test fails to reject a test of lognormality even at the 0.1 level. The UCL on the mean can be computed based on the Chebyshev Inequality as follows.

STEP 1: The arithmetic mean of the log-transformed data $\overline{\ln X}$ is 4.9690.

STEP 2: The associated variance $s^2_{\ln X}$ = 3.3389.

STEP 3: The MVUE of the mean for a lognormal distribution $\hat{\mu}_{LN}$ = 666.95.

STEP 4: The MVUE of the variance of the mean σ^2_{μ} = 88552.

STEP 5: The resulting one-sided 95% upper confidence limit on the mean of the concentration

$$UCL_{95\%} = 666.95 + \sqrt{(19)88552} = 1{,}965$$

The 95% UCL based on the Land method for these data would be 2,658.

EPA (2000c, Table 7) suggests that the Chebyshev inequality method for computing the UCL may be preferred over the Land method, even for lognormal distributions, in certain situations. Exhibit 7 describes the conditions, in terms of the sample size and the standard deviation of the log-transformed data, under which the Chebyshev inequality method will probably yield more useful results than the Land method.

Exhibit 7

Conditions Likely to Favor Use of Chebyshev Inequality (MVUE) over Land Method

Standard deviation of log-transformed data	Sample Size	Recommendation
1 - 1.5	<25	95% Chebyshev (MVUE) UCL
1.5 - 2	<20	99% Chebyshev (MVUE) UCL
	20 - <50	95% Chebyshev (MVUE) UCL
2 - 2.5	<25	99% Chebyshev (MVUE) UCL
	25 - 70	95% Chebyshev (MVUE) UCL
2.5 - 3.0	<30	99% Chebyshev (MVUE) UCL
	30 - <70	95% Chebyshev (MVUE) UCL

UCLs for Other Specific Distribution Types

Methods for computing UCLs on the mean of other types of distributions have appeared in the statistical literature. For example, Johnson (1978) describe a method for computing the UCL for asymmetrical distributions such as the exponential. Schulz and Griffin (1999) described Wong's (1993) method for obtaining confidence limits on the mean of a gamma distribution. In general, if there are arguments that suggest a population of concentrations should fit a particular distribution shape, and if statistical testing confirms the expected shape reasonably conforms with available data, then the UCL computed by a method developed specifically for the distribution shape, if one exists, is likely to be appropriate for the data set. An analyst should consider using a distribution-specific method if possible because it is likely to produce more valid statistical results. The advice and support of a statistician may be invaluable in such cases, both for characterizing the distribution and for identifying and evaluating possible ways to derive confidence limits.

4.2 UCL Calculation With Nonparametric or Distribution-free Methods

There are also distribution-free approaches to computing UCLs on the mean that do not make specific assumptions about the shape of the underlying distribution of concentrations. While these methods assume the samples are representative of the underlying distribution of concentrations, they require no assumptions about the shape of that distribution and are applicable to a variety of situations. Although parametric statistical methods that depend on a distributional assumption are usually more efficient and powerful than nonparametric methods, it can be difficult to justify their use through empirical testing of the shape of the distribution. In such cases, one of the following nonparametric, or distribution-free techniques are often preferred. For information on how to account for non-detects, see the earlier discussion under "Data Evaluation" above.

Central Limit Theorem (Adjusted)

If sample size is sufficiently large, the Central Limit Theorem (CLT) implies that the mean will be normally distributed, no matter how complex the underlying distribution of concentrations might be. This is the case even if the underlying distribution is strongly skewed, has outliers, or is a mixture of different populations, so long as it is stationary (not changing over time), has finite variance, and the samples are collected independently and randomly. However, the theorem does not say how many samples are sufficient for normality to hold. When sample size is moderate or small the means will not generally be normally distributed, and this non-normality is intensified by the skewness of the underlying distribution. Chen (1995) suggested an approach that accounts for positive skewness. Singh et al. (1997) and EPA (2000c) call this approach the "adjusted CLT" method. They suggest it is an appropriate alternative to the distribution-specific Land's method even if the distribution is lognormal when the standard deviation is less than one and sample size is larger than 100. Exhibit 8 describes the steps for this method, and Exhibit 9 gives a numerical example.

Exhibit 8: Directions for Computing UCL Using the Central Limit Theorem (Adjusted)

Let $X_1, X_2, \ldots, X_n$ represent the n randomly sampled concentrations.

STEP 1: Compute the sample mean $\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$.

STEP 2: Compute the sample standard deviation $s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2}$.

STEP 3: Compute the sample skewness $\beta = \frac{n}{(n-1)(n-2)}\sum_{i=1}^{n}\left(\frac{x_i - \bar{x}}{s}\right)^3$. This can be calculated in Microsoft® Excel with the SKEW function.

STEP 4: Let z_α be the $(1-\alpha)^{th}$ quantile of the standard normal distribution. For the 95% confidence level, $z_\alpha = 1.645$.

STEP 5: Compute the one-sided $(1-\alpha)$ upper confidence limit on the mean

$$UCL_{1-\alpha} = \overline{X} + \left(z_\alpha + \frac{\beta}{6\sqrt{n}}\left(1 + 2z_\alpha^2\right)\right)s/\sqrt{n} .$$

Exhibit 9: Example UCL Computation Based on the Central Limit Theorem (Adjusted)

60 samples were collected at random from an exposure unit. The values observed are 35, 111, 105, 27, 25, 20, 17, 21, 32, 32, 23, 17, 35, 32, 29, 25, 97, 20, 26, 18, 17, 18, 26, 25, 16, 28, 29, 28, 21, 119, 23, 98, 20, 21, 24, 21, 22, 117, 27, 25, 22, 21, 26, 24, 33, 33, 21, 24, 30, 31, 23, 30, 28, 25, 22, 23, 25, 28, 26, and 107 mg/L. Filliben's test shows that this distribution is significantly different (at the 1% level) from both a normal and a lognormal distribution. The UCL based on the Central Limit Theorem is computed as follows.

STEP 1: The sample mean of the *n*=60 values is $\overline{X} = 34.57$.

STEP 2: The sample standard deviation of the values is $s = 27.33$.

STEP 3: The sample skewness β = 2.366.

STEP 4: The z statistic is 1.645.

STEP 5: The one-sided 95% upper confidence limit on the mean is

$$UCL_{95\%} = 34.57 + \left(1.645 + \frac{2.366}{6\sqrt{60}}\left(1 + 2\times 1.645^2\right)\right)27.33/\sqrt{60} = 42$$

Caveats about this method. A sample size of 30 is sometimes prescribed as sufficient for using an approach based on the Central Limit Theorem, but when using this CLT or adjusted CLT method and the data are skewed (as many concentration data sets are), larger samples may be needed to approximate normality. EPA's ProUCL User's Guide (2001) suggests that a sample size of 100 or more may be needed, based on Monte Carlo studies by EPA (2000c).

Bootstrap Resampling

Bootstrap procedures (Efron 1982) are robust nonparametric statistical methods that can be used to construct approximate confidence limits for the population mean. In these procedures, repeated samples of size *n* are drawn with replacement from a given set of observations. The process is repeated a large number of times (e.g., thousands), and each time an estimate of the desired unknown parameter (e.g., the sample mean) is computed. There are different variations of the bootstrap procedure available. One of these, the bootstrap *t* procedure, is described in the ProUCL User's Guide (EPA 2001a). An elaborated bootstrap procedure that takes bias and skewness into account is described in Exhibit 10 (Hall 1988 and 1992; Manly 1997; Schulz and Griffin 1999; Zhou and Gao 2000).

Caveats about resampling. Bootstrap procedures assume only that the sample data are representative of the underlying population. However, since they involve extensive resampling of the data and, thus, exploit more of the information in a sample, that sample must be a statistically accurate characterization of the underlying population in all respects (not just in its mean and standard deviation). In practice, it is random sampling that satisfies the representativeness assumption. Therefore the data must be random samples of the underlying population. Bootstrapping procedures are inappropriate for use with data that were idiosyncratically collected or focused especially on contamination hot spots.

Exhibit 10: Steps for Calculating a Hall's Bootstrap Estimate of UCL

Let $X_1, X_2, \ldots, X_n$ represent the *n* randomly sampled concentrations.

STEP 1: Compute the sample mean $\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$.

STEP 2: Compute the sample standard deviation $s = \sqrt{\frac{1}{n}\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2}$.

STEP 3: Compute the sample skewness $k = \frac{1}{ns^3}\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^3$.

STEP 4: For $b = 1$ to B (a very large number) do the following:
4.1: Generate a bootstrap sample data set; i.e., for $i = 1$ to n let j be a random integer between 1 and n and add observation X_j to the bootstrap sample data set.
4.2: Compute the arithmetic mean $\overline{X}_b$ of the data set constructed in step 4.1.
4.3: Compute the associated standard deviation s_b of the constructed data set.
4.4: Compute the skewness k_b of the constructed data using the formula in Step 3.
4.5: Compute the studentized mean $W = (\overline{X}_b - \overline{X}) / s_b$.
4.6: Compute Hall's statistic $Q = W + k_b W^2/3 + k_b{}^2 W^3/27 + k_b/(6n)$.

STEP 5: Sort all the Q values computed in Step 4 and select the lower α^{th} quantile of these B values. It is the $(\alpha B)^{th}$ value in an ascending list of Q's. This value is from the *left* tail of the distribution.

STEP 6: Compute $W(Q) = \frac{3}{k}\left(\left(1 + k\left(Q_\alpha - \frac{k}{6n}\right)\right)^{1/3} - 1\right)$.

STEP 7: Compute the one-sided (1-α) confidence limit on the mean.

$$UCL_{1-\alpha} = \overline{X} - W(Q_\alpha)s$$

Exhibit 11: An Example Computation of Bootstrap Estimate of UCL

Using the same concentration values given in Exhibit 4, the UCL can also be computed based on the Bootstrap Resampling method.

STEP 1: The sample mean of the n =31 values is $\overline{X}$= 9.59.

STEP 2: The standard deviation (using n as divisor) of the values is s = 8.946.

STEP 3: The skewness k = 1.648.

The Pascal-language software shown in Appendix B estimates the UCL with 100,000 bootstrap iterations. The one-sided 95% UCL on the mean is 13.3. Because this value depends on random deviates, it can vary slightly on recalculation.

Jackknife Procedure

Like bootstrap, the jackknife technique is a robust procedure based on resampling (Tukey 1977). In this procedure repeated samples are drawn from a given set of observations by omitting each observation in turn, yielding n data sets of size n-1. An estimate of the desired unknown parameter (e.g., sample mean) is then computed for each sample. When the standard estimators are used for the mean and standard deviation, this procedure reduces to the UCL based on Student's t. However, when other estimators (such as MVUE) are used this jackknife procedure does not reduce to the UCL based on Student's t. Singh et al. (1997) suggest that this method could be used with other estimators for the population mean and standard deviation to yield UCLs that may be appropriate for a variety of distributions.

Chebyshev Inequality Method

As described previously, Singh et al. (1997) and EPA (2000c) suggested the use of the Chebyshev inequality to estimate UCLs which should be appropriate for a variety of distributions as long as the skewness is not very large. The one-sided version of the Chebyshev inequality (Allen 1990, page 79; Savage 1961, page 216) is appropriate in this context (cf. Singh et al. 1997, EPA 2000c). It can be applied to the sample mean to obtain a distribution-free estimate of the UCL for the population mean when the population variance or standard deviation are known. In practice, however, these values are not known and must be estimated from data. Singh et al. (1997) and EPA (2000c) suggest that the population mean and standard deviation can be estimated by the sample mean and sample standard deviation. This approach is described in Exhibit 12 and is available in the ProUCL software tool (EPA 2001a). A numerical illustration of the Chebyshev inequality method using the sample mean and standard deviation appears in Exhibit 13.

Caveats about the Chebyshev method. Although the Chebyshev inequality method makes no distributional assumptions, it does assume that the parametric standard deviation of the underlying distribution is known. As Singh et al. (1997) acknowledge, when this parameter must be estimated from data, the estimate of the UCL is not guaranteed to be larger than the true mean with the prescribed frequency implied by the α level. In fact, using only an estimate of the standard deviation can substantially underestimate the UCL when the variance or skewness is large, especially for small sample sizes. In such cases, a Chebyshev UCL with a higher confidence coefficient such as 0.99 may be used, according to Singh, et al.

Exhibit 12: Steps for Computing UCL Based on the Chebyshev Inequality — Nonparametric

Let $X_1, X_2, \ldots, X_n$ represent the n randomly sampled concentrations.

STEP 1: Compute the arithmetic mean of the data $\overline{X} = \frac{1}{n}\sum_{i=1}^{n} X_i$.

STEP 2: Compute the sample standard deviation $s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}\left(X_i - \overline{X}\right)^2}$.

STEP 3: Compute the one-sided (1-α) upper confidence limit on the mean

$$UCL_{1-\alpha} = \overline{X} + \sqrt{\frac{1}{\alpha} - 1}\,(s / \sqrt{n})$$

Exhibit 13: An Example Computation of UCL Based on Chebyshev Inequality — Nonparametric

Using the same concentration values given in Exhibit 4 and used in Exhibit 11, the UCL on the mean can also be computed based on the Chebyshev inequality.

STEP 1: The sample mean of the n=31 values is $\overline{X}$= 9.59.

STEP 2: The sample standard deviation of the values is s = 9.094

STEP 3: The one-sided 95% upper confidence limit on the mean is therefore

$$UCL_{95\%} = 9.59 + 4.3589 \times 9.094 / \sqrt{31} = 16.7$$

5.0 OPTIONAL USE OF MAXIMUM OBSERVED CONCENTRATION

Because some of the methods outlined above (particularly the Land method) can produce very high estimates of the UCL, EPA (1992) allows the maximum observed concentration to be used as the exposure point concentration rather than the calculated UCL in cases where the UCL exceeds the maximum concentration.

It is important to note, however, that defaulting to the maximum observed concentration may not be protective when sample sizes are very small because the observed maximum may be smaller than the population mean. Thus, it is important to collect sufficient samples in accordance with the DQOs for a site. The use of the maximum as the default exposure point concentration is reasonable only when the data samples have been collected at random from the exposure unit and the sample size is large.

6.0 UCLs AND THE RISK ASSESSMENT

Risk assessors are encouraged to use the most appropriate estimate for the EPC given the available data. The flow chart in Figure 1 provides general guidelines for selecting a UCL calculation method. Exhibit 14 summarizes the methods described in this guidance, including their applicability, advantages and disadvantages. While the methods identified in this guidance may be useful in many situations, they will probably not be appropriate for all hazardous waste sites. Moreover, other methods not specifically described in this guidance may be most appropriate for particular sites. The EPA risk assessor and, potentially, a trained statistician should be involved in the decision of which method(s) to use.

When presenting UCL estimates, the risk assessor should identify:

- how the shape of the underlying distribution was identified (or, if it was not identified, what methods were used in trying to identify it),
- the chosen UCL method,
- reasons that this UCL method is appropriate for the site data, and
- assumptions inherent in the UCL method.

It may also be appropriate to include information such as advantages and disadvantages of the distribution-fitting method, advantages and disadvantages of the UCL method, and how the risk characterization would change if other assumptions were used.

Exhibit 14
Summary of UCL Calculation Methods

Method	Applicability	Advantages	Disadvantages	Reference
For Normal or Lognormal Distributions				
Student's *t*	means normally distributed, samples random	simple, robust if *n* is large	distribution of means must be normal	Gilbert 1987; EPA 1992
Land's *H*	lognormal data, small variance, large *n*, samples random	good coverage[1]	sensitive to deviations from lognormality, produces very high values for large variance or small *n*	Gilbert 1987; EPA 1992
Chebyshev Inequality (MVUE)	skewness and variance small or moderate, samples random	often smaller than Land	may need to resort to higher confidence levels for adequate coverage	Singh et al. 1997
Wong	gamma distribution	second order accuracy[2]	requires numerical solution of an improper integral	Schulz and Griffin 1999; Wong 1993
Nonparametric/Distribution-free Methods				
Central Limit Theorem - Adjusted	large *n*, samples random	simple, robust	sample size may not be sufficient	Gilbert 1987; Singh et al. 1997
Bootstrap t Resampling	sampling is random and representative	useful when distribution cannot be identified	inadequate coverage for some distributions; computationally intensive	Singh et al. 1997; Efron 1982
Hall's Bootstrap Procedure	sampling is random and representative	useful when distribution cannot be identified; takes bias and skewness into account	inadequate coverage for some distributions; computationally intensive	Hall 1988; Hall 1992; Manly 1997; Schultz and Griffin 1999
Jackknife Procedure	sampling is random and representative	useful when distribution cannot be identified	inadequate coverage for some distributions; computationally intensive	Singh et al. 1997
Chebyshev Inequality	skewness and variance small or moderate, samples random	useful when distribution cannot be identified	inappropriate for small sample sizes when skewness or variance is large	Singh et al. 1997; EPA 2000c

[1] Coverage refers to whether a UCL method performs in accordance with its definition.
[2] As opposed to maximum likelihood estimation, which offers first order accuracy.

7.0 PROBABILISTIC RISK ASSESSMENT

The estimates of the UCL described in this guidance can be used as point estimates for the EPC in deterministic risk assessments. In probabilistic risk assessments, a more complete characterization of the underlying distribution of concentrations may be important as well. Risk assessors should consult *Risk Assessment Guidance for Superfund, Volume 3 - Part A, Process for Conducting a Probabilistic Risk Assessment* (EPA 2001b) for specific guidance with respect to probabilistic risk assessments.

8.0 CLEANUP GOALS

Cleanup goals are commonly derived using the risk estimates established during the risk assessment. Often, a cleanup goal directly proportional to the EPC will be used, based on the relationship between the site risk and the target risk as defined in the National Contingency Plan. In such cases, the attainment of the cleanup goal should be measured with consideration of the method by which the EPC was derived. For more details, see *Surface Soil Cleanup Strategies for Hazardous Waste Sites* (EPA, to be published).

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Appendix A: Using Bounding Methods to Account for Non-detects

This appendix presents an iterative procedure that can be used to account for non-detects in data when estimating a UCL. It provides a step-by-step approach for computing an upper bound on the UCL using the "Solver" feature in Microsoft ® Excel spreadsheets.

STEP 1. Enter all the detected values in a column.

STEP 2. At the bottom of the same column, append as place holders as many copies of the formula

=RAND( )**DL*□

as there were non-detects. In these formulas, *DL* should be replaced by the detection limit.

STEP 3. Copy all the cells you have entered in steps 1 and 2 to a second column.

STEP 4. In another cell, enter the formula for the UCL that you wish to use. For instance, to use the 95% UCL based on Student's *t*, enter the formula

=AVERAGE(*range*)+TINV((1-0.95)*2, *n*-1)*SQRT(VAR(range)/n)

where *range* denotes the array of cell references in the second column you just created and *n*□ denotes the number of measurements (both detected values and non-detects).

STEP 5. From the Excel menu, select Tools / Solver.

STEP 6. In the "Solver Parameters" dialog box, specify the cell in which you entered the UCL formula as the Target Cell.

STEP 7. To find the upper bound of the UCL click on the Max indicator; to find the lower bound of the UCL click on the Min indicator.

STEP 8. Enter references to the cells containing the place holders for the non-detects in the field under the label "By Changing Cells." (Do not click the "Guess" button.)

STEP 9. For each cell that represents a non-detect, add a constraint specifying that the cell is to be greater than or equal to (">=") the detection limit *DL*.

STEP 10. Click on the Options button and check the box labeled "Assume Non-Negative."

STEP 11. Then click OK and then the Solver button. The program will automatically locate a local extreme value (i.e., maximum or minimum) for the UCL.

STEP 12. Record this value. You can use the Save Scenario button and Excel's scenario manager to do this.

STEP 13. Again copy all the detected values and randomized place holders for the non-detects from the first column to the same spot in the second column.

STEP 14. Select Tools / Solver and click the Solve button.

STEP 15. If calculating the upper bound, record the resulting value of the UCL if it is larger than previously computed. If calculating the lower bound, record the resulting value of the UCL if it is smaller than previously computed.

STEP 16. Repeat steps 13 through 15 to search for the global maximum or minimum value for the UCL.

Appendix B: Computer Code for Computing a UCL with the Hall's Bootstrap Sampling Method

This appendix presents Pascal code that can be used to compute the bootstrap estimate of a UCL. To use it, place data in the vector *x*. Then specify the sample size *n*, the vector *x* and the alpha-level, and call the procedure bootstrap. When the procedure finishes, the estimated value will be in the variable UCL. To obtain a 95% UCL, let alpha be 0.05. Up to 100 data values and up to 10,000 bootstrap iterations are supported, but these limits may be changed.

```
const
  max = 100;
  bmax = 10000;

type
  index = 1..max;
  bindex = 1..bmax;
  float = extended;{could just be real}
  vector = array[index] of float;
  bvector = array[bindex] of float;

var
  qq : bvector;

function getmean(n : integer; x : vector) : float;
  var s : float; i : integer;
  begin
  s := 0.0;
  for i := 1 to n do s := s + x[i];
  getmean := s / n;
  end;

function getstddev(n:integer; xbar:float; x:vector) : float;
  var s : float; i : integer;
  begin
  s := 0.0;
  for i := 1 to n do s := s + (x[i] - xbar) * (x[i] - xbar);
  getstddev := sqrt(s / n); {not n-1}
  end;

function getskew(n:integer; xbar:float; stddev:float; x:vector) :
float;
  var s,s3 : float; i : integer;
  begin
  s := 0.0;
  s3 := stddev * stddev * stddev;
  for i:=1 to n do s:=s+(x[i]-xbar)*(x[i]-xbar)*(x[i]-xbar)/s3;
  getskew := s / n;
  end;

procedure qsort(var a: bvector; lo,hi: integer);
  procedure sort(l,r: integer);
  var i,j : integer; x,y: float;
  begin
  i:=l; j:=r; x:=a[(l+r) div 2];
  repeat
    while a[i]<x do i:=i+1;
    while x<a[j] do j:=j-1;
    if i<=j then
      begin
      y:=a[i]; a[i]:=a[j]; a[j]:=y;
      i:=i+1; j:=j-1;
      end;
```

```
    until i>j;
  if l<j then sort(l,j);
  if i<r then sort(i,r);
  end;
  begin {qsort}
  sort(lo,hi);
  end;

procedure bootsample(n : integer; x : vector; var y : vector);
  var i,j : integer;
  begin
  for i := 1 to n do
    begin
    j := random(n) + 1;
    y[i] := x[j];
    end;
  end;

procedure bootstrap(n:integer; x:vector; alpha:float; var
ucl:float);
{let alpha be 0.05 to compute a 95% UCL}
var
  i,b,bb : integer;
  xbar, stddev, skew, bxbar, bstddev, bskew, k, w, q, a : float;
  bx : vector;
begin
bb := bmax;
for b:=1 to bmax do qq[b] := 0.0;
xbar := getmean(n,x);
stddev := getstddev(n,xbar,x);
skew := getskew(n,xbar,stddev,x);
for b := 1 to bb do
  begin
  bootsample(n,x,bx);
  bxbar := getmean(n,bx);
  bstddev := getstddev(n,bxbar,bx);
  k := getskew(n,bxbar,bstddev,bx);
  w := (bxbar - xbar) / bstddev;
  q := w + skew * w*w / 3 + k*k * w*w*w / 27 + k / (6 * n);
  qq[b] := q;
  end;
qsort(qq,1,bb);
q := qq[round(alpha * bb)];
a := 1 + skew * (q-skew / (6 * n));
if a = 0.0 then w := -3 / skew
          else w := (3 / skew) * (exp((1/3) * ln(a)) - 1);
ucl := xbar - w * stddev;
end;
```

“Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual, Supplemental Guidance ‘Standard Default Exposure Factors’”
OSWER Directive 9285.6-03

PB91-921314

OSWER DIRECTIVE: 9285.6-03

March 25, 1991

RISK ASSESSMENT GUIDANCE FOR SUPERFUND

VOLUME I: HUMAN HEALTH EVALUATION MANUAL

SUPPLEMENTAL GUIDANCE

"STANDARD DEFAULT EXPOSURE FACTORS"

INTERIM FINAL

Office of Emergency and Remedial Response
Toxics Integration Branch
U.S. Environmental Protection Agency
Washington, D.C. 20460
(202)475-9486

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 25 1991

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER Directive 9285.6-03

MEMORANDUM

SUBJECT: Human Health Evaluation Manual, Supplemental Guidance: "Standard Default Exposure Factors"

FROM: Timothy Fields, Jr., Acting Director
Office of Emergency and Remedial Response

Bruce Diamond, Director
Office of Waste Programs Enforcement

TO: Director, Waste Management Division,
Regions I, IV, V, & VII
Director, Emergency & Remedial Response Division,
Region II
Director, Hazardous Waste Management Division,
Regions III, VI, VIII, & IX
Director, Hazardous Waste Division,
Region X

Purpose

The purpose of this directive is to transmit the Interim Final Standard Exposure Factors guidance to be used in the remedial investigation and feasibility study process. This guidance supplements the Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A that was issued October 13, 1989.

Background

An intra-agency workgroup was formed in March 1990 to address concerns regarding inconsistencies among the exposure assumptions used in Superfund risk assessments. Its efforts resulted in a June 29, 1990, draft document entitled "Standard Exposure Assumptions". The draft was circulated to both technical and management staff across EPA Regional Offices and within Headquarters. It was also discussed at two EPA-sponsored meetings in the Washington, D.C., area. The attached interim final document reflects the comments received as well as the results of recent literature reviews addressing inhalation rates, soil ingestion rates and exposure frequency estimates.

Objective

This guidance has been developed to reduce unwarranted variability in the exposure assumptions used by Regional Superfund staff to characterize exposures to human populations in the baseline risk assessment.

Implementation

This guidance supplements the Risk Assessment Guidance for Superfund (RAGS): Human Health Evaluation Manual, Part A. Where numerical values differ from those presented in Part A, the factors presented in this guidance supersede those presented in Part A.

This guidance is being distributed as an additional interim final guidance in the RAGS series. As new data become available and the results of EPA-sponsored research projects are finalized, this guidance will be modified accordingly. We strongly urge Regional risk assessors to contact the Toxics Integration Branch of the Office of Emergency and Remedial Response (FTS 475-9486) with any suggestions for further improvement; as we will begin updating and consolidating the series of RAGS documents in 1992.

Attachment

cc: Regional Branch Chiefs
Regional Section Chiefs
Regional Toxics Integration Coordinators
Workgroup Members

* * * * NOTICE * * * *

The policies set out in this document are not final Agency action, but are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on an analysis of site-specific circumstances. The Agency also reserves the right to modify this guidance at any time without public notice.

* * * * * * * *

ACKNOWLEDGEMENTS

This guidance was developed by the Toxics Integration Branch (TIB) of EPA's Office of Emergency and Remedial Response, Hazardous Site Evaluation Division. Janine Dinan of TIB provided overall project management and technical coordination in the later stages of its development under the direction of Bruce Means, Chief of TIB's Health Effects Program.

TIB would like to acknowledge the efforts of the interagency work group chaired by Anne Sergeant of EPA's Exposure Assessment Group in the Office of Health and Environmental Assessment. Workgroup members, listed below, and Regional staff provided valuable input regarding the content and scope of the guidance.

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TABLE OF CONTENTS

1.0 INTRODUCTION

The Risk Assessment Guidance for Superfund (RAGS) has been divided into several parts. Part A, of the Human Health Evaluation Manual (HHEM; U.S. EPA, 1989a), is the guidance for preparing baseline human health risk assessments at Superfund sites. Part B, now in draft form, will provide guidance on calculating risk-based clean-up goals. Part C, still in the early stages of development, will address the risks associated with various remedial actions.

The processes outlined in these guidance manuals are a positive step toward achieving national consistency in evaluating site risks and setting goals for site clean-up. However, the potential for inconsistency across Regions and among sites still remains; both in estimating contaminant concentrations in environmental media and in describing characteristics and behaviors of the exposed populations.

Separate guidance on calculating contaminant concentrations is currently being developed in response to a number of inquiries from both inside and outside the Agency. The best method for calculating the reasonable maximum exposure (RME) concentration for different media has been subject to a variety of interpretations and is considered an important area where further guidance is needed.

This supplemental guidance attempts to reduce unwarranted variability in the exposure assumptions used to characterize potentially exposed populations in the baseline risk assessment. This guidance builds on the technical concepts discussed in HHEM Part A and should be used in conjunction with Part A. However, where exposure factors differ, values presented in this guidance supersede those presented in HHEM Part A.

Inconsistencies among exposure assumptions can arise from different sources: 1) where risk assessors use factors derived from site-specific data; 2) where assessors must use their best professional judgement to choose from a range of factors published in the open literature; and 3) where assessors must make assumptions (and choose values) based on extremely limited data. Part A encourages the use of site-specific data so that risks can be evaluated on a case-by-case basis. This supplemental guidance has been developed to encourage a consistent approach to assessing exposures when there is a lack of site-specific data or consensus on which parameter value to choose, given a range of possibilities. Accordingly, the exposure factors presented in this document are generally considered most appropriate and should be used in baseline risk assessments unless alternate or site-specific values can be clearly justified by supporting data.

Supporting data for many of the parameters presented in this guidance can be found in the Exposure Factors Handbook (EFH; U.S. EPA, 1990). In cases where parameter values are not available in EFH, this guidance adopts well-quantified or widely-accepted data from the open literature. Finally, for factors where there is a great deal of uncertainty, a rationally-derived, conservative estimate is developed and explained. As new data become available, this guidance will be modified to reflect them.

These standard factors are intended to be used for calculating reasonable maximum exposure (RME) estimates for each applicable scenario at a site. Readers are reminded that the goal of RME is to combine upper-bound and mid-range exposure factors in the following equation so that the result represents an exposure scenario that is both protective and reasonable; not the worst possible case:

$$\text{Intake} = \frac{C \times IR \times EF \times ED}{BW \times AT}$$

C = Concentration of the chemical in each medium (conservative estimate of the media average contacted over the exposure period)

IR = Intake/Contact Rate (upper-bound value)

EF = Exposure Frequency (upper-bound value)

ED = Exposure Duration (upper-bound value)

BW = Body Weight (average value)

AT = Averaging Time (equal to exposure duration for non-carcinogens and 70 years for carcinogens)

Please note that the Agency is presently evaluating methods for calculating conservative exposure estimates, such as RME, in terms of which parameters should be upper-bound or mid-range values. If warranted, this guidance will be modified accordingly.

1.1 BACKGROUND

An intra-agency workgroup was formed at the Superfund Health Risk Assessment meeting in Albuquerque, New Mexico (February 26 - March 1, 1990). Its efforts resulted in a June 29, 1990, draft document entitled “Standard Exposure Assumptions”. The draft was distributed to Superfund Regional Branch Chiefs, and members of other programs within the Agency, for their review and comment. It was also presented and discussed at two EPA/OERR sponsored meetings. The meetings, facilitated by Clean Sites, Inc., brought members of the "Superfund community" and the Agency together to focus on technical issues in risk assessment.

A final review draft was distributed on December 5, 1990, which reflected earlier comments received as well as the results of more recent literature reviews addressing inhalation rates, Soi1 ingestion rates and exposure frequency estimates (these being areas commented on most frequently).

1.2 PRESENT AND FUTURE LAND USE CONSIDERATIONS

The exposure scenarios, presented in this document, and their corresponding assumptions have been developed within the context of the following land use classifications: residential, commercial/industrial, agricultural or recreational. Unfortunately, it is not always easy to determine actual land use or predict future use: local zoning may not adequately describe land use; and unanticipated or even planned rezoning actions can be difficult to assess. Also, the definition of these zones can differ substantially from region to region. Thus, for the purposes of this document, the following definitions are used:

Residential

Residential exposure scenarios and assumptions should be used whenever there are or may be occupied residences on or adjacent to the site. Under this land use, residents are expected to be in frequent, repeated contact with contaminated media. The contamination may be on the site itself or may have migrated from it. The assumptions in this case account for daily exposure over the long term and generally result in the highest potential exposures and risk.

Commercial/Industrial

Under this type of land use, workers are exposed to contaminants within a commercial area or industrial site. These scenarios apply to those individuals who work on or near the site. Under this land use, workers are expected to be routinely exposed to contaminated media. Exposure may be lower than that under the residential scenarios, because it is generally assumed that exposure is limited to 8 hours a day for 250 days per year.

Agricultural

These scenarios address exposure to people who live on the property (i.e., the farm family) and agricultural workers. Assumptions made for worker exposures under the commercial/industrial land use may not be applicable to agricultural workers due to differences in workday length, seasonal changes in work habits, and whether migrant workers are employed in the affected area. Finally, the farm family scenario should be evaluated only if it is known that such families reside in the area.

Recreational

This land use addresses exposure to people who spend a limited amount of time at or near a site while playing, fishing, hunting, hiking, or engaging in other outdoor activities. This includes what is often described as the 'Trespasser" or "site visitor" scenario. Because not all sites provide the same opportunities, recreational scenarios must be developed on a site-specific basis. Frequently, the community surrounding the site can be an excellent source of information regarding the current and potential recreational use of a site. The RPM/risk assessor is encouraged to consult with local groups to collect this type of information.

In the case of trespassers, current exposures are likely to be higher at inactive sites than at active sites because there is generally little supervision of abandoned facilities. At most active sites, security patrols and normal maintenance of barriers such as fences tend to limit (if not entirely prevent) trespassing. When modeling potential future exposures in the baseline risk assessment, however, existing fences should not be considered a deterrent to future site access.

Recreational exposure should account for hunting and fishing seasons where appropriate, but should not disregard local reports of species taken illegally. Other activities should also be scaled according to the amount of time they could actually occur; for children and teenagers, the length of the school year can provide a helpful limit when evaluating the frequency and duration of certain outdoor exposures.

2.0 RESIDENTIAL

Scenarios for this land use should be evaluated whenever there are homes on or near the site, or when residential development is reasonably expected in the future. In determining the potential for future residential land use, the RPM should consider: historical land use; suitability for residential development; local zoning; and land use trends. Exposure pathways evaluated under this scenario routinely include, but may not be limited to: ingestion of potable water; incidental ingestion of soil and dust; inhalation of contaminated air; and, where appropriate, consumption of home grown produce.

2.1 Ingestion of Potable Water

This pathway assumes that adult residents consume 2 liters of water per day, 350 days per year, for 30 years.

The value of 2 liters per day for drinking water is currently used by the Office of Water in setting drinking water standards. It was originally used by the military to calculate tank truck requirements. In addition, 2 liters happens to be quite close to the 90th percentile for drinking water ingestion (U.S. EPA, 1990), and is comparable to the 8 glasses of water per day historically recommended by health authorities.

The exposure frequency (EF) of 365 days/year for the residential setting used in RAGS Part A has been argued both inside and outside of the Agency as being too conservative for RME estimates. National travel data were reviewed to determine if an accurate number of “days spent at home” could be calculated. Unfortunately, conclusions could not be drawn from the available literature; as it presents data on the duration of trips taken for pleasure, but not the frequency of such trips (OECD, 1989; Goeldner and Duea, 1984; National Travel Survey, 1982-89). However, the Superfund program is committed to moving away from values that represent the "worst possible case". Thus, until better data become available, the common assumption that workers take two weeks of vacation per year can be used to support a value of 15 days per year spent away from home (i.e., 350 days/year spent at home).

In terms of exposure duration (ED), the resident is assumed to live in the same home for 30 years. In the EFH, this value is presented as the 90th-percentile for time spent at one residence. (Please note that in the intake equation, averaging time (AT) for exposure to non-carcinogenic compounds is always equal to ED; whereas, for carcinogens a

70 year AT is still used in order to compare to Agency slope factors typically based on that value).

2.2 Incidental ingestion of Soil and Dust

The combined soil and dust ingestion rates used in this document were presented in OSWER Directive 9850.4 (U.S. EPA, 1989b), which specifies 200 mg per day for children aged 1 thru 6 (6 years of exposure) and 100 mg per day for others. These factors account for ingestion of both outdoor soil and indoor dust and are believed to represent upper-bound values for soil and dust ingestion (Calabrese, et al., 1989; Calabrese, et al., 1990a,b; Davis, et al., 1990; Van Wijnen, et al., 1990). Presently, there is no widely accepted method for determining the relative contribution of each medium (i.e., soil vs. dust) to these daily totals, and the effect of climatic variations (e.g., snow cover) on these values has yet to be determined. Thus, a constant, year round exposure is assumed (i.e., 350 days/year).

Please note that the equation for calculating a 30-year residential exposure to soil/dust is divided into two parts. First, a six-year exposure duration is evaluated for young children which accounts for the period of highest soil ingestion (200 mg/day) and lowest body weight (15 kg). Second, a 24-year exposure duration is assessed for older children and adults by using a lower soil ingestion rate (100 mg/day) and an adult body weight (70 kg).

2.3 Inhalation of Contaminated Air

In response to a number of comments, the RME inhalation rate for adults of 30 m^3/day (presented in HHEM Part A) was re-evaluated. Activity-specific inhalation rates were combined with time-use/activity level data to derive daily inhalation rate values (see Attachment A). Our evaluation focused on the following population subgroups who would be expected to spend the majority of their time at home: housewives; service and household workers; retired people; and unemployed workers (U.S. EPA, 1985). An inhalation rate of 20 m^3/day was found to represent a reasonable upper-bound value for adults in these groups. This value was derived by combining inhalation rates for indoor and outdoor activities in the residential setting. This rate would be used in conjunction with ambient air levels measured at or downwind of the site. Although sampling data are preferred, procedures described in Hwang and Falco (1986) and Cowherd, et al. (1985) can be used to estimate volatile and dust-bound contaminant concentrations, respectively.

In cases where the residential water supply is contaminated with volatiles, the assessor needs to consider the potential for exposure during household water use (e.g., cooking, laundry, bathing and showering). Using the same time-use/activity level data described above, a total of 15 m^3/day was found to represent a reasonable upper-bound inhalation rate for daily, indoor, residential activities. Methods for modeling volatilization of contaminants in the household (including the shower) are currently being developed by J.B. Andelman and U.S. EPA's Exposure Assessment Group. Assessors should contact the Superfund Health Risk Assessment Technical Support Center for help with site-specific evaluations (FTS-684-7300).

2.4 Consumption of Home Grown Produce

This pathway need not be evaluated for all sites. It may only be relevant for a small number of compounds (e.g., some inorganic and pesticides) and should be evaluated when the assessor has site-specific information to support this as a pathway of concern for the residential setting.

The EFH presents figures for "typical" consumption of fruit (140 g/day) and vegetables (200 g/day) with the "reasonable worst case" proportion of produce that is homegrown as 30 and 40 percent, respectively. This corresponds to values of 42 g/day for consumption of homegrown fruit and 80 g/day for homegrown vegetables. They are derived from data in Pao, et al. (1982) and USDA (1980). EFH also provides data on consumption of specific homegrown fruits and vegetables that may be more appropriate for site-specific evaluations. Although sampling data are much preferred, in their absence plant uptake of certain organic compounds can be estimated using the procedure described in Briggs, et al. (1982). No particular procedure is recommended for quantitatively assessing inorganic uptake at this time; however, the following table developed by Sauerbeck (1988) provides a qualitative guide for assessing heavy metal uptake into a number of plants:

Plant Uptake of Heavy Metals

High	Moderate	Low	Very Low
lettuce	onion	corn	beans
spinach	mustard	cauliflower	peas
carrot	potato	asparagus	melon
endive	radish	celery	tomatoes
cress		berries	fruit
beet and beet leaves			

2.5 Subsistence Fishing

This pathway is not expected to be relevant for most sites. In order to add subsistence fishing as a pathway of concern among the residential scenarios, onsite contamination must have impacted a water body large enough to produce a consistent supply of edible fish, and there must be evidence that area residents regularly fish in this water body (e.g., interviews with local anglers). If these criteria are met, the 95th-percentile for daily fish consumption (132 g/day) from Pao, et al. (1982) should be used to represent the ingestion rate for subsistence fishermen. This value was derived from a 3-day study of people who ate fish, other than canned, dried, or raw. An example of this consumption rate is about four 8-ounce servings per week.
This consumption rate can also be used to evaluate exposures to non-residents who may also use the water body for subsistence fishing. In this case, the exposure estimate would not be added to estimates calculated for other residential pathways, but may be included in the risk assessment as an exposure pathway for a sensitive sub-population.

For further information regarding food chain contamination the assessor is directed to the following documents:

- Methodology for Assessing Health Risks Associated with Indirect Exposures to Combustor Emissions (PB-90-187055). Available through NTIS.
- Development of Risk Assessment Methodology for Land Application and Distribution and Marketing of Municipal Sludge (EPA/600/6-89/001). Available from OHEA/Technical Information at FTS 382-7326.
- Estimating Exposure to 2,3,7,8-TCDD (EPA/600/6-88/005A). Available from OHEA/Technical Information at FTS 382-7326.

3.0 COMMERCIAL/INDUSTRIAL

Occupational scenarios should be evaluated when land use is (or is expected to be) commercial/industrial. In general, these scenarios address a 70-kg adult who is at work 5 days a week for 50 weeks per year (250 days total). The individual is assumed to work 25 years at the same location (95th-percentile; Bureau of Labor Statistics, 1990]. This scenario also considers ingestion of potable water, incidental ingestion of soil and dust, and inhalation of contaminated air.

Please note that under mixed-use zoning (e.g., apartments above storefronts), certain pathways described for the residential setting should also be evaluated.

3.1 Ingestion of Potable Water

Until data become available for this pathway, it will be assumed that half of an individual's daily water intake (1 liter out of 2) occurs at work. All water ingested is assumed to come from the contaminated drinking water source (i.e., bottled water is not considered). For site-specific-cases where workers are known to consume considerably more water (e.g., those who work outdoors in hot weather or in other high-activity/stress environments), it may be necessary to adjust this figure.

A lower ingestion rate is used in this pathway so that a more reasonable exposure estimate may be made for workers ingesting contaminated water. However, it is important to remember that remedial actions are often based on returning the contaminated aquifer to maximum beneficial use; which generally means achieving levels suitable for residential use.

3.2 Incidental Ingestion of Soil and Dust

In the occupational setting, incidental ingestion of soil and dust is highly dependent on the type of work being performed. Office workers would be expected to contact much less soil and dust than someone engaged in outdoor work such as construction or landscaping. Although no studies were found that specifically measured the amount of soil ingested by workers in the occupational setting, the one study that measured adult soil ingestion included subjects that worked outside of the home (Calabrese, et al., 1990a). Although the study had a limited number of subjects (n=6) and did not associate the findings with any particular activity pattern, it is the only study that did not rely on modeling to estimate adult soil ingestion. Thus, the Calabrese, et al. (1990a) estimate of 50 mg/day is selected as an interim default for adult ingestion of soil and dust in the "typical" workplace. Please be aware that this value may change when the results of ongoing soil ingestion studies sponsored by EPA's Exposure Assessment Group are finalized in 1991.

Attachment B presents modeled rates for adult soil ingestion that should be used to estimate exposures for certain workplace activities where much greater soil contact is anticipated, but with limited exposure frequency and/or duration.

3.3 Inhalation of Contaminated Air

As in the previous discussion regarding inhalation rates for the residential setting, specific time-use/activity level data were used to estimate inhalation rates for various occupational activities. The results indicate that 20 m^3 per 8-hour workday represents a reasonable upper-bound inhalation rate for the occupational setting (see Attachment A). Although analytical data are much preferred, procedures described in Hwang and Falco (1986) and Cowherd, et al. (1985) can be used to estimate volatile and dust-bound contaminant concentrations, respectively.

4.0 AGRICULTURAL

These land use scenarios include potential exposures for farm families living and working on the site, as well as, individuals who may only be employed as farm workers.

4.1 Farm Family Scenario

This scenario should be evaluated only if it is known or suspected that there are farm families in the area. The animal products pathway should not be used for areas zoned residential, because such regulations generally prohibit the keeping of livestock. Farm family members are assumed to have most of the same characteristics as people in the residential setting; the only difference is that consumption of homegrown produce will always be evaluated. Thus, default values for the soil ingestion, drinking water, and inhalation pathways would be the same as those in the residential setting.

4.1.1 Consumption of Homegrown Produce

The values used in evaluating this pathway are the same as those presented in Section 2.4. While it is more likely for farm families to cultivate fruits and vegetables, it is not necessarily true that they would be able to grow a sufficient variety to meet all their dietary needs and tastes. Thus, the consumption rate default values will be 42 g/day and 80 g/day for fruits and vegetables, respectively. Again, EFH presents consumption rates for specific homegrown fruits and vegetables. The assessor is reminded that the plant uptake pathway is not relevant for all contaminants and sampling of fruits and vegetables is highly recommended. However, in the absence of analytical data, plant uptake of organic chemicals can be estimated using the procedure described in Briggs, et al. (1982). No particular procedure is recommended for quantitatively assessing inorganic uptake at this time; however, the table (presented in Section 2.4) developed by Sauerbeck (1988) provides a qualitative guide for assessing heavy metal uptake into a number of plants.

4.1.2 Consumption of Animal Products

Animal products should only be addressed if it is known that local residents produce them for home consumption or are expected to do so in the future. The best way to determine which items are produced is by interviews or consultation with the local County Extension Service which usually has data on the type and quantity of local farm products.

EFH provides average ingestion rates for beef and dairy products and assumes that the farm family produces 75 percent of what it consumes from these categories. This corresponds to a "reasonable worst case" consumption rate of 75 g/day for beef and 300 g/day for dairy products. Although sampling data are much preferred, in their absence the procedure described in Travis and Arms (1988) may be used to estimate organic contaminant concentrations in beef and milk. This procedure does not provide transfer coefficients for poultry and eggs. Thus, the latter two pathways can be evaluated only if site-specific concentrations for poultry and eggs are available, or if transfer coefficients can be obtained from the literature.

Additional references addressing potential exposures from contaminated foods are listed in Section 2.0.

4.2 Farm Worker

Many farm activities, such as plowing and harrowing, can generate a great deal of dust. The risk assessor should consider the effects of observed (or expected) agricultural practices when using the fugitive dust model suggested under the residential scenario. Note that soil ingestion rate may be similar to the outdoor yardwork scenario discussed in Attachment B, although it will be necessary to modify the exposure frequency and duration to account for climate and length of employment. The local County Extension Service should be able to provide information on agricultural practices around a site. In addition, the Biological and Economic Analysis Division in the Office of Pesticide Programs maintains a database of the usual planting and harvesting dates for a number of crops in most U.S. states. This information may be very helpful for estimating times of peak exposure for farm workers, and, if needed, can be obtained through the Superfund Health Risk Assessment Technical Support Center (FTS 684-7300).

5.0 RECREATIONAL

As stated previously, sites present different opportunities for recreational activities. The RPM or risk assessor is encouraged to consult with the local community to determine whether there is or could be recreational use of the property along with the likely frequency and duration of any activities.

5.1 Consumption of Locally Caught Fish

This pathway should be evaluated when there is access to a contaminated water body large enough to produce a consistent supply of edible-sized fish over the anticipated exposure period. Although the local authorities should know if the water body is used for fishing, illegal access (trespassing) and deliberate disregard of fishing bans should not necessarily be ruled out; the risk assessor should check for evidence of these activities. If required, the scenario can be modified to account for fishing season, type of edible fish available, consumption habits, etc.

For recreational fishing, the average consumption rate of 54 g/day from Pao, et al. (1982) is used. This value is derived from a 3-day study of people who ate finfish, other than canned, dried or raw. An example of this consumption rate is about two 8-ounce servings per week. Other values presented in EFH, for consumption of recreationally caught fish, are from limited studies of fishermen on the west coast and may not be applicable to catches in other areas.

When evaluating this pathway please consider the possibility of subsistence fishing. Unlike the residential scenario, exposure estimates from this pathway would not necessarily be added to any other exposure estimates (see Section 2.5). Instead, it would be included as an estimate of exposure for a sensitive sub-population.

5.2 Additional Recreational Scenarios

A number of commentors requested standard default values for the following recreational scenarios: hunting, dirtbiking, swimming and wading. One approach to address exposure during swimming and wading is presented in HHEM Part A. The Agency is currently involved in research projects designed to estimate dermal uptake of contaminants from soil, water and sediment. Results of these studies will be used to update the swimming and wading scenarios as well as other scenarios that rely on estimates of dermal absorption. Unfortunately, lack of data and problems in estimating exposure frequencies and durations based on regional variations in climate have precluded the standardization of other recreational scenarios at this time. Additional guidance will be developed as data become available.

6.0 SUMMARY

This supplemental guidance has been developed to provide a standard set of default values for use in exposure assessments when site-specific data are lacking. These standard factors are intended to be used for calculating reasonable maximum exposure (RME) levels for each applicable land use scenario at a site.

Supporting data for many of the assumptions can be found in the Exposure Factors Handbook (EFH; U.S. EPA, 1990). When supporting information was not available in EFH, well-quantified or widely-accepted data from the open literature were adopted. Finally, for factors where there is a great deal of uncertainty, a rationally conservative estimate was developed and explained.

As new data become available, either for the factors themselves or for calculating RME, this guidance will be modified accordingly.

The following table summarizes the exposure pathways that will be evaluated on a <u>routine</u> basis for each land use, and the current default values for each exposure parameter in the standard intake equation presented below (refer to HHEM: Part A, U.S. EPA, 1989a for a more detailed discussion of each exposure parameter):

$$\text{Intake} = \frac{C \times IR \times EF \times ED}{BW \times AT}$$

c = Concentration of the chemical in each medium

IR = Intake/Contact Rate

EF = Exposure Frequency

ED = Exposure Duration

BW = Body Weight

AT = Averaging Time

SUMMARY OF STANDARD DEFAULT EXPOSURE FACTORS (1)

Land Use	Exposure Pathway (2)	Daily Intake Rate	Exposure Frequency	Exposure Duration	Body Weight
Residential					
	Ingestion of Potable Water	2 liters	350 days/year	30 years	70 kg
	Ingestion of Soil and Dust	200 mg (child) 100 mg (adult)	350 days/year	6 years 24 years	15 kg (child) 70 kg (adult)
	Inhalation of Contaminants	20 cum (total) 15 cum (indoor)	350 days/year	30 years	70 kg
Commercial/ Industrial					
	Ingestion of Potable Water	1 liter	250 days/year	25 years	70 kg
	Ingestion of Soil and Dust	50 mg	250 days/year	25 years	70 kg
	Inhalation of Contaminants	20 cum/workday	250 days/year	25 years	70 kg
Agricultural					
	Ingestion of Potable Water	2 liters	350 days/year	30 years	70 kg
	Ingestion of Soil and Dust	200 mg (child) 100 mg (adult)	350 days/year	6 years 24 years	15 kg (child) 70 kg (adult)
	Inhalation of Contaminants	20 cum (total) 15 cum (indoor)	350 days/year	30 years	70 kg
	Consumption of Homegrown Produce	42 g (fruit) 80 g (veg.)	350 days/year	30 years	70 kg
Recreational					
	Consumption of Locally Caught Fish	54 g	350 days/year	30 years	70 kg

(1) - Factors presented are those that should generally be used to assess exposures associated with a designated land use. Site-specific data may warrant deviation from these values; however, use of alternate values should be justified and documented in the risk assessment report.

(2) - Listed pathways may not be relevant for all sites and, other exposure pathways may need to be evaluated due to site conditions. Additional pathways and applicable default values are provided in the text of this guidance.

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ATTACHMENT A

ACTIVITY SPECIFIC INHALATION RATES

Background

The standard default value of 20 m^3/day has been used by EPA to represent an average daily inhalation rate for adults. According to EFH, this value was developed by the International Commission on Radiologic Protection (ICRP) to represent a daily inhalation rate for “reference man” engaged in 16 hours of “light activity” and 8 hours of “rest”. EPA (1985) reported on a similar study that indicated the average inhalation rate or a man engaged in the same activities would be closer to 13 m^3/day. EFH, in turn, reiterated the findings of ICRP and EPA (1985) then calculated a “reasonable worst case” inhalation rate of 30 m^3/day. This reasonable worst case value was used in Part A of the Human Health Evaluation Manual as the RME inhalation rate for residential exposures.

Commentors from both inside and outside the Agency expressed concerns that this value may be too conservative. Many also added their concern that exposure values calculated using this inhalation rate would not be comparable to reference doses (RfD) and cancer potency factors (ql*) values based on an inhalation rate of 20 m^3/day. Thus, the Toxics Integration Branch of Superfund (TIB) conducted a review of the literature to determine the validity of using 30 m^3/day as the RME inhalation rate for adults. Members of EPA’s Environmental Criteria Assessment Office-Research Triangle Park (A. Jarabek, 9/20/90) and the Science Advisory Board (10/26/90) have suggested that inhalation rates could be calculated using time-use/activity level data reported in the “Development of Statistical Distributions or Ranges of Standard Factors Used in Exposure Assessments” (OHEA; U.S. EPA, 1985). Thus, TIB used this data to calculate an RME inhalation rate for both the residential and occupational settings, as follows.

Methodology

- o The time-use/activity level data reported by OHEA (1985) were analyzed for each occupation subgroup;
- o The data were divided into hours spent at home vs. hours spent at the workplace (lunch hours spent outside of work and hours spent in transit were excluded);
- o The hourly data were subdivided into hours spent indoors vs. outdoors (to allow for estimating exposures to volatile contaminants during indoor use of potable water);

- The corresponding activity level was assigned to each hour and the total number of hours spent at each activity level was calculated;

- For time spent inside the home, 8 hours per day were assumed to be spent at rest; and

- The total number of hours spent at each activity level was multiplied by average inhalation rates reported in the EFH. Note: average values were used since only minimum, maximum and average values were reported. The use of maximum values would have to be considered "worst case". Values for average adults were applied to all but the housewife data (where average rates for women were applied).

The results showed that the highest weekly inhalation rate was 18.3 m^3/day for the residential setting and 18 m^3/day for the workplace. These values represent the highest among the weekly averages and were derived from coupling “worst case” activity patterns with “average“ adult inhalation rates. It was concluded from these data that 30 m^3/day may in fact be too conservative and that 20 m^3/day would be more representative of a reasonably conservative inhalation rate for total (i.e., indoor plus outdoor) exposures at home and in the workplace.

RAGS Part B will specifically model exposure to volatile organics via indoor use of potable water. Using the method described previously, it was determined that 15 m^3/day would represent a reasonably conservative inhalation rate for indoor residential exposures.

<u>ATTACHMENT B</u>

ESTIMATING ADULT SOIL INGESTION IN THE COMMERCIAL/INDUSTRIAL SETTING

Most of the available soil ingestion studies focus on children in the residential setting; however, two studies were found that address adult soil ingestion that also have application to the commercial/industrial setting (Hawley, 1985; Calabrese, et al., 1990).

Hawley (1985) used a number of assumptions for contact rates and body surface area to estimate the amount of soil and dust adults may ingest during a variety of residential activities. For indoor exposures, Hawley estimated levels based on contact with soil/dust in two different household areas, as follows: 0.5 mg/day for daily exposure in the "living space"; and 110 mg/day for cleaning dusty areas such as attics or basements. For outdoor exposures, Hawley estimated a soil ingestion rate during yardwork of 480 mg/day. The assumptions used to model exposures in the residential setting may also be applied to similar situations in the workplace. The amount of soil and dust adults contact in their houses may be similar to the amount an office or indoor maintenance worker would be expected to contact. Likewise, the amount of soil contacted by someone engaged in construction or landscaping may be more analogous to a resident doing outdoor yardwork.

Calabrese, et al. (1990) conducted a pilot study that measured adult soil ingestion at 50 mg/day. Although the study has several drawbacks (e.g., a limited number of participants and no information on the participants daily work activities), it included subjects that worked outside the home. It is also interesting to note that this measured value falls within the range Hawley (1985) estimated for adult soil ingestion during indoor activities.

From these studies, 50 mg/day was chosen as the standard default value for adult soil ingestion in the workplace. It was chosen primarily because it is a measured value but also because it falls within the range of modeled values representing two widely different indoor exposure scenarios. The 50 mg/day value is to be used in conjunction with an exposure frequency of 250 days/year and an exposure duration of 25 years. For certain outdoor activities in the commercial/industrial setting (e.g., construction or landscaping), a soil ingestion rate of 480 mg/day may be used; however, this type of work is usually short-term and is often dictated by the weather. Thus, exposure frequency would generally be less than one year and exposure duration would vary according to site-specific construction/maintenance plans.

- The corresponding activity-level was assigned to each hour and the total number of hours spent at each activity level was calculated;

- For time spent inside the home, 8 hours per day were assumed to be spent at rest; and

- The total number of hours spent at each activity level was multiplied by average inhalation rates reported in the EFH. Note: average values were used since only minimum, maximum and average values were reported. The use of maximum values would have to be considered "worst case". Values for average adults were applied to all but the housewife data (where average rates for women were applied).

The results showed that the highest weekly inhalation rate was 18.3 m^3/day for the residential setting and 18 m^3/day for the workplace. These values represent the highest among the weekly averages and were derived from coupling "worst case" activity patterns with "average" adult inhalation rates. It was concluded from these data that 30 m^3/day may in fact be too conservative and that 20 m^3/day would be more representative of a reasonably conservative inhalation rate for total (i.e., indoor plus outdoor) exposures at home and in the workplace.

RAGS Part B will specifically model exposure to volatile organics via indoor use of potable water. Using the method described previously, it was determined that 15 m^3/day would represent a reasonably conservative inhalation rate for indoor residential exposures.