Development of Remediation Goals under CERCLA

BACKGROUND: **The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 required the development of ". . . methods and criteria for determining the appropriate extent of removal, remedy, and other measures. . ." for responding to releases of hazardous pollutants and contaminants. [CERCLA Section 105(a)(3); 42 USC 4605(a)(3)] In response to that mandate, the U. S. Environmental Protection Agency (EPA) developed a formal process for the comparative evaluation of potential remedial alternatives after it has been determined that remediation is warranted. That process is elucidated in the revised National Oil and Hazardous Substances Pollution Contingency Plan (NCP).**

A central component of EPA's alternatives evaluation process is the development of remedial action objectives or remediation goals for the response action that are protective of human health and the environment. [40 CFR 300.430(e)] Numerical remediation goals (RGs) can be based on existing environmental standards or risk calculations, thus providing crucial targets for successful remedial alternatives to meet.

This Information Brief, which is one of a series of briefs addressing various CERCLA risk assessment topics, explains the requirements for development and application of preliminary RGs (PRGs), which are used for screening purposes, and final RGs, which are the remedial action objectives to be attained by the selected remedy.

STATUTE: **The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986**

REGULATION: **National Oil and Hazardous Substances Pollution Contingency Plan, Final Rule; 55 *FR* 8666, March 8, 1990; 40 CFR Part 300.**

REFERENCES:

1. ***Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals), Interim,*** **U. S. Environmental Protection Agency, Office of Emergency and Remedial Response, Publication 9285.7-01B, PB92-963333, December 1991.**

2. ***Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA, Interim Final,*** **U. S. Environmental Protection Agency, Office of Emergency and Remedial Response, OSWER Directive 9355.3-01, October 1988.**

3. ***Site Conceptual Exposure Model Builder (Beta Version).*** **U. S. Department of Energy, Office of Environmental Policy and Assistance, RCRA/CERCLA Div., EH-413. This PC software tool is accessible by logging onto the OEPA Internet site, URL http://tis-nt.eh.doe.gov/oepa/.**

4. ***Clarification of the Role of Applicable and Relevant and Appropriate Requirements in Establishing Preliminary Remediation Goals under CERCLA,*** **U. S. Environmental Protection Agency, Office of Solid Waste and Emergency Response, OSWER Directive No. 9200.4-23, August 22, 1997 (Memorandum from Timothy J. Fields, Acting Assistant Administrator).**

5. ***Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual (Part A, Interim Final),*** **U. S. Environmental Protection Agency, Office of Emergency and Remedial Response, Publication EPA/540/1-89/002, PB90-155581, December 1989.**

6. ***Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions,*** **U. S. Environmental Protection Agency, Office of Emergency and Remedial Response, OSWER Directive 9355.0-30, PB 91-921359, April 22, 1991.**

What are Remediation Goals how do they relate to Preliminary Remediation Goals?

Remedial Action Objectives or final Remediation Goals (RGs) are media-specific cleanup goals for a selected remedial action. Remediation efforts would be considered complete and no further action would be necessary upon attainment of the Remediation Goals. Preliminary remediation goals (PRGs) are the initial or proposed cleanup goals developed to provide risk reduction targets (Reference 1). PRGs are refined into RGs during the course of the Remedial Investigation/ Feasibility Study (RI/FS) process based on cost, technical feasibility, community acceptance, uncertainty in the baseline risk assessment, schedule, and other risk management considerations. In the Record of Decision (ROD) where final cleanup targets are documented, RGs may also be called "remediation levels" (Reference 1). [40 CFR 300.430(f)]

Development of RGs constitutes a core component of the development and screening of potential remedial alternatives conducted in the Feasibility Study (FS). RGs can be qualitative statements or numerical values expressed as concentrations of a chemical in an environmental medium. Achieving the RGs in the remedial action should result in residual contamination levels that are protective of human health and the environment. [40 CFR 300.430(e)(2)(i)] RGs must be properly described in order to identify a set of potentially viable remedial alternatives. This description should include: (1) contaminants of concern, (2) exposure routes and receptors, and (3) acceptable contaminant levels for each exposure route (Reference 2). Numerical RGs are generally not required or applicable for alternatives that employ containment or engineered barrier technologies.

When are and how are Preliminary Remediation Goals established?

PRGs can be established as soon as information about site risk indicates that the site poses unacceptably high risks to human health or the environment. PRGs should be developed for principal threat chemicals, i. e., those chemicals that are major contributors to unacceptable cancer risks or non-cancer hazards. PRGs can initially be formulated prior to the completion of the baseline risk assessment (i.e., in the scoping stage or concurrent with early RI activities).Based upon available site information and Applicable or Relevant and Appropriate Requirements (ARARs), PRGs can be developed for complete exposure pathways identified in the site conceptual exposure model (SCEM, Reference 3), which should be developed prior to the development of PRGs. When there are multiple pathways or contaminants present, EPA will develop risk-based PRGs. When only a single pathway or contaminant is present, EPA will establish PRGs based on ARARs. However, in a new policy directive (Reference 4) EPA states that the agency establishes ARAR-based PRGs on the assumption that an individual ARAR will be protective. The new EPA policy directive also states that in rare cases where, based on information available to EPA, the agency concludes that this assumption is not accurate, the agency may establish PRGs at levels that are more protective than required by the ARAR even at sites with a single pathway or contaminant. This means that the resulting PRGs may achieve a level of risk that is more protective than that associated with the ARAR.

As RI activities are completed, and as baseline risk assessment results become available, additional PRGs may need to be identified or developed if previously unidentified exposure pathways or contaminants of concern are identified. It should be noted that until the final remedy is selected and documented in the ROD, these PRGs, whether ARARs-based or risk-based, constitute initial guidelines, not final cleanup goals (Reference 1). [40 CFR 300.430(e)(2)(i)] Where ARARs are not available or where numerical PRGs must be developed to derive RGs, calculated values or EPA's published risk-based values have been used as PRGs. EPA Regions III and IX periodically publish PRGs as risk-based concentration tables and PRG tables, respectively.

What are the factors involved in developing Remediation Goals?

Where remediation is warranted based on the result of a baseline risk assessment or other risk management considerations, the selected remedy must be able to meet the RGs. The NCP directs selection of a remedy from potential remedial alternatives based in part on two threshold criteria: 1) overall protection of human health and the environment; and, 2) compliance with ARARs [40 CFR 300.430(e)(9)(iii)]. These criteria are also used to identify PRGs for refinement into RGs. The following factors should be considered in the development of RGs from PRGs:

- **Media of Concern** - The relevance of PRGs to the medium of concern must be evaluated. For example, if the PRG is a primary drinking water standard and the medium to be remediated is shallow perched water in discontinuous sand lenses but it is not tapped for drinking purposes, then the PRGs should not be considered to be relevant to actual groundwater use, and thus may be too stringent to be an RG.
- **Contaminants of Concern** - The RGs must address the key contaminants of concern or principal threat chemicals which contribute to the baseline risk. As such, the RGs, whether qualitative or quantitative, must identify how performance of the selected remedy will be evaluated for its success in cleanup. Numerical RGs that identify acceptable contaminant levels in the medium after remediation must be quantifiable (i.e., readily achievable and within the laboratory's practical quantitation limits).
- **Future Land Use** - The RGs should be based on the "stakeholder preferred" future land use and should not present unacceptable risks from the future exposure pathways, migration mechanisms, and exposure routes which result from these future uses.
- **Exposure Pathways and Receptors** - PRGs used to derive RGs must be based on exposure pathways that are realistic, reasonable, and complete, and receptors that have the highest exposure (as determined by the baseline risk assessment and the stakeholder-preferred future land use). If PRGs are not based on site-specific exposure information (human activity patterns, recreational exposure factors, ecological exposures factors,

etc.) they must be modified before they can become RGs.

- **Toxicity Information** - The toxicity information should be verified with the most recent data (i.e., hazard and dose-response information) available through the Integrated Risk Information System (IRIS). Toxicity values used in developing risk-based PRGs may be out of date. RGs that are derived from outdated PRGs may be overly or not adequately protective.

- **Target Risk Levels** - Numerical PRGs are typically based on the upper bound carcinogenic risk of one in a million (10^{-6}) or a hazard quotient of unity. PRGs can be proportionally adjusted upward to become RGs for a higher acceptable carcinogenic risk or hazard level to account for the conservatism inherent in the PRGs (i. e., toxicity values and exposure assumptions). Specifically, the RG can be based on a 10^{-4} cancer risk that is still within the NCP's acceptable range (10^{-4} to 10^{-6}) for carcinogenic risk. Similarly, the RG for a noncarcinogen can be several times higher than the corresponding PRG based on the uncertainty factor associated with the reference dose and exposure factors. In certain instances, RGs may have lower values than PRGs based on a downward adjustment because of many co-occurring principal threat chemicals and complete exposure pathways. RGs for protecting ecological receptors should be developed in consultation with ecological risk assessment experts like those in the EPA's Regional Biological Technical Assistance Group (BTAG) and the Natural Resource Trustees.

  The carcinogenic risk level corresponds with the excess likelihood (over a lifetime) of an individual developing cancer as a result of exposure to a specific contaminant from all potential site exposure pathways. The non-cancer risk level equates with a contaminant level which would not be expected to adversely affect the exposed population, including sensitive sub-populations, if exposed over a lifetime or part of a lifetime. [40 CFR 300.430(e)(2)(i)(A)] When both a carcinogenic and a non-carcinogenic risk-based PRG are calculated for a particular chemical in a particular medium, the more health protective of the two should be used. Note, however, that these target risk levels (and the resulting numerical risk-based PRGs) do not necessarily represent realistic exposure and risk and therefore realistic or appropriate cleanup levels. The final RGs should be determined through the remedy selection process, taking risk management considerations into account.

- **Other Factors** - Other factors related to technical limitations (e.g., detection or quantification limits for specific contaminants) as well as factors such as community acceptance, cost, schedule, etc. should be considered when developing RGs.
  [40 CFR 300.430(e)(2)(i)(A)]

How does development of Remediation Goals for radionuclides differ from chemical contaminants?

Earlier it was mentioned that a recent EPA policy directive (Reference 4) states that in rare cases where, based on information available to the EPA, the agency concludes that an individual ARAR is not sufficiently protective, the agency may establish PRGs at levels that are more protective than required by the ARAR even at sites with a single pathway or contaminant. The EPA policy directive states that EPA headquarters has determined that sites with radioactive contamination are examples of sites at which the more protective policy on PRG development may be implemented. This means that a resulting radionuclide PRG may achieve a level of risk that is more protective than that associated with a radionuclide ARAR.

Risk-based PRGs and RGs for radionuclides are derived in essentially the same manner as for chemical contaminants except for the following (References 1 and 5). First, input quantities for radionuclides are expressed in terms of activity (e.g., picocuries), not mass. Second, only the carcinogenic effects of radionuclides are considered (because they emit ionizing radiation, radionuclides are considered Class A carcinogens, and their health risks are usually associated with this radiotoxicity rather than their chemical toxicity). Third, slope factors for radionuclides provided by IRIS or Health Effects Assessment Summary Tables already internalize consideration of such factors as potential absorption into the body, retention in body organs, etc. Therefore, radionuclide slope factors are not expressed as a function of body weight or time, and do not require corrections for lung transfer efficiency or gastrointestinal absorption.

Do all contaminant remediation goals affect remedial implementation equally?

No. Some contaminants may be responsible for much of the overall risk identified in the baseline risk assessment, or may be harder to treat than others. Selecting a remedial alternative that will achieve the goals for such "limiting chemicals" may result in cleaning up other contaminants to levels more protective than their individual goals (Reference 1). [40 CFR 300.430(e)(2)(i)(A)(3)]

Where and how are final cleanup levels documented?

Chemical-specific remediation levels, and the corresponding reduced risk levels to be attained upon completion of the selected remedial alternative, should be documented in tabular form in the Decision Summary section of the ROD as chemical-specific remediation levels or qualitative definition of the risk-reduction cleanup objective to be achieved for non-numerical RGs (Reference 6). In addition, the basis for these values (e.g., risk or ARARs) also should be identified. That table should include such information for all affected media addressed in the ROD. [40 CFR 300.430(f)(5)]

Questions of policy or questions requiring policy decisions will not be dealt with in EH-413 Information Briefs unless that policy has already been established through appropriate documentation. Please refer any questions concerning the subject material covered in this Information Brief to John Bascietto, RCRA/CERCLA Division, EH-413, (202) 586-7917, or john.bascietto@eh.doe.gov.