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Cumulative Risk in CERCLA Generically and a Hanford Model

Presentation to the
Hanford Advisory Board –
River and Plateau Committee
October 12, 2011

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Cumulative Risk Assessment Program

http://www.epa.gov/spc/2cumrisk.htm

The public is exposed to multiple contaminants from a variety of sources, and tools are needed to understand the resulting combined risks. The ***Framework for Cumulative Risk Assessment*** represents an important milestone for EPA in expanding our focus from an individual chemical-based approach to a community or population-based approach for multiple stressors. (web page dated Jan 25, 2011)

Framework for Cumulative Risk Assessment
EPA/630/P-02/001F. May 2003 Page 4

Cumulative risk: The combined risks from aggregate exposures to multiple agents or stressors.

Aggregate exposure: The combined exposure of an individual (or defined population) to a specific agent or stressor via relevant routes, pathways, and sources.

Aggregate risk: The risk resulting from aggregate exposure to a single agent or stressor.

Framework for Cumulative Risk Assessment
EPA/630/P-02/001F. May 2003 Page 7

First, cumulative risk involves multiple agents or stressors
Second, there is no limitation that the "agents or stressors" be only chemicals... may also be biological or physical agents or even the absence of a necessity such as habitat
Third, risks from multiple agents or stressors be combined. This does not necessarily mean that they be "added," but rather that some analysis should be conducted on if and how the effects or risks from the various agents or stressors interact.

Framework for Cumulative Risk Assessment
EPA/630/P-02/001F. May 2003 Page 10 (Summary box)

Cumulative Risk Assessment Features

Although many different types of exposures, stressors and other factors can be included, the definition of cumulative risk might be better understood by contrasting the featured and optional considerations. The following features are included:

- Multiple stressors.
- Consideration of how the stressors act together rather than individually.
- Population-focused assessment. Although this does not mean that the assessment must start with a population and work "backwards" toward the source, it does mean that the population needs to be defined, and multiple stressors are assessed with regard to impact on that population, although not every individual will see the same (or all) effects.

Additional layers of complexity, such as those listed below, may or may not be addressed:

- Multiple durations, pathways, sources, or routes of exposure.
- Multiple effects or impacts.
- Nonconventional stressors or risk factors (e.g., lifestyle, access to health care). These in general need continued research.
- Quantification of risks.

Framework for Cumulative Risk Assessment
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Example of Cumulative Risk Assessment Scope

Human health risks for a specific neighborhood associated with exposure via all routes to all pollutants present or being released from a set of adjacent sources, including several industries, two hazardous waste sites, traffic, and a municipal landfill.

The Toxicity of Poisons Applied Jointly
Annals of Applied Biology Volume 26, Issue 3,
pages 585–615, August **1939**

combined action can be classified into one of three types:
(1) The first type is that in which the constituents act independently and diversely...
toxicity of any combination can be predicted from that of the isolated components
(2) The second type of joint action is that in which the constituents act independently but similarly
(3) Synergism forms the third type of joint action, characterized by a toxicity greater than that predicted from studies on the isolated constituents

http://www.epa.gov/oswer/riskassessment/

Within EPA's waste and cleanup programs, risk assessment informs regulatory and program decisions to protect human health and the environment from the risks of contamination and chemical accidents. The National Academy of Sciences Risk Assessment Paradigm forms the basis for risk assessment within EPA's waste and cleanup programs. Existing policy, evolving research, and risk assessment advances converge to inform risk management decisions. Each of EPA's waste and cleanup programs - **Superfund**, solid waste, chemical accident prevention, underground storage tanks - has **adapted and reshaped this paradigm to fit their particular regulatory mandates**. (web page dated Jan 22, 2010)

40 CFR Section 300.430(e)(9)(iii)

Overall protection of human health and the environment
Compliance with ARARs
Long-term effectiveness and permanence
Reduction of toxicity, mobility, or volume through treatment
Short-term effectiveness
Implementability
Cost
State acceptance
Community acceptance

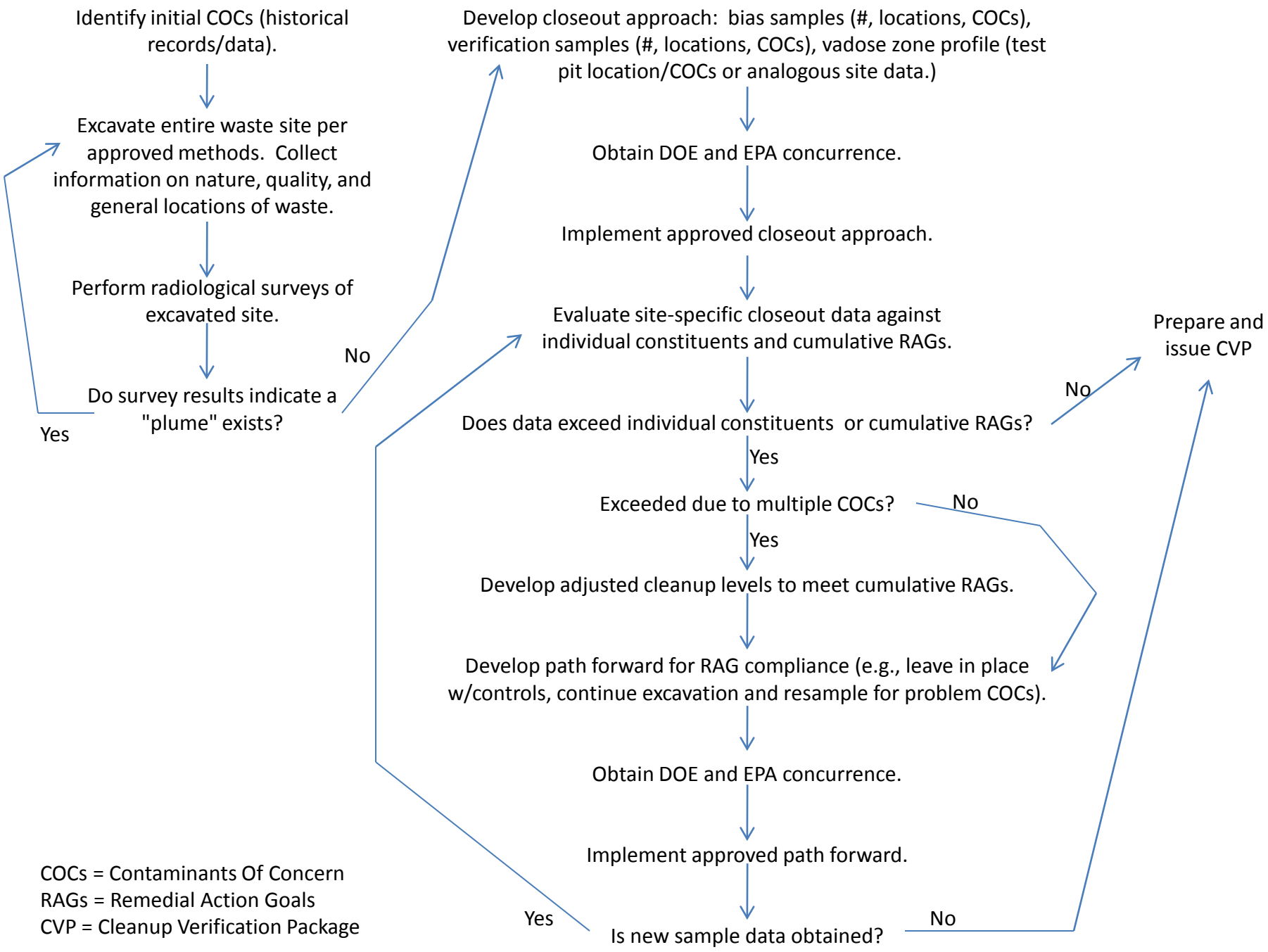
http://www.epa.gov/superfund/health/contaminants/radiation/radarars.htm
EPA Radiation Guidance for CERCLA: Cleanup Levels and ARARs

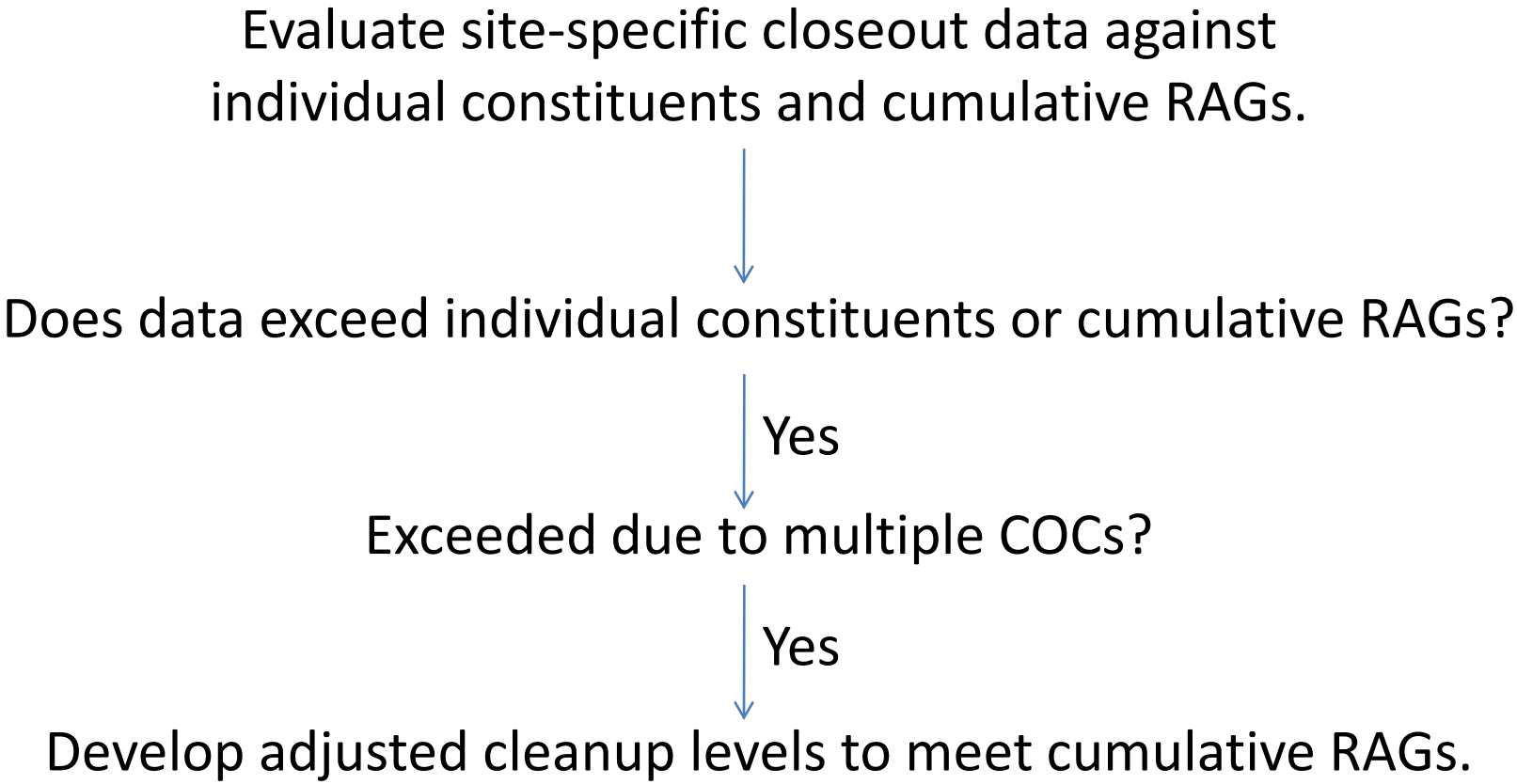
An Examination of EPA Risk Assessment Principles and Practices
2004. EPA 100/B-04/001 Page 22
http://www.epa.gov/OSA/pdfs/ratf-final.pdf

EPA typically cannot protect every individual but rather attempts to protect individuals who represent high-end exposures (typically around the 90th percentile and above) or those who have some underlying biological sensitivity; in doing so, EPA protects the rest of the population as well. In general, EPA tries to protect sensitive individuals based on normal distribution of sensitivities. EPA considers the most sensitive individuals where there are data, but does not necessarily attempt to protect “hypersensitive” individuals. The degree to which sensitive individuals are protected, or explicitly defined, may vary between programs based on factors such as the need to balance risk reductions and costs as directed and constrained by statutory authority.

An Examination of EPA Risk Assessment Principles and Practices
2004. EPA 100/B-04/001 Page 101
Whom Does the Superfund Program Seek To Protect?
The Reasonable Maximum Exposure Scenario

One of the policy goals of the Superfund program is to protect a high-end, but not worst-case, individual exposure: the reasonable maximum exposure (RME). The RME is the highest exposure that is reasonably expected to occur at a Superfund site. As described in the preamble to the NCP, the RME will "result in an overall exposure estimate that is conservative but within a realistic range of exposure. Under this policy, EPA defines “reasonable maximum” such that only potential exposures that are likely to occur will be included in the assessment of exposures. The Superfund program has always designed its remedies to be protective of all individuals and environmental receptors that may be exposed at a site; consequently, EPA believes it is important to include all reasonably expected exposures in its risk assessments. In addition to evaluating the risks to the RME individual, EPA evaluates risks for the central tendency exposure (CTE) estimate, or average exposed individual. This approach is consistent with the Risk Characterization Policy and Handbook. CTE estimates give the risk manager additional information to consider while making decisions.


Identify initial COCs (historical records/data).
Excavate entire waste site per approved methods. Collect information on nature, quality, and general locations of waste.
Perform radiological surveys of excavated site.
Do survey results indicate a "plume" exists?
No
Yes
Develop closeout approach: bias samples (#, locations, COCs), verification samples (#, locations, COCs), vadose zone profile (test pit location/COCs or analogous site data.)
Obtain DOE and EPA concurrence.
Implement approved closeout approach.
Evaluate site-specific closeout data against individual constituents and cumulative RAGs.
Does data exceed individual constituents or cumulative RAGs?
No
Prepare and issue CVP
Yes
Exceeded due to multiple COCs?
No
Yes
Develop adjusted cleanup levels to meet cumulative RAGs.
Develop path forward for RAG compliance (e.g., leave in place w/controls, continue excavation and resample for problem COCs).
Obtain DOE and EPA concurrence.
Implement approved path forward.
Yes
Is new sample data obtained?
No
COCs = Contaminants Of Concern
RAGs = Remedial Action Goals
CVP = Cleanup Verification Package


Evaluate site-specific closeout data against individual constituents and cumulative RAGs.
Does data exceed individual constituents or cumulative RAGs?
Yes
Exceeded due to multiple COCs?
Yes
Develop adjusted cleanup levels to meet cumulative RAGs.

Example: CVP for UPR-300-46

WASTE SITE RECLASSIFICATION FORM
Reclassified to “Interim Closed Out”
[Classification options are "Closed Out" "Interim Closed Out"
"No Action" "RCRA Post closure" "Rejected" "Consolidated“]

Basis for reclassification

Verification sampling for the UPR-300-46 waste site was performed on January 6, 2010. Evaluation of the analytical results found that residual contaminant concentrations are protective of human health, groundwater, and the Columbia River. In accordance with this evaluation, the verification sampling results support a reclassification of this site to Interim Closed Out. The current site conditions achieve the remedial action goals established by the 300-FF-2 ROD. The results of verification sampling show that residual contaminant concentrations meet cleanup standards for industrial land use and also do not preclude any future uses (as bounded by the rural-residential scenario), allowing for unrestricted use of shallow zone soils (i.e., surface to 4.6 m [15 ft] deep). The results also show that contaminant levels remaining in the soil are protective of groundwater and the Columbia River. Site contamination did not extend into the deep zone soils; therefore, institutional controls to prevent uncontrolled drilling or excavation into the deep zone are not required. The basis for reclassification is described in detail in the Cleanup Verification Package for the 300-109, 333 Building Stormwater Runoff and UPR-300-46, Contamination North of 333 Building.

Example: CVP for UPR-300-46

Regulatory Requirement	Remedial Action Goals	Results	RAOs Attained?
Direct Exposure Radionuclides	Attain 15 mrem/yr dose rate above background over 1,000 years.	Maximum dose rates from sum of fractions evaluations for the decision units using individual radionuclide dose-equivalent lookup values are <15 mrem/yr. The maximum dose rate for UPR-300-46 is 0.4515 mrem/yr, for 300-109 is 0.24 mrem/yr, and for the waste staging pile areais 0.435 mrem/yr.	Yes
Direct Exposure Nonradionuclides	Attain individual COPC RAGs.	All individual COPC concentrations are below the direct exposure RAGs.	Yes

Example: CVP for UPR-300-46

Regulatory Requirement	Remedial Action Goals	Results	RAOs Attained?
Risk Requirements - Nonradionuclides	Attain a hazard quotient of <1 for all individual noncarcinogens	All individual hazards quotients are <1.	Yes
Risk Requirements - Nonradionuclides	Attain a cumulative hazard quotient of <1 for noncarcinogens.	The cumulative hazard quotient 0.0028 is < 1.	Yes
Risk Requirements - Nonradionuclides	Attain an excess cancer risk of <1x10-6 for individual carcinogens.	The excess cancer risk for each individual carcinogenic contaminant detected above background levels is <1 x 10-6.	Yes
Risk Requirements - Nonradionuclides	Attain a total excess cancer risk of <1 x 10-5 for carcinogens.	The total excess cancer risk value (4.6 x 10-9) is <1 x 10-5.	Yes

Example: CVP for UPR-300-46

Regulatory Requirement	Remedial Action Goals	Results	RAOs Attained?
Groundwater/river Protection - Radionuclides	Attain single COPC groundwater and river protection RAGs.	No radionuclide COPCs were quantified above groundwater/river protection lookup values.	Yes
Groundwater/river Protection - Radionuclides	Attain national primary drinking water regulations: 4 mrem/yr (beta/gamma) dose rate to target receptor/organs.	No radionuclide COPCs were quantified above groundwater/river protection lookup values.	Yes
Groundwater/river Protection - Radionuclides	Meet drinking water standards for alpha emitters: the more stringent of 15 pCi/L MCL or 1/25th of the derived concentration guide from DOE Order 5400.5	No alpha-emitting radionuclide COPCs were quantified above groundwater/river protection lookup values.	Yes
Groundwater/river Protection - Radionuclides	Meet total uranium standard of 21.2 pCi/L	Uranium was quantified below levels that are protective of 300 Area groundwater.	Yes

Example: CVP for UPR-300-46

Regulatory Requirement	Remedial Action Goals	Results	RAOs Attained?
Groundwater/river Protection - Nonradionuclides	Attain individual nonradionuclide groundwater and river cleanup requirements.	Aroclor-1254 and aroclor-1260 are present at concentrations slightly above soil RAGs for groundwater and river protection. However, vertical migration modeling predicts that these constituents will not reach groundwater (and, therefore, the Columbia River) within 1,000 years. Therefore, the residual concentrations achieve the remedial action objectives for groundwater and river protection.	Yes