

Bechtel

401 West A Street
Suite 1000
San Diego, CA 92101-7905

CLEAN II Program
Bechtel Job No. 22214
Contract N68711-92-D-4670
File Code: 0217.3

IN REPLY/REFERENCE: CTO-0080/ 0083

September 20, 1995

Juan Jimenez, RPM Base Closure Branch
State of California Environmental Protection Agency
Department of Toxic Substances Control
245 West Broadway, Suite 350
Long Beach, CA 90802-4444

Subject: Submittal of Final Notes Regarding "Response to Comments Document Prepared in Conjunction with the Final Risk Assessment Work Plan, Phase II RI/FS MCAS El Toro, CA, CTO-0059."

Dear Mr. Jimenez:

I am providing this submittal of Final Notes Regarding Response to Comments on the Final Risk Assessment Work Plan. My review did not identify any fatal flaws; however, there are a few items noted which require additional clarification.

I have also attached a technical note related to the development of Remedial Action Objectives for MCAS El Toro. I suggest that the BCT increase their focus on this issue in the next few months in anticipation of work on the feasibility study.

If I can be of any further assistance please call me in Bechtel's San Diego office at (619) 687-8780.

Sincerely,



Dante J. Tedaldi, Ph.D., P.E.
Technical Quality Assurance MCAS El Toro

Attachment: Final Notes Regarding Response to Comments on the Final Risk Assessment Work Plan for MCAS El Toro.

cc: Larry Vitale, Remedial Project Manager
Joseph Joyce, BRAC Environmental Coordinator
Bonnie Arthur, RPM



Originator J.M. Paull, USEPA Region IX

General Comment-Response Number 2

For clarification, in the future, reference should be made to a rigidly defined set of exposure scenarios. In the response three *scenarios* are identified: residential, recreational, and industrial-commercial. However, the industrial-commercial *scenario* includes two *settings*: office worker and excavation worker. Later, in Specific Comment-Response 3 to J.P. Christopher of DTSC the Navy describes three *settings*: residential, industrial, and recreational.

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The objectives of site remediation need to be clearly defined to identify and assess remedial alternatives at MCAS El Toro, and ultimately to select a final remedy which is protective of human health and the environment. This is accomplished by the determination of remedial action objectives.

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Remedial Action Objectives

Remedial action objectives describe in general terms what any remedial action needs to accomplish in order to be protective of human health and the environment. They specify the contaminants and environmental media of concern, the potential exposure pathways to be addressed by remedial actions, the exposed populations and environmental receptors to be protected, and acceptable contaminant concentrations (or concentration ranges) in each environmental medium. Those acceptable exposure concentrations are known as the remediation goals. Remedial action objectives and remediation goals are described in the National Contingency Plan (NCP) (EPA, 1990; 40 CFR 300.430(e)(2)(i). See also the NCP preamble discussions at 55 Federal Register 8708 et seq.)

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Remediation goals (action levels) are subset of the remedial action objectives. They provide numerical goals for remedial actions to meet. The risk assessment process relates contaminant concentrations in environmental media with levels of human exposure and potential health risks. The NCP preamble (55 Federal Register 8709) discusses risk assessments in Superfund as follows:

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The selection of numerical remediation goals involves both risk assessment and risk management. Risk assessment is referred to as the scientific process for evaluating the nature and magnitude of threats to human health and the environment. Risk management is the decision-making process which incorporates the results of the risk assessment, technological feasibility, economic considerations, statutory requirements, public concern, and other factors to arrive at a decision on an acceptable action level, and the actions to take the mitigate risk.

The NCP (40 CFR 300.430(e)(2)(i) addresses the selection of remediation goals as follows:

"...Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following...

- (1) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;

- (2) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives....:
- (3) Factors related to technical limitations such as detection/quantification limits for contaminants:
- (4) Factors related to uncertainty; and
- (5) Other pertinent information"

EPA has described the development of remediation goals for carcinogenic contaminants, as a practical matter, as a two-step process (55 Federal Register 8717). A concentration equivalent to a lifetime cancer risk of 10^{-6} will first be established as a point of departure. Then site-specific or remedy-specific factors will be considered to determine where within the acceptable risk range the remediation goal for a given contaminant at a specific site will be established.

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Larry Vitale, Remedial Project Manager
California Regional Water Quality Control Board - Santa Ana Region
2010 Iowa Avenue, Suite 100
Riverside, CA 92507-2409

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Bechtel National, Inc. Civil and Environmental Engineers, Constructors

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Arthur, RPM
Environmental Protection Agency Region IX
Hazardous Waste Management Division, H-9-2
1400 North Street
San Francisco, CA 94105-3901

Subject: Submittal of Final Notes Regarding "Response to Comments Document Prepared in Conjunction with the Final Risk Assessment Work Plan, Phase II RI/FS MCAS El Toro, CA, CTO-0059."

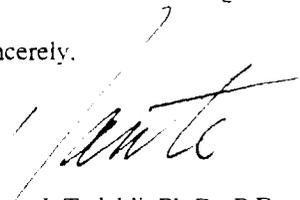
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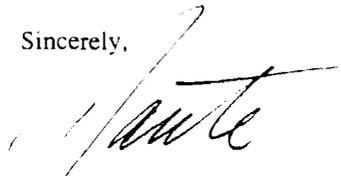
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cc: Larry Vitale, Remedial Project Manager
Juan Jimenez, RPM Base Closure Branch
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Originator **J.M. Paull, USEPA Region IX**

General Comment-Response Number 2

For clarification, in the future, reference should be made to a rigidly defined set of exposure scenarios. In the response three *scenarios* are identified: residential, recreational, and industrial-commercial. However, the industrial-commercial *scenario* includes two *settings*: office worker and excavation worker. Later, in Specific Comment-Response 3 to J.P. Christopher of DTSC the Navy describes three *settings*: residential, industrial, and recreational.

General Comment-Response 3

The response directs the reader back to General Comment-Response 1. However, Response 1 does not adequately address Comment 3. The Risk Assessment Work Plan is not the appropriate document to incorporate a response to Comment 3 regarding the development of "Target Cleanup Levels." Rather, a separate document, a Remedial Action Objectives Decision Memorandum could describe the approach for the establishment of site specific preliminary remediation goals beyond those listed in the generic PRGs.

I have included additional thoughts on this issue in the two pages which follow.

Specific Comment-Response 2

The response directs the reader back to General Comment-Response 1. Response 1 does not address Comment 2. The Navy has not yet provided the criteria for the determination of adequate support.

Originator **R. Barnett, USEPA Region IX**

General Comment-Response Number 2

Both here and the response to Specific Comment 1 indicate that at some later date technical memoranda will be prepared to address issues raised in the comments. The MCAS El Toro Federal Facility Agreement identifies the RI/FS Work Plans (which includes the Risk Assessment Work Plan) as primary documents. Technical memoranda do not have such a distinction and can be designated as secondary documents. The response to these comments, if unavailable at this time, should therefore be considered as an addendum to the Work Plan and thus a primary document component. In support of this modification, note that Specific Comment-Response 7 to J.P. Christopher of DTSC indicates that a basewide risk assessment work plan will be submitted as an addendum to the current risk assessment work plan.

In addition, the Navy should indicate in the response the reason for deferring the selection of receptors and COPECs.

Originator **J.P. Christopher, DTSC**

Specific Comment-Response Number 15

The response indicates that many details requested could not be provided because the Phase I RI screening ecological risk assessment relied heavily on literature data. The Navy should indicate if they concur with the requests in the comment and intend to incorporate the details requested at a later time.

Framework for Development of Site Specific Preliminary Remedial Action Objectives and Goals

The objectives of site remediation need to be clearly defined to identify and assess remedial alternatives at MCAS El Toro, and ultimately to select a final remedy which is protective of human health and the environment. This is accomplished by the determination of remedial action objectives.

The MCAS El Toro BCT and SWDIV should increase their attention to this critical aspect of risk assessment in the coming months and prepare for the risk management decisions which are necessary for the completion of environmental restoration activities at the base. The discussion which follows advocates a less conservative definition of action levels while remaining in conformance with the intent of the NCP. I have attempted to include adequate citations to support this position. Interestingly, at the same time however, I have been unable to identify any cleanup levels established by SWDIV which do not correspond to an excess lifetime cancer risk of greater than 10^{-6} .

Remedial Action Objectives

Remedial action objectives describe in general terms what any remedial action needs to accomplish in order to be protective of human health and the environment. They specify the contaminants and environmental media of concern, the potential exposure pathways to be addressed by remedial actions, the exposed populations and environmental receptors to be protected, and acceptable contaminant concentrations (or concentration ranges) in each environmental medium. Those acceptable exposure concentrations are known as the remediation goals. Remedial action objectives and remediation goals are described in the National Contingency Plan (NCP) (EPA, 1990; 40 CFR 300.430(e)(2)(i). See also the NCP preamble discussions at 55 Federal Register 8708 *et seq.*).

Remedial Action Goals

Remediation goals (action levels) are subset of the remedial action objectives. They provide numerical goals for remedial actions to meet. The risk assessment process relates contaminant concentrations in environmental media with levels of human exposure and potential health risks. The NCP preamble (55 Federal Register 8709) discusses risk assessments in Superfund as follows:

"...the purpose of risk assessment in the Superfund program is to provide framework for developing risk information necessary to assist decision-making at remedial sites...The results of the baseline risk assessment are used to determine whether remediation is necessary, to help provide justification for performing remedial action, and to assist in determining what exposure pathways need to be remediated...A second major objective of risk assessment in Superfund is to use the risks and exposure pathways developed in the baseline risk to target chemical concentrations associated with levels of risk that will be adequately protective of human health for a particular site (i.e., remediation goals)."

The selection of numerical remediation goals involves both risk assessment and risk management. Risk assessment is referred to as the scientific process for evaluating the nature and magnitude of threats to human health and the environment. Risk management is the decision-making process which incorporates the results of the risk assessment, technological feasibility, economic considerations, statutory requirements, public concern, and other factors to arrive at a decision on an acceptable action level, and the actions to take to mitigate risk.

The NCP (40 CFR 300.430(e)(2)(i) addresses the selection of remediation goals as follows:

"...Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following...

- (1) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;

- (2) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-7} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives...
- (3) Factors related to technical limitations such as detection/quantification limits for contaminants:
- (4) Factors related to uncertainty; and
- (5) Other pertinent information"

EPA has described the development of remediation goals for carcinogenic contaminants, as a practical matter, as a two-step process (55 Federal Register 8717). A concentration equivalent to a lifetime cancer risk of 10^{-6} will first be established as a point of departure. Then site-specific or remedy-specific factors will be considered to determine where within the acceptable risk range the remediation goal for a given contaminant at a specific site will be established.

The NCP, in the section cited above, discusses an acceptable risk range of 10^{-4} to 10^{-6} . EPA has further clarified the extent of the acceptable risk range (EPA, 1991) by stating that the upper boundary is not a discrete line at 1×10^{-4} . Risks slightly greater than 1×10^{-4} may be considered to be acceptable (i.e., protective) if justified based on site-specific conditions, including any uncertainties on the nature and extent of contamination and associated risks.

EPA has discussed the types of factors that should be considered in establishing a remediation goal within the acceptable risk range as follows (55 Federal Register 8717):

"Preliminary remediation goals for carcinogens are set at a 10^{-6} excess cancer risk as a point of departure, but may be revised to a different risk level within the acceptable risk range based on the consideration of appropriate factors including, but not limited to: exposure factors, uncertainty factors, and technical factors. Included under exposure factors are: the cumulative effect of multiple contaminants, the potential for human exposure from other pathways at the site, population sensitivities, potential impacts on environmental receptors, and cross-media impacts of alternatives. Factors related to uncertainty may include: the reliability of alternatives, the weight of scientific evidence concerning exposures and individual and cumulative health effects, and the reliability of exposure data. Technical factors may include: detection/quantification limits for contaminants, technical limitations to remediation, the ability to monitor and control movement of contaminants, and background levels of contaminants."

Final remediation goals are not determined until the selection of a final remedy for the site (40 CFR 300.430(e)(2)(i)). Preliminary remediation goals are required to establish the goals to be met by remedial alternatives in the Feasibility Study and to guide the development of a proposed plan for remedial action. Those preliminary remediation goals may be modified at the time of remedy selection based on a balancing of the major tradeoffs among the alternatives as well as on the public and agency comments on the proposed plan. Such balancing among alternatives and consideration of community acceptance will establish the specific level of protection the remedy will achieve. It must, however, achieve a level within the acceptable risk range in order to be adequately protective.

USEPA. 1990. National Contingency Plan, 40 CFR Part 300. Final Rule issued March 8, 1990, at 55 Federal Register 8666 et seq., with preamble discussion (preamble from Proposed Rule issued December 21, 1988 at 53 Federal Register 51394 et seq. incorporated by reference, except as amended in the preamble to the final rule).

USEPA. 1991. Role of Baseline Risk Assessment in Superfund Remedy Selection Decisions. OSWER Directive 9355.0-30. April 22, 1991.