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HSWA LANL 6/1/5/97

Mr. Benito Garcia, Chief
Hazardous & Radioactive Materials Bureau
New Mexico Environment Department
2044A Galisteo
P.O. Box 26110
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Dear Mr. Garcia:

Enclosed is Revision 1 of the joint Los Alamos National Laboratory (LANL) and Sandia National Laboratories/New Mexico (SNL/NM) *Risk-Based Corrective Action Process* (RBCAP). It incorporates revisions resulting from the NMED/EPA comments dated May 2, 1996, and specific concerns identified in your January 23, 1997 letter. The document has had significant contributions from the Department of Energy, Albuquerque Operations Office, the Kirtland Area Office (KAO) and the Los Alamos Area Office as well as from LANL and SNL/NM Environmental Restoration (ER) Project personnel.

In addition, the RBCAP has been updated to reflect current procedures in practice at the ER Projects at both laboratories. For example, SNL/NM has completed the screening assessment process for all of its potential release sites while the screening process is still relevant to site evaluations at LANL. As the technical approaches to surface water, ground water, and ecological risk become finalized, the approaches will be integrated into the RBCAP for both laboratories. All ~~decision~~ logic/decision process diagrams will continue to evolve to enhance ER Project efficiency and decision-making and to reflect regulatory concerns.

The RBCAP document continues to be a joint effort by the laboratories to ensure consistency, where appropriate, and facilitate coordination with NMED. Both LANL and SNL/NM believe this document is the key building block for our risk-based approaches and both laboratories are committed to ensuring that the process is followed within each of our projects. We would like to schedule a meeting with your staff as soon as possible to discuss the RBCAP and incorporation of any agreed-upon assumptions into a future Document of Understanding annex.

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If you should have any questions or require additional information, please contact Joe Mose (LAAO) at (505) 667-5808 or Beth Oms (KAO) at (505) 845-7862.

Sincerely,

Deborah D. Griswold, for

George J. Rael
Director
Environmental Restoration Division

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RISK-BASED CORRECTIVE ACTION PROCESS

Revision 1

The Environmental Restoration Projects at Los Alamos and Sandia National Laboratories

Prepared by the
Los Alamos National Laboratory
Environmental Restoration Decision Support Council
A. M. Dorries (Ed.)
August 20, 1997

LA-UR-96-2811

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LIST OF ACRONYMS

AL	Action level
ALARA	As low as reasonably achievable
AOC	Area of concern
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CMI	Corrective measures implementation
CMS	Corrective measures study
COC	Contaminant of concern
COPC	Contaminant/constituent of potential concern
COPEC	Contaminants of potential ecological concern
DOE	US Department of Energy
DOE/AL	US Department of Energy /Albuquerque Operations Office
DOU	Document of Understanding
DQO	Data quality objective
EEU	Ecological exposure unit
EM/ER	Environmental Management/Environmental Restoration Group
EPA	US Environmental Protection Agency
EQL	Estimated quantitation limit
ER	Environmental restoration
HSWA	Hazardous and Solid Waste Amendments of 1984
LANL	Los Alamos National Laboratory
MCE	Multiple chemical evaluation
NFA	No further action
NMED	New Mexico Environment Department
NPL	National Priorities List
PAH	Polyaromatic hydrocarbon
PCB	Polychlorinated biphenyl
PRS	Potential release site
RAGS	Risk Assessment Guidance for Superfund
RBCAP	Risk-Based Corrective Action Process
RCRA	Resource Conservation and Recovery Act
RESRAD	Residual radioactive material (computer code)
RFI	RCRA facility investigation
SACM	Superfund Accelerated Cleanup Model
SAL	Screening action level
SAP	Sampling and analysis plan
SSG	Soil Screening Guidelines
SNL/NM	Sandia National Laboratories, New Mexico
SWMU	Solid waste management unit
UCL	Upper confidence limit
UTL	Upper tolerance limit
VCA	Voluntary corrective action
VCM	Voluntary corrective measure

I. INTRODUCTION

The purpose of this document is to identify the risk-based assumptions and methodologies being used by Los Alamos National Laboratory (LANL) and Sandia National Laboratories, New Mexico (SNL/NM) in the implementation of the corrective action process within their Environmental Restoration (ER) Projects. The technical approach for data collection and evaluation at LANL and SNL/NM depends on a number of assumptions related to the way in which data will be used to support decision-making and risk assessment. One of the ER Project's primary roles is to design and conduct data collection activities that will be sufficient to support each decision made during the corrective action process. LANL and SNL/NM recognize that the regulators have final decision authority and will base their decisions on data generated by the Laboratories.

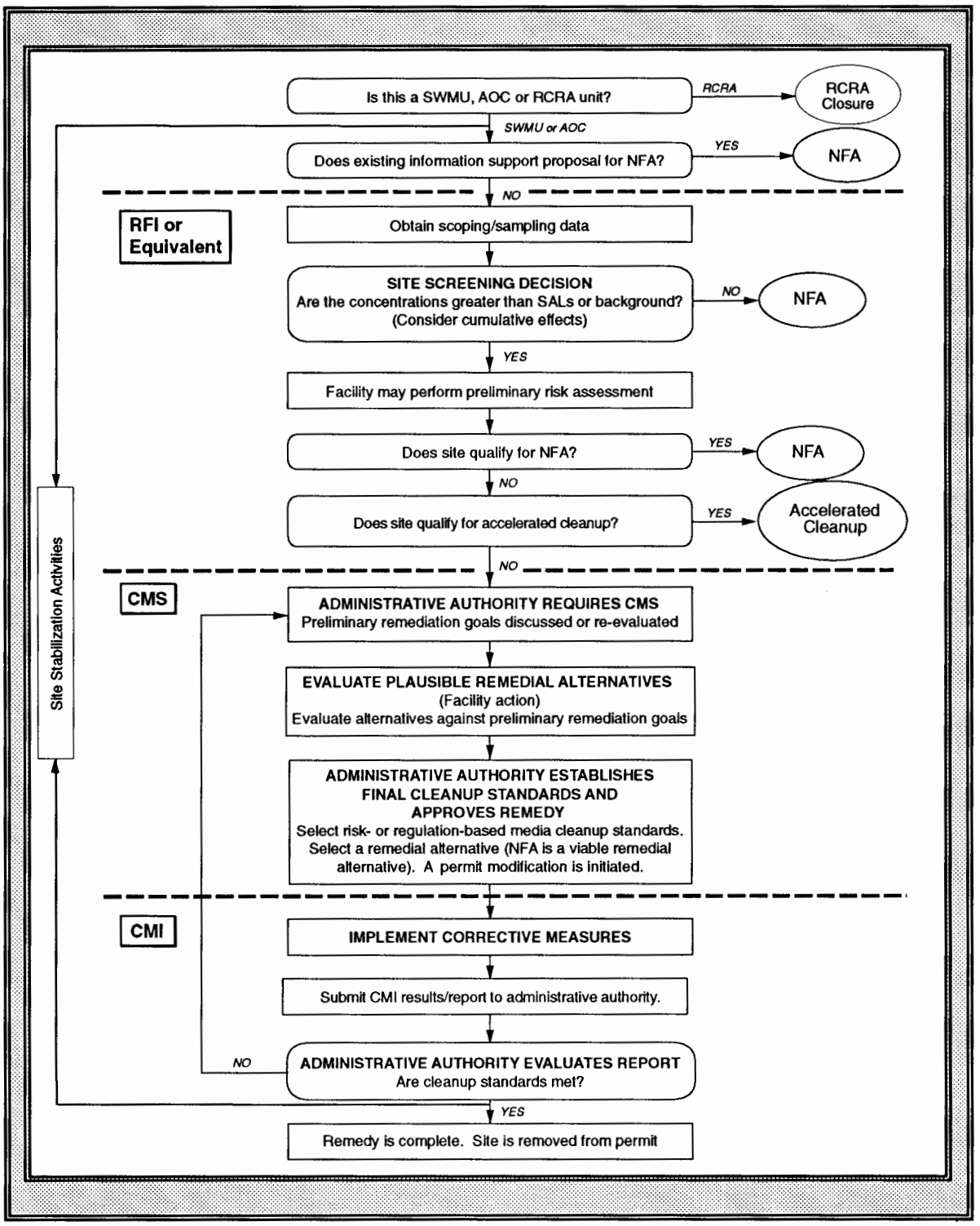
Many of the assumptions that follow in the *Risk-Based Corrective Action Process* (RBCAP) are agreed upon in the Document of Understanding (DOU) (NMED et al. 1995). Specifically, Annex B, *No Further Action (NFA) Process and Criteria*; Annex C, *Voluntary Corrective Action (VCA) Process and Criteria*; Annex E, *Land Use*; Annex F, *Cleanup Levels*; Annex G, *Sampling and Analysis Guidelines*; and Annex L, *Permit Modifications (HSWA Module)* of the DOU have information relative to RBCAP assumptions. As LANL and SNL/NM regulators concur with additional RBCAP assumptions, the agreed-upon assumptions will be formalized in future annexes of the DOU or in facility-specific documents, as necessary.

The development of agreed-upon technical assumptions and definitions of terms is necessary to make RCRA requirements fully operational in planning and implementing ER work. The technical assumptions described herein are intended to supplement and be consistent with those regulations. Although the technical approaches at LANL and SNL/NM follow the same fundamental assumptions, at times the diversified nature of the environmental settings and population characteristics of the two Laboratories dictate a divergence in approach. Throughout this document, any facility-specific approaches, assumptions or nomenclature are presented in shaded boxes.

The proposed approach for implementing the corrective action process at LANL and SNL/NM is summarized in the generic decision flow illustrated in Figure 1. The overall technical approach will be carried out within the framework of a modified DOE streamlined approach that incorporates Data Quality Objectives (DQOs) and risk assessment as well as elements of EPA's Superfund Accelerated Cleanup Model (SACM) to facilitate the rapid cleanup of those units that potentially pose risk. Both the technical approach and decision logic are tied to NMED and EPA regulations and guidance. For all sites, the ultimate objective is to achieve and document that acceptable levels of risk to human health and the environment have been reached and that no further action (NFA) is necessary. Following initial identification of a solid waste management unit (SWMU) or an area of concern (AOC), archival information is reviewed to determine if existing data will support NFA. If not, sampling and analysis plans are developed and implemented. Data obtained are screened to determine whether NFA is appropriate or potential risk-based concerns exist. If so, a preliminary risk assessment may follow to determine whether potential risks suggest NFA is appropriate, or that stabilization or accelerated cleanup should be implemented. Sites posing risks but not appropriate for stabilization or accelerated action will proceed under administrative authority to a corrective measures study (CMS). Following evaluation of preliminary remediation goals, plausible remedial alternatives are evaluated and the administrative authority establishes cleanup standards and approves a remedy. Corrective measures implementation (CMI) and the results of CMI are evaluated by the administrative authority to assure that the completed remedy supports NFA.

Figure A-1 in Appendix A shows the process the Laboratories have developed with NMED to accelerate the corrective action process when appropriate. In general, the accelerated corrective action approach is the same approach stated above and shown in Figure 1. However, the intent of the accelerated approach is to undergo the standard RFI/CMS process with minimal review, thus providing more rapid decisions.

Figure 1. LANL-SNL/NM Decision Framework for the RCRA Corrective Action Process



II. SITE SCREENING DECISION ASSUMPTIONS

i. General Assumptions

1. Sites can be proposed for NFA under the HSWA Module when sufficient archival data/ information exist(s), site characterization data is complete, or cleanup confirmation data is complete. Sufficient documentation must exist to support one or more of the five criteria listed below. These criteria were agreed upon by NMED, EPA, DOE, and the Laboratories in Annex B of the Document of Understanding (NMED et al. 1995). Upon approval from regulators, sites meeting one of the NFA criteria are removed from the HSWA Module. The same criteria are applied to sites not listed in the HSWA Module. Non-HSWA Module sites are proposed for NFA to the DOE. Upon DOE approval, the sites are removed from the total list of potential release sites (PRSs).
   - NFA Criterion 1. The site cannot be located or has been found not to exist, is a duplicate PRS, or is located within and therefore, investigated as part of another PRS.
   - NFA Criterion 2. The site has never been used for the management (that is, generation, treatment, storage, or disposal) of RCRA solid or hazardous wastes and/or constituents or other CERCLA hazardous substances.
   - NFA Criterion 3. No release to the environment has occurred, nor is likely to occur in the future.
   - NFA Criterion 4. There was a release, but the site was characterized and/or remediated under another authority which adequately addresses corrective action, and documentation, such as a closure letter, is available.
   - NFA Criterion 5. The PRS has been characterized or remediated in accordance with current applicable state or federal regulations, and the available data indicate that contaminants pose an acceptable level of risk under current and projected future land use.
2. Historical process knowledge and screening samples can be sufficient to focus the analyses of samples to those chemicals that are plausible at a site, rather than performing a full-scan analysis on all samples. However, when any degree of uncertainty is involved, a full-scan analysis may be necessary.
   - For example, where historical process information clearly shows that certain chemicals (e.g., high explosives, plutonium) were never handled at a site, analyses for these constituents need not be performed.
3. Professional judgment and/or results from field survey techniques can be used to bias the location and the number of samples needed for site characterization in order to increase the probability of detecting contaminants relative to purely random sampling approaches.

ii. Background Comparison Assumptions

4. Only constituents that exceed background concentrations are considered potential contaminants. Background data sets differ for classes of contaminants and between Laboratories. Choice of appropriate background screening values is defined for each Laboratory in the boxes below. In addition,
   - Site data are considered indistinguishable from background when:
     - Site concentrations are statistically indistinguishable from background as defined below, even if observed concentrations exceed the risk-related criteria described below in Assumption 5.

— Statistical analyses can include graphical comparisons of background and PRS data; parametric statistical procedures such as the t-test and regression analysis; and non-parametric statistical tests such as the Wilcoxon Rank Sum and Quantile tests. (Project Consistency Team [EM/ER:96-PCT-010]; Ryti et al. 1996).

- Any contaminant detected for which no background data exists will be carried to the next screening step.
- Because Laboratory-specific background data sets differ, flow charts of statistical assumptions and tests used for background comparisons have been provided to regulators by LANL and SNL separately.

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At LANL,

Background can vary from site to site and for chemical classes and is defined as follows:

—LANL-wide inorganic background is used in screening comparisons. The LANL-wide background soil concentrations of inorganics have been determined for specific soil horizons; geological strata; and sediments in the canyons (Project Consistency Team [EM/ER:96-PCT-010]; Ryti et al. 1996).

—Site data are compared to the appropriate subset unless the soil horizon is neither known nor relevant (e.g., fill of unknown origin).

—Site-specific background data may be required in cases where site data exceed both LANL-wide background and screening action levels (SALs, see next section); when ecological risk is the primary decision point; or when arsenic or beryllium are known (or suspected) to have been released at the PRS (LANL-wide concentrations of these two inorganics are known to routinely exceed SALs).

—Radionuclide background values for soil, sediment, and fill material consist of the maximum and/or upper tolerance limit (UTL) from data in regional sites published in LANL environmental surveillance reports and sediment background sample data collected by the ER Project. Uranium and thorium background values for tuff are estimated based on total uranium and thorium. (Project Consistency Team [EM/ER:96-PCT-010]; Ryti et al. 1996; Ryti et al. 1997, in preparation).

—For background comparisons, contaminant values are the maximum reported values for PRS radionuclide data sets. For inorganics, the calculated 95th percentile (95% confidence) UTL for the best-fit normal, lognormal, or square root-transformed normal distribution is used when sufficient data are available to estimate a distribution. If data are insufficient, the maximum reported value is used for inorganics. UTLs are checked for consistency within the appropriate data group to ensure that inflated values are not used.

At SNL/NM,

—Site-specific contaminant concentrations (usually the maximum value obtained) are compared to background screening values as defined below. If all potential chemical of concern (COC) values are below their respective background screening values, the site is deemed suitable for an NFA proposal. Otherwise, all potential COCs are carried into the next screening step, with the exception of lead. Lead is compared to the EPA guidance screening for lead (EPA 1994).

—SNL/NM has a facility-wide background study data set approved by the NMED (IT 1996). The facility wide background study has a list of background screening values based on either the 95th UTL or percentiles, as applicable, of the populations analyzed.

—Site-specific background values may be used to compliment the site-wide background study or be used exclusively in areas where site-wide background values do not apply or exist.

iii. Screening Assumptions

5. A screening assessment is performed to evaluate potential soil contaminants. The facility specific screening processes for LANL and SNL/NM are presented below. The basic concept for screening is similar between the facilities. Because SNL/NM has fewer potential release sites, the screening process has been completed at that facility.
   - At LANL, SALs are used as action levels. At SNL/NM, the functional equivalent of the SAL is the action level (AL).
   - SALs/ALs are used to identify chemicals of potential concern (COPCs) and determine the need for further investigation.
   - SALs are not used as target risk levels or cleanup standards unless supported by site-specific risk calculations.
   - A target dose[1] level is used to derive SALs/ALs for radioactive constituents. SALs/ALs for radioactive constituents are calculated using RESRAD.
     - — Standard residential default exposure values are used in radionuclide models for body weight, intake rate, etc.
     - — Dose is summed over multiple pathways, e.g., external irradiation, dust inhalation, and produce ingestion are considered as well as direct soil ingestion.
     - — Environmental parameters required by radionuclide models are set conservatively, but appropriately, for each Laboratory.
   - In general, the maximum observed concentration, rather than an average of several observations, is compared with SALs/ALs in order to identify COPCs. SAL/AL comparisons are based on measured concentrations, unadjusted for natural or anthropogenic (e.g., atmospheric fallout) background.
     - — In some cases (with prior approval from regulators), observations made on composite samples, or averages of closely related samples such as field duplicates, may be compared with SALs/ALs to identify COPCs.
     - — SALs are based on exposure to contaminants in surface soils.

At LANL,

- Screening action levels (SALs) are used to identify chemicals of potential concern (COPCs) and determine the need for further investigation. Analytes that exceed background require further action if they also exceed SALs or if the analyte contributes significantly to the multiple chemical evaluation (MCE).
- SALs for chemical constituents are based on EPA Region IX preliminary remediation goals for residential soil. These values are based on risk at 10^{-6} and HI <1.
  - —As required and when sufficient toxicity data are available in the peer-reviewed literature, LANL ER Decision Support Council personnel will calculate SALs for chemicals not included in the Region IX database. SALs are calculated using Region IX default parameters for the residential scenario. The scenario includes the ingestion pathway, the inhalation pathway, and dermal contact. When toxicity data are not available, surrogate chemicals will be chosen to evaluate toxicity.
  - —For PCBs, a SAL of 1 ppm will be used for field screening at industrial sites. (EPA 1994: Section [a][3][ii]). A SAL of 0.1 ppm will be used at residential sites.
- The dose level selected to calculate radionuclide SALs is 10 mrem/yr, based on it being a fraction of the DOE's annual effective dose rate of 100 mrem/yr from all sources. DOE also requires that doses to the public exceeding 10 mrem/yr at DOE facilities be reported to DOE Headquarters (DOE 5400.5, Ch. II, Section 7). Therefore, further investigation of sites exceeding 10 mrem/yr is consistent with regulatory guidance and appropriate as a screening dose level for an area such as LANL where residential land use is frequently possible.

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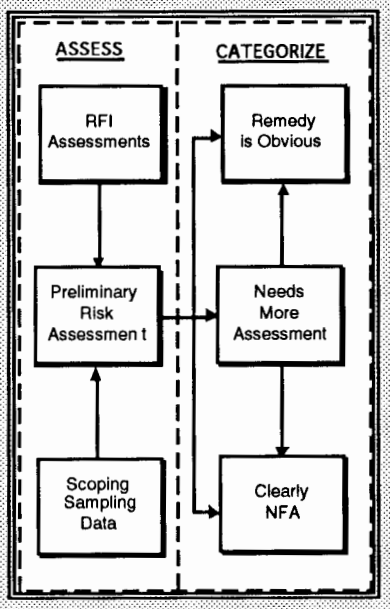
[1] Dose is defined as the effective dose equivalent as incurred by exposure of an individual to external radiation and to internal radiation from inhalation or ingestion of radionuclides.

At SNL/NM,
The SNL/NM ER Project has already completed its screening process. As can be seen in the figure below, sites were categorized based on scoping assessments and early RFA/RFI data. A preliminary risk evaluation was conducted to determine the likely outcome of the sites (e.g., needs remediation, likely candidate for NFA). The preliminary risk evaluations were performed with probalistic techniques (Monte Carlo) in order to assess uncertainty and predict the likely range of possible risks posed by a site. If the site posed no risk, an NFA proposal was prepared. Sometimes this included confirmatory sampling to demonstrate compliance (see Assumption 1). If the site posed a significant threat, a remedy selection process was initiated (see accelerated cleanup discussion under Assumption 8). If the preliminary risk evaluation showed that the outcome was uncertain (i.e., not clearly an NFA or remediation), additional assessment activities were planned. Following the assessment activities, another risk evaluation was or will be made to ascertain whether an NFA proposal is likely or a cleanup action is warranted.



6. Multiple contaminants below SALs/ALs may together require further evaluation due to the potential for additive or synergistic toxic effects. EPA Region IX PRGs do not address potential interactions. EPA soil screening guidelines (SSG) suggest that interactions among carcinogens are unlikely to result in an excess risk greater than 10^{-4} if screened individually to a 10^{-6}-based action level, and, therefore, recommend no additional MCE for carcinogens. For non-carcinogens, the SSG recommends interactions be considered only for contaminants having the same target organ (EPA 1996a). As a screening tool, the procedure described below is seen as consistent with and more protective than these guidelines.
   - Constituents that exceed background, but are below SALs/ALs, are screened for potential additivity by summing the normalized maximum observed concentration (maximum concentration divided by respective SAL/AL) for all constituents in this group within a given PRS or PRS aggregate. This approach is conservative because it assumes simultaneous exposure to all constituents by a given receptor.
   - Multiple chemical evaluations (MCEs) are conducted separately for carcinogens, non-carcinogens, and radionuclides. Additivity is assumed within a category.
   - If the sum of the normalized maximum values (rounded to the nearest 10th) is less than 1, no further evaluation of these constituents is required.

At LANL,

- If the sum of the normalized maximum values is greater than 1, the appropriateness of the sum-of-the-maximum approach is evaluated based on professional judgment. For example, if the PRS is larger than a predicted exposure unit (.i.e., the area over which a receptor might be exposed to residual contamination), an additional evaluation such as the maximum sum of normalized values at a given sample location may also be reported to evaluate realistic exposure.
- If the results of an additional analysis (such as described in the previous bullet) also suggest that multiple chemical exposure may be of concern, then constituents will be identified as COPCs and retained for further evaluation if their individualized normalized values (i.e., the maximum or mean, for ample data sets, detected concentration divided by the SAL) are greater than or equal to 0.1. The final decision to retain a constituent as a COPC for further evaluation will also depend on other site-specific considerations and the professional judgments of the risk assessor. Constituents with normalized values less than 0.1 will be dropped from further evaluation.
- Constituents that are in more than one category (e.g., carcinogen, non-carcinogen) are typically included in the category in which they are most potent. However, when the addition of a constituent's toxicity may influence decisions in another category, it will be included in both categories. In addition, uranium is evaluated both as a radionuclide and as a noncarcinogen because these effects occur at a similar dose.
- The means of evaluating data for COPCs having concentrations less than SALs is outlined in the following table:

Detection Status	Relation Between EQLs[a] and SALs	Decision Considerations[d]	Possible Decision Actions
All non-detects	EQL > SAL[c]	Process knowledge and data for similar chemicals	COPC or elimination
All non-detects	EQL < SAL[c]	Process knowledge and data for similar chemicals	MCE[e] or elimination
Some detects[b]	EQL > SAL[c]	Process knowledge and data for similar chemicals	COPC or MCE[f]
Some detects[b]	EQL < SAL[c]	n/a	MCE[g]

a. The estimated quantitation limit (EQL) is the lowest concentration that can be reliably achieved within specified limits of precision and accuracy suring routine analytical lavoratory operating conditions.
b. Assumes none of the detects are at concentrations greater than SALs.
c. Considers the maximum reported EQL for the non-detects.
d. Process knowledge and sample data for similar chemicals are considered to determine the decision action under some scenarios. For example, under the first scenario, if process knowledge indicates that the analyte in question may be present at the site or similar analytes were detected, then this analyte may be retained as a COPC, otherwise it is eliminated from further consideration.
e. If the chemical is not eliminated from further consideration, then the value used in the MCE is the maximum reported EQL.
f. If the chemical is not retained immediately as a COPC based on the relation between EQLs and SAL, then the value used in the MCE is the maximum reported detected concentration.
g. The value used in the MCE is the maximum reported detected concentration.

At SNL/NM,

- Constituents that are both carcinogens and non-carcinogens are included in both categories in MCEs.

7. Appropriate choices of analytical chemistry methods can maximize the ability to detect constituents at or below SAL/AL concentrations.
   - SW 846 methods (when available) are used for fixed analytical laboratories unless other methods are justified.
   - Field measurement and analytic techniques are used where appropriate. If field analytical techniques are not sufficient to detect constituents at SAL/AL concentrations, EPA-approved fixed analytical laboratory methods are used.

- If the detection limit of the fixed analytical laboratory method is above the SAL/AL, and the chemical is expected to be present at the site, then the chemical will be identified as a COPC.

At LANL,
- If field measurement techniques are used to guide fixed analytical laboratory sampling locations and to support site decisions, correlation to laboratory analyticals will be statistically verified.

8. Identification of COPCs indicates only that a problem may exist.
   - Further action may take several forms, to be determined on a case-by-case basis.
     - — Further Evaluation. More in-depth analysis of available data, e.g. using site-specific exposure assumptions, or collection of additional data following screening. Results of these further evaluations could be either NFA, baseline risk assessment, CMS, or accelerated cleanup.
     - — Risk assessment. If one or more measurements at a site are found to be above SALs/ALs and background, a preliminary and/or baseline risk assessment may be used to determine if corrective action is required. Preliminary risk can be assessed using conservative assumptions and existing data. Additional data may be required for the baseline risk assessment if the current data are not adequate to support a risk assessment decision (see assumptions 10 - 17).
     - — Accelerated Cleanup. Accelerated cleanups can proceed without further evaluation and/or a baseline risk assessment under the following conditions:
       - ◊ cleanup levels are based on background concentrations, promulgated standards, or previously determined site-specific risk-based levels;
       - ◊ the remedy is obvious and can be readily applied;
       - ◊ the remedy will be a final resolution in order to prevent potential releases or future migration of contaminants from the site;
       - ◊ acceptable knowledge is available to adequately identify COPCs, e.g., previous sampling data and/or existing data are available to adequately identify COPCs;
       - ◊ adequate waste treatment, storage or disposal capacity is available (including mixed waste if applicable);
       - ◊ the remedy is not worse for the ecosystem, worker safety, or public health than the problem;
       - ◊ uncertainties can be handled by contingencies in the accelerated cleanup plan, and stopping criteria are defined; and
       - ◊ the estimated cost of remediation is expected to be less than the cost of moving forward with further data collection and/or data analysis and risk assessment.

       In the case where extent of contamination is not adequately defined, the accelerated action planning document shall include a sampling and analysis plan (SAP) that outlines the procedures for bounding extent of contamination during field operations. These procedures will consider fate and transport properties for all site contaminants. Cleanup verification SAPs will be designed to confirm the adequacy of the accelerated action.

       The regulator may require and/or the facility may request enhanced regulatory involvement in some accelerated actions. These actions are referred to as voluntary corrective measures (VCMs). Enhanced involvement by the regulator includes review and approval of the VCM plan, potential involvement of the remediation activities, and review and approval of the VCM report.

       Those accelerated actions not requiring enhanced regulatory involvement are referred to as voluntary corrective actions (VCAs). The regulator will be informed of VCA activities. See Appendix A, Figure A-1, for details of where and how the accelerated cleanup approach fits into the overall accelerated corrective action process.

— Stabilization. At any time during the RFI/CMS process, sites may be considered for stabilization if all of the following are true:

◊ sufficient information about contaminants and the environmental setting are known, but the site fails one or more specific accelerated action criteria;

◊ near-term opportunities exist for significant risk reduction, prevention of further contamination, and/or long-term cost savings;

◊ appropriate technologies are available to deal with the known contaminants;

◊ proposed action will not impede or be inconsistent with the expected approach for the final remedy;

◊ the stabilization activity is not worse than the problem for the ecosystem, worker safety, or public health; and

◊ if waste is generated, adequate waste treatment, storage, or disposal capacity is available (including mixed waste if applicable).

At LANL,

- Special Considerations for Specific Constituents
  - — PAHs:
    - ◊ PAHs will be carried forward as COPCs when the following conditions exist:
      - PAHs are present at a site above SALs;
      - a current source for PAHs due to non-LANL industrial operations is not identified; and
      - a Laboratory release cannot be ruled out.
    - ◊ PAHs will not be carried forward as COPCs when the following conditions exist:
      - PAHs are present above SALs, but;
      - no Laboratory release is suspected; and
      - a current source for PAHs due to non-LANL industrial operations is identified.

    Thus, if PAHs are not considered COPCs, a risk assessment will not be done for the site unless warranted by the presence of other constituents. If a risk assessment is done, PAHs will not be included as COPCs. However, the risk related to the PAHs will be presented as part of the background risk characterization

9. Approaches for ecological screening and risk assessment will be consistent with guidance in the EPA *Framework for Ecological Assessment* as further detailed in the draft *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments.* This approach is presented in more detail under assumption 17.

III. RISK-BASED DECISION ASSUMPTIONS

10. Human health and ecological risks can only be appropriately evaluated on a scale of relevant exposure units.
    - Individual sites will be aggregated as necessary for appropriate risk evaluation.
    - Aggregate sizes may differ for human health and ecological evaluations depending on the exposure models.

11. Risks to human health and the environment posed by contamination at the site are necessary considerations in further decisions about a site (beyond identification of COPCs and stabilization activities).
    - Decisions made after comparison of individual observations to a SAL/AL are based on generic, conservative assumptions. Appropriate site-specific risk assessments may differ from screening conclusions because the exposure assumptions underlying the SAL/AL calculation are not site-specific, and also because risk depends on the extent and distribution of contamination rather than the maximum observed concentration.
    - Chemicals identified as COPCs because the detection limit was greater than the SAL/AL may be evaluated qualitatively based on process knowledge. If a chemical is not expected to be present at a site, the chemical needs no further consideration.

- If a chemical having a detection limit greater than SAL is expected to be present, it will be included in the risk assessment calculations with the assumption that it is present at a concentration equal to one-half the detection limit.

i. Human-Health Risk Assessment

12. For sites requiring risk assessment and/or cleanup decisions, appropriate land-use scenarios can be identified based on:
    - The facility Site Development Plan; Future-Use Project Report; property management including deed restriction; and current land use.
    - Conceptual models for specific sites consider all exposure pathways appropriate for the site and all populations potentially exposed in a specific scenario. See Appendix B for considerations on the evaluation of dermal exposure.

At LANL,

- Based on the LANL 30-year Site Development Plan (LANL 1994) and other avail-able information, appropriate site-specific scenarios are developed, including residential and commercial use for the townsite or other lands slated for release from DOE control; industrial use for sites of continued Laboratory use; recreational use for areas accessible to the public, but not appropriate for residential development (i.e., steep hillsides inappropriate for residential construction); and a Native American scenario developed in cooperation with the adjoining Pueblos for areas with potential impact on Pueblo populations (canyon regions). Parameters for evaluating these scenarios are being developed with the Accord Tribes.

AT SNL/NM,

- Land use in the future is recreational or industrial. These designations are consistent with those approved by the Citizen's Advisory Board.

13. Estimation of risks to human health is based on reasonable and site-specific exposure assumptions. In particular, site-specific land-use assumptions will be used.

14. The water exposure pathway is selected when data indicate that water resources may be impacted. Surface water pathways are also considered, as appropriate.

At LANL,

- Potential contaminant migration to groundwater may be modeled at those mesa-top sites where contamination is detected and the potential for transport to groundwater exists, as determined on a case-by-case basis.
- The groundwater pathway will be considered for canyon-bottom sites.
- Contaminant transport model(s), model inputs, assumptions, and uncertainties will be provided to regulators.
- When contaminant transport/migration is a problem, further action may be triggered by finding concentrations exceeding background levels or method detection limits, because this may be an indication that migration has occurred. LANL will evaluate various contaminant transport models for application and use. Transport models will be presented to regulators prior to their use for site decision-making.

AT SNL/NM,

- The water exposure pathway will be considered for every site, although most SNL/NM sites are not expected to have a groundwater pathway. For those sites with a potential groundwater pathway, flow and transport calculations will be performed to determine the potential impact.

15. Baseline risk assessment may provide a basis for NFA at sites where COPCs have been identified.
    - Superfund's RAGS (EPA 1989) provides the basic guidance for performing baseline risk assessments.
    - If the total carcinogenic risk posed by a PRS is within the 10^{-4} - 10^{-6} risk range (or lower), and the non-carcinogenic risk threshold has not been exceeded, the site may be proposed for NFA.
    - The approach used to conduct the risk assessment will be determined by preliminary information available on the site. In some cases, deterministic approaches may be the most expedient choice, e.g. where sites are well-characterized; the number of COPCs is small; or concentrations clearly indicate a health risk. For other sites, site complexity and decision consequences may necessitate the use of more complex stochastic models or alternative approaches necessary to define sources of uncertainty to guide future decisions. The choice of specific models will be determined by site characteristics. When stochastic models are used, assumptions will be explicitly stated and a reasonable maximal exposure based on deterministic calculations will be included. Models will be presented to regulators prior to their use for site decision-making.
    - Guidelines in proposed 10 CFR 834 and DOE Order 5400.5 (Radiation Protection of the Public and the Environment) establish proper procedures for determining acceptable levels of dose for radiological evaluations. Screening and cleanup level derivation and use of RESRAD and ALARA as methods of determination are supported by these regulations. For volumetric radiological contamination (soil, rubble, etc.), cleanup levels are proposed on a site-specific basis for each nuclide present and are generally calculated using the RESRAD computer code. For unrestricted release and continued Laboratory control, a target dose limit of 15 mrem/yr above background (DOE/AL 1996) is used as a basis for cleanup level calculations.
    - In most cases, radionuclide health assessments are presented in terms of dose (the DOE and EPA measure for limiting risk associated with radionuclides). In those cases for which the risk associated with radionuclides influences decisions associated with other COPCs at the site, the radionuclide risk may also be presented in terms of carcinogenic risk (for qualitative comparison only). The Laboratories caution strongly against adding radioactive risk results with hazardous chemical carcinogen risk estimates due to the marked difference in methods for establishing the respective health effects. This cautionary note is consistent with the EPA's RAGS document (EPA 1989).

16. Exposure estimates are based on the distribution of contamination throughout areas/volumes of contaminated media and over time periods that are consistent with land use assumptions
    - Current EPA guidance for deterministic models suggests using the 95% upper confidence level (UCL) for the mean concentration within such areas/volumes as an estimate of the reasonable maximum exposure associated with that area/volume.
        - When appropriate, alternative statistical models will provide estimates of reasonable maximum exposure.
    - Exposure areas/volumes are established through the DQO process using appropriate land use assumptions.
        - In general, the areas/volumes will be consistent with the selected exposure scenario. That is, the smallest area or volume to which a receptor would be exposed over the entire exposure period determined by that scenario will be used.

ii. Ecological Risk Assessment

17. Ecological risk assessment will be performed on PRSs that are aggregated by vegetation type into habitat patches that form reasonable ecological exposure units (EEUs) for ecological receptors. The general approach follows a tiered process as outlined in EPA guidance (EPA 1992; 1994; and 1996b). The final process is being developed in conjunction with NMED.
    - Ecological screening assessment will proceed using a two-step approach in which immediately available data will be used to perform a preliminary screening. Requirements for further assessment will be evaluated for those PRSs that are not screened out in the first step.
    - Contaminants of potential ecological concern (COPECs) will be selected on the basis of detected presence at PRSs.
    - Representative receptors will be selected from food webs established for EEUs in order to protect Threatened and Endangered species, general ecosystem structure, and critical ecological functions.
    - Exposures will be calculated on the basis of contaminant concentrations, contaminant distribution patterns, receptor home range sizes, and receptor foraging strategies.
    - Risk will be assessed by comparing exposures to relevant toxicity data.
    - At sites where remediation is indicated, the ecological effects of leaving COPECs in place will be balanced against the ecological effects of remediation activities.

IV. REMEDY SELECTION AND IMPLEMENTATION ASSUMPTIONS

18. Site-specific land-use assumptions and exposure scenarios (Assumptions 12 and 13) are considered in establishing preliminary remediation goals and media cleanup standards, and also in risk assessments to estimate the reduction of risk realized by a potential corrective action.
19. Target risk and dose levels will be set following EPA, NMED, and DOE guidance.
    - Following EPA guidance, preliminary remediation goals and media cleanup standards for non-radioactive carcinogens are derived using EPA's target incremental risk range of 10^{-4} to 10^{-6}. A target hazard index value of 1 is used for non-carcinogens.
    - For volumetric radiological contamination (soil, rubble, etc.), cleanup levels are proposed on a site-specific and ALARA basis for each radionuclide present. For unrestricted release of residential sites, a target level of 15 mrem/yr above background is used.
    - Cleanup levels will be presented in a table of risk levels for recreational, industrial, and residential scenarios, as appropriate. All parameters used in the derivation of cleanup levels will be detailed in appropriate reports. Although cost factors will be included, these will not form the sole basis of the cleanup level decisions.
    - Risk due to background inorganics will be calculated and presented to regulators for consideration in the establishment of appropriate cleanup levels.
20. For CMSs, media cleanup standards will be established after the results of the CMS have been considered. DOE and the Laboratories will propose a remedy selection following evaluation of alternatives as described below. The administrative authority will approve the proposed plan, negotiate changes, or select an alternative remedy.
    - Remedy selection takes into consideration the potential impacts on the health and safety of workers and the public that will be associated with increased exposure during implementation of the remedy. Other considerations for selection of a remedy may include the cost of the remedial options, Laboratory land-use needs, transportation risk, future liability concerns (e.g., off-site disposal liability), and Natural Resource Damage Assessment.

21. Cleanup actions for radionuclides will incorporate ALARA considerations.
    - The principle of ALARA was developed in the occupational radiation protection discipline in order to ensure that radiation exposure remained well below standards.
    - The ALARA principle has been adapted to radiological cleanup activities as follows:
      - Dose-based cleanup goals are based upon:
        - ◊ nature and extent of contamination,
        - ◊ anticipated future use of the site, and
        - ◊ practicality of alternative cleanup techniques.
      - ALARA takes into account technical practicability, economic factors, variability of site conditions, accessibility of pockets of contamination, access controls, and other factors that influence the costs and benefits of a remedial action.
      - ALARA considerations, at this point, may lead to selecting a goal below the dose-based goal, if the lower goal can be economically and easily achieved.
      - Conversely, ALARA considerations may lead to selection of a goal above the dose-based goal (up to 100 mrem/yr) if conditions make the ultimate goal unachievable.
    - Elements of subjectivity remain in any ALARA decision.
    - ALARA decisions must be made with input and concurrence from the DOE.
    - The principle of ALARA is consistent with the CERCLA process for remedy selection.
22. The attainment of cleanup standards is based on comparison of site verification sampling data to the cleanup standards.
    - Verification sampling plans based on nature and extent will be designed to collect the appropriate number of samples to calculate a 95% UCL to compare to cleanup levels.
    - The 95% UCL will estimate average residual concentrations in appropriate risk-based areas/volumes of contaminated media. For radionuclides, identification of hot spots and evaluation of non-uniform radiological contamination will follow RESRAD and other applicable DOE guidance.
23. If media cleanup standards are unattainable using the selected remedy, an alternative remedy (e.g., conditional) and/or cleanup goals/standards will be negotiated.

V. RISK-BASED DECISION FACTORS AND RISK MANAGEMENT ASSUMPTIONS

24. The procedures described to this point are used to develop a consistent qualitative or quantitative evaluation of site risks at LANL and SNL/NM. The results of these evaluations, however, are only one part of the basis for risk-management decisions. Within the regulatory framework, ranges of acceptable risks are defined, and where in that range a management decision will fall for any given site will be modified by factors including:
    - stakeholder concerns;
    - likelihood of the exposure pathways that were evaluated existing either now or in the future;
    - the weight of scientific evidence for toxicity of site contaminants;
    - limits of the best available technologies for mitigating the problem;
    - potential interactions with other exposure sources in the vicinity;
    - feasibility and reasonable relationship of benefits to costs;
    - other political, social, legal, and cultural considerations.

    The goal of SNL and LANL is to ensure protection of human health and the environment from any contamination that might have occurred during past Laboratory activities. For non-radionuclide contamination, the EPA has established standards by which to judge these potential effects. For radionuclides, DOE, EPA, and the Nuclear Regulatory Commission have established or are in the process of establishing standards and guidance. These risk standards are applied considering the current and potential future land-use and the other modifying factors listed above.

Noncarcinogenic health effects are evaluated by the hazard index. Sites with a hazard index less than 1 are not associated with adverse health effects (EPA 1991a).

Carcinogenic health effects for non-radionuclides are evaluated by comparison of estimated excess cancer risk to the risk range that EPA has designated in the National Contingency Plan and RCRA Subpart S. The EPA considers an excess cancer risk level of 10^{-6} as the value below which no human health effects are likely to occur. Remedial action at a site is warranted if the risk value is above approximately 10^{-4}. For calculated risks in the range of 10^{-4} to 10^{-6}, negotiations are required with the regulatory agency to determine if the excess cancer risk is acceptable.

For sites where radioactive contamination is present, the DOE has authority to protect the public from radiation and radioactive materials. DOE has published health and safety orders of which DOE Order 5400.5, Radiation Protection of the Public and the Environment (DOE 1991), is the most pertinent to development and application of cleanup guidelines. DOE Order 5400.5 requires that doses be reduced to a level as low as reasonably achievable (ALARA) below the primary dose limit of 100 mrem/yr from all DOE sources. As stated in 5400.5, radionuclides are not managed by a risk standard, but rather by dose.

The calculated risk parameter value for the contaminated site is compared to the appropriate regulatory standard. If the risk is greater than the regulatory standard for the appropriate land-use, remedial action is generally warranted. Comparison of site risk parameter values to noncarcinogenic and radiological standards is relatively direct. For sites with potential carcinogens present as contaminants of concern, the EPA has provided a range of values for comparison. The intent of both SNL and LANL is to try to clean-up sites to the lower end of the target range as practical from both technical and economic considerations. As stated in an EPA/OSWER directive (EPA 1991b):

> "Once a decision has been made to take action, the Agency has expressed a preference for cleanups achieving the more protective end of the range (i.e., 10^{-6}), although waste management strategies achieving reductions in risks anywhere within the risk range may be deemed acceptable by the EPA risk manager. Furthermore, the upper boundary of the risk range is not a discrete line at 1×10^{-4}, although EPA generally uses 1×10^{-4} in making risk management decisions. Specific risk estimates around 10^{-4} may be considered acceptable if justified based on site-specific conditions, including any remaining uncertainties on the nature and extent of contamination and associated risks. Therefore, in certain cases EPA may consider estimates slightly greater than 10^{-4} to be protective."

The concept of a range of acceptable risk is also supported in the EPA SSG which states that no evaluation of multiple contaminant interactions is deemed necessary for carcinogens screened to a 10^{-6} risk level because

> "...setting a 10^{-6} excess risk level for individual chemicals and pathways generally will lead to cumulative site risks with the 10^{-4} to 10^{-6} risk range for the combinations of chemicals typically found at NPL sites." (EPA 1996a)

Risk management decisions must involve careful consideration of the uncertainties involved in the risk assessment and the understanding of the site. For example, COPCs for which the weight of evidence for carcinogenicity in humans is high may have target risk levels that are more conservative than COPCs having a weaker weight of evidence for carcinogenicity.

As mentioned in the beginning of this section, risk management decisions must also involve the consideration of technical feasibility, cost, legal issues, potential effects on worker safety and the environment, and socio/political concerns for the remedial action. A detailed discussion of these and other risk management considerations is presented in the Presidential/Congressional Commission on Risk Assessment and Risk Management report, *Framework for Environmental Health Risk Management* (Presidential/Congressional Commission on Risk Assessment and Risk Management 1997).

REFERENCES

DOE/AL (US Department of Energy/Albuquerque Operations Office) March 14, 1996. "Radiological Cleanup Standards," Memorandum from Julianne F. Levings, Environmental Restoration Division Team Leader, to J. F. Guelker, G. P. Keary, M. A. Jackson, T. J. Taylor, and D. S. Ingle, Albuquerque, New Mexico. (DOE/AL 1996)

DOE (US Department of Energy), March 8, 1991. "DOE Guidance on the Procedures in Applying the ALARA Process for Compliance with DOE 5400.5, Interim Guidance," Office of Environmental Guidance, Washington, DC. (DOE 1991)

DOE (US Department of Energy), June 5, 1990. "Radiation Protection of the Public and the Environment," DOE Order 5400.5, Washington, DC. (DOE 1990)

EPA (US Environmental Protection Agency), July 1996. "Soil Screening Guidance: User's Guide," Report No. EPA540/R-96/002B, Washington, DC. (EPA 1996a)

EPA (US Environmental Protection Agency), August1996. "Proposed Guidelines for Ecological Risk Assessment," Report No. EPA630/R-95/002B, Washington, DC. (EPA 1996b)

EPA (US Environmental Protection Agency), 1994. "Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments," (Review Draft), Washington, DC. (EPA 1994)

EPA (US Environmental Protection Agency), 1992. "Framework for Ecological Risk Assessment," Report No. EPA 630/R-92/001, Washington, DC. (EPA 1992)

EPA (US Environmental Protection Agency), December 1991. "Risk Assessment Guidance for Superfund, Volume I—Human Health Evaluation Manual (Part B, Development of Risk-Based Preliminary Remediation Goals)," Interim, EPA/540/R-92/003, Publication 9285.7-01B, Office of Research and Development, Washington, DC. (EPA 1991a)

EPA (US Environmental Protection Agency), April 22, 1991. "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions," (OSWER Directive No. 9355.0-30), memorandum to Directors, Waste Management Division, Regions I, IV, V, VII, VIII; Director, Emergency and Remedial Response Division, Region II; Directors, Hazardous Waste Management Division, Regions III, VI, IX; and Director, Hazardous Waste Division, Region X; from D. R. Clay, Assistant Administrator, Washington, DC. (EPA 1991b)

EPA (US Environmental Protection Agency), December 1989. "Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual (Part A)," Interim Final, EPA 540/1-89/002, Office of Emergency and Remedial Response, Washington, DC. (EPA 1989)

IT (International Technology Corp.) 1996. "Background Concentrations of Constitutents of Concern to Sandia National Laboratories/New Mexico Environmental Restoration Project and the Kirtland Air Force Base Installation Restoration Program," Albuquerque, NM. (IT 1996)

LANL (Los Alamos National Laboratory) 1994. "Site Development Plan, Annual Update 1994," Los Alamos National Laboratory Publication, LALP-94-21, Los Alamos, New Mexico. (LANL 1994)

NMED (New Mexico Environment Department), EPA (US Environmental Agency), DOE (US Department of Energy), LANL (Los Alamos National Laboratory), and SNL (Sandia National Laboratory–New Mexico), November 16, 1995. "Environmental Restoration Document of Understanding," Santa Fe, New Mexico. (NMED et al. 1995)

REFERENCES (cont.)

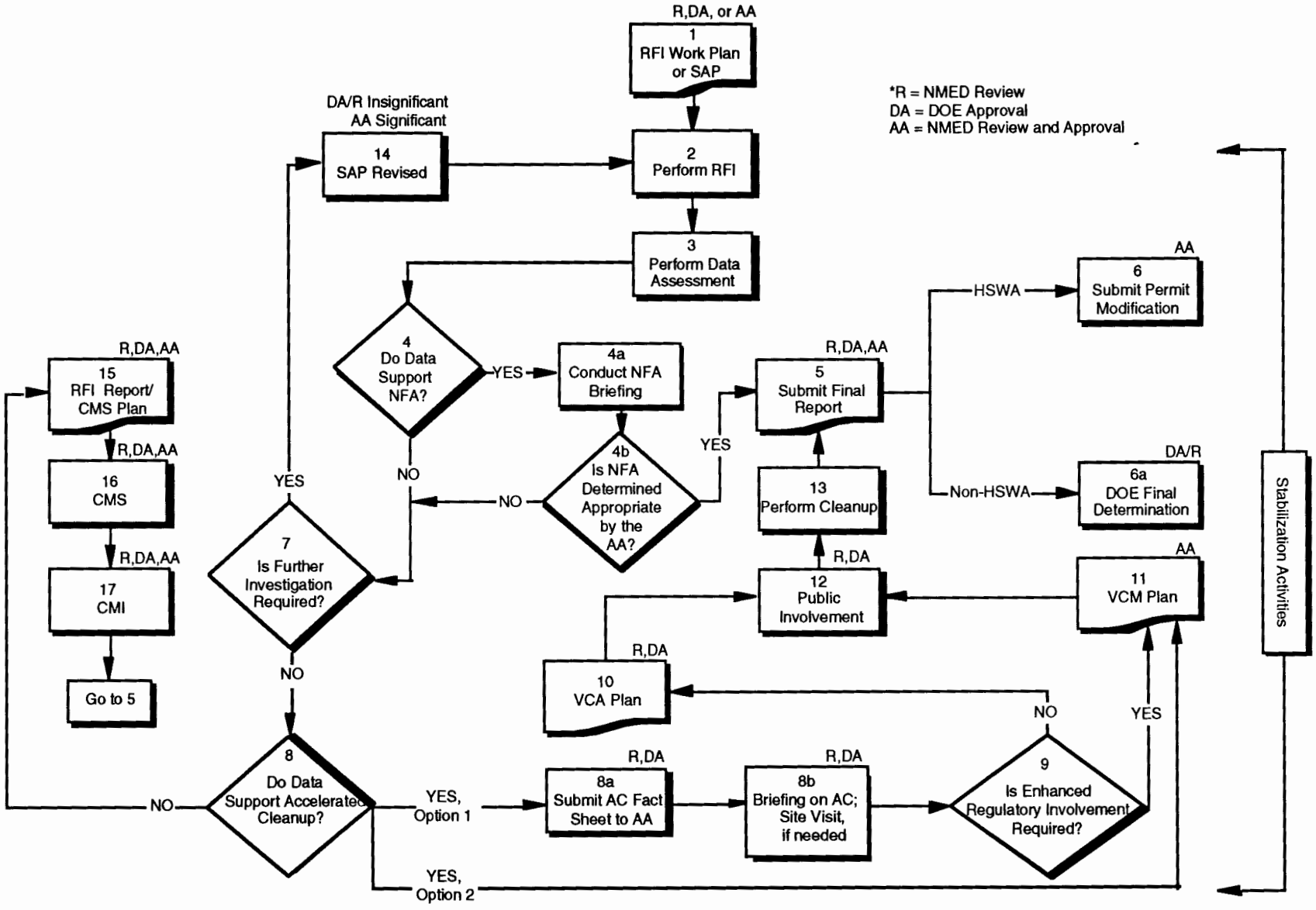
Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997. "Framework for Environmental Health Risk Management," Final Report, Volume 1, Washington, DC. (Presidential/Congressional Commission on Risk Assessment and Risk Management 1997)

Project Consistency Team. "Project Consistency Team (PCT) Policy Memo Notebook," (Controlled), Environmental Restoration Project, Los Alamos National Laboratory, Los Alamos, New Mexico. (Project Consistency Team)

Ryti, R., P. Longmire, and E. McDonald, March 1996. "Application of LANL Background Data to ER Project Decision-Making, Part I: Inorganics," Los Alamos National Laboratory Report LA-UR-96-1534, Los Alamos, New Mexico. (Ryti et al. 1996)

Ryti, R., P. Longmire, K. Campbell, and R. Perona, 1997. "Application of LANL Background Data to ER Project Decision-Making, Part II: Radionuclides in Soil, Sediments, and Tuff," Los Alamos National Laboratory Report LA-UR-96-????, Los Alamos, New Mexico. (Ryti et al. 1997)

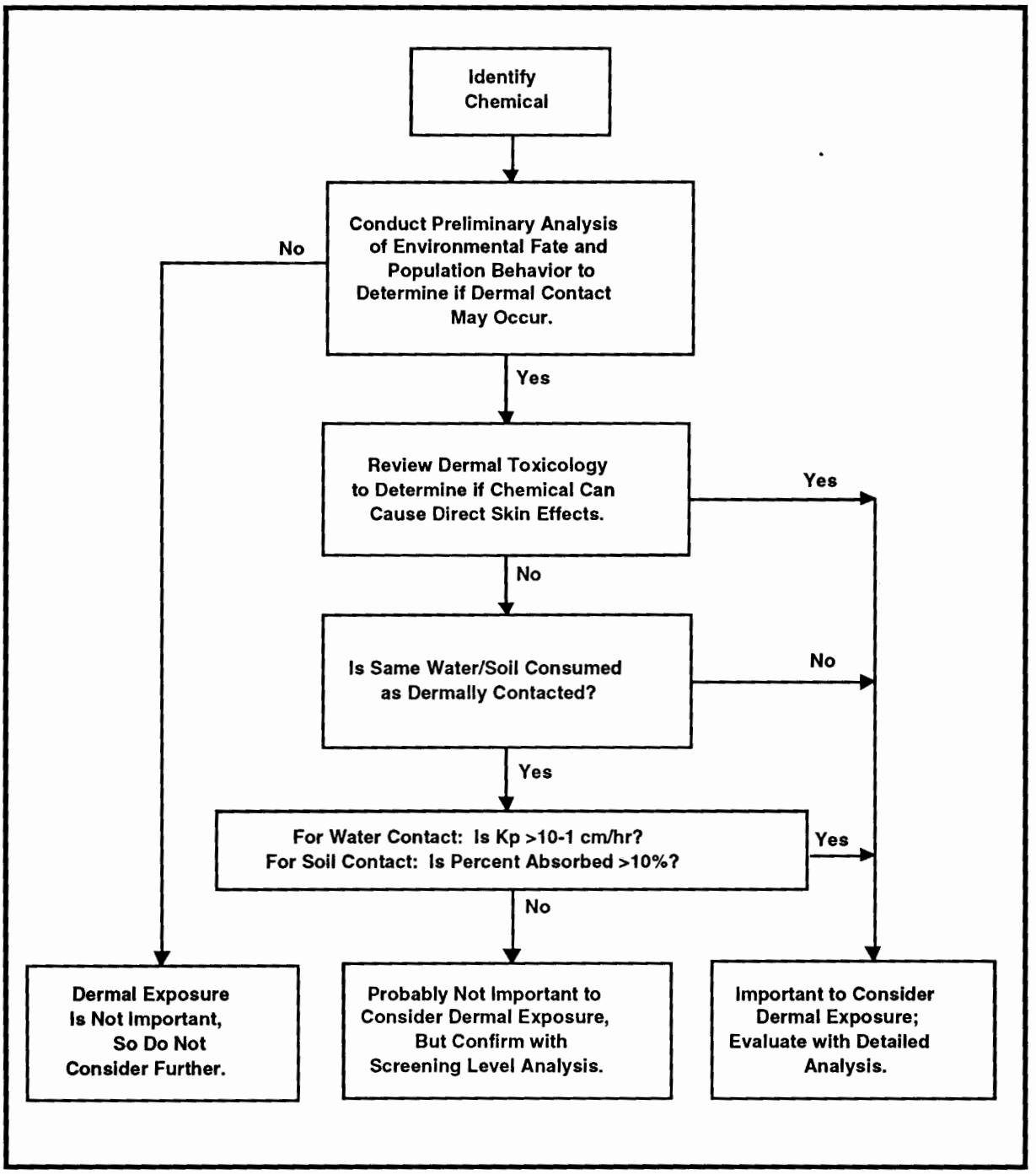
APPENDIX A: ACCELERATED CORRECTIVE ACTION PROCESS



Explanatory text for this diagram can be found in a future annex (nearly completed) of the Document of Understanding (NMED et al. 1995).

APPENDIX B: DERMAL EXPOSURE ASSESSMENT

Figure B-1. Framework to Evaluate the Importance of Dermal Exposure Decisions



Taken from EPA (EPA 1992, 1012, figure, 9-1, page 9-2)

Dermal exposure assessment is associated with substantial uncertainty. For inorganic COPCs in soil, exclusion of the soil-to-dermal pathway is not likely to affect the overall risk estimate assuming other pathways such as soil ingestion are included. This occurs because inorganics are not well absorbed across the skin due to their limited water and lipid solubilities. Also these metals tend to bind strongly to soil further reducing their availability for transport across the skin. Because there are no chemical-specific skin absorption data for inorganics (with the exception of arsenic (3%) and cadmium (1%)), all inorganics are assumed to have a default dermal absorption factor of 1%. This leads to the same percent contribution to total dose regardless of the chemical, i.e., at 1% absorption, the dermal dose is estimated to be 10% of the oral dose from soil ingestion for adults. (EPA 1992)

Dermal Absorption Dose = Csoil x Dermal Absorption Rate = Csoil x Absorption Factor x Adherence Factor x Surface Area

$$\frac{\text{Dermal Absorption Dose}}{\text{Csoil}} = \text{Dermal Absorption Rate} = \text{Absorption Factor x Adherence Factor x Surface Area}$$

Oral Ingestion Dose = Csoil x Oral Ingestion Rate

Using the EPA Region 9 default assumptions for Adherence Factor and Surface Area, and the default Absorption Factor of 1%:

Dermal Absorption Rate = 0.01 x 0.2 mg/cm^2-day x 5000 cm^2 = 10 mg/day

Therefore, in the case of the default Ingestion Rate of 100 mg/day, the 10 mg/day Dermal Absorption Rate is estimated to contribute 10% of the Oral Ingestion Dose from soil.

Because dermal absorption factors for organics can be significant due to their greater lipid solubility, dermal exposure will be evaluated for organic COPCs. This process is consistent with the decision framework presented in EPA's *Dermal Exposure Assessment: Principles and Applications* and reproduced in Figure B-1.

REFERENCES FOR APPENDIX B

EPA (US Environmental Protection Agency), January 1992. "Dermal Exposure Assessment: Principles and Applications," Interim Report, EPA/600/8-91/011B, Office of Research and Development, Washington, DC. (EPA 1992)