

ES/ER/TM-232

**Risk Assessment Program
Data Management
Implementation Plan**

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**Risk Assessment Program
Data Management
Implementation Plan**

Date Issued—November 1997

Prepared by
Environmental Restoration Risk Assessment Program

Prepared for the
U.S. Department of Energy
Office of Environmental Management
under budget and reporting code EW 20

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managing the
Environmental Management Activities at the
East Tennessee Technology Park
Oak Ridge Y-12 Plant Oak Ridge National Laboratory
Paducah Gaseous Diffusion Plant Portsmouth Gaseous Diffusion Plant
under contract DE-AC05-84OR21400
for the
U.S. DEPARTMENT OF ENERGY

PREFACE

This Environmental Management (EM) Risk Assessment Program (RAP) Data Management Implementation Plan (DMIP) specifies data management requirements and applicable command media for the RAP. The DMIP was produced by the EM RAP under Work Breakdown Structure 1.4.112.2.3.04.07.01, entitled Risk Assessment Review, Planning, and Coordination and within the Activity Data Sheet 8304, Technical Integration. The primary objective of this document is to establish a DMIP that meets the requirements of the *Environmental Data Management Implementation Handbook for the Environmental Restoration Program* (LMES 1996a).

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ACRONYMS AND ABBREVIATIONS

ADP/SDM	Automated Data Processing Systems Development Methodology
CAS	Chemical Abstract Service
COC	chemical of concern
COPC	chemical of potential concern
CSM	conceptual site model
DMIP	Data Management Implementation Plan
DOE	U.S. Department of Energy
EM	Environmental Management (Program)
EPA	U.S. Environmental Protection Agency
ERA	ecological risk assessment
FTP	file transfer protocol
HHRA	human health risk assessment
HHRADE	human health risk assessment data evaluation
LMES	Lockheed Martin Energy Systems, Inc.
OREIS	Oak Ridge Environmental Information System
ORNL	Oak Ridge National Laboratory
ORO	Oak Ridge Operations
PC	personal computer
PRG	preliminary remediation goal
RAIS	Risk Assessment Information System
RAP	Risk Assessment Program
RGO	remedial goal option
SAS®	Software manufactured by SAS Institute, Inc.
TIC	tentatively identified compounds
UCL95	95% Upper Confidence Limit on the Mean Concentration

EXECUTIVE SUMMARY

The Environmental Management (EM) Risk Assessment Program's (RAP's) main objective is to produce high-quality, consistent, and scientifically defensible risk assessments. To achieve this objective, the RAP Data Management Implementation Plan (DMIP) was developed. This document meets all RAP data needs and complies with the *Environmental Data Management Implementation Handbook for the Environmental Restoration Program* (LMES 1996a), which required the formation of this DMIP to control RAP data management activities. Specifically, this DMIP provides guidance to control data receipt, processing, and use. The document also discusses measures to ensure configuration control and access control to software changes.

This document will be used by RAP in conjunction with existing RAP and EM command media. This DMIP will be updated as necessary to ensure compliance with the latest RAP and EM data management requirements.

1. INTRODUCTION

The Risk Assessment Program (RAP), as part of the Environmental Management Program (EM), takes the lead role in all risk assessment activities under the auspices of the U.S. Department of Energy–Oak Ridge Operations (DOE-ORO) Environmental Restoration Division. RAP provides overall management and coordination of all risk-related activities performed by prime contractors and subcontractors for the Environmental Restoration Division at the Oak Ridge K-25 Site, Oak Ridge National Laboratory (ORNL), the Oak Ridge Y-12 Plant, Paducah Gaseous Diffusion Plant, and Portsmouth Gaseous Diffusion Plant.

Risk assessment is a data-intensive activity that takes, as input, environmental measurements resulting from sampling and analysis activities, and provides qualitative and quantitative evaluation of human health and ecological risks posed by anthropogenic contaminants in the environment. This Data Management Implementation Plan was required by the *Environmental Data Management Implementation Handbook for the Environmental Restoration Program* (LMES 1996a) to control the data management activities supporting RAP.

The scope of this plan covers only those data management activities occurring within RAP. This plan does not cover data transformations occurring within data management systems external to RAP. Responsibility for establishing a data management framework for systems external to RAP is held by those respective programs.

The reader should note that occasionally there are constraints (e.g., time and monetary constraints) that require some steps of the risk assessment process to be omitted. Any deviations from this plan must be approved by the Risk Assessment Manager and documented.

1.1 RAP DATA MANAGEMENT OBJECTIVES

The overall objective of data management within RAP is to maintain a data management system that will meet the needs of the program as well as comply with relevant requirements of *Automated Data Processing Systems Development Methodology*, (ADP/SDM) (MMES 1990). These objectives will be attained through recognizing and controlling the mechanisms involving data receipt from sources external to RAP, processing into useful formats, and using data in assessing risk. An environment that supports these activities includes a system of software configuration control and access control to software changes.

2. DATA MANAGEMENT ACTIVITIES

This chapter summarizes the major processes involved in managing electronic and hard-copy environmental measurements data within RAP. Because the human health risk assessment (HHRA) and ecological risk assessment (ERA) process flows differ, Sect. 2.1 presents the HHRA data management scope, and Sect. 2.2 presents a discussion of data management for ERAs.

2.1 STEPS IN THE HUMAN HEALTH RISK ASSESSMENT DATA MANAGEMENT PROCESS

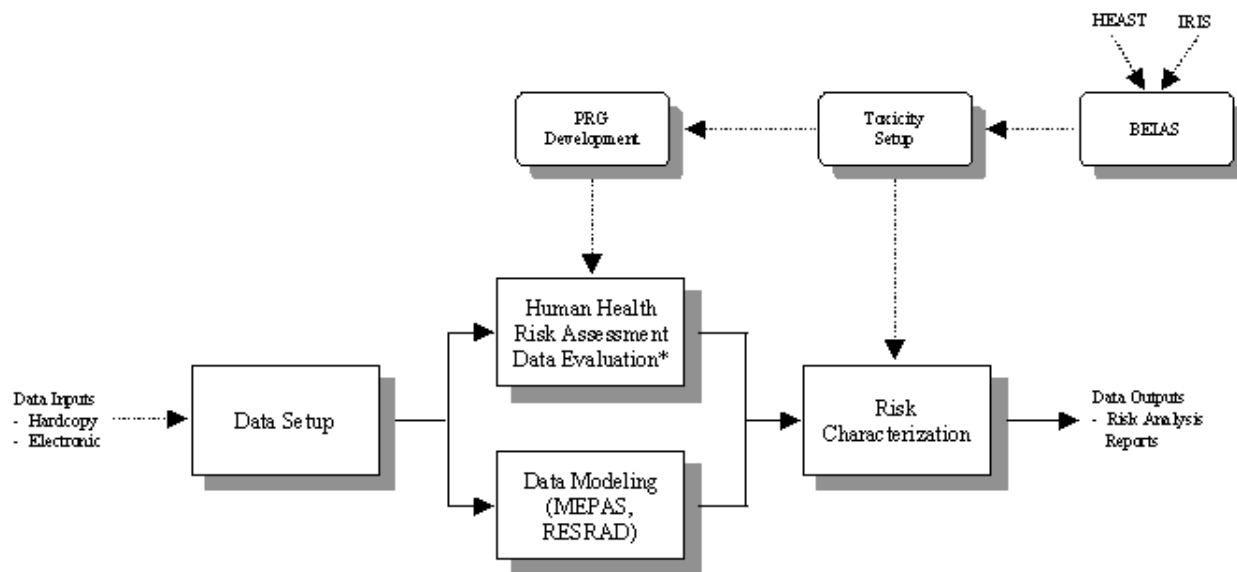
Figure 1 illustrates the data management process flow for HHRAs. Sects. 2.1.1–2.1.7 detail the steps outlined in Fig. 1.

2.1.1 Human Health Risk Assessment Data Inputs

Environmental measurements data are received by RAP in different formats and from different sources. Environmental measurements data are typically obtained from EM project data files or from organizations subcontracted to perform sampling, analysis, and/or data validation.

Data are typically submitted by the data provider in electronic format on diskette or through electronic transfer. In the future, along with the electronic version, a hard copy and/or electronic copy of the statistical descriptors (e.g., means, minimum, and maximum values) that summarize the transferred data set will also be requested. After receiving the statistical descriptors and the electronic data set, RAP will verify that the electronic version of the data set produces identical statistical descriptors, an indication that all data have been transferred accurately. When differences are found between the data provider's statistical descriptors and the statistical descriptors produced by RAP, RAP will contact the data provider to initiate corrective action; this contact with the data provider may be by phone, electronic-mail, or by memo and will serve as the beginning of the corrective action process. When data are received exclusively in hard-copy format (i.e., no electronic transfer was made to RAP), the data are hand-keyed into RAP's data system; this data entry is verified by another individual manually checking the resulting electronic files against the original hard-copy data. These measures ensure that the data sets used in risk assessment match the data sets submitted from the provider. All verification documentation will be retained in the project files, as appropriate, according to "Environmental Data Entry, Transfer, and Transformation Verification" (LMES 1996b).

As mentioned, data are received by RAP in a variety of formats and from a variety of sources. Naturally, as the number of sources/formats increases, RAP will need to spend more time making the various data sets consistent with each other (see Sect. 2.1.2). Therefore, the preferred scenario for receiving data is for all data to be provided to RAP (and to all other groups involved in the EM project) by one source and in one format. Using this approach, all project team members (e.g., the risk assessment team members, the remedial investigation team members, the feasibility study team members) receive the same data. This process is efficient, saving both time and money. An example of this type of data management organization would be for personnel from the Oak Ridge Environmental Information System (OREIS) to be involved in the EM project discussions concerning what data are needed for the project; OREIS personnel could then perform all data research and actually create one data base for the EM project. Similarly, a subcontractor involved in the EM project might be tasked to set up the project's one data base for all data users to access.



Notes:

- Input into Ecological Risk Process Flow
- Denotes Process Flow
- Denotes Inputs
- PRG Preliminary Remediation Goals
- HEAST Health Effects Assessment and Summary Table
- IRIS Integrated Risk Information System
- BELAS Biomedical and Environmental Information Analysis Section
- MEPAS Multimedia Environmental Pollutant Assessment System
- RESRAD RESidual RADioactivity

Fig. 1. Data management process flow for human health risk assessments.

Sources of data to be processed by RAP might include, but are not limited to: OREIS; the EM Project Environmental Measurements System; site OREIS computer systems (e.g., the Y-12 Bechtel Environmental Integrated Data Management System); subcontractors; hard-copy reports; laboratory systems (e.g., the Paducah Environmental Information Management System); the Oak Ridge Environmental Laboratory Information Management System; and in the future, data in the DOE Environmental Management Electronic Data Deliverable Master Specification format. When obtaining data from OREIS, RAP data management and evaluation personnel will follow appropriate OREIS guidance. RAP personnel obtaining access to OREIS will also receive training in the use of that system.

Formats for the data sent to RAP might include, but are not limited to: Statistical Analysis System (SAS®)¹ transport files [when the data provider has the SAS software but runs this software under a different platform than RAP (e.g., PC/SAS versus ULTRIX/SAS)]; SAS data sets (when both the data provider and RAP run SAS under the same platform); Excel spreadsheets; dBase files; ASCII files (e.g., space-delimited files, tab-delimited files, comma-delimited files); and WordPerfect tables. Because RAP's data management system involves extensive use of the SAS software, all data sets received will eventually be read into (e.g., converted to) SAS data sets.

2.1.2 Data Setup

This step involves a series of electronic checks that result in the data being put into a usable format. For specific, detailed information on data setup, refer to Appendix A ("Data Evaluation") of *Risk Assessment Strategy at DOE-ORO* (LMES 1996c). The major steps include, but are not limited to the following:

- data formatting (reading data into the preferred electronic format for evaluating risk)
- data cleanup (includes some or all of the following):
 - checking chemical names for consistency in spelling
 - checking Chemical Abstract Service (CAS) registration numbers for accuracy
 - matching location identifiers with sample numbers
 - checking qualifier codes
 - checking units to conform with eventual calculations
 - checking for duplicate (identical) entries in the data set
 - removing fields that are not required for HHRA
 - locating and adding additional fields required for HHRA, as necessary

The data provider may have already processed the data set through one or more of these steps. Steps completed prior to data receipt do not need to be duplicated within RAP. All modifications of data by RAP, as well as justifications for these modifications, must be documented within the SAS programs that are created specifically for the data setup process. New SAS data sets are created during the data setup process so that there is traceability from the original (as received) data set to the final data set used in the risk assessment.

¹Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise, does not necessarily constitute or imply endorsement, recommendation, or favoring by the United States Government or any agency thereof.

Data setup is often the most labor- and time-intensive step in the data management process. This is due to the many differences in formats for the project data. Mapping of data elements from an existing format to the preferred format is usually necessary, and compounding the transformation are inconsistencies in data elements, which must be clarified with the data provider. Some examples of these inconsistencies are various synonyms used within a data set for the same analyte, different concentration units, and inconsistencies in the CAS numbers assigned to the analytes. A short discussion of these three common data problems and how these problems are addressed follows.

RAP preference is to use a single designation for a given analyte within a given data set [as opposed to several designations (synonyms) for the same analyte]. Therefore, it may be necessary to change an analyte name to a corresponding synonym that appears elsewhere on the data set. All changes are electronically documented in the SAS programs. Also, the original version of the data set (with the multiple synonyms for the same analyte) is maintained by RAP.

To be consistent with the units of measure for toxicity values that will be used in the risk assessment process, all concentrations on the data set must be expressed in one of the following units of measure: mg/L for nonradionuclides in water-type media (e.g., groundwater, surface water, leachate); mg/kg for nonradionuclides in soil-type media (e.g., soil, sediment); pCi/L for radionuclides in water-type media; and pCi/g for radionuclides in soil-type media. Concentrations not received in these units of measure will be converted to these units of measure. Again, all such conversions are electronically documented in the SAS programs, and the original version of the data set (with the original concentrations and units of measure) is maintained by RAP.

The CAS number assigned to each analyte is extremely important. The CAS number must be correct in order to merge the EM data set with RAP's toxicity data set (see Sect. 2.1.4). CAS numbers for project data are checked for consistency with the CAS numbers on RAP's toxicity data set, and changes are made to the project data set, if necessary. All such conversions are electronically documented in the SAS programs, and the original version of the data set (with the original CAS number assignments) is maintained by RAP.

Often an analyte will appear on the EM data set that does not have specific toxicity data, but a closely related analyte (i.e., similar chemically and toxicologically) may exist that does have toxicity data. In these cases, an assumption may be made by RAP to evaluate the identified analyte as the closely related analyte with toxicity data. A similar situation involves analytes with concentrations provided for multiple combinations of a given radionuclide. In these cases, RAP will evaluate the analyte as the isotope with the most conservative (i.e., highest) toxicity. Examples of such assignments/assumptions made by RAP include, but are not limited to: evaluating uranium (total uranium) as uranium metal (soluble salts); evaluating fluoride as fluorine (soluble fluoride); evaluating plutonium-239/240 as plutonium-240; evaluating strontium-89/90 as strontium-90; and evaluating uranium-233/234 as uranium-234. Note that when evaluating these analytes as analytes with toxicity information, CAS numbers may need to be modified in order to merge the data with the toxicity data set. All such changes are electronically documented in the SAS programs, and the original version of the data set (with the original CAS numbers) is maintained by the RAP.

Another data scenario that is often encountered involves evaluating "total chromium" as either chromium III or chromium VI [both of which contain U.S. Environmental Protection Agency (EPA)-approved toxicity data]. Because there is currently no EPA-approved toxicity data available for total chromium, the risk assessor may evaluate total chromium in the most conservative fashion. If chromium VI has not been measured and reported in the same data set then the total chromium might

be evaluated as chromium VI. However, if chromium VI is already measured and reported in the same data set that contains total chromium data then the risk assessor may want to evaluate the total chromium as chromium III. Note that by evaluating total chromium in this fashion, CAS numbers may need to be modified in order to merge the data with the toxicity data set. All such changes are electronically documented in the SAS programs, and the original version of the data set (with the original CAS numbers) is maintained by the RAP.

Yet another data scenario that may be encountered involves the need to estimate specific radionuclide concentrations. If a suspected radionuclide of concern (e.g., uranium-238) does not appear on the data set but its nonradionuclide counterpart (e.g., uranium in mg/kg or mg/L) or its nonisotopic radionuclide counterpart (e.g., uranium in pCi/g or pCi/L) does appear on the data set, the risk assessor may want to estimate the isotopic concentration [activity (pCi/g or pCi/L)] from the nonradioactive concentration (mg/kg or mg/L) or to evaluate the nonisotopic radionuclide counterpart as a specific isotope (e.g., strontium in pCi as strontium-90 in pCi). This situation is site specific; that is, the estimation should only take place if the isotope is a suspected chemical of concern (COC) and if the EM project team desires such information.

A typical example of this scenario would be a site where the three major uranium isotopes (uranium-234, -235, and -238) are of concern due to knowledge of site operational history but for some reason were never analyzed as specific isotopes. In this situation, if total uranium concentrations (mg/kg) are available, the risk assessor could use site-specific information concerning the abundance of uranium (e.g., assume natural abundance, if appropriate) in order to estimate the concentrations (activities) for the three major uranium isotopes from the total uranium concentrations. These estimations could be made if the total uranium concentrations were reported in radionuclide or nonradionuclide units of measure. Again, all such estimations are electronically documented in the SAS programs, and the original version of the data set (without the estimated concentrations) is maintained by the RAP.

As noted earlier, programs used in the Data Setup steps are based on SAS code. For every data file, a general version of this code is modified as necessary to meet the specific needs of the data transformation. These modifications are electronically documented with the date and a record of who made the changes. Access to change any code is restricted to individuals authorized to perform that function.

2.1.3 Data Evaluation

Data evaluation makes use of the data set prepared through Data Setup. These steps may be performed differently for HHRAs and ERAs. The data may also be used in modeling to determine future risk from chemicals of potential concern (COPCs). For detailed information on data evaluation, refer to Appendix A (“Data Evaluation”) of the strategy document (LMES 1996c). The major steps include, but are not limited to, the following:

- identifying false-positive data (ensuring that data have been subjected to the appropriate data validation steps by comparing analytical data to the appropriate method blanks)
- reducing the data set (removal of data points qualified as rejected through validation)
- comparing results of duplicate analyses

- categorizing observations as detected or not detected
- summarizing the data according to established criteria (by Waste Area Groupings, wells, etc.)
- evaluating tentatively identified compounds (TICs)
- screening against appropriate background concentrations
- screening against appropriate preliminary remediation goals (PRGs)
- screening against available essential nutrient criteria
- determining the exposure concentration to be used in risk characterization

Various screenings of data are performed in the data evaluation step. The end point of these screenings is a determination of which contaminants are to be included in the COPC list, which is used to assess overall risk (see Sect. 2.1.6). The data provider may have already processed the data set through one or more of these screening steps. Steps completed prior to data receipt do not need to be duplicated within RAP. A brief discussion of these steps follows.

The validation process should identify false-positive concentrations. If validation has not been performed on all (i.e., 100%) of the data, and if the associated Quality Control data are available, then the risk assessor should perform the appropriate comparisons of analytical data with the associated method blanks in order to determine if laboratory contamination is contributing to the analyte concentrations. Appropriate adjustments, as noted in the EPA document *Risk Assessment Guidance for Superfund (RAGS), Volume I, Human Health Evaluation Manual (Part A)* (EPA 1989), must be made to false-positive data.

Data designated as rejected by validation should not be used in the HHRA, unless overwhelming evidence supports using the data (this decision is typically made by the EM project team). Another type of data excluded from the HHRA is filtered-water data. Note, however, that filtered-water data are used in the ERA.

Duplicate (replicate) analyses results must be dealt with by the risk assessor. Some of the common options used include: using only the largest concentration among the replicates, using the average concentration of the replicates, or using all individual replicate concentrations. This decision is typically an EM team decision (e.g., so that all team members evaluate the data in a consistent fashion).

Mainly through an analysis of the available qualifiers provided on the data set (e.g., laboratory qualifiers and/or validation qualifiers), the risk assessor must determine which concentrations are detected concentrations. This will aid in the determination of a frequency of detection for each analyte. Analytes that are never detected will be removed from the COPC list; however, the detection limits for these analytes will be evaluated against human health risk-based concentrations to determine whether the detection limits were appropriate (i.e., not above the risk-based concentrations).

The EM project team should provide direction in how the data are to be grouped (aggregated) for analyses. The team may want to see the risk assessment performed for each individual sampling

location (e.g., for each well) as well as for aggregated data (e.g., a subgrouping of several wells together).

TICs are evaluated to determine relevance at the site. If appropriate, TICs can be eliminated from the risk assessment (EPA 1989), but justification must be provided.

Comparison to relevant background values screens out analytes with concentrations at or below ambient levels at the site. Appropriate background data must be used in this comparison; refer to Appendix B (“Background Comparison”) of the strategy document (LMES 1996c) for specific details.

Comparison to appropriate PRGs screens out analytes that would not individually pose a risk as defined in the conceptual site model (CSM). If a contaminant has a bio-uptake factor greater than 100 then it must not be eliminated from the COPC list. See Appendix A (“Data Evaluation”) of the strategy document (LMES 1996c) for specific details on PRG comparison.

Certain scenarios and pathways are considered in the screen of compounds and analytes against a listing of essential human nutrients. Where appropriate, these essential human nutrients can be eliminated from the COPC list. Refer to *Supplemental Guidance to RAGS: Region 4 Bulletins, Human Health Risk Assessment* (EPA 1995) for details.

A major output from the data evaluation process is the estimation of the exposure concentration, which will be used in the risk characterization (see Sect. 2.1.6). EPA guidance (EPA 1989 and EPA 1995) indicate that the 95% upper confidence limit on the mean concentration (UCL95) shall be used as the exposure concentration unless the maximum detected concentration is smaller, in which case the latter would be used as the exposure concentration. Factors to be considered when estimating the UCL95 include: the statistical distribution of the concentrations [e.g., using a normal, lognormal, or some other distribution, or possibly using a nonparametric (distribution-free) approach]; the number of records available for analysis (e.g., a better estimate of the UCL95 is obtained with a large number of data points than with a small number of data points); and the frequency of detection (e.g., there is no real need to estimate the UCL95 for an analyte that is never detected). Calculating the UCL95 will be discussed in a future strategy document version (LMES 1996c).

The SAS code used by RAP to perform all screens in the data evaluation section is recorded both electronically and in hard-copy format within the project work documentation. The original data set, as received by RAP, is maintained for traceability purposes.

2.1.4 Toxicity Setup

Toxicity values (reference doses, reference concentrations, and slope factors for analytes) are provided to RAP from other members of the Life Sciences Division (of which RAP is also a part). The toxicity values are received from two EPA-approved sources: the Health Effects Assessment and Summary Table and the Integrated Risk Information System and are summarized in table format. These values are continually updated electronically on the World Wide Web at the Risk Assessment Information System (RAIS). Several separate data sets are provided that include chemical, radionuclide, and dermal information.

RAP performs checks to verify changes to the toxicity data sets from the previous deliverable. RAP reads the data sets into SAS data sets and begins the process of adding appropriate chemical-specific information needed for the development of PRGs (see Sect. 2.1.5) and for use in the risk characterization (see Sect. 2.1.6). Refer to the “Introduction” section of the toxicity values document

(LMES 1996d) for other modifications made by RAP to the data sets. All changes to the toxicity data sets are documented in the SAS programs used to make the changes. The original version of the toxicity data sets is maintained by RAP.

The final result of this process is a single SAS data set containing all available and most current toxicity values. The name of the data set contains the year and month consistent with its creation (e.g., a possible name might be SF_9606 for the toxicity data set created in June 1996). This data set is used in the development of the PRGs (see Sect. 2.1.5) and in risk characterization (see Sect. 2.1.6). The data set is stored with protection levels, ensuring that only the owner of the data set can make modifications. All SAS programs used to develop the toxicity data set are also maintained, with proper access privileges (e.g., only the owner can edit), by RAP. RAIS, which is currently available through the OREIS home page, is maintained by OREIS.

2.1.5 PRG Development

PRGs are developed in RAP from a combination of site-specific and chemical-specific information in order to provide a comparison between chemical concentrations at the EM project site and concentrations that would not, on their own, pose a risk as defined in the CSM (developed by the EM project team). The *Preliminary Remediation Goals for Use at the U.S. Department of Energy Oak Ridge Operations Office* (LMES 1996e), as well as RAIS, contain equations, parameters, and calculated PRGs for several land-use scenarios. All PRG calculations are performed by executing SAS programs, which are maintained by RAP. A separate SAS program is maintained for the development of PRGs for each land-use/media-type combination (for example, there are separate programs for the residential land use of water and the exposure to soils under an industrial land-use scenario). Again, the PRGs available on RAIS are currently maintained by OREIS.

2.1.6 Risk Characterization

The activities in risk characterization involve taking the quantitative outputs (exposure concentrations) from data evaluation (Sect. 2.1.3) and assessing the level of human health risk for carcinogens and hazard quotients for noncarcinogens posed by the COPCs. Each EM project must develop its CSM, which determines the land uses, pathways, and media available for the potential and actual receptors in the HHRA.

RAP has set up standard risk and hazard quotient equations in SAS. These programs combine agreed-upon parameter values and exposure concentrations from data evaluation (Sect. 2.1.3) with toxicity values (Sect. 2.1.4) to quantify risks and hazard quotients. Access to these standard programs is controlled, and any modifications to the programs are documented.

Based on the CSM, the appropriate standard risk and hazard quotient equations will be called in a SAS program in order to calculate the appropriate risks and hazard quotients. As noted in the strategy document (LMES 1996c), any deviations from the standard equations must be approved by the Risk Assessment Manager. COCs are determined after summarizing total risk and hazard indexes for a given grouping (e.g., aggregate). If the total risk for a specified grouping exceeds $1.0E-04$ or the hazard index exceeds 1.0, then each analyte with a total risk (i.e., across all appropriate pathways) of at least $1.0E-06$ or a total hazard index (i.e., across all appropriate pathways) of at least 0.1 is considered to be a COC. At this point, remedial goal options (RGOs) are calculated for the site's COCs (for each media) by multiplying the analyte's exposure concentration by a ratio of the desired risk or hazard index to the existing risk or hazard index. Refer to *Supplemental Guidance to RAGS: Region 4 Bulletins, Human Health Risk Assessment* (EPA 1995) for details on calculating RGOs. Typically, RGOs are equal to PRGs unless site-specific parameters different than those specified in

the strategy document (LMES 1996c) were used in the risk and hazard quotient equations. Figure 2 presents the flow of data in RAP from data input to RGOs.

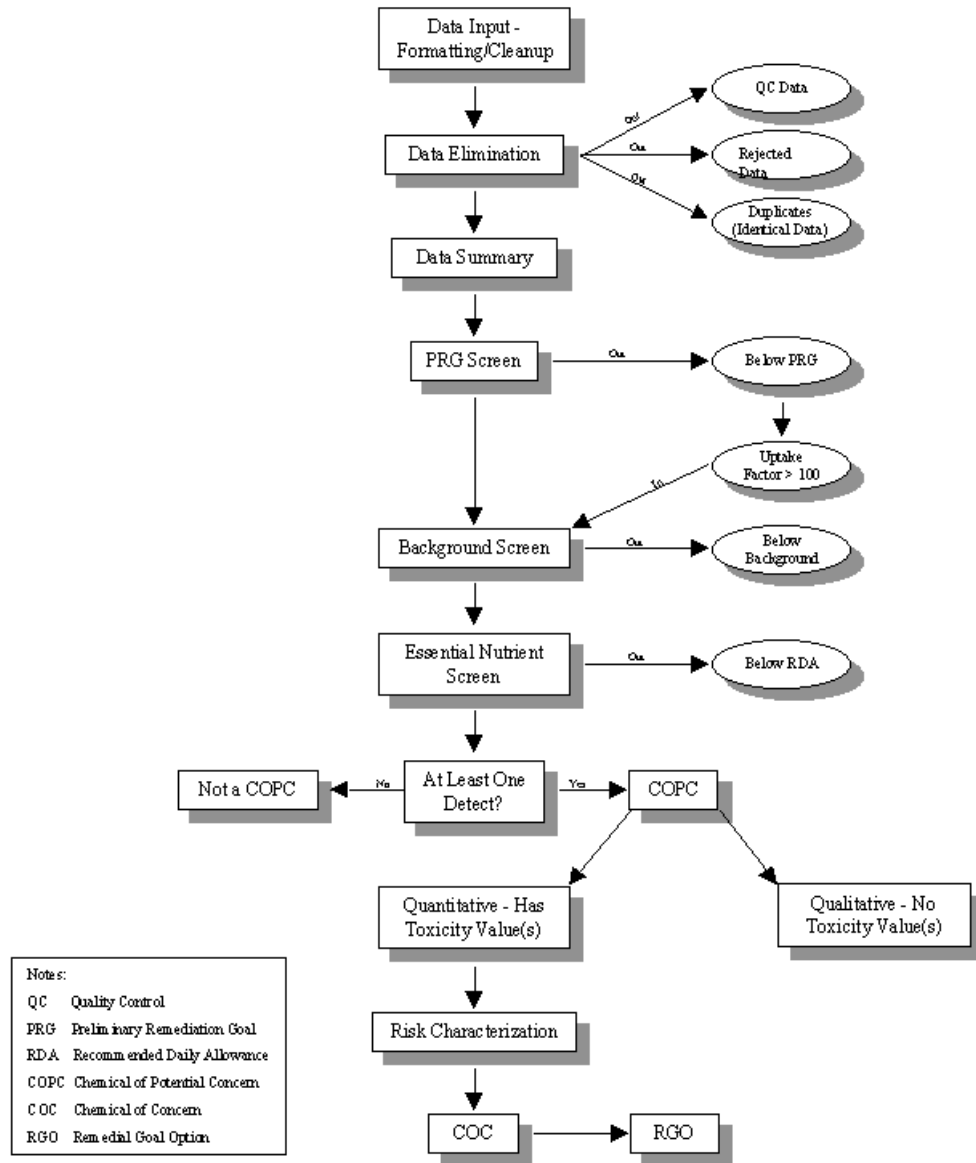


Fig. 2. Data flow for human health risk assessments.

RAP has a system in place to verify that (1) the equations in the SAS program match the equations requested by the EM project, (2) the parameters in the SAS program match the requested parameters, (3) the toxicity values used in the SAS programs match the current toxicity values (LMES 1996d), and (4) the risks and hazard quotients calculated by the SAS program are correct. Independent verifications of these four steps are made, and a verification report is signed and dated. See “Verifying Calculations in Human Health and Ecological Risk Assessments” (LMES 1996f) for details.

2.1.7 Human Health Risk Assessment Data Outputs

The final result of the risk assessment process is a report detailing the level of risk and hazard posed to a human receptor from the COPCs, the resulting COCs, and the uncertainty inherent in the human health risk calculations. The report also details the data management steps taken in acquiring and transforming the data set into a preferred format. This report is peer reviewed prior to presentation to the client (typically the EM project manager) and is included as a component of the remedial investigation.

A variety of tables are produced by RAP and presented in the report. Depending on the EM project, these tables might appear in one of a variety of possible formats (e.g., WordPerfect tables, Excel tables, SAS output). To obtain tables in different formats, a conversion from SAS output to the desired format will need to be made (for example, tab-delimited SAS output can be imported directly into an Excel spreadsheet or into a WordPerfect table). These tables might include, but are not limited to the following:

- summary statistics for all available analytes considered in the HHRA (starting point for the HHRA)
- analytes eliminated from the COPC list and reasons why they were eliminated
- PRG comparison results
- comparison of detection limits with PRGs
- quantitative COPC list (COPCs with toxicity values)
- qualitative COPC list (COPCs without toxicity values)
- toxicity information for the quantitative COPCs
- risk results (including totals across pathways)
- hazard quotient results (including totals across pathways)
- COCs
- RGOs

The SAS programs used and the resulting output are maintained by RAP, with protections set so that only the owner of the programs and output has edit privileges. Typically, specific areas on the hardware (workstation) are used to store data, output, and SAS programs (e.g., a specific area is created for a given project, with all SAS programs for this specific project in the same general area, all data for this specific project in the same general area, and all output for this specific project in the same general area).

2.2 STEPS IN THE ECOLOGICAL RISK ASSESSMENT DATA MANAGEMENT PROCESS

Figure 3 illustrates the data management process flow for ERAs. Sects. 2.2.1–2.2.6 detail the steps outlined in Fig. 3.

2.2.1 Ecological Risk Assessment Data Inputs

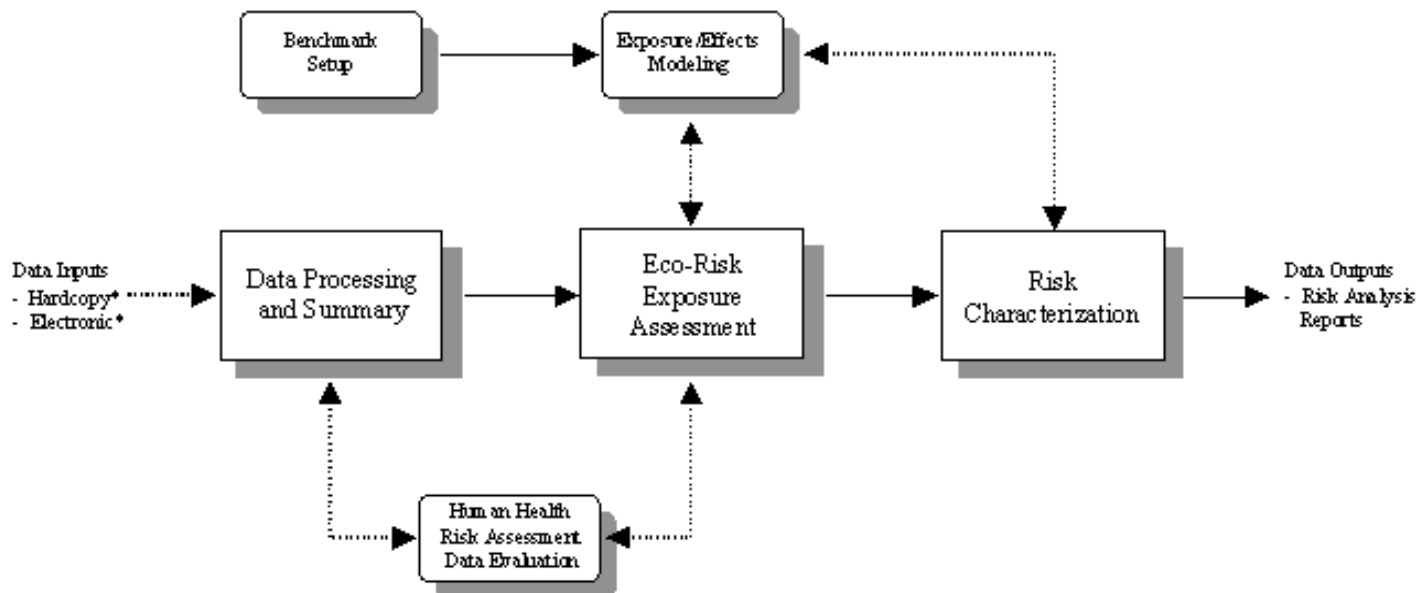
Inputs to the ERA process include hard copy reports and electronic files. These data are input into various data processing systems (e.g., spreadsheets, data bases). Data may be obtained by two routes. The first is directly from the generators, including EM projects; the Biological Monitoring and Abatement Programs for the sites; and other organizations performing sampling, analysis, or data validation. In such cases, data verification and setup will be performed by the ecological risk assessors in a manner equivalent to that described in Sects. 2.1.1 and 2.1.2. The second route is indirectly from the HHRA data evaluation (HHRADe). In that case, the verification, formatting, and cleanup will already have been performed. Prior to removal of fields not required for HHRA, the verified and cleaned SAS data set used by HHRADe will be made available to the ecological risk assessors. This data sharing will be accomplished for the sake of consistency between the risk assessments and to avoid duplication of effort. However, some data verification and setup will need to be performed by the ecological risk assessors because certain data used by in ERA are not used by human health risk assessors (e.g., filtered water data), and ecological assessors may independently verify and set up data used by the human health assessors when circumstances suggest that it is necessary (LMES 1996b).

2.2.2 Data Processing and Summary

Once data are input into the data system, summarization of pertinent data takes place. Data that are of no use to the ecological risk assessor are removed from the system. Useful data are kept and organized in a manner useful to the ecological risk assessor. Statistics are developed on the data set, such as maximum and minimum and average concentrations. To the extent that data evaluation performed by HHRADe (see Sect. 2.1.3) are also useful for ERAs, these evaluations will be performed prior to making the data available for the ERA. The first four steps from Sect. 2.1.3 should always be consistent between the ERA and HHRA. The summarization of data may be different for HHRAs and ERAs (for example, the HHRA may not divide a stream into reaches like those in the ERA). The evaluation of TICs would be the same for ERAs and HHRAs, and the screening against background will be the same in most cases if the data summarization is the same. The next two screening steps in Sect. 2.1.3 (PRG screen and essential nutrient screen) are specific to HHRAs. The exposure concentration would be the same in most cases if the data summarization is the same.

2.2.3 Ecological Risk Exposure Assessment

Most ecological receptors (fish, invertebrates, and plants) are assumed to be exposed to contaminants in a single medium. Therefore, the summarized chemical concentration data for soil, water, and sediment are sufficient models of exposure. However, the multimedia exposures of wildlife must be modeled using the equations and assumptions in *Estimating Exposure of Terrestrial Wildlife to Contaminants* (Sample and Suter 1994). This modeling is performed using spreadsheets on a personal computer (PC).



Notes:

- * Includes reports from Biological Monitoring and Abatement Program (BMAP) and Fate and Transport
- Denotes Process Flow
- - - - - Denotes Inputs

Fig. 3. Data management process flow for environmental risk assessments.

2.2.4 Ecotoxicological Data

Two types of ecotoxicological data are used in the ecological effects assessment. Ecotoxicological benchmark values (benchmarks) are used in screening assessments. They are available in the reports cited in Sect. 2.3.1.3 or on the ERA home page, available through OREIS on the Internet. Ecological toxicity profiles (profiles) are compilations of data concerning the ecotoxicology of individual chemicals. Profiles have been developed *ad hoc*, but standard profiles are being developed by the Environmental Sciences Division at ORNL. Ecological risk assessors should check with the site ERA team leader for recent updates of the benchmarks and availability of profiles.

2.2.5 Risk Characterization

Risk characterization in screening ERAs involves calculation of the quotients of exposure concentrations by ecotoxicological benchmarks as described in a forthcoming technical memorandum. Risk characterization for definitive ERAs involves, for each endpoint, estimation of risks for each line of evidence and weighing of the evidence provided by each estimate to generate an overall estimate of risk to the endpoint. Guidance for ecological risk characterization is being developed.

2.2.6 Ecological Risk Assessment Data Outputs

Outputs of the ERA process are similar to that of the HHRA. Summary reports are prepared delineating the process of ecological risk characterization and presenting the overall level of risk to an ecological community and uncertainty inherent in the ecological risk calculations. These summary reports are typically included with reports on remedial investigations.

2.3 DATA MANAGEMENT IMPLEMENTING PROCEDURES

RAP will use command media for data management written at either the LMES level (Environmental Surveillance Procedures) or at the EM level (Environmental Management and Enrichment Facilities Programs Intersite Procedural Command Media). Where command media do not exist, efforts will be initiated to identify the most appropriate approach to writing the procedure and the most appropriate level for its implementation.

2.3.1 ER-Level Command Media

The following documents currently exist at the EM level and are implemented within the RAP data management structure.

2.3.1.1 Quality Assurance

- *Risk Assessment Program Quality Assurance Plan* (LMES 1997)
- “Identification, Distribution, and Maintenance of Environmental Restoration Records” (LMES 1995a)
- “Backup and Restoration Processes for Environmental Data Management Systems Within the Environmental Restoration Program” (LMES 1995b)

- *Environmental Data Management Implementation Handbook for Environmental Restoration Programs* (LMES 1996a)
- “Environmental Data Entry, Transfer, and Transformation Verification” (LMES 1996b)
- “Archival of Environmental Data Within the EM Program” (LMES 1996g)

2.3.1.2 Data Screening

Data evaluation involves a significant screening process that removes data not appropriate to use in risk assessment (see Sect. 2.1.3). The following guidance provides an implementation framework for this screening process: Appendix A (“Data Evaluation”) of *Risk Assessment Strategy at DOE-ORO* (LMES 1996c)

2.3.1.3 Human Health Data Evaluation

The following documents are used to screen data through the data evaluation framework.

- *Toxicity Values for Use in Hazardous Waste Risk Assessment and Remediation* (LMES 1996d)
- *Toxicity Profiles for Use in Hazardous Waste Risk Assessment and Remediation* (LMES 1996h)

Also, see *Risk Assessment Strategy at DOE-ORO* (LMES 1996c) regarding the following topics.

- incorporating biomedical and environmental information analysis data in toxicity assessments for EM risk assessments
- setting PRGs for EM sites [see also *Preliminary Remediation Goals for Use at the U.S. Department of Energy Oak Ridge Operations Office* (LMES 1996e)]
- uncertainty analysis in HHRAs and ERAs [see also *An Introductory Guide to Uncertainty Analysis in Environmental and Health Risk Assessment* (Hammonds, Hoffman, and Bartell 1994)]

2.3.1.4 Ecological Data Evaluation

The following documents are used to screen data through the ecological data evaluation framework.

- *Toxicological Benchmarks for Wildlife: 1996 Revision* (Sample, Opresko, and Suter 1996)
- *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants: 1995 Revision* (Will and Suter 1995a)
- *Toxicological Benchmarks for Screening Contaminants of Potential Concern for Effects on Sediment-Associated Biota: 1996 Revision* (Jones, Hull, and Suter 1996)
- *Toxicological Benchmarks for Screening Contaminants of Potential Concern for Effects on Aquatic Biota: 1996 Revision* (Suter and Tsao 1996)

- *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Soil and Litter Invertebrates and Heterotrophic Processes* (Will and Suter 1995b)
- *Preliminary Remediation Goals for Ecological Endpoints* (Efroymsen et al. 1996)
- *Estimating Exposure of Terrestrial Wildlife to Contaminants* (Sample and Suter 1994)

3. ROLE DESCRIPTIONS

This chapter presents documented references where RAP roles and responsibilities can be located and presents RAP-specific roles for data management.

3.1 GENERAL DESCRIPTION

Roles and responsibilities for DOE-ORO and RAP are presented in the following documents.

- DOE-ORO Office of the Director, ER Division—“Policy Guidance, Environmental Restoration Risk Assessment Implementation and Interaction” (DOE 1996)
- *Risk Assessment Program Quality Assurance Plan* (LMES 1995c)
- “Risk Assessment Roles and Responsibilities” (MMES 1992a)
- “Integrating Contractor Issues in Risk Assessment” (MMES 1992b)
- “Requirements for Conducting Human Health and Ecological Risk Assessments” (LMES 1996i)

3.2 RAP DATA MANAGEMENT

Data management responsibilities are identified in this section. Responsibilities presented here should be referenced to the activities identified in Fig. 1, Process Flow.

3.2.1 Internal RAP Responsibilities

Data Evaluation Team

- Data Evaluation Manager
 - Develops source code for performing data evaluation tasks
 - Copies and modifies source code for use with various project data sets in data evaluation
 - Ensures that electronic backup schedules are maintained
 - Ensures adherence to RAP and EM data management procedure requirements
 - Ensures adherence to system maintenance schedule
 - Interacts with external hardware and software support personnel
- Data Evaluation Technical Personnel
 - Develop source code for performing data evaluation tasks
 - Copy and modify source code for use with various project data sets in data evaluation
 - Receive and set up toxicity data sets, which in turn are used to develop the PRG data sets

3.2.2 External Support

System Administrator/Workstation Support Staff (hardware and software)

- Interact with the RAP data evaluation team to provide hardware and software (UNIX) support, including regularly scheduled system backups and data archival, when necessary

SAS Support Staff (software)

- Interact with the RAP data evaluation team to provide SAS software support.

4. DATA REQUIREMENTS

4.1 RAP HUMAN HEALTH RISK ASSESSMENT DATA DICTIONARY

The HHRA data dictionary is presented in Appendix A.

4.2 ECOLOGICAL RISK ASSESSMENT DATA DICTIONARY

ERAs use highly diverse data from a variety of sources, including biological surveys, biomarker studies, and toxicity tests. In addition, the risk characterization is performed by weight of evidence, which requires some flexibility in data analysis. Therefore, it is not possible to specify a data dictionary for ERA.

When HHRA data are received for an ERA, the HHRA data dictionary is used as a starting point, prior to ecological data analysis.

5. DATA MANAGEMENT SYSTEM

This chapter describes the RAP data management system objectives and hardware/software components and provides a description of compliance with the LMES ADP/SDM documentation.

5.1 DATA MANAGEMENT SYSTEM OBJECTIVES

The RAP data management system fulfills a need to receive, organize, and present environmental measurements data in a controlled and documented manner. The system should provide maximum usefulness to the risk assessment process.

5.2 DESCRIPTION OF SYSTEM COMPONENTS

5.2.1 Hardware Components

The main hardware component used in the RAP HHRA data management system is a DEC Station 5000/240 (workstation with a 1-gigabyte hard drive) with the following peripherals: 2-gigabyte, 8 mm tape drive (for backups and data archival); CD ROM; storage expansion drive (5.25" floppy drive); and two external hard drives (one with a 2-gigabyte drive and one with a 9-gigabyte drive).

Also, the HHRA data management system uses a SUN Sparc 5+ workstation with one tape drive, one CD ROM, and a DEC Station 5000/200 workstation but not as primary hardware. Other hardware used includes IBM-compatible PCs and Hewlett Packard Laser Jet printers.

Hardware used for ERAs includes a Sun SparcStation 10, IBM-compatible PCs, and an Apple Macintosh. Various personal and network printers are used.

All systems are unclassified; therefore, no classified data can be transferred to or stored on RAP computer systems. If analysis of classified data is ever required, it will be performed on an appropriate classified computer system by appropriate personnel. Additional hardware components may be added as necessary.

5.2.2 Software Components

The main software used in the RAP data management system is SAS[®] software (from SAS[®] Institute, Inc., in Cary, North Carolina). SAS is installed on the DEC workstation, on the SUN workstation, and on one of the PCs (three different SAS "platforms").

Other software used in the data evaluation process is a function of the format in which data are submitted to RAP. Included are the following PC-based software applications: Microsoft Excel, Microsoft FoxPro, Microsoft Access, and WordPerfect. Although not a software, file transfer protocol (FTP) is a mechanism used to transfer data between PCs and the workstation or from other computer systems (e.g., OREIS) to the workstation. Modeling programs such as Multimedia Environmental Pollutant Assessment System or RESidual RADioactivity may also be used after initial data evaluation.

The ERA also uses SAS software for data management and analysis and FTP for file transfer. Other software used for ERAs include Lotus 123, Microsoft Excel, Lotus Freelance, Microsoft Powerpoint, Word Perfect, and Palisade @Risk.

Additional software components may be added as necessary.

5.3 COMPLIANCE WITH SOFTWARE QUALITY ASSURANCE DOCUMENTATION

The data management system used by RAP makes use of developed programs such as SAS. SAS code is written to import environmental data sets and to evaluate the data. RAP does not develop software applications pursuant to ADP/SDM (MMES 1990). However, if software development is pursued, RAP will recognize and comply with the life cycle requirements in LMES ADP/SDM.

More pertinent to the RAP data management system are the requirements for software quality assurance outlined in the LMES standard, "Software Quality Assurance" (MMES 1992c). RAP will adhere to the requirements in this document. Guidance for implementation of this standard is contained in the procedure "Quality Assurance for Oak Ridge National Laboratory Computer Software" (MMES 1993).

5.3.1 Access and Configuration Control

All SAS® original programs are electronically maintained by RAP for traceability purposes. All program changes are also electronically maintained with protections so that only authorized individuals have edit privileges. All changes are documented with the date and a record of who made the changes.

5.3.2 Data Records Management

All electronic records, which include project-specific data bases, program changes, etc., are maintained on the workstation. Because adequate space exists on the workstation to store all electronic records for each project and because some projects are too large and complex to maintain hard-copy records, records will be maintained in electronic form only. This electronic form will serve as the "record copy." Only appropriate hard-copy information (e.g., location of electronic records on the workstation) will be maintained in the project files, according to "Identification, Distribution, and Maintenance of Environmental Restoration Records" (LMES 1995a). When space becomes a problem on the workstation, RAP will maintain all hard-copy records in accordance with the EM procedure (LMES 1995a).

For HHRA data management, system backups on the workstations are automated to be performed daily. Backups occur after work hours, and a report of the occurrence and backup difficulties is automatically sent to the HHRA data evaluation manager via e-mail. The requirements of "Backup and Restoration Processes for Environmental Data Management Systems Within the Environmental Restoration Program" (LMES 1995b) are implemented within the RAP data management system to control data backup and restoration. Ecological data stored on the Sun SparcStation 10 are backed up on a regular schedule by the system administrator for that workstation; incremental backups (changes since the last backup) are performed daily, and full backups are performed weekly.

5.3.2 Data Archival

For most EM projects, RAP's data are a subset of the official data set for that project; therefore, the EM project manager has the responsibility of archiving the entire data set (LMES 1996g). If it is appropriate for RAP to archive EM project data (e.g., if the EM project manager delegates that responsibility to RAP or if RAP is the only organization managing the data), then upon closure of the project, all electronic data associated with that project will be converted to ASCII file format, verified according to "Environmental Data Entry, Transfer, and Transformation Verification" (LMES 1996b), and sent to the EM Document Management Center for archival according to "Archival of Environmental Data Within the ER Program" (LMES 1996g).

In general, data archival will be performed on an as-needed basis. The RAP data manager assigned to the specific EM project will be responsible for data archival.

6. RAP DATA REQUESTS

At the present time, electronic data used in HHRA are obtained from the level of an EM project data base. HHRA data management presently requests a standard format for electronic data deliverables from data providers. However, future plans include requesting data from providers to OREIS in ready-to-load format. This format is discussed in *Transmitting ER Data in Ready-To-Load Form to the Oak Ridge Environmental Information System (OREIS)* (MMES 1995). In cases where this request cannot be satisfied, RAP data management will request data in a specified format agreeable to both RAP and the data provider.

As ERA data management uses data that are not typically submitted to OREIS, these data will continue to be gleaned from project-level data bases and hard-copy reports into the foreseeable future.

6.1 RAP DATA DICTIONARY

The RAP data dictionary (Appendix A) has been developed for use only within RAP. It serves to provide a common framework with which RAP data management can organize electronic data. The variable names presented in the RAP data dictionary may serve as a starting point for future incorporation of RAP variable names into the OREIS structure. At the present time, however, this set of variable names will be used exclusively within the HHRA and ERA data management structure. Variable names may be added as necessary.

7. REFERENCES

- DOE (U.S. Department of Energy). 1996. "Policy Guidance, Environmental Restoration Risk Assessment Implementation and Interaction," Oak Ridge, Tenn.
- Efroymsen, R. A., et al. 1996. *Preliminary Remediation Goals for Ecological Endpoints*, ES/ER/TM-162/R1, Oak Ridge, Tenn.
- EPA (U.S. Environmental Protection Agency). 1989. *Risk Assessment Guidance for Superfund (RAGS), Volume 1, Human Health Evaluation Manual (Part A)*, Interim Final, EPA/540/I-89/002, Office of Emergency and Remedial Response, December.
- EPA. 1995. *Supplemental Guidance to RAGS: Region 4 Bulletins, Human Health Risk Assessment*, Office of Emergency and Remedial Response, November.
- Hammonds, J. S., F. O. Hoffman, and S. M. Bartell. 1994. *An Introductory Guide to Uncertainty Analysis in Environmental and Health Risk Assessment*, ES/ER/TM-35/R1, Oak Ridge, Tenn., December.
- Jones, D. S., R. N. Hull, and G. W. Suter II. 1996. *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Sediment-Associated Biota: 1996 Revision*, ES/ER/TM-95/R2, Oak Ridge, Tenn., June.
- LMES (Lockheed Martin Energy Systems, Inc.). 1995a. "Identification, Distribution, and Maintenance of Environmental Restoration Records," ERWM/ER-P1110, Rev. 1, Oak Ridge, Tenn., December.
- LMES. 1995b. "Backup and Restoration Processes for Environmental Data Management and Systems Within the Environmental Restoration Program," ERWM/ER-P2207, Rev.0, Oak Ridge, Tenn., August.
- LMES. 1995c. *Risk Assessment Quality Assurance Plan*, ES/ER/TM-117/R1, Oak Ridge, Tenn., September.
- LMES. 1996a. *Environmental Data Management Implementation Handbook for the Environmental Restoration Program*, ES/ER/TM-88/R1, Environmental Restoration Data Quality Program, Oak Ridge, Tenn., April.
- LMES. 1996b. "Environmental Data Entry, Transfer, and Transformation Verification," EM&EF/ER-P2214, Rev. 0, Oak Ridge, Tenn., September.
- LMES. 1996c. *Risk Assessment Strategy at DOE-ORO*, ES/ER/TM-180, Oak Ridge, Tenn., September.
- LMES. 1996d. *Toxicity Values for Use in Hazardous Waste Risk Assessment and Remediation*, ES/ER/TM-76/R1 (or current version), Biomedical and Environmental Information Analysis Section, Oak Ridge, Tenn.

- LMES. 1996e. *Preliminary Remediation Goals for Use at the U.S. Department of Energy Oak Ridge Operations Office*, ES/ER/TM-106/R1 (or current version), Oak Ridge, Tenn., May.
- LMES. 1996f. "Verifying Calculations in Human Health and Ecological Risk Assessments," EM&EF/ER-P2009/Rev.0, Oak Ridge, Tenn., June.
- LMES. 1996g. "Archival of Environmental Data Within the ER Program," EM&EF/ER-P2215, Rev. 0, Oak Ridge, Tenn., September.
- LMES. 1996h. *Toxicity Profiles for Use in Hazardous Waste Risk Assessment and Remediation*, ES/ER/TM-77/R1 (or current version), Oak Ridge, Tenn.
- LMES. 1996i. "Requirements for Conducting Human Health and Ecological Risk Assessments," EM&EF/ER-S2010, Rev.0, Oak Ridge, Tenn., July.
- LMES 1997. *Risk Assessment Program Quality Assurance Plan*, ES/ER/TM-117/R1, Oak Ridge, Tenn., November.
- MMES (Martin Marietta Energy Systems, Inc.). 1990. *Automated Data Processing Systems Development Methodology*, K/CSD/INF/86-3/R3, Oak Ridge, Tenn., March.
- MMES. 1992a. "Risk Assessment Roles and Responsibilities," ER/C-S2001, Rev. 0, Oak Ridge, Tenn., July.
- MMES. 1992b. "Integrating Contractor Issues in Risk Assessment," ER/C-S2002, Rev. 0, Oak Ridge, Tenn., June.
- MMES. 1992c. "Software Quality Assurance," ESS-QA-19.0, Rev.1, Oak Ridge, Tenn., August.
- MMES. 1993. "Quality Assurance for Oak Ridge National Laboratory Computer Software," X-QA-8, Oak Ridge, Tenn., July.
- MMES. 1995. *Transmitting Environmental Restoration Data in Ready-To-Load Form to the Oak Ridge Environmental Information System (OREIS)*, ERWM/ER-P2701, Rev. 2, Oak Ridge, Tenn., March.
- Sample, B. E., and G. W. Suter II. 1994. *Estimating Exposure of Terrestrial Wildlife to Contaminants*, ES/ER/TM-125, Oak Ridge, Tenn., September.
- Sample, B. E., D. M. Opresko, and G. W. Suter II. 1996. *Toxicological Benchmarks for Wildlife: 1996 Revision*, ES/ER/TM-86/R3, Oak Ridge, Tenn., June.
- Suter, G. W., II, and C. L. Tsao. 1996. *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Aquatic Biota: 1996 Revision*, ES/ER/TM-96/R2, Oak Ridge, Tenn., June.
- Will, M. E., and G. W. Suter II. 1995a. *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Terrestrial Plants: 1995 Version*, ES/ER/TM-85/R2, Oak Ridge, Tenn., September.

Will, M. E., and G. W. Suter II. 1995b. *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effects on Soil and Litter Invertebrates and Heterotrophic Processes*, ES/ER/TM-126/R2, Oak Ridge, Tenn., September.

APPENDIX A

**HUMAN HEALTH RISK ASSESSMENT
DATA DICTIONARY**

Unique fields and descriptions for human health risk assessment data dictionary

Variable	Type	Description
ABS	Numerical	Absorption factor (for dermal/soil)
ADRFDOC	Numerical	Dermal chronic reference dose
ADRFDOS	Numerical	Dermal sub-chronic reference dose
ADSFO	Numerical	Dermal slope factor
ANA_TYPE	Character	Analyte Type (SVOA, VOA, etc.)
ANALYSIS	Character	Analyte's Name
ANAT_OLD	Character	Original Value for ANATYPE
ANAT_ORD	Character	ANATYPE for sorting purposes
ANATYPE	Character	Analyte Type (Organics, Inorganics, Rad.)
ANLY_OLD	Character	Original Value for ANALYSIS
ANLY_ORD	Character	ANALYSIS for sorting purposes
AREA	Character	Area within OU
BEEFBTF	Numerical	Bio-transfer factor for beef
BVDRY	Numerical	BVDRY (dry soil to plant uptake) for pasture
BVWET	Numerical	BVWET (wet soil to plant uptake) for leafy vegetables
BVWNON	Numerical	BVWET (wet soil to plant uptake) for non-leafy vegetables
C	Numerical	Representative Concentration (used in HHRA)
C_VS_PRG	Character	Statistic used to compare against PRG
C01DER	Numerical	PRG for dermal with HI=0.1
C01ING	Numerical	PRG for ingestion with HI=0.1
C01INGA	Numerical	PRG for adult ingestion with HI=0.1
C01INGC	Numerical	PRG for child ingestion with HI=0.1
C01INGD	Numerical	PRG for ingestion of deer with HI=0.1
C01INGF	Numerical	PRG for ingestion of fish with HI=0.1
C01INGHD	Numerical	PRG for ingestion and inhalation and dermal with HI=0.1
C01INH	Numerical	PRG for inhalation with HI=0.1
C1DER	Numerical	PRG for dermal with HI=1
C1ING	Numerical	PRG for ingestion with HI=1
C1INGA	Numerical	PRG for adult ingestion with HI=1
C1INGC	Numerical	PRG for child ingestion with HI=1
C1INGD	Numerical	PRG for ingestion of deer with HI=1
C1INGF	Numerical	PRG for ingestion of fish with HI=1
C1INGHD	Numerical	PRG for ingestion and inhalation and dermal with HI=1
C1INH	Numerical	PRG for inhalation with HI=1
C4DER	Numerical	PRG for dermal with risk level = 1E-4
C4EXT	Numerical	PRG for external with risk level = 1E-4
C4ING	Numerical	PRG for ingestion with risk level = 1E-4
C4INGD	Numerical	PRG for ingestion of deer with risk level = 1E-4
C4INGF	Numerical	PRG for ingestion of fish with risk level = 1E-4
C4INGH	Numerical	PRG for ingestion and inhalation with risk level = 1E-4
C4INGHD	Numerical	PRG for ingestion and inhalation and dermal with risk level = 1E-4
C4INGHX	Numerical	PRG for ingestion and inhalation and external with risk level = 1E-4
C4INH	Numerical	PRG for inhalation with risk level = 1E-4
C6DER	Numerical	PRG for dermal with risk level = 1E-6

Variable	Type	Description
C6EXT	Numerical	PRG for external with risk level = 1E-6
C6ING	Numerical	PRG for ingestion with risk level = 1E-6
C6INGD	Numerical	PRG for ingestion of deer with risk level = 1E-6
C6INGF	Numerical	PRG for ingestion of fish with risk level = 1E-6
C6INGH	Numerical	PRG for ingestion and inhalation with risk level = 1E-6
C6INGHD	Numerical	PRG for ingestion and inhalation and dermal with risk level = 1E-6
C6INGHX	Numerical	PRG for ingestion and inhalation and external with risk level = 1E-6
C6INH	Numerical	PRG for inhalation with risk level = 1E-6
CASN_OLD	Numerical	Original Value for CASNUM
CASNUM	Numerical	CAS Number (Numeric, without dashes)
CASR_OLD	Character	Original Value for CAS_NUM
CASRN	Character	Chemical Abstract Registry Number (with dashes)
CB01	Numerical	PRG in beef at HI=0.1
CB1	Numerical	PRG in beef at HI=1
CB4	Numerical	PRG in beef at risk level = 1E-4
CB6	Numerical	PRG in beef at risk level = 1E-6
CENSORED	Character	Censored Data? (YES/NO)
CKCOCDH	Character	Check dermal HQ for COC status?
CKCOCDR	Character	Check dermal risk for COC status?
CKCOCGH	Character	Check ingestion HQ for COC status?
CKCOCGHA	Character	Check adult ingestion HQ for COC status?
CKCOCGHC	Character	Check child ingestion HQ for COC status?
CKCOCGR	Character	Check ingestion risk for COC status?
CKCOCIH	Character	Check inhalation HQ for COC status?
CKCOCIR	Character	Check inhalation risk for COC status?
CKCOCXR	Character	Check external exposure risk for COC status?
CLASS	Character	EPA class
CLASSSRC	Character	EPA class source
CM4	Numerical	PRG in milk at risk level = 1E-4
CM6	Numerical	PRG in milk at risk level = 1E-6
CMA01	Numerical	Adult PRG in milk at HI=0.1
CMA1	Numerical	Adult PRG in milk at HI=1
CMC01	Numerical	Child PRG in milk at HI=0.1
CMC1	Numerical	Child PRG in milk at HI=1
COC_DER	Character	Is Analyte a COC for Dermal Pathway?
COC_EXT	Character	Is Analyte a COC for External Exposure Pathway?
COC_ING	Character	Is Analyte a COC for Ingestion Pathway?
COC_ING	Character	Is Analyte a COC for Ingestion Pathway?
COC_INGA	Character	Is Analyte a COC for Adult Ingestion Pathway?
COC_INGC	Character	Is Analyte a COC for Child Ingestion Pathway?
COC_INH	Character	Is Analyte a COC for Inhalation Pathway?
CONC	Numerical	Conc. used to compare vs. PRG
COPC	Character	Is analyte a COPC? (YES/NO)
CS_B01	Numerical	Soil PRG at HI=0.1 based on CB with HI=0.1
CS_B1	Numerical	Soil PRG at HI=1 based on CB with HI=1

Variable	Type	Description
CS_B4	Numerical	Soil PRG at Risk=1E-4 based on CB with risk level = 1E-4
CS_B6	Numerical	Soil PRG at Risk=1E-6 based on CB with risk level = 1E-6
CS_M4	Numerical	Soil PRG at Risk=1E-4 based on CM with risk level = 1E-4
CS_M6	Numerical	Soil PRG at Risk=1E-6 based on CM with risk level = 1E-6
CS_MA01	Numerical	Soil PRG at HI=0.1 for adult based on CMA with HI=0.1
CS_MA1	Numerical	Soil PRG at HI=1 for adult based on CMA with HI=1
CS_MC01	Numerical	Soil PRG at HI=0.1 for child based on CMC with HI=0.1
CS_MC1	Numerical	Soil PRG at HI=1 for child based on CMC with HI=1
CS_V01	Numerical	Soil PRG at HI=0.1 based on CV with HI=0.1
CS_V1	Numerical	Soil PRG at HI=1 based on CV with HI=1
CS_V4	Numerical	Soil PRG at Risk=1E-4 based on CV with risk level = 1E-4
CS_V6	Numerical	Soil PRG at Risk=1E-6 based on CV with risk level = 1E-6
CSAT	Numerical	Soil saturation concentration
CV1	Numerical	PRG in vegetables at HI=1
CV4	Numerical	PRG in vegetables at risk level = 1E-4
CV6	Numerical	PRG in vegetables at risk level = 1E-6
CW_B01	Numerical	Water PRG at HI=0.1 based on CB with HI=0.1
CW_B1	Numerical	Water PRG at HI=1 based on CB with HI=1
CW_B4	Numerical	Water PRG at Risk=1E-4 based on CB with risk level = 1E-4
CW_B6	Numerical	Water PRG at Risk=1E-6 based on CB with risk level = 1E-6
CW_M4	Numerical	Water PRG at Risk=1E-4 based on CM with risk level = 1E-4
CW_M6	Numerical	Water PRG at Risk=1E-6 based on CM with risk level = 1E-6
CW_MA01	Numerical	Water PRG at HI=0.1 for adult based on CMA with HI=0.1
CW_MA1	Numerical	Water PRG at HI=1 for adult based on CMA with HI=1
CW_MC01	Numerical	Water PRG at HI=0.1 for child based on CMC with HI=0.1
CW_MC1	Numerical	Water PRG at HI=1 for child based on CMC with HI=1
CW_V01	Numerical	Water PRG at HI=0.1 based on CV with HI=0.1
CW_V1	Numerical	Water PRG at HI=1 based on CV with HI=1
CW_V4	Numerical	Water PRG at Risk=1E-4 based on CV with risk level = 1E-4
CW_V6	Numerical	Water PRG at Risk=1E-6 based on CV with risk level = 1E-6
DATE_COL	Numerical	Date Sample Collected (MMDDYY)
DCCDI	Numerical	Dermal carcinogenic CDI
DEP_END	Numerical	Ending Sample Depth (soil)
DEP_STRT	Numerical	Starting Sample Depth (soil)
DEP_UNIT	Character	Depth Units
DEPVELOC	Numerical	Deposition velocity in m/day
DERRISK	Numerical	Dermal risk after 1-hit rule
DET	Numerical	# Samples Detected
DET_CNT	Numerical	Detect Counter (0/1)
DET_LIM	Numerical	Detection Limit
DETECTED	Character	Detected Concentration? (YES/NO)
DHQ	Numerical	Dermal hazard quotient
DIST	Character	Distribution Used for exposure concentration
DL_OLD	Numerical	Original Value for DET_LIM
DNCDI	Numerical	Dermal noncarcinogenic CDI

Variable	Type	Description
ELEMENT	Character	Periodic Table id if inorganic or radionuclide
ELIMINAT	Character	Eliminate analyte based on screen?
EVALTYPE	Character	Evaluation Type (Qual./Quant.)
EXTRISK	Numerical	External Exposure risk after 1-hit rule
FILTERED	Character	Filtered Sample? (YES/NO)
FISHBTF	Numerical	Bio-transfer factor for fish
FOODUSE	Character	Use toxicity value for food?
FREQ_DET	Character	Freq. of Detection
GCCDI	Numerical	Ingestion carcinogenic CDI
GHQ	Numerical	Ingestion hazard quotient
GHQ_A	Numerical	Ingestion hazard quotient for an adult
GHQ_C	Numerical	Ingestion hazard quotient for a child
GIABS	Numerical	Gastrointestinal absorption factor
GIABSSRC	Character	GIABS source
GNCDI	Numerical	Ingestion noncarcinogenic CDI
GNCDI_A	Numerical	Adult ingestion noncarcinogenic CDI
GNCDI_C	Numerical	Child ingestion noncarcinogenic CDI
GTPRG6	Character	Is maximum > PRG at Risk=1.0E-06 (YES/NO)
GTPRGPT1	Character	Is maximum > PRG at HQ=0.1? (YES/NO)
HALFLIFE	Numerical	Radioactive half-life
HALFUNIT	Character	Units for half-life
ICCDI	Numerical	Inhalation carcinogenic CDI
IHQ	Numerical	Inhalation hazard quotient
INCDI	Numerical	Inhalation noncarcinogenic CDI
INGRISK	Numerical	Ingestion risk after 1-hit rule
INT_B01	Numerical	Intercept at HI=0.1 based on CB with HI=0.1
INT_B1	Numerical	Intercept at HI=1 based on CB with HI=1
INT_B4	Numerical	Intercept at Risk=1E-4 based on CB with risk level = 1E-4
INT_B6	Numerical	Intercept at Risk=1E-6 based on CB with risk level = 1E-6
INT_M4	Numerical	Intercept at Risk=1E-4 based on CM with risk level = 1E-4
INT_M6	Numerical	Intercept at Risk=1E-6 based on CM with risk level = 1E-6
INT_MA01	Numerical	Intercept at HI=0.1 for adult based on CMA with HI=0.1
INT_MA1	Numerical	Intercept at HI=1 for adult based on CMA with HI=1
INT_MC01	Numerical	Intercept at HI=0.1 for child based on CMC with HI=0.1
INT_MC1	Numerical	Intercept at HI=1 for child based on CMC with HI=1
INT_V01	Numerical	Intercept at HI=0.1 based on CV with HI=0.1
INT_V1	Numerical	Intercept at HI=1 based on CV with HI=1
INT_V4	Numerical	Intercept at Risk=1E-4 based on CV with risk level = 1E-4
INT_V6	Numerical	Intercept at Risk=1E-6 based on CV with risk level = 1E-6
IUR	Numerical	Inhalation unit risk
IURSRC	Character	IUR source
KOC	Numerical	Octanol-carbon partition coefficient
KOW	Numerical	Octanol-water partition coefficient
KOWSORCE	Character	KOW source

Variable	Type	Description
KP	Numerical	Permeability constant
KPNOTE	Character	KP reference (source)
LAB_QUAL	Character	Laboratory Qualifier
LANDUSE	Character	Land Use Scenario being evaluated
LOCATION	Character	Location
LOGKOW	Numerical	Ln(kow)
LOGKP	Numerical	Ln(kp)
LOGSTAT	Numerical	Test Statistic for Lognormality Test
LUNGCLAS	Character	ICRP Lung Class
MAX_DET	Numerical	Maximum Detected Concentration
MAX_NOND	Numerical	Maximum Nondetected Concentration
MAXGTPRG	Character	Is maximum concentration > PRG? (YES/NO)
MEAN	Numerical	Mean Concentration
MEDIA	Character	Media
MEDIUM	Character	Medium
MEDTYPE	Character	Media type - soil, water, or both
MILKBTF	Numerical	Bio-transfer factor for milk
MIN_DET	Numerical	Minimum Detected Concentration
MIN_NOND	Numerical	Minimum Nondetected Concentration
MKOW	Numerical	Multimedia Environmental Pollutant Assessment value for kow
MWEIGHT	Numerical	Molecular weight
N	Numerical	# Samples Analyzed
NICKNAME	Character	VOC/SVOC distinction
NORSTAT	Numerical	Test Statistic for Normality Test
NOTE	Character	Rad note: m=metastable, +D=+ daughters
OUR	Numerical	Oral unit risk
OURSRC	Character	OUR source
PEFU95	Numerical	Particulate emission factor
PRG_6	Numerical	Residential PRG for Screening, based on Risk=1E-6
PRG_PT1	Numerical	Residential PRG for Screening, based on HI=0.1
PRG_TYPE	Character	PRG Type (Water/Soil)
PROBL	Numerical	p-value for Lognormal Test
PROBN	Numerical	p-value for Normal Test
PROJECT	Character	Project Name
RADUSE	Character	Radionuclide use in risk assessment (yes/no)
RESULT	Numerical	Concentration
RFCIC	Numerical	Inhalation chronic reference concentration
RFCICSRC	Character	RFCIC source
RFCIS	Numerical	Inhalation subchronic reference concentration
RFCISSRC	Character	RFCIS source
RFDIC	Numerical	Inhalation chronic reference dose
RFDOC	Numerical	Ingestion chronic (oral) reference dose
RFDOCSRC	Character	RFDOC source
RFDOS	Numerical	Ingestion subchronic (oral) reference dose
RFDOSSRC	Character	RFDOS source

Variable	Type	Description
RSLT_OLD	Numerical	Original Value for RESULT
S	Numerical	Solubility in mg/l
SCENARIO	Character	Scenario being evaluated for agriculture (dirty/clean, soil/water combinations)
SFI	Numerical	Inhalation slope factor
SFISRC	Character	SFI source
SFO	Numerical	Ingestion slope factor
SFOSRC	Character	SFO source
SFX	Numerical	External exposure slope factor
SLOPE_B	Numerical	Beef slope
SLOPE_M	Numerical	Milk slope
SLOPE_V	Numerical	Vegetable slope
SMP_ID	Character	Sample Identifier
SMP_TYPE	Character	Sample Type (REG, DUP, TIC, etc.)
SOILUSE	Character	Use toxicity value for soil?
STATION	Character	Sample Station
SYNONYM	Character	Alias (for analyte name)
TEST	Character	Perform Distributional Test? (YES/NO)
THRESH	Numerical	Limiting Value for PRG (1e+6 mg/kg or 1e+6 mg/L)
TOTALHI	Numerical	Total hazard index (across all appropriate pathways)
TOTRISK	Numerical	Total risk after 1-hit rule
TYPE	Character	Chemical type: rad or nonrad
UCL95	Numerical	Upper 95% Confidence Limit on the Mean
UNC	Numerical	Measurement Uncertainty
UNIT_OLD	Character	Original Value for UNITS
UNITS	Character	Units of Measure
USE_HHRA	Character	Use Data in HHRA? (YES/NO)
VAL_QUAL	Character	Validation Qualifier
VARN	Numerical	Variance(RESLT2) assuming Normal Distribution
VFU95	Numerical	Volatilization factor
VOL_COM	Character	VOC/SVOC comments
VOL_ORG	Character	Is the analyte a volatile organic? (YES/NO)
VOL_REF	Character	VOC/SVOC reference
VV	Character	Validation Performed ? (YES/NO)
WATERUSE	Character	Use toxicity value for water?
WELL_DEP	Numerical	Well Depth
WTHDRAWN	Character	Date toxicity value was withdrawn
XCCDI	Numerical	External exposure carcinogenic CDI