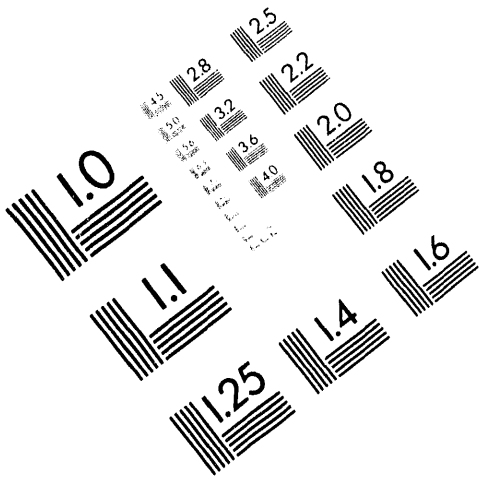


AIIM

Association for Information and Image Management

1100 Wayne Avenue, Suite 1100
Silver Spring, Maryland 20910

301/587-8202

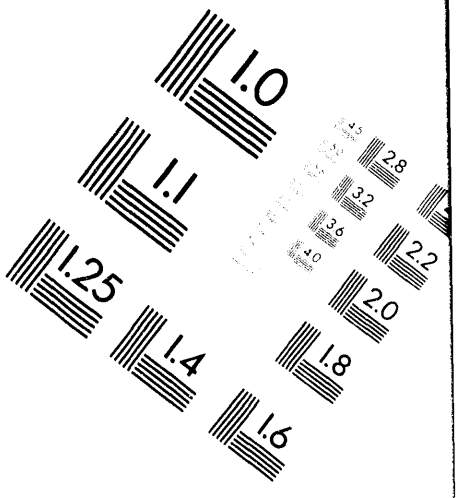
Centimeter

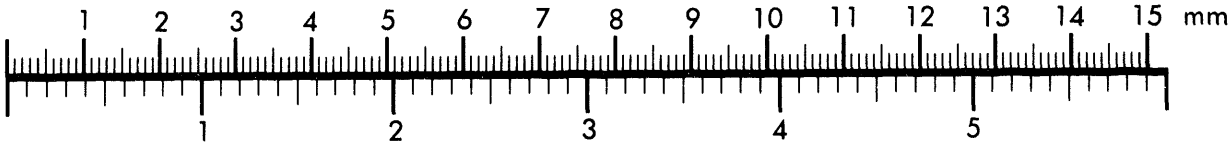
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 mm

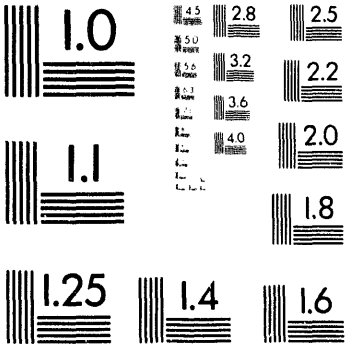
1 2 3 4 5

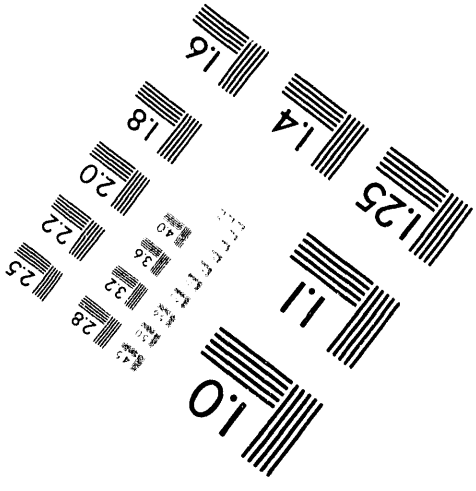
Inches

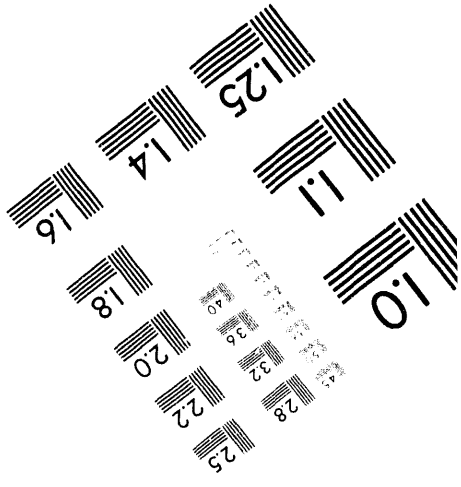
MANUFACTURED TO AIIM STANDARDS
BY APPLIED IMAGE, INC.











1 of 1

CONF-9403102--1

Defining the Role of Risk Assessment in the Comprehensive Environmental Response Compensation and Liability Act Remedial Investigation Process at the DOE-OR

P.D. Miller
C.W. McGinn
S.T. Purucker[1]
A. Redfearn[1]
R.K. White

*Oak Ridge National Laboratory, Health Sciences Research Division, Risk Analysis Section, P.O. Box 2008
Oak Ridge, TN 37831-6492

Human Health Risk Assessment Strategy for the Oak Ridge Reservation
Jacobs Engineering
Knoxville, TN

March 8, 1994

[1]University of Tennessee, Knoxville, TN

*Managed by Martin Marietta Energy Systems, Inc. with the U.S. Department of Energy under contract DE-AC05-84OR21400.

"The submitted manuscript has been authored by a contractor of the U.S. Government under contract No. DE-AC05-84OR21400. Accordingly, the U.S. Government retains a nonexclusive, royalty-free license to publish or reproduce the published form of this contribution, or allow others to do so, for U.S. Government purposes."

DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.

MASTER

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

DRAFT

ES/ER/TM-58

Defining the Role of Risk Assessment in the Comprehensive Environmental Response Compensation and Liability Act Remedial Investigation Process at the DOE-OR

P. D. Miller
C. W. McGinn
S. T. Purucker
A. Redfearn
R. K. White

Prepared by
Health and Safety Research Division
Oak Ridge National Laboratory
under direction from the
Environmental Restoration Risk Assessment Council

prepared for
U. S. Department of Energy
Office of Environmental Restoration and Waste Management
under budget and reporting code EW 20

MARTIN MARIETTA ENERGY SYSTEMS, INC.
managing the

Oak Ridge K-25 Site
Oak Ridge Y-12 Plant
Oak Ridge National Laboratory
under contract DE-AC05-84OR21400

Paducah Gaseous Diffusion Plant
Portsmouth Gaseous Diffusion Plant
under contract DE-AC05-76OR00001

for the
U.S. DEPARTMENT OF ENERGY

DRAFT

TABLE OF CONTENTS

1. INTRODUCTION 4

2. CURRENT CONDITIONS ON THE OAK RIDGE RESERVATION 6
   2.1 Description of the RI process on the Oak Ridge Reservation 6
   2.2 Clarifying the Term "Operable Units" 8

3. RISK ASSESSMENT OVERVIEW 10
   3.2 Preliminary Remediation Goals 13
   3.3 Most Likely Exposure and Integration Point Assessments 15
   3.4 Baseline Risk Assessments 15

4. QUALITATIVE RISK/COST PRIORITIZATION PROCESS 16

5. MOST LIKELY EXPOSURE ASSESSMENTS 17
   5.1 Derivation of the Exposure Concentration 18
   5.2 Performing the Most Likely Exposure Assessment 18

6. INTEGRATION POINT ASSESSMENTS 20
   6.1 Integration Point Assessment Method 20
   6.2 Modeling 22
   6.3 Uncertainty 22

7. BASELINE RISK ASSESSMENTS 24

1. INTRODUCTION

Cleanup of hazardous waste sites under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) is a complicated and painstaking process, particularly at facilities with a multitude of individual hazardous waste sites, each having a multitude of chemicals and radionuclides.[1] The U. S. Department of Energy-Oak Ridge, Environmental Restoration Division (DOE-OR/ERD) administers five such facilities which are undergoing environmental cleanup under the CERCLA Remedial Investigation and Feasibility Study (RI/FS) process or the Resource Conservation and Recovery Act (RCRA) investigation process. The nature of the wastes treated, stored, or disposed of at the U.S. DOE-OR sites is heterogeneous and often unknown. The amount of environmental sampling, chemical analysis, and document preparation and review required to support a baseline risk assessment alone at each facility often requires years before arriving at a final Record of Decision[2, 3]. Therefore, there is clearly a need to streamline the investigative and decision processes in order to realize the U. S. Environmental Protection Agency's (EPA) goal of reducing contaminant levels to those that are protective of human health and the environment in a timely and cost-effective manner.[4]

The goal of a RI/FS is "to gather information sufficient to support an informed risk management decision regarding which remedy appears to be most appropriate for a given site".[2] Risk assessment is one of many tools which are used to support that decision-making process. The goal of human health risk assessment is:

> *"to focus on providing information necessary to justify action at a site and to select the best remedy for the site. This should include characterizing the contaminants, the potential exposures, and the potentially exposed population sufficiently to determine what risks need to be reduced or eliminated and what exposures need to be prevented. It is important to recognize that information should be developed only to help EPA determine what actions are necessary to reduce risks, and not to fully characterize site risks or eliminate all uncertainty from the analysis"*[2]

The purpose of this document is to present the proposed risk assessment strategy for the Oak Ridge Reservation with respect to each of the phases of the RI process. By documenting not only the goals and objectives of the risk assessment strategy but also the level/rigor of assessment to be performed at each phase of the process, this document will provide the U.S. DOE-OR, the Tennessee Department of Environment and Conservation, and the U.S. EPA with a point of reference from which the strategy can be discussed and some type of agreement can be reached.

The information contained in this document is not intended to supercede the requirements/guidance called for in the existing regulations and risk assessment guidance documents. Rather, this information has been documented to provide risk assessors with guidance at points in the process where "best professional judgement" is required. In addition, the document proposes evaluating a limited set of pathways and land uses for certain sites and performing a limited quantitative evaluation for areas where interim or removal actions are to be

performed.

The information contained herein is specific only to human health risk assessment. The document entitled *Approach and Strategy for Performing Ecological Risk Assessments for the Department of Energy Oak Ridge Field Office Environmental Restoration Program.* ES/ER/TM-33 (Suter. 1992) addresses the implementation of ecological risk assessment for DOE-OR.

Of the facilities administered by the U.S. DOE-OR. only those located on the Oak Ridge Reservation (Oak Ridge National Laboratory, Oak Ridge Y-12Plant, and Oak Ridge K-25 Site) have been listed on the CERCLA's National Priorities List. As such, this strategy has been tailored for application to those facilities only.

2. CURRENT CONDITIONS ON THE OAK RIDGE RESERVATION

The Oak Ridge Reservation consists of three major U.S. DOE-OR installations (Oak Ridge National Laboratory, the Oak Ridge Y-12 Plant, and the Oak Ridge K-25 Site) constructed in the early to mid 1940s as research, development, and process facilities in support of the Manhattan Project. In addition to the three installations, the Oak Ridge Reservation Superfund Site also includes areas outside the installations, land used by the Oak Ridge Associated Universities and waterways that have been contaminated by releases from the U.S. DOE-OR installations. In 1989, the Oak Ridge Reservation was evaluated by the U.S. EPA using the Hazard Ranking System. As a result of this evaluation, the Oak Ridge Reservation was placed on the National Priorities List and, as such, was required to comply with the requirements of the CERCLA. To date, ~400 areas requiring evaluation have been identified and categorized as either operable units or study areas. Cleanup of the Oak Ridge Reservation is expected to take two to three decades and cost several billion dollars.

Under the CERCLA, the U.S. DOE was required to enter into an Interagency Agreement, with the U.S. EPA, and the Tennessee Department of Environment and Conservation, hereafter known as "the Parties." This agreement is referred to as the Oak Ridge Reservation Federal Facility Agreement. The primary purpose of the agreement is to coordinate remediation activities undertaken on the Oak Ridge Reservation pursuant to CERCLA, RCRA, and the National Environmental Policy Act (NEPA).

The Parties have a common goal to ensure that releases of hazardous substances to the environment associated with past waste management and operational activities at the Oak Ridge Reservation are adequately investigated and that appropriate remedial action is taken to protect human health and the environment. The general purposes of the Agreement are to:

- Establish a procedural framework and schedule for developing, implementing, and monitoring appropriate response actions at the Oak Ridge Reservation in accordance with the CERCLA, the RCRA, and the NEPA, appropriate U.S. DOE and U.S. EPA guidance and policy, and Tennessee laws.
- Coordinate response actions under the CERCLA, with the RCRA closure, postclosure care, and corrective measures under way or planned under any applicable state laws, in such a manner as to maximize flexibility and preclude redundant activity.
- Minimize the duplication of investigative and analytical work and documentation and ensure the quality of data management.
- Expedite response actions with a minimum of delay.

2.1 Description of the RI process on the Oak Ridge Reservation

The implementation of the CERCLA process on the Oak Ridge Reservation will generally follow the process described in the document *Guidance for Conducting Remedial*

Investigations and Feasibility Studies Under CERCLA. EPA/540/G-89/004.[1] The Oak Ridge Reservation CERCLA strategy contains all of the elements required by the U.S. EPA guidance plus additional pre-remedial investigation activities and interaction (i.e., scoping workshop and status meetings) between the Parties. The strategy emphasizes using early response actions (e.g., removal actions, some routine maintenance actions, and interim remedial actions) to address contaminated areas or selected releases of contaminants to the environment to ensure immediate attention is paid to areas where risk to the public, workers, and/or the environment is unacceptable. The strategy also emphasizes using risk assessment for identifying sites where early response actions are warranted, prioritizing early and final response actions, and providing a baseline against which alternatives can be compared, clean-up criteria can be established, and alternative performance can be assessed.

Areas of concern at the Oak Ridge Reservation are grouped as either 1) study areas subject to preremedial investigation or 2) operable units for remedial action. As additional areas are identified, they will be reviewed for removal action classification or placed in a study area group for preremedial investigation. If a removal action is determined appropriate, an empowered removal action task team will meet to determine the appropriate approach for the area, the prioritization, and the resources and schedule necessary to support those activities.[5]

Preremedial investigation activities are currently limited to the traditional preliminary assessment/site inspection activities. This document proposes that the preremedial investigation activities be broadened to include prioritizing operable units based on a qualitative risk/cost analysis, comparing existing/historical data with preliminary remediation goals, and performing most likely exposure and integration point assessments. These additional activities would provide the RI team with information concerning:

- contaminants of potential concern,
- data gaps/limitations associated with the historical data base,
- detection limits for subsequent environmental sample analysis,
- quantitative risk information on which to base subsequent prioritization efforts,
- risk information on which to base early action if necessary, and
- risk information on which to baseline risk reduction resulting from early action.

Areas of concern which have already undergone preremedial investigation have been grouped into operable units or waste area groupings. These operable units/waste area groupings will undergo the RI process with most likely exposure and integration point assessments being performed prior to the development of a RI workplan so that the results may be used to develop data quality objectives for the RI. Subsequent to the implementation of the workplan the assessments will be updated as appropriate and will be used to determine the need for early response actions (removal actions or interim actions) that might be conducted prior to the final action for the operable unit. The determination of whether some type of early response action is necessary will be decided at a status meeting which will include all the Parties. Based on the outcome of the most likely exposure and integration point assessments and other information obtained during the RI, the Parties will decide

whether an early response action, final action, or a combination of both is feasible and/or appropriate.

All remedial activities will continue at an operable unit until a Record of Decision for final action has been signed by the Parties and the remediation activities have been performed. Unit monitoring information collected for operable units for which an interim action Record of Decision has been developed will be incorporated into the associated operable unit which will reach a final action decision.

2.2 Clarifying the Term "Operable Units"

An operable unit as defined in 40 CFR §300.5 and in the Oak Ridge Reservation/U.S. Environmental Protection Agency Federal Facilities Agreement is:

> *"A discrete action that comprises an incremental step toward comprehensively addressing site problems. This discrete portion of a remedial response manages migration, or eliminates or mitigates a release, threat of a release, or pathway of exposure. The cleanup of a site can be divided into a number of operable units, depending on the complexity of the problems associated with the site. Operable units may address geographical portions of a site, specific site problems, or initial phases of an action, or may consist of any set of actions performed over time or any actions that are concurrent but located in different parts of a site."*[6]

Previously, operable units for the Oak Ridge Reservation have been designated based primarily on **geographic location**, and the RIs for such operable units included evaluation of all environmental media and exposure pathways. However, to effectively evaluate the cumulative impact of releases from multiple sources of contamination, the Parties have agreed to a structured approach for designating operable units on the Oak Ridge Reservation based on studies of the groundwater and surface water (referred to as integrator operable units), which in most instances will be addressed separately from studies of the sources of contamination. Based on the highly complex hydrogeologic regime of the Oak Ridge Reservation and the fact that there are numerous sources contributing to groundwater contamination within a geographical area, the Parties agreed that more timely investigations, at lower cost, can be achieved at some operable units by addressing the sources of contamination separately. The result will be more immediate attention to controlling the sources of contamination while continuing to investigate longer term remediation for both the sources of contamination and/or hydrogeologic regimes. Therefore, the designation of operable units for final action may/will be determined based either on **specific site problems**, or **initial phases of an action**, or may consist of any **set of actions** performed over time to manage migration or eliminate or mitigate a release, threat of a release, or pathway of exposure. The following example scenario illustrates this point:

For a given area of concern:

- the risk assessment for an area indicates that direct ingestion of surface soils will result in an adverse health effect.
- based on the results of the risk assessment and other technical information concerning the site, a decision is made to propose action for the area to mitigate exposure to surface soils.
- all appropriate documentation is prepared and submitted for regulatory and public review and comment
- a record of decision for the **action** to be taken is formulated and approved by the regulators.

Upon completion of remedial actions to manage migration or eliminate or mitigate a release, threat of a release, or pathway of exposure, sufficient monitoring data from the groundwater/surface water operable units will be available to determine if the remedial actions taken to control/remove the sources of the contamination have been effective, and, if not, further remediation would be undertaken in the appropriate operable units.

3. RISK ASSESSMENT OVERVIEW

The definition of ***risk*** is any chance of a loss or injury from a given condition. A ***risk assessment*** is defined as a qualitative and/or quantitative evaluation performed in an effort to define the risk posed to human health and the environment by the presence or potential presence and/or use of specific pollutants. The purpose of a risk assessment is to provide interested parties (managers, regulators, workers, and the general public) with an evaluation of the human and environmental health threats posed by hazardous waste areas.

The proposed risk assessment strategy for the Oak Ridge Reservation is graphically displayed in Fig. 1. In general, the strategy follows the guidelines provided by the U.S. EPA in the *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*, EPA/540/G-89/004[1] and the *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual (Part A, B, & C)*, EPA/540/1-89/002.[2] However, the rigor of the risk evaluation that is associated with activities in the streamlined process (removal and interim actions) has been reduced, and additional risk evaluations have been incorporated.

The human health risk assessment activities typically conducted during a RI on the Oak Ridge Reservation will be composed of four distinct exercises:

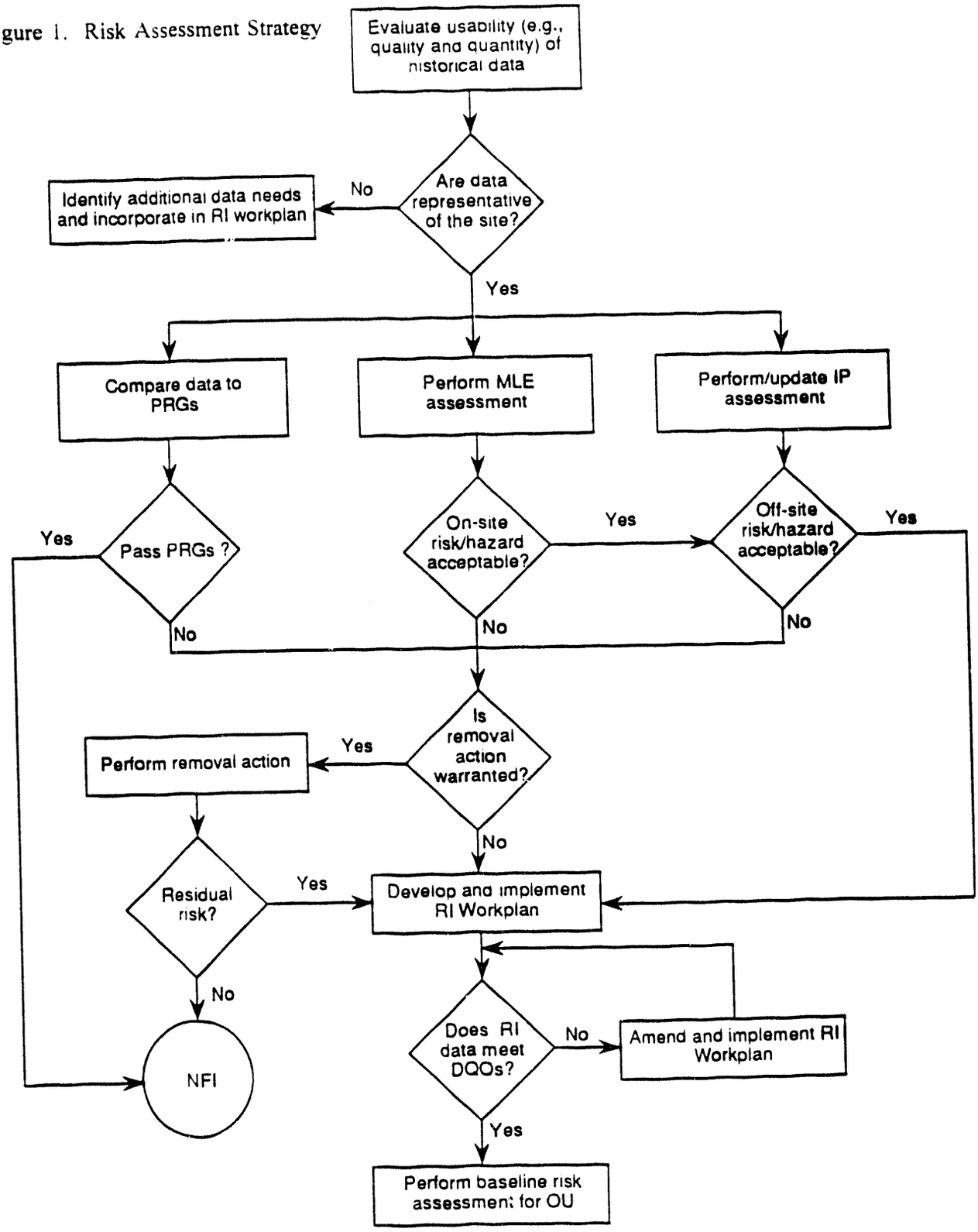
1) Determining the useability of existing data and additional data requirements (if any).
2) Developing and using preliminary remediation goals.
3) Performing a most likely exposure assessment and/or an integration point assessment.
4) The baseline risk assessment.

In addition, a qualitative risk/cost prioritization effort is currently underway for the operable units on the Oak Ridge Reservation. This activity will allow for a more quantitative evaluation of the relative risk of the operable units which can then be factored into the budget prioritization activities for fiscal year 1995 and beyond. The details of each of the risk assessment activities is discussed in detail in the following sections of this document. The remainder of this section focuses on the chronology of risk assessment activities relative to the RI process.

3.1 Data Useability

Past as well as current activities on the Oak Ridge Reservation result in the generation of various types (radioactive, nonradioactive, and mixed) of waste streams. Wastes treated, stored, or disposed of on the Oak Ridge Reservation range from sanitary waste and construction debris to massive quantities of highly radioactive materials. As such, U.S. DOE Orders, as well as state and federal regulations, require a certain level of environmental surveillance and monitoring; this has been especially true within the past 10 years. The result of these monitoring activities is a large environmental sampling data base. The problem with using these data for risk assessments is that the environmental monitoring and waste sampling activities were not performed as a comprehensive program. Rather, environmental compliance

Figure 1. Risk Assessment Strategy



departments performed sampling and analyses to meet the requirement of their various permits, while the environmental safety and health departments performed sampling and analysis to meet their requirements, as did the various biological monitoring departments. Therefore, the data resulting from these programs are of varying quality relative to the sampling and analysis methods used and the corresponding detection limits. Although the data quality was sufficient to meet the project requirements for which it was gathered, the data quality requirements under the CERCLA are more stringent: therefore, a determination of the useability of these data for risk assessment purposes must be made. This decision on data worth, must be based on project-specific data quality objectives. That is, in order to determine if data are of sufficient quantity and quality for risk assessment the decisions to be made must be identified.

Prior to development of a RI workplan for an operable unit, all relevant existing/historical data will be obtained and subjected to a "data useability evaluation." This evaluation will follow the guidelines outlined in both the *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual (Part A)*. EPA/540/1-89/002,[2] and the *Guidance for Data Useability in Risk Assessment*, EPA/540/G-90/008.[7] In general, the data evaluation process has eight components:

- Combining data available from site investigation and/or other data collection efforts
- Evaluating analytical methods
- Evaluating quantitation limits
- Evaluating qualified and coded data
- Evaluating blanks
- Evaluating tentatively identified compounds
- Comparing site data with background, and
- Identifying chemicals of potential concern

The purposes of performing such an evaluation are 1) to identify any data gaps that may exist (i.e., lack of data for certain environmental media or time periods), 2) to focus any additional sampling efforts on the chemicals of potential concern, and 3) to ensure that future analytical methods are sensitive enough to be protective of human health and the environment. The results of the "data useability evaluation will result in one of three possible situations:

Situation 1:

If, the results of the "data useability evaluation" indicate that the data are of sufficient quality and quantity to be used in a baseline risk assessment, then:

- compare the existing/historical data with chemical-specific preliminary remediation goals if the data are less than the preliminary remediation goals, pursue a no further investigation determination;
- perform a most likely exposure assessment;
- perform or update the integration point assessment for the surface water body associated with the operable unit under consideration;
- based on the results of previous steps, determine if an early action is warranted at the site;

- use the existing/historical data to summarize the nature and extent of contamination and proceed with the development of a remedial investigation report and baseline risk assessment.

Situation 2:

If, the results of the "data useability evaluation" indicate that the data are not of sufficient quality and quantity to be used in a baseline risk assessment, but could be used to support most likely exposure and/or integration point assessments, then:

- identify data gaps and limitations;
- recommend types and quantities of additional samples necessary to meet the baseline risk assessment criteria;
- compare proposed analytical detection limits with preliminary remediation goals to ensure that the detection limits are sensitive enough to be protective of human health and the environment
- perform a most likely exposure assessment
- perform or update the integration point assessment for the surface water body associated with the operable unit under consideration
- based on the results of previous steps, determine if an early action is warranted at the site
- incorporate risk assessment recommendations into the remedial investigation workplan

Situation 3:

If, the results of the "data useability evaluation" indicate that the data are not of sufficient quality and quantity to be used in a baseline risk assessment or a most likely exposure and/or integration point assessment, then:

- identify data gaps and limitations
- recommend sample types/quantities necessary to meet the risk assessment criteria
- compare proposed analytical detection limits with preliminary remediation goals to ensure that the detection limits are sensitive enough to be protective of human health and the environment
- incorporate risk assessment recommendations into the remedial investigation workplan

3.2 Preliminary Remediation Goals

Chemical-specific preliminary remediation goals are concentration goals for individual chemicals for specific medium and land use combinations. The preliminary remediation goal is a concentration that is derived from a specific excess cancer risk level or hazard index. Because preliminary remediation goals do not take into account site-specific pathways, they do not represent clean-up criteria. The Risk Analysis Section of the Health Sciences Research Division at the Oak Ridge National Laboratory has developed chemical-specific preliminary remediation goals for the pathways and routes of exposure listed in the following table:

Residential	Industrial
Groundwater	**Groundwater**
Ingestion	Defaults to residential per guidance.
Inhalation of vapor-phase chemicals	
Ingestion & Inhalation	**Soil**
	Ingestion
Soil	Inhalation
Ingestion	Ingestion & Inhalation
External Exposure	External Exposure
Ingestion and External Exposure	Ingestion. Inhalation. & External Exposure

The preliminary remediation goals were derived in accordance with the methodology outlined in the *Risk Assessment Guidance for Superfund Vol. 1 - Human Health Evaluation Manual (Part B. Development of Risk-based Preliminary Remediation Goals)*, EPA/54011-89/002B OSWER Directive 9285.7-01B. June 1991.[8] Preliminary remediation goals for agricultural and recreational land use scenarios are currently under development.

The preliminary remediation goals are initial guidelines that are protective of human health and the environment. based on readily available information, and comply with applicable, relevant. and appropriate requirements. As part of the risk assessment strategy for the Oak Ridge Reservation. risk-based preliminary remediation goals will be compared to existing/historical data to aid in identifying:

1) contaminants of potential concern,
2) transport and exposure pathways which need to be adequately characterized in subsequent sampling and analysis activities,
3) data gaps/limitations, and
4) appropriate detection limits for subsequent sampling efforts
5) operable units for which no further investigation required is appropriate.

If the data points exceed the preliminary remediation goals. then an early response action (removal or interim measure) may be warranted for the site. The results of this comparison should be used in conjunction with the results of the most likely exposure assessment and the integration point assessment for the operable unit to determine if early action is warranted. Comparison of the data to preliminary remediation goals alone does not provide the justification necessary to undertake an early action because the preliminary remediation goals do not take into account site-specific exposure parameters.

If the data points are all less than the preliminary remediation goals. then a determination of no further investigation may be appropriate for the site. In this case. because the preliminary remediation goals are the most conservative estimate of risk associated with a particular concentration. the comparison of site-specific data with the preliminary remediation

goals would be adequate for justifying no further investigation.

3.3 Most Likely Exposure and Integration Point Assessments

Most likely exposure and integration point assessments (as described in Sect. 5 and 6, respectively) may be performed for 1) operable units and study areas on the Oak Ridge Reservation which are undergoing development of a RI workplan: 2) operable units for which RI workplans have been developed, but not yet implemented: and 3) operable units that warrant early action (removal or interim action). The most likely exposure and integration point assessments are not meant to replace or substitute for the performance of a baseline risk assessment for operable units proceeding to final action: instead, the most likely exposure and integration point assessments are intended to 1) use the existing/historical data in a manner that will result in the identification of sites where early action is warranted, 2) focus attention on the contaminants which will be "risk-drivers" to ensure that the sampling and analytical methods used in the RI are appropriate, and 3) provide the assessor with an indication of the risk/hazard to on-site receptors as well as an indication of the relative contribution of that operable unit to off-site risk.

As stated in subsection 3.2, a comparison of data points with preliminary remediation goals alone cannot serve as justification to implement an early action. However, the results of the most likely exposure and integration point assessments can be used independently or in conjunction with one another to justify the need for performing an early action to mitigate exposure to contaminants either on- or off-site. Therefore, for operable units proceeding to either emergency or interim action, no baseline risk assessment will be performed as is stated in OSWER Directive 9355.0-30,

> *"Early and interim action RODs do not require a completed baseline risk assessment, although enough information must be available to demonstrate the potential for risk and the need to take action. Data sufficient to support the interim action decision can be extracted from the ongoing RI/FS for the site and set out in a focused feasibility study or other appropriate document that includes a short analysis of a limited number of alternatives. These data should include a summary of contaminants of concern, concentrations and relevant exposure information. A discussion should accompany these data explaining the need for immediate remedial action based on the presence of contamination that, if left unaddressed in the short-term, either contributes immediate risk or is likely to contribute to increased site risk or degradation of the environment/natural resources. The early and interim action RODs should note that some exposure pathways at the site may not be addressed by the action."*[3]

3.4 Baseline Risk Assessments

Baseline risk assessments will be performed for all operable units proceeding to final action. The contents of these baseline risk assessments as well as a discussion of exposure pathways and other critical issues is discussed in detail in Sect. 7 of this document.

4. QUALITATIVE RISK/COST PRIORITIZATION PROCESS

As appropriate, a formalized, qualitative risk- and cost-based prioritization will be conducted for environmental restoration areas. The objectives of this qualitative prioritization are to 1) provide a qualitative assessment of the potential risks posed to the environment, public, and site personnel by ER activities; 2) ensure that prioritization efforts are consistent across the program; and 3) facilitate the allocation of resources in a defensible, cost-effective manner. The qualitative prioritization effort is independent of the other risk assessment activities to be performed for the Oak Ridge Reservation. This effort will be revisited, as necessary, to ensure that, as more data become available and additional areas of concern are identified, the prioritization will reflect the relative risk/cost-based prioritization of the study areas and operable units as accurately as possible.

Risk scores will be derived for activities by multiplying a numerical weight representing the severity of an impact by the likelihood of occurrence of that impact. The impacts evaluated will fall into seven categories: public health and safety, environmental protection, site worker safety, regulatory compliance, mission and operational performance, and business efficiency.

This activity will be conducted for all environmental restoration activities regardless of their current status (study area or operable unit). The information generated will be used in conjunction with the results of most likely exposure and integration point assessments, as they become available, to ensure that the prioritization of environmental activities is both defensible and cost effective.

5. MOST LIKELY EXPOSURE ASSESSMENTS

As previously stated, the most likely exposure assessment was developed to support expedited actions (interim record of decisions and removal actions) at operable units and to serve as an indicator of current on-site risk. The degree of rigor associated with the baseline risk assessment process is not and has never been deemed necessary or appropriate for supporting interim actions. As stated in the CFR, March 8, 1990, Vol. 55, No. 46:

"To implement an early action under remedial authority, an operable unit for which an interim action is appropriate is identified. Data sufficient to support the interim action decision is extracted from the ongoing Remedial Investigation/Feasibility Study that is underway for the site or final operable unit and an appropriate set of alternatives is evaluated. Few alternatives, and in some cases perhaps only one, should be developed for interim actions. A completed baseline risk assessment generally will not be available or necessary to justify an interim action. Qualitative risk information should be organized that demonstrates that the action is necessary to stabilize the site, prevent further degradation, or achieve significant risk reduction quickly. Supporting data, including risk information, and the alternatives analysis can be documented in a focused Remedial Investigation/Feasibility Study. However, in cases where the relevant data can be summarized briefly and the alternatives are few and straightforward, it may be adequate and more appropriate to document this supporting information in the proposed plan that is issued for public comment."

The most likely exposure assessment was developed for use in conjunction with the results of the integration point assessment to identify those sites of highest priority relative to both off- and on-site risk. The most likely exposure assessment provides the risk manager with information concerning the relative on-site risk to workers, while the integration point assessment provides him/her with information concerning the relative contribution of the operable unit under investigation to off-site contaminant transport and migration. Therefore, the results of the most likely exposure, the integration point, or a combination of both provide the risk manager with the risk information needed to demonstrate that the proposed interim action *"is necessary to stabilize the site, prevent further degradation, or achieve significant risk reduction quickly."* In addition, the results of these assessments can be used to prioritize the operable units with respect to risk.

The exposure pathways evaluated in the most likely exposure assessment include the ingestion of and dermal contact with contaminated soil or sediment, inhalation of wind-generated particulates, and external exposure to radioactive contaminants. The ingestion of, inhalation of, or dermal contact with surface water or groundwater contaminants and the resulting risk/hazard associated with such exposures will not be evaluated as part of the most likely exposure assessment. In the case of exposure to surface water, the risk/hazard associated with the various types/magnitudes of exposure will be evaluated as part of the integration point assessment. Exposure to groundwater contaminants will be evaluated in the integrator groundwater operable unit risk assessments. The purpose/goal of the most likely

exposure assessment is to identify, expedite, and support interim actions at the operable units, which are high-risk with respect to on-site exposures.

5.1 Derivation of the Exposure Concentration

The derivation of the exposure concentrations used in the most likely exposure assessment will depend on the analytical quality control level of the available data. If the data are quality control Level B [8], then the exposure concentration will be estimated by deriving the geometric mean of the dataset. The geometric mean is used as an estimate of the exposure concentration because it is often less conservative than the arithmetic mean (which is usually driven by the highest values in a distribution). For historical data that are quality control Level B[8], the geometric mean is considered to be less likely to overestimate the calculated exposure concentrations due to the outliers that are contained within the dataset.

For a dataset composed of quality control Level C data or higher (may contain quality control Level B data that have been confirmed by a higher quality control level), the upper 95% confidence limit of the arithmetic mean of the site data will be used as the exposure concentration. As the quantity and degree of analytical rigor of the data increases, the upper 95% confidence limit of the arithmetic mean should become less likely to significantly overestimate the actual mean. Therefore, a more accurate representation of actual site concentrations will be obtained while recognizing the natural variation in environmental data.

5.2 Performing the Most Likely Exposure Assessment

The most likely exposure assessment is performed using the methodology outlined in the *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual (Part A). EPA/540/1-89/002*. However, the most likely exposure assessment is limited to evaluation of four exposure pathways: 1) external exposure to radiation in soil/sediment, 2) ingestion of soil/sediment, 3) inhalation of volatile compounds and wind-generated dust, and 4) dermal contact with soil/sediment. In addition, the intake and exposure duration parameters have been modified to reflect the "most likely exposure" that would occur on-site.

Intake and exposure parameters for the four exposure pathways are provided in Table 1. The parameters were derived based on the assumption that an adult enters the facility 8 hours per day, 5 days per week, 50 weeks per year for 25 years. Parameter values are generally industrial default occupational values provided as U.S. EPA guidance[7, 9] but are adjusted based on the assumption that the receptor spends only 10% of the day within the boundaries of the individual operable unit under investigation. For example, for use in the most likely exposure assessment, the default air intake (20 m^3/day) is multiplied by 10% resulting in an intake of 2 m^3/day. These parameters are considered to be conservative in representing actual exposure of current workers. If site-specific exposure parameters are available they will be used in the most likely exposure assessment instead of the parameters listed in Table 1.

Table 1. Most Likely Exposure Intake and Exposure Parameters

Exposure Pathway	EPA Default Parameters[a]	most likely exposure Parameters[d]
External exposure	2000 hours/year	200 hours/year
Ingestion of soil/sediment	50 mg/day	0.005 g/day
Inhalation of wind-generated dust	20 m^3 air/day	2 m^3 air/day
Dermal contact with soil/sediment	Surface area[b] Hands: 0.082 m^2 Arms: 0.23 m^2 Adherence Factor: 1.0 mg/cm^2[c] Absorption Factor[c] Organics: 1% Inorganics: 0.1% 1 hour/day	Surface area[b] Hands: 0.082 m^2 Arms: 0.23 m^2 Adherence Factor: 1.0 mg/cm^2[c] Absorption Factor[c] Organics: 1% Inorganics: 0.1% 1 hour/day

a Exposure parameters are based on occupational values provided by the U. S. Environmental Protection Agency (1991b, 1991c).

b 50th percentile adult body-part surface area (EPA 1989).

c Adherence Factor and Absorption Factors based on U. S. Environmental Protection Agency Region IV guidance.

d Exposure parameters are based on occupational values provided by the U. S. Environmental Protection Agency (1991b, 1991c) with the added assumption that the worker spends one-tenth of his or her working day at the site under investigation.

6. INTEGRATION POINT ASSESSMENTS

For Oak Ridge Reservation sites, the majority of any off-site public exposure to contaminants results from surface water which is the major transport mechanism for contaminant fluxes to off-site receptors. Other potential transport mechanisms such as the food chain, the air pathway, and direct groundwater transport are not currently primary sources of off-site fluxes. The integration point assessment discussed in this section is designed to actively use monitoring, surveillance, compliance, and RI data to evaluate the off-site risk from a variety of sources that input into the surface water integrator operable unit. The data will be used to establish a baseline for evaluating the risk at different points within the integrators, to identify and prioritize source areas within the context of the integrator, and to establish the degree of risk reduction an action to control contaminant sources can potentially achieve.

The integration point assessment is a flux-based risk assessment. Flux is an important concept for controlling contaminant sources because of the number of actual and potential sources of contaminants that exist on the Oak Ridge Reservation and the variability in flow rates of the different surface water systems that transport these contaminants to the surface water integrator operable units and eventually to the Clinch River. Actions to control sources of contamination that are taken at areas having high fluxes of integrator contaminants of concern are the quickest means of reducing off-site exposure to levels that are as low as reasonably achievable.

One of the more important objectives during early phases of an integrator operable unit investigation is to assimilate available information from existing programs to estimate fluxes and mass balances of contaminants within the integrator system. The information is then used to assess fluxes within the watershed and compare them to fluxes that input into public access areas to differentiate between various contaminant sources at the Oak Ridge Reservation. Mass balance information is important to describe the accumulation and discharge of contaminants within a system where inputs and outputs are known. The integration point assessment provides a means for communicating this information in terms of risk to the public and to risk managers. It also provides an important risk link between the source operable units and integrator operable units so that the effects of actions to control contaminant sources can be evaluated in the integrator.

6.1 Integration Point Assessment Method

The first step in performing the integration point assessment is selecting the actual point of assessment. In general, an integration point assessment should be performed at systems that drain catchment areas at the boundaries of the Oak Ridge Reservation. Examples would include White Oak Lake, East Fork Poplar Creek, Bear Creek, Poplar Creek, and the Clinch River. These large-scale integration point assessments can assist in prioritizing sources. Other points can be selected as needed to support activities taken to control contaminant sources. Integration point assessments can be used to support RIs and may assess only a portion of the

larger integrator watershed to ensure that smaller subsystems of the watershed are cleaned to safe risk levels.

The integration point assessment is then performed at the chosen point using the 95% upper confidence limit on the arithmetic average for yearly concentration data. Surface water pathways are assessed at the point with the assumption of residential land use of the water. This would entail using standard risk assessment parameters, which are available in *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual (Part A)*, EPA/540/1-89/002, for these pathways.[2] Primary pathways to be assessed include ingestion of surface water, dermal contact while showering, and indoor inhalation of contaminants resulting from water use. The risk at this point is then compared with action levels of excess cancer risk of 1E-4 and to the noncarcinogenic hazard index of 1. Action under CERCLA is generally warranted if either of these action levels are exceeded. The next step is to use contaminant fluxes and risk to identify the primary contributors to the risk at the integration point.

Generally, the results generated by a risk assessment are driven by a few high priority contaminants only. Determination of high priority contaminants can be achieved by selecting those comprising 90% of the total risk at the integration point. For those identified contaminants that drive the risk, the annual fluxes for each should be quantified to the degree possible at the integration point and at the major sources. The spatial resolution of the sources is dependent upon the amount of source data available.

The flux data for each of the sources are then used with the integration point flux data to rank the relative importance of the different sources within the context of the integration point. Given the generalized cancer risk equation for multiple substances:

$$Risk_T = \sum Risk_i$$

where:

$Risk_T$ = the total cancer risk, expressed as a unitless probability; and
$Risk_i$ = the risk estimate for the ith substance.

The equation for calculation of carcinogenic effects for the flux-based risk assessment at each of the sources is:

$$Risk_{sf}\,(\%) = \{\sum [\, Risk_i \;\; (Flux_{is} / Flux_{ip})]\} \;/\; Risk_T$$

where:

$Risk_{sf}$ = percentage of risk at the integration point which originates at the identified source;
$Flux_{is}$ = flux of the ith substance originating at the identified source; and

$Flux_{ip}$ = flux of the ith substance identified at the integration point.

Similarly, the standard equation for calculation of noncarcinogenic effects is:

$$\text{Hazard Index}_t = \sum E_i/RfD_i$$

where:

E_i = exposure level (or intake) for the ith toxicant:
RfD_i = reference dose for the ith toxicant: where
E and RfD are expressed in the same units and represent the same exposure period (i.e., chronic, subchronic, or shorter term).

The calculation for the flux-based risk assessment of noncarcinogenic effects is:

$$\text{Hazard}_{sf}\ (\%) = \sum[\ E_i Flux_{is}/RfD_i Flux_{ip}]/\text{Hazard Index}_t$$

where:

$Hazard_{sf}$ = percentage of the hazard index at the integration point that originates at the identified source.

The reader should note that carcinogenic and noncarcinogenic effects cannot be combined if the integration point assessment indicates both are of concern.

6.2 Modeling

Specific source areas that pose a threat of major release or sites that are situated in exceedingly complex groundwater regimes where numerous source terms cannot be differentiated may have to be modeled. The modeling results can be used to show the need to mitigate a potential off-site risk or to confirm the role they are suspected to play in releases to the environment. The modeling results should be within the context of the larger scale integration point assessment, and its impact on selected integration points should be compared with other releases for which more information is known.

6.3 Uncertainty

Because of the dynamic nature of the Oak Ridge Reservation watershed systems and fiscal restraints in data collection, it is recognized that significant amounts of uncertainty are necessarily present in performance of these integration point assessments, especially if modeled results are used. Uncertainties are inherent in the flux determination process because of difficulties in actually measuring the flux and the temporal variability of fluxes in both short- and long-term time frames. Temporal variability is caused by the effects of climate and

human actions at the sources as well as the relationships between mass balances and hydrologic conditions.

However, given a bias for action at sites on the Oak Ridge Reservation, the uncertainty present in the process should not preclude activities to control contaminant sources. The integration point assessment is designed to use risk to identify sources that are clear off-site contributors of high priority contaminants. These sites can then be addressed in an expedited manner with actions that are interim or final in nature. Consistent implementation of this process can assist in meeting short-term goals of reducing off-site exposures to levels that are as low as reasonably achievable and in meeting long-term goals of cleaning the watershed systems within the plant boundaries to safe risk levels.

7. BASELINE RISK ASSESSMENTS

The baseline risk assessment is an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action). The baseline risk assessment contributes to the characterization and subsequent development, evaluation, and selection of appropriate response alternatives. The results of the baseline risk assessment are used to:

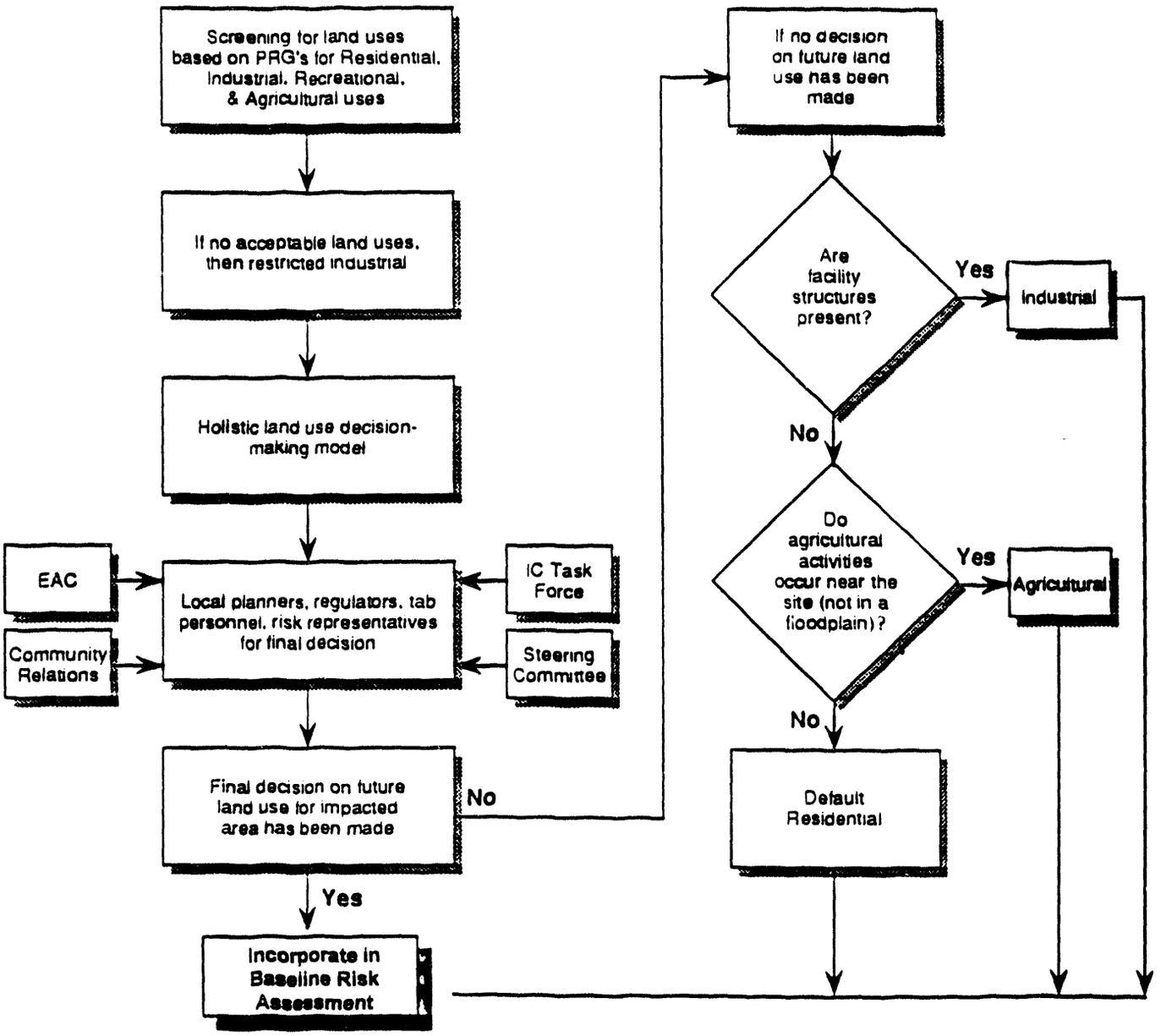
- help determine whether additional response action is necessary at the site;
- modify preliminary remediation goals;
- help support the selection of the "no-action" remedial alternative, where appropriate; and
- document the magnitude of risk at a site and the primary causes of that risk.

As previously stated, a baseline risk assessment will be performed for all operable units on the Oak Ridge Reservation proceeding to final action. The exposure pathways and associated exposure parameters to be used in these baseline risk assessments will depend on:

- the sources, releases, types, and locations of chemicals at the operable unit;
- the likely environmental fate of the chemicals; and
- the potentially exposed populations.

The results of the most likely exposure assessment will be used in conjunction with the baseline risk assessment's reasonable maximum exposure scenario to provide an estimate of both current and future risk/hazard, respectively. For operable units on the Oak Ridge Reservation, no decision has been reached concerning the potential future land use of the area. In the absence of a consensus on this matter, the following strategy as outlined in Fig. 2 is proposed. As is evidenced in this figure, an effort is currently underway to identify (using preliminary remediation goals and existing/historical data) the possible acceptable land uses relative to risk. This information would then be input into a holistic land use decision-making model. The output from the model would be used in conjunction with input from the local planners, regulators, risk representatives, and other stakeholders to reach a consensus on the future land use for an area. If a consensus is not reached, or if remedial activities at the operable unit proceed before a decision is reached, then based on the questions/criteria indicated on Fig. 2, a default land use will be assigned. Default land uses as indicated in Fig. 2 include residential, agricultural, and industrial.

Figure 2. Land Use Decision-Making Strategy



The exposure pathways to be evaluated for the default future land uses are listed in the following table.

	Residential	Agricultural	Industrial
Groundwater			
Direct Ingestion	Yes	Yes	No
Incidental Ingestion	No	No	Yes
Inhalation of volatile contaminants during showering	Yes	Yes	No
Dermal Contact	Yes	Yes	No
Soil/Sediment			
Ingestion	Yes	Yes	Yes
Dermal Contact	Yes	Yes	Yes
External Exposure	Yes	Yes	Yes
Surface Water			
Direct Ingestion	If applicable[1]	If applicable[1]	No
Ingestion During Swimming	If applicable[1]	If applicable[1]	No
Inhalation of volatiles	If applicable[1]	If applicable[1]	No
Dermal Contact	If applicable[1]	If applicable[1]	No
Air			
Inhalation of volatile contaminants	Yes	Yes	No
Inhalation of wind-blown particulates	Yes	Yes	No
Ingestion of wind-blown particulates	Yes	Yes	No
Fish Ingestion	If applicable[1]	If applicable[1]	No
Produce/Vegetable Ingestion	No	Yes	No
Meat/Eggs/Dairy Products Ingestion	No	Yes	No

The exposure parameters for the variables of the exposure equations associated with each of the pathways listed in the previous table will be taken directly from the *Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual (Part A)*,[2] and the

Human Health Evaluation Manual. Supplemental Guidance: Standard Default Exposure Factors. OSWER Directive 9285.6-03.[9] In general, the exposure parameters will be those that comprise the 90th-95th percentile for all variables.

8. REFERENCES

1. *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA*, EPA/540/G-89/004. Office of Emergency and Remedial Response. U. S. Environmental Protection Agency, 1988.

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

3. *Role of the Baseline Risk Assessment in Superfund Remedy Selection Process*, OSWER Directive 9355.0-30. Office of Solid Waste and Emergency Response. U. S. Environmental Protection Agency, 1990.

4. *National Oil and Hazardous Substance Pollution Contingency Plan*, The Federal Register 55, No. 46, 1990. U. S. Environmental Protection Agency, 1990.

5. Oak Ridge Reservation Site Management Plan for the Environmental Restoration Program, DOE/OR-1001/R3. U.S. Department of Energy-Oak Ridge, Environmental Restoration Division, December, 1993.

6. *Federal Facility Agreement for the Oak Ridge Reservation*, DOE/OR-1014. U.S. Department of Energy, Oak Ridge, TN. January, 1992.

7. *Guidance for Data useability in Risk Assessment, Interim Final*, EPA/540/G-90008. Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C., October 1990.

8. *Risk Assessment Guidance for Superfund Vol. 1 - Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals)*, EPA/54011-89/002B OSWER Directive 9285.7-01B, June 1991.

9. *Human Health Evaluation Manual Supplemental Guidance: Standard Default Exposure Factors*, OSWER Directive 9285.6-03. Office of Solid waste and Emergency Response. U.S. Environmental Protection Agency, Washington, D. C., 1991.

DATE

FILMED

6/24/94

END