

ES/ER/TM-117/R1

Risk Assessment Program Quality Assurance Plan

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**Risk Assessment Program
Quality Assurance Plan**

Date Issued—November 1997

Prepared by
Environmental Management and Enrichment Facilities
Risk Assessment Program

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LOCKHEED MARTIN ENERGY SYSTEMS, INC.
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

APPROVALS

Risk Assessment Program Quality Assurance Plan

ES/ER/TM-117/R1

November 1997

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PREFACE

This Quality Assurance Plan (QAP) for the Environmental Management and Enrichment Facilities (EMEF) Risk Assessment Program (RAP) specifies quality assurance requirements and applicable standards and procedures. The QAP was produced by the EMEF RAP under Work Breakdown Structure 1.4.12.2.3.04.05.01 entitled Risk Assessment Review, Planning, and Coordination and within the Activity Data Sheet 8304. This document provides a plan that identifies the responsibilities of RAP personnel and the chain of command for executing quality requirements. The primary objective of this document is to establish a QAP that will be in compliance with U.S. Department of Energy Order 5700.6C, *Quality Assurance* (DOE 1991) and based on requirements specified in the *ER Quality Program Plan* (MMES 1994a).

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ACRONYMS AND ABBREVIATIONS

DMC	Document Management Center
DMIP	Data Management Implementation Plan
DOE	U.S. Department of Energy
DOE-ORO/EMD	U.S. Department of Energy, Field Office, Oak Ridge Operations Environmental Management Division
DQO	data quality objective
EMEF	Environmental Management and Enrichment Facilities
EPA	U.S. Environmental Protection Agency
Energy Systems	Lockheed Martin Energy Systems, Inc.
NCR	Nonconformance Report
OREIS	Oak Ridge Environmental Information System
QA	quality assurance
QAP	Quality Assurance Plan
QAS	Quality Assurance Specialist
QC	quality control
PGDP	Paducah Gaseous Diffusion Plant
PORTS	Portsmouth Gaseous Diffusion Plant
PRG	preliminary remediation goal
RAC	Risk Assessment Council
RAIS	Risk Assessment Information System
RAM	Risk Assessment Manager
RAP	Risk Assessment Program
RATL	Risk Assessment Technical Lead
SAS®	Statistical Analysis System (software)

EXECUTIVE SUMMARY

The Environmental Management and Enrichment Facilities (EMEF) Risk Assessment Program (RAP) performs or manages all risk assessment activities conducted for the U.S. Department of Energy, Field Office, Oak Ridge Operations Environmental Management Division . To accomplish this role, the EMEF RAP is divided into two functional areas: Central EMEF Oversight and Integration Activities and Risk Assessment Project Support. The program's main objectives are to oversee and review all risk activities; to produce high-quality, consistent, and scientifically sound human health and ecological risk assessments in accordance with the requirements of the Comprehensive Environmental Response, Compensation, and Liability Act; to develop and apply new methodologies in risk assessment; and to implement risk prioritization evaluations.

The purpose of this document is to establish a Quality Assurance Plan (QAP) for the EMEF RAP so that the program's objectives can be met effectively in a consistent and logical manner. This QAP has been developed in compliance with DOE Order 5700.6C, *Quality Assurance* (DOE 1991), American Society of Mechanical Engineers document *Quality Assurance Program Requirements for Nuclear Facilities* (ASME 1989a), and the software quality assurance (QA) requirements from *Quality Assurance Requirements for Nuclear Facility Applications* (ASME 1989b). This plan is also based on requirements specified in the *ER Quality Program Plan* (MMES 1994a) and in Lockheed Martin Energy Systems, Inc., quality procedures.

Specifically, this plan identifies the chain of command for executing quality requirements, the responsibilities of EMEF RAP staff, and applicable command media to meet the QA requirements. In addition, this QAP includes consideration of the technical aspects of the risk assessment process in the context of QA. This QAP applies to any risk assessment activity performed by or for the EMEF RAP.

This QAP will be supplemented by procedures that outline steps involved in various risk-related tasks. Revisions or additions to the QAP will be made as necessary to conform to the changing needs of the program. All revisions will be dated and referenced on an approval page at the front of the document.

1. PROGRAM

1.1 GENERAL

The Environmental Management and Enrichment Facilities (EMEF) Risk Assessment Program (RAP) was officially chartered on April 4, 1991, to centralize all risk assessment efforts under the U.S. Department of Energy, Field Office, Oak Ridge Operations Environmental Management Division (DOE-ORO/EMD) and to ensure the development of consistent and scientifically defensible risk assessments. Interim policy guidance was provided with the charter letter that defined the role of risk assessment and established the Risk Assessment Manager (RAM) and Risk Assessment Council (RAC) positions to provide technical expertise and support in the area of risk assessment to all parties (including prime contractors and their subcontractors) involved in DOE-ORO/EMD risk assessment activities. RAP oversees all EMEF-related risk assessment activities, leads and manages RAC; provides risk assessment support for the five Lockheed Martin Energy Systems, Inc. (Energy Systems), EMEF sites at Oak Ridge, Tennessee; Paducah, Kentucky; and Piketon, Ohio; and conducts human health and ecological risk assessments for the EMEF Program. Throughout the remainder of this document, the EMEF RAP will be referred to as RAP.

The primary goals of RAP are to oversee and review all EMEF risk activities; develop, implement, and ensure compliance with risk methodologies; produce high-quality, consistent, and scientifically defensible human health and ecological risk assessments; and implement risk prioritization evaluations. According to Energy Systems' EMEF Program requirements, all risk assessment activities will be consistently conducted with U.S. Environmental Protection Agency (EPA) and state guidance, based on best scientific judgement, and carried out in a cost-effective manner. As a result of adhering to these guidelines, risk assessment activities will meet all of the pertinent requirements of the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act. All RAP personnel, program staff, contractors, and subcontractors involved in risk assessment under the auspices of the Energy Systems RAP must follow the procedures set forth in this document; all EMEF procedures, standards, and instructions; and applicable Energy Systems command media. All data used within RAP must be subjected to a documented review prior to use.

1.2 PURPOSE

This document sets forth requirements for establishing and executing quality assurance (QA) measures for RAP to facilitate the development of high-quality, consistent, and scientifically defensible risk assessments. The purposes of this document are to ensure that:

- RAP management provides planning, organization, direction, control, and support to achieve DOE-ORO/EMD's objectives;
- RAP achieves quality in DOE-ORO/EMD risk assessments; and
- overall performance is frequently reviewed and evaluated .

This document describes the RAP organizational structure; specifies the QA-related roles and responsibilities of individuals within RAP to ensure that program objectives are achieved as planned; and describes or references the controls, quality procedures, and guidelines that must be implemented during all risk assessment activities.

1.3 SCOPE

This Quality Assurance Plan (QAP) applies to all personnel performing risk assessment activities for RAP. Specifically, this QAP applies to RAP personnel, EMEF program staff, and all prime contractors and subcontractors involved in risk activities at the five sites operated by Energy Systems and at the off-site locations under the auspices of RAP. Control of work activities affecting quality will be maintained as necessary throughout the life of the program to ensure that quality objectives are met.

This document may be modified as necessary to meet the specific needs of other prime contractors or subcontractors. If modifications are made, RAM approval must be received, and the changes and justifications for the changes must be clearly documented, signed, dated, and attached to this QAP.

1.4 SOURCE AND APPLICATION OF QUALITY ASSURANCE REQUIREMENTS

The QAP elements identified in this document meet the requirements of DOE Order 5700.6C, *Quality Assurance* (DOE 1991); the American Society of Mechanical Engineers *Quality Assurance Program Requirements for Nuclear Facilities* (ASME 1989a); and the software QA requirements from *Quality Assurance Requirements for Nuclear Facility Applications* (ASME 1989b). The QAP has also been written in compliance with *ER Quality Program Plan*, ES/ER/TM-4/R4 (MMES 1994a); Energy Systems' QA procedures; and the *Health Sciences Research Division, Management Plan for CY 1996* (LMES 1996a).

Table 1 presents the parallel relationship of the RAP QAP with the *ER Quality Program Plan* and lists the appropriate command media (Energy Systems, EMEF, or other) to implement each RAP QAP chapter. Figure 1.1 illustrates the interrelationships of EMEF QA requirements.

1.5 QUALITY ASSURANCE

The RAP's QA Program will be planned, implemented, and maintained in accordance with this QAP. QA is the responsibility of all individuals within RAP. The RAP QA Program will implement all applicable Energy Systems and EMEF QA policies, standards, and procedures. In addition, the QA Program will work to ensure the implementation of the most current policies and procedures as specified in the various risk assessment guidance documents produced by EPA, the state, and RAP.

Depending on the objectives for a particular project, the level of QA may be adjusted accordingly. In other words, some QA requirements specified in this plan may be relaxed or waived; however, all deviations from the QA process as established in this plan must receive RAM prior approval, and there must be documentation of the changes and their justifications.

This RAP QAP will be approved by the RAP DOE Sponsor, EMEF Quality Assurance Specialist (QAS), the RAP RAM, and the RAP QAS.

Table 1. Comparison of RAP QAP to ER Quality Program Plan (ES/ER/TM-4/R4)

RAP QAP Section	ER QPP Section	Implementing Documents (Energy Systems, EMEF, or other)
Executive Summary	Executive Summary	-
1. Program	1. Program	* ER/C-S2001, Rev. 0; * ER/C-S2002, Rev. 0
2. Training and Qualification	2. Training and Qualification	* ER/C-P1613, Rev. 1
3. Quality Improvement	3. Quality Improvement	* ER/C-P1608, Rev. 0; ^ESS-QA-15.0, Rev. 4; ^ESS-QA-15.1, Rev. 1; ^ESP-QA-16.2, Rev. 2; ^QA-331, Rev. 0
4. Documents and Records	4. Documents and Records	* ERWM/ER-P1110, Rev. 1; * ER/C-P1104, Rev. 1; * EM&EF/C-P1100, Rev. 1; ORNL-IRO-1, Rev. 4; ^IO-201, Rev. 3
5. Work Processes	5. Work Processes	* EM&EF/ER-S2010, Rev. 0; ES/ER/TM-180; ES/ER/TM-33/R2; ^ESS-QA-5.0, Rev. 0; EPA/540/I-89/001 and 002
6. Design	6. Design	* EM&EF/ER-P2305, Rev. 0; * EM&EF/ER-P2009, Rev. 0; ES/ER/TM-??? ^QA-601, Rev. 0; ^ESS-QA-19.0, Rev. 1;
7. Procurement	7. Procurement	^QA-701, Rev. 0
Not Applicable	8. Inspection and Acceptance Testing	
8. Management Assessment	9. Management Assessment	^QA-911, Rev. 0
9. Independent Assessment	10. Independent Assessment	* ER/C-P1600, Rev. 0; * ER/C-P1606, Rev. 0; ^QA-901, Rev. 0; ^QA-904, Rev. 0; ^ESP-QA-16.2, Rev. 2; ^QA-331, Rev. 0

* Refer to the EMEF Programs Intersite Procedural Command Media Home Page at <http://www-internal.ornl.gov/ER/ERCM/ercmedpg.htm> for a listing of EMEF risk assessment procedures.

^ Refer to the Energy Systems Command Media Home Page at <http://www-internal.ornl.gov/acm/company/qa.html> for a listing of Energy Systems QA procedures.

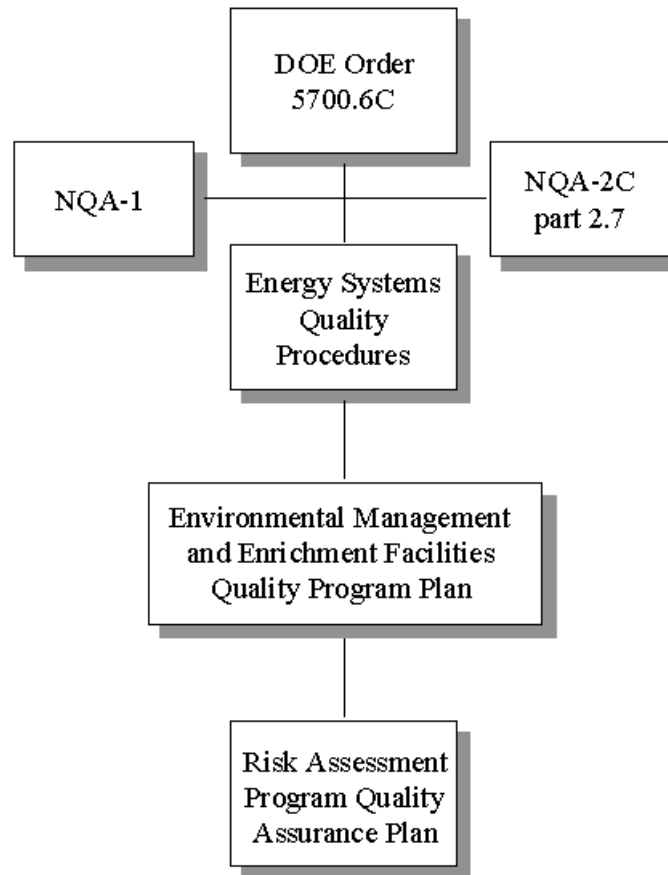


Fig. 1. Interrelationships of EMEF QA requirements.

1.6 ORGANIZATION AND PROGRAM RESPONSIBILITIES

The RAP organizational structure and responsibilities are outlined in this section. Figure 2 provides the organizational chart for RAP. RAP is managed by the RAM, who is ultimately responsible for the proper implementation of QA measures within the program. Responsibilities for specific individuals in the RAP are delineated in Sects. 1.6.1–1.6.7. Additional responsibilities can be found in “Risk Assessment Roles and Responsibilities” (MMES 1992a).

Because Energy Systems is the lead DOE contractor for risk assessment, RAP is responsible for the integration, consistency, and accuracy of all risk assessment activities conducted by prime contractors or subcontractors for the EMEF Program. All risk assessment activities, therefore, should be centralized through the RAM. Refer to “Integrating Contractor Issues in Risk Assessment” (MMES 1992b) for specific requirements.

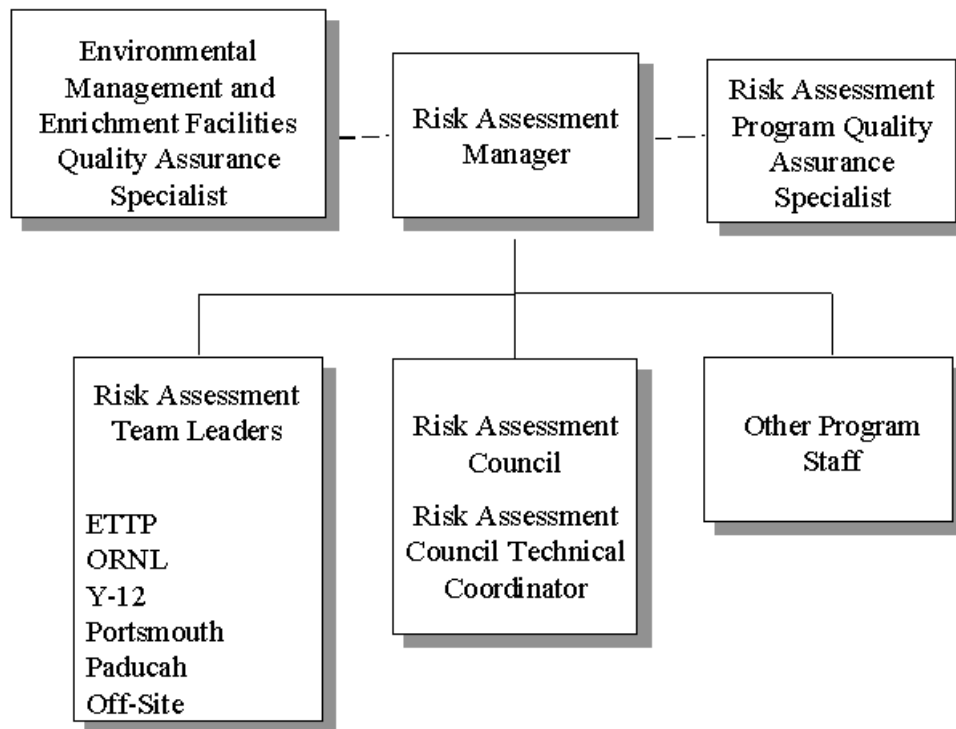


Fig. 2. EMEF Risk Assessment Program organization chart.

1.6.1 Energy Systems EMEF Risk Assessment Manager

The RAM is responsible for the following:

- approving the RAP QAP;
- ensuring implementation of the QAP and the most recent version of the quality procedures referenced therein by all prime contractors and subcontractors;
- overseeing all required QA activities within the program;
- designating the RAP QAS;
- establishing internal and external personnel interfaces for risk assessment activities;
- advising Risk Assessment Technical Leads (RATLs), program managers, and project managers on quality matters;

- ensuring that RATLs meet the QA requirements for all risk assessment projects;
- establishing and conducting a self-assessment program;
- investigating quality-related problems, determining their root causes, proposing solutions, and implementing corrective action;
- preparing, reviewing, and providing input for Nonconformance Reports (NCRs);
- ensuring that surveillances are conducted on project activities by the RAP QAS or designee;
- ensuring that documents prepared by RAP are submitted to the appropriate organizations and persons for review, comment, and approval;
- ensuring proper configuration control of all RAP data and databases;
- consulting with the EMEF QAS, as needed, on all quality-related matters;
- specifying the appropriate QA/quality control (QC) requirements in subcontracts;
- implementing cost-effective quality improvements;
- ensuring the qualification of all RAP personnel concerning quality-related measures; and
- initiating a stop-work order action when the severity of conditions adverse to quality warrants immediate action.

1.6.2 EMEF Quality Assurance Specialist

The EMEF QAS is responsible for the following:

- reviewing and approving this QAP;
- conducting independent verification activities, such as audits and surveillances on RAP; and
- initiating a stop-work order action when the severity of conditions adverse to quality warrants immediate action.

1.6.3 Risk Assessment Program Quality Assurance Specialist

The RAP QAS is responsible for the following:

- preparing this QAP;
- ensuring that applicable quality requirements are met;
- helping RAP management track corrective actions and analyze data pertaining to quality;

- ensuring that any necessary detailed operating procedures are developed and implemented to establish and maintain consistency of program activities;
- ensuring that quality-related issues and problems are promptly identified and resolved;
- conducting training needs assessments;
- interfacing with the assigned EMEF Program QAS and the RAM on all quality-related matters;
- implementing continual, cost-effective quality improvements;
- maintaining a QA surveillance schedule for the RAP;
- performing surveillances of project activities; and
- recommending stop-work action to the RAM when the severity of conditions adverse to quality warrants immediate action.

1.6.4 Energy Systems Risk Assessment Council

RAC is responsible for the following:

- providing advice and guidance on appropriate risk assessment methodologies and procedures;
- developing appropriate methods, procedures, models, and/or data needed to fulfill site program risk assessment needs;
- providing appropriate review of site program risk assessment implementation to ensure consistent application and interpretation of risk assessment guidance and methodology;
- supporting Energy Systems EMEF Program risk assessment needs through research and development that address critical risk assessment data gaps;
- reviewing and commenting on documents produced by the RAP; and
- addressing QA matters on an as-needed basis.

1.6.5 Energy Systems Risk Assessment Team Leaders (both human health and ecological)

The Energy Systems RATLs are responsible for the following:

- working on the day-to-day implementation of RAP policy;
- serving as the liaison between the site EMEF teams, subcontractors, and RAM;
- identifying site-specific QA issues that require specific guidance and recommending them to the RAM;
- ensuring that operating procedures are effectively implemented;

- ensuring that QA requirements are met;
- ensuring the quality of assigned work;
- interfacing with the project and/or program managers, the RAP QAS, RAM, and/or RAC on all quality-related matters; and
- recommending stop-work action when the severity of conditions adverse to quality warrants immediate action.

1.6.6. Risk Assessment Council Technical Coordinator

The RAC Technical Coordinator is responsible for:

- assisting the RAM in investigating quality-related problems, determining their root causes, proposing solutions, and implementing corrective actions;
- coordinating and assisting in the determination of procedures, instructions, and other documents that need to be written for EMEF risk assessment activities;
- ensuring that documents prepared by RAP are submitted to the appropriate organizations and persons for review, comment, and approval; and
- coordinating the interaction between RAP and the EMEF Document Management Center (DMC) (the RAC Technical Coordinator may delegate these responsibilities but shall retain responsibility for ensuring the appropriate review of all risk assessment documents); and
- recommending stop-work action when the severity of conditions adverse to quality warrants immediate action.

1.6.7 All Other Program Staff

All other staff are responsible for the following:

- ensuring that applicable QA requirements are met;
- ensuring the quality of assigned work;
- consulting with the assigned RAP QAS on all quality-related matters;
- ensuring that operating procedures are identified, required, and effectively implemented; and
- recommending stop-work action when the severity of conditions adverse to quality warrants immediate action.

2. TRAINING AND QUALIFICATION

2.1 GENERAL

Program activities that affect quality are planned and accomplished under suitably controlled conditions. These controlled conditions include the use of appropriate procedures and equipment, proper training and qualification, and assurance that prerequisites for the given activities have been satisfied.

Personnel managing or performing activities affecting quality shall receive the necessary training [e.g. Procedure Use Exercise or required reading] to ensure that suitable proficiency is achieved and maintained prior to performing work. Any special controls, processes, tools, and skills necessary to attain the required quality are to be applied, and the quality of the final product will be verified. Training will emphasize the correct work procedure and the reasoning for particular quality requirements. Training will be conducted to establish initial qualifications or to adapt to continual changes in technique, technology, and job responsibilities. Training is conducted through the EMEF training coordinator and will follow the EMEF training procedure, "Implementation of Training Program Requirements for Environmental Restoration Program Personnel" (MMES 1993a).

2.2 TRAINING NEEDS ASSESSMENT

The RAM, in conjunction with appropriate EMEF staff and the RAP QAS, will be responsible for conducting training needs assessments and ensuring appropriate training of all RAP personnel concerning quality-related measures. A RAP designee will ensure that training needs assessments are performed and documented on a routine basis. The designee will also review the training program periodically to ensure effectiveness and suggest improvements to the RAM.

2.3 TRAINING PROGRAM IMPLEMENTATION

Personnel shall be trained in the following subjects as they relate to a particular function: (1) applicable regulatory requirements and EMEF requirements or procedures, (2) this RAP QAP, and (3) specific job responsibilities and authority. Training should stimulate personnel development and improvement. Retraining may also be necessary in any of these areas as procedures or assigned activities change.

If needed, training shall be provided to (1) achieve initial proficiency; (2) maintain and enhance proficiency; and (3) adapt to changes in technology, methods, or job responsibilities (except in the case of subcontractors where proficiency is an initial requirement of the position). Performance-based training shall be provided for detailed procedures when the level of quality obtained is directly proportional to the individual's ability to implement the procedure. In some instances, required reading is all that is necessary to complete training.

Quality-related training may be conducted by appropriate EMEF staff, the on-site training organization, EMEF site program managers, the RAM, the RAC Technical Coordinator, or qualified RAP staff. Other training needs may be conducted by qualified personnel who are appointed by the RAM or other EMEF training personnel.

2.4 RECORDS

Training records may be in the form of (1) attendance sheets, (2) training logs/plans, (3) personnel training records, or (4) performance checklists and/or written exams. Division-level training records will be kept with the appropriate division personnel. The RAM will work with EMEF training coordinators to ensure proper maintenance of training records, as necessary.

3. QUALITY IMPROVEMENT

3.1 GENERAL

Continual improvement is the goal of RAP. All employees are encouraged to identify nonconformances and suggest improvements of any process used to accomplish RAP's goals and objectives. The Energy Systems quality policy endorses a no-fault environment where personnel have the freedom and responsibility to identify nonconforming activities, items, and procedures without fear of reprisal. Periodic group and RATL meetings enable effective communication of quality issues. Additionally, results of management and independent assessment activities will be continually evaluated, and lessons learned will be applied to improve organizational performance. The focus of quality improvement should be to identify quality trends and set expected performance standards in order to reduce the number of nonconformances and promote continuous quality improvement.

3.2 CONTROL OF NONCONFORMING ITEMS OR SERVICES

Nonconforming items and services are defined as items or processes that do not meet established requirements/goals or do not result in the anticipated quality. Control of nonconforming items is necessary to ensure that nonconforming activities or items are identified, reported, segregated, disposed of, and corrected and that proper personnel and organizations are notified. For RAP purposes, nonconforming items or services will be interpreted as risk equations, results, etc. that do not comply with requirements established in *Risk Assessment Strategy at DOE-ORO* (LMES 1996b) [or appropriate guidance for the Paducah Gaseous Diffusion Plant (PGDP) or the Portsmouth Gaseous Diffusion Plant (PORTS)]; *Approach and Strategy for Performing Ecological Risk Assessments for the U.S. Department of Energy's Oak Ridge Reservation: 1995 Revision* (LMES 1995a) (or appropriate PGDP or PORTS guidance); and "Verifying Calculations in Human Health and Ecological Risk Assessments" (LMES 1996c). These nonconformances will be controlled with the Verification Report (LMES 1996c). Nonconformances related to the transfer of environmental measurements data to RAP are addressed in the *Risk Assessment Program Data Management Implementation Plan* (LMES 1996d).

In most cases, RAP-related nonconforming items or services will not warrant the completion of an NCR; however, if the nonconformance poses a threat to health or safety, then all appropriate EMEF procedures should be implemented. Additional quality requirements for control of nonconforming items are identified in the latest issuances of *Control of Nonconforming Items (and Services)* (LMES 1996e) and *Preparation of a Nonconformance Report* (LMES 1996f).

3.3 CORRECTIVE ACTIONS

Corrective actions will be initiated when conditions adverse to quality may affect safety, health, the environment, or the reliability of RAP activities or data. Conditions adverse to quality are those that exceed predetermined acceptability limits, deviate from required methods, fail to meet performance requirements or data quality objectives (DQOs), or fail to meet customer or regulatory requirements and expectations. Results of internal and external audits, surveillances, assessments, reviews, NCRs, etc. may identify conditions that require corrective action.

The root cause of conditions significantly adverse to quality must be determined, corrected to prevent recurrence, properly documented, and reported to the RAM in a timely manner. The RAM must be involved from the identification of the adverse conditions to the implementation of corrective action. It is important that adverse conditions (1) be identified and corrected quickly to prevent further decline in the situation and (2) be reviewed for potential applicability to other elements of the RAP or EMEF Program. The RAM shall ensure the necessary resources to provide for timely resolution of identified problems.

Results obtained from assessment activities will be collected and reviewed by the RAP QAS in an ongoing effort to identify, trend, and correct quality deficiencies according to “Identifying and Correcting Quality Deficiency Trends” (MMES 1993b). Direct and root causes will be determined, and a corrective action plan to correct the deficiencies and prevent their reoccurrence will be developed. The RAM will review the plan and share the lessons learned with the RATLs at the same time that corrective actions are put in place.

Additional quality requirements are identified in the latest issuances of *Issues Management Program* (LMES 1996g) and *Lessons Learned Program* (LMES 1996h).

4. DOCUMENTS AND RECORDS

4.1 QUALITY ASSURANCE RECORDS

Control of QA records ensures identification, collection, retrieval, and maintenance of quality records. QA records include, but are not limited to, this QAP, procedures written specifically for RAP and other documents that provide traceable evidence to the required quality of items or activities.

QA records must be legible, accurate, and appropriately complete for the work accomplished. All corrections should be initialed and dated. Records may be originals or reproduced copies. Superseded and canceled documents will be removed from active use but will be controlled as appropriate until final disposition.

Record copies shall be forwarded to the DMC, as appropriate. Specifically, RATLs are responsible for working with project managers, on a project-by-project basis, to determine the appropriate strategy of forwarding project files to the DMC according to the EMEF Procedure "Identification, Distribution, and Maintenance of Environmental Restoration Records" (LMES 1995b). Requirements and responsibilities for receiving, processing, and maintaining EMEF records and documents are presented in this procedure. As a last resort, the RAC Technical Coordinator, RAP QAS, or other appropriate staff will assist in forwarding project records to the DMC.

4.2 DOCUMENT CONTROL

Document control is the process of ensuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed. It is also a means to ensure that personnel are using the most recent release of procedures, instructions, and plans in performing work functions. Document control applies to documentation distributed both within Energy Systems and externally (e.g., DOE, subcontractors, the public) via hard copy or electronically on the World Wide Web, and it is essential to ensure consistent and scientifically defensible risk assessments.

4.2.1 Document Preparation

The RAM or RAC Technical Coordinator will act as or designate a RAP Document Coordinator, who will be responsible for overseeing and conducting all activities required to carry out the document preparation process for RAP procedures and instructions. In this role, the RAP Document Coordinator will identify an appropriate author(s); work with the author(s) to complete all EMEF requirements according to "Initiation, Review, Revision, Approval, and Issuance of EM&EF Programs Intersite Procedural Command Media" (LMES 1996i); and maintain all documents and revisions produced by RAP. All changes or revisions of RAP documents will also be organized through the RAP Document Coordinator. Revisions to controlled documents will be reviewed and approved by the organization that originally reviewed and approved the documents.

All RAP documents must follow the textual conventions for punctuation, abbreviation, acronym, and stylistic usage as specified in the Energy Systems *Document Preparation Guide* (Langford, McConathy, and Travis 1989) and in supplemental EMEF Publications Office documents.

RATLs are responsible for ensuring that all risk assessments are prepared according to *Risk Assessment Guidance for Superfund, Volumes I and II* (EPA 1989a&b), *Risk Assessment Strategy at DOE-ORO* (LMES 1996b) (or appropriate PGDP or PORTS guidance); *Approach and Strategy for Performing Ecological Risk Assessments for the U.S. Department of Energy's Oak Ridge Reservation: 1995 Revision* (LMES 1995a); the FFA Annotated Outline for Remedial Investigation; the DQO process; and other guidance provided by RAP. Appendix A presents a checklist of requirements to be completed when conducting a risk assessment; this checklist may be a useful tool for risk assessors when completing or reviewing a risk assessment report.

4.2.2 Document Review

To ensure quality, all risk assessment results or documents must be technically reviewed according to “Technical Review of Environmental Restoration Program Documents” (MMES 1993c) before they are released to the public. Specifically, all risk-related documents must be reviewed by two RAC members or designees. Reviewers will be technically qualified individuals that were not involved in writing the document. Document revisions will be reviewed by qualified individuals familiar with the original document.

4.3.2 Controlled Documents

A “controlled document” is any document for which distribution and status are to be kept current by the issuer to ensure that authorized holders or users have the most up-to-date version available.

To achieve document control, all RAP documents are maintained on the Risk Assessment Information System (RAIS) of the World Wide Web. Configuration control of this system is accomplished by the following:

- reviewing the information periodically to ensure it is current and accurate;
- updating documents in a timely manner;
- protecting information with passwords to prevent unauthorized access, when necessary; and
- controlling the information administratively to prevent unauthorized changes.

In addition to controlling documents electronically, some hard-copy documents are maintained by EMEF according to “Initiation, Review, Revision, Approval, and Issuance of EM&EF Programs Intersite Procedural Command Media” (LMES 1996i).

Additional quality requirements are identified in the latest issuance of *Document Control* (LMES 1996j).

5. WORK PROCESSES

5.1 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

All RAP personnel are responsible for the quality of their work. The RAM is responsible for ensuring that RAP personnel are familiar with and comply with all quality requirements.

Appropriate quality can be achieved by performing work according to required procedures and instructions. Specifically, all risk assessment activities should be consistently conducted according to *Risk Assessment Guidance for Superfund, Volumes I and II* (EPA 1989a&b) as well as relevant DOE, regulatory agency, and state guidance. For the Oak Ridge Reservation, additional quality requirements are specified in the latest version of “Requirements for Conducting Human Health and Ecological Risk Assessments” (LMES 1996k). This standard identifies all RAP guidance documents that must be followed for risk assessment activities and presents *Risk Assessment Strategy at DOE-ORO* (LMES 1996b) and *An Approach and Strategy for Performing Ecological Risk Assessments for the U.S. Department of Energy’s Oak Ridge Reservation: 1995 Revision* (LMES 1995a) as the strategy documents for human health and ecological risk assessments, respectively. These strategy documents were prepared to ensure that consistent and technically defensible risk assessments are performed for the DOE-ORO/EMD by all prime contractors and subcontractors. They provide a comprehensive overview of risk assessment and define specific guidance and standardized information that must be used in the risk assessment process. At PGDP, however, *Methods for Conducting Human Health Risk Assessments and Risk Evaluations at the Paducah Gaseous Diffusion Plant* (LMES 1996l) provides additional requirements for human health assessments. An ecological strategy document is currently in development. At PORTS, human health and ecological risk assessment strategies are delineated in a series of work plans.

The RAM, RAC Technical Coordinator, and RAC will collectively determine the procedures and instructions to be written for RAP activities and ensure their review and approval. Procedures and instructions will be kept current with existing requirements and practices; they will be reviewed periodically by appropriate personnel to determine the need for revision, deletion, or additional instruction.

Risk assessment requirements and guidance documents will be presented on-line at RAIS. This system will be frequently updated and under configuration control to ensure access to the most current information. Standardized equations and data [e.g. preliminary remediation goals (PRGs), toxicity values, etc.], which are frequently updated to provide the best available data, will also be available on-line at RAIS. Deviations from this information must be approved by the RAM.

Additional quality requirements are identified in the latest issuance of *Instructions, Procedures, and Drawings* (MMES 1992c).

6. DESIGN

6.1 DESIGN CONTROL

Design control, as applied to RAP, is intended to define, control, and verify the quality of all risk assessment activities. Specifically, design control measures are used to define quality objectives and ensure that they are met.

Risk assessment guidance documents (e.g. procedures, technical memoranda, etc.) define these quality objectives. Proper training and consistent implementation of the guidance documents will ensure achievement of the quality objectives. Refer to Chap. 2, “Training,” and Chap 5, “Work Processes,” for specific information regarding training and guidance documents, respectively. In general, the guidance documents provide the necessary structure and requirements to ensure consistent and accurate risk assessments.

During the scoping phase of each remedial investigation/feasibility study project, DQO meetings will be initiated to ensure that all data needs and responsibilities are identified. In these meetings, RATLs, or their designees, will be responsible for identifying and discussing any issues applicable to risk assessment to ensure compliance with the human health (LMES 1996b) and ecological (LMES 1995a) risk assessment strategy documents (or appropriate guidance for PGDP or PORTS). At the end of the meeting, the DQO facilitator will compile a DQO meeting summary to document all objectives, agreements, action items, etc. according to “Implementing and Documenting the Data Quality Objectives (DQO) Process for Environmental Restoration (ER) Projects” (LMES 1996m). This summary is the basis for how the risk assessment will be performed.

In addition to the DQO meeting summary, RATLs may choose to complete the Risk Assessment Readiness Review Checklist (see Appendix B). This checklist is a tool that may help the risk assessor identify the project schedule and budget, materials, QA/QC criteria, management plan, and required procedures or instructions. Whether the RATL uses the checklist or their own review process, all appropriate documentation should be included in the project files. This documentation, along with specific procedures, instructions, and standardized equations and data, act as a measure of design control to ensure appropriate quality of work.

Another measure of design control, the verification of risk assessment calculations, is completed at the end of the risk assessment process. According to the procedure “Verifying Calculations in Human Health and Ecological Risk Assessments” (LMES 1996c), all risk assessment calculations (e.g., excess cancer risks and hazard quotients) calculated with Statistical Analysis System (SAS®)¹ (or comparable software) must be independently verified (hand checked or independently computer calculated) by an individual independent of the computer program generation and usage. This verification must be completed before the D1 version of the risk assessment document is finalized, but it is recommended to complete the verification before finalizing the D0 version. In a similar manner, maps created by RAP that contain risk numbers must be independently verified with a “Risk Mapping

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.

Verification Form,” which can be obtained from the RAP QAS. An example of this form is included in Appendix C.

All documentation that supports the attainment of appropriate quality (e.g., DQO meeting summaries, calculation verification forms, mapping verification forms, etc.) should be maintained in the project files or forwarded to the RAP QAS, as applicable, for inclusion in the RAP QA file.

Additional quality requirements for design control are identified in the latest issuance of *Design* (LMES 1996n).

6.2 AUTOMATED DATA-PROCESSING SOFTWARE

In addition to defining design control for the application of the risk assessment process, automated data-processing software (including modifications) used to produce or manipulate data for RAP activities will be documented, verified, validated, approved, and controlled. The requirements that ensure design control of automated data-processing software are prescribed in the RAP Data Management Implementation Plan (DMIP) (LMES 1996d). This plan provides a system of verification and validation activities and software configuration control.

6.2.1 Software Verification and Validation

Software verification and validation activities shall ensure that (1) the software adequately and correctly performs all intended functions and (2) the software does not perform any unintended function that either by itself or in combination with other functions can degrade the entire system.

Software verification and validation activities will be planned and performed for each system configuration that may affect the software. The results of the software verification will be electronically documented in the SAS[®] program (or other software), and validation activities will be performed by individuals other than those who designed the software.

Additional quality requirements for automated data-processing software are identified in the latest issuance of “Software Quality Assurance” (MMES 1992d).

6.2.2 Configuration Control of Automated Data-Processing Software

Configuration control of automated data-processing software shall ensure adequate evaluation, implementation, and documentation of all changes to a computer system. At a minimum, the following requirements must be met to achieve configuration control:

- access to all RAP databases is restricted to appropriate individuals;
- all data transferred to SAS[®] (or other software) must be spot checked against the original version (e.g., Excel spreadsheet) to ensure correct entry and the original version (hard-copy or electronic) must be maintained;
- all changes to SAS[®] (or other software) must be documented with the SAS[®] program (or other software), and the original code must be stored for tracking purposes;

- all data discrepancies must be verified with the data provider and documented within the SAS[®] program (or other software); and
- periodic back-ups of the SAS[®] programs (or other software) and data sets must be completed to prevent data loss.

As another design measure, standardized RAP models, equations, PRGs, federal and state guidelines, toxicity values, etc., will be maintained under configuration control on RAIS. When changes to this information are requested, a change/request form must be completed and approved by the RAM. After the changes have been made to the “test area,” there is an internal review and completion of a QA review form. Finally, the changes are made to the “production area,” where they can be accessed by users. The purpose of this process is to document and trace all changes made to RAIS. An example of a change/request form and a QA review form are included in Appendix D. These forms may be modified or replaced by similar forms, as necessary.

Additional requirements to achieve configuration control of Automated Data-Processing Software are defined in the RAP DMIP (LMES 1996d).

7. PROCUREMENT

7.1 GENERAL

Procurement activities will include documentation of the tasks to be performed, the milestones, and the assignment of responsibilities. Every procured service will be accompanied by a statement of work and a list of due dates for deliverables. All procurement documents must be reviewed and approved by the RAM. In addition, procured services must adhere to this QAP or provide evidence of an appropriate QAP.

7.2 CONTROL OF PURCHASED ITEMS AND SERVICES

Control of procured items and services will ensure conformity with RAP requirements and provide evidence of quality. Control mechanisms apply to organizations both inside and outside Energy Systems. Control of purchased items and services specifically applies to areas in which the failure of an item could harm personnel or jeopardize a vital mission of the RAP. Purchased services, as applied to RAP, mainly refers to subcontractor support. Subcontractors are required to follow all technical and operating procedures set forth by Energy Systems, Energy Systems EMEF, and RAP. Purchased items may include computer hardware and software.

Responsibility for control of purchased items and services secured by RAP will rest with the RAM. The RAM's responsibilities will include providing requirements to purchasing and procurement officials, as needed; authorizing the procurement of items and services; and giving the authority to accept, approve, or reject procured items and services.

Minimum requirements for organizations or individuals soliciting risk assessment work under the auspices of the DOE-ORO/EMD include appropriate experience, manpower, resources, and knowledge of applicable risk assessment guidance. The RAM has the final decision in approving procured services. Additionally, supplier selection may include a review of the supplier's past history, a review of current records, or evaluations performed at the supplier's facility.

Subcontracted services performed within RAP are monitored by the RAM, the on-site subcontract coordinator, monthly progress reports, and ongoing peer review. Services performed external to RAP will be evaluated by RAC review and may include the following:

- review of the statement of work to determine if deliverables will meet all technical and quality requirements,
- surveillances, and
- review of NCRs.

Corrective action will be necessary when noncompliant conditions are discovered.

Additional quality requirements are identified in the latest issuance of *Procurement Quality* (LMES 1996o).

8. MANAGEMENT ASSESSMENT

8.1 GENERAL

Planned and periodic management assessments will be established and implemented as a means of identifying problems and improving quality. Management assessments are primarily driven by the need to address organization, employee roles, customer expectations, quality improvement, and better utilization of human resources through evaluation of the programmatic mission and strategic objectives. Management assessments will focus on how well the integrated QA Program is working and identify management problems that hinder RAP in achieving its objectives in accordance with quality, safety, programmatic, and environmental requirements.

Management of all levels will be incorporated into the process; however, the RAM will retain overall responsibility for management assessments. Continual, open-ended assessment by management at all levels will lead to successful evaluation of the program as a whole.

Management assessments results will be documented and followed up by corrective action, as necessary. Periodic evaluations of corrective actions, lessons learned, trend analyses, etc. by the RAM and the RAP QAS will help promote quality improvement.

A significant element of the management assessment is the self-assessment. Self-assessment is important because it requires management to identify measurable performance criteria, assess program activities against performance criteria, and report the results found from the assessment. RAP will perform periodic self-assessments according to EMEF requirements. All resulting documentation will be maintained in the RAP QA file.

Additional quality requirements are identified in the latest issuance of *Management Assessment* (LMES 1997a).

9. INDEPENDENT ASSESSMENT

9.1 INDEPENDENT ASSESSMENTS

Independent audits and surveillances will be scheduled, planned, performed, and documented to examine quality and effectiveness of the QA Program and promote improvement. Compliance will be based on how well RAP complies with established procedures, instructions, and other applicable documents that set standards for the particular task being assessed. Performance audits or surveillances focus on compliance with the project's self-determined objectives, and system audits or surveillances examine project activities in relation to established procedures. Predetermined criteria will be used to conduct assessments, and responses to assessments will include the following, as applicable: corrective action to correct the deficiency, root cause identification, actions to prevent recurrence, lessons learned, and follow-up actions for improvement.

Personnel performing independent assessments will act in a management advisory function. Their responsibilities are to monitor work performance, identify unsatisfactory performance and precursors of potential problems, identify opportunities for improvement, report results to a level of management having the authority to effect corrective action, and verify satisfactory resolution of problems. Personnel performing independent assessments should be technically qualified, knowledgeable, and not have direct responsibilities in the area they are assessing.

9.1.1 Surveillance

Surveillance is the act of monitoring or observing to verify whether an item or activity conforms to specified requirements. Independent surveillances will be conducted in support of RAP goals and objectives. Surveillances will be performed according to EMEF procedure "Performance of Environmental Restoration Division Surveillance Activities" (MMES 1991), which assigns responsibilities for identifying, scheduling, planning, and performing surveillance activities. The EMEF QAS will be responsible for conducting independent surveillances on RAP. In this role, the EMEF QAS will document and track findings, observations, and management responses; implementation and verification of corrective action; and final closure of findings and negative observations.

9.1.2 Audits

An audit is a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents and the effectiveness of implementation. If performed, audits should be conducted early in a project when possible to determine whether activities comply with documented requirements and if DQOs are clearly defined and implemented in documentation. Corrective action will be taken upon audit completion as necessary.

Audits will be performed by personnel who are independent of the organization or entity being evaluated. Audits should be performed by auditors with proper training and qualification and shall be performed according to Energy Systems' quality procedure *Independent Assessment* (LMES 1997b). The reporting of findings, observation, management, and responses will be documented and tracked.

Additional quality requirements are identified in the latest issuance of *Surveillance* (LMES 1997c).

9.2 CORRECTIVE ACTION

Once conditions adverse to quality have been identified, prompt action will be taken to rectify the situation. Actions to correct the deficiency, root cause identification, actions to prevent recurrence, lessons learned, and actions to be taken for improvement will occur as part of the corrective action process; emphasis will be placed on preventing recurrence of the adverse condition to quality.

The EMEF RAM must be included in and approve all corrective actions decisions. The procedure for responding to findings and negative observations, evaluating the response, and verifying the corrective action implementation for independent assessment is outlined in the EMEF surveillance procedure (MMES 1991). Identification of findings or negative observations that may be applicable to other areas of the EMEF Program will be handled according to “Review and Transmittal of Audit and/or Surveillance Findings and Observations for Potential Applicability” (MMES 1992e).

Additional quality requirements are identified in the latest issuances of *Issues Management Program* (LMES 1996g), *Root Cause Analysis* (MMES 1994b), and *Lessons Learned Program* (LMES 1996h).

9.3 INTERNAL SURVEILLANCES

Internal surveillances on RAP and its subcontractors will be conducted by the RAP QAS, RAM, or designee following the EMEF surveillance procedure (MMES 1991). Results and NCRs obtained from the internal surveillances will be collected and reviewed in an ongoing effort to identify, trend, and correct quality deficiencies. As appropriate, direct and root causes will be determined, and a corrective action plan to correct the deficiencies and prevent their reoccurrence will be developed. The RAM will review the plan and share the lessons learned with RATLs or other appropriate staff at the same time that corrective actions are put in place. All internal surveillance documentation will be maintained in the RAP QA file.

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APPENDIX A

RISK ASSESSMENT REQUIREMENTS

The following list is a tool that may be used in the preparation and review of a baseline risk assessment. This list includes all the basic requirements that need to be completed for both human health and ecological risk assessments. The RATL is responsible for implementing all EPA, DOE, LMES, and RAP requirements when conducting a risk assessment, and the RAC reviewer is responsible for ensuring the implementation of these requirements. The source of each requirement is indicated in parentheses following the requirement.

As stated in Sect. 1.5 of the plan, some of the following requirements may be relaxed or waived due to time and/or funding constraints. All deviations must receive the RAM's approval and must be documented in the risk assessment report.

General Requirements

- All risk assessment activities must be consistently conducted according to EPA and state guidelines, based on best scientific judgement, and carried out in a cost-effective manner. (ES/ER/TM-117/R1, ES/ER/TM-180, ER/C-S2001, EM&EF/ER-S2010, policy)
- All risk activities, through completion of the remedial investigation, must be centralized through the RAM. (ER/C-S2001, ER/C-S2002, EM&EF/ER-S2010, policy)
- Everyone involved in risk assessment activities under the auspices of RAP must follow the most recent versions of all applicable Energy Systems and EMEF procedures, standards, and instructions. Deviations must be approved by the RAM and documented in the risk assessment report. (ES/ER/TM-117/R1, ES/ER/TM-180, EM&EF/ER-S2010)
- All RATLs must serve as the liaison with the EMEF project, subcontractors, and the RAM. Site project managers must ensure risk integration at the project onset and throughout the life of the project. (ES/ER/TM-117/R1, ER/C-S2001, ER/C-S2002, EM&EF/ER-S2010, policy)
- All QA matters, risk issues, deviations, suggestions of the need for new/revised guidance, etc. must be brought to the RAM's attention. (ES/ER/TM-117/R1, ER/C-S2001, ER/C-S2002, EM&EF/ER-S2010, policy)
- All nonconforming items or services that affect health or safety must be reported to the RAM, and appropriate EMEF documentation must be completed. (ES/ER/TM-117/R1)
- All management levels are responsible for continual, open-ended improvement. (ES/ER/TM-117/R1)

Risk Assessment Report Requirements

- All risk assessments should be consistently documented according to Risk Assessment Guidance, ES/ER/TM-180 or ES/ER/TM-33/R2 (or appropriate PORTS or PGDP guidance); the FFA Annotated Outline for Remedial Investigations; the DQO Process; and other guidance provided by RAP. (ES/ER/TM-117/R1, EM&EF/ER-S2010)
- All risk assessments must contain documentation to support the implementation of recent EPA guidance/instructions that are not addressed in the latest version of ES/ER/TM-180. (RATL meeting)

- All risk assessments must follow four distinct stages: (1) data collection and evaluation/problem formulation, (2) exposure assessment, (3) toxicity assessment/effects assessment, and (4) risk characterization. (EM&EF/ER-S2010, EM&EF/ER-P2009)
- All risk assessments must use the exposure pathways identified in ES/ER/TM-180 or ES/ER/TM-33/R2 (or appropriate PORTS or PGDP guidance). Deviations must be approved by the RAM and documented. (ES/ER/TM-180, EM&EF/ER-P2009)
- All risk assessments must use the latest toxicity values as specified by RAIS, ES/ER/TM-76, or the appropriate benchmark document. Deviations must be approved by the RAM, RATL, or environmental RATL and documented in the risk assessment report. (ES/ER/TM-180, EM&EF/ER-P2009)
- The risk assessment document must specify all assumptions and uncertainties. (ES/ER/TM-180)
- All risk or hazard quotients must be interpreted in the context of uncertainties and assumptions associated with the data and the risk assessment process. (ES/ER/TM-180)
- Multiple RGOs must be calculated for each COC, and all RGOs should equal PRGs unless site-specific parameters are used. (ES/ER/TM-180, DMIP)
- All risk-related documents must be submitted for RAC review. (ES/ER/TM-117/R1, ER/C-S2002)

Scoping Requirements

- All risk issues must be identified in DQO meetings in order to ensure compliance with RAP guidance. (ES/ER/TM-117/R1, ES/ER/TM-180)
- During the initial scoping, the remedial investigation and feasibility study teams must review integration points and determine points of contact, data needs, and conceptual site model and modeling needs. (ES/ER/TM-180, EM&EF/ER-S2010, policy)
- During the scoping stage, all risk assessors must determine if fate and transport modeling would benefit the risk assessment, and site-specific modeling should be discussed in the context of DQO decisions. (ES/ER/TM-180)

Verification Requirements

- All risk calculations (and developed PRGs) must be verified according to EM&EF/ER-P2009 before finalization of the D1 version of the document, and all calculations affected by regulator, internal, or external comments must be reverified according to the same procedure. (ES/ER/TM-117/R1, EM&EF/ER-P2009, EM&EF/ER-S2010)
- The verification report must contain all signatures and be completed in nonerasable media. Every page of attachments must be signed and dated, with all cross-outs initialed and dated, and attached to the verification report. (EM&EF/ER-P2009)

- All maps containing risk information must be verified and documented with the “Risk Mapping Verification Form.” (ES/ER/TM-117/R1)

Records Requirements

- All documentation that supports the attainment of quality (e.g., DQO meeting minutes, verification report, RAC review comments and responses, etc.) must be included in the project files or sent to the RAP QAS, as appropriate. (ES/ER/TM-117/R1, EM&EF/ER-P2009)
- All applicable project files (e.g., RAC review comments and responses, verification report, etc.) must be sent to the DMC upon completion of the project. (ES/ER/TM-117/R1)

Data Requirements

- All RAP data must be subjected to a documented review (e.g., data useability evaluation) prior to use. Some of the review steps may be omitted because of time and/or monetary constraints. Any deviations require the RAM’s approval and appropriate documentation. (ES/ER/TM-117/R1, ES/ER/TM-180, DMIP)
- All software verification/validation must be planned and documented. All modifications and their justifications must be documented. (ES/ER/TM-117/R1, DMIP)
- All risk assessments must conduct a data evaluation process to identify data of acceptable quality and COPCs according to Appendix A of ES/ER/TM-180. This process includes the following steps: (1) ensure appropriate analytical methods, quantification limits, detection limits, validation qualifiers and codes, and blanks; (2) determine if TICs are significant and provide justification for eliminations; (3) compare data set to appropriate background data; (4) eliminate essential nutrients; (5) screen against appropriate PRGs (but if contamination of bio-uptake factor is greater than 100, the data must not be eliminated); (6) compare quantification limits for nondetects to PRGs; and (7) compile list of COPCs. (ES/ER/TM-180, ES/ER/TM-117/R1)
- Appropriate QC comparisons must be performed on the data if it is not 100% validated and QC data are available. (DMIP)
- EMEF project team approval must be obtained in order to use data that was rejected by validation or filtered water data (for human health risk assessments only). (DMIP)
- The EMEF team must decide how to evaluate duplicate (replicate) analyses and how to group (aggregate the data) for analysis. (DMIP)
- If the total risk within a land-use scenario is greater than 1.0E-04 or the hazard index is greater than 1.0, then every analyte with an individual risk greater than or equal to 1.0E-06 or an individual hazard index greater than or equal to 0.1 must be defined as a COC. (DMIP)
- Classified data must not be transferred to or stored on RAP computers. (DMIP)
- Regular back-ups must be performed on all RAP workstations. (DMIP)

Ecological Risk Assessment Requirements

- All human health and ecological activities must be communicated and coordinated. (ES/ER/TM-33/R2)
- Ecological risk assessments must address the ecological values and endpoints distinct to every operable unit as well as ongoing contributions and risks every operable units has to other operable units. (ES/ER/TM-33/R2)
- Multimedia exposures of wildlife must be modeled using equations and assumptions in ES/ER/TM-125. (ES/ER/TM-33/R2)

APPENDIX B

RISK ASSESSMENT READINESS REVIEW CHECKLIST

The following readiness review checklist is a tool that may be used during the scoping stage of risk assessment projects. The RATL is responsible for organizing projects and ensuring their timely and accurate completion; this checklist will assist in ensuring that all significant issues are discussed. Whether this checklist is used or the RATL determines his/her own review process, project team members must be informed of all decisions for conducting the risk assessment activity before the associated work begins.

Risk Assessment Readiness Review Checklist

This form may be completed by the RATL at the beginning of a risk assessment project. Team members should sign the bottom of the form acknowledging they have been informed of each of the following items.

Project Name: _____ RATL: _____

A. Schedule and Budget

- Awareness of schedule requirements and ability to meet all deliverables.
- Awareness of budget restraints (if applicable).
- Availability of staff to meet schedule requirements. Staff may consist of the following: risk assessor, statistician, toxicologist, technical editor, QA specialist, fate and transport expert (modeling). Identification of responsibilities of all team members.

B. Materials

- Hardware and software capabilities necessary to support risk assessments in place with all computer systems having met QA guidelines. (Refer to the DMIP.)

C. Quality Assurance/Quality Control

- Appropriate filing system in place.
- System in place for forwarding all project and QA records to the central EMEF DMC. (Refer to ERWM/ER-P1110, Rev. 1.)
- Identified storage for project files.
- Identification of project contacts for technical exchange (to ensure that all members of the team are aware of major technical changes), document tracking and coordination, and QAS, etc. List of project contacts should be available from RATL.
- Team awareness of project QA requirements. (Refer to EM&EF/ER-S2010, Rev. 0.)
- Method in place for QA/QC of risk result. (Refer to EM&EF/ER-P2009, Rev. 1.)

D. Project/Task management Plan and/or Scope of Work

- Understanding of project roles and responsibilities. (Refer to ER/C-S2001, Rev. 0 and ER/C-S2002, Rev. 0.)
- Understanding of DQOs and documentation requirements. (Refer to EM&EF/ER-P2305, Rev. 0.)
- Understanding of Site Operational History and Site Conceptual Model.
- Identification, documentation, and complete understanding of risk assessment exposure scenarios and assumptions. (All team members must be informed of changes that are made in the exposure scenarios and assumptions throughout the entire project by adequate documentation.)

APPENDIX C

RISK MAPPING VERIFICATION FORM

The following form, or a similar form, is used to verify the accuracy of risk information associated with maps. Specifically, this form verifies that correct risk numbers are used; that risk numbers are displayed in the correct locations on the map; and that the scale, legend, and title are correctly labeled.

Risk Mapping Verification Form

This form should be completed when risk assessment information is used for mapping purposes.

Instructions:

1. Obtain a MapInfo (or other map software) printout of risk values from the computer programmer.
 2. Complete this form, marking the boxes that apply. Specifically note any issue(s) identified for each of the steps and describe how the issue(s) were resolved. This form must be legible and completed in nonerasable media.
 3. Attach the MapInfo printout of risk values to this form and provide a copy to the computer programmer and the RAP QAS.
-

Map Title: _____

Project Title: _____

1. Have the risk numbers in the MapInfo printout previously been verified according to the procedure *Verifying Calculations in Human Health and Ecological Risk Assessments* ?

Yes

No

If no, verify the numbers according to the procedure and attach the Conformance Form to this form. Then check the box to indicate that the numbers have been verified.

2. Do the risk numbers on the MapInfo printout match the original risk numbers submitted for MapInfo incorporation?

Yes

No

If no, note the issue(s) below.

How was the issue(s) resolved? Attach any additional documentation of how the issue(s) was resolved to this form.

3. Are the risk numbers displayed in the correct location on the map?

Yes

No

If no, note the issue(s) below.

How was the issue(s) resolved? Attach any additional documentation of how the issue(s) was resolved to this form.

4. Are the scale, legend, and title correctly labeled on the map?

Yes

No

If no, note the issue(s) below.

How was the issue(s) resolved? Attach any additional documentation of how the issue(s) was resolved to this form.

Signature of MapInfo Programmer: _____ Date: _____

Signature of RATL or designee: _____ Date: _____

APPENDIX D

RISK ASSESSMENT INFORMATION SYSTEM CONFIGURATION

The following forms, or similar forms, are used to maintain configuration control of all information located on RAIS. The Change/Request Form is used to request changes and obtain approval for the changes from the RAM. The QA Review Form is used to verify that all requested changes have been made. Both forms are maintained in the RAP QA file.

OREIS Change Request/Approval

I. REQUESTER INFORMATION		
1. Name:	2. Phone:	3. Mailing address:
4. Affiliation: (organization, company)	5. Fax:	6. E-mail address:
II. CHANGE REQUESTED		
7. Change requested to: (one selection per form)		
<input type="checkbox"/> data values (measurements; geographic)	<input type="checkbox"/> capital hardware/commercial software	<input type="checkbox"/> other: _____
<input type="checkbox"/> reference tables	<input type="checkbox"/> user interface/customized software	
<input type="checkbox"/> geographic (spatial) data structure	<input type="checkbox"/> data model	
<input type="checkbox"/> documentation	<input type="checkbox"/> risk models/data	
8. Description of change requested: (attach additional pages as needed)		
9. Requester signature:		10. Date submitted:
III. OREIS/USER REVIEW		
11. Date rec'd/reviewed by CMC:	12. Change ID #:	
III-A. DATA VALUES/REF TABLES/DOCUMENTATION/RISK CHANGE REQUESTS		
13. Date sent for review/approval: _____		
14. Sent to: <input type="checkbox"/> Data Base Mgr. <input type="checkbox"/> Geo. Data Mgr. <input type="checkbox"/> Doc. Coordinator <input type="checkbox"/> Risk Coordinator		
15. User review/comment required? <input type="checkbox"/> Yes <input type="checkbox"/> No (if no, skip to # 18)		
16. Sent out for review (date): _____		
17. Review period Begin: _____ End: _____		
18. Notification of reference table additions required? <input type="checkbox"/> Yes <input type="checkbox"/> No Date: _____		
III-B. CAPITAL HW AND COMMERCIAL SW/CUSTOMIZED UI SOFTWARE/DATA MODEL CHANGE REQUESTS		
19. Change type is: <i>Category:</i> <input type="checkbox"/> Enhancement <input type="checkbox"/> Maintenance <i>Priority:</i> <input type="checkbox"/> Routine <input type="checkbox"/> Immediate		
20. Determined by: (initial) _____ CMC _____ OREIS staff		
21. For immediate maintenance type, reviewed by: (initial) _____ OREIS staff _____ OREIS staff		
22. CRC meeting required? <input type="checkbox"/> Yes <input type="checkbox"/> No		
23. Meeting date: _____		
24. User review period: FROM _____ TO _____		
IV. APPROVAL		
25. Signature:	26. Date:	27. <input type="checkbox"/> Approved as requested <input type="checkbox"/> Approved as modified* <input type="checkbox"/> Rejected**
28. Comments: (use additional pages as needed) * <input type="checkbox"/> State change as modified ** <input type="checkbox"/> State reason(s) for rejection		
V. USER NOTIFICATION		
29. Users notified of approval status (date)	30. Users notified by (initial):	

OREIS Implementation of Risk Assessment Information System QA Review Form

Title/URL:					1. Change ID #:
2. Problems/Resolution: <input type="checkbox"/> None		3. <input type="checkbox"/> As Indicated below (<i>attach additional information as needed</i>)			
Problem	Resolution	QA Reviewer	Date	Content Author	Date
4. QA Reviewer Signature:			Date:		
5. Content Author Signature:			Date:		
6. Implementer Signature:			Date:		

NOTES:

Attach a QA Review sheet to a Change Request when the change is in the test area and ready for review.