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GUIDANCE FOR PREPARING, CONDUCTING, AND REPORTING THE RESULTS OF MANAGEMENT SYSTEMS REVIEWS

EPA QA/G-3

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FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Management Systems Review (MSR) as an important tool for managers to measure the effectiveness of Quality Systems applied to environmental data collection activities. Data produced by air toxics and hazardous waste sampling or monitoring activities are used by EPA extensively in problem definition, rule-making, and enforcement decisions. These activities are supported through implementation of the Agency-wide Quality System, which requires all organizations to develop and operate management processes and structures for assuring that the data collected are of the needed and expected type and quality for their desired use. The MSR has emerged as an effective means by which senior managers may measure the effectiveness of the quality management processes encompassing quality assurance (QA) and quality control (QC) applied to environmental data operations, and which may provide both recognition of noteworthy accomplishments and identification of needed improvements. The MSR is a process in which the planning, implementation, and retrospective review phases of a project are examined and the effectiveness of the quality management activities applied is measured. These elements are consistent with the fundamental principles of Quality Management which have been successfully applied in business and which form the foundation of the Agency's Quality System for environmental data operations.

The purpose of this document is to provide general guidance to organizations on evaluating the effectiveness of their quality system of QA/QC activities being applied to environmental data collection. The guidance assumes that approved management practices have been established and are operational.

This document is one of a series of Quality System requirements and guidance documents that have been prepared by the EPA Quality Assurance Management Staff (QAMS) to assist users in implementing appropriate quality management practices.

CHAPTER I

INTRODUCTION

The Environmental Protection Agency (EPA) spends annually about $500 million in the collection of environmental data for scientific research and regulatory decision-making. In addition, the regulated community may spend as much as an order of magnitude more each year to respond to Agency compliance requirements. In order to assure that the collection and evaluation of environmental data will produce the type and quality of data needed and expected for critical decisions, EPA has established the requirement that quality management practices be applied to these activities and that such practices be defined by a quality system[1] for planning, implementing, and assessing the effectiveness of such practices. EPA policy further requires that each EPA Quality System be documented in a Quality Management Plan (QMP)[2] that has been reviewed and approved for implementation in Agency environmental programs.

The success of a quality system depends on its continuing effectiveness in meeting the mission requirements of the organization to which it is applied. In order to ensure the on-going effectiveness of the quality system, periodic management assessments are necessary to provide managers with an evaluation of the program. EPA policy[1] requires that such management assessments be performed routinely as part of Agency-wide oversight of environmental programs.

Quality Management Practices

Since the late 1980s, the application of recognized quality management principles to the Agency's Quality System has produced new and effective tools to assist senior managers in planning, implementing, and evaluating the results of environmental data operations. One of these tools is the **Management Systems Review (MSR) process**, which enables senior management to determine whether an organization's quality system is operating as designed.

Continuous Improvement is a process used extensively in some areas of the private sector in which management philosophy and operating methodology are completely committed to quality improvement in the organization or program. The elements of continuous improvement are straight forward and embrace a common-sense approach to

management. These elements are key to an effective quality system and include:

- a focus on the needs of the customer or client;
- effective communication of customer needs among all participants;
- top management commitment, support, and direction; and
- reliance on standards and measures of performance to demonstrate satisfaction of customer needs.

In the case of EPA, every environmental data operation has a customer or decision maker who uses the data collected, whether the customer is outside the Agency, such as a regulated industry, or inside the Agency, such as a Region or Program Office. Satisfaction of the needs of the customer largely determines the success of the data operation. The use of measures of performance provides the basis for what is needed to satisfy the customer. The other elements - effective communication, management commitment, and reliance on performance measures - are reflected in the process and structure used to implement the data collection operation and to measure its success. In order to demonstrate how these elements have been institutionalized in the Management Systems Review process, it is appropriate to briefly examine the origins of the EPA Quality System and then the evolution of the MSR process itself.

Management Assessments in EPA's Quality System

Over a decade ago, EPA recognized the need to ensure that the data being used for important decisions were of the needed and expected quality. EPA management directed that all organizations engaged in any aspect of environmental data operations should develop, implement, and periodically review the process and structure for determining the quality of data produced by those operations[3]. This process and structure is called the Quality System and is documented by EPA organizations in Quality Management Plans (QMP).

Since its inception, the EPA Quality Assurance Management Staff (QAMS) has conducted management assessments of the quality systems in various organizations to ensure the effectiveness of the programs. From 1982 to 1986, QAMS conducted several Management Systems Audits (MSA) of different organizations within the Agency. The MSAs were largely guided by the organization's approved Quality Assurance Program Plan, the predecessor of QMPs. These MSAs focused on single organizations and

covered all of the major data collection activities in which the organization was involved. QAMS found that the audits were very time and resource intensive, and, while they did allow for a comprehensive examination of the audited organization, the MSAs do not examine the critical QA linkages among different organizations participating in a single data collection program. For example, an MSA conducted on a single Region would not tell the National Program Manager of a major air monitoring program how effectively quality management practices had been implemented in this Agency-wide program. Consequently, the manager may not know how consistently the quality assurance (QA) and quality control (QC) processes were applied by the participating Regions, thereby creating uncertainty in the decision process. Moreover, the time required to conduct an MSA, which carefully examined all of the principal data collection programs, was often several months, frequently causing the findings to be outdated. For these reasons, QAMS believed that the MSA concept should be revised to ensure greater timeliness and usefulness to management.

To address these concerns, QAMS developed the MSR as an alternative management assessment tool. The difference in philosophy between the MSA and the MSR may be seen in the definition of "audits" and "reviews," as follows:

AUDITS: *Assessments of the conformance of systems to quantitative specifications.*

REVIEWS: *Assessments of the conformance of systems to qualitative requirements or specifications.*

The experience of doing MSAs has shown that management systems deal largely with **qualitative** criteria; that is, management systems do not generally have quantitative performance specifications to provide a measure of their effectiveness. The effectiveness of a management system is generally measured using judgement based on non-technical information assembled and analyzed. On the other hand, Technical Systems Audits (TSAs) and Performance Evaluations (PEs) may utilize such performance specifications defined for a particular technical activity or project to determine **quantitatively** the success of the project in meeting technical and quality objectives. That is, given a set of specifications, conformance of the technical measurement system to those specification can be measured quantitatively. Consequently, the term Management Systems **Review** has been selected to describe the process of qualitatively assessing the effectiveness of management practices in applying QA/QC to environmental data operations.

Approach to Management Systems Reviews

The MSR process is designed to provide more accurate and complete assessments of how well quality management practices are functioning. Through cooperative interactions and discussions with the organizations involved in data operations, the MSR process:

- identifies the critical linkages among the participants in the data collection program which are necessary to assure that the quality of the data meets established requirements,

- does not evaluate data; it does not examine or pass judgement on the quality of the environmental data or on the decisions based on those data, and

- establishes where the Quality System is working well and where improvements should be considered by management.

The MSR process will study only the *STRUCTURES* of the management systems and the *PROCESSES* by which they are implemented. The guiding principles for MSRs, consistent with accepted quality management principles, are listed in Table I.

The MSR process is a management tool and is designed to be used by managers to understand and evaluate the technical activities that they must manage. This guidance document describes the application to the MSR process to quality systems supporting the collection and evaluation of environmental data, but it can be applied generally to any management system that needs to be assessed.

For EPA Quality Systems, the MSR process used by QAMS as part of its Agency-wide oversight responsibility to perform periodic management assessments of EPA organizations and data collection programs. In addition, the MSR process is used by senior managers to assess the effectiveness of the quality system(s) applied to their organization or to major data collection programs involving multiple organizations, including the National Program Offices, Regions, States, or Office of Research and Development (ORD) laboratories.

The use of Process Flow Models in the MSR has been shown to significantly improve the understanding of the process being reviewed. As a result, Flow Models are encouraged as an integral element of the MSR. The use of Flow Models in MSRs is described in Appendix A. The complete MSR process described in this guidance is shown in a Flow Model in Appendix B.

TABLE I

GUIDING PRINCIPLES FOR MSRs

- No surprises - keep all participants informed through open and effective communications.
- Apply the "So What" Test to every finding - be sure that the finding is significant and that value and benefit are added as a result of the finding.
- Seek to present everything from the positive.
- Provide written drafts for comments.
- Seek reviewee ownership in the review, the determination of findings, and in the development of recommendations.

MSRs have successfully employed the principles listed in Table I. In each MSR, the findings identified and applauded those aspects of the program being done well in addition to those areas. This was equally as important as identifying any areas where some improvement might be warranted. Herein lies the key difference between the MSR and its predecessor, the MSA: ***MSRs presume that every operation or process can be improved.*** Identifying areas of improvement is intended to add value or benefits to the process, not to assess blame for any problems. No one "flunks" in an MSR. The MSR is designed to be a learning experience, not a "report card."

Perhaps the greatest obstacle to the success of the MSR process is the perception by those being reviewed that it is an audit and that it will seek to identify problems and where to assign blame for the problems. Such a perception, not surprisingly, creates considerable anxiety and defensiveness. This is why the MSR approach emphasizes ownership by the reviewees and a "no surprises" attitude by the reviewers. Results are presented in a *positive* tone so that no one will feel threatened or blamed. As noted earlier, identifying those parts of the reviewed program that are being done well is equally as important as noting where improvements are needed. Again, the MSR is an

assessment tool and its purpose is quality improvement: finding better ways to do a job the next time.

Types of MSRs

There are two types of Management Systems Reviews generally performed. They are:

- Institutional MSRs

  *Reviews which focus on the **entire** QA program of a single organization and measure the effectiveness of the management systems applied to all major environmental programs undertaken by that organization.*

- Programmatic MSRs

  *Reviews which focus on a **single** environmental program and measure the effectiveness of the management systems applied to that program by **multiple** organizations.*

When Are MSRs Needed

EPA policy requires that periodic management assessments of Agency Quality Systems be conducted. The type, scope, and frequency of an assessment should be determined by management in accordance with the organization's approved QMP. As noted earlier, QAMS conducts MSRs of Agency Quality Systems at the direction of the Assistant Administrator for Research and Development (AA/ORD), who is the senior quality management official for EPA. The AA/ORD has determined that each EPA organization collecting environmental data should be reviewed at least every three years.

For consistency throughout this guidance, the person or organization for whom the MSR is performed shall be referred to as the **client.**

The process involved in carrying out the MSR is basically the same for both types. The MSR process has four distinct phases:

- Planning
- Data Gathering
- Analysis of Findings
- Report Preparation

The time required to plan, conduct, and report the results of the MSR will vary according to the complexity of the data operation being studied and the number of participants. In some cases, it may be necessary to examine only a representative group of participants due to resource and time constraints. This is particularly true for programs involving the Regional Offices.

CHAPTER II

PLANNING THE REVIEW

The purpose of the Planning Phase is to define the scope of the review and obtain concurrence on the scope from the requesting office or client. The scope of the study is determined through discussions with the client. The steps which follow describe the sequence of planning activities which are recommended for effective MSRs. A Flow Model of the Planning Phase is given in Figure 1 at the end of this chapter.

Step 1: Identify the MSR Purpose and Client

The purpose of an MSR in general is to understand how well a particular quality system applied to environmental programs is functioning. In practice, however, there is usually a specific objective for an MSR; that is, what do you wish to learn about a process from the MSR. Such an objective is usually defined by the client.

It is essential that a specific manager be identified as the principal client for the MSR. This manager will participate in the scoping of the MSR and will be the recipient of all reports produced by the MSR. There may be situations in which the client is a particular group or organization. Here again, it is essential that one individual be designated as the principal client and the recipient of the products of the MSR. In most instances, the principal client will be the manager who has requested the MSR.

Step 2: Determine Scope of MSR and Issues/Questions to Be Addressed

There must be a purpose and a subject for the MSR. This step identifies the scope of the study, including the program (or programs) to be reviewed. Conceptually, this step is analogous to the scoping steps of the Data Quality Objectives (DQO) process.[4] The client is asked to formulate specific issues or questions to be addressed by the MSR. Typical questions which have been used in MSRs include:

- How effective is the Headquarters guidance on QA for this program?

- What guidance is being used to plan and implement the sampling program?
- How are environmental data being used in program decision making?
- What mechanisms are being employed to provide or obtain analytical services?

Such general questions provide a starting point for discussions with the client (senior manager) in order to develop more specific questions for the MSR. In many cases, the client will have a clear set of goals for the MSR. In others, however, the specific questions may not be obvious. This is particularly true in those cases in which the client is learning about the program and wants to understand how the program actually operates. In this situation, the MSR will not likely seek to answer specific questions, but will attempt to obtain sufficient information about the program and its operation to enable the client to get a clear understanding of the process. As will be discussed later, the Process Flow Model is especially helpful in these cases.

Planning for each MSR should be documented in a written plan that details what the MSR will accomplish and how it will be done. The initial discussions with the client and determination of the scope and the issues/questions to be addressed by the MSR provide the beginning of the written MSR plan, which will be discussed in more detail in Step P-7.

Step 3: Identify Review Team for the MSR

The composition of the review team is critical and its selection must be made carefully. The necessary characteristics of an effective review team are given in Table II. It must be noted that individual members of the review team may not possess all of these characteristics; however, it is strongly recommended that the team as a whole have them. The review team must be technically qualified in order to establish its credibility with the reviewee. As before, this does not mean that individual team members must be experts in the subject program being reviewed; however, team members should be able to understand the underlying principles of the program. For example, if the program being reviewed involves extensive field sampling and laboratory analyses, then the review team should include members knowledgeable about the type of field sampling involved and about the chemical analyses required.

There should be no conflict of interest, either real or perceived. The review team should not include anyone from the organization being reviewed, except as an observer.

The size of the review team should reflect the scope of the MSR, the constraints of resources, and the allowed schedule. Again, considerations analogous to the DQO

process should be addressed in selecting the membership of the review team. As will be discussed in more detail in a later chapter, there should be a minimum of two interviewers for each interview team. As will be discussed later, having only one interviewer could introduce undesirable complications and should be avoided. If multiple organizations are to be visited, multiple interview teams may be appropriate in order to save time by conducting simultaneous interviews. In addition, the number of team members may be influenced by the magnitude of the MSR; that is, a review of a large data collection program involving several Regions could require a larger review team than a review of a small program at a single research laboratory. The resources available to perform the MSR may place practical limits on the number of team members, and there may be constraints imposed in terms of schedule. Historically, MSR teams have had as few as two members and as many as ten.

CHARACTERISTICS OF
REVIEW TEAM

- Members must be knowledgeable in technical principles pertaining to the subject of the MSR.
- Review team should have no real or perceived conflict of interest.
- Minimum of two members per interview team is needed.
- Members should have basic active listening and interviewing skills.

The Planning Phase of the MSR is critical. While the Quality Management Plans will provide a blueprint for participating organizations' processes and structures, they do not generally reflect the unique policies and procedures of individual data collection programs. It is essential, therefore, that the review team become familiar with all applicable guidance and procedures of the organization responsible for the program studied. Where possible, the review team should include a representative of the requesting office, preferably from the QA program. This fosters the spirit of participation and management "ownership" of the review. Moreover, it tells the reviewees that senior management takes the review seriously and expects to learn from the MSR experience.

Step 4: Identify and Provide Training Needed by the Review Team

In seeking qualified review team members, it is generally not difficult to identify candidates with the necessary technical skills. Unfortunately, finding candidates with the needed communications skills may be more difficult. As shown in Table II previously, team members should have basic active listening and interviewing skills. It is likely, therefore, that some specialized training in these skills may be needed to prepare team members for conducting effective interviews. The value of active listening will be discussed in considerable detail in Chapter III. It will suffice here to emphasize that communication skills are a critical element in being able to successfully conduct MSRs and that training may be necessary for the MSR team to ensure that those skills are present.

Depending on the nature of the MSR and the experience of the review team members, other training may be necessary to prepare the team for the MSR. This may occur when the review team members are not fully knowledgeable about the organization or program to be reviewed. Such training could encompass briefings to augment available guidance or documentation on a program. There could also be formal lectures on the program to provide a full in-depth discussion on the management processes used. For example, a MSR of the Discharge Monitoring Report Quality Assurance (DMR/QA) program in the Regions may be preceded by a familiarization briefing by the Headquarters Office of Water on how the process is intended to work. All training should be completed before commencing the first interviews.

Step 5: Identify Potential Sources of Information

The next step is to identify the possible sources of information for answers to the issues and questions. For EPA programs, the major sources usually available are:

- Existing documentation (e.g., QMPs, program descriptions, guidance documents)
- Interviews of program personnel
- Case studies (e.g., examples of program outputs)

Existing documentation is usually the starting point for most MSRs. A listing of the documents pertaining to the program(s) being reviewed should be compiled and the means of acquiring the documents identified. While these documents will not actually be used until a later step in the MSR process, it is wise to begin early to determine which

documents will be needed and how to get them. It may be necessary for the client to assist in the acquisition of these documents in some cases. This documentation will provide the basis for answering the first of several key process questions: *What is the program or organization supposed to do?*

Generally, the most useful information will be obtained from interviews of program personnel. In this step, the personnel to be interviewed should be identified at least by job titles or functions. Examples include:

- Senior managers (e.g., division directors, office directors)
- Middle managers (e.g., branch chiefs, section chiefs)
- Project managers (e.g., project officers, technical managers)
- Technical-level staff (e.g., chemists, engineers, hydrogeologists)

It is not necessary at this point to name specific individuals, rather the need is to relate the information needed to specific types of people who can likely supply that information. The interviews will provide the basis for answering the second key process question: *What does the program or organization say that it does?*

Case studies, examination of related files and records, and examples of products from the program provide tangible evidence of how the program actually operates. Case studies also provide important information on trending and consistency in the execution of the process. MSR experience has shown that the choice of which case studies to be provided to the reviewers is best left to the reviewee. This will promote their ownership of the MSR, but there is also a practical aspect in that the reviewers may not know which case studies are applicable to this MSR. While there may be some potential for bias in the case studies chosen by the reviewee, this is easily detected from the significant divergence in story consistency from the interviews.

File reviews are an important means of assessing the completeness of required documentation and for confirming the implementation of required management activities as described in the QMP. Similarly, examples of products such as final reports, standard operating procedures (SOPs), and assessment results are helpful in documenting the effectiveness of activities prescribed in the quality system. This information will provide the basis for answering the third key process question: *What did the program or organization really do?*

Step 6: Compile and Review Existing Guidance and Information

For every MSR, whether institutional or programmatic, there is existing information available. Both the quantity and usefulness of the information may vary. In general, existing documentation will not answer all of the MSR questions posed, but it will provide two important contributions to the MSR process. They are:

- Definition of the knowledge base of the review team; that is, what is known about the organization or program being reviewed.

- Provides a basis for developing specific interview questions or identifying files, case studies, or assessment results that will help to answer the overriding MSR questions; that is, what information is needed.

The review of existing documentation establishes the foundation for the study. It is essential that the review team understand what is already known about the organization or program in order to be able to formulate relevant questions for the interviews and to identify pertinent case studies, files, or reports to be examined. In some situations, the credibility of the reviewers will be established by the maturity of their knowledge of the organization or program. The organization being reviewed may already feel threatened or intimidated by the expected visit by the review team. It is essential that the reviewers have a sufficient understanding of the MSR subject to assure the organization being reviewed that the MSR is relevant and is taken seriously. This understanding comes from a thorough evaluation of the existing information. The questions to be asked during the interview phase will be formulated to fill the gaps in the data base developed from the existing information. It is important, therefore, that the review team have a clear understanding of the existing information. During the interviews, the questions must focus on the "unknown" elements and not ask for information that is already available.

A review of the existing information must assess its relevance to the scope of the review. Many environmental data operations are described by a wealth of documentation, but much of it may have no bearing whatsoever on the purpose of the MSR. The review team may need to discuss the quantity and availability of existing documentation with the client for the MSR. In some cases, such as that of a major program like Superfund, there may be too much existing information. Consultation with the client may help to identify existing documents and information that are really relevant to the study. The review team should carefully examine the relevance of a document to the MSR and plan only to use those that are clearly applicable. In saying this, it is also recognized that

relevance may be difficult to ascertain in some situations. In such cases, questionable information should be retained until its relevance can be clarified later. When information is clearly irrelevant or unusable, it should be labeled so and set aside.

The review team may discover that not all existing information is readily available and that there may be some information unknown to them. The MSR client may be instrumental in obtaining the needed documents or information, particularly if they are not readily available at the review team's "home base."

Since all existing information may not be readily available, the review team must allow ample time during the planning process to obtain the information and to review the material. The review of this documentation is admittedly tedious but necessary. The documentation may include the following for institutional and programmatic MSRs:

- Institutional: Quality Management Plans, guidance documents, operating plans, mission planning documents, and previous management assessment results.

- Programmatic: Quality Management Plans, implementation guidance documents, program descriptions, work plans, and previous management assessment results.

During the process of reviewing the existing information on the MSR subject, the review team should discuss their evaluation of the information among themselves. Often one reviewer may recognize an important piece of data that another reviewer might overlook. This point underscores again the value of having multiple reviewers. Such discussions will also enable the review team to assess the value of the information to the issues posed in the MSR. Again, not all information is relevant and the information found not to be pertinent should be discarded from the study. It is usually helpful to create some working notes to aid in the reviews and discussions. Such notes may include written summaries of key guidance documents or briefings by the requestor. The notes provide a means of documenting the source of specific information for reference during the evaluation and reporting phase and a basis for completion of a formal review plan..

As noted earlier, sufficient time must be set aside to enable the review team to conduct a thoughtful evaluation of the existing information. This may require several weeks, depending upon the complexity of the study. If reviewers are used repeatedly and gain MSR process experience, or are already familiar with the MSR subject, this period may be shortened.

Step 7: Develop Draft Plan for Conducting the MSR

When the information needs are fully defined, they are documented in a written plan which outlines what is to be done, when it will be done, and who will be involved. The draft MSR plan should contain the initial set of questions to be asked during the interviews as well as a list of the files, reports, and case studies that the review team wishes to examine on site. The plan should outline how the data gathered from the interviews and from files, reports, or case studies are going to be used. Table III lists the general structure of the MSR Plan. It should clearly present the results of the planning process so that the reader will understand the subject of the MSR and what the MSR is to accomplish. The plan serves as a check for the review team to assure that all of the relevant questions and issues have been addressed during planning. If not, the draft plan should be revised accordingly.

The proposed schedule in the draft MSR plan reflects the best estimate of the review team for completing the MSR. The schedule should include the time needed to conduct the site visits, evaluate the results, and prepare the draft finding report.

TABLE III

GENERAL STRUCTURE OF MSR PLAN

I.	Title and Subject of the MSR
II.	Purpose and Objectives
III.	Key Questions to be Answered
IV.	Organizations to be Visited and Personnel to be Interviewed
V.	Proposed Schedule

The MSR plan does not have to be a lengthy document. There is no established criteria for length, but the plan should be sufficiently detailed to give the client a clear understanding of the scope of the MSR.

Step 8: Client Review and Approval of MSR Plan

Once the draft MSR plan has been completed by the review team and the team is satisfied with its content, the plan must be presented to the client for the MSR for concurrence and approval. This step is essential. The client must be given the opportunity to review the scope of the proposed MSR and to be assured that the MSR will accomplish the expected objectives.

The preferred approach is to provide the draft MSR plan to the client, followed by a briefing. This will allow the client the opportunity to ask questions about the plan or to discuss the rationale for the proposed approach. The client must be satisfied with the approach before the MSR can proceed. If sufficient concerns or issues are raised, it may be necessary for the review team to revise the plan and to re-submit it for approval. In most cases, however, this situation is unlikely to occur if the review team has been thorough in its planning. The briefing with the client also serves to engage the client in the MSR process with the review team. All concerns or issues must be resolved with the client before proceeding any further.

Step 9: Propose Schedule for Data Gathering and Notify the Reviewee(s)

When the MSR plan has been approved by the client, the review team should propose a schedule for any needed site visits. Input from the client on the schedule is very helpful so that obvious conflicts may be avoided. The schedule should be realistic and should allow for some possible delays, particularly when visits to multiple sites are necessary.

It is preferred that the notification of the organization(s) to be reviewed be accomplished by a joint memorandum from the client and the review team leader. This memorandum will:

- state the purpose and objectives of the MSR,
- list the review team members and their affiliations,
- briefly describe the approach to be used and the expected time needed, and
- propose the schedule for site visits.

The memorandum should also identify any case studies and reports needed, and files to be examined, so that they can be compiled and be available when the MSR team arrives at the site. In addition, the memorandum should schedule the entrance briefing with the senior managers. Last, the memorandum should request that an office or conference room be reserved for use by the review team during the on-site visit.

The joint memorandum is important. The client's signature establishes the credibility and authority of the review team. The team leader's signature acknowledges the independence of the MSR review team. The memorandum should be sent to the organization(s) to be reviewed at least one month prior to the expected start of the site visit(s).

At this time, the team leader should again review with the team members the process for evaluating and reporting the results. This includes identifying to whom the interim findings reports will be sent in the reviewed organizations for review before there is any submittal to the client.

Step 10: Resolve Any Conflicts and Finalize Schedule for Data Gathering

After any schedule conflicts have been resolved regarding the site visits, the next step is to finalize the schedule for the data gathering phase. The final schedule for the MSR should include the expected numbers of interviews and briefings and the time required for them. The schedule is intended to indicate to the management of the organization to be reviewed that a thoughtful, systematic approach has been developed and that there is a clear rationale for the actions proposed. The schedule will also enable the reviewee to identify any conflicts or obstacles to the execution of the plan.

The finalization of the schedule for data gathering requires agreement by the reviewed organization(s) for the timing of the site visits. The joint memorandum discussed in Step 8 will propose the dates for the site visits and request confirmation of the dates from the reviewed organizations. If there is a problem with a set of dates, it may be necessary to re-examine the original schedule and resequence the site visits where multiple sites are planned. To expedite matters, this should be done by telephone.

When all organizations to be reviewed in the MSR have agreed to the schedule, a memorandum should be sent by the MSR team leader to confirm the final arrangements. This memo should also re-confirm the MSR team's expectations of any case studies or other documentation to be provided by the organization(s) to be reviewed.

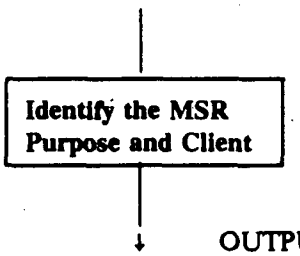
Step 11: Complete Logistical Needs for Data Gathering

When the final schedule has been approved by all organizations to be reviewed, it will be necessary to complete the arrangements for travel to the site. As discussed in more detail in the next chapter, a site visit may require a week at the site. Other MSRs may require fewer days on-site. The actual time on site is determined by the complexity of the study.

While it has not been mentioned previously, adequate resources must be committed to enable the MSR plan to be implemented effectively. This is part of management's responsibility and commitment to the assessment process. It is assumed, therefore, that sufficient funds shall be available to support required site visits.

STEP P-1

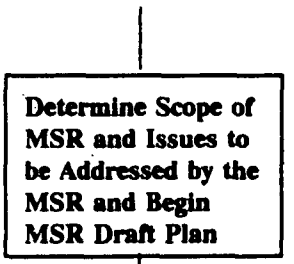
INPUT: Request/Need for MSR



OUTPUT: Understanding of who is the Client for the MSR and why it is needed.

STEP P-2

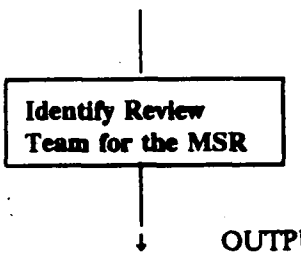
INPUT: Purpose of the MSR



OUTPUT: Definition of Scope of the Study, including Technical Program to be Reviewed

STEP P-3

INPUT: MSR Scope; Technical Program to be Reviewed



OUTPUT: Review Team

Figure 1. Flow Model of MSR Planning Phase

STEP P-4

INPUT: Review Team; Scope of MSR

Identify and Provide Training Needed by the Review Team

OUTPUT: Review Team Trained for this MSR

STEP P-5

INPUT: MSR Scope and Issues

Identify Potential Sources of Information Needed to Resolve MSR Issues

OUTPUT: Sources of Information to Resolve Issues

STEP P-6

INPUT: Sources of Information Relevant to the MSR Subject

Compile and Review Existing Guidance and Information to Determine Its Applicability to the MSR

OUTPUT: Information Relevant to Study

Figure 1 (Continued). Flow Model of MSR Planning Phase

STEP P-7

INPUT: Relevant Existing Information; Scope of MSR

Complete Draft Plan for Conducting the MSR, including Specific Interview Questions

↓ OUTPUT: Draft MSR Plan

STEP P-8

INPUT: Draft MSR Plan

Review MSR Plan with Client, Determine if Recommendations are Expected, and Obtain Client Approval of MSR Plan

APPROVED

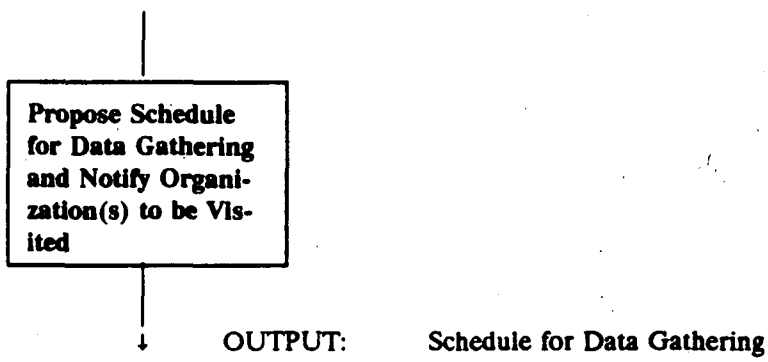
↓ OUTPUT: Client-Approved MSR Plan

(IF NOT APPROVED, REPEAT STEPS P-7 AND P-8 AS NEEDED TO ASSURE CUSTOMER UNDERSTANDING AND APPROVAL.)

Figure 1 (Continued). Flow Model of MSR Planning Phase

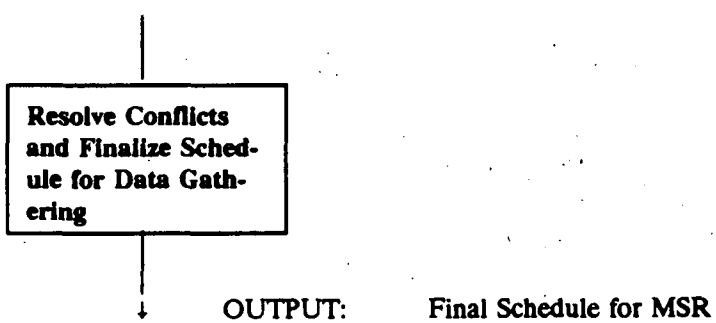
STEP P-9

INPUT: Approved MSR Plan



STEP P-10

INPUT: MSR Plan and Schedule



STEP P-11

INPUT: MSR Plan and Final Schedule

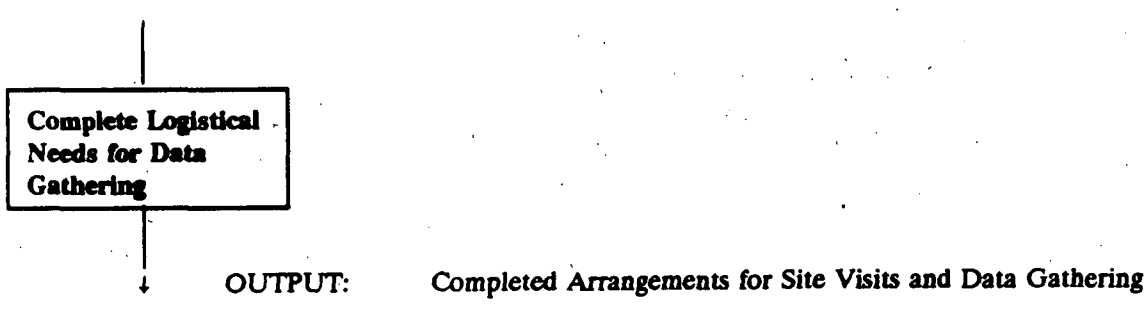


Figure 1 (Concluded). Flow Model of MSR Planning Phase

CHAPTER III

CONDUCTING THE REVIEW

Conducting the MSR at a site will usually involve interviews of participating personnel and reviews of applicable files, documents, and case studies. In this phase, interviews may be the most valuable source of information. Consequently, the review team should be familiar with interviewing techniques so that information is obtained effectively. MSRs should always be conducted in a collegial and businesslike manner. When visiting other organizations, it is very important to conduct entrance and exit briefings with the senior management of the organization. Tell them what you are going to do, then tell them what you did. Keep the lines of communication open at all times. Last, thank the managers and staff for their time. It is courteous and acknowledges your recognition of the value of their time and their contribution to the MSR. A Flow Model of the implementation phase of the MSR is given in Figure 2 at the end of this chapter.

Table IV provides the general format for a typical site visit of five days duration.

Step 1: Conduct Entrance Briefing for Management

A successful entrance briefing with the senior accountable managers of the organization to be reviewed is critical to the success of the MSR. The MSR team should arrive for the entrance briefing on-time. It should be assumed that the managers attending the briefing will be anxious about the MSR or perhaps even irritated at having to spend time on the MSR. The MSR team leader should make every attempt to reduce the anxiety level by focusing on the purpose of the MSR and by emphasizing that every possible effort will be made to minimize disruptions.

During the briefing, the team leader will introduce the MSR team members and will review the objectives of the MSR, the principal questions to be asked during interviews, and the expectations from file reviews, case studies, and reports. This should take no longer than 15-20 minutes. Afterwards, the managers of the organization being reviewed shall be allowed to ask any questions about the MSR. As stated earlier, there

TABLE IV

TYPICAL ON-SITE SCHEDULE

Day 1	Arrival; Entrance Briefing; Begin Interviews
Day 2	Conduct Interviews and Recap
Day 3	Conduct Interviews and Recap
Day 4	Conduct Interviews; Summarize Interviews
Day 5	Exit Briefing; Departure

should be no hidden agenda and no surprises. Questions should be answered truthfully and without hesitation. The entire briefing should last no longer than 30-45 minutes.

At the conclusion of the entrance briefing, the host organization should provide the MSR team with a list of prospective interviews and the schedule for the interviews. It is recommended that the MSR team leader offer to provide the host senior manager with a daily synopsis of the information obtained from the interviews and case studies.

Step 2: Interview Key Staff

The process of interviewing of the reviewed organization's staff is the most critical step of the MSR process. Table V lists twelve elements of positive interviewing skills that should be utilized during the interviews. It is preferred that the interviews be conducted in a "neutral" location, such as a conference room or vacant office, rather than in the interviewee's office. Each interview should last no more than one hour unless the interviewee specifically wishes to continue. Then the interview should continue only for another fifteen minutes. If more time is needed, then another time should be scheduled for later. The limit of 75 minutes for an interview has a practical basis. The interviewers must have some time between interviews to collect their thoughts and notes, and to "recharge" for the next interview.

Another practical consideration is that there should always be a minimum of two interviewers. This enables a "tag-team" approach to the interviews; that is, while one interviewer is asking a question and recording the response, the partner is able to listen actively to the response and to formulate a more thoughtful follow-up question based on the response. As has been emphasized throughout the MSR process, the questions should be "open-ended" to enable the respondent to answer in a descriptive manner. "Yes/no" and leading questions should be avoided. The use of two interviewers will help to ensure that what was said is recorded accurately. The corroboration provided by the second interviewer reduces the likelihood of anyone claiming later that a particular answer was never given. Moreover, if there is any confusion about what was heard, the two interviewers can discuss the response and agree on what was said.

Using only two interviewers helps to put the interviewee at ease. More than two may cause the interviewee to feel outnumbered or surrounded. However, it may be appropriate sometimes to use a third person to take notes provided that this person is so identified at the start of the interview. An alternative may be to request the reviewee to provide a note taker. This may increase the sense of "ownership" in the MSR by the reviewee. An advantage of using a note taker is that it enables the interviewers to focus more intently on the questions posed and responses given.

The attitude and "body language" of the MSR team must convey a non-threatening demeanor to the host organization. On rare occasions there may be some hostility expressed by the host, but at no time may any member of the team respond to anger. If the situation continues to deteriorate, the interview should be suspended. A short break may enable the participants to calm down and "defuse" the situation. Afterwards, resume the interview by restating the purpose and objectives of the MSR. If the situation still does not improve, the review team should seek assistance from the interviewee's management.

Team members should always remain calm and professional at all times. One of the most readily perceived qualities by interviewees is attitude. Being in a situation of potential conflict may require more mental fortitude by the reviewer than factual knowledge. While a lack of knowledge of a subject may be compensated for by other team members, attitude problems cannot. Each interview team member must contribute to a harmonious demeanor in order to ensure an effective interview. They must be supportive of one another and avoid disagreements in the presence of the reviewee.

At the conclusion of the interview, the discussion should be summarized briefly to confirm the key points from the interview. Next, the interviewee should be thanked for taking the time from his or her busy schedule to participate in the MSR. After the interviewee leaves, the team members who conducted the interview should review their

notes to identify any areas of question or misinterpretation and to assure than they are in agreement on the notes compiled. It is recommended that at least 30 minutes be scheduled between interviews to allow the interviewers to get prepared for the next interview. After several interviews have been conducted and trends emerge in some of the responses to the planned questions, this time may be used to revise the questions in order to capture some different information or to drop some questions altogether.

Step 3: Conduct File Reviews and Obtain Case Studies/Reports

This step can be completed at any time during the site visit but prior to the exit briefing. The reviews of relevant files may be most effectively conducted during periods when interviews are not scheduled. This may occur early or late in the work day. If known, a list of the files to be reviewed should be sent prior to arrival on site so that the reviewee organization will have ample time to retrieve them.

The nature of reports and case study material needed is documented in the MSR plan. Often the material is voluminous and will require considerable time to examine, usually longer than the review team can afford to spend on site. If extra copies are unavailable and it cannot be copied on site, the MSR team leader should ask to borrow the materials long enough to return to the team's home base and have the material copied. In either case, the team leader should make arrangements to have the case study materials sent to the team home base.

The review team should anticipate that evidence or documentation not anticipated during planning may be disclosed during the site visit. This additional information may significantly augment the interviews and other evidence.

Step 4: Summarize Interviews and Compile Initial Impressions

Prior to the exit briefing for the organization's senior managers, the review team should assemble its notes from the interviews and the file reviews, etc., and discuss the initial impressions from the site visit. The purpose is to be able to provide the managers with some indication of the results of the MSR. This does not mean that specific findings should be developed, although it is likely that some impressions will be so strong as to also become findings. As noted earlier, the presence of the review team creates anxiety for the organization and it is important to provide them with at least some impressions before leaving.

TABLE V

POSITIVE INTERVIEWING SKILLS
by
Linne Bourget, Ph.D.

1. Attending to another means turning off our tendency to evaluate, keeping an open mind, and walking a mile in their mental moccasins.

2. Be willing to set yourself aside and focus totally on the other person. Shelve your negative emotions.

3. Listen for other's points and feelings and respond to both, verbally or nonverbally, to show that you understand.

4. Ask open-ended rather than yes-no questions.

5. Ask why, what if, be more specific, give an example, what would be the best way to.....types of questions.

6. Repeat back or paraphrase interviewee's responses, for clarifying or empathizing, including facts and feelings.

7. Be responsible for the communication--"I am not sure I understand, could you clarify?"

8. Ask additional questions as follow-up to obtain more information if necessary.

9. Keep as much eye contact as possible even though you are taking notes. Keep a supportive facial expression.

10. Keep the interview moving, yet allow interviewee time to make her/his points.

11. Be sure to thank interviewee for time and input.

12. Prepare an opening statement which explains clearly your purposes and process clearly and sets a positive climate.

The summary exercise also offers an opportunity for the review team to talk about what has happened while they are on site. Such discussions may identify differing interpretations of what was heard in some interviews and enable clarifications to be made. It is advantageous to do this now while there is still access to the people interviewed in case some follow-up is needed. For example, two interviewees may have provided conflicting information on a particular topic. By identifying the conflict on site, it may be possible to check back with the interviewees to verify the information.

Step 5: Conduct Exit Briefing

The exit briefing enables the review team to summarize for management what was heard or found during the visit. Preliminary impressions may be given with the understanding that additional review and evaluation of notes, reports, and case studies will be needed before specific findings can be determined. The review team leader should be the principal spokesperson for the team, but all members should participate in the discussions.

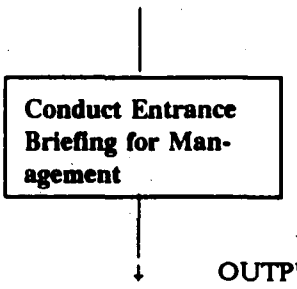
The briefing should be opened with a restatement of the purpose and objectives of the MSR and of what information was expected from the interviews, files reviews, etc. Next, list the people who were interviewed and provide a general summary of what they said in response to the questions asked. At this point, it is appropriate to make some observations about the information collected. During the briefing, it is very likely that the review team will be pressed to provide conclusions; however, the team should be very careful to avoid giving conclusions or detailed findings that could be inferred as conclusions.

At the end of the discussions, the review team leader should give an indication of when the draft Findings Report will be available for review and explain what will happen to the MSR results. Last, the team leader should thank the managers for their time and for the cooperation of their staff during the review.

The exit briefing concludes the data gathering phase on site and the review team will depart following the briefing.

STEP C-1

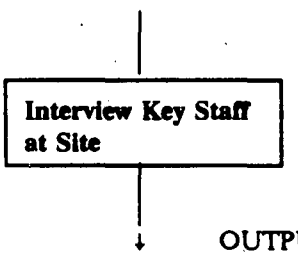
INPUT: MSR Plan



OUTPUT: Understanding of Scope of MSR by Management at Site.

STEP C-2

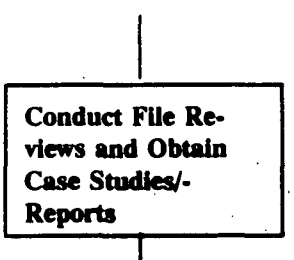
INPUT: MSR Plan



OUTPUT: Notes from Interviews

STEP C-3

INPUT: MSR Plan; Interview Notes

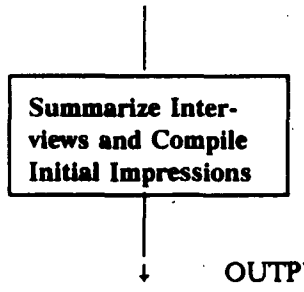


OUTPUT: Relevant File Information, Case Studies, and Other Documentation

Figure 2. Flow Model of MSR Data Gathering Phase

STEP C-4

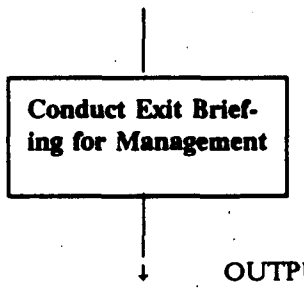
INPUT: Interview Notes and Other Information Collected; MSR Plan



OUTPUT: Initial Impressions of MSR Findings for the Site

STEP C-5

INPUT: Initial Impressions of MSR Findings for the Site; MSR Plan



OUTPUT: Completion of Data Gathering Phase

Figure 2 (Concluded). Flow Model of MSR Data Gathering Phase

CHAPTER IV

EVALUATING THE RESULTS

At the conclusion of the data gathering phase of the MSR, the review team returns home to the task of compiling and evaluating all of the information collected. Depending on the number of sites visited and amount of case study information accumulated, this can be a formidable task. The steps in this phase of the MSR process may be the most critical to the success of the assessment. The data must be compiled, then evaluated according to the criteria stated in the MSR Plan to produce interim findings. To ensure the relevance of the findings, the "So What?" test is applied; that is, a test to determine if a finding is significant and affects the quality of the operation or the data produced. Insignificant findings should not be included in the reporting of the MSR because they weaken the effect of the findings that really matter. Moreover, the client should not have to deal with trivial issues, but should need only to focus only on the significant ones.

The time needed to complete the evaluation phase will be determined largely by the volume of information to be reviewed and analyzed. It is not necessary for all review team members to be together when reviewing the data, but they should be together when they reach a consensus on the findings or consider preliminary conclusions or recommendations. For a complex MSR, it would not be uncommon for this phase to require 10 work days to adequately review the data and formulate relevant findings. A Flow Model of the evaluation phase of the MSR process is given in Figure 3 at the end of this chapter.

When the data from interviews, file reviews, documents, and case studies have been compiled, they must be analyzed to identify key findings that pertain to the goals of the MSR. When complex data operations are involved, it is very helpful to develop a flow model of the data operation to ensure that all key steps are identified and that the inputs and outputs from each step are understood. Such a flow model will help to define clearly the critical linkages among the key steps in the process. The flow model should define the criteria used to execute the step and the approach taken to produce the desired outputs. Using the flow model, identification of the important findings becomes very straightforward. More importantly, perhaps, the flow model provides management with a powerful tool which may be used to evaluate possible changes to the structure and process of the data operation in the future. The flow modeling technique and its use are described in Appendix A.

Step 1: Assemble and Review Information According to MSR Plan Criteria

The results from the data gathering phase will include notes from the on-site interviews, summaries of documentation reviewed prior to and during the site visits, results of file reviews, case studies pertaining to the subject of the MSR, and other evidence acquired during the MSR. This step provides for the sorting of this information into a manageable data base so that an effective evaluation may be performed. The time required to accomplish this activity will be determined by the volume of material acquired and the complexity of the MSR.

As noted earlier, the use of a flow model of the process reviewed becomes particularly helpful by providing a structure for the sorting of the information. In some cases, gaps in the data base may be identified and the opportunity presented to obtain the missing information (if it is available) before proceeding with the evaluation. It should be noted that a information gap may itself be a significant finding from the MSR.

The MSR plan provides the criteria for the review of the MSR data base. The data base should be organized first to seek answers to the issues and questions posed in the MSR plan. Often, other material will emerge that may provide helpful information to the client even though it wasn't specifically within the scope of the MSR. The review may be accomplished effectively by allowing the review team to work independently of each other and to identify preliminary findings separately.

As the information is reviewed, the flow model may be updated as additional evidence is discovered to help define or explain the process. During this step, the original questions posed in the MSR will be addressed, assuming that sufficient data are available to answer them.

Step 2: Identify Interim Findings

This step brings into focus all of the preceding activities. The identification of interim findings represents the principal outputs of the MSR process. The findings should reflect the original issues and questions posed by the client and should be stated in a manner that answers those questions whenever possible. Findings should always be based on documented facts and not on the reviewer's speculation. The supporting documentation for the finding must be identified and referenced in case such documentation is required later.

In some literature, the term *finding* refers only to negative impacts on the quality system. The MSR process takes a broader interpretation. A finding is a statement based

on the evidence found relative to a specific criterion or question. For example, consider the following question: "Does the organization perform annual inspections of the monitoring instruments?" Depending on the evidence discovered either from files or from interviews, the *finding* would indicate whether or not the inspections were performed. To address whether or not a sufficient number of instruments in the network had been inspected would go beyond the *finding* and would require a *conclusion*; that is, a judgement of the adequacy of the finding. Conclusions will be discussed in Step 4.

Step 3: Apply the "So What?" Test to the Findings

As stated earlier, the analysis of findings from a MSR must include the "So What?" test. The "So What?" test helps the reviewer to eliminate findings that really have little or no relevance to the questions posed by the client. The value of the MSR process lies in being able to tell the client what he or she needs to know so that effective response actions may be taken. Accordingly, care must be exercised in applying the "So What?" test to ensure that the trivial is separated from the significant. This ties back to the planning phase and the emphasis on gaining a clear understanding of the client's perception of the issues and what the client regards to be significant. The "So What?" test will also help to prioritize the findings to aid the client in evaluating the results of the MSR.

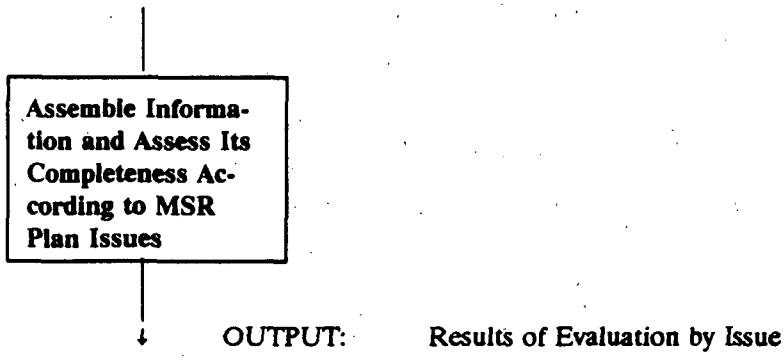
It is essential that the findings be important and that they add value to management's understanding of the data operation. Superficial or trivial findings diminish the value of the MSR.

Step 4: Formulate Preliminary Conclusions and Recommendations

It is almost impossible to be totally objective when identifying findings. Invariably findings will lead to conclusions and probably recommendations in the minds of the reviewers. Such is the nature of most reviewers. This is not entirely undesirable, but reviewers must be cautioned not to allow their conclusions to overly influence the evaluation of the findings by the client. In some cases, conclusions and recommendations may have been specifically requested by the client. It is then proper to develop conclusions based on the evidence compiled and to prepare recommendations based on those conclusions. As will be shown in the reporting phase, conclusions and recommendations must be carefully controlled until the final report is prepared.

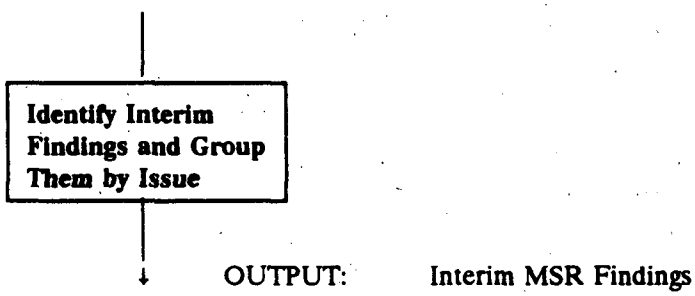
STEP E-1

INPUT: Results from Interviews and Documentation Collected



STEP E-2

INPUT: Results of Evaluation by Issue



STEP E-3

INPUT: Interim MSR Findings

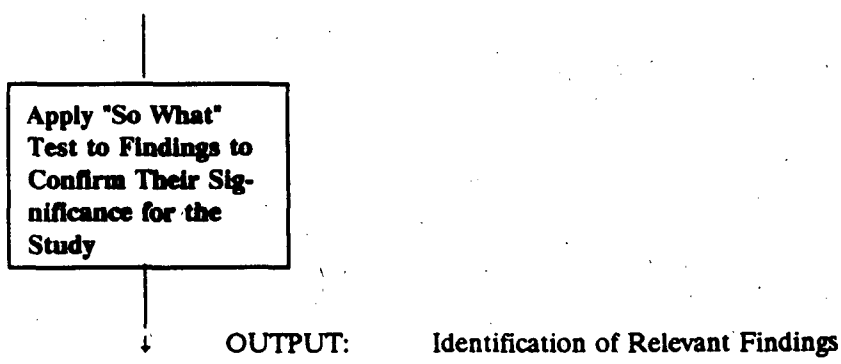


Figure 3. Flow Model of MSR Evaluation Phase

STEP E-4

INPUT: Relevant MSR Findings

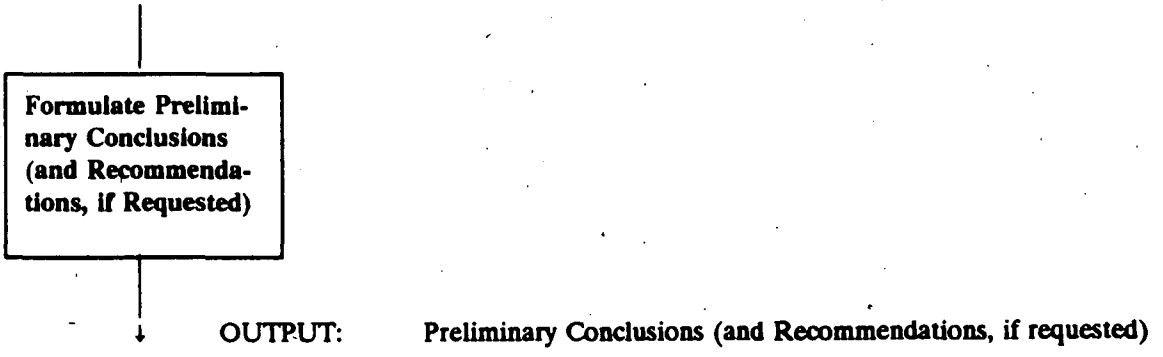


Figure 3 (Concluded). Flow Model of MSR Evaluation Phase

CHAPTER V

REPORTING THE FINDINGS AND RECOMMENDATIONS

One of the basic truths of reviews and audits is that the written word has several orders of magnitude greater impact than the spoken word. As a consequence, great care and thoughtfulness must go into the preparation of the draft Findings Report and final MSR Report. The findings should always be presented in a non-pejorative manner. When areas needing improvement are found, the findings should point toward a solution to the problem, not toward assigning blame for the problem. Inflammatory language should be avoided in all reports. Recognize that bad news can be presented in a manner and tone that are helpful. The discussions should be candid, but dispassionate.

The effectiveness of this approach in creating positive change has been demonstrated in previous MSRs. The following steps describe the key elements in reporting the findings and recommendations of the MSR. They are described in a flow model in Figure 4 at the end of this chapter.

Step 1: Prepare a Written Draft Findings Report

A written draft report on the findings of the MSR must be prepared. The format of the report is not critical; however, it should contain the following information:

- the statement of objectives for the MSR; that is, why was the MSR needed and what was to be accomplished by the study,
- when and where did the study take place,
- who was involved in the study, including the review team and the group being reviewed,
- what were the principal findings,
- what are the impacts of the findings (i.e., the results of the "so what?" test),

The review team may also include some recommendations at this stage if they were requested to do so at the beginning of the MSR by the client. However, the purpose of the draft Findings Report is to present the facts of the study, not to draw conclusions from those facts. It is fair to say that some findings will automatically lead the reader to obvious conclusions and recommendations without having to state them in the report. Generally, conclusions and recommendations should be brought forward after the reviewee has concurred with the accuracy of the statements made in the draft Findings Report. In this regard, conveying the sense of the "So What?" test is very important. The credibility of the MSR will rest largely on how the findings are received by the reviewee. It is, therefore, essential that the findings reflect significant issues or impacts relative to the program or institution being reviewed. Credibility can be easily destroyed if the findings are frivolous or irrelevant to the program.

If there are multiple reviewees, it may be necessary to prepare separate draft Findings Reports for each reviewee. This is done to protect the confidentiality of each reviewee. If a reviewee chooses to share his report with others, he may do so, but, the reviewer should **never** reveal or distribute the contents of a draft Findings Report to anyone other than the client of the MSR.

Step 2: Obtain Comments from the Reviewees

The draft findings should always be shared in writing with the reviewees to assure that no factual errors have been included. This enables the reviewer and the reviewee to seek a consensus on the findings and, in some cases, on the recommendations. Where multiple reviewees are involved, it will be necessary to allow ample time for their thoughtful examination of the report. This approach enhances the "ownership" of the study by the reviewee and increases the likelihood that the recommendations will be implemented.

It is **absolutely** essential that the reviewee see the draft before the MSR client, who requested the study. The reviewee must be given the maximum opportunity to assure that the statements in the draft Findings Report accurately describe what was said or documented during the study. However, there may be some disagreement between the review team and the reviewee regarding what is Truth. The intent here to be certain that the reviewees statements, case studies, documentation, etc., are portrayed accurately as they were presented. Should any disagreements arise regarding the conclusions and recommendations, an accurate draft Findings Report provides a common basis for discussing those differences.

Step 3: Reconcile Reviewees Comments and Prepare Draft Final MSR Report

The review team has the responsibility to correct any "errors in fact" in the draft Findings Report. If the errors alter the preliminary conclusions and recommendations developed during the analysis of the findings, then they also must be resolved. As noted above, the issue pertains only to errors which are supported by evidence to the contrary. Opinions are not valid cause to alter the report.

The conclusions (and recommendations, if they were requested by the client) are added to the draft Findings Report at this time. As noted earlier, some conclusions and recommendations may be shared with the reviewee in the draft Findings Report. This is particularly helpful for those conclusions in the reviewee and the Review Team are in complete agreement. Where there is (or may be) disagreement, the conclusions should be presented to the MSR client for resolution. The review team may also consider including a written response by the reviewee to the draft Findings Report. Any discussions regarding the conclusions reported should be between the MSR client and the reviewee.

Step 4: Brief Client on MSR and Finalize Conclusions/Recommendations

Where possible, the draft Final MSR Report should be accompanied by a formal briefing for the client. This provides the client with an opportunity for questions and discussion. More importantly, the review team has the opportunity, if asked, to describe the events of the MSR candidly and to present information or perspectives that would be inappropriate in a written report. Such a subjective discussion should be initiated by the client, not the review team.

The briefing should include a careful review of the findings and the conclusions. The presentation should include the rationale for the conclusions reached. The client may or may not ask for recommendations. If the request is made, the recommendations should be supported by the rationale for them. Often, the client may have only a general knowledge of the quality system and the QA/QC activities involved, and may choose to rely significantly on the expertise of the reviewers. The briefing should, therefore, present the conclusions and recommendations in a context and using terminology familiar to the client.

Step 5: Prepare Final MSR Report and Issue to Client

When the client has reviewed and concurred with the draft Final MSR Report, the Final MSR Report will be prepared and issued to the client only. Any further distribution of the report must be made by the client. The reviewers must never distribute copies of the

MSR Report. The report is the property of the client.

As in the case of the draft Findings Report, MSRs involving reviews of multiple organizations will have multiple draft Final MSR Reports. These may be compiled into the Final MSR Report as individual sections or as appendices, but the report should include an executive summary containing the MSR objectives and the principal findings and conclusions.

Step 6 (Optional): Identify any Follow-up to the MSR

As an option, the client may want to follow the MSR with further assessments or with a request for technical assistance. The period immediately following the MSR presents opportunities for various responses depending on the needs of the client.

Conclusion

The MSR process provides managers with a powerful management assessment tool. While developed to evaluate the EPA Quality Systems for environmental programs, its field of application is not limited to this subject. The steps comprising the MSR process are sufficiently generic such that the MSR process may be applied to any management systems to be evaluated. It is expected that the MSR process will continue to evolve and be improved through growing use.

STEP R-1

INPUT: Results of MSR; Preliminary Findings and Conclusions

Prepare a Written Draft Findings Report for Each Group Reviewed in the MSR

↓ OUTPUT: Draft MSR Findings Report

STEP R-2

INPUT: Draft MSR Findings Report

Obtain Comments from Each Reviewee on the Draft Findings Report

↓ OUTPUT: Reviewee Comments on Draft Findings Report

STEP R-3

INPUT: Reviewee Comments; Draft Findings Report

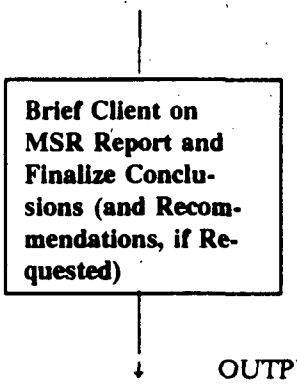
Resolve Comments on Draft(s) and Compile Draft Final MSR Report

↓ OUTPUT: Draft MSR Report Containing Final Findings and Conclusions (and Recommendations, if Requested)

Figure 4. Flow Model of MSR Reporting Phase

STEP R-4

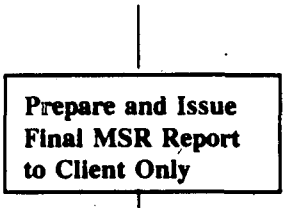
INPUT: Draft Final MSR Report



OUTPUT: Client Acceptance of Report,including Final Conclusions (and Recommendations, if Requested)

STEP R-5

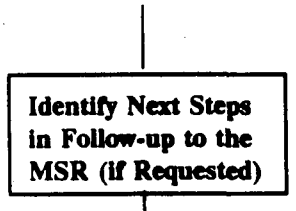
INPUT: Draft Final MSR Report; Final Conclusions (and Recommendations, if Requested)



OUTPUT: Final MSR Report

STEP R-6 (OPTIONAL)

INPUT: Final MSR Report; Client Request for Additional Assistance



OUTPUT: Identification of Next Steps (as required)

END OF MSR PROCESS

Figure 4 (Concluded). Flow Model of MSR Reporting Phase

REFERENCES

1. *U.S. EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency (1994).

2. *EPA Requirements for Quality Management Plans*, U.S. Environmental Protection Agency, EPA QA/R-2 (1994).

3. EPA Order 5360.1, Policy and Program Requirements to Implement the Mandatory Quality Assurance Program, U.S. Environmental Protection Agency (April 1984).

4. *Guidance for Planning for Data Collection in Support of Environmental Decision Making Using the Data Quality Objectives Process*, U.S. Environmental Protection Agency, EPA QA/G-4 (1994).

APPENDIX A

USE OF PROCESS FLOW MODELS IN MSRs

The use of a process flow model is particularly helpful in enabling management to gain additional insights on the relationship of all activities in an operation. In addition, managers can experiment with potential process modifications and observe their impacts. Traditionally, process flow models have been used in the engineering design of complex systems to help engineers understand the intricacies of the process, observe how inputs and outputs from each step were interrelated, and assure that the sequence of the steps provided the desired output from the process. Likewise, the application of the process flow model technique to environmental data operations provides added information and clearer understanding of the activities under review. For example, the model presents the data operation as a series of interlinked activity and decision steps which describe the sequence of logic flow and use of data throughout the process.

Components of Process Flow Models

In this application, the process flow model is composed of all of the steps needed to describe fully an environmental data operation and the quality assurance and quality control (QA/QC) activities applied. The model covers the entire scope of the data operation, including planning (or scoping), implementation, and evaluation of the results, and shows the logical sequence in which actions or decisions must occur in order to produce a desired result or product. A typical flow model step is given by Figure A-1. For each step in the process, the input and output is identified in terms of specific environmental data used. If a decision is involved in the step, the decision paths emerging from the decision are shown. The steps are linked together in the appropriate sequence to show the flow of decisions and data throughout the process.

For each step in the flow model, there is a detailed Data Sheet that contains the following information:

- the purpose of the step,
- the goal or objective of the step,

- a description of the activity performed in the step and how environmental data are used,
- the criteria for performing the activity in the step, and
- any implications of the step relative to preceding or succeeding steps.

An example Data Sheet is given in Figure A-2. The Data Sheets provide the necessary "data base" on each step in order to present the user of the flow model with a clear picture of what the step involves and how it relates to other steps in the process. The Data Sheets are not essential to getting benefits from the flow model. The sequencing of steps and decisions can provide very powerful information on the effectiveness of the process. However, there are often subtleties in processes which may not be clear until critical relationships among steps are fully identified. The Data Sheets provide a record of each step that captures the necessary detail to allow a fuller utilization of the flow model technique.

Use of the Flow Models in Reviews

The principal benefit of the flow model is to make complex processes easier to understand. Environmental data operations associated with major Agency programs, such as the Superfund Remedial Investigation/Feasibility Study (RI/FS), involve many complicated and diverse steps that produce and use environmental data throughout the process. Frequently, such operations have many users (or clients) of the data generated, and satisfying the data needs of such a large array of clients becomes increasingly difficult. The process flow model provides a framework in which the data needs for each step in the process may be identified and their sequence examined. This information is very helpful to the planners of the data operations in assuring that data needs are met within the available resources. In addition, a flow model of a complex process can be an effective training tool in helping newcomers to understand all of the important activities and the order in which they should occur.

Perhaps the greatest value of the flow model is the opportunity it allows for optimizing the process. By ordering the steps in their proper sequence in a flow model, it is possible to visualize the interrelationships among various steps, which otherwise may not be obvious. For example, one may find that a particular step produces data that are not used until much later in the process. Such a finding could allow the step using the data to occur earlier and possibly save time and resources. Similarly, it may be possible to identify more effective sequencing of the steps, which again could yield time and cost savings or provide significant technical improvements to the process.

Case Study: The SUPERFUND RI/FS MSR

The value of process flow models to Management Systems Reviews (MSRs) can be shown best through example. The Office of Emergency and Remedial Response (OERR) invited the Quality Assurance Management Staff (QAMS) to perform a review of the Superfund Remedial Investigation/Feasibility Study (RI/FS) program in order to provide an independent assessment of this important process. The collection and analysis of environmental data are the most significant cost and time components of the RI/FS. These data are also key to the efficacy and reliability of important RI/FS decisions, such as determining if an unacceptable risk is posed by a site and selecting an appropriate remedy.

As part of its ongoing efforts to reduce costs and improve the effectiveness of Superfund activities, OERR requested that QAMS conduct a comprehensive review of the RI/FS process, focusing on the role of environmental data. The review had the following objectives:

- identify the RI/FS decisions that rely on environmental data;
- determine how data needs are defined and how their collection is planned and executed; and
- examine the impacts of the planning, collection, and use of RI data on the scheduling and quality of RI/FS outputs, including remedy selection.

The review was conducted by QAMS with the assistance of the OERR Hazardous Site Control Division and the Office of Program Management, and included participation by Regional QA Managers. From the outset of the MSR, the process flow model was an integral element of the study. During the planning of the MSR, documents such as QA program plans and RI/FS guidance provided a general blueprint of the data collection and QA operations, and gave a picture of how the RI/FS is supposed to operate. This information was used to define the first-order process flow model of the major RI/FS activities, and to assemble these activities or steps into logical groups for data gathering and analysis. The flow model became a template for obtaining and organizing information during subsequent interviews with Regional personnel.

Data gathering for the MSR involved interviews of more than 25 Remedial Project Managers (RPMs) and their management in three Regions. The interviews traced the logic and decision flow of the RI/FS, with emphasis on:

- the types of environmental data collected and how data needs were determined;

- the participants in RI/FS scoping and their roles;
- the way in which remedial alternatives were identified, evaluated, and selected;
- how the RPM decides that sufficient RI data have been collected; and
- factors that facilitated or impeded timely, effective remedial investigations.

Just as the review of Superfund planning documents and guidance helped to formulate a framework for the flow model and to describe how the RI/FS process was supposed to operate, the interviews showed how the RI/FS was performed in practice. There was significant variability among RI/FSs within a Region and across Regions. However, the planning and site investigation activities were sufficiently similar to identify a typical or representative RI/FS in the process flow model. The outcome was then used as a basis for analyzing the process.

In order to validate the process captured in the flow model and to add to the understanding of how environmental data were being used, case studies were obtained for eight sites. These sites were identified by the Regions as fairly typical sites and had Records of Decision (RODs) completed in 1987 or 1988 to ensure that they reflected recent procedures. The case study documentation generally included, for each site: the work plan, sampling and analysis plan, quality assurance project plan, Remedial Investigation (RI) report, Feasibility Study (FS) report, and ROD. This information was critical to understanding what data were typically collected and how the data were used in making site-related decisions, and was very helpful in validating the process flow model of the RI/FS.

When the data from the interviews and case studies had been integrated into the process flow model, the model and the data were analyzed with respect to the study objectives. It was found that many of the steps in the RI/FS process depend to some degree on environmental data. The flow model simplified the identification of the major decisions that rely on data. These are:

- assessment of risk and determining if the no-action alternative is appropriate for the site;
- identification and screening of remedial process options; and
- screening, evaluation, and selection of remedial alternatives.

Having confirmed the specific and critical role of environmental data in the RI/FS (the first objective of the MSR), the flow diagram was used to document the process typically used by the Regions for defining data needs. Next, the process used for planning and executing field sampling activities (the second MSR objective) was identified and

documented in the flow model.

Further analysis indicated several opportunities for process changes related to the third objective of the MSR; i.e., how the collection and use of environmental data impacts the scheduling and quality of RI/FS outputs. These included:

1) knowing when to stop sampling;

2) reducing the number of unplanned sampling episodes;

3) reducing false starts and rework through structured planning;

4) beginning feasibility study planning during scoping;

5) reducing the number of alternatives considered and evaluated during the feasibility study; and

6) conducting treatability studies during remedial investigation field work.

While some of the improvements were already known to management, the process flow model demonstrated the feasibility of additional changes. These changes show significant promise for improving the effectiveness of the RI/FS process.

STEP PP-4

INPUT: PP-1, PP-2 OUTPUT: Determination that removal action is needed or not

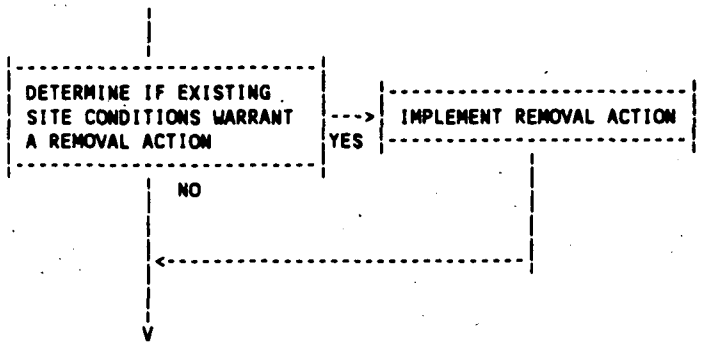
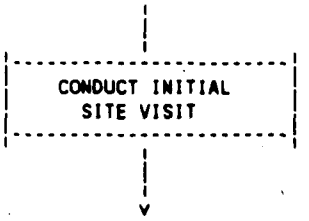


Figure 1. Sample Step from RI/FS Process Flow Model

STEP PP-2

INPUT: PA/SI Results OUTPUT: Assessment of current surface conditions and potential receptors.



PURPOSE: To obtain first-hand observations of current site conditions.

GOAL/OBJECTIVE: Acquire current information about the site through visual inspection and/or limited field measurements.

ACTIVITY PERFORMED/DATA USE:

Historical data are used to guide the visual inspection of the site, which may include observations on the presence and appearance of surface water, and obvious evidence of impacts from contamination such as stressed vegetation and soil discoloration. Very limited sampling with portable equipment may be conducted.

CRITERIA/ISSUES:

Information that may be collected include:

- Have site surface conditions changed from the historical data? What are the implications of the change?
- Visual evidence of contamination.
- Apparent stability of site (e.g., weakened beams, leaking tanks).
- Proximity of population or sensitive ecosystems to the site.

IMPLICATIONS:

- Visual inspection may identify areas of concern which may require removal action or short-term mitigation.
- Provides the RPM with a subjective view of the site which helps to define the magnitude of the effort required for the RI/FS (i.e., where to sample, what site preparations are needed, etc.).

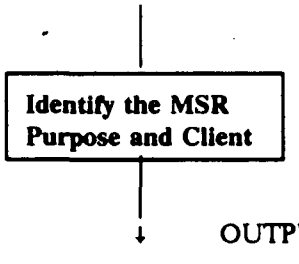
Figure 2. Sample Process Flow Model Data Sheet

APPENDIX B

FLOW MODEL OF MSR PROCESS

STEP P-1

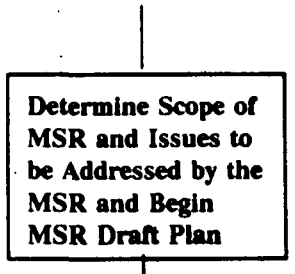
INPUT: Request/Need for MSR



OUTPUT: **Understanding of who is the Client for the MSR and why it is needed.**

STEP P-2

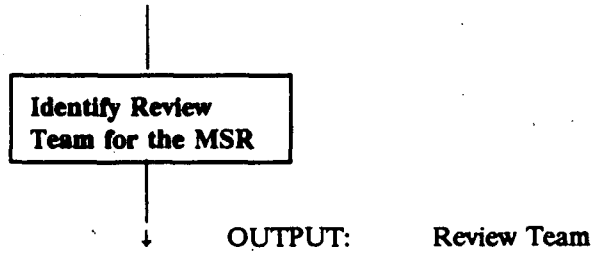
INPUT: Purpose of the MSR



OUTPUT: **Definition of Scope of the Study, including Technical Program to be Reviewed**

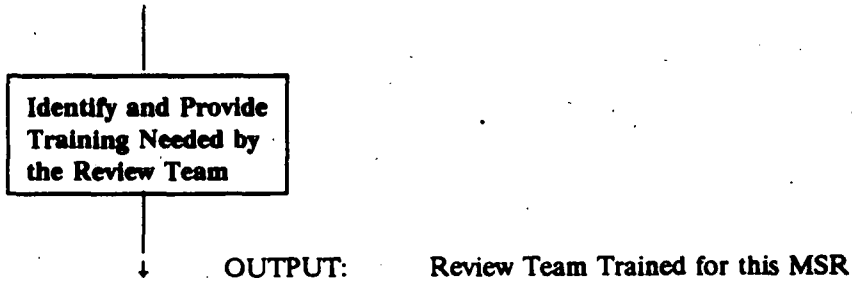
STEP P-3

INPUT: MSR Scope; Technical Program to be Reviewed



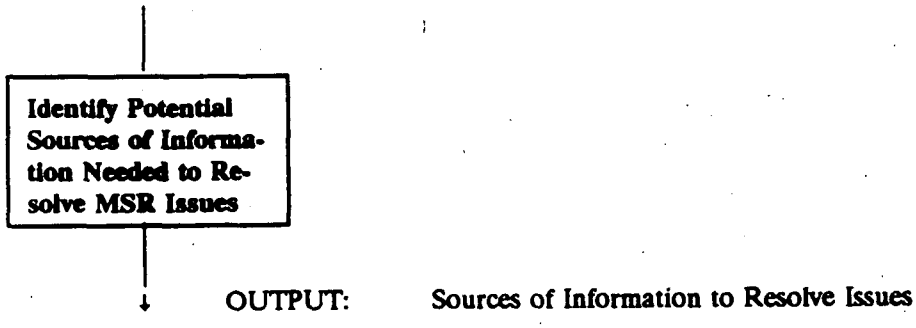
STEP P-4

INPUT: Review Team; Scope of MSR



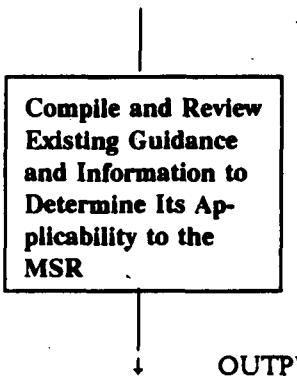
STEP P-5

INPUT: MSR Scope and Issues



STEP P-6

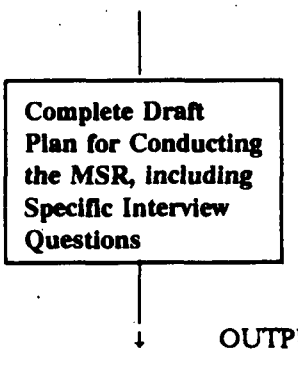
INPUT: Sources of Information Relevant to the MSR Subject



OUTPUT: Information Relevant to Study

STEP P-7

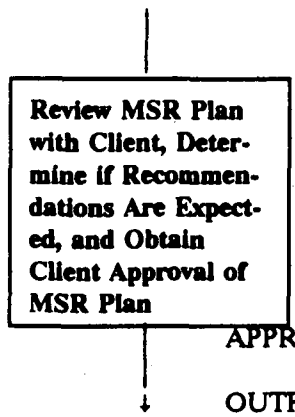
INPUT: Relevant Existing Information; Scope of MSR



OUTPUT: Draft MSR Plan

STEP P-8

INPUT: Draft MSR Plan

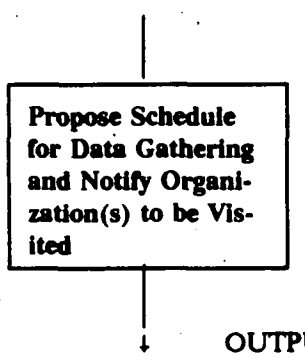


OUTPUT: Client-Approved MSR Plan

(IF NOT APPROVED, REPEAT STEPS P-7 AND P-8 AS NEEDED TO ASSURE CUSTOMER UNDERSTANDING AND APPROVAL.)

STEP P-9

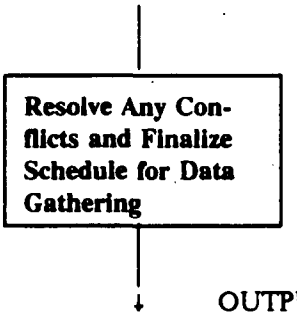
INPUT: Approved MSR Plan



OUTPUT: Schedule for Data Gathering

STEP P-10

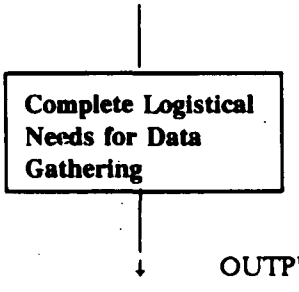
INPUT: MSR Plan and Schedule



OUTPUT: Final Schedule for MSR

STEP P-11

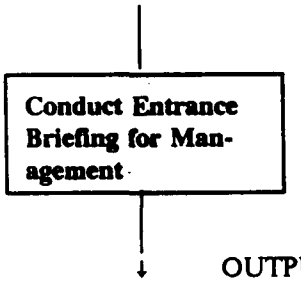
INPUT: MSR Plan and Final Schedule



OUTPUT: Completed Arrangements for Site Visits and Data Gathering

STEP C-1

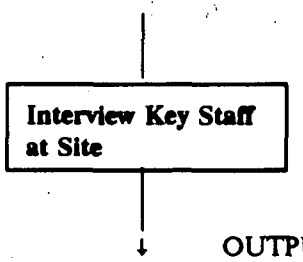
INPUT: MSR Plan



OUTPUT: Understanding of Scope of MSR by Management at Site.

STEP C-2

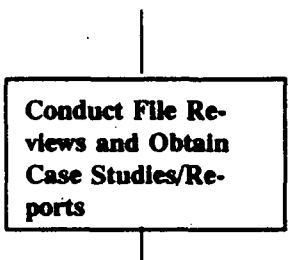
INPUT: MSR Plan



OUTPUT: Notes from Interviews

STEP C-3

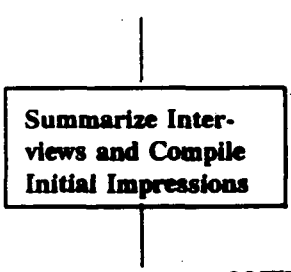
INPUT: MSR Plan; Interview Notes



OUTPUT: Relevant File Information, Case Studies, and Other Documentation

STEP C-4

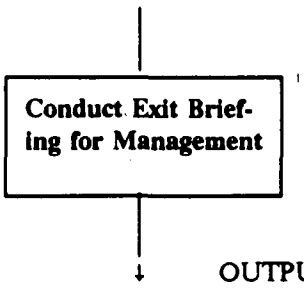
INPUT: Interview Notes and Other Information Collected; MSR Plan



OUTPUT: Initial Impressions of MSR Findings for the Site

STEP C-5

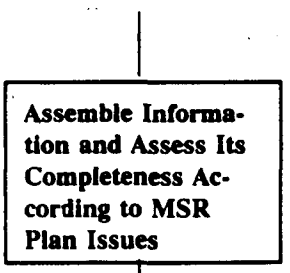
INPUT: Initial Impressions of MSR Findings for the Site; MSR Plan



OUTPUT: Completion of Data Gathering Phase

STEP E-1

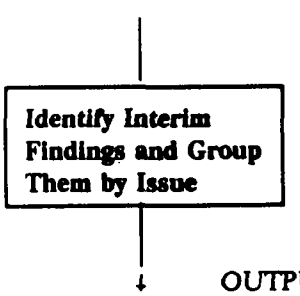
INPUT: Results from Interviews and Documentation Collected



OUTPUT: Results of Evaluation by Issue

STEP E-2

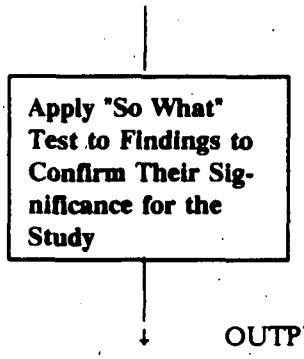
INPUT: Results of Evaluation by Issue



OUTPUT: Interim MSR Findings

STEP E-3

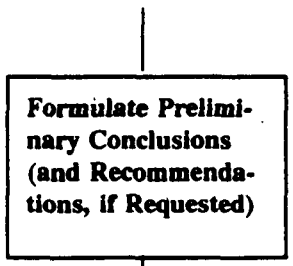
INPUT: Interim MSR Findings



OUTPUT: Identification of Relevant Findings

STEP E-4

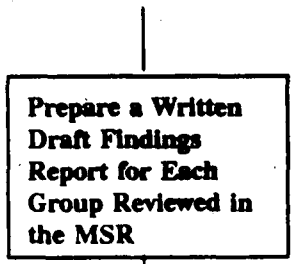
INPUT: Relevant MSR Findings



OUTPUT: Preliminary Conclusions (and Recommendations, if requested)

STEP R-1

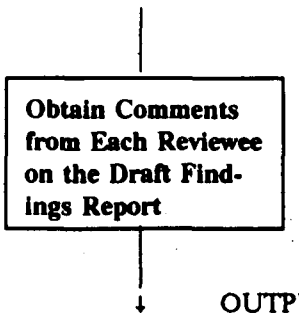
INPUT: Results of MSR; Preliminary Findings and Conclusions



OUTPUT: Draft MSR Findings Report

STEP R-2

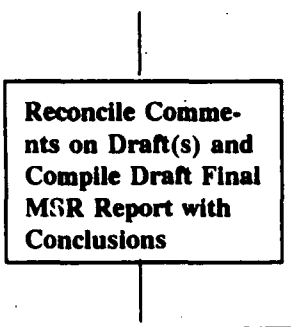
INPUT: Draft MSR Findings Report



OUTPUT: Reviewee Comments on Draft Findings Report

STEP R-3

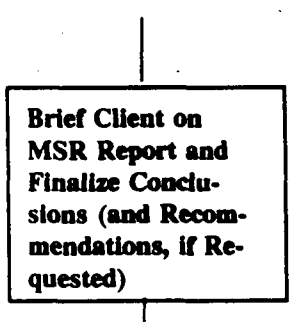
INPUT: Reviewee Comments; Draft Findings Report



OUTPUT: Draft MSR Report Containing Final Findings and Conclusions (and Recommendations, if Requested)

STEP R-4

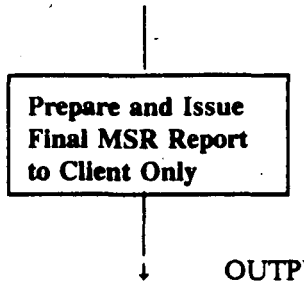
INPUT: Draft Final MSR Report



OUTPUT: Client Acceptance of Report,including Final Conclusions (and Recommendations, if Requested)

STEP R-5

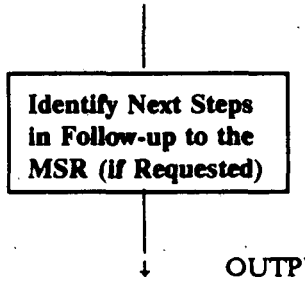
INPUT: Draft Final MSR Report; Final Conclusions (and Recommendations, if Requested)



OUTPUT: Final MSR Report

STEP R-6 (OPTIONAL)

INPUT: Final MSR Report; Client Request for Additional Assistance



OUTPUT: Identification of Next Steps (as required)

END OF MSR PROCESS