DISCLAIMER

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

DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.

27
3-3-82 24 DNTS
JWB
SANDIA REPORT

Printed December 1981

① I-1729
SAND81-0642 • Unlimited Release • UC-41

Guidance for Implementing an Environmental, Safety and Health Assurance Program

MASTER

Volume 11. Model Guidelines for Line Organization Environmental, Safety and Health Review Activities

Andrew C. Ellingson, Charles A. Trauth, Jr.

Prepared by
Sandia National Laboratories
Albuquerque, New Mexico 87185 and Livermore, California 94550
for the United States Department of Energy
under Contract DE-AC04-76DP00789

Issued by Sandia National Laboratories, operated for the United States Department of Energy by Sandia Corporation.

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

Printed in the United States of America
Available from
National Technical Information Service
U.S. Department of Commerce
5285 Port Royal Road
Springfield, VA 22161

NTIS price codes
Printed copy: \$6.00
Microfiche copy: A01

PAGES 1 to 2
WERE INTENTIONALLY
LEFT BLANK

SAND81-0642
Unlimited Distribution
Printed January 1982

UC-41

SAND--81-0642 Vol. 11

DE82 011683

GUIDANCE FOR IMPLEMENTING
AN ENVIRONMENTAL, SAFETY AND HEALTH
ASSURANCE PROGRAM

Volume 11. Model Guidelines for Line Organization
Environmental, Safety and Health
Review Activities

Andrew C. Ellingson
Charles A. Trauth, Jr.
Special Projects Division, 1418

ABSTRACT

This is 1 of 15 documents designed to illustrate how an Environmental, Safety and Health (ES&H) Assurance Program may be implemented. The generic definition of ES&H Assurance Programs is given in a companion document entitled "An Environmental, Safety and Health Assurance Program Standard." This document is concerned with the performance of reviews--a technique useful for both control and assurance aspects of ES&H Assurance Programs. Emphasis is given to reviews conducted at the operational level of an institution.

DISCLAIMER

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

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

Acknowledgments

This work was sponsored by the Department of Energy (DOE), and among those many persons at the DOE who have been supportive and helpful, we would like to especially thank Messrs. Hal Hollister, John O'Connor, Mike Dix (now retired), and Ruben Pritchard for their support, encouragement, and patience. In addition, Ms. Karen Marston of Tech. Reps., Inc. and Mrs. Margaret Carroll and Mr. L. M. Jercinovic of Sandia National Laboratories are owed many thanks for their valuable technical inputs, discussion, and reviews.

CONTENTS

	<u>Page</u>
Introduction	7
Background	11
Management Obligations in ES&H Areas	11
Criteria for Meeting Management Obligations	11
The Role of Working Level Line Organization Review Activities in Satisfying These Criteria	14
Guidance for the Review of Working Level Line Organization ES&H Plans and Documentation	15
An Overview	15
Working Level Line Organization Control Reviews	16
Working Level Line Organization Assurance Reviews	18
Review Criteria	19
Conducting Reviews	21
Reporting Reviews	22
Discussion	23
Notes and References	25
Appendix A -- Sample Review Criteria for Working Level Line Organization ES&H Plans	29
Appendix B -- Some Very Generic Design Review Criteria	35

ILLUSTRATIONS

Figure

1	Institutional Structure and Generic Functions in ES&H Assurance Programs	8
2	ES&H Assurance Program Documentation	9
3	Human and Environmental Categories of Concern in ES&H Assurance Programs	12

MODEL GUIDELINES FOR LINE ORGANIZATION
ENVIRONMENTAL, SAFETY AND HEALTH REVIEW ACTIVITIES

Introduction

This is 1 of a set of 15 guidance documents designed to illustrate how an Environmental, Safety and Health (ES&H) Assurance Program may be implemented. The generic definition of ES&H Assurance Programs is given in a companion document entitled "An Environmental, Safety and Health Assurance Program Standard,"¹ often referred to as simply the Standard or the Program Standard. As suggested by the title, the Program Standard defines the functions and some of the structure needed within an institution for it to possess an "ES&H Assurance Program." The Standard is, on the other hand, relatively generic, flexible, and nonprescriptive--focusing on the general framework of ES&H Assurance Programs and on *what functions must be performed*, not on *how* these may be accomplished. This was done intentionally in order to provide maximum flexibility in implementation.

The ES&H Assurance Program Standard requires that an institution possess an independent "ES&H Staff." The remainder of the institution is considered "Line" and "Management" as suggested in Figure 1.* Generic functions of these three organizational components, as required by the Standard, are delineated in Figure 1. The Program Standard is more explicit about the nature of these functions. Specifically, Line organization *plans* are required--and these must reflect the *guidance* from the ES&H Staff, which itself must prescribe activities consistent with the Standard. In addition, the total program, planned by the ES&H Staff and approved by management, must be well

* Management in this context refers to *upper* (or institutional) management, with the Line organization presumed to have its own managerial hierarchy--designated Line management.

Figure 1: Institutional Structure and Generic Functions in ES&H Assurance Programs

defined. Thus, as illustrated in Figure 2, certain documentation must exist within the ES&H Assurance Program.

The intent of this series of guidelines is to provide an *illustration of this documentation*. No suggestion is intended that the program definition given in these guidelines provides a unique or even the most cost-effective means of performing the functions required by the Program Standard. Certainly, it is not intended that they are mandatory requirements stemming from the Program Standard.

We feel, however, an obligation to present one relatively specific program definition that effectively and (we believe) efficiently meets the requirements of the generic Program Standard in order to

Figure 2. ES&H Assurance Program Documentation

- Demonstrate the feasibility of the Standard,
- Provide a specific, well-defined program that can be tested for cost-effectivity, and
- Aid others in structuring programs that are consistent with the Standard.

It was precisely with this in mind that this set of guidance documents was prepared. The set, generically entitled "Guidance for Implementing an Environmental, Safety and Health Assurance Program," consists of the following documents (see also References):

I. Institutional Models and ES&H Staff Program Documents

- Volume 1 A Model Plan for Institutional Environmental, Safety and Health Assurance Programs²
- Volume 2 A Model Plan for Environmental, Safety and Health Staff Audits and Appraisals³
- Volume 3 A Model Plan for Environmental, Safety and Health Staff Review Activities⁴

- Volume 4 A Model Plan for Institutional Emergency Response Programs⁵
- Volume 5 A Model Plan for Institutional Accident Investigations⁶
- Volume 6 Model Documentation for an Environmental, Safety and Health Assurance Information System⁷
- Volume 7 A Model Plan for Institutional Environmental, Safety and Health Assurance Training Programs⁸

II. Model ES&H Staff Guidance Documents

- Volume 8 Model Guidelines for Line Organization Environmental, Safety and Health Committee Operations⁹
- Volume 9 Model Guidelines for Environmental, Safety and Health Analysis Activities¹⁰
- Volume 10 Model Guidelines for Line Organization Environmental, Safety and Health Audits and Appraisals¹¹
- Volume 11 Model Guidelines for Line Organization Environmental, Safety and Health Review Activities¹²
- Volume 12 Model Guidelines for Line Organization Environmental, Safety and Health Inspection and Monitoring Activities¹³
- Volume 13 Model Guidelines for Line Organization Environmental, Safety and Health Meetings¹⁴
- Volume 14 Model Guidelines for Utilizing Quality Assurance Support in Environmental, Safety and Health Assurance Programs¹⁵

III. Model Line ES&H Plans Which Reflect the Above Model Policies and Plans

- Volume 15 A Model Plan for Line Organization Environmental, Safety and Health Assurance Programs¹⁶

Background

Management Obligations in ES&H Areas

Because many hazards associated with today's operations or with new products themselves have the *potential* for impacting large numbers of people--and because many of those *at risk* cannot exercise direct control over that risk--*management* in today's environment *has an obligation to exercise controls that lead to an acceptable perceived level of risk by those at risk.*^{17,18} This may seem a debatable moral statement, but in many cases it has the force of law. In fact,

- When expending federal funds on programs that could have a public or environmental impact, the National Environmental Policy Act¹⁹ and subsequent regulation mandate elaborate procedures for public input designed to ascertain public acceptability.
- Portions of the Occupational Safety and Health Act²⁰ are designed to ascertain acceptability to employees.
- Most ES&H laws and regulations are designed to *express* societally acceptable levels of control and/or permit public input with the same end result.

Among other things, this basic management obligation requires that *management decisions consider*, to an appropriate extent, *ES&H objectives of employees and the public* on a routine and thorough basis. And, in addition, it becomes a management obligation to keep those at risk informed in a credible fashion about protection efforts being undertaken on their behalf.

The ES&H Assurance Program Standard was designed to assist in meeting these obligations of today's management. How it does this is described in more detail in References 17 and 18.

Criteria for Meeting Management Obligations

ES&H programs based on the ES&H Assurance Program Standard are intended to satisfy six basic generic criteria for "success" in ES&H programs. By design, the *intent* of these six basic criteria is to provide a *measure* of program performance that does not rely solely on accidents or incidents, so that one's *positive steps* to provide protection to humans and their environment can be used, in part, to describe one's *success*. These six criteria may be described briefly as follows. (More detail can be found in References 10, 17, and 18.)

I. Identify all significant hazards, specifically or by class.

"Hazards" are defined as *things* which have the *potential* for causing injury to or illness in humans or damage to the environment. The environmental and human categories in which possible impact is of concern are shown in Figure 3. These are discussed in detail in Reference 10. *Unusual* hazards are defined as those hazards not routinely encountered and accepted by the general public, while *routine* hazards are all others, that is, those that *are* routinely encountered and accepted by the general public. Either type of hazard may be *significant*.

Figure 3. Human and Environmental Categories of Concern in ES&H Assurance Programs

II. Define acceptable controls over the significant hazards.

Acceptable controls are developed through an assessment or analysis process (see Reference 10, Volume 9 in this series) which examines the ways (*events*) through which the potential *consequences* (that is, possible types and scope of injury, illness, or damage) of hazards may actually be incurred. Possible controls over the *factors* that affect how these events occur are then identified, and a collection of controls which appears to be cost-effective and acceptable to

persons who might be harmed, or whose environment might be damaged, is then selected.

III. Routinely use the controls as they have been defined.

One of the major contributory factors in accidents or incidents involving significant hazards is the failure to *use* defined controls. "Use," here, is intended to imply implementation, use, and/or maintenance. This is discussed in Reference 21. In order to verify control use, an adequate definition of each control is needed.

IV. Accommodate changing circumstances.

In a way, this is intended to imply only that activities for meeting Criteria I, II, and III are routinely and systematically reviewed and updated, as required. The possibility always exists that new hazards will be introduced into an operation or that factors affecting the nature or scope of, or the likelihood of incurring, consequences from existing hazards will be modified. When such changes do occur, their effect upon the adequacy and reliability of controls must be analyzed and appropriate adjustments made, when necessary.

V. Define an emergency response program consistent with existing hazards and routinely verify its reliability.

There is, of course, no zero risk. In the above framework, acceptable controls carry with them a connotation of *acceptable risk*. One must therefore assume that accidents or incidents will occur--and prepare accordingly. The ES&H Assurance Program Standard requires an emergency response program based on the understanding of the potential consequences that may arise from a hazard and the events (or sequences of events) that may lead to their realization that is gained in the performance of activities which satisfy Criterion II, above.

VI. Provide reliable independent evidence that Criteria I through V are satisfied.

This is the *assurance function* implied in the title of the ES&H Assurance Program Standard. Assurance is accomplished through independent reviews and audits which are efficiently based on information provided by those responsible for an operation or a product.

The primary intent of ES&H Assurance Programs is to provide independent credible *evidence* that Criteria I through V are properly

satisfied. These first five criteria are designed to provide a *systematic* means for the *management of hazards* and may be thought of as defining the objectives of a *control subprogram* of the total ES&H Assurance Program, including both *direct controls* over hazards and *indirect administrative controls*. The latter are designed to provide a management system in which the direct controls are *defined*, and are *routinely used*, and which generates *verifiable evidence* that this is the case.

Assurance is then provided by an overlay subprogram which *verifies* the *adequacy* and *use* of the controls using the verifiable evidence just described. Specifically, *adequacy* is typically verified through document *reviews* (of plans, procedures, etc.), while the *use* of the controls is verified through *audits* and *monitoring actions*. Independent reviews by the institutional ES&H Staff form the basis for credibly reporting on the positive efforts made to protect humans and their environment. In addition, data maintained by the ES&H Staff form a hypothesis about institutional performance that may be efficiently verified by statistical sampling methods by external agencies, as appropriate. The efficiency of performance verification sampling by both the ES&H Staff and external agencies is discussed in Reference 22.

The Role of Working Level Line Organization Review Activities in Satisfying These Criteria

A review, as the term is used in ES&H Assurance Programs, is a formal, objective examination of any document designed either to judge its adequacy or to influence, or gain information about, the degree to which defined programs are actually implemented. Such document examinations are used in the implementation of both the control and assurance subprograms noted above. When used in the control subprogram, they are aimed at adequately defining, performing, or enforcing adequate performance of an operation or part of an operation and are therefore classified as controls. When used in the assurance subprogram, they provide independent evidence of program *adequacy* and are used to gather information during audits that verify program *use*.

Control reviews contribute to satisfying the first five criteria of the previous section, while assurance reviews at the working level of a Line organization are designed to generate part of the evidence needed to satisfy Criterion VI.

Guidance for the Review of Working Level Line Organization ES&H Plans and Documentation

An Overview

At the working level of Line organization, there are basically five types of review efforts that should be undertaken. These may be characterized as

Control Reviews

- Formal examination of ES&H plans, and the documents referenced therein for which the organization is responsible, to verify their adequacy from the perspective of management.
- Formal examination of selected documents, including
 - designs,
 - schedules,
 - budgets, and
 - purchase requisitions,to verify that these adequately address ES&H issues from the perspective of management.
- Informal examination of all ES&H-related documents that are relevant to one's work, and/or areas of responsibility, by all personnel in the organization to promote or enforce performance consistent with that required in ES&H plans and references therein.

Assurance Reviews

- Formal examination of ES&H plans and attendant documents by a pseudoindependent group or individual to provide evidence of plan use in conjunction with internal audits.¹¹ In the model presented in this series of guidance documents (References 2 through 16), this review responsibility is assigned to an ES&H Committee⁹ composed of working level Line organization personnel.
- Formal examination of selected documents (as above) to provide an independent view of their adequacy.

Each of these is discussed in the following sections.

In addition to the five types above, assurance reviews of ES&H plans and referenced documents for whose contents the working level Line organization is directly responsible may be undertaken by pseudoindependent persons to verify *adequacy*, at the discretion of

management. In general, this type of activity would not be necessary since control reviews with the same abstract intent are performed by or for management, and these are followed by assurance reviews of the same type performed by ES&H Staff personnel⁴ to verify management performance.

Working Level Line Organization Control Reviews

By or For Management -- The control reviews for which management is responsible within the working level Line organization are of two types: (1) examinations of the organization's ES&H plan, and referenced documents for which the organization is responsible, for adequacy (before approval and before assurance efforts by the ES&H Staff⁴) and (2) examination of selected documentation for adequacy (conducted as a part of proper ES&H performance of an operation).

The examination of ES&H plans and subsidiary documentation may be conducted by or for management, but management is responsible for approving plans and proposals based on the results of the review. When the working level Line organization management elects to obtain the assistance of a special team in the review of the organization's plan and subsidiary documentation, a formal team should be appointed and the position of team Chairman assigned. The team should consist primarily of individuals from within the organization, but the assistance of specialists (for example, from the ES&H Staff, human factors, quality, or reliability organizations) should be obtained whenever appropriate. The team should prepare a report of its efforts and findings, and this report, together with associated notes, calculations, and so forth, should be filed and maintained in the organization's ES&H records as evidence that the plan has been formally examined. Management's signature approval of the plan is also part of the review evidence, and, if management does not elect to use assistance, the signature may be a major part of the evidence that the plan has been formally examined.

Formal reviews of ES&H plans and attendant documents (such as procedures) for which the organization is directly responsible should be undertaken at least annually to support the annual assurance efforts of the ES&H Staff that are described in Reference 4. They should be based on precise criteria, as discussed below.

The examination of selected documentation that itself is not a part of ES&H plans, but that nevertheless has significant ES&H implications, is also a responsibility of working level Line organization management. This refers to the review of the ES&H adequacy of such things as

- Budgets,
- Schedules,
- Designs, and
- Purchase requisitions.

The formal examination of budgets and schedules may be appropriately performed by first-line supervision. However, in such cases as design reviews of equipment or products involving significant hazards,¹⁰ the assistance of specialists may need to be obtained, and management may elect to appoint a formal team, if appropriate. Since these reviews are intended as a routine part of the proper ES&H performance of an operation and indeed should be specified in the ES&H plan of the organization,¹⁶ approval for proceeding with an activity (or making a significant change in an activity) should be dependent upon satisfactory results from them. While documentation reviews are often less formal than plan reviews, evidence must always exist that they were performed, if only in the form of signature approvals. The level and formality of the effort should correlate with the seriousness of the hazards involved, in keeping with the specifications of the Program Standard.¹

Formal documentation reviews should be undertaken as appropriate documents become available and before approval to proceed is given. Criteria should be used, and their nature should be a function of the possible ES&H significance^{6,10} involved in the document being examined. This is discussed below.

By All Personnel -- All persons at the working level of Line organization must be knowledgeable about those portions of ES&H plans and referenced documents (including, now, institutional program documents) that are relevant to their work responsibilities. Performance, or the enforcement of performance, in accordance with ES&H plans cannot realistically occur without a familiarity with the plans. As discussed in References 10 and 14, for example, reasons for failure to use ES&H control procedures include

- Lack of familiarity with them and
- Lack of understanding of them.

A similar observation would apply to the failure to enforce the use of procedures.

Both these failure modes can be addressed, in part, by plan and document reviews. These may be accomplished individually or as a part of ES&H meetings¹⁴ or training sessions.⁸ For most organizations, some combination of all three approaches is probably preferable. How informal reviews are to be accomplished, on what time scales, and with what evidence of performance should be specified in an organization's ES&H plan (see Reference 16 for an example).

Working Level Line Organization Assurance Reviews

Of Plans and Referenced Documents -- The ES&H Program Standard specifies that assurance activities within a working level Line organization are to be performed by a group or individual having sufficient independence to evaluate the effectiveness of the ES&H controls used in the organization. In this series of guidance documents (References 2 through 16), it is assumed that an ES&H Committee reporting to working level Line organization management performs this function. As part of its assurance function, the Committee performs audits^{11,14} of the organization's program, and reviews are used as a means of gathering information in these audits (see Reference 11 for details). These assurance-type reviews include examination of the organization's ES&H plan itself (as a part of verifying that the plan is being followed) and examination of selected documentation (to verify that the ES&H controls are used and, at management's discretion, to verify control adequacy).

Assurance reviews that are performed in conjunction with audits should be scheduled in accordance with required audit schedules (see Reference 11). The model program discussed in References 2 through 16 assumes that the ES&H Committee that performs assurance functions at the working level of Line organization is properly trained. Such a committee is not a requirement of the ES&H Assurance Program Standard.¹ If other means of performing assurance functions are elected, those performing them should be trained in review and audit procedures and should be reasonably independent of the ES&H control processes of the organization.

Assurance reviews that are undertaken as a part of audit efforts should have an informal character since their purpose is primarily to familiarize auditors with the contents of plans and referenced documents in order that the degree to which they are implemented, or support plan implementation, can be measured. No criteria are involved, but audit criteria will influence the information needed from the review process (see audit criteria and plans in Reference 11 for examples). This guidance also applies to audits of the working level Line organization performed by or for the ES&H Staff (Reference 3). If an institutional committee is used, as in this model (the ES&H Assurance Committee, or ES&HAC^{2,3,4}), members should be trained in review procedures and should undertake similar document examination efforts in conjunction with their audit activities.

When management requests that assurance reviews be performed to determine the adequacy of plans and attendant documents, the same criteria involved in control reviews should be used. This same statement applies to ES&H Staff efforts, as discussed in Reference 4.

Of Selected Documentation -- The examination of such documents as budgets, schedules, designs, and purchase requisitions should be performed by a pseudoindependent group or individual on a statistical sampling basis. The object is to verify that adequate control reviews are being performed. Depending upon circumstances, these reviews may require expert assistance from outside the organization, and, in this case, the help should be provided by the ES&H Staff.* No more than five such samples should be taken in any given year with, at most, one verification of design adequacy involved.

Review Criteria

Criteria are essential for the control reviews performed over ES&H plans, attendant documentation, and other planning documents. These should be developed by management based on institutional requirements and be provided to the reviewers in order that the ES&H program may be evaluated both objectively and uniformly. The criteria should allow different reviewers to obtain essentially similar results. Normally, the ES&H Staff would be expected to provide generic criteria for the

* Such assistance supports the requirement in Reference 4 that the ES&H Staff selectively verify the adequacy of such documentation at the institutional level.

examination of ES&H plans to promote uniformity throughout an institution. This has been done in the model described here and in Reference 4. One basic criterion that applies to all plans or documents being examined is that they must be in a form that can be understood. This means that they must be

- Clearly identified,
- Legible,
- Written in clear language (acronyms defined, for instance), and
- Complete.

Appendix A presents an example set of criteria for the review of working level Line organization ES&H program plans. These are generalized criteria, derived from the Program Standard, and should be evaluated and modified as necessary before use in a particular application. Even specific criteria developed within a given organization should be similarly evaluated before each application--not only to ensure that the criteria are appropriate for that application, but also to aid in familiarizing the reviewers with the criteria.

To illustrate how a criterion from Appendix A might be adapted for a particular working level Line organization, consider the criterion, *there should be a listing of all significant hazards*. If the organization includes only office areas, with no significant hazards, the criterion might be changed (for that organization) to read, *there should be a statement that no significant hazards exist*.

Both control and assurance reviews of ES&H program plans (including referenced documents) undertaken to judge their adequacy should use the same generic criteria, such as those in Appendix A. There may be some differences in the specifics of the criteria (particularly if the control and assurance activities are performed at different times), but the same generalized criteria should apply to both cases. Thus, in particular, as described in Reference 4, the ES&H Staff and Line organization should derive criteria from the same generic institutional list.

Appendix B presents similarly generalized criteria for the examination of design documentation as an example of the criteria that might be developed for documentation reviews (again, whether performed for control or for assurance purposes). The use of such generalized criteria promotes uniformity and also provides for more focused, efficient

reviews when modified for specific application. In some cases, as in the example in Appendix B, the generalized criteria may include built-in modifications (e.g., "ES&H analysis is included, or its exclusion is justified").

For the examination of less complex types of documentation, one may require less complex criteria, and indeed these may be *ad hoc* criteria developed only for a particular application. However, criteria should always be specified and evaluated prior to each review, whatever the format or the complexity.

Conducting Reviews

Some administrative details should be taken care of in preparation for a formal review undertaken to judge adequacy, particularly when a program plan or a large-scale design is involved. These details include scheduling, checking availability of documents and personnel, and arranging for facilities (if appropriate). For the examination of documentation, these administrative items may be extremely simple. In all cases, the reviewers must become familiar with the criteria that will be used.

As previously noted, those responsible for, or performing, the review should request assistance from specialists whenever special disciplines are involved. These specialists may include those from some of the following fields (or others):

- Safety and health disciplines,
- Environmental sciences,
- Law,
- Public policy,
- Quality assurance,
- Fire protection engineering,
- Human factors, and
- Reliability.

The performance of the review consists of evaluating the plan or documentation on the basis of all the criteria. Much of this evaluation will require only a reading of the plan or the documentation, but other activities may be required. Direct observation of operational areas may be needed, for example, when checking the adequacy of hazard identification in a program plan. In other cases, it may be necessary to perform alternate calculations of some sort to verify the adequacy of analyses or of designs.

Plan Reviews -- Illustrations of how the adequacy of a plan might be checked during a review are given in Reference 4.

Documentation Reviews -- Design reviews may be used as an example for addressing two of the considerations that may be involved in examining documentation for ES&H adequacy. First, reviews may be performed both for providing or verifying adequacy from an ES&H point of view and for providing or verifying adequacy from an efficiency or productivity point of view. Consider, for instance, the criterion from Appendix B that specifies that the design should be adequate for prevention or mitigation of hazard realization using methods such as redundant components. There are cases where redundant components will prevent occurrences that are detrimental to ES&H protection and other cases where the redundant components will not enhance ES&H protection but will improve equipment or product performance. They might, and often do in fact, support both.

This dual purpose of the design reviews may be served either by conducting two evaluations (one for the ES&H program and one for the engineering aspect) or by performing one jointly. The latter is perhaps more common and efficient--with one or two members of the team assigned responsibility for judging the ES&H aspects of the design. Management has the responsibility for ensuring that the ES&H portion of such a review is complete.

The second consideration in documentation reviews is the wide variety of documents under each type and the resulting problems in developing criteria. Design documents, for example, provide the design for anything from a transistor to a power plant. With such a broad range of design documents, the generalized sort of criteria given in Appendix B may be the only effective format at a policy level--with specific criteria developed from these for each different type of review.

Reporting Reviews

Formal reviews performed by teams should be documented in the form of a report. The report should provide information on by whom and how the review was conducted and on the conclusions reached as to the adequacy with which each of the established criteria is met. The report should contain a summary that discusses positive and negative

findings on a prioritized basis, the mode of resolution of negative findings, if any, and a conclusion about the adequacy of the program or document. Such a summary provides working level Line organization management with a concise, expert opinion concerning the program or proposal, facilitating the decision to approve or disapprove an operation; and/or it provides evidence of performance for use by the ES&H Staff in performing its assurance functions.^{3,4}

Discussion

This guideline discusses the types of reviews of working level Line organization documents that should be undertaken in ES&H Assurance Programs. These include

- Formal examination of ES&H plans and attendant documents for which the organization is directly responsible. This is performed by or for management to gauge the adequacy of ES&H program documents from the perspective of organizational management based on well-defined review criteria.
- Formal examination of other documents that may have ES&H implications while not being exclusively related to ES&H functions. These include such things as
 - designs,
 - budgets,
 - schedules, and
 - purchase requisitions.These reviews, based on well-defined criteria, are also performed by or for management and are intended to demonstrate that documents of the above sort adequately address ES&H issues.
- Formal examination of the same types of documents whose intent is to verify management performance. This is performed by those responsible for assurance functions at the working level of Line organization and/or by ES&H Staff personnel on a statistical sampling basis, using the same criteria as those used in the management review process.
- Formal examination of ES&H plans and attendant documents performed by ES&H Staff personnel to verify program adequacy and management performance. This uses essentially the same criteria as the ES&H plan reviews by management, described above.

- Formal examination of program documents as a part of program audits that are designed to verify program use or implementation. This is performed by persons responsible for the working level Line organization's assurance functions and also by or for the ES&H Staff.
- Informal examination of those parts of plans and referenced documentation needed to fulfill work responsibilities. This must be undertaken by all organizational personnel.

For both control and assurance purposes, reviews are the primary activities that question the ES&H *adequacy* of existing or proposed plans, designs, budgets, and so forth. Control reviews should always precede a decision to start, modify, or proceed with an operation, facility, or product. Assurance reviews may be undertaken on a sampling basis, as described in References 3 and 4, and are used to independently judge the ES&H adequacy and use (or implementation) of documented plans, designs, budgets, and so forth.

Reference 4 addresses policy issues related to reviews within an institution and the performance of reviews at institutional and middle-management levels, while this document emphasizes the need for and the development of criteria applicable to the examination of working level Line organization ES&H-related documents. Because of the potentially broad nature of such documents, only fairly generic guidance is given, and, in implementing an ES&H Assurance Program, organizations would need to develop more explicit policies and review criteria that directly apply to their programs.

Notes and References

1. This Standard occurs in several references. The first version was preliminary and was altered as a result of a broad review process. It is found in A. C. Ellingson, C. A. Trauth, Jr., and M. S. Tierney, A Proposed Standard for ES&H Assurance Programs, SAND79-0240 (Albuquerque: Sandia Laboratories, March 1979).

A version, revised as a result of this review, is given in

A. C. Ellingson and C. A. Trauth, Jr., An Environment, Safety and Health Assurance Program Standard, SAND79-1536C (Albuquerque: Sandia Laboratories, October 1979).

and in

A. C. Ellingson and C. A. Trauth, Jr., An Environment, Safety and Health Assurance Program Standard: An Analysis in the Context of DOE ES&H Requirements, SAND79-1536 (Albuquerque: Sandia Laboratories, September 1979).

See also Reference 17, below.

References 2 through 16 are a part of a series generically entitled "Guidance for Implementing an Environmental, Safety and Health Assurance Program." Separate volume titles are as follows.

2. C. A. Trauth, Jr., A. C. Ellingson, and K. Marston, Volume 1. A Model Plan for Institutional Environmental, Safety and Health Assurance Programs, SAND81-0632 (Albuquerque: Sandia National Laboratories, June 1981).
3. A. C. Ellingson, Volume 2. A Model Plan for Environmental, Safety and Health Staff Audits and Appraisals, SAND81-0633 (Albuquerque: Sandia National Laboratories, September 1981).
4. A. C. Ellingson and C. A. Trauth, Jr., Volume 3. A Model Plan for Environmental, Safety and Health Staff Review Activities, SAND81-0634 (Albuquerque: Sandia National Laboratories, January 1982).
5. A. C. Ellingson and E. L. Gunderson, Volume 4. A Model Plan for Institutional Emergency Response Programs, SAND81-0635 (Albuquerque: Sandia National Laboratories, June 1981).
6. C. A. Trauth, Jr. and A. C. Ellingson, Volume 5. A Model Plan for Institutional Accident Investigations, SAND81-0636 (Albuquerque: Sandia National Laboratories, January 1982).
7. "Volume 6. Model Documentation for an Environmental, Safety and Health Assurance Information System," SAND81-0637 (Albuquerque: Sandia National Laboratories, to be published).
8. A. C. Ellingson, C. A. Trauth, Jr., and K. Marston, "Volume 7. A Model Plan for Institutional Environmental, Safety and Health Assurance Training Programs," SAND81-0638 (Albuquerque: Sandia National Laboratories, to be published).
9. A. C. Ellingson, C. A. Trauth, Jr., and L. M. Jercinovic, Volume 8. Model Guidelines for Line Organization Environmental, Safety and Health Committee Operations, SAND81-0639 (Albuquerque: Sandia National Laboratories, June 1981).

Notes and References (Continued)

10. C. A. Trauth, Jr. and K. Marston, Volume 9. Model Guidelines for Environmental, Safety and Health Analysis Activities, SAND81-0640 (Albuquerque: Sandia National Laboratories, June 1981).
11. A. C. Ellingson, Volume 10. Model Guidelines for Line Organization Environmental, Safety and Health Audits and Appraisals, SAND81-0641 (Albuquerque: Sandia National Laboratories, October 1981).
12. A. C. Ellingson and C. A. Trauth, Jr., Volume 11. Model Guidelines for Line Organization Environmental, Safety and Health Review Activities, SAND81-0642 (Albuquerque: Sandia National Laboratories, January 1982).
13. A. C. Ellingson, Volume 12. Model Guidelines for Line Organization Environmental, Safety and Health Inspection and Monitoring Activities, SAND81-0643 (Albuquerque: Sandia National Laboratories, August 1981).
14. A. C. Ellingson, C. A. Trauth, Jr., and L. M. Jercinovic, Volume 13. Model Guidelines for Line Organization Environmental, Safety and Health Meetings, SAND81-0644 (Albuquerque: Sandia National Laboratories, June 1981).
15. A. C. Ellingson, Volume 14. Model Guidelines for Utilizing Quality Assurance Support in ES&H Assurance Programs, SAND81-0645 (Albuquerque: Sandia National Laboratories, August 1981).
16. A. C. Ellingson and C. A. Trauth, Jr., "Volume 15. A Model Plan for Line Organization Environmental, Safety and Health Assurance Programs," SAND81-0646 (Albuquerque: Sandia National Laboratories, to be published).
17. C. A. Trauth, Jr., A. C. Ellingson, H. Hollister, and L. M. Jercinovic, A Program Standard for Assuring That Today's Management Obligations in Environmental, Safety and Health Areas Are Met, SAND81-1359C (Albuquerque: Sandia National Laboratories, June 1981).
18. Two papers are of relevance here. First, C. A. Trauth, Jr. and Jay B. Sorenson, "A New Approach for Assuring Acceptable Levels of Protection from Occupational Safety and Health Hazards," an invited presentation to the Southwest Labor Studies Conference held at the University of New Mexico, 1 May 1981.
The second paper is
Jay B. Sorenson and C. A. Trauth, Jr., "The Political Side of Risk: A New Approach," in the Proceedings of the 1980 Annual Meeting of the American Political Science Association, August 1980, Washington, D.C.
19. The National Environmental Policy Act (42 U.S.C. 4321 et seq.), as amended, and regulations issued by the Council on Environmental Quality (40CFR Part 1500, 36FC 20550).
20. The Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1600; U.S.C. 655, 657), as amended.

Notes and References (Continued)

21. C. A. Trauth, Jr., A. C. Ellingson, D. E. Farr, and L. M. Jercinovic, A Study of the Application of Quality Assurance, Human Factors and Reliability Principles to the Prevention of Major Environmental, Safety and Health Incidents, SAND78-2176 (Albuquerque: Sandia Laboratories, December 1978).
22. A. C. Ellingson, Audit/Appraisal Guidelines for Organizational ES&H Assurance Programs, SAND79-1812 (Albuquerque: Sandia Laboratories, November 1979).
23. H. Rosenthal, "Safety Analysis and Review System, A Department of Energy Safety Assurance Tool," a paper presented to the 15th Annual Loss Prevention in Chemical and Petroleum Plants Symposium, Detroit, Michigan, 16-19 August 1981.
24. Anon., "Working Guidelines for Performing Safety Analysis Activities and for Reviewing Safety Analyses" (Washington: The U.S. Department of Energy, to be published).

APPENDIX A
Sample Review Criteria for Working Level Line
Organization ES&H Plans

The criteria presented here are based, in part, on the model approach to implementing ES&H Assurance Programs presented in References 2 through 16 in the body of this report. These are intended as illustrations only, though some of the criteria stem directly from the ES&H Assurance Program Standard and should be used.

Hazard Control Section

1. Facility/Project Description

There should be a listing of facilities and projects under organizational control. The listing may be in various formats, such as a description of organizational operations, the important point being that it should identify all organizational areas, all products designed, manufactured, or serviced by the organization, and all operations that take place under the control of the organization. The listing should be sufficiently comprehensive that it can be judged whether significant hazards other than those identified in the plan might be present.

In reference to the administrative section of the plan, there should be a system for periodically reviewing and updating this listing.

The facilities and projects in the listing should be classified by categories relevant to ES&H. The classification may be by type of hazard present. For example, the list may treat all office areas and all shop areas as groups and may still describe areas with unusual significant hazards individually.¹⁰

2. Hazard Listing

There should be a listing of all significant hazards. Completeness of the list may be judged, in part, by observation of organizational areas. The facility/project description above should be used in determining completeness, and the methods used in the organization to identify hazards should also be examined. The use of illustrative

hazard types, a system of checking against mandatory requirements, and planned observations are all means of providing completeness in the hazard identification function. The use of sampling during onsite verification is discussed in Reference 3.

In reference to the administrative section of the plan, *there should be a system for periodically reviewing and updating the hazard list.*

The hazards on this list should be categorized by the degree of potential impact perceived. Routine significant hazards (those routinely encountered and accepted by the general public) may be listed generically but should identify quantities, while the "unusual" significant hazards should all be identified individually.

*The hazards listed should be correlated with the applicable requirements. Such correlation may be presented as part of the hazard listing but may also be included as part of the ES&H analysis.*¹⁰

3. Hazard Analysis and Establishment of Controls

There should be an analysis of the modes through which each unusual hazard's potential impact might be realized. When the hazard is routine, the analysis may consist merely of a statement that this is so. Unusual hazards with modest potential impact may be analyzed by class, when such classes exist, but unusual hazards with a high potential impact or for which a high degree of public or employee concern exists should be analyzed individually.

The analysis/control-establishment operation for each hazard should be documented in the plan as follows:¹⁰

- a. *The potential consequences of any significant hazard should be identified. This should include harm to persons (in terms of involved employees, noninvolved employees, and the public) and property or environmental damage. Both the severity of the potential impact and the humans or the environment potentially exposed should be described.*
- b. *The series of events through which the potential consequences of an unusual hazard might be realized should be analyzed. The analysis should consider first the "primary" events, through which consequences might be realized, and then trace*

through the "secondary events" or "subevents" that might lead to the primary events. The end result of this analysis is the identification of *all of the credible subevents over which control can be exercised*. As part of this analysis, the *likelihood of each subevent occurring* should be considered and calculated, if appropriate to the severity of the consequences. If consensus standards or mandatory requirements are used as controls over routine hazards, it may be assumed that such an analysis already exists.

- c. *Control options and possible mitigation measures should be identified*. There are usually many options for control and/or mitigation measures, including controls over either likelihood of exposure or mitigation of exposure. Some control options identified may be applicable for many events or for different hazards (training, for example), and there will also be controls that are exercised in emergency situations (emergency response drills, for example). Both *technical* (hardware) and *administrative* types of controls should be identified and their inherent reliability discussed.
- d. *The identification of control and mitigation measure options should be followed by a selection of options*, based upon the previous analysis, requirements, and institutional policy.
- e. There should be evidence that the controls selected *are acceptable* (and therefore the risk is acceptable) to persons who might potentially be affected by the consequences or whose environment might potentially be damaged.

The controls and mitigation measures selected should be described in sufficient detail that their adequacy may be judged. For the technical controls, this will require a close correlation with requirements (standards, etc.). The administrative controls should include those identified in the ES&H Assurance Program Standard:

- Budget reviews,
- Schedule reviews,
- Design reviews,
- Quality assurance,
- Qualification and training,
- Written operating procedures,
- Change control,
- Record maintenance, and
- Corrective action.

Each of the administrative controls should be well defined in the plan, with responsibilities and procedures for initiating, implementing, verifying, and documenting described.

Administrative Section of Plan

1. Management Support

The plan should include a statement of ES&H policy for the organization. The policy should include a commitment to comply with ES&H requirements and to limit the risk of injury and damage to acceptable levels. Working level Line organization policy may be viewed as a transmittal of institutional policy to the employees--in fact, unless the two policy statements make the same commitments, there should be some vehicle for transmitting the institution's policy directly to the employees.

There should be evidence in the administrative portion of the plan that management intends to maintain a continuous involvement in ES&H activities. The plan should specify, for example, that the ES&H program plan of the organization is to be submitted to management for review. The plan may also specify required management documentation reviews, briefings for management, and the direct participation of management in ES&H planning efforts.

2. Organization, Responsibilities, and Authorities

The plan should assign responsibilities and authorities for all ES&H activities. Responsibilities of supervision and employees should be specified, as well as those of personnel with specific assurance functions. ES&H assurance functions should be assigned to an ES&H Committee or other independent group or person per institutional policy. The ES&H Committee should report directly to management. The assurance functions assigned should include review and audit functions, and periodic evaluations of the organizational ES&H program should be specified.

The plan should specify the communication channels for ES&H activities. The channels should include those for input from personnel on hazards, recommendations for controls, and recommendations for assurance activities; for dissemination of information to personnel on all elements of the ES&H program; for information flow between the ES&H Committee (or other group) and management, supervision, and the ES&H

Staff organization; for special communications such as those required in the emergency response program; and for the use of specialists.

There should be provision for the participation of all personnel in the ES&H program. Such participation should be solicited through such things as periodic ES&H meetings. A formal system of personnel participation is viewed as vital to the success of the ES&H program.

3. ES&H Support Provision

The plan should include specific provisions for supporting the ES&H activities of the organization. First, *the plan should make provision for consideration of ES&H in all project planning and should require documentation of such consideration.* This type of requirement in the plan will ensure continuous application of the program.

Also, provisions should be included for training in ES&H policies and practices, as furnished by the ES&H Staff organization, for all personnel. Training should be as extensive as possible for supervision and the ES&H Committee (if it exists), and the Committee should be required to receive training in ES&H assurance activities. There should be requirements for maintaining and updating training records. The plan should specify the consideration of ES&H qualifications in making job assignments.

A record storage system should be defined in the plan. The system should provide for strict controls over the issuance of documents and for ease of retrieval.

The intent of the administrative section of the working level Line organization plan is to describe how the program enforces compliance with the ES&H Program Standard in the context of institutional policy. This can be done in a relatively straightforward manner, as illustrated in Reference 16. The basic issues are how, by whom, and when

- Hazards are routinely identified,
- Controls are defined,
- Control use is encouraged and enforced,
- Change is accommodated,
- Emergencies are planned for and managed, and
- Evidence of performance is maintained.

Reviews, under each of the headings above, should always emphasize these points.

APPENDIX B

Some Very Generic Design Review Criteria

This appendix presents a very generic set of criteria for judging the ES&H adequacy of designs. Because designs may be associated with such a diverse collection of things (including products) that have associated hazards, specific criteria should be tailored to each set of circumstances. As discussed in Reference 10, there is often a strong interaction between designs and ES&H analyses--the generic design leading to more explicit ES&H control needs that in turn lead to more explicit design details. The end result should be a design that is adequate from an ES&H perspective and compatible with the associated ES&H analysis. In addition to the material in Reference 10, an excellent, brief discussion of this interrelationship will be found in References 23 and 24 in the body of this report.

1. ES&H analysis is included, or its exclusion is justified.
2. ES&H analysis is based on identification of all significant hazards, failure modes, factors that affect risk, and controls over these factors.
3. Design is based on correct calculations, including those used in ES&H analysis.
4. Design is adequate for prevention or mitigation of hazard realization, using
 - Redundant components,
 - Derating of components,
 - Protective devices,
 - Warning signals, and
 - Adequate machine/human interfaces, as appropriate.
5. Design has been verified by appropriate application of alternate calculations, analyses, and/or a test program.
6. Design satisfies applicable ES&H requirements.

DISTRIBUTION

U.S. Department of Energy (2)
Office of Environmental Protection, Safety
and Emergency Preparedness
Washington, DC 20585
Attn: Mr. Hal Hollister

U.S. Department of Energy (10)
OOS
Washington, DC 20545
Attn: Mr. Henry Rosenthal

U.S. Department of Energy
OQA
Washington, DC 20545
Attn: Mr. J. T. O'Connor

DOE -- Albuquerque Operations Office (6)
P.O. Box 5400
Albuquerque, NM 87115
Attn: Mr. J. R. Roeder, Director, OSD

Ms. Karen Marston (5)
Tech. Reps., Inc.
5000 Marble NE
Albuquerque, NM 87110

Ms. Kelly King (2)
Safety Sciences, Inc.
7586 Trade St.
San Diego, CA 92121

Mr. Leslie M. White
Safety Sciences, Inc.
291 G Street, SW
Washington, DC 20024

400	C. Winter
1220	J. M. Wiesen
1400	L. J. Heilman
1410	W. C. Kraft
1417	F. W. Muller
1418	A. C. Ellingson
1418	C. A. Trauth, Jr. (70)
3300	P. B. Mossman
3310	W. D. Burnett
3400	D. S. Tarbox
3440	L. M. Jercinovic
3442	D. L. Rost
3442	M. M. Carroll
3652	V. L. Duke
8275	P. K. Lovell
8214	M. A. Pound
3141	L. J. Erickson (5)
3151	W. L. Garner (3)
3154-3	C. Dalin (25)

DOE/TIC (unlimited release)

[illegible]

Sandia National Laboratories