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DOE STANDARD

PRINCIPLES FOR PROCEDURE SYSTEM MANAGEMENT

U.S. Department of Energy
Washington, D.C. 20585

AREA MGMT

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Principles for Procedure System Management

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Foreword

1. This Department of Energy standard is approved for use by all DOE Components and their contractors.

2. Beneficial comments (recommendations, additions, deletions) and any pertinent data that may improve this document should be sent to the Office of Nuclear Safety Policy and Standards (EH-53), U.S. Department of Energy, Washington, D.C. 20585, by letter or by using the self-addressed Document Improvement Proposal form (DOE F 1300.3) appearing at the end of this document.

3. DOE Technical Standards, such as this standard, do not establish requirements. However, all or part of the provisions in a DOE standard can become requirements under the following circumstances:

(1) they are explicitly stated to be requirements in a DOE requirements document; or

(2) the organization makes a commitment to meet a standard in a contract or in an implementation plan or program plan required by a DOE requirements document.

Throughout this standard, the word "shall" is used to denote actions which must be performed if the objectives of this standard are to be met. If the provisions in this standard are made requirements through one of the two ways discussed above, then the "shall" statements would become requirements. It is not appropriate to consider that "should" statements would automatically be converted to "shall" statements as this action would violate the consensus process used to approve this standard.

This Standard was prepared by the DOE Technical Standards Procedure Topical Committee. Members include: Maggie Sturdivant - EH, Earl Carnes - EH, Charles Billups - SC, Joe King - DP, John Tseng - EM, John Psaras - EM, Fred Carlson, consultant, Dick Nolan, DOE LBNL, Joyce Sylvester – PWI, OR, Peery Schaffer - Bechtel Jacobs, OR, Dan Plung - WSRC, Jacquie Lewis - BWXT INNEL, Steve Greene – UC, LANL, Susanne Guleke – BWXT, PANTEX. The team wishes to acknowledge the assistance of Dr. Daryl Grider and Mr. Bill Mullins for their assistance in the preparation of this Standard.

Purpose

This Technical Standard (Standard) provides principles derived from lessons learned and best practices from within the Department and industry for integrating management and technical knowledge, requirements and standards into procedures that effectively support the missions of the Department of Energy (DOE). These missions include scientific research and development, energy supply, nuclear weapons stockpile stewardship, and cleanup of the environmental legacy from weapons production. This Standard relies on principles rather than on prescription, and promotes reasoned adaptability in recognition of the diversity of work, hazards, work environments, technical complexity, risks, knowledge, and experience associated with accomplishing DOE's missions. Reliance on principle offers two important benefits to providing a critical level of consistency in addressing this very diversity. First, reliance on principle is intended and essential to retaining a consistent and recognized level of proven performance excellence throughout DOE when it comes to codifying proven historical work practices and newly developed work practices into approved procedures. Second, reliance on principle ensures the direction is equally applicable to support all types of mission work: scientific, technical , operational, maintenance, environmental, management and administrative work such as finance and personnel.

Introduction:

Over the past decade changes in DOE's missions have placed heightened attention on DOE's methods for performing work. The result of this focus has been progress in matching work methods to missions. For work where risk is understood, much collective experience has been codified. For work with unconventional risks, good practices are being systematically and continuously learned by those working at the edge of technology to develop standards and procedures for dealing prudently with the unconventional.

Mission changes prompted the Department to establish a tailored standards-based approach for all DOE work. This standards-based approach was developed in response to several factors: DOE's highly specialized and experienced work force was aging and retiring; because of changing social expectations new methods were needed to allow more open disclosure and discussion of how DOE work is performed; new missions posed challenges that are on the edge of current knowledge. The government as a whole was moving toward a system of regulation based on performance accountability. The Department of Energy has responded by developing a body of performance-based policies, contracts, rules and directives.

The standards-based approach is expressed in the DOE Safety Management System Policy, which requires work in accordance with an Integrated Safety Management System (ISMS). This establishes a formal framework to: (1) define work, (2) analyze hazards, (3) develop controls, (4) perform work and (5) use feedback for correction and continuous improvement. These five functions are guided by seven principles which address (1) line management responsibility for safety, (2) roles and responsibilities, (3) personnel competence, (4) balanced priorities, (5) standards and requirements, (6) tailored hazards controls, and (7) authorization of work. This framework is intended to apply in a tailored way to technical work as well as the management and administrative work necessary to accomplish assigned missions.

The ISM Policy is expressed through a hierarchy of agreements that take the form of mission, program, and project descriptions and a variety of local work controls that individuals use to produce the outcomes expected of their work. Work controls, particularly procedures, provide detailed expression of management expectations for completing work tasks.

Throughout DOE the maintained, written documents describing work performance may be referred to by terms such as management controls, work instructions, operations aids, checklists, protocols, administrative controls and standard operating procedures. This diversity of terminology has emerged over time as part of the culture of individual DOE operations. Regardless of the terms used, local level task work controls are considered the domain of procedures. Procedures serve to carry forward the organization's collective knowledge of how to perform work, maintain design integrity, protect the health and safety of people and the environment, and convey the management expectations for the degree of autonomy of decisions and actions available to individual work performers. The value of procedures in promoting the mutual goals of safety and quality is widely recognized by regulatory bodies and professional associations such as the Occupational Safety and Health Agency, the Nuclear Regulatory Commission, the Environmental Protection Agency, the Institute of Nuclear Power Operations, the International Atomic Energy Agency, the Center for Chemical Process Safety, the American Society for Quality and the International Organization for Standards. Just as these bodies do not all mandate the same detailed methods for documenting procedures, so the set of Principles set forth in this Standard is intended to accommodate a wide range of very different work realities.

What the agencies mentioned above do require is procedures that produce consistently high levels of safe, efficient work results. The set of Principles established in this Standard also requires that work performed according to written procedures achieve similar consistently high levels of safety and efficiency. In the past, the Department of Energy has invested extensive effort and significant resources on procedures, with uneven results. Procedures continue to be identified as principal causal factors in DOE accidents, operating events, and lessons learned. Event reviews often specify a lack of management attention to procedure development and procedure system management. To support implementation of Integrated Safety Management at the task work control level, a DOE Procedures Topical Committee was chartered as part of the DOE Technical Standards Program. The intent of this committee is to address procedures from an enterprise view, that is, in a way applicable to all of the Department's work.

The members of the Topical Committee are managers, workers, operators, scientists, engineers and technical specialists from both DOE and contractor organizations who have years of experience with procedures and management systems. To support the ISM goal of doing work safely, the Committee has focused attention on how procedures promote safe, efficient performance. The Committee has worked to foster appropriate procedures that reduce the potential for human error. Members are mindful that imposing inappropriate models of procedures would be counterproductive. The need to avoid the one-size fits all approach to procedures was felt to be an essential aspect of providing guidance that would be productive, supported and used.

A comprehensive set of Principles for procedure system management and procedure development was determined to provide the appropriate level of guidance. Establishing such a set of Principles was deemed to be consistent with both the DOE need for an enterprise approach that respects the diversity of DOE work and the management needs to communicate expectations and maintain awareness of procedure systems and development activities. The guiding concept for these Principles is that the work, the hazards, the environment in which the work occurs, and the skills, knowledge and experience that the work demands give rise to the type of procedures to be used and how procedures will be used to aid in performing work.

Applicability

This Standard can be applied to any DOE mission work. Contractors may use this Standard to tailor their specific methods for managing the development, review, approval, distribution, use, maintenance and retirement of

procedures. This Standard is consistent with and supports requirements and guidance found in 10 CFR Part 830 "Nuclear Safety Management," DOE Order 414.1A "Quality Assurance," DOE G 414.1-2 "Quality Assurance Management System Guide," DOE Order 5480.19 "Conduct of Operations Requirements for DOE Facilities," and DOE Order 440.1A "Worker Protection Management for DOE Federal and Contractor Employees."

Part I: Description of Procedures and Procedure Systems

This section describes the role of procedures, the concept of a procedure system, typical types of procedures, and the relationship of procedures to other management controls.

The Department of Energy has made a commitment that work will be done consistent with contractual agreements, laws and regulations and the principles and functions of ISM. This commitment is to ensure that work is planned, performed, and appropriately documented to protect the environment and the safety and health of the public and workers. This approach to doing work is intended to:

- Increase safety and effectiveness of work
- Support safe and effective human performance
- Allow for good judgment in planning work
- Create consistency and stability in expectations and accountability
- Maintain protection, while establishing a balance between costs and benefits
- Encourage decision making at the appropriate level

Procedures are components of Integrated Safety Management

The procedure system is the broad administrative program that encompasses the development, review, approval, distribution, use, maintenance and retirement of procedures.

Procedures play an essential role in implementing the components of ISM (Figure 1) by:

- Capturing agreements - Capturing the agreements and requirements for performing work as expressed in the approved contract and the ISM System description. DOE and contractors establish up-front agreements on basic approaches to doing institutional, facility and activity work, for example, the acceptable degree of risk associated with particular work. These agreements are established in the contracts, the ISM System Description and associated authorization documents. Procedures integrate these agreements into directions for performing the work.
- Implementing controls - Procedures implement the administrative, design, operating and quality controls.
- Implementing standards - Procedures provide work instructions that implement standards and requirements.
- Supporting human performance - Procedures provide accurate and authorized information and direction to enable individuals to perform assigned tasks safely and effectively.

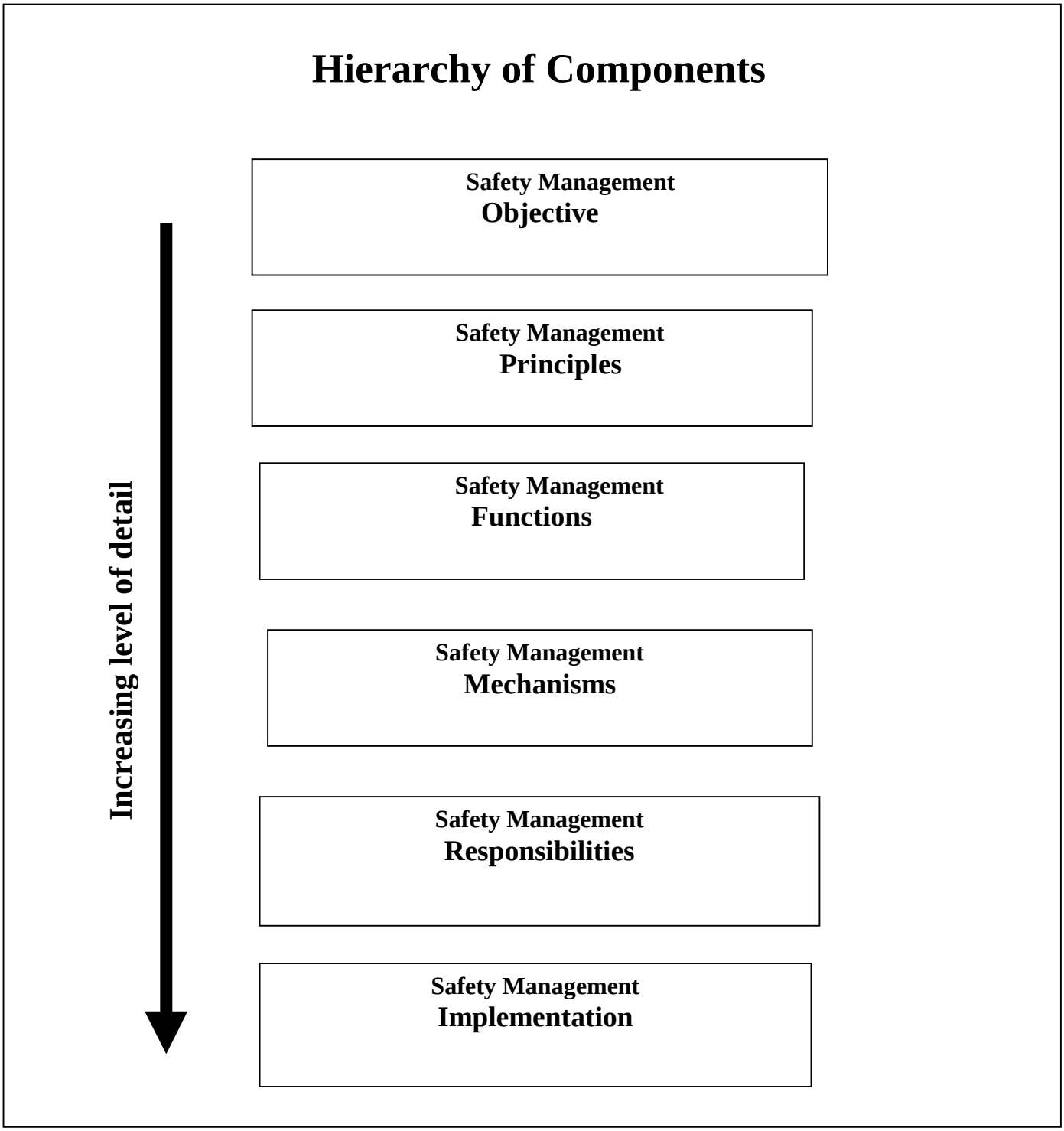
Hierarchy of Components
Safety Management
Objective
Safety Management
Principles
Safety Management
Functions
Safety Management
Mechanisms
Safety Management
Responsibilities
Safety Management
Implementation
Increasing level of detail

Figure 1

For most DOE work, implementation of work design, expectations, requirements and standards are communicated through a set of interrelated documents. Depending upon the work involved, risk, or safety implications, a document hierarchy may be needed to express and achieve full implementation, for example, to communicate policy and direction, support effective human performance, provide necessary information, establish an organization's written intent to comply with applicable regulations and commitments, and to direct task activities.

Figure 2 provides an example of a document hierarchy for capturing and implementing expectations, requirements, commitments and direction.

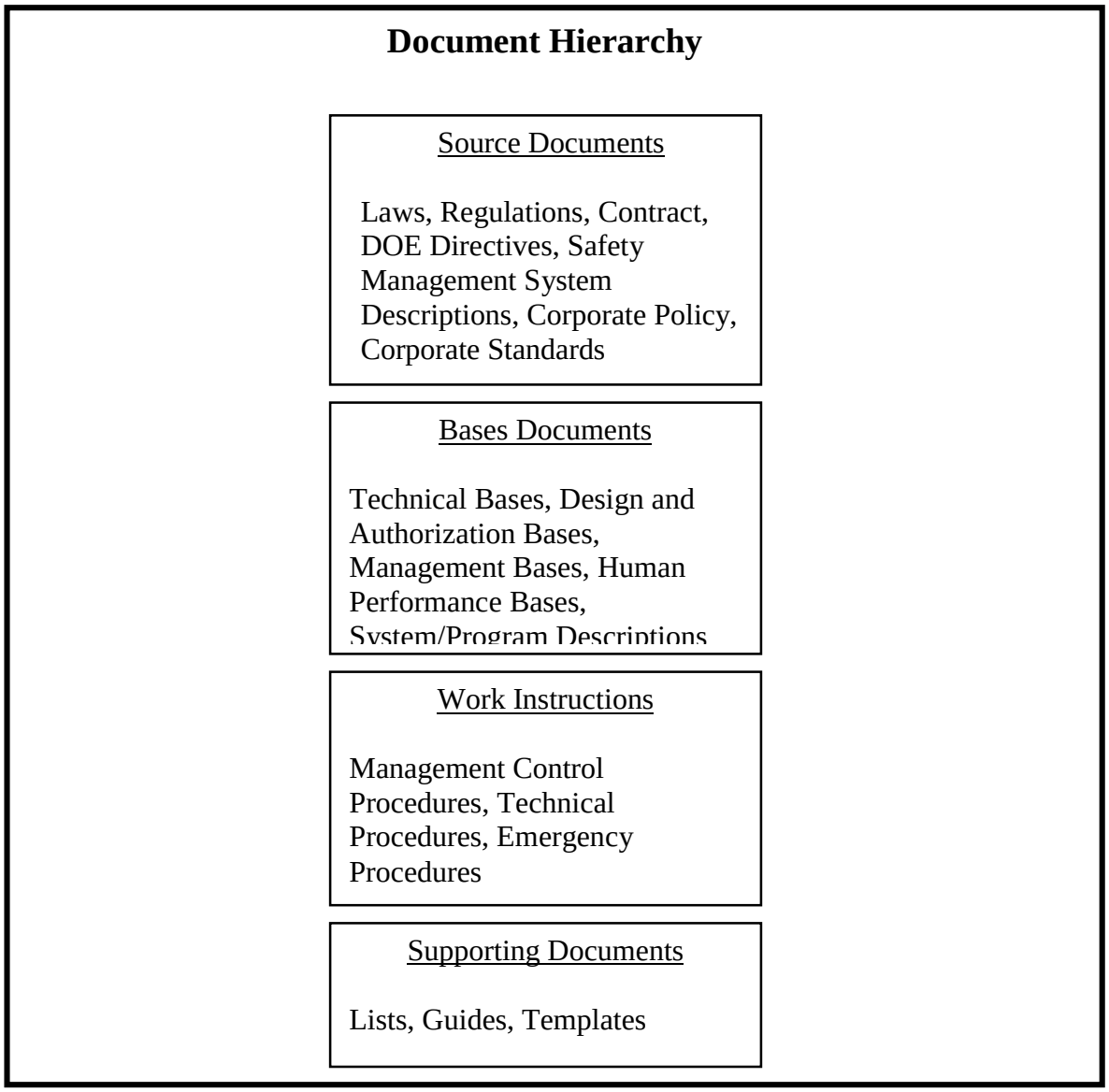

Figure 2

As illustrated in Figure 2, work control is the jurisdiction of procedures. Within the control document types, only procedures establish task direction for how administrative, technical, and emergency activities are to be accomplished. Procedures, in other words, constitute the document type by which work is actually accomplished.

To ensure procedures represent a commitment to doing work safely and effectively, procedures are products of professional collaboration and integration of the knowledge and experience from multiple disciplines. Line management, subject matter experts and workers are responsible for ensuring that procedures are correct and usable. That is, they are responsible for ensuring that procedures:

- Support work accomplishment in the safest, most effective way
- Fully implement the standards and commitments
- Are compatible with related procedures, programs, and initiatives
- Are as easy to comprehend and as easy to perform as possible
- Are consistent with the guiding principles and core functions of ISM

Procedures support different types of work

Procedures are tailored to precisely and effectively support the levels of work: institutional, facility and activity. Because work activities and situations require different means for communicating effectively to personnel performing the work, different procedure types may be needed. These procedure types differ in level of detail and format consistent with their intended application and the bases used for their development.

- Management Control Procedures

Management control procedures, most typically associated with institutional-level activities, provide formal direction for accomplishing interactions, maintaining communications, and ensuring consistency of operations. Management control procedures define the processes (methods) required to ensure that the goals and objectives of the organization's programs are implemented. They are sometimes referred to as administrative procedures, program descriptions or management system descriptions. Unlike technical procedures, management control procedures are not directly used to operate or maintain facilities or equipment. Collectively, management control procedures describe a comprehensive set of controls, interactions, and communications deemed essential by management for the safe and efficient operation of the entire organization. One way of thinking about Management Control procedures is that they translate policy into action. They are based less on quantitative analyses and design standards than on the management’s philosophy of operation, and agreements on how operations will be accomplished. In some ways, they represent much of the “culture” of the organization. For instance, one company might require plan of the day meetings to transmit lessons learned; another might opt for classroom training to communicate recently learned lessons; while a third company might choose required reading; and a fourth company might employ all of these options. The method is tailored to meet the management’s strategy for meeting its corporate goals and commitments.

Examples of activities most typically administered by management control procedures include:

- Quality assurance
- Configuration management
- Personnel management
- Emergency management
- Fire protection
- Human performance
- Work planning
- Safeguards and security
- Lessons learned

- Technical Procedures

Technical procedures focus primarily on accomplishing facility and activity level activities. They are based upon design controls (specifications, drawings), operational controls (documented safety analysis reports, technical specifications), management controls (industrial safety, training) and experience (lessons learned programs). Technical procedures provide direction and information on how to accomplish the technical tasks associated with the full life cycle of performing work, including:

- conducting research
- design
- construction
- testing,
- starting up,
- operating,
- periodically surveilling the equipment, facilities, and processes,
- maintaining,
- shutting down,
- transitioning to new missions
- deactivation and decommissioning

- Alarm Response and Emergency Procedures

Alarm response and emergency procedures delineate the steps to take when an abnormal condition exists. Alarm response procedures signal when operations approach established safety margins, allowing appropriate intervention prior to encountering conditions that are more serious. Emergency procedures detail the responses when safety margins have been breached or seriously jeopardized. Both alarm response and emergency procedures are based upon systems design specifications, safety analyses, hazards analyses, process flow diagrams, and vulnerability studies.

Summary

Procedures communicate direction for performing work when the consequences of that work are important to safety, quality and regulatory compliance. For many types of work, the use of procedures is required by regulation or corporate policy. To support effective safe work, procedures must be based on the work to be done, hazards or business vulnerabilities associated with that work, appropriate requirements, standards

and expectations. The purpose of a procedures management system is to control the development and maintenance of procedures so that individual procedures and the collective set of procedures support effective, safe work throughout the organization.

Part II: Principles for Procedures

Part II contains (1) principles on which a comprehensive procedure system is based, (2) principles by which procedures are developed and (3) principles for supporting the procedure system though the organization's infrastructure. Within the framework of these principles, specific criteria and system elements can be developed based on the work to be performed. Each principle is followed by an explanation of why the principle is significant, what it entails, and how it is fulfilled. In some instances, there is overlap among explanations. This overlap is intentional and warranted not only to support the different types of users, but also to afford each principle sufficient depth so that it can be understood both as an independent principle and as one part of an integrated system.

Fifteen principles are identified for developing, reviewing, approving, distributing, using, maintaining and retiring procedures and managing these procedure functions. To promote a clearer understanding of the interrelationships among the principles, they are organized into three categories.

Procedure system principles. These principles establish the necessary management controls for a procedures system to support the principles and functions of ISM.

Principle 1: The procedure system is an integral component of the Integrated Management System.

Principle 2: The management of procedures is established through policy.

Principle 3: The organization directs when and how procedures are to be used.

Principle 4: Authority and accountability for the procedure system and for individual procedures are defined.

Procedure process principles. These principles establish the necessary controls for the identification, development, review, approval, maintenance, continuous improvement, and evaluation of procedures.

Principle 5: The procedure process begins with identifying the need for procedures.

Principle 6: The procedure bases are identified and documented.

Principle 7: Standards are defined for procedure development and design

Principle 8: Affected organizations conduct formal reviews of procedures.

Principle 9: Procedure verification and validation are required prior to use.

Principle 10: Procedure authorization attests to procedure usability and readiness to implement.

Procedure system support principles. These principles address the interrelated programs needed to ensure the procedure system functions effectively and maintains procedures over time.

Principle 11: Change control is established for procedures.

Principle 12: A document control and delivery system ensures that the correct and current versions of procedures are available for use.

Principle 13: Procedure records are accessible and retrievable

Principle 14: Information management resources support the procedure system.

Principle 15: An effective training and qualification program supports the procedure system.

Procedure System Principles

An effective procedure system produces work-focused, accurate and usable procedures, integrates input for performance of work communicated from other management control systems, and incorporates ISM principles and functions for performing work at all working levels.

- A Procedure System is established for developing, reviewing, approving, distributing, using, maintaining and retiring procedures
- Procedure management and use are established through policy
- Responsibilities and accountabilities are assigned for the procedure system and the procedures
- Mechanisms are identified for integrating work inputs communicated through other management control systems

Principle 1: The procedure system is an integral component of the Integrated Safety Management System

The ISM Principles and Core Functions are codified through contracts, the ISM System Description and associated documents that collectively comprise an organization's management controls. The procedure system is a mechanism that supports institutional, facility and activity work consistent with requirements, standards, management, technical and performance bases, agreements and commitments. The organization's hierarchy of documents should clearly describe the procedures system and how the guiding principles and core functions of ISM are used within the procedures system.

<u>Evidence that the Principle is fulfilled</u>

To fulfill this principle, an organization should describe how it controls the development and maintenance of procedures. Descriptions may be documented at the institutional,

facility or activity level. Descriptions include the organization's overall policy on procedures, the organizational roles and responsibilities for procedure development and maintenance, and the management controls that inter-relate to perform procedure management functions.

Principle 2: The management of procedures is established through policy.

An organization's policy on procedures is derived from the nature of the work, i.e., the levels of complexity and uncertainty involved and the hazards associated with that work. The appropriate degree of formality of procedures and documentation should be tailored to the work and hazards. Policy on procedure system management should be conveyed using the appropriate levels of the organization's document hierarchy such as the Safety Management System Description, formal policy statements, program descriptions or standards.

The function of the Procedure System

Policy should set the management expectations for developing, reviewing, approving, distributing, using, maintaining and retiring procedures.

Evidence that the Principle is fulfilled

To fulfill this principle, establish policy for:

- The procedure management system
- The functional purposes and limitations of procedures

Principle 3: The organization directs when and how procedures are to be used.

All activities associated with defining the procedure system, developing the procedure process, and ensuring suitable support and integration are aimed at making procedures available to increase safety, maintain quality objectives, and enhance human performance. Clear and unambiguous direction should stipulate when to use, how to use and who should use the procedures once approved and issued. To support a clear and consistent use of procedures, requirements are established on use, documentation of use and verification of use. The organization should identify circumstances in which formal, written procedures will be required to promote and support the safe and effective performance of work. At the same time, the organization should define work where controls other than written procedures are more appropriate to accomplishing work safely and efficiently. Procedures may not always be the best vehicle to solve process, performance, integration, and safety problems. Boundaries should be established on the work situations requiring formal written procedures, and those situations in which work plans or verbal instructions combined with worker qualifications and experience provide sufficient assurance that work can be performed safely.

Determining when and how procedures are to be used

- Identify the types of procedures that the organization intends to use
- Establish the criteria for determining which steps in a procedure are to be documented as they are completed, and which are to be independently verified.
- Establish who is responsible for using procedures
- Establish how to use procedures, i.e., reference only, in-hand, or verbatim compliance
- Establish how procedure use will be verified and documented
- Establish what to do during actual use of a procedure if something unanticipated occurs, if an emergency situation arises, or if steps delineated in a procedure cannot be followed as written.
- Determine the levels of training, experience and qualification associated with procedures and their use
  - when training must include formalized testing and qualification
  - what allowances to make for skills associated with craft competency

Evidence that the Principle is fulfilled

To fulfill this principle, establish direction on when to use, how to use, who will use procedures and how procedure performance is documented.

Principle 4: Authority and accountability for the procedure system and for individual procedures are defined.

The procedure system includes development, review, approval, distribution, use, maintenance and retirement of procedures. Authority and accountability should be defined for each of these elements of the procedure system. In addition, authority and accountability should be assigned for individual procedures to ensure procedure quality and to promote procedure ownership. The organization should formally assign authority for performing tasks associated with the procedure system and individual procedures. Accountability is assigned to individuals deemed capable by experience, knowledge and training to perform certain functions for an organization. They have demonstrated they can perform assigned functions and that the organization and the individual(s) have agreed that assigned functions will be performed as expected.

In some instances, authority and accountability may be assigned to different individuals or organizations for each of the procedure types. This separation may be warranted because of the differences in the development and administrative processes for the procedure types, to afford greater attention on each type of procedure, or to support organizational structures (e.g., assigning responsibility for technical procedures to an operating division and management control procedures to an administrative function).

Procedure system accountability

Authority and accountability should be established for the procedure system. Although the overall procedure system may have distributed elements, authority and accountability should be clearly described. Assignment of authority and accountability is also important

to assure availability of resources - personnel, data management, technical expertise (subject matter experts, technical and safety reviews), and associated production resources.

Process accountability

No single individual or organization can ensure that all needed procedures are generated or that all procedures remain current, accurate, and complete. Management must ensure that procedure-related operating experience information is directed into the procedure system so that necessary revisions or improvements may be made. Collectively, all designated procedure owners are held accountable for ensuring that procedures within their purview are developed as necessary and updated:

- When work changes,
- When requirements change,
- When Authorization bases change,
- When feedback identifies opportunities to improve a procedure,
- When procedure deficiencies (errors, omissions) are identified,
- When Unreviewed Safety Questions are identified.

Examples of accountability and authority that should be assigned include:

- Line managers are designated to ensure that procedures:
  - Are consistent with contract provisions,
  - Are in keeping with the approved ISMS,
  - Correctly interface with other procedures,
  - Complement and are consistent with the administrative controls of the procedures system ,
  - Are routinely assessed,
  - Are used as directed by organizational policy.

- Procedure developers (subject matter experts, workers and others as designated by management) are capable of and responsible for developing technically correct procedures that:
  - are work focused,
  - are based on the established design, operating and administrative controls;
  - implement the standards, recognize the operating environment and conditions, and consider the knowledge obtained through lessons learned and related work experience;
  - are designed to optimize human performance,
  - reflect, as in the case of many Management Control procedures, the expectations and philosophy of management;
  - adhere to writer's guides and basic tenets of procedure design.

- Procedure users share responsibilities for ensuring that work experience is appropriately considered, including ensuring that finished procedures can be effectively used in the field under the prevailing work conditions.

- Technical reviewers share the responsibility for making sure that all elements of procedures are true and accurate representations of the work, hazards, workplace, the requirements, and work experience.

- Cross-disciplinary experts share the responsibility to identify and evaluate supporting, affected, and related initiatives and programs when developing or revising procedures.

- Validation personnel are responsible for ensuring procedures, in final form, are usable in the actual environment where the work is to be accomplished.

- The owning organization is responsible for the content, usability and final review. The owning organization confirms that the procedure remains responsive to the original purposes and to the requirements and standards being implemented.

Evidence that the Principle is fulfilled

To fulfill this principle, define accountability and authority for the procedure system, including:

- Designate the line management accountability for the procedure system.
- Designate accountability and authority for development, review, approval, distribution, use, maintenance and retirement of procedures.
- Identify responsibilities for organizational interfaces.
- Identify accountabilities for routine assessment of the procedures.

Procedure Process Principles

The procedure development process is designed to ensure that procedures are accurate and usable and they are consistent with the as-is equipment, work environment, organizational structure, established business agreements and processes, and approved ISM concepts. A comprehensive procedure development process includes the following elements:

- Identification of needed procedures,
- Identification of the bases to support procedure development,
- Qualified, responsible procedure developers,
- Use of established standards for procedure development,
- Interfaces with other procedures,
- Verification through formal interdisciplinary reviews,
- Validation through walk-throughs or similar methods,
- Formal procedure approval to establish accountability,
- Revision and performance evaluation requirements,
- Maintenance of procedures and supporting documentation,
- A method of feedback for continuing improvement.

Principle 5: The procedure process begins with identifying the need for procedures.

Not all work requires procedures, nor do procedures add value to the performance of all work. Training or day-to-day supervision, for example, may be more appropriate and effective for many work activities. Therefore, the first task in a procedure process is to determine which activities need or would benefit from a procedure and to determine the most efficient form of the procedure (for example, traditional 8 ½" x 11" step-by-step, or electronic procedures, job aids, operator aids, decision aids, checklists). This determination is made considering such factors as risk, work experience, lessons learned, informed judgments, capability and constraints (for example, available technology).

Procedures are warranted when any one of the following criteria is met:

- TO REDUCE RISK: When work entails risk to the worker, public, environment or the organization. This criterion is important when any of the following conditions exist:

  - Authorization bases require procedure use
  - Infrequent performance of the operation
  - A complex operation
  - Conditions that entail significant uncertainty
  - A high consequence of error
  - High personnel turnover on the operation
  - Frequent change in information or methods

In addition, procedures may be warranted for reducing significant business risks, e.g., financial or legal liability, intellectual property loss, loss of company-sensitive information.

- TO ENSURE CONSISTENCY: to prescribe a specific way of doing work where consistency is important to safety, quality, human performance or reliability; or where consistency is essential to maintaining compliance with laws, regulations, and commitments.

Evidence that the Principle has been fulfilled

To fulfill this principle, establish guidelines for determining when procedures are needed.

Principle 6: The procedure bases are identified and documented.

The bases documentation, the referenceable collection of documents and information from which the procedures are developed, is the " library" that affords a high level of confidence that the procedures in use are complete, appropriate, usable, technically correct and promote effective human performance. The traceability between the procedures and the bases documentation must be identified and be clear and consistent. All procedures, whether management control, technical or emergency should have an

identifiable basis. However, the bases documents vary. For technical procedures, documents such as hazards analyses and design specifications are principal information sources. For management control procedures bases documents tend to be regulations, standards, and best practices.

An essential step in the procedure process is to pull together or identify the need for current, accurate, complete bases from which to write procedures. The bases may contain any or all of the following based on the work:

Standards basis Management control basis Technical Basis Design and Authorization bases Work Process definition Human Performance basis Operating Experience Procedure Interfaces

Standards basis

A goal of ISM is to have all DOE activities governed by sufficient sets of standards to provide protection during the accomplishment of work. Standards bases are included in approved ISM System Descriptions and listed by contract in Lists A and B. Contracts typically identify requirements and standards that are important for management control, technical and emergency procedures. The standards basis is derived from the work and the hazards (or vulnerabilities) and furnishes essential input from which to develop procedures.

Management control basis

Included in the management control basis for procedures are documents that address commitments to meeting contractual and regulatory obligations, and organizational policy through:

- Administrative programs,
- Operational programs,
- Technical support programs,
- Contracts,
- Memoranda of Agreement/Understanding.

Technical Basis

The technical basis for procedures includes the documents that establish the boundaries within which normal and emergency operations can be performed safely. The Technical Basis includes the design and authorization bases, work process definition, and operating experience.

- Design and Authorization Bases

The design and authorization bases for procedures include design and construction criteria, materials, design engineering drawings and specifications, hazards analyses, documented safety analysis reports, unidentified safety questions (USQ) documents and vendor information. The Authorization Basis may also include facility permits, emergency plans, waste management plans, pollution prevention plans, quality management plans, conduct of operations plans and, in cases of multiple user facilities, tenant agreements.

- Work Process Definition

A significant part of developing the procedure is analysis of the work process, activity, or task represented in the procedure. These analyses examine work sequences: what initiates the action, the steps to be followed in response to that action, and the results from completing those steps. The analyses include potential hazards, vulnerabilities or the areas that increase the probability of errors, and the consequence of these errors. The intent of such analyses is to produce a set of directions and information to be addressed in the procedure, to identify human performance issues, indicate the appropriate warnings and cautions, and determine qualification or training necessary for persons who will carry out the procedure. In Management Control procedures work process analyses focus on maximizing efficiency, cost effectiveness, productivity, and communication.

- Operating Experience

The purpose of collecting and evaluating operating experience is to avoid repeating errors, to continually improve and to learn from others. Operating experience includes experience from within a given organization and from other external organizations that perform similar work. Each DOE contractor organization has a number of systems and processes intended to capture operating experience, analyze causes, identify corrective actions and identify opportunities for continuing improvement. The organization must ensure that these operating experience systems and processes examine and identify causes and corrective actions related to procedures. At the same time, a healthy focus on continuous improvement will encourage identification of opportunities for improved work process flows, introduction of new technologies, automation, and elimination of unnecessary or redundant procedure steps.

Human Performance Basis

The process, activity, task, workplace and organizational factors that affect human performance should be addressed during the procedure development process. Human error is often attributable to management practices, organizational weaknesses, unnecessary or excessive organizational interfaces, equipment deficiencies, adverse environmental conditions or circumstances involving high degrees of uncertainty. In addition, lessons learned during previous or similar work performance should be evaluated to identify potential for error and common types of human error associated with given work or procedures.

Procedure Interfaces

A new procedure or a change to an existing procedure may impact related procedures. The development process should include identifying interfaces with existing procedures and a means to determine if changes are needed to existing procedures to ensure that the collective set of procedures is integrated.

Documenting the Procedure Bases

The bases for procedures should be identified and documented to support development and review of procedures and be maintained as part of procedure history records. Information supporting the justification for the procedure, how procedure bases were developed, and assumptions and informed judgments used to integrate requirements into procedures is maintained with records of the corresponding procedure so that this information may be retrieved. Procedure developers use basis documentation to establish the foundation for procedures. Sets of related procedures might be developed from one group of bases; it is not necessary to have a unique group of bases for each procedure. However, every procedure is tied to the appropriate bases information.

Evidence that the Principle is fulfilled

To fulfill this principle, the procedure process description should describe how procedure development integrates and documents contributing information:

- Management controls basis,
- Standards basis,
- Technical basis,
- Human performance basis,
- Interfaces with related procedures,
- Operating history and lessons learned programs.

Principle 7: Standards are defined for procedure development and design

The organization should define standards for developing and designing procedures. These standards may take the form of institution, facility, or activity documents. Developing procedures consistent with the organization's standards ensures that individual procedures are sound, that the procedure process is coherent, and that documents are controlled and retrievable. The standards should address how all necessary skills, expertise, and experience are captured in the procedure development and review, and the processes for developing and revising procedures. Such standards are often referred to as Procedure Guides.

Multi-discipline skills and knowledge guidelines

Effective procedure development demands full knowledge of the bases and work experience related to a procedure. The organization should develop guidelines for how

the procedure development process will ensure participation of all those needed to provide a thorough knowledge of the work and its hazards and those to perform work and human performance task analyses. This expertise must also involve those involved in the performance and outcome of the work addressed by the procedure. In addition to ensuring this primary expertise, the process must also ensure the development process includes persons knowledgeable about the ISM system, the procedure system, the development and use of bases, and the organization's documentation standards. Further, guidelines should address how participants will be qualified on these related topics.

Development guides

The DOE has issued a DOE Technical Standard for developing technical procedures, DOE-STD-1029-92 "Writers Guide for Technical Procedures." DOE and contractor organizations can use this standard or tailor guides for their specific circumstances. While the Writers Guide is oriented to technical procedures, the basic concepts presented are useful for developing other types of procedures as long as the application of the concepts is based on the nature of the work involved and the skills, knowledge and experience of those who will perform the work. Tailored development guides should define a procedure process, describe guidelines for presenting procedures (content, format, and style) and include a plan for managing the records generated.

Procedure Design guides

The purpose of procedure design is to optimize human performance: (1) by presenting information in ways that are most readily understood by the user, and (2) by presenting information in a manner that reduces or eliminates those errors commonly made during the use of procedures. Procedure design offers methods for eliminating common errors of commission and omission. Design issues include:

- Document Structure
  - Document layout (how to structure the document presentation to increase comprehension and usability)
  - Page layout (how to use headings, white space and typographic techniques to increase performance and quality)
  - Language (how to use terminology, reading levels and sentence structure to enhance understanding and usability)
  - Common error types (knowledge of common errors made when using procedures and strategies for preventing these)
- Use of alternative media to present procedures (e.g., electronic media, paper hard copies),
- Graphical presentations (the use of non-narrative formats such as tables, figures, graphs, and forms) to better articulate required actions and documentation,
- Alternative presentation structures (such as job performance aids) to optimize human performance.

These design concepts, much like the management principles that define the procedures program, are the fundamentals from which the development guides are built.

Evidence that the Principle is fulfilled

To fulfill this principle, the procedure system must include:

- Procedure development standards,
- Procedure process standards,
- Procedure design standards,
- Training and qualification programs for procedure development personnel.

Principle 8: Affected organizations conduct formal reviews of procedures.

Review of procedures by affected organizations (those involved in performing, supporting, or owning the outcome of the work) is important to ensure every aspect of a procedure is technically correct and usable. Any procedure may involve and affect many organizations, each with different responsibilities and expertise. Representatives from these organizations review the procedures from technical, safety, operational, human performance, worker and management perspectives. Involving relevant organizations and individuals for review is equally important for developing new procedures, reviewing infrequently used procedures or revising existing procedures.

Defining the review focus

Although subject matter experts and procedure users develop the bases for a procedure, peer review is essential. Peer review means that the same skills, knowledge and experience mixture is applied to review a procedure as is applied to development of the procedure. Involvement of reviewers should occur as early as possible in the development process.

The procedure review process draws on experts (including procedure users and developers), facilitates the interfaces of the procedure with other activities, and encourages commitment to the process and product. The type and depth of review depends on the procedure content, complexity of the activity, levels of uncertainty, the operational and safety considerations, and the degree of coordination needed among programs and areas of expertise. For example, a procedure for processing hazardous waste streams requires a different set of reviewers and reviews than will a management control procedure on property management.

The procedure process allows for clear definition of which groups review which procedure, disposition of review comments, and documentation of the review in the procedure history file.

Evidence that the Principle is fulfilled

To fulfill this principle, promote the importance of the review process and describe how the organization:

- Develops guidelines to define the review requirements, participants, and expectations,
- Dedicates appropriate resources to support the review effort,
- Provides training for review personnel.

Principle 9: Procedure verification and validation are required prior to use.

A final assessment of the completed procedure is performed by the organization that owns the procedure to ensure the procedure is technically correct, is consistent with operating practices, fulfills the original need for the procedure, and is useable by the intended work force in the intended work environment.

Verification addresses technical accuracy

The line manager responsible for performance of the procedure is responsible for verification. Verification is not intended to replicate the development or review process; verification substantiates the procedure's technical accuracy. To the degree possible, verification is incorporated into the technical review process, but additional actions may be required to ensure that each procedure is of highest quality.

The verification process is intended to ensure:

- The procedure is technically accurate,
- The development and review processes have been conducted consistent with the applicable management controls,
- The procedure is consistent with existing related procedures and consistent with ongoing initiatives,
- The development and review processes have not inadvertently introduced requirements for actions that are inconsistent with contracts and approved operating practices.

Validation addresses procedure usability

A validation is conducted prior to authorization to ensure the procedure can be used as written. This validation focuses on use, a factor that should have already been incorporated in the development phase by subject/technical experts, but which needs reassessment prior to approval. Specifically, the validation allows independent assessment after resolution of review comments to demonstrate that the procedure can be used as written and in the environment where the actual task is to be performed.

For management control procedures affecting general plant or administrative systems, the validation is part of the technical and interdisciplinary reviews conducted of the procedure.

For technical procedures, some level of simulation of the actual practice is used. At the highest level of confidence validation involves use of a mock up or simulator in which the actual steps are practiced. At the next confidence level is a walkdown, in which personnel take the procedure to the location where the task is to be done and, without actually performing the task, ensure that each step is correct and readily useable as written. At the lowest level of confidence, validation is an analytical review that does not simulate actual operation, but validates the procedure based on the knowledge and experience of the reviewers.

Whereas all procedures are validated, the level of confidence needed differs with several factors:

- Type of procedure (management controls, technical procedures or emergency procedures),
- Types of work and the degree of hazard,
- Operating experience or the degree of familiarity with the operation (for example, a small change to a well documented and mature process as contrasted with work involving minimally characterized hazards, high uncertainty or high complexity),
- Successful work experience, including lessons learned materials and other supporting documentation.

First use of a procedure

Irrespective of the validation method used, no procedure is truly validated until it has been used. The procedure system should contain special provisions for first use of procedures based on the risk associated with the work. Procedures that warrant mock-ups, simulator validation or walkdowns should be identified within the procedure system as needing special attention for first use. Such procedures, when authorized after the validation, are identified to let the user know that no one has ever used the procedure before. Therefore, when using a procedure so identified careful scrutiny (possibly including additional observers) is warranted when the procedure is first used.

Infrequent use of a procedure

Infrequently performed work is a major source of accident or injury potential. If a particular work activity has not been performed for some time, the procedure for performing that activity should be reviewed, verified and validated with the same level of rigor as required for a new procedure. During the intervening period of procedure use a number of changes may have occurred. Examples include facility modifications, introduction of new materials in the facility or process, development of new hazards reduction techniques, change in the skills, knowledge and experience of workers or changes in formality of work. These type changes should be identified and resolved through the organization’s change control or configuration management systems. However, the procedure system should contain provisions to identify infrequently used procedures and invoke special infrequent use review.

Evidence that the Principle is fulfilled

To fulfill this principle, establish the criteria associated with verification and validation of each type of procedure and establish a means for identifying the first-use or infrequent use procedures.

Principle 10: Procedure authorization attests to procedure usability and readiness to implement.

The approval process confirms completion of the procedure development phase and establishes accountability and ownership for each procedure. To establish accountability at the proper level, the procedure system should require an approval signature for each procedure. The procedure is generally signed by the person at the lowest level with authority to direct implementation of the procedure. This signature attests that the procedure is technically correct, that workers can understand and use the procedure, that appropriate verification and validation activities have been completed and that the new procedure or a change to an existing procedure has been reviewed for impact on related procedures. Authorization to use a given procedure must be based on a determination that related work would not be adversely affected by implementing the new or revised procedure. (Although the original procedure may be signed, copies issued may not show the signature (as in many electronic systems). Where the signature is not evident, the procedure system must have administrative controls to establish authentication for the copies.

The approval process also should require the approval authority to determine an effective date for implementing the procedure. The approval authority considers the technical and management interfaces as well as the implementing requirements associated with the procedure prior to establishing the effective date. These requirements include, but are not limited to:

- Available resources to implement the requirements of the procedure. Resources include personnel, hardware and associated equipment.
- Status of related procedures. Status includes other procedures under development or revision that interrelate with the procedure to be approved.
- Training needed for workers who will use the procedure. Depending on the complexity of the work and experience and qualification of personnel, training may range from reading the procedure, to reviewing it with supervisors, to formal training.

Evidence that the Principle is fulfilled

To fulfill this principle, establish an approval process that:

- Identifies procedure approval criteria,
- Includes an approval signature for each procedure,
- Defines an approach for determination of the effective date for implementation of the procedure,
- Ensures effective and timely issuance of procedures.

Principle 11: Change control is established for procedures.

A change control process ensures the continued integrity of a procedure. Revision and periodic evaluation of procedures are necessary ongoing processes required to keep procedures current with changes in mission, work, hazards, requirements, systems, personnel or equipment; and to promote procedural adherence.

Revisions to procedures are typically driven by one or more of the following factors:

- Change in the technical basis, requirements, facility configuration, standards, or commitments or other bases;
- Unusual operating conditions and configurations,
- Evaluations, such as user feedback, periodic review, lessons learned, self-assessment, and audits;
- Changes in requirements, commitments, or expectations.

Focused review process

The procedure revision control process balances the need for thorough, disciplined reviews of proposed revisions, with the flexibility to allow timely completion of a revision in order to support the needs of the users. When revisions are made to a procedure, a process should be in place to identify who reviews which type of changes, based on the scope of material changes, the implications, and the affected organizations. As with the initial review process, maintaining the integrity of the procedure system and procedures is dependent on assigning the right resources at the right times.

Expedited revisions

In addition to supporting routine changes introduced as part of regular operations, the revision process also includes an expedited process for reviewing and approving procedure changes whose urgency demands immediate resolution. The ability to modify procedures expediently is key to maintaining the highest standards for worker safety, performance, and responsiveness to changing regulations or commitments.

Periodic review and cancellation

Revisions to procedures are made as necessary; however, the procedure process should contain specific requirements to periodically assess the procedures. Such requirements are established to ensure continued need for the procedure, technical correctness, usability, and compliance with requirements. Organization policy may provide that low risk procedures that are used frequently are "reviewed with use" and do not require separate periodic review. This is only acceptable if the change control process strictly controls the technical basis of the procedure. Procedures that are used infrequently may require a full review prior to use depending on the hazards, complexity and uncertainty associated with the work, irrespective of whether in the interim revisions have been processed to specific sections of the procedure. While the organization may select a variety of review and assessment strategies for various types of procedures, all authorized procedures should have appropriate periodic review.

A process for canceling existing procedures is also established to provide a method for ensuring that procedures that are no longer necessary or no longer used are effectively removed from the system.

Evidence that the Principle is fulfilled

To fulfill this principle, develop change control provisions that:

- Include adequate restrictions to ensure the revision process contributes to maintaining procedure integrity,
- Ensure timely completion of revisions,
- Ensure all affected organizations review the proposed revisions,
- Provide a mechanism for periodic review and cancellation of procedures.

Procedure System Support Principles

A procedure process does not end once a procedure is signed off as approved. Support processes and resources are needed that:

- Make sure procedures are provided in a timely and disciplined manner to the users,
- Maintain and ensure retrievability of records of the procedures development and use,
- Match production resources to the numbers and complexity of procedures generated and to the distribution needs,
- Maintain an effective link between the procedure system and the training program.

Principle 12: A document control and delivery system ensures that the correct and current versions of procedures are available for use.

An important part of the overall procedure system is controlled delivery to ensure that the correct and current version of a procedure is available where and when needed. Control of procedures should be an integral part of an organization's document control system. Several elements are needed to properly control procedure distribution: a procedure index, standardized distribution lists, a method for providing receipted control, and a delivery system commensurate with the volume and types of procedures.

Procedure index

A procedure index lists all approved procedures, listing at a minimum the procedure name, number, and revision. This list is maintained to ensure that the most current version of the procedure is used to perform the task. Because selecting an outdated or superseded procedure is a frequent cause of procedure-related human performance error, the index is not only a basic administrative control but also allows procedure users to locate the correct, current, and approved procedure.

Delivery control system

The delivery control system provides a means to ensure procedures are in place, are made available to procedure users, and the procedure users know where to find them. All procedure presentation types, hard copy, electronic and user aids must be controlled in accordance with procedure system requirements. As appropriate, the delivery system is able to accommodate:

- Procedures to be issued on a routine basis,
- Procedures that require expedited processing,
- Procedures that may require special controls due to inclusion of sensitive, proprietary, or classified information.

Each of these attributes carries specific requirements for reproduction activities, access control, and delivery administration. Therefore, several factors - not only the number of procedures or the number of procedure users - demonstrate why document control is recognized as integral to the overall procedures system.

Delivery lists identify the location where controlled procedures are available. These lists may be structured on a procedure-by-procedure basis or may be grouped in support of the work (for example, by institution, facility or activity). These lists are maintained to ensure that those who use the procedure receive the appropriate procedure and subsequent revisions.

The receipt system - which is often accomplished by written receipts or computer records from electronic distribution - records which version of the procedure has been issued, identifies each controlled copy of a procedure, provides notifications and updates when procedure changes are released, and logs the procedures back -if a mandatory return program is used.

Evidence that the Principle is fulfilled

To fulfill this principle, design and implement a document control program capable of handling the types, number, and volume of procedures. This document control program includes:

- An index of procedures,
- Controlled delivery lists for hard copy or electronic distribution,
- Mechanisms for documenting and monitoring custodial assignments,
- Production and distribution capabilities.

Principle 13: Procedure records are accessible and retrievable

A records program provides the historical counterpart to the document control program. Ready access to the history of proceduralized operations is needed for development of new procedures, revision of existing procedures, procedure reviews and audits. The records program includes access to and retrievability of procedure records, including:

- procedure history files that document the bases and decisions made in the development of the initial procedure and its revisions,
- superseded versions of procedures,
- feedback records generated following use of the procedures,
- periodic reviews.

The procedure system must ensure:

- that procedure files and procedure-generated records such as checklists, forms, and logs, are retained and made part of institution records program.
- that results of periodic procedure reviews and audits are maintained to document that procedures were reviewed for technical accuracy and usability on a regularly scheduled basis.
- that the records program affords a timely and effective means to retrieve superseded procedure revisions and interrelated supporting materials (e.g. bases information). The latter is important because reviews may require support materials, not just the superseded procedure.

Evidence that the Principle is fulfilled

To fulfill this principle, establish a records program that:

- Identifies and collects designated procedure materials as part of the ongoing records program.
- Allows for retention and retrieval of interrelated procedure materials (superseded revisions, development materials) as part of an overall effort to document the historical integrity of operations.
- Ensures personnel are knowledgeable of records requirements and deliver materials to the records program in an appropriate and timely fashion.

Principle 14: Information management resources support the procedure system.

A comprehensive procedure system requires significant information management support. This support includes production capabilities for procedures, integration programs to track commitments and interrelationships among procedures, document control systems, records management for retrieval of support documentation, and distribution capabilities. Therefore, the development and design of the procedures system requires up front acknowledgement, design, and allocation of information management resources.

Among the information management resources needed to support the processing and production of the procedures are:

- Production capabilities to support effective use of development and design principles,
- Production capabilities consistent with the anticipated volumes and to support effective use of development and design principles,

- Information management resources that support tracking of commitments and requirements to ensure agreed to obligations are traceable and visible within the procedure system,
- Identification and tracking of procedure bases documentation to ensure development logic is retrievable as needed,
- Integration of procedures to afford coordinated processing of all procedures affected when a revision or new procedure is introduced,
- Technology assessment and upgrades for other production activities such as printing, distribution, and control of procedures. This support may include distributed processing of a document, multiple distribution centers, on-demand printing, and electronic procedure programs.

During all phases of the document life cycle, it is important that information is available on the status of a document (whether in development, review, revision, etc.), the current version of the document, the availability of the document (for example, where it can be accessed), and who has ownership and custodial responsibility for the document. For these reasons, allocation of appropriate information management support services is a significant contributor to establishing and maintaining an effective procedures program.

Evidence that the Principle is fulfilled

To fulfill this principle, assess the kinds and amount of information management resources needed to operate the procedures system. These resources include support for:

- Procedure production,
- Tracking of commitments, requirements, and procedure bases documentation,
- Document control and records activities,
- Procedure duplication and distribution,
- Continued technology reassessment and upgrades to the procedure management program.

Principle 15: An effective training and qualification program supports the procedure system.

Procedure systems are supported by training and qualification designed to ensure personnel understand the procedure system requirements, and that they are capable of developing, using, and revising procedures.

Managers' training

Managers responsible for the work are trained on:

- the logic of procedure system management requirements,
- when procedures are needed,

- how procedures support ISM and safe and efficient operation,
- how procedures interconnect with other procedures and support management control systems,
- how procedures support management expectations and commitments.

Most importantly, the training emphasizes that procedures, as with systems, equipment and tools, should be owned by managers and workers who are accountable for their proper production and use.

Procedure users' training

The procedure training program shows employees how and when to use procedures and the procedure system including:

- operation by procedure,
- how the procedure process works,
- the employee's obligation in ensuring the integrity of the procedure system.

Training on specific procedures is also provided and training logic and resources (for example, simulators) made available, consistent with objectives of the procedure system.

Procedure developers' training

Procedure developers are trained in performing work and human performance task analyses, developing and documenting the procedure bases, and in the use of writer's guides. Reviewers and validators are trained to understand the procedure system and its relationship to ISM, and to perform appropriate technical and interdisciplinary reviews. Validators are trained to understand the methods of validation and the requirements for validation.

Qualification

In addition to training, the organization should establish provisions to determine that managers, procedure developers, procedure reviewers and procedure users are qualified to perform their responsibilities. Qualification factors include knowledge and experience, the level of supervision involved in assigned tasks and whether assigned tasks will be performed individually or by a team.

Evidence that the Principle is fulfilled

To fulfill this principle, ensure the availability of procedures system training and qualification for:

- Management,
- Procedure users,
- Procedure developers,
- Procedure Reviewers.