Instructor Background Material

Module Title: Necessary and Sufficient Overview

References: (1) Criteria for the Department's Standards Program - Department of Energy/EH/-0416-August 1994

(2) The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards - Draft dated March 14, 1995

Note: The following background materials and examples are provided for the instructors use as appropriate. The Alpha-Numeric outline below refers to the outline used in the Instructor Preparation Pages for the training module "Necessary and Sufficient Overview"

A. Introduction

A.2 Why are we here?

A.2 Achieve an awareness of the Necessary and Sufficient Closure Process - an important new initiative designed to bring predictability, stability, and cost effectiveness to our work practices.

A.2 A brief overview of how the necessary and sufficient process fits as an important first step in the Standards Based Management System.

A.2 If, as we proceed, you sense that we are not identifying any revolutionary ideas, tricks, or easy answers, you are absolutely on target. We are talking today about getting back to basics.

A.2 Remember, throughout this training session, the protection of workers, public, and the environment must remain the principle focus.

A.3 Where are we Now?

A.3 Over the past several years, the Department of Energy's approach to identifying safety standards has emphasized nuclear safety requirements for high hazard radiological facilities such as nuclear reactors. The Department developed nuclear safety orders and rules (pursuant to the Price Anderson legislation), worker safety orders based on OSHA standards, environmental orders based on EPA requirements and technical standards.

Department of Energy contractors were directed to review all the Department of Energy orders and rules as well as state and local requirements and identify which requirements from this collective body of standards should apply to the sites and facilities they were contracted to operate.

A.3 Contractors were expected to comply with all Department of Energy safety orders, in addition to the applicable Department of Energy rules, and state and local laws, unless it could be established that certain requirements were not applicable and specific

exemptions were granted. In instances where facilities were not reactors or were not nuclear related, contractors were to apply the concept of "grading" and justify why Department of Energy safety requirements should be less stringent.

A.3 Weaknesses in the infrastructure and management systems resulted in the selection/exemption process becoming dysfunctional. Thus, the graded approach was dysfunctional in many cases.

A.3 In many cases, Contractors had too little flexibility in selecting the best method for implementing standards because many discretionary standards were declared mandatory by Department of Energy personnel.

A.3 In other cases, regulatory interpretations or personal opinions by internal and external reviewers led to low value or incorrect application of requirements based on an otherwise appropriate standard.

A.3 These past practices have led us to a situation where identifying the standards that should govern safety, and demonstrating compliance with those standards, is cumbersome, resource intensive and subject to differing interpretations.

A.3 Prescriptive, One Size Fits All Approach - Many Department of Energy safety orders were written to control hazards of nuclear reactors or other high hazard facilities but were applied to lower hazard work without appropriate grading.

A.4 So, What are the Challenges?

A.4 **DOE Mission Changes** - The very real need to clearly identify safety standards for Department activities was complicated by fundamental changes in departmental missions. At sites involved with nuclear weapons development the emphasis shifted from weapons production to shutting down unneeded facilities, and cleaning up the residue of some 50 years of production activities while maintaining a much smaller core capability for weapons development. At the department's laboratories and research operations, the need for new technologies, international competitiveness and national budget reductions has heightened the need to shorten the research and development time cycles and to become more cost effective and comparable to private industry and international competitors.

A.4 **Multiple Improvement Initiatives** - Confusion about the path forward sometimes exists in the face of multiple initiatives. The Department of Energy is issuing new rules and orders. Some sites are preparing S/RIDs. Others are doing order compliance reviews. Until now, there has not been a consistent approach for identifying standards and doing work to those standards.

A.4 **Management Issues** - Department of Energy and contractor management have identified several areas where past management practices need to improve including the need for clear ownership, defining clear expectations, delegation of decision making to the proper management level, coordination and integration of improvement initiatives, and consistent follow through.

A.4 **Experience Base Eroding** - Many people who designed and built our facilities and technologies have left or are soon retiring. In many cases, it is impossible to replace their knowledge and experience.

A.4 **Budget Cuts** - It is a reality that the Federal budget is being reduced. But Department of Energy missions remain vital to national interests. So we must change our way of doing business so we can do more with less.

A.4 **Gridlock** - All of the above have contributed to a condition where large sums of money have been diverted from program work to requirements identification and compliance processes which have frequently resulted in less than desired, and, in some cases, low value results.

B. Necessary and Sufficient Closure Process

Note to Instructor: *With the exception of the following supplementary materials associated with the "Introduction" material, the background information and examples for Section B of the training module have been incorporated into the Instructor Preparation Pages of the lesson plan.*

B.1 Where do we Start?

B.1 The Department has committed to realign the way we do business to a standards based approach to work. This new approach will require that all business functions work together to support the work directly related to defense, research, and development.

B.1 If this standards based approach seem pretty simple and straightforward, it is because "it is". Every successful American business incorporates these or similar elements and processes to define and control their business. Some that have not are history.

B.1 One caution as we move forward, this initiative is designed to help us "do it right," not to avoid today's more rigorous safety expectations and the difficult changes they often entail.

B.1 Remember, Safety and Protection must remain the principle focus.

B.1 A key component of the integrated standards based management system is the "necessary and sufficient" process for identifying standards to control the work we do. This necessary and sufficient process differs in fundamental ways from previous techniques that the Department used to identify standards.

B.1 The Department's overall mission is to serve the nation's needs in a variety of defense, research and development areas in ways that meet legal requirements and satisfy customer expectations. A standards based approach to doing business, starting with the necessary and sufficient closure process, enables us to meet the challenges in the current environment and offers several improvements compared to past practices. Examples include:

- Improved Work Planning and execution
    - Ownership at the appropriate level
- Establish and maintain appropriate protection while balancing cost and benefits
- Promote predictability and stability
- Increase effectiveness of work
- Encourage the exercise judgement
- Empower people who perform and control the work

C. Implementation

1. Background

Most DOE and Contractor organizations are familiar with the basic techniques and management systems involved in implementing new or revised programs and processes. In fact, the dramatic changes in missions and regulatory environment over the past five years have challenged almost every organization in the complex to implement new or revised programs. Implementation involves a wide array of tools and techniques including**:**

- training
    - policies a/o procedures
- communications
- safety and hazards assessment
- assessments including criteria
- performance baselines
- planning and scheduling
- resources availability
- implementation plans

2. Questions:

Will the policies, guidance and processes associated with the SBMS, including the N&S process, significantly change the management systems now in place that support the implementation activities across the complex?

3. Answer:

Probably Not! However, there will be significant implementation challenges for many organizations which, if not effectively dealt with, will negatively impact meeting the goals of the SBMS. This prediction is based on past experience where many of the most severe criticisms of DOE by its Stakeholders have been associated with "failure to follow through" on programs and improvements emanating from past improvement initiatives.

The following are examples of areas that may require special attention in order to avoid past pitfalls:

- Each set of changes must have a realistic implementation plan that puts into place the outcome and expectations resulting from the N&S process. By "realistic" we mean realistic in time (schedule), realistic in resource identification and acquisition, and realistic in its funding (priority) for accomplishment.

- DOE and its contractors must "follow through" with their work plans and implementation schedules. Once approved, close monitoring and strict change controls must be applied. DOE and its Contractors must be held accountable to follow the plans unless formal change control has been exercised. A number of people have concluded that, unless the SBMS changes can bring predictability and stability to our work environment, we will have missed the mark.

- Implementation actions must be coordinated and integrated within DOE, within the contractor organization, and between DOE and its contractors. Without effective coordination and integration, attempting to make basic and wide ranging changes will result in confusion and dilution that will make things worse rather than better.

- Implementation constraints must be identified and understood from the outset of the process. Based on recent and potential future down sizing and the resulting loss of key

people with process knowledge and years of experience, one can predict that availability of technical and operational experts will impose a very real constraint in the number of and extent of changes/improvements that can be achieved in a given time period. This reality demands, in many cases, that high quality planning, scheduling, and resource loading be used.

- Changes will be required to the management systems for regulatory implementation as new or revised sets of requirements are defined. These changes may involve two levels. The first is straightforward and relates to training for inspectors and DOE regulators on the agreed upon set. The second is more subtle but critical. It involves changes needed to eliminate informal expansion of requirements through ratcheting. In many cases, otherwise appropriate standards have resulted in low value or incorrect application of requirements and restrictions due to regulatory interpretations or personal opinions of internal and external reviewers. Other regulatory agencies have experienced these types of challenges and have succeeded in meeting them (Nuclear audiences will recognize the NRC backfit rule as an example).

- Implementation plans must ensure <u>continuity</u> between existing programs and new or revised requirements defined by the necessary and sufficient set . It is extremely important that safety expectations not become confused during the implementation process. We are guaranteed to fail if we abandon current standards and work practices before we implement a new set.

D. Infrastructure

Introduction:

Every successful enterprise has a corporate infrastructure that supports both the strategic and tactical activities involved in delivery of their products in a manner that meets all regulatory and contractual requirements and customer expectations. This infrastructure typically consists of a variety of management systems and tools that are defined by a "Roles and Responsibilities" policy. So too, the DOE and its contractors must have an effective infrastructure and management systems.

Question:

Does the implementation of a Standards Based Management System, including the Necessary and Sufficient Closure Process mean that a major revolution is required in the infrastructure and management systems of DOE and its Contractors?

Answer:

No. However, any business undergoing substantial change, including changes in mission, customer expectations, or regulatory environment, must continuously evaluate its infrastructure and management systems to ensure that all business equations remain balanced. This need is no different for the DOE and its contractors. In fact, DOE management has identified that difficulties in transitioning to Standards Based Safety Management have included infrastructure weaknesses. A few examples of areas where some institutions will need to review and strengthen their management systems include:

1. ***Planning/Scheduling*** - Successful change demands that planning and scheduling be integrated and carried out in a manner that results in predictable, stable and believable action plans. This is particularly true for the processes associated with the necessary and sufficient closure process and other Standards Based Management System actions since progress and quality will often be controlled by the critical availability of technical and operational experts. These people, who are already pressed to meet normal work functions, will be further challenged by their mandatory involvement in the necessary and sufficient closure process and SBMS activities and the predicted additional reductions in work force occasioned by financial pressures. Further, failure to develop realistic integrated plans and schedules coupled with frequent instances of management's failure to "follow through" is a major source of past stakeholder criticisms of the DOE and its Contractors.

2. ***Records Management/Document Control*** - It will not be sufficient to "develop" and "implement" necessary and sufficient requirements unless the implementation includes management systems that maintain configuration control of the requirements and implementing media in a credible and living manner. Many organizations have not yet settled on a cost effective way to meet this need.

3. ***Work Activity Based Business Systems*** - Implementation and continued maintenance of the "Necessary and Sufficient" set of standards demand that business systems, such as contract change control, be responsive to the need for incremental changes, including technical, financial, and schedule. Many of the current business systems are focused or used more for major financial or mission changes and may not support the control of many continuing small issues. Failure to deal with the myriad of small changes is sometimes described as **"death by a thousand duck bites."**

4. ***Roles/Responsibilities/Accountability*** - It is expected that many organizations, as they develop and test their specific protocols for the necessary and sufficient closure process,

will examine and appropriately adjust their Roles and Responsibilities policies. Such changes may include the roles and responsibilities of process participants or the changes in roles and responsibilities of those people or organizations who are responsible for the various management systems that support the Standards Based Management System.

5 . ***Regulatory Interface*** **-** It is reasonable to expect that those areas of infrastructure that implement and support the regulatory process will require adjustment as specific necessary and sufficient sets of standards are identified and placed into the contract. Many feel that inappropriate application of regulatory interpretations (or award fee expectations) result in excessive or low value requirements. Examples of areas needing improvement include training on changes for regulators based on the new necessary and sufficient sets, methods for dealing with differences in interpretation, and formal techniques for imposing new or additional requirements.

6 . ***Other*** **-** There is no attempt here to define a complete list of potential infrastructure issues. One may expect that some organizations or facilities within organizations are better positioned than others based on significant program improvements accomplished over the past several years. For example, many organizations have made significant enhancements in areas such as commitment/action tracking systems, infrastructure for dealing with external stakeholders (Regulatory/Political/Public), training, communications, and developing contemporary planning and scheduling systems. There may be significant opportunity for lessons learned across the complex as adjustments are made.

E. Assessments/Audits (Evaluate Work Performance)

Introduction:

Assessment is a tool to determine if work is performed as expected and to identify opportunities to perform work more efficiently. For assessments to provide value, the expectations or standards for doing work must be clear, appropriate to the activity, and agreed to by people doing the work and performing the assessment. Numerous assessment and audit functions exist throughout the complex. They include audits and assessments within contractor organizations, by DOE field, HQ and regulatory organizations and, in some cases by external bodies. There are numerous examples where this multiplicity of oversight activities are not being fully integrated in approach, purpose or performance expectations. Most organizations have made improvements in some aspects of the assessment function and DOE has in progress a significant initiative to coordinate and consolidate the various DOE oversight activities. However, changing missions and expectations, coupled with downsizing of resources, increases the need that assessments be streamlined and focus on criteria appropriate to the activity.

Question:

Will the N&S process cause improvement in the assessment process or add still another set of criteria against which the work activities will be evaluated?

Answer:

While the implementation of the necessary and sufficient closure process or the resulting set of standards does not directly require changes to the assessment/oversight process, it will provide the tools and highlight the need for alignment of expectations among the various assessment entities. It can make an important contribution to the alignment of standards/expectations to the work activity versus the one-size-fits-all approach. In doing so, the necessary and sufficient sets developed as the common basis of work expectations will help to focus assessments on issues important to the work and associated hazards.

1. Common Basis and Baseline

   Defining a necessary and sufficient set will allow common expectations to be built into work planning, operations, and oversight activities.

   Both internal and external assessment functions must become aligned and rebaselined to the new set of standards through a deliberate transition period.

2. Alignment of Internal and External Assessments

   Assessments/Audits are performed by a variety of internal and external entities. The objectives of these functions vary from internal improvement to regulatory enforcement, but must be common in the elements of performance expectations and performance standards/criteria.

   Internal assessments are performed for efficiency and deficiency improvements and vary from line management reviews to the use of performance indicators and QA/QC information, to internal evaluations independent of those performing the work.

   External assessments vary more widely in purpose because the background and responsibilities of the involved parties are widely dissimilar, ranging from DOE as an owner/regulator, to the DNFSB as external nuclear safety oversight, to the external regulators (EPA, DHEC, etc.) as enforcement entities. The high degree of independence of the external regulators will detract from their full involvement in the identification of necessary and sufficient sets. However, since the necessary portion of the standards will include all mandatory laws and regulations, a properly applied set should be transparent to the legal authorities. External assessment parties should be appropriately brought into the necessary and sufficient closure process early to gain confidence in the process and set.

3. Feedback/Enforcement

   The goal of feedback in a standards-based management system is to make improvements in the work performance or the Standards basis. Unfortunately, inappropriate or inconsistent expectations often lead to non-integrated responses just to make individual findings "go away." Establishing the common, agreed upon, necessary and sufficient sets of requirements and the associated performance measures can greatly focus and improve the efficiency of current, corrective action programs.

F . Integrated Approach to Management

Introduction:

During the past decade of major changes in customer expectations, competition, and regulatory explosion, most major US corporations have repeatedly identified the need for an holistic and integrated approach to management both within their business and between their corporation and their contractors. Many who failed to see and act effectively on this imperative no longer exist.

Question:

Will the current management practices, attitudes, and behavior support the successful implementation of the Necessary and Sufficient Closure Process and an effective Standards Based Management System?

Answer:

In some cases, no. However, the nature and demands of the Necessary and Sufficient Closure Process on the Standards Based Management System should provide a pathway for the changes in management techniques, policy and behavior that have led to major successes in corporate America. *For example, it is reasonable to expect that the necessary and sufficient process will produce drivers to shore up soft areas in current management practices*. However, this driver will only be effective if specific weaknesses are acknowledged and addressed.

A. Areas where needed management improvements have been identified by senior DOE and Contractor Management include:

   - Ownership
   - Management resolve for a standards-based system
   - Communication of performance expectations
   - Incorporation of clear requirements/standards into contracts
   - Reasonable arbitration of differences in interpretation
   - Consistent program direction
   - Integrated strategic planning
   - Delegation of decision making

B. At the bottom line, an effective Necessary and Sufficient Closure Process and Standards Based Management System will only be achieved with significant management integration and teamwork at all levels:

   - Within DOE
   - Within Contractor Organizations
   - Between and Among DOE and Contractor Entities
   - With Stakeholders

G. Conclusion

1. What have we learned?

A. Necessary and Sufficient Closure Process

What it is -- what it is not

The Necessary and Sufficient Closure Process is a critical front end element of the Standards Based Management System.

The Necessary and Sufficient Closure Process focuses first on the work and hazards without initial assumptions of applicability of an arbitrary set of standards.

Performance expectations are established and agreed upon by DOE and its contractors. Determination of the appropriate necessary and sufficient set of standards is made by an integrated team comprised of technical and operational experts and line management who are familiar with the work. This enhances knowledge and ownership of the safety requirements by the line.

The Necessary and Sufficient Closure Process integrity is vital. Failure to be able to defend the process will likely result in failure to defend the results.

The Necessary and Sufficient Closure Process goal must remain focused on the "right stuff" and not on "all the stuff" or the "minimum amount of stuff."

B. Standards Based Safety Management System

We have made a firm commitment to protect the environment and the safety and health of the public and workers.

Neither the Standards Based Management System nor the Necessary and Sufficient Closure Process are new concepts. They are elements of a continuous improvement strategy that builds on our past safety management initiatives.

DOE and Contractor management systems and infrastructure elements must be continuously examined and, where necessary, strengthened to support the Necessary and Sufficient Closure Process and the Standards Based Management System.

All elements of the Standards Based Management System must be supported by an integrated management approach that fosters ownership, teamwork and continuous improvement.

2. Why must you care!

Our world is continuing to change! We will change with it! In this vehicle of change, we can either become better drivers and determine our appropriate destinations or we can remain passengers in a trip to someone else's destination.

3. Closure

Many of you will directly participate in the Standards Based Management System and, in particular, in the Necessary and Sufficient Closure Process. For those who do, the next step is to receive the advanced Necessary and Sufficient Closure Process training which focuses on and practices the process elements. Your management will determine how and when this next step will occur.

I hope this class has given you a better understanding of the Necessary and Sufficient Closure Process and the Standards Based Management System -- and gets you thinking about how you may be involved in supporting it in the future.