Department of Energy
Washington, DC 20585
March 29, 2007

Mr. Matthew Moury
Defense Nuclear Facilities Safety Board
625 Indiana Ave, Suite 700
Washington, D.C. 20004

Dear Mr. Moury:

This letter transmits to you the Department of Energy draft Standard DOE-STD-1189-YR, *Integration of Safety into the Design Process*.

Please forward any comments regarding this draft document by May 30, 2007. If you have any questions, please contact me or David Compton of my staff at (202) 586-3887.

Sincerely,

Mark B. Whitaker, Jr.
Departmental Representative to the
Defense Nuclear Facilities Safety Board
Office of Health, Safety and Security

Enclosure

cc:
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This draft March 2007, prepared by the Office of Nuclear Safety and Environmental Policy, has not been approved and is subject to modification. Project No. SAFT-0108

NOT MEASUREMENT SENSITIVE

DOE-STD-1189-YR
DRAFT

DOE STANDARD

INTEGRATION OF SAFETY INTO THE DESIGN PROCESS

U.S. Department of Energy
Washington, DC 20585

AREA SAFT

PREFACE

The U.S. Department of Energy (DOE) has approved this Standard for use by DOE and its contractors.

This Standard provides the Department's expectations for incorporating safety-in-design into new or major modifications to DOE hazard category 1, 2, and 3 nuclear facilities, the intended purpose of which involves the handling of hazardous materials, both radiological and chemical, in a way that provides adequate protection for the public, workers, and the environment. The Standard implements the safety-in-design philosophies listed in DOE Order 413.3A, *Project Management*, and incorporates the facility safety criteria listed in DOE O 420.1B, *Facility Safety*, as a key foundation for safety-in-design determinations.

The requirements provided in the above DOE Orders and the expectations in this Standard ensure identification of hazards early in the project and the use of an integrated team approach to design safety into the facility. The basic safety-in-design precepts are as follows:

- appropriate and reasonably conservative safety structures, systems, and components are included early in project designs;
- project cost estimates include these structures, systems, and components; and
- project risks associated with the selections are specified for informed risk decision making by the Project Approval Authorities.

A working group of about 25 design and safety experts representing DOE and the Energy Facility Contractors Group (EFCOG) Working Groups on Safety Analysis, Engineering Practices, and Project Management developed this Standard.

The Standard does not instruct designers how to design nor instruct safety personnel how to perform safety analyses. Rather, the Standard provides guidance on how these two disciplines and project management can interface and work together to incorporate safety into design.

Some of the key concepts that the teams have developed and included in the Standard are the following.

- The importance of the Integrated Project Team (IPT), supported by the design contractor, including a Safety Design Integration Team (SDIT). The SDIT comprises both safety and design subject matter experts and is the heart of the safety and design integration effort.
- The development of a Safety Design Strategy (SDS) that provides a roadmap for strategizing how important safety issues will be addressed in the design and in the development of key safety documentation. The SDS should be initiated during the preconceptual design stage and updated and refined through the conceptual design stage. The SDS also becomes part of the Project Execution Plan.
- The development, in the conceptual design stage, of facility-level Design Basis Accidents (DBA) that provide the necessary input to the identification and classification of important safety functions. These classifications (i.e., Safety Class, Safety Significant,

seismic design basis) provide design expectations for safety structures, systems, and components (SSC).

- The development of objective radiological criteria for safety and design classification of SSCs. These criteria relate to public and collocated worker safety design considerations.
- The identification and application of nuclear safety design criteria as provided by DOE O 420.1B and its associated guides.
- The development of guidance for the preparation of a Conceptual Safety Design Report (CSDR), a Preliminary Safety Design Report (PSDR), and the Preliminary Documented Safety Analysis (PDSA). These reports are required by DOE O 413.3A for new or major modifications of DOE hazard category 1, 2, and 3 nuclear facilities. They must be approved by DOE as part of the project approvals to proceed to the next design or construction phase. The intent of these reports and their approval is to ensure that the directions and decisions made regarding project safety are explicitly identified and dealt with in early stages of design. The objective is to reduce the likelihood of costly late reversals of design decisions involving safety.
- The definition of a Risk and Opportunities document that recognizes the risks of proceeding at early stages of design (especially conceptual design) on the basis of incomplete knowledge or assumptions regarding safety issues and the opportunities that may arise during preliminary and final design to reduce costs through alternative or refined design concepts or better knowledge regarding the uncertainties. This document is intended to be input to the Risk Management Plan for a project.

These key elements of the Standard have several intersections and possible overlaps with the series of guides for the implementation of DOE O 413.3A. These guides should also be consulted for more complete information on the associated activities and documents.

Nuclear safety basis documents required by Title 10, Code of Federal Regulations (CFR) Part 830, *Nuclear Safety Management*, Subpart B, *Safety Basis Requirements*, for new projects and major modifications should be developed consistent with the expectations and guidance in this Standard.

SAFETY DESIGN GUIDING PRINCIPLES

1. DOE Order 420.1B, *Facility Safety*, must be utilized and addressed in all design activities. Design teams should be able to clearly articulate strategies in the design that address DOE O 420.1B expectations and include them in the design/safety basis information.
2. Control selection strategy to address hazardous material release events should be based on the following at all stages of design development.
    - Minimization of hazardous materials (material at risk) is the first priority.
    - Safety structures, systems, and components (SSC) are preferred over Administrative Controls.
    - Passive SSCs are preferred over active SSCs.
    - Preventative controls are preferred over mitigative controls.
    - Facility safety SSCs are preferred over personal protective equipment.
    - Controls closest to the hazard may provide protection to the largest population of potential receptors, including workers and the public.
    - Controls that are effective for multiple hazards can be resource effective.
3. Design standards incorporated into the DOE O 420.1B guides are to be followed unless specific exceptions are taken to the codes listed and approved by DOE.
4. The risk and opportunity analysis must include consideration of the safety-in-design approaches selected to address project contingencies and must include appropriate mitigation strategies for the safety-in-design approaches selected.
5. Early project decisions on a technical approach should be conservative to establish appropriate cost and schedule baselines for the project.
6. The Critical Decision (CD) packages must portray safety-item selections, bases, risks, and opportunities, with proposed mitigation strategies and cost and contingencies, to enable informed risk decision making by the project approval authorities regarding the project technical basis and cost.
7. The project team must include appropriate expertise and be established early in the project cycle.
8. Safety personnel must be used from the onset of project planning to help ensure that appropriate hazards and techniques for hazard management are considered (e.g., material-at-risk [MAR] limitation, prevention techniques, and operationally effective design solutions).
9. Important safety functions, including facility building confinement, confinement ventilation approach and systems, fire protection strategies and systems, security requirements, life-safety considerations, emergency power systems, and associated seismic design criteria should be addressed as early as possible in the project.

10. Details may not be available in early project stages to identify all hazards and needed safety controls. The safety design team should strive to ensure sufficient process definition is available, particularly at the conceptual and preliminary design stages, to enable major safety cost drivers to be included in the design documentations along with their associated safety functions and design criteria. The team should also identify the risks and opportunities associated with the selections identified and should develop mitigation strategies that are included in the cost-estimate contingencies.
11. All stakeholders are important to the process. Stakeholder issues should be identified early and resolved.
12. The project is expected to evolve over time, and the project safety basis and design basis are also expected to evolve. The expectation is that within this evolution process, unanticipated issues will be minimized.
13. To ensure that the project/facility configuration can be managed appropriately, the basis for decisions related to safety should be clearly documented. This includes decisions related to controls selection, MAR, process options, inputs, assumptions, and similar decisions. Documentation allows later decisions to modify the design or safety basis to be based on knowledge of the original decision rather than on current understanding of the issue, only.

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ABBREVIATIONS AND ACRONYMS

AEGL	Acute Exposure Guideline Level
AHJ	Authority Having Jurisdiction
ALARA	As Low as Reasonably Achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
ARF	Airborne Release Fraction
ARR	Airborne Release Rate
ASME	American Society of Mechanical Engineers
BOD	Basis of Design
BPV	Boiler and Pressure Vessel Code
CD	Critical Decision
CDR	Conceptual Design Report
CFR	Code of Federal Regulation
CIPT	Contractor Integrated Project Team
COA	Condition of Approval
CSDR	Conceptual Safety Design Report
CSE	Criticality Safety Evaluation
CSP	Criticality Safety Program
CX	Categorical Exclusion
DA	Design Authority
DBA	Design Basis Accident
DBT	Design Basis Threat
DCF	Dose Conversion Factor
DID	Defense-in-Depth
DNFSB	Defense Nuclear Facilities Safety Board
DOE	U.S. Department of Energy
DR	Damage Ratio
DSA	Documented Safety Analysis
EEGL	Emergency Exposure Guidance Level
EMP	Emergency Management Program
EPA	U.S. Environmental Protection Agency

EPHA	Emergency Preparedness Hazard Assessment
ERPG	Emergency Response Planning Guideline
FONSI	Finding of No Significant Impact
FHA	Fire Hazard Analysis
FMEA	Failure Modes and Effects Analysis
FW	Facility Worker
GFE	Government Furnished Equipment
HA	Hazards Analysis
HASP	Health and Safety Plan
HAZOP	Hazard and Operability Analysis
HCN	Health Code Number
HEPA	High Efficiency Particulate Air
HPR	Highly Protected Risk
IPT	Integrated Project Team
ISM	Integrated Safety Management
ITS	Important To Safety
MAR	Material-at-Risk
MC&A	Material Control and Accountability
NCS	Nuclear Criticality Safety
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NPH	Natural Phenomena Hazard
OECM	Office of Engineering and Construction Management
OMB	Office of Management and Budget
ORR	Operational Readiness Review
OSHA	Occupational Safety and Health Administration
P&ID	Piping and Instrumentation Diagram
PC	Performance Category
PDSA	Preliminary Documented Safety Analysis
PEP	Project Execution Plan

PFD	Process Flow Diagram
PHA	Preliminary Hazards Analysis
PrHA	Process Hazards Analysis
PSDR	Preliminary Safety Design Report
QA	Quality Assurance
RF	Respirable Fraction
ROD	Record of Decision
RMP	Risk Management Plan
SAC	Specific Administrative Control
SC	Safety Class
SCAPA	Subcommittee on Consequence Assessment and Protective Actions
SDIT	safety-in-design Integration Team
SDC	Seismic Design Criteria
SDS	Safety Design Strategy
SE	System Engineer
SER	Safety Evaluation Report
SME	Subject Matter Expert
SMP	Safety Management Program
SNM	Special Nuclear Material
SPEGL	Short-Term Public Emergency Guidance Level
SRI	Safeguards Requirements Identification
SRID	Standards and Requirements Identification Document
SS	Safety Significant
SSC	Structure, System, and Component
STD	Standard
SVR	Safety Validation Report
TEDE	Total Effective Dose Equivalent
TEEL	Temporary Emergency Exposure Limit
TPQ	Threshold Planning Quantity
TSR	Technical Safety Requirements
USQ	Unreviewed Safety Question

DEFINITIONS

Conceptual Safety Design Report (CSDR) – This document, approved by DOE in a Safety Validation Report (SVR), documents the preliminary safety positions adopted during conceptual design and demonstrates that they form a reasonably conservative basis to proceed to preliminary design. The preliminary hazards analysis, the sufficiency of the control suites selected, approaches being taken for the DOE O 420.1B design criteria applicable to the project, and a summary of the key risks and opportunities of the strategies selected are examples of items discussed in the CSDR.

Documented Safety Analysis (DSA) – The document that describes (along with the Technical Safety Requirements document) the safety basis for hazard category 1, 2, and 3 DOE nuclear facilities required by 10 CFR 830, Subpart B.

Integrated Project Team (IPT) – A multi-disciplined team that is formed to facilitate decision making at all phases of a project's life cycle. Team membership will change as the project evolves, and subgroups to the IPT may be chartered for specific tasks or deliverables. The IPT may be composed of both Federal and contractor (or subcontractor) personnel, and it will support and report to the Federal Project Director. For complex or hazardous projects, a subordinate contractor IPT may be formed to support the Federal IPT and Project Director.

Preliminary Documented Safety Analysis Report (PDSA) – For new nuclear facilities and major modifications, this is the principal safety basis for the DOE decision to authorize design, procurement, construction, and pre-operational testing. The PDSA is required by 10 CFR 830.206 and may need updating to sustain the reliability of the information therein, until such time as it is superseded by a DSA.

Preliminary Hazards Analysis (PHA) – This document provides a broad hazard-screening tool that includes a review of the types of operations that will be performed in the proposed facility and identifies the hazards associated with these types of operations and facilities. The results of the PHA are used to determine the need for additional, more detailed analysis; serve as a precursor where further analysis is deemed necessary; and serve as a baseline hazard analysis when further analysis is not indicated. The PHA is most applicable in the conceptual design stage, but it is also useful for existing facilities and equipment that have not had an adequate baseline hazard analysis.

Preliminary Safety Design Report (PSDR) – This document is developed during Preliminary Design and updates and provides additional site and design details to those provided in the CSDR. The PSDR follows the format and content of the PDSA produced during final design.

Process Hazards Analysis (PrHA) – This analysis supports the PDSA development during Preliminary and Final Design and identifies the types and magnitudes of hazards that are anticipated in the facility.

Safety Design Strategy (SDS) – The SDS provides details to support the safety basis initial development during conceptual design and documents all applicable safety-in-design

expectations for the early project phases. It should be included in, or be referenced from the Project Execution Plan.

Safety-in-Design – The process of identifying and incorporating appropriate structures, systems, and components (SSC) and their associated safety functions and design criteria into the project design and cost estimates to provide adequate protection for workers and the public.

Safety-in-Design Integration Team (SDIT) – This team, when established, is a component of either the Federal or the Contractor Integrated Project Team (IPT) to ensure the integration of safety into the design process. The composition of the team is adjusted as necessary to ensure the proper technical representation commensurate with the analyzed hazards and the specific project phase. The SDIT ultimately supports decisions to be made by the Federal Project Director.

Safety Validation Report (SVR) – The report prepared by DOE that documents DOE review and approval of the Conceptual Safety Design Report and the Preliminary Safety Design Report.

Safety Evaluation Report (SER) – The report prepared by DOE that documents DOE review and approval of the Preliminary Documented Safety Analysis and the Documented Safety Analysis.

1.0 INTRODUCTION

1.1 Background

Federal program and project managers are accountable for the planning, programming, budgeting, and acquisition of capital assets. The principal DOE goal is to deliver capital assets on schedule, within budget, and fully capable of meeting mission performance and environment, safety, and health standards. DOE Federal program and project managers are responsible for managing capital asset projects with integrity and in compliance with applicable laws and contractual provisions. Major DOE objectives include obtaining quality products, ensuring timeliness of performance, controlling cost, and preventing or mitigating adverse events. To achieve these goals, Federal program and project managers assemble an integrated team that includes other DOE functional areas, such as budget, financial, legal, safety, and contracting, to assist them with the planning, programming, budgeting, and acquisition of capital assets.

DOE Order 413.3A, *Program and Project Management for the Acquisition of Capital Assets*, was developed to implement the DOE acquisition policy and Office of Management and Budget (OMB) Circulars[1] regarding planning, budgeting, and acquisition of capital assets; management accountability and control; financial management; and management of Federal information resources. The process, described in the Order and associated DOE directives and guidance[2] and implemented by DOE organizational elements, is referred to as the DOE Acquisition Management System.

A fundamental element that is necessary to achieve the DOE goal for capital asset acquisition is the integration of safety throughout the DOE Acquisition Management System. This Standard supports the DOE objective by providing guidance on those actions and processes important for integrating safety into the acquisition process for DOE hazard category 1, 2, and 3 nuclear facilities. Integrating safety into design is more than just developing safety documents that are accepted by the design function and organization: it requires that safety be understood by and integrated into all functions and processes of the project. Therefore, this Standard identifies organizational needs, interfaces, methodologies, and documentation strategies that might support proper integration. In addition, the Standard provides format and content guidance for the development of safety documentation required by DOE O 413.3A (or successor document)[3] and 10 CFR Part 830, *DOE Nuclear Safety Management Rule*. These required documents include the Conceptual Safety Design Report (CSDR), Preliminary Safety Design Report (PSDR), and Preliminary Documented Safety Analysis (PDSA). The Standard provides information and the

[1] OMB Circulars A-11 (Part 3), A-123, A-127, and A-130.
[2] The DOE Office of Engineering and Construction Management (OECM) also publishes Project Management Practices that are available on the OECM web page: oecm.energy.gov.
[3] The application and use of any revision to DOE O 413.3A will be determined by DOE for any ongoing project.

methodology for identifying and analyzing hazards, selecting and classifying appropriate safety systems and controls, and integrating safety personnel at pertinent phases of project initiation, definition, and execution.

1.2 Applicability

This Standard applies to the design and construction of the following:

- new DOE hazard category 1, 2, and 3 nuclear facilities;
- major modifications to DOE hazard category 1, 2, and 3 nuclear facilities (as defined by 10 CFR Part 830); and
- other modifications to DOE hazard category 1, 2, and 3 nuclear facilities managed under the requirements of DOE O 413.3A.

The activities and processes in this Standard may be applied to new facilities and to modifications to those facilities not listed above.

DOE O 413.3A (or successor document) fundamentally establishes the roles, responsibilities, and requirements for the Department in the DOE Acquisition Management System. The tasks, deliverables, and suggested tools in this Standard are primarily for DOE contractors, unless they are specifically identified as DOE actions.

1.3 Purpose

This Standard provides guidance on activities, processes, and methodologies by which safety considerations can be integrated into the early design activities for the facilities or projects defined in Section 1.2. DOE intends for this Standard to be implemented and complied with for its complex and hazardous nuclear projects. As such, it should be included in contract terms and conditions or otherwise formally directed to contractors.

1.4 Must and Should

The verbs "*must*" and "*should*" are used throughout this Standard. If this Standard is listed as a contract requirement, or otherwise directed by DOE for a facility or project, the DOE contractor or other organization required to meet this Standard *must* comply with all of the applicable provisions that include the word "*must*." Provisions that use the word "*should*" are not required but they are recommended, particularly for complex or hazardous activities.

1.5 Supplementary Guidance Documents

Office of Engineering and Construction Management (OECM) guidance documents

and other appropriate guides developed in support of DOE O 413.3A should be referred to and used in conjunction with this Standard to enhance safety integration into project management processes and decisions.

2.0 PROJECT INTEGRATION AND PLANNING

DOE O 413.3A, Section 5k (5), requires the DOE Federal Project Director to form an Integrated Project Team (IPT). Subgroups to the IPT may be chartered during the project, including a Contractor Integrated Project Team (CIPT) led by the Project Manager, as well as subgroups to the IPTs for specific tasks or deliverables. Further information on the roles, responsibilities, and functions of the IPT are provided in the Office of Engineering and Construction Management (OECM) Project Management Practices, *Integrated Project Teams* (see footnote 2).

The Federal Integrated Project Team (IPT) will comprise both DOE Federal staff and contractors, and the contractor Project Manager will be a key member of the Federal IPT. If a Contractor IPT is formed for certain complex or hazardous projects, interfaces between the two IPTs must be established to ensure synchronization of information and reviews for all disciplines and functions essential to the project. The interfaces and interactions necessary for effectively integrating safety into project design are addressed in this Standard. Contractor IPT activities and deliverables support the Federal IPT and project decisions that must be made by DOE.

Similar to the roles and functions of the Federal IPT, safety-in-design roles and functions for each project should be specifically tailored for that project. For complex or hazardous projects, the contractor should establish a Safety-in-Design Integration Team (SDIT). The SDIT would be the safety team support for the CIPT, if a CIPT is established, and would also be the key safety interface with the Federal IPT. For small or less-complex projects with a straightforward safety strategy, an SDIT may not be required, and any contractor safety input for design would go directly to the CIPT or Federal IPT through appropriate subject matter experts (SME). If an SDIT is formed, it should implement the Safety Design Strategy (SDS). The SDS and SDIT are discussed in sections 2.2 and 2.3.

DOE Order 413.3A requires the appointment of a Federal Project Director (FPD) and formation of an Integrated Project Team (IPT) during the conceptual design phase. Based on the documentation required at CD-1, such as an acquisition strategy, project execution plan (PEP), a design review, and preparation of a Conceptual Safety Design Report (CSDR), appointment of a FPD, formation of an IPT and the SDIT should be among the first orders of business as soon as mission need is approved (CD-0), if not before.

2.1 Contractor Integrated Project Team

A CIPT may be formally established for complex or hazardous projects, with the Contractor Project Manager serving as the team leader.[4] If established, the CIPT

[4] It is recommended that a CIPT be considered for all hazard category 1 and 2 nuclear projects. If a Federal IPT is collocated with the contractor project team and has an active direct and dedicated management role for the project, a CIPT may not be warranted. The intent is to form a dedicated IPT, ultimately reporting to and supporting the Federal Project Director, that will have active day-to-day roles and responsibilities on complex nuclear projects.

provides the overarching contractor focal point specifically charged with executing a project through interactions with and support to the IPT and Federal Project Director. As the team members are representative of all competencies that influence or affect the execution of the project, the CIPT provides an important initial forum where project issues can be openly discussed and resolved. As a project progresses from initiation to transition/closeout completion, the CIPT membership may change to incorporate the necessary skills and expertise required. Although a core team is expected to provide direct support to the project, team membership may be either full-time or part-time, depending on the scope and complexity of the project.

The contractor safety lead should be a member of the CIPT and should be responsible for representing all safety issues before the team and for ensuring that project issues are appropriately shared with the SDIT.

2.2 Safety-in-Design Integration Team

If established, the SDIT should include the key members of the contractor project team who implement safety-in-design for the project. The SDIT is expected to be a dynamic organization that will be made up of a limited core team comprising safety, design, and operations personnel, as well as subject matter experts (SME), who will come together for short or extended periods of time to accomplish a task. Often these task-specific teams may consist of the same people each time, but they will have a targeted responsibility that requires their time and attention away from their normal activities. For example, the SDIT will be quite active, and the membership will increase while performing a hazard analysis. As noted previously, the CIPT may fulfill the role of the core SDIT for small projects or projects with a simple, straightforward safety strategy.

Team composition is critical for the SDIT to be successful. A multi-disciplinary team is needed to identify and analyze the hazards in the facility and to ensure that the designed controls:

- are adequate to perform the safety function;
- do not create an undue burden on operations;
- can be designed to fulfill the safety function; and
- fit within the project cost and schedule.

Although the appropriate team composition will depend on the process or unit operation being developed, it should always include the core team and appropriate supporting specialists. The core SDIT should consist of safety personnel (CIPT safety lead), engineering and design personnel responsible for the process or facility, operations personnel, and the line management design authority (DA) (as well as project management, for a greenfield facility). In addition to the core team, supporting specialists may be included as appropriate from the following areas:

- security (depending on the project, security may need to be a core team member);
- design, including appropriate disciplines -Civil, and Structural, Electrical, Instrumentation, etc. ;
- health physics and radiological protection (shielding, uptakes, or exposure to hazardous materials, etc.);
- safety, accident, or risk analysts with expertise needed by the team;
- criticality safety;
- research and development (process, equipment development specialists);
- process chemistry;
- industrial safety (Occupational Safety and Health Administration [OSHA] issues);
- fire protection;
- emergency preparedness;
- environmental protection and waste management;
- human factors; and
- interfacing system representatives.

The presence of specialists will vary according to the process or unit operation that will be designed or analyzed and with the phase of the project.

Communication within the CIPT and the SDIT is paramount to understanding the major issues and ensuring that the solutions put forward as design or planned operations are appropriate and fully meet the needs of design, construction, project constraints, facility operations, and safety. Timely and effective interactions between the CIPT and the Federal IPT are crucial for mission success.

2.3 Safety Design Strategy

In accordance with DOE O 413.3A, Section 5.k (4), the first formal safety document submittal, a CSDR, is required at Critical Decision-1 (CD-1) for hazard category 1, 2, and 3 nuclear projects. In preparation for this submittal, an SDS should be developed in the earliest stages of the project cycle. The SDS is a tool to guide design, document the safety analysis approach, and establish concurrence on major safety decisions related to project cost and schedule. The SDS provides a single source for project safety policies, philosophies, major safety requirements, and safety goals to guide the design process. Concurrence on these topics with approving authorities, while acknowledging associated risks, establishes a critical baseline for project execution.

As the initial project safety management integration tool, the SDS provides the

preliminary information to gauge the scope of significant hazards and the general strategy for addressing those hazards. The SDS may be included in the Project Execution Plan (PEP) or may be prepared as a separate document referenced in the PEP. An initial SDS should be prepared in support of mission need, CD-0, and updated for each succeeding phase through project completion. Beyond CD-2, much of the information may be reflected in the formal safety documents developed prior to CD-2. However the SDS should lay out the Safety-in-Design elements required for the completion of the project, to assure successful implantation of the decisions made up to that point in the project. For projects that may not follow the traditional project cycle, the SDS provides a vehicle to describe how requirements for safety documentation will be tailored to that particular project approach while satisfying the intent of DOE O 413.3A.

The SDS should address the following three main attributes of safety integration as the project progresses through project planning and execution.

- The guiding philosophies or assumptions to be used to develop the design. This should include significant inputs and assumptions, potential impacts of new technology, and project constraints in the context of their potential for placing key safety design decisions at risk.
- The safety-in-design and safety goal considerations for the project; that is, providing discussions regarding the hazardous materials associated with the facility and preliminary hazard categorization; commitment to DOE O 420.1B and its design requirements; and certain high cost design attributes and approaches relevant to design and project risk. As the project progresses, this should include seismic design criteria; evaluation of potential for offsite impact requiring Safety Class controls, including building confinement and ventilation strategies that encompass the need for active confinement ventilation, emergency power; and fire protection systems. Appendices A, B, C, and D of this Standard provide criteria and guidance for classification of safety systems. Risk management approaches associated with the safety approach should also be described, if relevant and appropriate for the decision-maker.
- The approach to developing the overall safety basis for the project. This will describe such items as the types of analyses to be conducted and documents to be developed through the project cycle. Any tailoring approaches selected for satisfying the DOE O 413.3A requirements for safety documentation should be described. Application of an SDS using existing safety documents created under DOE-STD-3009-94, *Preparation Guide for U.S Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses* or DOE STD-3011-2002, *Guidance for Preparation of Basis for Interim Operation (BIO) Documents*, or DOE-STD-1120-2005, *Integration of Environment, Safety, and Health into Facility Disposition Activities*, could be appropriate for legacy facilities or departmental decontamination and decommissioning activities.

The goal of the SDS is to set the tone for, and maintain the alignment of, the safety basis and design basis during the early evolution of the project. It is not intended to be redundant to or include information that should be contained in other project documentation (e.g., schedules, resource requirements). As the project progresses, it is important that the safety basis documents capture the critical safety elements important to the project at the time of submittal to DOE, with appropriate attention to the safety aspects and potential impacts on future project phases.

The primary focus of the SDS should be goals, assumptions, and criteria to guide design and support the safety basis development during each project phase starting at conceptual design. To ensure appropriate attention and buy-in by project approval authorities, the SDS should contain enough detail to guide design on overarching design criteria, establish major safety structures, systems, and components (SSC), and identify significant project risks associated with the proposed facility relative to safety. Further information and guidance on the SDS, including format and content, are provided in Appendix E.

In accordance with DOE O 413.3A and 10 CFR 830, Subpart B, contractors responsible for the design of DOE hazard category 1, 2, and 3 nuclear facilities must submit the following safety basis documents for DOE approval at the project critical decision points (unless otherwise agreed to).

- CD-1: Conceptual Safety Design Report (CSDR)
- CD-2: Preliminary Safety Design Report (PSDR)
- CD-3: Preliminary Documented Safety Analysis (PDSA)
- CD-4: Documented Safety Analysis (DSA)

Figure 2-1 below depicts the required DOE safety basis approvals at various CD phases and follows an acquisition process in which safety basis documents are linked with typical project baseline and design documents. Other linkages might be applicable for a particular project as agreed to by DOE.

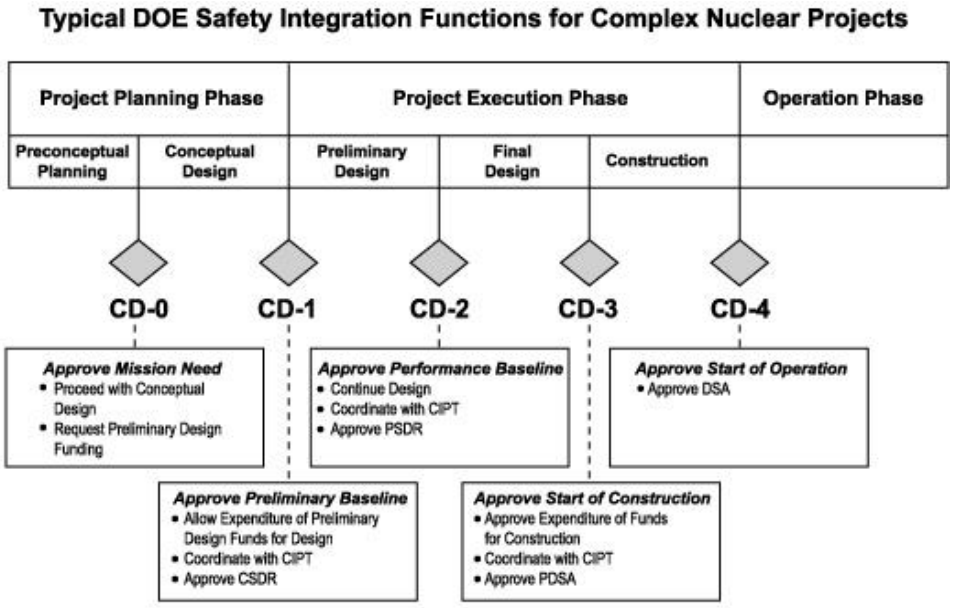

Figure 2-1, Typical DOE Safety Integration Functions for Complex Projects

An SDS should be developed early in project planning and design to identify the required hazards analysis effort and to support the safety basis documents to be developed. For certain projects, safety assumptions and criteria may be known when DOE approves the mission need at CD-0 (e.g., the facility will be a hazard category 2 nuclear facility). These assumptions and criteria will be in the SDS and used for developing the conceptual design and CSDR. The CSDR should identify the safety controls that a bounding analysis may require at CD-1. These controls can be modified based upon additional analysis and a maturing design in the PSDR or PDSA submittals. For new projects that rely on existing designs and process technologies, it may be appropriate to proceed to final design. In these cases, an SDS still should be developed to reach project concurrence and the selected approach.

The SDS is not intended to supplant or duplicate the required safety deliverables. This Standard invokes its specific use only in the preconceptual, conceptual, and preliminary design phases. Revision to the SDS should be focused on maintaining a high level focus at those major safety decisions that influence project cost (e.g., seismic design criteria, confinement ventilation safety functional classification and strategy). As an important baseline agreement document, the SDS can be a useful tool throughout the remainder of the project to maintain concurrence on these key decisions and assumptions.

Modification projects that do not involve a “substantial change to the safety basis” to an existing nuclear facility as defined in 10 CFR 830 are not considered “major

modifications" and do not require a PDSA. These projects are subject to the USQ process. However, these modifications still may be a high-cost capital project and be subject to the acquisition processes in DOE O 413.3A. This Standard and the included safety-in-design approaches may be tailored for these modifications. As previously mentioned, in such cases the basis for determining that the modification is not a major modification and a PDSA is not required should be documented in the PEP or other appropriate project authorization documents. Guidance for determining whether a facility modification involves a "substantial change to the facility safety basis" and is considered to be a "major modification," is provided in detail in Section 9.1.

This Standard anticipates that the eventual safety basis for the facility being constructed or modified is based on the methodology of DOE-STD-3009. If a different safe harbor is applicable to the project or modification, the SDS should establish that expectation, and the format of the PSDR/PDSA as provided in this Standard should be modified as appropriate. However, the expectations for integration of safety into the design process and application of nuclear safety design criteria apply to all projects and modifications within the scope of this Standard.

The required safety documentation for major modification projects, at a minimum, includes an SDS and a PDSA. All modification projects that require a new or revised hazards/accident analysis or require new safety controls must be evaluated using the Major Modification Evaluation Criteria to determine if the modification constitutes a "major modification" and requires a PDSA. This evaluation should be documented in the SDS section of the PEP.

Modifications not requiring a new or revised hazard analysis/accident analysis and new safety controls are considered simple modifications. These modifications need not be subject to the safety integration provisions of this Standard. Modifications that are more complex modifications but not "major modifications," requiring a PDSA, may require some supporting safety documentation (e.g., safety evaluation) and a revision to an existing DSA. For these modifications, the SDS section of the PEP or the Unreviewed Safety Question (USQ) documents should describe the supporting safety documentation and DSA amendment or revision to be prepared and should explain the process to develop and review and approve these documents.

Projects that do not pose significant design challenges with well-characterized hazards and prescribed safety controls may only require a PDSA to document the safety basis.

The SDS should provide supporting documentation on the type and scope of the hazard/accident analysis and safety documents for a project (see Section 2.4.6, "Tailoring").

The SDS is discussed in detail in Appendix J and the SDS role in each project phase is discussed in Chapter 3 of this Standard, along with the safety-in-design activities for that phase. Section 6.4 addresses the change control process that is applicable to safety documentation and design requirements.

2.4 Safety Interface with Project Management

2.4.1 Relationship to Project Management

DOE Order 413.3A governs the execution of most DOE capital asset acquisition projects. The integration of the safety design development and approval processes into the execution cycle for DOE hazard category 1, 2, and 3 nuclear facilities is the focus of this Standard. This section defines how the project management requirements in DOE O 413.3A relate to this Standard. Except for the subsection that identifies requirements herein, no project management requirements are specified in this Standard.

Many projects are executed as "design-bid-build" projects with defined conceptual, preliminary and final design phases. This is the underlying acquisition model presumed in this Standard. However, many projects are executed using different acquisition models and strategies. Accordingly, it is incumbent upon the Federal Project Director and the IPT to examine the provisions in this Standard and apply its processes and guidance appropriately to the project. This appropriate application of the processes, guidance, and methodologies in this Standard to the relevant phases of a project is known as "tailoring." However, the project management requirements of DOE O 413.3A will govern the timing and substance of critical DOE project decisions.

2.4.2 General Expectation

This Standard focuses on establishing the safety design for a nuclear facility in an incrementally progressive way to provide some assurance that the safety basis will be demonstrated to be acceptable when the design is completed. Accordingly, early project decisions on the technical approach should be reasonably conservative in establishing appropriate cost and schedule baselines for the project. The project is expected to evolve over time; the project design and safety basis are also expected to evolve. The expectation is that within this evolution process, unanticipated issues will be minimized.

To ensure that the project/facility configuration can be managed appropriately, the basis for decisions related to safety should be clearly documented. This includes, for example, controls selection; material-at-risk (MAR); process options; inputs; and assumptions. This documentation allows later decisions to modify the design or safety basis based on knowledge of the original decision and not just on the current understanding of the issue.

The overarching philosophy and logic in this Standard is that a heightened degree of conservatism is demanded in the earlier phases of a project when the design details are not available. In this vein, a broader or more conservative set of SSCs that would be designated as safety systems might be provisionally selected for conceptual design than might actually be required when the

design is completed. The degree of conservatism can be relaxed, and, accordingly, the provisional set of SSCs may be refined when justified by evolving information as design progresses. This strategy should minimize the need for significant safety and major cost revisions to the project in later design cycles.

2.4.3 Planning

The project management practices required by DOE Order 413.3A emphasize appropriate planning for the execution of projects. The development and approval of the safety design is an essential element of the project execution cycle that must be planned appropriately. The overall planning for project execution, of which safety is an integral part, is documented and approved in the PEP. Safety planning as defined in this Standard (e.g., the SDS) is subordinate to the PEP. To the extent desired by the IPT, and as specified in the project's tailoring documentation, the SDS and other safety planning documentation may be included within the PEP, or must be included in other required project management or safety documentation as described is subsection 2.4.4 below.

2.4.4 Bundling of Documentation and Tailoring of Requirements

DOE Order 413.3A specifies what safety documentation is required as prerequisites to obtaining specified CDs. This Standard provides guidance on the format and content of the safety documentation. As established in the tailoring strategy for the project, the information and approvals for documentation, as required by this Standard, can be sequenced, organized, and bundled as the project team desires to meet the safety performance measures in this Standard. For example, this option allows the project team to satisfy requirements often associated with separate documents or documents that are produced sequentially to be delivered in a manner that is effective and efficient for project team decisions. This Standard does not specify how a project would be phased or how the project should support its CDs. Instead, it specifies the safety expectations for a project during the project's execution cycle. The mapping of when CDs are sought, what information requirements pertain to the CDs, and how the project will be executed will be specified in the tailoring strategy or, if desired, in the PEP.

2.4.5 Safety Interface Requirements

The following are the requirements for the safety interface.

- In the process of selecting early, design-phase safety SSCs using reasonably conservative principles, it is recognized that project and design progression might cause the SSC designation to evolve. The

impacts on the cost and schedule for any potential change in SSC designation must be captured in the evolving cost and schedule baseline projections for the project, either explicitly (as part of projections for the evolving baseline design) or as an explicit contingency on those projections if they are not included in the baseline design.

- The methods and criteria by which SSCs are designated (either Safety Class, Safety Significant, or defense-in-depth) during project phases must be justified and documented.
- The IPT must include applicable expertise to advise the Federal Project Director on matters relating to nuclear safety. The appropriate expertise of member(s) of the IPT must be certified by a formal DOE process to ensure that the planned resource commitment is appropriate for the project.

2.4.6 Tailoring

DOE O 413.3A allows tailoring of the CD process for projects based on "risk, size, and complexity." The tailoring approach for the CD process is typically described in a "tailoring strategy" or as part of the PEP. Tailoring of the safety basis development steps and documents for a project is also permitted based on the level of risk posed by the facility chemical and radiological hazards, the complexity of the processing operations, and the scope of the hazards analysis required for the project. Tailoring of the safety basis steps and documents is described in Section 2.3. The tailoring approach for safety basis documents should be:

- described in the SDS;
- summarized in the PEP; and
- included in the formal project tailoring strategy, where applicable.

3.0 SAFETY CONSIDERATIONS FOR THE DESIGN PROCESS

This Chapter discusses general concepts for fostering integration of safety considerations into design activities (safety-in-design) during the design stages (preconceptual, conceptual, preliminary, and final).

As a project design progresses, the design team must determine the appropriate safety features to be incorporated into a project and these features must be agreed to by the Integrated Project Team (IPT). The design authority (DA)[5] should strive to identify and reach agreement on these features as early in the process as it is possible and practical to do so. The goal is to make decisions at as early a point as possible, recognizing that as design progresses, these decisions may need to be revisited. In particular it is important that the design decisions be transparent and visible to all stakeholders and that any related issues regarding them are recognized and included in the Risk Management Plan (RMP) as discussed in Appendix F.

The design process for a complex facility is highly interactive and iterative. Equally important in the process is the need for coordination and communication. Coordination and communication among the activities and the individuals performing them is vital to the overall success of these activities. Since the design is evolving as the hazards and safety analyses are performed, it is essential that the IPT and Safety-in-Design Integration Team (SDIT) are aware of the current state of the design at all times and that design staff are current on the status of the hazards/safety analyses work. Mechanisms must be established to ensure these communications.

Failure to incorporate safety considerations early in the design process can result in prohibitively expensive changes later in the design process if they are recognized only at the Preliminary Documented Safety Analysis (PDSA) development stage (during final design). To document safety design features early in the design process, DOE O 413.3A prescribes reports at both the conceptual design phase, in the Conceptual Safety Design Report (CSDR), and the preliminary design phase, in the Preliminary Safety Design Report (PSDR), in addition to the required PDSA. The content and detail of these reports should be tailored to the safety information and maturity of the design as appropriate for the specific project.

This section discusses the safety-in-design considerations and activities to be performed during the initiation (preconceptual planning), conceptual design, preliminary design and final design phases. The section also depicts the typical flow and interrelationships among project management, design development, and safety basis development activities for these four phases. The design process for a specific project may vary considerably commensurate

[5] The design authority is the single organization responsible for establishing and maintaining design requirements, ensuring that design output documents accurately reflect the design basis, and maintaining design control and ultimate technical adequacy of the design process. When facilities or systems are turned over from one organization to another, the design authority may also change. This may occur over a period of time. Procedures should be developed to govern this turnover. However, at any given time, there should be a single, defined authority. See also DOE STD-1073-2003.

with the tailoring of a project. The tailored design process is identified in the Project Execution Plan (PEP), which also evolves with the project activities.

Table 3-1 lists the typical activities and deliverables for the four phases of the project discussed in this Chapter.

Table 3-1, Typical Activities and Deliverables Relating to Safety for the Four Phases of the Project[6]			
Initiation Phase (Preconceptual)	**Conceptual Design Phase**	**Preliminary Design Phase**	**Final Design Phase**
• Mission Needs • Scoping Analysis • Initial Alternatives Analysis • Preconceptual Hazard Analysis • Safety Design Strategy (SDS)	• Requirements Analysis • Alternatives Analysis • Preliminary Hazard Analysis (PHA) • Design Basis Accident (DBA) Analysis • Risk & Opportunity Assessment • Conceptual Design Report (CDR) • Conceptual Safety Design Report (CSDR) • Updated SDS • Safety Validation Report (SVR) • Required Technical Studies • Baseline Range Estimates	• Updated Requirements Analysis • Project Technical Design Requirements • Process Hazards Analysis (PrHA) • Risk & Opportunity Assessment • Project Cost Range • Updated SDS • Preliminary Safety Design Report (PSDR) • Preliminary Design Report (PDR) • Facility Design Description • System Design Descriptions • Updated Required Technical Studies	• Preliminary Documented Safety Analysis (PDSA) • Facility Design Description • System Design Descriptions (SDD) • Updated SDS • Updated Risk and Opportunity Assessment • Documented Safety Analysis (DSA)

3.1. Initiation Phase

Safety-in-design efforts must begin during the initiation phase of the project when preconceptual planning activities occur. The project team must consider the Safety Design Guiding Principles in this Standard in the development of the project requirements to support the Mission Needs package. To ensure these principles are incorporated at this phase, a project safety lead should be designated as early as

[6] Although these activities and deliverables are discussed in this section, the requirements for many of the deliverables are found in regulations and directives outside this Standard.

practical as a key member to be assigned to the IPT when it is formed. The project safety lead will be responsible for providing safety input to guide early project planning consistent with the Guiding Principles.

An initial alternative analysis should be performed during the preconceptual planning phase to determine if a new facility or a modification to an existing facility would best satisfy the mission need. The analyst must have some understanding of the process technology that will be used for the facility to perform this analysis. In some cases, separate alternative analyses may be required to select the best process technology to achieve the facility mission. The material inputs and outputs, together with the process technology options, must be identified to provide the minimum amount of information needed for an initial assessment of the hazards posed by each proposed process. Detailed alternatives analyses will be completed later during the conceptual design phase.

Upper-level facility functions and performance requirements are also developed in this phase. The physical form and quantities of the nuclear materials to be generated and received, and the waste materials to be produced, should be identified. This is important to ensure that the initial material release analyses can provide meaningful information. Generally, a simple process model that shows the material inputs and outputs will satisfy this purpose.

3.2 Conceptual Design Phase

The overall goal for safety-in-design at the conceptual design phase is to provide a conservative safety basis for proceeding with preliminary design. The intent is to perform sufficient analyses to make sound safety decisions during conceptual design and to document any residual safety risks and the associated project cost range and schedule impacts.

A quality assurance program (QAP), compliant with 10 CFR Part 830, Subpart A, should be established early in the project. The QAP should describe the planned quality related activities, surveillances, and assessments and should be developed in the project conceptual phase and updated as the project matures. Section 8.9 of this Standard addresses the QAP in more detail.

The conceptual design phase presents a key opportunity for the safety analysis to influence the design. Figure 3-1 illustrates the interactions of project management, design development, and safety-basis development activities during the conceptual design phase. As can be seen in the figure, there are many activities that rely upon each other and, in some cases, are iterative.

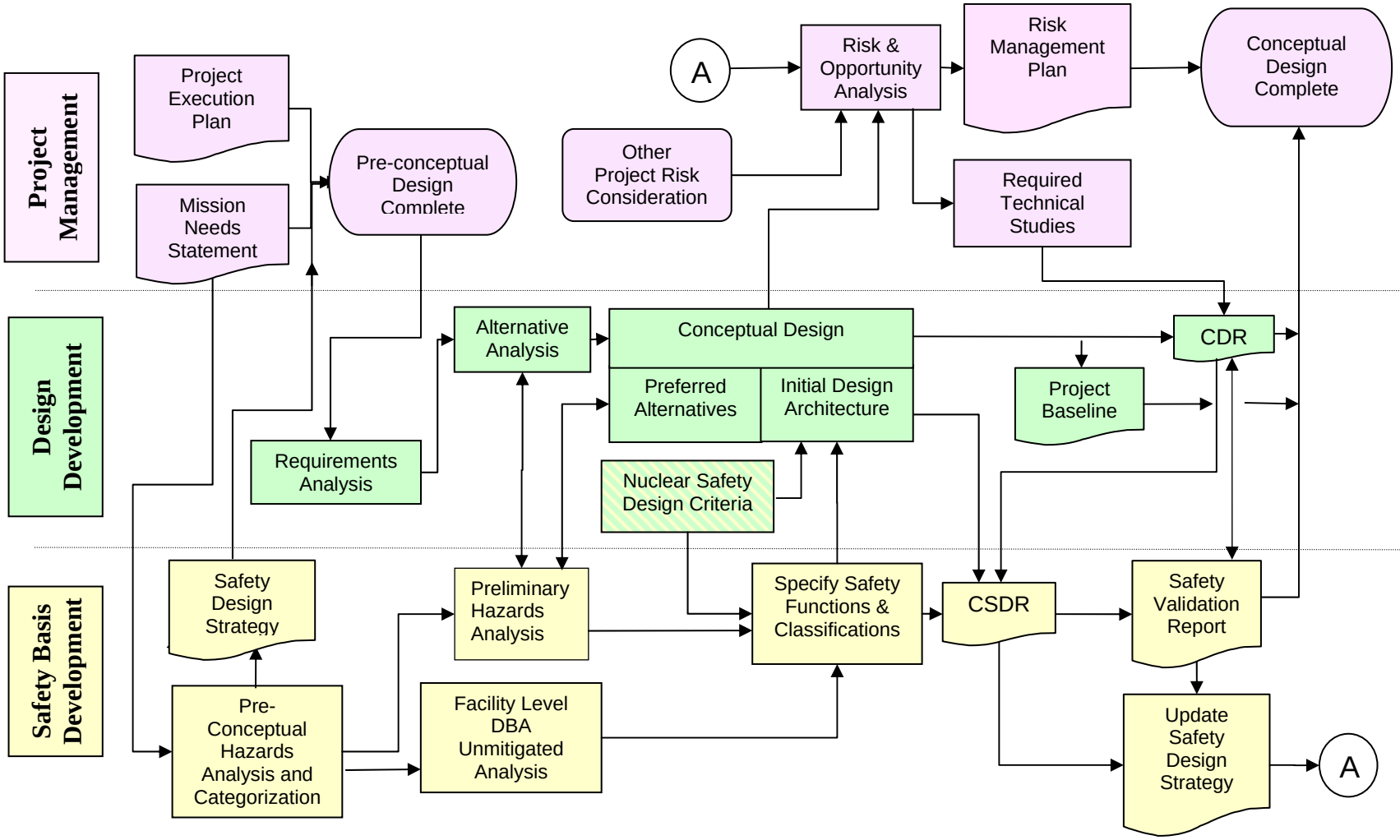

Figure 3-1, Conceptual Design Phase

The earlier in the project life cycle that requirements are identified and defined, the more effectively and efficiently the project will progress through the various phases and will meet project baselines, agreements, and commitments. As a project progresses from identification of the mission need through concept exploration, development, and design, the process of identifying, analyzing, and refining requirements is continual and is always ultimately traceable to specifications and designs. Once approved, the requirements document becomes part of the baseline requirements and is to be controlled through the change control process described in the PEP.

When design requirements are established, alternatives are evaluated to establish a process approach, and facility and equipment arrangements are determined. The configuration alternatives are evaluated against technical, safety, and cost and schedule criteria.

As design requirements are established for each alternative, engineering and safety personnel will begin to identify alternative facility layout and processing configurations. The Safety Design Guiding Principles (see the Preface of this Standard) must be applied to these efforts to ensure that the design requirements and the selection of the preferred processing and facility arrangement alternatives are performed in a way that will result in a safe design. To ensure optimum considerations of the Guiding Principles, a process safety analyst must be involved as part of the IPT and SDIT during the evaluation of the processes for each of the various alternatives.

As the processing approach and facility arrangements are being developed, alternatives are evaluated to select the design architecture; that is, the structures, systems and components (SSC). During the alternative analysis process, the IPT and SDIT must ensure that the relative hazards, as well as the costs and uncertainties associated with the safety controls that may be required to address these hazards, are considered for each alternative. The IPT and SDIT should also consider alternative facility locations that minimize the exposure of the public and collocated workers to facility releases or that minimize the threat of external events associated with nearby facilities.

Once the alternatives have been evaluated and a preferred alternative selected, the design and safety work to identify and describe the SSCs to satisfy the facility performance requirements and to perform the facility processing operations is initiated. The focus of safety work at this point in conceptual design, through the PHA and the facility level DBA Analysis, is to evaluate the SSC design sufficiently to allow a more formal hazards analysis process to begin. This hazard analysis process is described in Chapter 4 and Appendix G.

As a result of the requirements analysis and the alternatives analyses, a general process block flow diagram or description of the process operations based on the selected technology and a general description of the more significant safety controls should be developed for the project.

A Risk and Opportunity Assessment for the conceptual design is used to evaluate the

overall programmatic, technical, and safety basis risks and opportunities associated with the project. The risks include the uncertainties related to the possibility that there may be additional costs and schedule impacts that are not yet identified because the design is still immature. Opportunities refer to the potential opportunities to reduce the costs or improve the schedules as the design matures and to select proposed safety controls or other cost and schedule drivers that are identified as not being necessary after all.

The Risk and Opportunity Assessment is developed using guidance in Appendix F of this Standard, and the results of the assessment provide input to the Risk Management Plan described in DOE M 413.3-1. The Risk and Opportunity Assessment must identify technical issues associated with the chosen safety-in-design strategies that could affect the outcome of the hazards analysis. It is imperative that all pertinent subject matter experts (SME) participate in the risk assessment process to properly portray the level of technical maturity in the conceptual design and develop appropriate mitigation strategies (e.g., safety analysts, criticality analysts, designers, security personnel). Risks and opportunities identified during the hazards analysis process described in Chapter 4 and in Appendix G, "Hazards Analysis Table Development," of this Standard are key inputs to the Risk and Opportunity Assessment.

The results of the Risk and Opportunity Assessment should be considered in the development of the project cost range in the Conceptual Design Report (CDR). The Risk and Opportunity Assessment results should be conservatively applied by enveloping the integrated effects of the risks identified in the estimated cost and schedule baselines identified in the CDR. Such prudent use of the Risk and Opportunity Assessment should ensure that the final or baseline project cost and schedule is within the range estimate established in the CDR.

In determining the overall risks for the project, technical risks must be included along with programmatic risks. The contingency and management reserve cost estimates should be established and maintained based on the technical risks alone and should not be influenced by what is perceived to be an arbitrary permissible cost-estimating ceiling. All risks that impact the safety basis must be specifically considered in the Risk and Opportunity Assessment. Risks associated with safety basis issues should be specifically annotated as such in the Risk and Opportunity Assessment. As required by DOE O 413.3A, risk mitigation strategies must be identified for each risk and documented in the Risk Management Plan.

In the conceptual design phase, the CDR must identify the studies that still need to be completed to verify key safety strategy assumptions, make technology selections, or better understand the process operations or safety implications. These studies may include such items as assumption validation studies, technology selection studies (i.e., trade studies), and design optimization studies for equipment layout options, etc. Studies that could affect the safety basis developed for the conceptual design should be highlighted in the SDS and in the CSDR. In addition, the results of the studies should be included in the baseline range estimates. Corresponding risks associated with possible outcomes of the studies identified should be included in the Risk and

Opportunity Assessment for the Conceptual Design Phase.

The following major safety activities take place during the conceptual design phase.

- The requirements analysis from the preconceptual phase is further developed to include safety functions and SSC requirements and is documented in the project technical requirements documents and in the CDR.
- Alternative design concepts are analyzed and a preferred alternative is selected.
- A Preliminary Hazards Analysis (PHA) is performed to provide the basis for facility preliminary hazard categorization.
- A facility-level DBA Analysis is performed to identify the major facility safety functions needed.
- SSCs and their safety classifications are proposed for the major safety functions. (Appendices A, B, C and D provide guidance on safety classifications.)
- The initial Risk and Opportunities Assessment is developed based on assumptions that may have been necessary and on uncertainties in safety and design considerations. (This assessment is input to the project Risk Management Plan.)
- The CDR is developed to document the final conceptual design architecture.
- The CSDR is developed to document the bases for the safety design aspects of the facility. (Appendix H provides guidance on the development and format and content of a CSDR.)
- Required technical studies necessary to resolve risks and opportunities are identified.
- The initial baseline range estimates are identified.
- DOE reviews the CSDR and prepares a Safety Validation Report (SVR).

3.3 Preliminary Design Phase

Safety-in-design efforts during the preliminary design phase are intended to be incremental rather than a complete reevaluation of the conceptual design. The hazard analysis should evolve from a facility-level analysis to a system-level process hazard analysis as design detail becomes available. As the hazard analysis is refined, some of the conservative selection of controls and classifications developed during the conceptual design phase should be revisited to ensure they are still appropriate.

Decisions made during the preliminary design phase provide the basis for the approach to detailed design and construction. Decisions that are reversed after this phase, for whatever reason, can have significant impacts on overall project cost and schedule. It is essential that contractor and DOE safety personnel are totally engaged

and fully participate in design reviews during this phase, so their views and advice can be considered in the evolving design in a timely fashion.

Figure 3-2 depicts the workflow for the preliminary design phase.

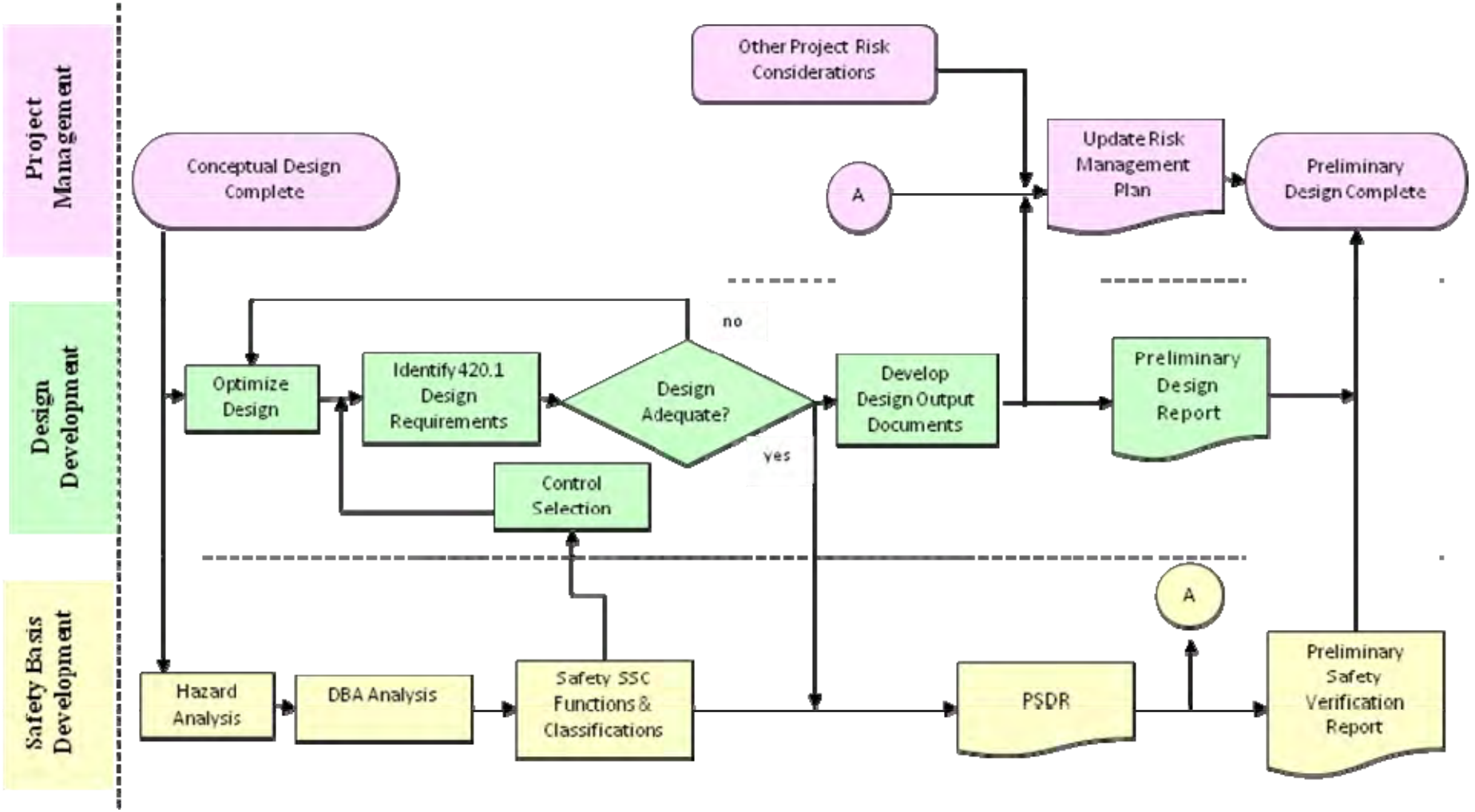

Figure 3-2, Preliminary Design Phase

The project technical design requirements for the preliminary design phase include the technical requirements for the project and embody many of the deliverables indicated in DOE O 413.3A for the preliminary design phase, including the Facility Design Description and the System Design Descriptions. These technical requirements include those derived from the safety analysis.

Because the design is still evolving at this point in the process, adequate safety-in-design for the preliminary design phase is based primarily on identifying viable engineering resolutions to nuclear design requirements and specifying an adequate set of more detailed safety design requirements that are based on safety analyses. During this phase a more complete assessment of safety controls, based on process hazards analyses, should be developed, including those intended for in-facility worker protection. Sections 4.2 and 4.3 of this Standard provide an expanded discussion of hazards analysis, safety control selection, and safety classification of these controls.

The approach for demonstrating how the preliminary design will satisfy the nuclear safety design criteria of DOE O 420.1B or proposed alternative criteria should be developed during this phase if it was not done earlier. Chapter 5 of this Standard provides guidance on the nuclear safety design criteria of DOE O 420.1B.

The Risk and Opportunity Assessment developed in the conceptual design phase must be updated during the preliminary design phase to reflect the results of any technical studies, design modifications, or other developmental work that impacts the risk assessment. The results must be documented in the Risk Management Plan to provide information for the development of the project baseline cost, as described in DOE O 413.3A and its guidance.

Additional information regarding the aspects to be considered in the Risk and Opportunity Assessment is provided in Appendix F, “Safety-in-Design Relationship with the Risk Management Plan.”

Any remaining studies that need to be performed to address specific details in the facility final design must be delineated in the preliminary design phase. These studies may include assumption validation studies, any remaining equipment selection studies (e.g., trade studies), and design optimization studies. Studies that could affect the safety basis developed for the preliminary design should be highlighted in the safety strategy section of the PDR and in the PSDR. Corresponding risks associated with possible outcomes of the studies identified should be included in the updated Risk and Opportunity Assessment.

Safety-in-design documentation also evolves during the preliminary design phase as follows:

- PHA is revised and updated to a PrHA (see Chapter 4 and Appendix G);
- PDSR is developed, building on the information in the CSDR (see Chapter 6);
- SDS is updated to reflect the evolution in the design and safety bases (see Chapter 2 and Appendix E; and
- Risk and Opportunity Assessment is updated and should reflect changes that

were made to take advantage of opportunities or address identified risks (see Appendix F).

By the end of design, the final National Environmental Policy Act (NEPA) documentation must be completed to support the selected site.

3.4 Final Design Phase

The work begun on the design during the preliminary design phase should be completed during the final design phase. During this phase, details for procurement in support of construction activities are developed. Typically about 30 to 40 percent of the design activity is completed during the preliminary design phase and the remainder of the design is completed during the final design phase.

By the final design phase both the preliminary design and the PSDR will have been reviewed and approved. These reviews may prompt changes to the conclusions and approaches taken for safety and design in the preliminary phase. Similarly, evolution of the design from preliminary to final may prompt the design approaches and commitments captured in the PSDR to be revised based on improved knowledge and process optimization.

At the final design phase the safety analyses must encompass the scope of the design and demonstrate that the designated Safety SSCs are adequately designed to reliably perform their intended safety functions. The safety analyses in the final design phase must address the broad range of issues necessary to demonstrate compliance with DOE O 420.1B and its guides; specifically, DOE G 420.1-1, -2, and -3 where applicable. Many of the design criteria are qualitative in nature and require an analysis to show how they are applied to a particular SSC. For system and component design, national codes and standards, in accordance with DOE G 420.1-1, should be adhered to, demonstrating that the design criteria have been met. Compliance with the requirements of these standards will be an important review consideration during acceptance of the safety documentation and during readiness activities in support of the CD-4 milestone.

The following safety activities are typically performed during the final design phase:

- update SDS;
- update of Facility Design Descriptions and System Design Descriptions,
- update Risk and Opportunity Assessment; and
- prepare PDSA.

Appendix I discusses how the PDSA evolves from the PSDR. Both documents have the same format to simplify the evolution process. Figure 3-3 depicts the workflow for the final design phase.

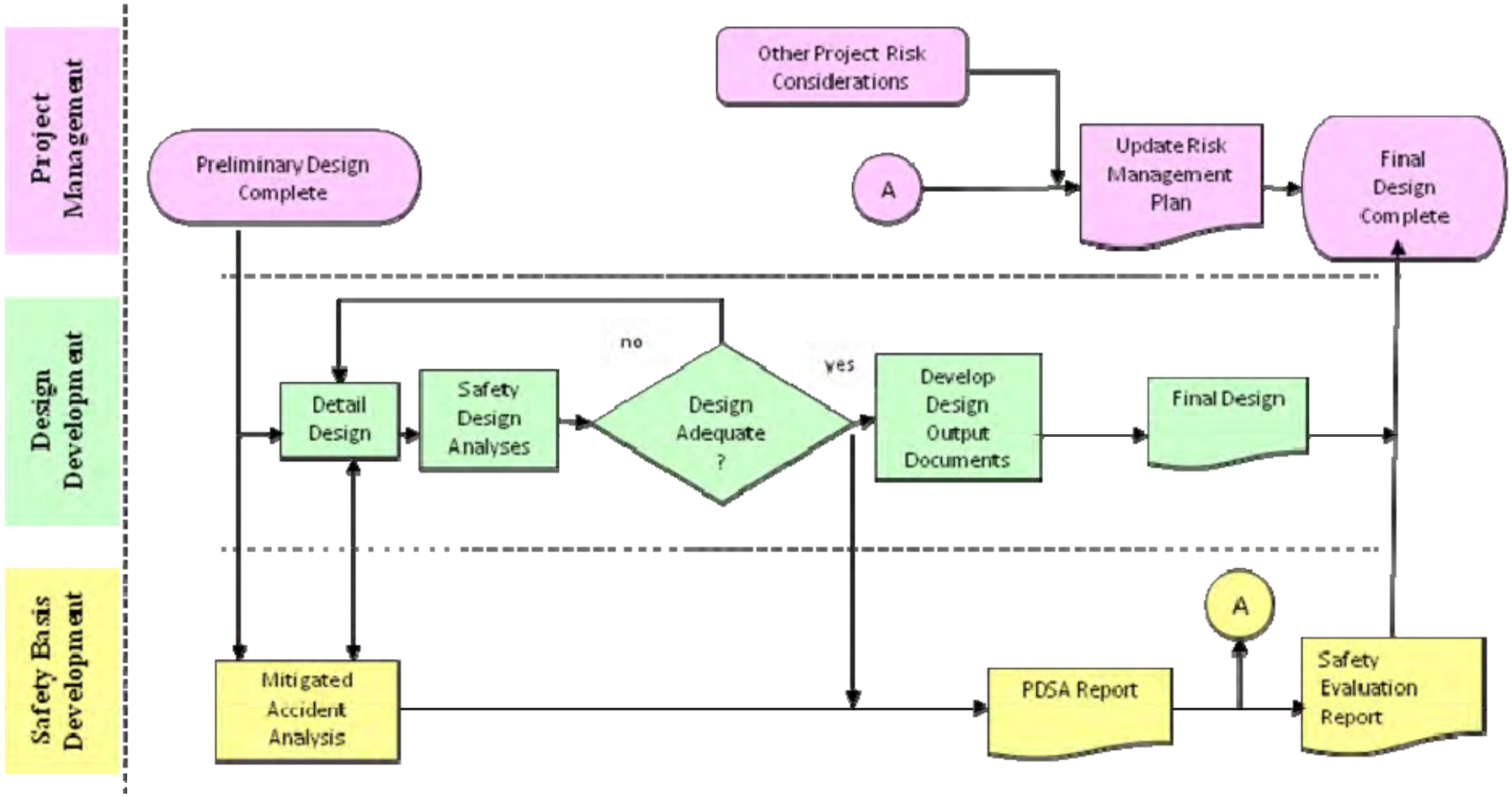

Figure 3-3, Final Design Phase

4.0 Hazard and Accident Analyses

This Chapter provides guidance on hazards and accident analyses as the design process progresses from scoping analyses in preconceptual design to the PHA and DBAs in conceptual design, process hazards analyses in preliminary design, and the related identification of needed safety functions, and the selection and classification of safety SSC).

4.1 Initiation Phase – Preconceptual Planning

A scoping analysis of potential hazards should be performed during the initiation phase (referred to as "preconceptual planning") to plan for the conceptual design phase. The scoping analysis is important for the development of a Safety Design Strategy (SDS).

Scoping hazard analysis during preconceptual planning involves a qualitative assessment of the facility/process risks in conjunction with any facility and initial technology selection alternative reviews performed. During and after the facility and technology selection process, project technical staff, in conjunction with nuclear safety project personnel, should evaluate the need for safety functions and associated safety controls that may be required given the nature of the hazards. The initial determination of safety controls that may be required is based on the qualitative assessment of the facility hazards and a preliminary determination of the approach to be taken to satisfy the defense-in-depth requirements of DOE O 420.1B. At this phase of the project, only the major safety controls that will have a significant influence on the facility design and cost need to be identified. The results of the initial hazards assessment, including a discussion of the overall major safety-in-design strategies, are documented in the SDS commensurate with the level of detail available during preconceptual planning.

4.2 Conceptual Design Phase

A formal, disciplined evaluation of the potential facility hazards must be performed during the conceptual design phase. The design information available at this phase will be limited and may involve several design alternatives, but this effort is needed to perform a preliminary identification of the required safety functions, as well as to identify a preliminary set of Safety SSCs. The hazards analyses performed in this phase include a PHA and identification of events warranting designation as Design Basis Accident Analyses (DBAs).

Early identification of Safety SSCs (particularly those that could have high cost or schedule impacts) is a major contributor to developing an accurate estimate of facility and project costs. The hazards analyses establish the foundation for identifying the Safety SSCs. At the conceptual design stage, this is achieved through hazards identification, hazards evaluation, and identification of major safety functions

necessary to provide adequate protection, primarily for accident conditions. Safety SSCs are then chosen that will satisfy those safety functions for the preferred alternative. Identifying and classifying the Safety SSCs (Safety Class and Safety Significant SSCs) is a fundamental part of the safety-in-design process.

Safety-in-design considerations for defense-in-depth and safety controls needs must be communicated to the design staff as they are identified. Similarly, the Integrated Project Team (IPT) and Safety-in-Design Integration Team (SDIT) must be cognizant of the design concept as it evolves to ensure that safety considerations are factored into each design decision.

Control strategies for DBAs must also be clearly identified in the hazards analysis, including the following:

- required safety functions and classifications;
- SSCs required to perform these functions; and
- Natural phenomena hazard (NPH) performance categories and seismic design bases for major SSCs.

Because preliminary cost and schedule baseline ranges being developed are strongly influenced by the selection of the safety controls (and by NPH design requirements), the hazards analysis process used to arrive at these controls must be thorough and based on sound safety principles. To ensure that the baseline range estimates are conservative, the hazards analysis process and the criteria for selection of Safety SSCs must also be conservative.

After the preliminary process flow diagrams are prepared, the facility design should further evolve before the formal hazards analysis documentation in the PHA is completed. Ideally, the project decisions and design documentation that should be drafted during the conceptual design phase and that are necessary for the formal hazards analyses during the conceptual design phase are as follows:

- facility site/location selection;
- general arrangement drawings;
- MAR estimates or assumptions and material flow balances;
- sizing of major process system containers, tanks, piping, and similar items;
- process block flow diagrams or equivalent documentation of the required major process flow steps and their sequence;
- Preliminary one-line diagrams for ventilation, electrical power and distribution, special mechanical handling, and instrumentation and control system architecture;
- Summary process design description and sequence of major operation; and
- confinement strategy.

Making the decision on the facility location will simplify the analysis process;

however, the hazards analysis might also be a factor in site selection. If the site has not been selected around the time of inception of conceptual design, the analyst must either use bounding conditions or worst case assumptions or must perform a parametric comparison of the hazards involved at each potential facility site location. Such analyses increase the uncertainties in the Risk and Opportunities Analysis.

When the preferred design alternative has been selected, the hazardous material release events should be evaluated more formally in a PHA. Development of the PHA during the conceptual design phase is an iterative process, and the PHA should evolve to include consideration of more refined design details as they become available. A strong PHA developed during this phase is the foundation for an effective safety-in-design approach for the project.

The PHA must be based on the following:

- project decisions and documentation described in this section;
- material-at-risk (MAR) quantities; and
- key project assumptions and strategies identified in the project SDS.

During the conceptual design phase, an objective of hazards analyses is to identify high-cost safety functions and design requirements (including those for NPH protection) for the SSCs that will be included in the project. Examples include the following:

- building structure;
- building and process confinement;
- power systems, including those associated with single failure criteria for Safety Class SSCs;
- fire protection provisions and;
- special mechanical equipment (e.g., gloveboxes)

The PHA must establish a suite of facility DBAs to define the full range of functional and performance requirements for the facility design. This is facilitated by grouping the hazardous release events according to the nature of the postulated release mechanisms. One such grouping is shown below.

- **Fire** Consequences are typically due to inhalation or ingestion of released hazardous material.
- **Explosion** Consequences are typically due to inhalation or ingestion of released hazardous material.
- **Loss of Containment/Confinement** Consequences are typically due to inhalation or ingestion of released hazardous material.
- **Direct Radiological/Chemical Exposure** Consequences are typically due to either routine or accident upset contact with chemical or external radiation exposure.

- **Nuclear Criticality** Consequences typically due to direct external exposure from event with potential for direct exposure from, or inhalation of, fission products.
- **External Hazards** Consequences typically due to inhalation or ingestion of released hazardous material. Depending on specific event, direct exposure may also be applicable.
- **Natural Phenomena Hazards** Consequences typically due to inhalation or ingestion of released hazardous material. Depending on specific event, direct exposure may also be applicable.

The categories of hazardous release events identified in these groupings essentially form the foundation for the facility level DBAs. The DBAs considered in the hazard analysis should represent the range of potential accidents for the facility processes and the results of that analysis should be used to identify the controls needed to protect against these accidents. All credible accident conditions (energy sources, intermediate process hazards, and similar conditions) should be considered.

The DBA analysis should include the accident environmental conditions for which the Safety SSCs must be designed to withstand and perform their safety function. These design basis conditions, together with the bounding consequences of an unmitigated release, provide the basis for selecting Safety Class and Safety Significant SSCs and their functional and performance requirements (See Appendix A , “Safety System Design Criteria” and Appendix B, Chemical Hazard Evaluation).

Once the Safety SSC functions are identified in the PHA (including the set of DBAs), the design team translates them into conceptual designs (e.g., drawings and initial system design descriptions). These conceptual designs are then the basis for cost estimates for the project.

In the conceptual design phase, the hazardous release event evaluations are based on facility-level events and are not a complete listing of all events possible in the facility. The events evaluated should be chosen by the SDIT to ensure that the hazards considered, and the controls selected, provide a reasonably conservative perspective of the high-risk/high-cost design requirements for the project. It is critical that the full SDIT be involved in the development of the PHA to ensure complete consideration of accidents and events, as well as design features to prevent or mitigate releases, to the degree practicable at this phase. (See Chapter 2, “Project Integration and Planning,” for additional details on team involvement expectations.)

Due to the critical nature of the PHA process in defining the MAR release events and associated safety systems, it is important that certain key information is developed and described for each event postulated for use by the project team. Appendix G, “Hazard Analysis Table Development,” provides detailed guidance on what should be discussed for each MAR release event postulated by the IPT.

Although many process details will not be available to perform a detailed PHA during the conceptual design phase high-level events, such as fires, explosions, , deflagrations, and NPH events, should be evaluated commensurate with the available

process definition of MAR locations. From these evaluations, reasonably conservative prevention and mitigation strategies, along with the appropriate functional classifications and safety functional requirements, should be developed.

For those events with consequences that do not lead to selection of Safety Class or Safety Significant Controls, the analysis should also identify the controls that are appropriate for collocated worker and public defense-in-depth protection. Safety controls other than Safety Class or Safety Significant are identified in the conceptual design phase only to the extent necessary to identify cost-dominant SSCs. These controls may be included to meet requirements defined by safety management programs and other administrative programs. Prevention and mitigation strategies must be identified for all events that exceed the threshold criteria of Appendix A of this Standard. Additionally, prevention/mitigation strategies must be identified for chemical hazards. Guidance for chemical hazards is provided in Appendix B of this Standard.

Information from the PHA, as well as any uncertainties related to necessary safety controls, should be considered in the Risk and Opportunity Assessment so that appropriate cost contingencies and mitigation strategies for the items can be presented in the final Conceptual Design Report (CDR) and in the Conceptual Safety Design Report (CSDR).

Project design reviews typically occur during the conceptual design phase. When such reviews are conducted, the results of the PHA should be included in the review. For example, before selecting alternatives, the PHA should identify top-level safety requirements, provide a basis for the classification (some level of unmitigated consequence analysis to help define whether Safety Class SSCs are likely), and identify uncertainties such as those associated with multiple sites.

The events postulated and the safety strategies selected in the PHA provide the foundation for the development of the CSDR. The PHA also provides the foundation for performing the PrHA for future design phases of the project.

4.3 Preliminary Design Phase

Hazard analysis effort during the preliminary design phase includes the following:

- updating the facility hazard categorization (if needed);
- updating the analysis of the DBAs analyzed in conceptual design to confirm the selection of facility-level safety controls and their functional classifications;
- developing a system-level PrHA and selecting and classifying safety controls for the in-facility worker; and
- considering beyond DBA consequences.

The objective for hazard analyses during the preliminary design phase is to confirm and add detail to the conceptual design stage analyses, including developing

functional requirements and performance criteria for Safety SSCs for in-facility worker hazards and identifying Specific Administrative Controls (SAC) (See DOE-STD-1186).

The hazard analysis performed during the preliminary design phase is the system-level PrHA.

Prerequisites for the PrHA include update or development of the following:

- facility general layout drawings;
- Process and Instrumentation Diagrams (P&IDs);
- updated process flow sheets;
- electrical one-line diagrams; and
- updated listing and locations of material at risk

The PrHA should:

- address the spectrum of accidents that may impact design and which may be initiated by facility operations, natural phenomena, and external man-induced events;
- evaluate potential accident consequences to the public and workers;
- estimate likelihood of occurrence of these events; and
- identify and assess associated preventive and mitigative features, including classification (i.e., Safety Class, Safety Significant, and SACs based on the significance of possible consequences.

The results of the PrHA should provide a comprehensive evaluation of the complete facility accident spectra necessary to define the design. This evaluation should be essentially qualitative in that its aim is to produce a well-reasoned and clear assessment of facility hazards and their associated controls. The hazard analysis should consider the accident spectrum, but may not provide a formalized definition of accident sequences and assumptions. The results of the PrHA are documented in the PrHA using the format and content guidance in Appendix G “Hazards Analysis Table Development.”

A graded approach should be used for the PrHA based on the magnitude and complexity of the hazards of the facility. The graded approach should also be used to select techniques for process hazard analysis. The techniques used for hazard evaluation can range from simple checklists or “What-If” analyses to systematic parameter examinations such as Hazard and Operability Analyses (HAZOP). The technique selected need not be more sophisticated or detailed than is necessary to provide a comprehensive examination of the hazards associated with the facility operations. For example, a simple storage operation may be adequately evaluated by a preliminary hazard analysis or a structured What-If analysis. However, for a more complex process facility, the expectation is that more detailed techniques (e.g., HAZOP) would be used.

Safety controls must be identified for scenarios involving hazards that exceed threshold criteria.[7] On the basis of the PrHA and the updated DBA Analyses, a suite of safety controls must be selected and classified as Safety Class, Safety Significant or important to safety in-facility workers, collocated workers, and the public. The DBA analysis also provides accident environmental conditions that Safety SSCs must be designed to withstand and continue to perform their safety function. Accident analyses are inherently graded in terms of the degree of physical modeling and engineering analysis needed to quantify accident consequences. The analysis to determine accident environmental conditions is generally included as part of the design process and may be documented as calculations separate from the safety documentation. Design details for Safety SSCs must be developed that incorporate design requirements derived from the PHA, DBA Analysis, and DOE O 420.1B.

The selected controls must be functionally classified based on the analysis of selected DBAs (where applicable) and on the results of the hazard analysis. The PHA results are reviewed to select bounding scenarios. The hazard analysis should also indicate whether a facility contains significant chemical hazard(s) that necessitate DBA analysis for consideration of SSCs for Safety Significant classification (see Appendix B).

Accident analyses are inherently graded in terms of the degree of physical modeling and engineering analysis needed to quantify accident consequences. An analysis to determine accident environmental conditions is generally included as part of the design process and may be documented as calculations separate from the safety documentation.

The safety basis requirements of 10 CFR 830 require considering the need for analysis of accidents that may be beyond the design basis of the facility to provide a perspective of the residual risk associated with the operation of the facility. It is prudent to examine beyond design basis DBAs at the preliminary design phase to provide insight into the possibility of additional facility features that could prevent or reduce severe beyond DBA consequences. They also serve as the bases for cost-benefit considerations for additional safety design provisions related to these postulated accidents. No lower limit of frequency for examination is provided for beyond DBAs. However, as frequencies become very low, little or no meaningful insight is attained. Beyond DBAs are not expected to be analyzed to the same level of detail as DBAs, and are not evaluated for man-made external events.

4.4 Final Design

During this phase the DBAs are revised to reflect any changes that are design dependent (such as a change in the planned location of a structure resulting in different potential impacts from collocated facilities). In addition, during this phase analyses that support final classification of Safety Significant SSCs and demonstrate

[7] See Appendix A, “Safety System Design Criteria,” and Appendix C, “Facility Worker Hazard Evaluation.”

the adequacy of the control suite (engineered features with necessary SACs) are finalized.

The major new safety analysis activity in this phase is completion of the safety analysis. The completed safety analysis demonstrates the adequacy of the design from the safety prospective. As with the design, it is not necessary to show the progression of the design that led to the final choices, only the final choices and the justification for their adequacy. The Preliminary Documented Safety Analysis (PDSA) guidance in Appendix I discusses how this information is applied to support the completion and documentation of the safety analysis.

The design adequacy of Safety SSCs must be demonstrated for new design projects. This is fundamental to the integration of safety-in-design activities. The burden of proof is on the design agency to demonstrate that the design and functional requirements derived from the safety analysis process are satisfied. At the final design phase, the safety analyses must encompass the scope of the design and demonstrate that the designated Safety SSCs are adequately designed to reliably perform their intended safety functions. The safety analyses in the final design phase must address the broad range of issues necessary to demonstrate compliance with DOE O 420.1B and its guides; specifically, DOE G 420.1-1 and -2, where applicable. Many of the design criteria are qualitative in nature and require an analysis to show how they are applied to a particular SSC. For system and component design, adherence to national codes and standards, in accordance with DOE G 420.1-1, -2, and -3 should be used to demonstrate that the design criteria have been met. Demonstrating compliance with the requirements of these standards will be an important review consideration during acceptance of the safety documentation and during readiness activities in support of the CD-4 milestone.

In the event the requirements of applicable standards were tailored, a justification that demonstrates the adequacy of the final design with the tailored requirements must be documented. A facility System Design Description should be used to capture and maintain such information.[8] As the design progresses, design reviews should be used to validate the selection of criteria, application of codes and standards, deviations, and design output.

To provide a baseline understanding of the adequacy of controls, the accident analysis in the PDSA should describe how the selected controls adequately prevent and mitigate the accidents, including how the controls provide defense-in-depth, if warranted, based on accident frequency and control reliability. The analysis need not be quantitative in either frequency or consequences, but should provide an adequate understanding of the baseline mitigated risk for the facility. The discussion puts the effectiveness of safety controls into accident context and provides the baseline safety analysis for the evaluation of changes, for example, under the Unreviewed Safety Question (USQ) process, as the facility DSA is developed for the transition to operation.

The development of safety design analysis information is important to the design

[8] See DOE STD 3024-98, *Content of System Design Descriptions*.

progression. In many instances, the results will define design requirements for the procurement of safety materials or components. These design requirements represent important quality assurance attributes that must be objectively demonstrated and should be tie to the procurement specifications. For example, a process control system may be selected as a safety system during the safety-design evolution. Once selected, the control system must be demonstrated to be capable of performing its safety function under all postulated process upsets or accidents as credited in the accident analysis.

If the control system is based on pressure instrumentation for some specified system transient, the system must be analyzed to ensure that instrument uncertainty is factored into the system response. If the system must operate following a postulated pipe break in its physical area, the instrumentation must be shown to be able to withstand the pipe break consequences, typically by qualification testing. Calculations are required to define the conditions for such testing. If the control system is deemed Safety Class and required to satisfy single failure criteria, Failure Modes and Effects Analyses (FMEA) or fault trees may be needed to ensure active single failures do not affect system function under postulated system faults ((ISA) S 84.01 *Application of Safety Instrumented Systems for the Process Industries* should be used to demonstrate compliance). If the control system is required to function during and/or following a seismic event, not only must the system and its active components be demonstrated capable of withstanding the acceleration forces, but any SSCs not part of the system must be evaluated to ensure their failure cannot endanger the control system (target-source interaction analysis). For example, instrument uncertainty, environmental qualification parameters, single failure, and seismic target-source interaction, must be considered in the selection of the actual components for installation and these requirements must be translated to the procurement specifications.

Typically the final design concepts necessary to develop the PDSA are completed before the final design phase, but changes may arise during final design that result in the need to revise the PDSA. In those cases where the PDSA may be developed before completion of the final design phase (such as a design-build), the content of the PDSA must be negotiated with DOE to recognize that there may be risks that the commitments and descriptions in the PDSA may change and adequate change controls will need to be established to accommodate this risk. These risks should be documented in the Risk and Opportunity Assessment.

Not all design issues related to safety may be resolved by the final design phase. Consequently, it may be necessary to identify where these issues remain open and describe the safety implications associated with them. This is particularly applicable for equipment, such as government furnished equipment (GFE) that will be procured by others in a later phase of the project. This ultimately translates to a project risk issue as well as a safety issue. These risks should also be documented in the Risk and Opportunity Assessment.

5.0 Nuclear Safety Design Criteria

As discussed in Chapter 4, the results of the Preliminary Hazard Assessment (PHA), the Design Basis Accident (DBA) Analysis and the identification of Safety structures, systems and components (SSC) must be considered in the design process. After the appropriate facility location and processing alternatives have been selected, other safety design requirements and considerations must be specifically addressed during design development. These requirements and considerations are in DOE O 4201.B, Facility Safety, in the following chapters:

- Nuclear and Explosives Safety Design Criteria (Ch. 1),
- Fire Protection (Ch. 2),
- Nuclear Criticality Safety (Ch.3), and
- Natural Phenomena Hazards Mitigation (Ch. 4)

In addition, specific guidance for implementing these requirements is contained in:

- DOE G 420.1-1, Nonreactor Nuclear Safety Design Criteria and Explosive Safety Criteria Guide for use with DOE O 420.1 Facility Safety
- DOE G 420.1-3, Fire Protection and Emergency Services Program
- DOE-STD-3007-2007, Guidelines for Preparing Criticality Safety Programs
- DOE G 420.1-2, Guide for the Mitigation of Natural Phenomena Hazards for DOE Nuclear Facilities and Nonnuclear Facilities

The SDIT should review the Order and its Implementation Guides and their referenced Standards and should compile a listing of the design requirements and associated guidance relative to each of the safety topics addressed in the chapters of the Order listed above (except criticality, if there will be not criticality hazards in the facility).

The Conceptual Safety Design Report (CSDR), Preliminary Safety Design Report (PSDR), Preliminary Documented Safety Analysis (PDSA), and Documented Safety Analysis (DSA) must address to the appropriate degree of design maturity, each of safety design requirements and considerations in DOE O 420.1B (unless an alternate set of requirements has been approved by DOE) and identify the extent to which the design incorporates them. Where the design does not fully satisfy one of these requirements, the rationale must be provided.

Specific SSCs should have been identified in the conceptual design phase. The design codes and standards to be used for the design of the Safety SSCs should have been identified during Preliminary Design. Guidance for mapping between the safety functions and the selected safety SSCs and applicable design codes and standards is provided in the guidance documents listed above for DOE O 420.1B. If the codes and standards chosen for the safety functions and safety SSCs differ from those identified, the rationale for the selection of alternate codes and standards should be provided. The PSDR is generally the first place where a linkage to the specifics of the selection and rationale in a document such as Design Criteria Document. The PSDR should summarize and reference the document where this

information is provided. The PSDR should summarize and reference the document where this information is provided.

Demonstrating compliance with the requirements in DOE O 420.1B generally involves a design analysis or series of analyses. For example, some Safety SSCs are required to be designed to withstand common cause effects and adverse interactions from natural phenomena hazard (NPH) events. The design analyses must demonstrate that those Safety SSCs that are required to function before, during, or after the NPH event will continue to do so. This may entail evaluation of a number of nearby or overhead SSCs that perform no direct safety function. Design documentation to demonstrate this requirement for "source SSCs" may involve design criteria for the facility or system and calculations demonstrating acceptable seismic design. Each applicable analysis for a project should be considered as important technical basis information to be maintained in support of the safety basis for the life of the facility.

In addition to the requirements and guidance discussed previously, for the purposes of preliminary facility hazard categorization (before final design), the use of Type B containers to exclude material at risk (MAR) from the facility inventory must not be depended upon. During final design, safety analyses must demonstrate that containers can withstand all accident conditions in order for the material within to be excluded from the inventory for final hazard categorization.

6.0 Safety Reports

6.1 Safety Input to the Conceptual Design Report

DOE O 413.3A requires a Conceptual Design Report (CDR) to be developed during the conceptual design phase. The CDR is intended to provide the Approval Authority with integrated information sufficient to understand the overall project scope and cost, the risk and opportunities, and the cost range for the selected conceptual design. The CDR for the selected conceptual design must incorporate an effective safety-in-design approach to address potential material-at-risk (MAR) release events.
DOE O 413.3A and its guidance establish the minimum content for the CDR, which summarizes the project requirements and the proposed design solution. The CDR is a necessary element in decision making because it documents the following:

- project design requirements;
- alternatives evaluated and selected for facility and the process configurations;
- design architecture (major structures, systems and components [SSCs]) selected to satisfy the design requirements, consistent with the selected alternatives; and
- safety basis for the proposed design.

Both the CDR and the Conceptual Safety Design Report (CSDR) provide the following:

- risk-informed decision making information for the DOE approval authorities; and
- detailed equipment safety classifications and design requirements, as well as a corresponding cost range that reflects the safety-in-design decisions made during the conceptual design phase.

As the design evolves, changes may affect both the Safety Design Strategy (SDS) and the CDR, and such changes should be reflected in both of these documents. The CDR should provide an integrated discussion of the key results of the hazards analysis including the following:

- facility hazard category determination;
- selected safety functions and controls;
- SSC functional classifications, performance categories, and seismic design criteria for natural phenomena hazard (NPH) protection;
- design criteria for the Safety SSCs; and
- approach to be taken to further develop and document the safety basis through the remaining project phases.

In addition, the SDS must also describe any remaining uncertainties with respect to the safety basis assumptions and selected safety controls and explain how the risks associated with these uncertainties will be managed.

6.2 Conceptual Safety Design Report

DOE O 413.3A requires a CSDR as a part of the approval package for CD-1. The purpose of the CSDR is to summarize the hazards analysis efforts and safety-in-design decisions incorporated into the conceptual design along with any identified project risks associated with the selected strategies. Appendix H provides specific guidance for preparing the CSDR.

DOE must review and approve the CSDR in a Safety Validation Report to confirm that the preliminary safety positions adopted during conceptual design constitute an appropriately conservative basis to proceed to preliminary design. These positions include the following:

- selection of the preliminary hazard categorization (HC-1, 2, or 3) of the facility;
- preliminary identification of facility Design Basis Accidents (DBA);
- assessment (based on the preliminary hazards analyses of DBAs) of the need for Safety Class and Safety Significant facility-level hazards controls;
- preliminary assessment of the appropriate seismic design criteria for the facility; and
- position(s) taken with respect to compliance with the safety design criteria of DOE O 420.1B or any alternate criteria proposed.

6.3 Preliminary Safety Design Report (and PDSA)

The key safety-in-design documents developed during the preliminary design phase are the Preliminary Hazards Analysis (PrHA) and the Preliminary Safety Design Report (PSDR). The format and content of the PSDR is designed to be built upon to produce the Preliminary Documented Safety Analysis (PDSA) during the final design phase. The format and content guidance for the PDSR are provided in Appendix I of this Standard. The PSDR addresses the following safety-in-design aspects for the Preliminary Design Phase.

- Site information of the type that can affect safety-in-design (e.g., location of nearby facilities and external hazards, meteorological information for dispersion analyses, seismic and other natural phenomena information).
- Facility and process descriptions, including facility structure types and layout, process description and flow sheet, and summary system descriptions for safety SSCs, consistent with the level of design.

- Summary of the hazard analysis, including PrHA approach; selected DBAs; selected safety controls and their safety function; functional classification; and required seismic and other natural phenomena design criteria, including their bases.
- For Safety Class and Safety Significant SSCs and Specific Administrative Controls (SAC), the functional requirements and performance criteria (including applicable design requirements from DOE G 420.1-1 and DOE G 420.1-2).
- Information regarding aspects of the preliminary design that are required to support the prevention of inadvertent criticality.
- Roadmap of project documentation addressing design aspects related to the effective implementation of safety management programs.
- Documentation of how the safety design criteria of DOE O 420.1B are met, including any exceptions or alternate approaches. This may include analyses performed to meet the safety analysis expectations.

The PSDR should demonstrate the adequacy of the hazards analyses and the selection and classification of the safety controls, including consideration of the application of the principles associated with the hierarchy of controls. If the commitments made in the PSDR and design documents are met, the result should be a final design and a constructed facility that could be approved for operation without major modifications. The PDSA at the final design stage is an evolution of the PSDR.

6.4 Change Control for Safety Reports as Affected by Safety in Design Activities

A clearly defined project configuration should be established at the conclusion of each phase of the design. DOE-STD-1073-2003, *Configuration Management*, states: "The objective of change control is to maintain consistency among design requirements, the physical configuration, and the related facility documentation, even as changes are made." At the conceptual design stage, change control should be implemented within the design organization to maintain consistency among the various concepts and their supporting documentation. The CSDR issued at the completion of the conceptual design must be under formal contractor configuration control. Critical relationships between safety and the concept that progresses to the final design are established in the CSDR

Change control rigor should increase as the conceptual design evolves to the preliminary design and is documented in a PSDR. The PSDR should reference the CSDR and applicable documentation that supports the preliminary design, and the PSDR and supporting documentation should be under formal contractor configuration control.

As the preliminary design progresses to the final design, the PSDR evolves into the

PDSA with its attendant supporting safety analyses, which have been formalized relative to earlier evaluations. The approved PDSA constitutes the basis upon which DOE agrees that procurement and construction may begin.

PDSA configuration baseline documents should be identified within the project baseline. The PDSA configuration baseline is the basis for determining if PDSA revision is needed, and formally establishing and maintaining the PDSA configuration baseline provides the means to ensure that "the Department can continue to rely on the information in the PDSA."

Not every change in the PDSA configuration baseline will necessitate a PDSA revision. The following criteria are suggested to determine whether a PDSA revision is needed because of post-PDSA approval design changes.

- The change alters a safety function for a Safety SSC identified in the current PDSA.
- The change results in a change in the functional classification, reliability, or rigor of the design standard for an SSC previously specified in the PDSA configuration baseline.
- The change requires implementation of new or changed Safety SSC or proposed Technical Safety Requirement (TSR) controls.
- The change significantly alters the process design or its bases, such as increased material at risk, changes to seismic spectra, major changes to process control software logic, new tanks, new piping, new pumps, or different process chemistry.

As explained in DOE-STD-1073-2003: "The design authority is the single organization responsible for establishing and maintaining the design requirements, ensuring that design output documents accurately reflect the design basis, and maintaining design control and ultimate technical adequacy of the design process."

7.0 TRANSITION/CLOSEOUT PHASE

7.1 Introduction

This Chapter describes those safety-basis-related activities that are accomplished after the final design and Preliminary Documented Safety Analysis (PDSA) are approved and before approval to operate is granted. The primary project activities that occur in this project interval include construction and transition to operations. The primary safety basis activities include preparation of the Documented Safety Analysis (DSA) and Technical Safety Requirements (TSR), review and approval of these by DOE, implementation of the commitments in the DSA and TSR, and verification that those requirements are met before normal operations begin.

7.2 Development of Documented Safety Analysis

Development of the DSA and the TSR begins in this phase. The DSA evolves from the PDSA with the addition of the final analysis of operational hazards and any upset conditions that were not considered previously. Safety Management Programs (SMP) are detailed in this document, and elements of those programs that are needed in process hazards analyses and other upset events are defined in the appropriate hazards analyses. Guidance for development of an operational TSR is contained in DOE G 423.1-1.

The DSA for a new facility documents a design and its associated safety design basis that has been approved by DOE as part of the Conceptual Safety Design Report (CSDR), Preliminary Safety Design Report (PSDR), and PDSA approval process. The DSA documents the approved design, its basis, and any changes that were necessary during the construction phase for future operational reference and review and for approval of annual updates,.

Additional analysis tasks that may be needed to prepare the DSA include evaluation of equipment that was not part of the preliminary and final design, such as government furnished equipment (GFE) or specialty equipment designs that were performed in separate design activities not fully addressed in the PDSA, and detailed operational analysis for those activities that did not need to be considered for development of the design. In addition, hazards analyses that were completed as part of the PDSA must be reviewed to ensure that they remain accurate and changes made as necessary. Note that GFE ideally should be included in the early hazard and accident analysis activities and treated as though it was part of the design. Otherwise the design interfaces and potentially the acceptability of the GFE may not be found in a timely fashion. Then this additional task would be a final check on interfacing facilities or systems that are not under the direct control of the project.

To complete the operational hazards analyses and analyze other upset conditions that were not developed in the PDSA, the hazards analysis process must engage the operations staff. Detailed operational concepts should be developed by the operations

staff in conjunction with the safety analysis efforts and should include GFE that may be used in these operations.

The DSA cannot be completed until there is a high degree of certainty that facility configuration matches the design documentation, safety basis documentation, and the operating procedures for that configuration. Final verification that the DSA information is consistent with the as-built configuration is necessary before sending the DSA and TSR to DOE for approval. A vigorous change control process will help in this regard.

The final development of the DSA and TSR must provide for implementation planning. The initial planning for these activities should be included in the Transition Plan, which should be baselined during preliminary design. The Transition Plan provides the concepts that support when and how many operations staff is brought into the project to support transition and defines (to the extent known at the time) the activities that need to be performed, including those needed to implement the commitments expected to be in the DSA and TSR. Many of the details of activities needed to implement the DSA and TSR are based on limited information available in preliminary design. Consequently, the detailed strategy and activities needed to implement the DSA and TSR must be addressed and compared to the baseline in the Transition Plan such that appropriate adjustments can be made. Additional adjustments may be required based on the DOE Safety Evaluation Report (SER) for the facility operational safety basis and other transition activities.

If not previously approved, a site Unreviewed Safety Question (USQ) procedure must also be prepared and submitted for DOE approval along with the DSA and TSR.

7.3 Checkout/Acceptance, Testing and Commissioning

Early turnover and transition activities include facility walkdowns to identify and correct physical, process, safety, quality, or environmental deficiencies; and planning, preparation, performance, and documentation of equipment and systems testing and operation. Checkout and test planning and preparation typically begin at the equipment (item) level, progress to the system level, and culminate at the facility level. Test planning begins during design to ensure that the physical features needed to support testing are provided. The following subsections identify safety issues that should be considered when performing these tasks.

7.3.1 Checkout/Acceptance

At the end of construction, project personnel verify that the construction is consistent with the design. The contractor, supported by the project organization, performs system checkouts and walkdowns to identify any equipment or installation deficiencies. The team maintains lists of findings and punch lists and initiates documentation to implement corrective actions. Identified corrective actions are tracked through closeout.

The primary safety basis efforts made during this process are to ensure that

the DSA and supporting documentation are consistent with the construction. If the structure and equipment are as described in the safety analysis, nothing more needs to be done. If the equipment is not as described, and changes are needed (some modification needed to meet design requirements or revision of design requirements), the safety basis for the facility, along with supporting documentation, needs to be changed and made consistent using an appropriate change control process.

7.3.2 Testing and Commissioning

The purpose of testing and commissioning is to ensure that the delivery product meets not only the technical specifications (design requirements), but also the functional requirements that the design was to achieve, and to ensure that the safety design commitments were fulfilled.

7.4 Readiness Reviews

Readiness reviews are performed to ensure that contractor programs, equipment, and personnel are ready to safely start up and operate the facility. DOE Order 425.1, *Startup and Restart of DOE Nuclear Facilities*, defines the requirements for conducting either an Operational Readiness Review (ORR) or a Readiness Assessment (RA).

8.0 SAFETY PROGRAM AND OTHER IMPORTANT PROJECT INTERFACES

There are multiple interfaces with required programs and project evolution steps that link with the safety-in-design process. The intent of this Chapter is to highlight the links where these areas, particularly Safety Management Programs (SMP), which are required to be addressed in sections 6 through 17 of the Documented Safety Analysis (DSA), directly interface with the design process; specifically, where they link to the development of safety bases. It is assumed that one has a basic familiarity with the subject matter, and the sections are not intended to provide comprehensive explanation of aspects of that subject matter. Table 8-1 shows the typical activities associated with these SMPs for each project phase.

For new facilities that will be built at existing DOE sites where SMPs have been established, much of the interface with the DSA will be similar to that for existing facilities. Exceptions may occur where new classes of hazards are introduced. For new sites, the development of SMPs must be a focus of management attention early in the project life cycle, and these programs should mature as the facility heads toward operational capability.

8.1 10 CFR 851 Worker Safety and Health Program

The focus of the Worker Safety and Health Program Rule (i.e., 10 CFR 851) is as follows:

- provide a place of employment that is free from recognized hazards that are causing or have the potential to cause death or serious physical harm to workers; and
- ensure that work is performed in accordance with (i) all applicable requirements of this rule; and (ii) with the worker safety and health program for that workplace.

This commitment to providing a workplace that is free of recognized hazards adds a layer of attention to the hazard analysis and facility controls that goes beyond that required for the Preliminary Documented Safety Analysis (PDSA).

The 10 CFR 851 rule requires establishing a worker safety and health program that is approved by the Department. Two required areas of this rule that are of particular relevance to safety-in-design are fire protection and pressure safety. The rule invokes National Fire Protection Association (NFPA) requirements for fire protection and American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel code (BPV). These consensus standards are also typically invoked by DOE G 420.1-1 for safety-significant and safety-class systems and components. These standards represent design input into any new construction and potentially to major modifications.

Applicability of worker safety-related national consensus codes and standards must be recognized at the earliest stages of conceptual design and captured in appropriate requirements documents. As the design evolves into preliminary and detailed design, these codes and standards will drive certain areas of design.

The worker safety and health program should ultimately be reflected in the SMPs of the DSA. Worker safety programs specifically described in the DSA are Hazardous Materials Program, Occupational Safety (which includes fire protection), Emergency Preparedness, Management, Organization, and Industrial Safety Provisions. These areas are discussed in more detail below.

8.2 Emergency Preparedness

Emergency preparedness planning includes identification of hazards and threats, hazard mitigation, development and preparation of emergency plans and procedures, and identification of personnel and resources needed for an effective response. The goal is to identify and evaluate the facility hazards to ultimately develop the Emergency Management Program (EMP) and to develop Chapter 15 of the DSA, "Emergency Preparedness."

Although the EMP includes specific documents and requirements for analyzing hazards unique to this discipline, there is much that can be gained in project integration between the EMP and the hazard analyses conducted for the safety analysis. A complete hazard identification process is needed for the EMP and, ultimately, for the PDSA. Ideally, the hazard analyses should be coordinated at appropriate times between EMP subject matter experts (SME) and hazard analyses performed for the nuclear safety documentation. In addition, there are hardware and related design requirements associated with the detection instrumentation used to guide emergency response measures.

At the early stages in the project, only major hazards are likely to be known. Any potential for exceeding the criteria found in the Occupational Safety and Health Administration (OSHA) requirements of 29 CFR 1910.119 or the threshold quantities given in the Environmental Protection Agency (EPA) requirements of 40 CFR 68 must be considered and identified. Although the hazard analysis process described for the prescribed safety documents will satisfy the requirements of these rules, tripping the threshold quantities invokes a requirement to interface with the public. Project plans must recognize and account for this possibility. In addition to potential emergencies, consideration should be given to subsequent recovery and re-entry needs. Provisions in the design may be appropriate to support recovery and re-entry.

The DSA should ultimately capture a description of the philosophy, objectives, organization, and emergency response of facility emergency preparedness.

8.3 Radiological Protection

Radiological controls to achieve As Low as Reasonably Achievable (ALARA) represent a fundamental design philosophy that is used at the earliest stages of design and which is a requirement of 10 CFR 835. Subpart K of 10 CFR 835 "Design and Control and Facility Design and Modifications," provides key inputs into the design process.

Radiological hazards will generally be considered as candidates for confinement or shielding strategies to minimize worker exposure. These strategies will evolve to design requirements through the project life cycle. In addition, detection or monitoring equipment is generally required to protect workers, the public, and the environment.

8.4 Regulatory External Reviews

The safety documentation development effort must anticipate and prepare for external interfaces and reviews. Periodic reviews are required by DOE project oversight. In addition, external regulatory reviews are conducted by DOE pursuant to nuclear safety rules (i.e., 10 CFR 830, 835). The principal DOE external safety basis regulatory review will be the review and approval of the Conceptual Safety Design Report (CSDR), Preliminary Safety Design Report (PSDR), PDSA, and, of course, the DSA and Technical Safety Requirements (TSR).

The safety documentation development team should initiate periodic coordination meetings with the Federal Safety Basis Review team leader as early in the process as possible; that is, before Critical Decision-1 (CD-1) and shortly after CD-0 is approved. Explicit exchange of Federal review expectations and DOE-STD 1104-96 approval-basis interpretations, as well as PDSA development team internal requirements and guidance, are essential to ensure that safety basis regulatory requirements are understood early in the project and satisfied during project execution.

Periodic formal project reviews, particularly those at the major project approval stages, are required by DOE O 413.3. The safety documentation development team should anticipate supporting these reviews. The team should expect focused reviews on safety functional classification determinations in relation to potential cost drivers for the project.

The Defense Nuclear Facility Safety Board (DNFSB) is an independent oversight agency with purview of nuclear safety at DOE defense nuclear facilities. The DNFSB evaluates the effectiveness of DOE regulatory oversight activities and the safety of defense nuclear facility design, construction, operations, and decommissioning. Various DOE defense nuclear sites have resident DNFSB staff located with the DOE Site Operations Offices. The resident staff can, and typically will, participate in reviews of the project at any stage. Additionally the DNFSB conducts their own review of the proposed facility design, including the safety basis development and construction, when determining the adequacy of project nuclear safety and the effectiveness of DOE oversight.

Other external regulatory reviews made for the purpose of permitting activities are conducted by independent agencies (local, state and Federal) pursuant to environmental regulations such as the Resource Conservation and Recovery Act, Clean Air Act, and Clean Water Act. Typically these permits or site permit modifications must be approved before formally declaring facility readiness. In certain situations, the state may establish limiting criteria on design (e.g., zero release criteria) that may be more limiting on the design and operation than the requirements derived from Safety Basis development.

The DOE National Environmental Policy Act (NEPA) process is a Federal process that the Integrated Project Team (IPT) must support, and which is conducted per 10 CFR 1021. DOE Site and Operations Office NEPA compliance officers must be coordinated before CD-0 to ensure that the NEPA process is fully executed by the IPT Federal project director. NEPA documentation must be developed early as possible in the project acquisition process and must be fully documented by CD-1. Final NEPA documents, including public involvement and resulting Record of Decision (ROD) or Finding of No Significant Impact (FONSI), must be issued prior to CD-2.

The project manager should anticipate and identify all stakeholders that could impact the development of the safety design case. Once identified, regular interaction with these key oversight groups should be planned to minimize unanticipated issues at critical review steps.

8.5 Hazardous Material

Similar to radiological hazards, DOE requirements invoke an ALARA concept for the protection of workers from hazardous materials. Protection strategies will generally involve confinement strategies, such as gloveboxes, piped systems, and tanks, as well as administrative controls. The approach will typically be driven by the magnitude of the hazard and inventory.

Major hazardous materials, typically associated with process requirements, should be identified and considered within the safety strategy. The process design will identify and refine inventory or maximum anticipated quantities to support structure, system, and component (SSC) functional classification. Codes and standards to be applied should be specified for application in detailed design. Provisions for facility monitoring and protection instrumentation for worker protection need to be considered.

DSA Chapter 8, “Hazardous Material Protection,” of the DSA must incorporate the ALARA approach, the elements to provide hazardous material exposure control, and facility protection instrumentation.

8.6 Nuclear Criticality Safety

Nuclear criticality safety (NCS) represents a specialized safety discipline. Given the

significance of an inadvertent nuclear criticality, the presence of quantities of fissionable materials sufficient to sustain a critical reaction can determine the facility hazard categorization. NCS controls can also result in Safety Significant functional classification of SSCs and, potentially, TSR controls. As a result, the NCS function must be represented on the project team and closely linked to the safety analysis effort from the earliest stages of project development. Criticality safety evaluations (CSE) must be integrated with the traditional safety analysis techniques to provide a comprehensive safety analysis. DOE has promulgated guidance for performing and documenting criticality safety evaluations in DOE-STD-3007-2007.

To support design development, it is important to develop fundamental design criteria to address typical criticality safety concerns (e.g., safe geometry) and incorporate these criteria early in the design process. The purpose of these criteria is to avoid the use of cumbersome and inherently less reliable administrative controls. An example set of design criteria is provided in Table 8-2.

One of the most important criticality safety design features is to prevent, by design, natural phenomena initiators for criticality accidents (e.g. seismic and wind). In addition, the fire prevention program at design will also drive criticality safety design requirements. For example, where a fire is credible by DSA standards, and sprinklers planned, the criticality safety evaluations must consider full flooding, depending upon the exact nature of the fire. The presence of sprinklers will also tend to drive engineered controls for criticality safety to prevent water ingress to fissionable material containers, both in process containers and in storage. Therefore, there is a need for close cooperation between fire protection/fire hazards analysis and criticality safety early in design.

Criticality safety includes human interaction with the potential criticality hazard. The double contingency principle requires that “no single credible event or failure can result in a criticality.” Addressing human interaction issues typically results in administrative controls. Minimizing use of administrative controls in lieu of more reliable engineered controls should be a focal point for design. This also points to the need to define an appropriate operating framework (e.g., material types of storage, operations, and methods) early in the project definition phase and the need to maintain that framework.

Designs should strive to make a criticality accident a beyond extremely unlikely event. If that is not practical, the Double Contingency Principle requires control of two independent parameters. Single parameter control must be specifically approved by DOE and typically results in layers of administrative controls. A singular focus of criticality safety in design must be to avoid the need for single parameter control in all processes where a criticality accident is credible.

8.7 Fire Protection

A key interface during the early phases is identifying fire hazards and scenarios that can drive selection of fire protection SSCs (i.e., suppression and detection) to a safety functional classification. Safety fire protection SSCs can represent a significant cost to the overall project and present special interface challenges between fire protection SMEs and safety analysis disciplines. A full understanding of the implications of fire protection selection is necessary to effectively implement such a strategy during detailed design. For example, selecting a confinement ventilation system that uses HEPA filtration necessitates considering potential particulate loading of the filters due to fire scenarios.

Another important facet of fire protection is the code-based requirement for an Authority Having Jurisdiction (AHJ). National Fire Protection Association (NFPA) standards require AHJ review and acceptance of design outputs relevant to fire protection and life safety. Appropriate interfaces with the AHJ must be anticipated and planned.

8.8 Human Factors

In the context of the safety bases development, DOE-STD-3009 defines human factors to consist of the following:

- human factors engineering that focuses on designing facilities, systems, equipment, and tools so they are sensitive to the capabilities, limitations, and needs of humans; and
- human reliability analysis that quantifies the contribution of human error to the facility risk.

These two factors apply to the design in (1) the layout and design of SSCs for operation, construction, maintenance, and testing or surveillance; and (2) in the evaluation of failure probability of human relied upon actions. In some instances, these factors overlap (e.g., control room operator action).

The connection to the safety analysis is in many cases indirect in that, by including this philosophy, inadvertent human errors can be minimized. This is specifically important to ensure that administrative controls can be implemented within the facility.

Within the project life cycle, the human error for facility risk is effectively addressed through the hazards analysis process and industrial or programmatic safety programs that identify other opportunities to avoid error potential. This is a normal part of design evolution and should be factored into the design process as those human factors reviews occur over the life cycle (particularly through preliminary and detailed design stages).

Human factors for design should be established as a design philosophy early in the conceptual design phase. This philosophy should evolve to consider standard human interface issues. Many codes and standards reflect this approach, and it is inherent in the standards. It is also important to include operator input and reviews by maintenance and test personnel to ensure access for maintainability and testability.

8.9 Quality Assurance

The quality assurance (QA) requirements of 10 CFR Part 830 and DOE O 414.1 apply to a DOE nuclear facility and activities. 10 CFR 830.120 defines the scope of the QA rule as follows:

> This subpart [Subpart A of 10 CFR Part 830] establishes quality assurance requirements for contractors conducting activities, including providing items or services, that affect, or may affect, nuclear safety of DOE nuclear facilities.

This wording was specifically chosen to include activities in the design and construction phases before completion of the facility and introduction of nuclear material. That is because the quality of the design and construction is integral to the safe operation of the facility.

Furthermore the inclusion of a robust QA program in the design and construction phases can greatly strengthen the ability to achieve the goals of safety-in-design, namely to identify and correct problems early in the design and construction phases when it is more cost effective to make corrections. With respect to the activities defined in this standard, QA should be viewed as an important tool. The successful completion of many nuclear facilities has occurred simply because of the quick response to QA findings during design and construction.

In particular, the following QA activities can help keep the design process on track:

1. Establishing and using formal work processes such as design reviews, document control, verification processes, and configuration management.
2. Training of design and review staff on applicable standards, requirements, and work processes.
3. Performing periodic assessments of the documentation, including drawing reviews, to ensure that the drawings, design calculations and other documents are in agreement. Key design and construction personnel should be involved in these reviews.

4. Performing independent design verifications, validations, assessments and design outputs by qualified persons to keep design and analysis errors to a minimum.
5. Identifying problems that occur in the design process, determining the root cause and taking timely corrective actions, both immediate and long term.
6. Developing and using approved vendor lists to ensure quality products.
7. Periodically evaluating the approved vendors to ensure their quality has not degraded – and if it has, examining the products already supplied to ensure they are adequate.
8. Controlling documents and drawings, as well as changes to them, to approved processes.
9. Ensuring the quality of safety software used for design activities.
10. Identifying and controlling design interfaces.
11. Periodically meeting with vendors to ensure safety components can in fact be constructed and function consistent with design specifications without unconsidered exceptions.

Ultimately the safety documentation must be validated against approved design outputs. The iterative nature of the safety and design processes demands a more flexible change control process at this stage, but ultimately design outputs must be verified and controlled under the applicable configuration management plan. DOE-STD-1073-2003, *Configuration Management*, Section 3.9, discusses activities to ensure a smooth turnover from design to construction that should be initiated during design.

A quality assurance program (QAP), compliant with 10 CFR Part 830, Subpart A, should be established early in the project. The QAP should describe the planned quality related activities, surveillances, and assessments and should be developed in the project conceptual phase and updated as the project matures.

DOE and commercial nuclear industry QA experience highlight the need to specifically consider:

- Tracking and verification of assumptions from the safety analysis or design to operational acceptance,
- Appropriate translation of inspection and test requirements for installation verification or safety SSCs,
- Use of sub-contractors with recent experience with nuclear QA, and,
- Documentation of safety SSC inspections and tests.

The project Quality Assurance Program (QAP), established in the conceptual design phase, should guide QA activities for the project. Appropriate assessments of the safety analysis process, specifically including the design aspects, should be planned and completed consistent with the project QAP.

8.10 Infrastructure

Infrastructure considerations are critical to a project. It is important to identify infrastructure needs and existing capabilities or constraints as early as practicable in the design process. In this discussion, infrastructure includes all existing facilities and utilities that will interface or that may coexist with the new facility or modification to an existing facility. The infrastructure considerations include, but are not limited to the following:

- supporting utilities (e.g., water, steam, power, industrial gases);
- surrounding or collocated facilities;
- supporting organizations and SMPs; and
- interfacing facility (modifications).

Of particular interest is the identification of any constraints that may hinder project planning and execution. Equipment compatibility (e.g., electrical) constraints can arise when interfaces with an aged infrastructure are possible. Gas systems should be investigated to fully understand interconnections with surrounding facilities and for features relevant to the hazard analysis. Utility interfaces should be identified in both preconceptual and conceptual design. In preliminary design, specific needs should be reconciled with the existing systems capabilities and capacities to support baseline cost estimation.

Surrounding or collocated facilities need to be considered in the early stages of the hazard analysis for conceptual design. Nearby facilities may present hazards (e.g., toxic or explosive gases) that must be considered in the hazard analysis as an external hazard. Provisions may be required within the planned facility to mitigate the effect of such events on personnel within the new facility. A full analysis should be completed in support of the Preliminary Safety Design Report (PSDR).

8.11 Security

Some measure of security must be addressed for most DOE facilities. However, for a limited number of facilities, security drivers for the design and operations are a key consideration for the project. In these limited cases, security requirements can represent a significant cost driver. Security protection schemes may involve one or more of the following: designed structural protection for key resources or materials; adversary deterrence and delay; intrusion detection systems; and protective force resources. Aspects of the security scheme should be coordinated with the design as it relates to safety in a two key areas: (1) structural design and (2) inadvertent or accidental discharge of weapons or weapon systems.

Where significant structural protective measures are warranted (e.g., special nuclear material storage or processing), Natural Phenomena Hazards (NPH) design and

security measures may be used in a complementary manner; that is, major structural components may be designed to serve both functions and result in efficient use of resources. The key factor is obtaining the security requirements early in the project in order to coordinate with the NPH design.

Accidental or unintended discharge of weapons or deterrent systems could present a hazard to workers and the public, and must be addressed for all credible scenarios. These events could be caused by human error, faulty security system design, or internal or external hazards. Moreover, accidental discharges could initiate accidents such as hazardous material releases, fires, nuclear criticality, or damage to safety SSCs or process systems. There is also the potential for common cause effects on security systems that should be considered in the safety analysis. Some accident initiators that could actuate the security system and exacerbate accident consequences include facility events, such as fires, and NPH, such as seismic events.

Given the rapid evolution of security requirements, security modifications in existing facilities could be candidates for consideration as a major modification. In that case, preparation of a PDSA and application of the nuclear safety design criteria of DOE O 420.1, *Facility Safety*, will be required.

As Safeguards and Security has their own independent set of directives that must be implemented and their disciplines often use similar terms, it is important to clearly define the areas for which these two do not interface, as well as areas for which interaction is needed. From the safety-in-design perspective, it is critical to address the interfaces and to clearly define when the protective measures implemented by the security system to meet the applicable requirements must be addressed by safety program measures to assure the safety and health of workers, public, and the environment. Interfaces with Safeguards and Security that are important to the safety case development include the development of the Safeguards Requirements Identification (SRI) and participation in the hazard analysis efforts.

There are no requirements to document security strategies within the DSA. However, security plans and vulnerability assessments are required in the security domain and these documents may be influenced by safety-driven interaction through the process.

8.12 Procedures, Training and Qualification

A systematic approach to operations involves the development of operating procedures based on the design and identified safety controls to operate SSCs within their design and DOE authorized limits through the TSRs. In turn, operators are trained on applicable process and hazard fundamentals, SSC operations and functions, and specific operating procedures. Operators are expected to understand important safety system features and any safety administrative controls, as well as the operator's role in the safety of the facility.

To accomplish this requirement, the results of the safety and design process must be incorporated into the procedures and training programs. This includes nuclear criticality safety derived requirements as well. System operating and test procedure

development should begin in the detailed design phase. System description documents should be used as a tool to capture both operating intent and safety design information for use by the safety analysts and procedure writers. Draft qualification requirements should begin in parallel with detailed design and should be completed early in the construction phase. Training will ensue in the construction phase.

8.13 Radiological and Hazardous Waste Management

Most processing facilities will generate waste. DOE-O-420.1B requires that facility process systems must be designed to minimize waste production and mixing of radioactive and nonradioactive waste. Hazardous waste streams, including types, sources, and quantities should be identified early in the design. Management strategy of these waste streams including treatment and disposal systems must be described in the DSA. Any potential for accidental releases from waste handling and treatment systems should be addressed during the hazard analysis process in the preliminary and detailed design processes.

8.14 System Engineer Program

DOE O 420.1 requires application of a System Engineer (SE) program to "active Safety Class and Safety Significant SSCs as defined in the facility's DOE-approved safety basis, as well as to other active systems that perform important defense-in-depth functions, as designated by facility line management." An objective of the program is to ensure operational readiness of systems within scope. This objective translates into ensuring proper configuration management of the systems and associated documentation and requirements. SE program requirements are also aimed at supporting operations and maintenance.

In preparation for the operational phase, it will be important to identify SEs and involve them in the design and hazard analysis process. Ideally, this should begin in the final design phase so that they may become familiarized with the design in preparation for more direct involvement in the construction phase. SEs should be involved in the planning for and conduct of system testing to allow detailed operational understanding. The SEs should also have a fundamental understanding of the safety function and performance requirements for their assigned system as well as for the associated design and safety documentation. Proper SE preparation will help facilitate a smooth transition to routine operation and maintenance following approval for operations.

Table 8-1, Typical Actions Associated with Project Life Cycle Stages

Actions Authorized by Critical Decision Approval						
Phase / Interface	**Mission Need**	**Conceptual Design**	**Preliminary Design**	**Detailed Design**	**Construction**	**Resource Requirements and Guidance**
Criticality Safety	• Determine criticality potential • Input to Hazard Categorization	• Criticality Control Philosophy • Criticality guidance for Design • DOE Approval of the formal Criticality Safety Program that conforms to DOE O 420.1B	• Preliminary CSEs • Updated criticality safety design requirements	• CSEs • Re-assess criticality limits and controls based on design and operating the process/facility • CSE input to PDSA (Hazard Analysis and TSR derivation)	• Update and issue CSEs • Criticality limits and controls are incorporated into TSRs and operating procedures • Validate NCS controls in field\ • Prepare DSA Ch. 6	• DOE-O-420.1B • DOE-STD-3007-2007 • DOE-G-421.1-1
Fire Protection	• Identify major fire scenarios and special fire considerations for input to likely safety SSC designation	• Develop Preliminary FHA • Separation of SSCs • Life Safety – Egress considerations (approach) • Identify Fire Zones • Preliminary Functional classification • Define design codes and standards	• FHA update • Design Basis Fire defined • Fire barrier design and fire zones finalized • AHJ review of building layout	• FHA update • Support PDSA development	• Final FHA • Program documented in DSA Ch. 11	• DOE-O-420.1B • DOE-O-440.1 • DOE-STD-1066 • 10 CFR 851

Actions Authorized by Critical Decision Approval						
Phase / Interface	**Mission Need**	**Conceptual Design**	**Preliminary Design**	**Detailed Design**	**Construction**	**Resource Requirements and Guidance**
• **Radiological Protection**		• ALARA strategy	• ALARA Review • Preliminary Shielding Analysis (Facility Layout and Material Location and Quantity) • ALARA Considerations in Design • Contamination Control • Zoning	• Final Shielding Analysis • ALARA review • Monitoring (area and personnel)	• Input to DSA Ch. 7	• 10 CFR 835
Hazardous Materials		ALARA strategy	• Toxicological Material Hazards Analysis • Contamination Control • Refine inventories • Codes and Standards defined • Zoning • ALARA review	• ALARA reviews • Codes and Standards Implementation • Monitoring (area and personnel) requirements	• Prepare DSA Ch. 8	• DOE-O-440.1A

Actions Authorized by Critical Decision Approval						
Phase / Interface	**Mission Need**	**Conceptual Design**	**Preliminary Design**	**Detailed Design**	**Construction**	**Resource Requirements and Guidance**
Emergency Preparedness	• Emergency Preparedness Hazard Survey and Screen	• Update Emergency Preparedness Hazard Survey and Screen	• Coordinate hazard evaluations • Preliminary EPHA	• Update EPHA	• EPHA updated and finalized • ERP updated and finalized • DSA Ch. 15 prepared	• 29 CFR 1910.119 • 40 CFR 368 • DOE-O-151.1C
Human Factors		• Define HF strategy and goals	• HF Engineering Plan HF Preliminary Review	• HF Review	• Develop DSA Ch. 13	• DOE-HDBK-1140-2001
Procedures, Training and Qualification				• Identify training and qualification needs • Develop draft operating and maintenance procedures • Define operator qualification requirements	• Complete procedures • Develop and conduct training • Input to DSA Ch. 12	• DOE-STD-1183-2004 • DOE O 5480.20A
Security	• Draft Safeguards Requirements Identification (SRI)	• SRI	• Design reviews	• Design Review	• Security Plans	• DOE-O-470.3[a] • DOE-O-470.4 • New Guide(1)

Actions Authorized by Critical Decision Approval						
Phase / Interface	**Mission Need**	**Conceptual Design**	**Preliminary Design**	**Detailed Design**	**Construction**	**Resource Requirements and Guidance**
Regulators & External Reviewers	• EPA • DNSFB • State Environmental Agency • Project Review • SBS review	• DNFSB • State Environmental Agency • EPA • CSDR Review • Project Review	• DNFSB • PSDR Review • Project Review	• DNFSB • PDSA Review • Project Review	• DNFSB • DSA/TSR Review • ORR	• DOE-O-226.1
QA	• QA strategy	• Update QA Plan • Conduct assessments	• Assessments	• Assessments	• Input to DSA Ch. 14	• 10 CFR 830 • DOE-O-414.1C
System Engineer Program			• Define systems requiring SE	• Identify SEs • SEs participate in Final Design	• SEs support testing	• DOE-O-420.1B
Radiological Protection		• Major shielding requirements • Fundamental Approach defined	• ALARA review	• Final shielding analysis • ALARA reviews	• Prepare DSA Section 8 • Design features tested	• 10 CFR 835
Radiological and Hazardous Waste Management		• Identify major waste streams		• Develop waste handling designs	• Prepare DSA Section 9	• 10 CFR 830 • DOE-O-420.1B • 10 CFR 850

Table 8-2, Example Nuclear Criticality Safety Design Criteria

Attribute	Criteria
Geometrically safe designs	1. Storage tanks, process piping, containers, etc. shall be designed for conservative enrichment or optimal concentration and reflection for all anticipated nuclides. 2. Designs shall be based on worst case fire suppression actuation or local pipe breaks. 3. Leaks from solution areas should be anticipated and flooring designed to be compatible with solutions and provide collection capability (prevent long term migration of fissionable material into sub-flooring materials). 4. Fissionable containing piping shall be spaced to preclude neutron interaction.
Layout processes to support material flow	1. Fissionable solution piping shall be arranged to minimize or eliminate manual transfers. 2. Transfers from safe to non-geometrically safe geometry shall be provided with engineered controls. 3. Avoid any favorable to unfavorable geometry solution transfers. If such must be made, active design features should be installed to mitigate the potential for a criticality accident due to transfer of fissionable solution to an unfavorable geometry vessel.
System design for holdup minimization	1. Employ vertical tanks to facilitate particulate collection and monitoring. 2. Allow methods to facilitate holdup verification/assay. 3. Locate filtration on exhaust systems as close to main processing loop as possible.
Maximize use of passive design features	1. Utilize positive isolation techniques to prevent unmonitored backflow potential (e.g., air breaks). 2. Avoid common ties between fissionable and non-fissionable systems. 3. Designs must eliminate potential for water ingress into fissionable material processes and containers in the event of fire.
Standardize Equipment	1. Storage racks shall be modular and prevent relocation of fissionable material up to the seismic DBA. 2. Gloveboxes shall be designed to address concerns. associated with spills or in-leakage of moderators. 3. All process equipment must withstand the facility seismic DBA.

9.0 ADDITIONAL SAFETY INTEGRATION CONSIDERATIONS FOR PROJECTS

9.1 Integration of Safety into Facility Modifications

The process for integration of safety into the design of facility modifications is similar to that for new facilities, but it is tailored to the scope, magnitude, and complexity of the modification (see Figure 9-1). The degree to which a facility may have to be modified to accommodate new or existing missions may range over a continuous spectrum from minor changes up to those involving the addition or upgrade of multiple safety systems and highly hazardous processes. The latter type of modification may be a capital project and require nearly all of the design phases and processes necessary to design and construct a new facility.

If a facility modification represents a "substantial change to the existing safety basis," it is considered a "major modification"; that is, one in which the design criteria of DOE O 420.1B and its Guides apply to new or upgraded structures, systems, and components (SSC) and for which a Preliminary Documented Safety Analysis (PDSA) is required to support the design process.

The interface of the facility modification with the facility being modified and its ongoing activities presents a challenge. The change control processes of the existing facility must be coordinated with the construction, installation, and testing activities supporting the modification. Frequently, the organization responsible for executing the modification is different from the one operating the facility; therefore, a disciplined process for controlling and coordinating construction activities is necessary.

This Chapter summarizes the integration of safety into the design and execution of facility modifications.

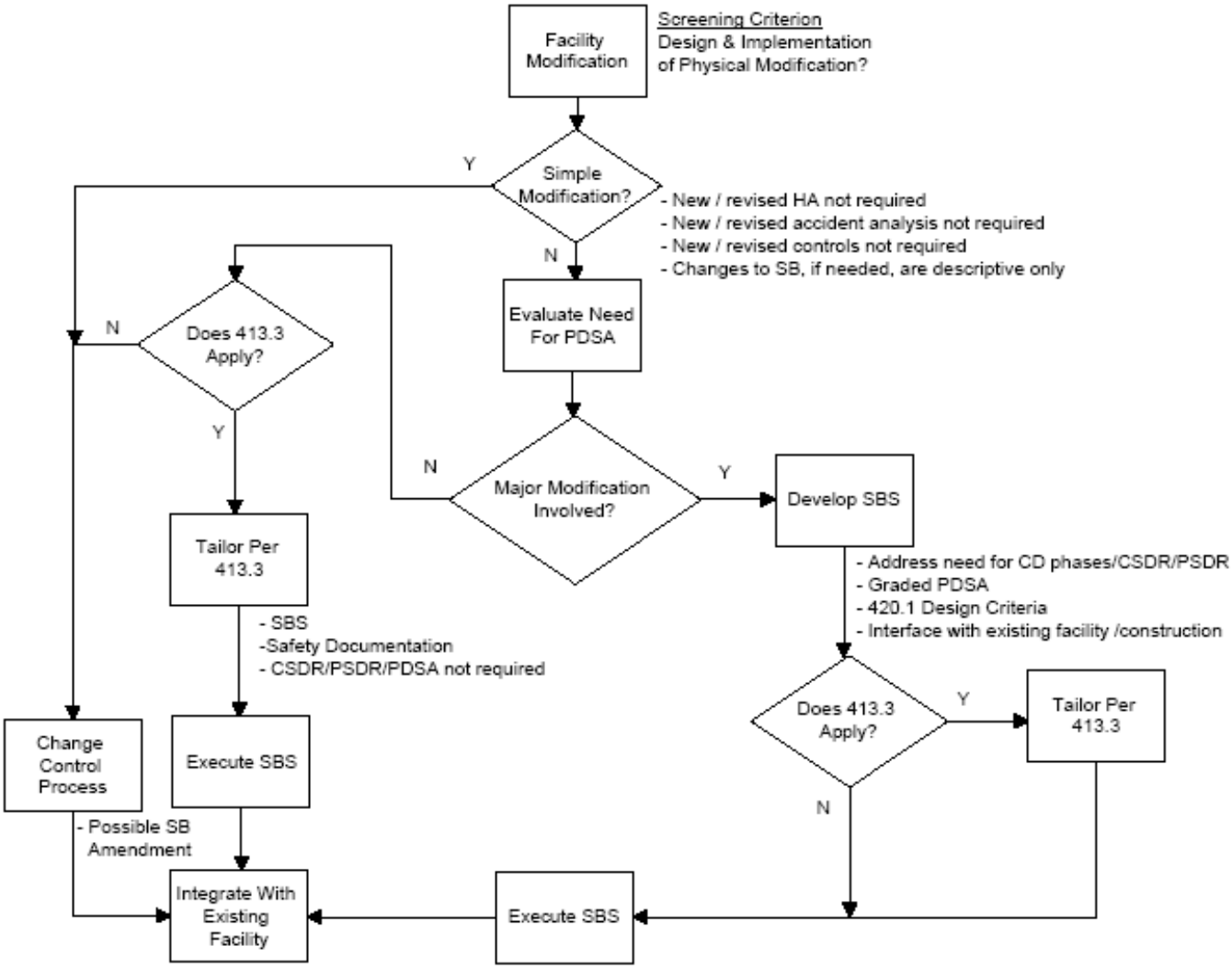

Figure 9-1, Facility Modification Process

9.1.1 Hazard Analysis

Review of the existing hazard analysis may determine that it is adequate for the modification, that the hazard controls adequately address the modification and associated activities, and that implementing the existing change control processes, such as the Unreviewed Safety Question (USQ) and configuration management processes, procedure changes, and training programs is adequate to support the proposed change. These are generally simple modifications that may require a change to the description of the facility or its activities but do not represent a substantial change to the safety basis.

The review may also indicate that a new or revised hazard analysis is required to support a proposed facility modification or associated activities. For modifications to existing processes, the hazard analysis revision may involve identifying additional hazards and updating an existing hazards analysis. A new hazard analysis may be performed for new discrete activities or for processes that were not previously evaluated. In this case, a hazards analysis should be performed to identify potential hazards, necessary hazard controls, and impacts to the existing safety basis. The intent of the hazards analysis is to identify safety functions and safety basis functional requirements as early as practical in the conceptual phase of the modification to ensure that they are integrated into the project design in a timely and cost-effective manner.

The new or revised hazards analysis may identify a number of safety functions and safety SSCs that are different than those previously considered. There are a number of reasons that a reassessment of facility hazards and identification of hazard controls is necessary at the conceptual phase, all of them associated with minimizing project risk, including the following:

- to ensure that the safety functions and safety SSCs are integrated into the design at the earliest and most effective phase;
- to allow a proactive assessment of potential impacts of the modification to the safety basis of the existing facility; and
- to enable a more realistic cost and schedule estimate for the modification.

The hazards analysis may address only the end-state (operational) risks associated with the modification project and not the interim risks encountered during construction or equipment installation activities. The interim risks may be identified, and necessary hazard controls implemented, as part of the facility work control process and the associated hazard analysis (e.g., job hazards analysis) and considered under the facility's USQ process.

9.1.2 Major Modifications

As defined by 10 CFR 830, major modifications are those that "substantially change the existing safety basis for the facility." A major modification requires the development of a Preliminary Documented Safety Analysis (PDSA) (830.206) and its approval by DOE (830.207).

As provided by Section 830.206 of the Rule, the PDSA is required to document the nuclear safety design criteria used for the modification, and DOE approval is required (with limited exceptions) before commencing procurement and construction activities.

While modifications to a nuclear facility occur almost constantly throughout its life cycle, not all may involve a "substantial change to the facility safety basis" and are not considered to be major modifications. Major modifications involve significant project liability such that the rigor of a PDSA and attendant DOE review and approval are established to reduce overall project risk. This approach ensures formal DOE concurrence in the establishment and implementation of nuclear safety design criteria and selection of hazard controls as early as possible in the modification process.

9.1.3 Determining a Major Modification

It is important to determine the need for a PDSA as early as feasible in planning for a modification so that actions to revise the existing safety basis documentation or develop the PDSA document may begin early in the design process. At the same time, the design should be mature enough to define the scope of the modification to allow a meaningful recommendation. This should occur before submittal of the conceptual design report or at a similar phase for modifications not subject to the critical decision process described in DOE O 413.3A.

In many situations, the need for a PDSA may be readily discernable with little or no detailed evaluation required. For example, a project that does not involve a design effort and the implementation of a physical modification (e.g., facility procedure upgrade project, facility maintenance or overhaul project) is not a major modification and does not require a PDSA. Any safety implications for such projects can be adequately addressed through the existing requirements related to safety basis management (such as the USQ process) or integrated safety management without the need for a PDSA.

However, situations will arise where this determination is not clear and a more rigorous evaluation is required. Table 9-1 provides recommended criteria for evaluating the need for a PDSA, and, therefore, the existence of a major modification. Each criterion addresses a key project characteristic relevant to the purposes of a PDSA.

In applying the PDSA evaluation criteria in Table 9-1, the intent is that each criterion should be assessed individually and then an integrated evaluation should be performed based on the collective set of individual results. In performing this evaluation, the focus should be on the nature of the modification and its associated impact on the existing facility safety basis. Examples of the application of the PDSA evaluation criteria are included in Appendix J, "Major Modification Determination Examples," to provide additional guidance.

Where a major modification is found to exist, an SDS should be developed that addresses 1) the need for a CSDR or PSDR (as well as the required PDSA) to support project phases, 2) the graded content of the PDSA necessary to support the design and modification, 3) the application of nuclear safety design criteria, and 4) the interface with the existing facility, its operations, and construction activities.

A facility modification that does not qualify as a major modification, but does involve a positive USQD, requires a safety analysis in support of a request for approval from DOE to proceed with the modification. A positive USQD at this step also provides DOE with an opportunity to check the validity of the initial finding (see Figure 9.1) of a simple modification.

Table 9-1, Major Modification Evaluation Criteria

Major Modification Evaluation Criteria		
Evaluation Criterion No.	**Evaluation Criteria**	**Clarifying Detail / Examples**
1	Add a new building or facility with a material inventory ≥ HC 3 limits or increase the HC of an existing facility?	A new building may be a structure within an existing facility segment. That structure may or may not have direct process ties to the remainder of the segment/process. The requirements of DOE-STD-1027-92 shall be used in evaluating Hazard Categorization impacts.
2	Change the footprint of an existing HC 1, 2 or 3 facility with the potential to adversely impact any SC or SS safety function or associated SSC?	A change in the footprint of an existing facility requires the identification and evaluation of any potential adverse impacts on SC or SS safety functions or associated SSC (e.g., structural qualification, evacuation egress path, fire suppression spray pattern) or safety analysis assumptions. Changes that may involve adverse impacts require careful attention to maintaining adherence to applicable engineering standards and nuclear safety design criteria.
3	Change an existing process or add a new process resulting in the need for a safety basis change requiring DOE approval?	A change to an existing process may negatively affect the efficacy of an approved set of safety controls for a given event or accident. Likewise potential safety concerns associated with a new process may not be adequately addressed by the existing approved control sets. In this case, it is assumed that the existing analyses addressed the hazards associated with the new or revised process, but the specified control set(s) may no longer be valid. The evaluation of any new hazards introduced by the revised or new process should be addressed via Criterion 6
4	Utilize new technology or GFE not currently in use or not previously formally reviewed / approved by DOE for the affected facility?	This assessment should include consideration of the impact that the use of new technology (including technology scale-up issues) or GFE may have on the ability to specify the applicable nuclear safety design criteria with a high degree of certainty in the early stages of the project. Additionally, refer to GFE discussion in Section 9**.3**. GFE may have a technical baseline that is not directly and fully supportive of the project functional and performance requirements. An example would be employing a new technology for removal of certain nuclides from a waste stream.

Major Modification Evaluation Criteria		
Evaluation Criterion No.	**Evaluation Criteria**	**Clarifying Detail / Examples**
5	Create the need for new or revised Safety SSCs?	Consideration should be given to the relative complexity of the controls and the ease with which the controls can be implemented. The use of a complicated multi-channel Safety Class seismically qualified instrumented system to provide multiple interlock and alarm functions would typically pose a higher risk to the project than the use of a Safety Significant passive design feature. The degree of design and regulatory uncertainty should be addressed for this criterion for the development, review, and approval of new or revised safety analysis and attendant controls (e.g., presence of multiple regulatory/technical agencies on a single project).
6	Involve a hazard not previously evaluated in the DSA?	Hazards can include the introduction of an accident or failure mode of a different type from that previously analyzed in addition to radiological or toxicological hazards. The need to address a new hazard early in the design process may lead to some degree of uncertainty related to the proper specification of applicable nuclear safety design criteria. In such cases, this uncertainty should be addressed within this evaluation.

9.2 Construction Projects within Operating Facilities

For major modifications or other projects that are being incorporated into or added onto existing nuclear facilities, it is necessary to ensure that the requirements of the approved and implemented safety basis for the facility being modified are observed and protected throughout the construction and testing processes. Existing construction work control processes should fully implement the guiding principles and core functions of the Integrated Safety Management System in a way that ensures the following.

- The scope of work is clearly defined for the overall project and individual activity-level work documents.
- Additional compensatory measures are implemented, as appropriate, to clearly identify system and work scope boundaries (e.g., signs, ribbons, physical barriers).
- Operations authorization is required for all construction work activities within the facility in accordance with plan-of-the-week and plan-of-the-day requirements, or equivalent.
- Work control processes fully identify and analyze hazards, particularly for those activities that can impact existing SSCs.
- Line management, both construction and facility, demonstrate ownership of safety.
- Roles and responsibilities for construction and facility personnel are defined and understood, particularly with respect to response of workers to alarms, facility training, oversight and supervision, and stop work authority.

During the work planning process it is necessary to determine the methods and processes by which the modifications will be constructed or installed. These documents need to consider impacts to the existing facility features and design bases that may include the following:

- effect of additional wall penetrations;
- increased or decreased loading on existing SSCs;
- capability of existing support systems to carry additional load demand (e.g., electrical, steam, air); and
- effects of startup testing of new components in conjunction with existing facility systems.

It is necessary to ensure that all proposed project activities are reviewed against the existing safety basis using the USQ process. If the result of the USQ determination is that DOE approval is necessary, the contractor may need to establish alternate or supplemental safety basis documentation to support construction and installation activities (e.g., specific amendment to existing and

implemented safety basis or standalone interim safety basis covering construction activities).

9.3 Government Furnished Equipment

DOE occasionally provides pre-existing SSCs, hereafter referred to as government furnished equipment (GFE), for use in a new project or a modification to an existing facility. Experience has shown that that the use of GFE can lead to the identification of significant safety issues after substantial project work has been completed if the GFE technical baseline, performance and operational characteristics, and the associated hazards are not fully understood and accounted for in the project design. The failure to fully integrate the use of GFE into the project baseline documentation in a timely manner can result in significant project cost and schedule impact that can ultimately lead to project cancellation. Guidance is provided in the following sections to ensure that GFE is properly and fully integrated into the project effort.

Also in the class of activity is equipment that was not part of the preliminary and final design process discussed previously. This situation is frequently encountered in science and technology efforts where the building and the equipment it houses are developed on different schedules. In such cases, interfaces are typically defined in the design process, and the development of the equipment conforms to those interfaces. However, hazardous operations and safety design requirements for to-be-installed equipment may not be fully defined in the final design. In such cases, the Documented Safety Analysis (DSA) should address the design issues along with the risk assessments conducted during all project phases. The safety strategy should define the appropriate approach for ensuring DOE agreement with the safety of the equipment.

Discussions that follow for GFE handling and information should be tailored to support equipment designs that are developed after the designs for the building to house the equipment are approved through final design. This guidance is intended to promote a thorough consideration of the necessary information and evaluations that must be supplied, performed, or otherwise developed if GFE is to be safely and effectively used in a project. This involves a mutually collaborative effort on the part of the GFE supplier and end user that can foster the timely integration of the necessary information into project planning and execution activities.

9.3.1 GFE-Provider Responsibilities

It is incumbent upon the provider of the GFE to also provide a thorough documentation package that defines the technical baseline, performance and operational characteristics, and associated hazards of the GFE. This documentation is typically in the form of specifications, drawings,

calculations, technical reports, test reports, operating manuals, operating procedures, hazard analyses, and similar documents. This collection of information should be sufficient to allow the original GFE technical basis to be readily and well understood by the end user (i.e., the project) and should define the following:

- codes and standards used in design, fabrication, assembly, inspection, and testing;
- materials of construction;
- key interface parameters (e.g., footprint dimensions, weights, anchor details, heat loads)
- key interface utility requirements (e.g., air, steam, electricity, cooling water);
- instrumentation and control provisions/needs and interface requirements (including local indication and alarms provisions as well as remote analog/digital indication, alarm, and interlock process parameter input capabilities);
- structural loads included in the design (e.g., deadweight, thermal, pressure, vibration, dynamic, seismic, tornado, wind, missile, snow, flood) along with associated functional capability under these loads;
- environmental qualification and capabilities, including effects from the process medium as well as ambient conditions;
- potential failure modes and hazards (preferably from an Failure Modes and Effects Analysis (FMEA) or Hazards Analysis (HA), if performed);
- performance and operating information, including normal process parameters (e.g., flows, pressures, temperatures, levels);
- upset conditions and associated parameters;
- design parameters;
- operating manuals and procedures for both normal and upset conditions;
- maintenance manuals, including specification of recommended spare parts;
- test reports; and
- operating and usage history

In addition to providing the foregoing information, the GFE provider should also make all supporting QA documentation available to the end user. Such information may include material certification and test reports,

certificates of compliance, nondestructive examination reports, and hydrostatic test reports. The intent is to provide the end user with auditable, objective evidence that all applicable code and standard QA requirements have been satisfied.

The lack of complete technical, performance and operational, and QA documentation as outlined above may result in concluding that the GFE baseline or history is indeterminate. Providing this information to the end user as early as possible in the project will minimize project impact should an indeterminate state render the GFE unusable or should the project have to pursue a baseline reconstruction effort.

9.3.2 GFE End User Responsibilities

After reviewing or reconstructing the necessary technical, performance and operational, and QA documentation, the end user will be in a position to assess the adequacy of the GFE relative to the needs of the project (i.e., the project functional and performance criteria). This assessment may identify gaps, including those related to the project safety basis, which the project will have to address should the GFE be used. Safety-basis-related gaps may be document-related or hardware-related with the recognition that documentation gaps could result in downstream hardware impacts. The risk for such safety basis noncompliance underscores the need to integrate the GFE information into the project safety basis development effort as early as possible to minimize downstream impacts.

An example of a document gap would be the absence of Failure Modes and Effect Analysis (FMEA) or hazards analysis (HA) information. This would result in the project having to perform the necessary analyses to identify potential GFE failure modes and hazards, which must then be integrated into the project safety basis work. The inclusion of this information may result in identifying the need for new or revised control sets that may not have been previously anticipated by the project. An example of a hardware gap would be a discrepancy between the GFE “as provided” condition and that required by the project safety basis (e.g., not seismically qualified with the appropriate attendant functionality). This may require a modification of the GFE to achieve the required level of performance with respect to structural capability, environmental compatibility, reliability, inspectability, testability, accuracy, and similar processes. Note that the need for such modifications may be derived indirectly through safety basis-supporting evaluations (e.g., ANSI/ISA-S84.01-1996, *Application of Safety Instrumented Systems for the Process Industries*.)

APPENDIX A
Safety System Design Criteria

This appendix provides guidance and criteria for specification of the seismic design basis and the safety classifications of structures, systems, and components (SSC). These criteria relate to radiological hazards only. Treatment of chemical hazards for Safety Significant classification purposes is discussed in Appendix B.

During conceptual design, when a conservative estimate of the total facility inventory of hazardous material can be made and facility-level Design Basis Accidents (DBA) are defined and analyzed, a preliminary assessment of safety design aspects for the facility can be formulated. This appendix specifies the methodologies to be applied to the major preventative and mitigative SSCs that are selected from the analyses of the DBAs. Classifications resulting from this guidance provide information that can be used to prepare a preliminary list of functional safety requirements for these safety SSCs. It is intended that this information be used to develop conservative cost estimates for the conceptual design. Note that support systems that are essential for a Safety Class (SC) or Safety Significant (SS) SSC to perform its safety function must also be classified at the same level as their supported SSC.

A.1 Seismic Design Basis

This section specifies how to apply two recently published national standards for seismic design of DOE non-reactor nuclear facilities. The standards were developed at the initiative of the DOE and provide methods, guidelines, requirements, and criteria for the seismic design of SSCs. The standards are as follows:

- ANSI/ANS 2.26-2004, *Categorization of Nuclear Facility Structures, Systems and Components for Seismic Design*; and
- ASCE/SEI 43-05, *Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities***.**

These national standards were developed by the American Nuclear Society (ANS) and the American Society of Civil Engineers (ASCE). The standards working groups that developed these included DOE, the Nuclear Regulatory Commission (NRC), the Defense Nuclear Facility Safety Board (DNFSB), and industrial representation. To a large degree, these national standards are based on DOE experience with application of seismic requirements in the following DOE natural phenomena hazards (NPH) standards.

- DOE-STD-1020, *Natural Phenomena Hazards Design and Evaluation Criteria for Department of Energy Facilities*.
- DOE-STD-1021, *Natural Phenomena Hazards Performance Categorization Criteria for Structures, Systems, and Components*.

ANS Standard 2.26, as interpreted in this appendix was adopted by DOE for the purposes of seismic design basis specification. The seismic design classifications of ANS 2.26 are to be used in association with DOE radiological criteria provided in this appendix. It is intended that the requirements of Section 5 of ANS Standard 2.26 and the guidance in Appendix A of that Standard be used for selection of the appropriate Limit States (LS) for SSCs performing the safety functions specified. The resulting combination of Seismic Design Category (SDC) and LS selection provides the seismic design basis for SSCs to be implemented in design through ASCE/SEI 43-05, *Seismic Design Criteria for Structures, Systems, and Components in Nuclear Facilities***.**

For DOE purposes, the criteria for selecting an SDC are to be based on the following methodologies and criteria.

- DOE implementation of ANS Standard 2.26 relies on conservative bases for unmitigated accident analysis.
- A worker, in the ANS Standard 2.26 is interpreted to mean a collocated worker, at a distance of 100 m from a facility (building perimeter) or estimated release point.
- For criteria associated with the public, the methodology of assessment to be followed is that of Appendix A of DOE-STD-3009.
- Criteria doses are Total Effective Dose Equivalent (TEDE)[9].
- In conceptual design, if there are no bases for defining seismic related DBAs, hazard category 2 facility structural designs must default to ANSI/ANS 2.26 SDC-3, Limit State D. If the hazards analysis conducted during subsequent stages of design shows that unmitigated consequences are less than the threshold criteria for SDC-3 shown in Table A-1 below, then this may be reflected in the evolving design stages.

[9] The concept of TEDE was introduced as a construct to represent the summation of Direct Exposure and Committed Dose from retained radionuclides from other pathways. This construct has also been referred as Total Effective Dose (TED) and Annual Effective Dose (AED) (when considering exposures received or committed to in a single year). Currently the ICRP supports the concept of TED although this terminology is not present within ICRP 60, 68, or 71.

Table A-1, Guidance for SDC Based on Unmitigated Consequences of SSC Failures in a Seismic Event

	Unmitigated Consequence of SSC Failure from a Seismic Event	
Category	Collocated Worker	Public
SDC-1	Dose < 5 rem	Not applicable (1)
SDC-2	5 rem < dose < 100 rem	5 rem < Dose < 25 rem
SDC-3	100 rem < dose	25 rem < dose

(1) A hazard category 1, 2, or 3 nuclear facility with consequences to a collocated worker from failure of an SSC in a seismic event will require that SSC to be classified as SDC-1 at a minimum. Therefore, a public criterion for SDC-1 is not needed.

This table, in comparison with criteria in ANS Standard 2.26, is truncated at SDC-3 on the following bases.

- No higher designations than Safety Significant or SDC-3 design requirements are judged to be necessary for collocated worker protection because (in addition to design features) site training and site emergency procedures provide for adequate protection for workers. Only in the case of an in-facility worker who must remain in the facility for safe shutdown or other safety-related purpose should SDC-3 be considered for SSCs required for protection of that worker. In that case, the mitigative effects of personal protective equipment may also be considered.
- It is likely that DOE will build only high-hazard, non reactor nuclear facilities at large sites, where it is more likely that the collocated worker criterion would be controlling for seismic design purposes. In such cases, it would be unlikely that the qualitative radiological criteria suggested by ANS Standard 2.26 for the public for SDC-4 would be exceeded. If the quantitative public criterion for SDC-3 of Table A-1 is exceeded significantly for any project, then the possibility that SDC-4 should be invoked must be considered on a case-by-case basis.

In performing the unmitigated accident analyses specified by ANS 2.26, material-at-risk (MAR) should be conservatively estimated. The source term quantities used should be derived, as appropriate to the situation, to consider damage ratio (DR) and airborne release fraction (ARF) for the DBAs, in accordance with the unmitigated accident analysis source term guidance of Appendix A, Section A.3.2 of DOE-STD-3009, and DOE G 420.1-1. A leak-path factor and respirable fraction of 1.0 should be used. Dose conversion factors consistent with ICRP Publications 68 and 72 should be used.

For the purposes of this Standard, a χ/Q value at 100 m of 3.5E-3 sec/m3 should be used for the dispersion calculation. This value is based upon NUREG 1140 (no buoyancy, F-stability, 1.0 m/sec wind speed at 100 m, small building size (10 m x 25 m), and 1 cm/sec deposition velocity). Dispersion analyses for public dose calculations should be done according to the guidance of DOE-STD-3009, Appendix A.

A.2 Safety Classification of SSCs

A.2.1 Public Protection Criteria

The guidance of DOE G 421.1-2 and DOE-STD-3009, Appendix A, should be used in classifying SSCs as Safety Class (SC) for radiological protection. The words "challenging" or "in the rem range" in those documents should be interpreted as radiological doses equal to or greater than 5 rem, but less than 25 rem. In this range, SC designation should be considered, and the rationale for the decision to classify an SSC as SC or not should be explained and justified. SSCs designated as Safety Class based on seismic hazards must also be designated as SDC-3 for seismic design, at a minimum.

A.2.2 Collocated Worker Protection Criteria

A conservatively calculated unmitigated dose of 100 rem TEDE has been chosen as the threshold for designation of facility-level safety controls as Safety Significant (SS), for the purpose of collocated worker protection. The radiological source term quantities used should be derived, as appropriate to the situation, to consider damage ratio (DR) and airborne release fraction (ARF) for the DBAs, and should be reasonably conservative. A leak-path factor and respirable fraction of 1.0 should be used. For the purposes of this Standard, a χ/Q value at 100 m of 3.5E-3 sec/m3 should be used for the dispersion calculation. This value is based upon NUREG 1140 (no buoyancy, F-stability, 1.0 m/sec wind speed at 100 m, small building size [10 m x 25 m], and 1 cm/sec deposition velocity).

A.3 Existing Facilities and Major Modifications of Existing Facilities

The seismic design classification and collocated worker Safety Significant criteria of this appendix shall not be applied in a backfit sense to existing facilities that are not undergoing modifications.

For major modifications of existing facilities, these criteria shall be used with the following caveats. Backfit analyses should examine (1) the need to upgrade interfacing structures, systems, and components in accordance with these criteria, and (2) whether there should be relief for the modification from the design requirements that application of these criteria in design would imply.

APPENDIX B
CHEMICAL HAZARD EVALUATION

Consistent with practice in nonnuclear hazardous facility design, DOE is not invoking classification of safety SSCs or specifying nuclear design requirements based on chemical hazards alone. This appendix, however, provides guidance for consideration of Safety Significant designation for SSCs, in terms of advisory criteria for chemical exposures. The guidance for consideration of Safety Significant designation for SSCs based on chemical hazards is based on a process of (1) screening chemicals (hazardous materials) to determine those that may have the potential to immediately threaten or endanger onsite (collocated) workers or the public and (2) evaluating the severity of potential exposures against advisory classification criteria for collocated workers and the public. Evaluation of chemical hazards for potential significant facility worker hazards is addressed in Appendix C, “Facility Worker Hazard Evaluation.”

B.1 Screening of Hazardous Materials

The hazardous material screening process must identify all hazardous materials in the facility/activity that require further evaluation. All chemicals with known or suspected toxic properties must be subjected to the screening process.

Chemicals that may be excluded from further analysis for functional classification and the identification of attendant design criteria include the following.

- Chemicals with no known or suspected toxic properties.
- Materials used in the same form, quantity, and concentration as a product packaged for distribution and use by the general public.
- Chemicals in a quantity that can be “easily and safely manipulated by one person.” Quantities of chemical hazardous materials considered to be "easily and safely manipulated by one person" can be locally determined in accordance with the provisions of 29 CFR 1910.1450(b).
- Materials that have a health hazard rating of 0, 1, or 2, based on National Fire Protection Association (NFPA) 704.
- Solid or liquid materials that, because of their physical form or other factors (e.g., plausible dispersal mechanisms), do not present an airborne exposure hazard.
- Chemicals that can be defined as a Standard Industrial Hazard for which national consensus codes and standards provide for safe design and operation. The Consensus Code or Standard needs to be identified and must be applicable to the use of the chemical in the facility that is to be screened from further evaluation.

Chemical hazardous materials that require further analysis include the following:

- chemicals with an assigned health hazard rating of 3 or 4 based on NFPA 704 in quantities greater than a quantity that can be "easily and safely manipulated by one person" [see 29 CFR 1910.1450(b)]; and
- chemicals without an assigned health hazard rating which require further analysis if in quantities greater than a quantity that can be "easily and safely manipulated by one person" [see 29 CFR 1910.1450(b)].

B.2 Public and Collocated Worker Protection Criteria

Potential exposures to the public and collocated workers are estimated as described in Section B.3. These exposures can be compared to the following threshold levels for consideration of SSC classification as Safety Significant in facility design to prevent or mitigated these exposures.

Public: Exposure > AEGL-2/ERPG-2/TEEL-2

Collocated Worker: Exposure > AEGL-3/ERPG-3/TEEL-3

The order of preference for evaluating a chemical is as follows: (1) Acute Exposure Guideline Levels (AEGL) promulgated by the EPA (60 minute AEGL); (2) Emergency Response Planning Guidelines (ERPG) published by the American Industrial Hygiene Association; and (3) Temporary Emergency Exposure Limits (TEEL) developed by DOE. In the event that a TEEL value cannot be obtained, users may select from one of the sets of chemical exposure guidelines issued by other agencies that are sometimes used as emergency planning criteria. These include the short-term public emergency guidance levels (SPEGL) and emergency exposure guidance levels (EEGL) developed by the National Research Council, and the levels of concern (LOC) published jointly by the Environmental Protection Agency, Federal Emergency Management Agency, and Department of Transportation.

B.3 Estimating Exposures to Collocated Workers and the Public

Exposures are chemical concentrations at the receptor location and depend primarily on the concentration of the chemical released, the rate of release, and the dispersion (dilution) that occurs between the release location and the receptor. Toxicological consequences of a release are based on the peak air concentration at the receptor location that occurs any time during the duration of the release.

Unmitigated chemical consequence analysis shall strive to use mean values for the parameters related to material release, dispersal in the environment and health consequences. In many instances the data available to support these analyses are not prototypic of the situation being analyzed, or there is large and poorly characterized uncertainty. Hence, judgment must be used to select a mean value for the parameter of concern. It is intended that the parameters used in the

evaluation be based on consideration of the range of possible values given the physical and chemical conditions involved with the failure and the basis for the value judged to be the mean to be documented. It is desirable to reduce any tendency toward over-conservatism to achieve the risk-informed balance in the design of the SSCs.

For hazardous material aerosols and gases with a density near that of air, standard Gaussian atmospheric dispersion can be used. If the toxic material is released at some average rate over some period of time, the peak concentration at the receptor is obtained directly from the definition of the steady state /Q'

$$C = Q'\left(\frac{\chi}{Q'}\right)$$

Where:

C = peak concentration (mg/m^3)

Q' = toxic material release rate (mg/s)

/Q' = steady state 1-hr dispersion coefficient (s/m^3).

The toxic material release rates (*Q'*) can be determined in a manner similar to that used to determine radiological source terms (*Q*) divided by the release duration (*t*).

The peak 15-minute, time-weighted average (TWA) chemical concentration should be compared to the suggested threshold values for Safety Significant designation. There should be no adjustment of the suggested threshold value or the calculated concentration to account for differences between the recommended 15-minute exposure time and the exposure time implicit in the definition of the concentration-limit parameter.

If the toxic effects of a chemical are known to be dose-dependent (i.e., the toxic effects depend upon the total quantity of material taken up by the body) and not concentration-dependent, then for these chemicals only, the 1-hour average concentration may be used. For short-duration releases (e.g., less than 15 minutes), the concentration at the receptor should be calculated as the TWA over the release period, but for no less than 1 minute.

Some consequence assessment dispersion codes will calculate the desired maximum 15-minute average concentration directly, by allowing the analyst to specify the averaging period.

To determine the average concentration manually, the following formula can be used.

$$TWA = \frac{C_1T_1 + C_2T_2 + C_nT_n}{T_1 + T_2 + T_n}$$

Where:

C = Concentration (ppm or mg/m^3)

T = Time period of exposure (min)

It is not recommended that individual time intervals less than 1 minute be used in the numerator of the above formula for calculating the TWA. For the peak 15-minute TWA, the 15-minute period of maximum exposure (concentration) is selected and input (as 15, one-minute segments) into the above formula. For exposure periods of less than 15 minutes, the product of CxTx may equal zero during the exposure period.

For release durations longer than 15 minutes, the peak 15-minute average concentration during the duration of the release is used for concentration dependent chemicals. These “zero" results may be factored into the 15-minute average or the use of a shorter averaging duration, such as the actual exposure period, may be warranted depending on the acute toxicity of the chemical of interest and the peak concentration observed.

Chemical releases that involve gas that have a density substantially different than air may require analysis using approved software codes designed and validated to handle the atmospheric dispersion for such gases (i.e., DOE Software Library codes such as ALOHA).

B.4 Chemical Mixtures

For chemical mixtures and concurrent releases of different substances, consequences should be assessed using the Mixture Methodology “Hazard Index” approach recommended by the Subcommittee on Consequence Assessment and Protective Actions (SCAPA) Chemical Mixtures Working Group (Craig, et. al., 1999).

A brief explanation of this approach and the published journal article are available on the SCAPA website, http://www.orau.gov/emi/scapa/index.htm, under Health Code Numbers (HCN). An EXCEL workbook that automates the implementation of the approach is also available on the SCAPA website.

Concurrent releases should be analyzed if a plausible scenario exists by which quantities of different substances, each exceeding the screening criteria discussed above, could be released from the same location at the same time.

APPENDIX C
FACILITY WORKER HAZARD EVALUATION

The hazard analysis includes the impacts of evaluated hazards on the facility worker (FW). For the purpose of this Standard, the FW is considered to be a worker that is not covered within the scope of the collocated worker, so it includes workers working within the facility).

For each hazardous condition evaluated for the public and collocated worker in the hazards analysis, a qualitative evaluation of unmitigated consequence to the FW and identification of candidate preventive and mitigative controls should be included. While safety management programs (SMP) may include most FW hazard controls, there are conditions that warrant consideration of Safety Significant structures, systems, and components (SSC). These include the following:

- energetic releases of high concentrations of radiological or toxic chemical materials where the FW would normally be immediately present and, therefore, unable to take self-protective actions;
- deflagrations or explosions within process equipment or confinement and containment structures or vessels where serious injury or death to a FW may result from the fragmentation of the process equipment failing or the confinement (or containment) with the FW close by;
- chemical or thermal burns to a FW that could reasonably cover a significant portion of the FW body where self-protective actions are not reasonably available due to the speed of the event or where there may be no reasonable warning to the FW of the hazardous condition; and
- leaks from process systems where asphyxiation of a FW normally present may result.

Safety Significant SSCs are also considered for cases involving significant exposure of the FW to radiological or other hazardous materials. This involves qualitatively evaluating unmitigated consequences in terms of radiation dose, chemical exposure, or physical injury at specified receptor locations. Appendix B provides chemical screening criteria that may be used to screen out low-risk or common chemical hazards from further consideration for the collocated worker with respect to plume pathway consequence. These screening criteria are equally applicable to the FW and may be used accordingly; however, all chemicals must be evaluated against the FW hazards discussed above.

Consequence estimates can rely on experience or can be determined from (1) simple source term calculations, (2) existing safety documentation, and/or (3) qualitative assessment supported by “back-of-the-envelope” calculations. Additional (more detailed) evaluation may be necessary in the form of semi-quantitative analysis, accident analysis, and other such analyses. The Safety-in-Design Integration Team (SDIT) uses its discretion, expertise, and knowledge of facility hazards to select one or more of the above methods appropriate for consequence determination.

For radiological consequences, the suggested evaluation criterion is 100 rem Total Effective Dose Equivalent (TEDE). For chemical exposure, the evaluation criterion is Acute Exposure Guideline Level-3 (AEGL-3) or equivalent (e.g., Emergency Response Planning Guideline-3 [ERPG-3], Temporary Emergency Exposure Limit-3 [TEEL-3]). By comparing the qualitatively derived FW radiological or chemical consequence to these evaluation criteria, an assessment can then be made about the need for SS preventive or mitigative controls. Figure C-1 illustrates this control selection process. Where the qualitative consequence assessment yields a result that is not clearly above or below the evaluation criteria, then the need for SS FW controls shall be more closely considered by the project.

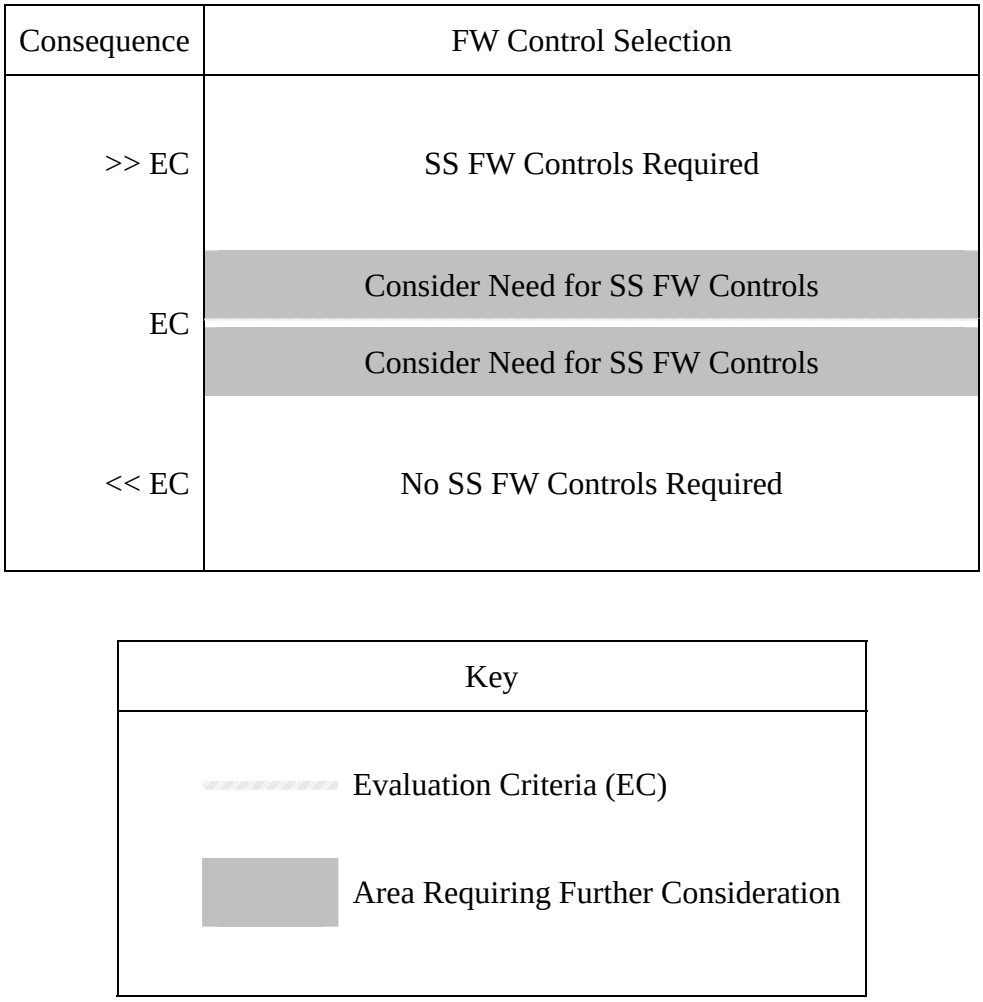

Figure C-1. Facility Worker Selection Process

APPENDIX D
ADDITIONAL FUNCTIONAL CLASSIFICATION CONSIDERATIONS

D.1 Selection and Classification of a Complete Control Set

When controls are selected to perform a Safety Class (SC) or Safety Significant (SS) function, the control set must be adequate to fully perform the identified safety function. This control set must include all structures, systems, and components (SSC) that are either required to operate to perform the safety function or required not to fail if that failure would prevent the function from being performed. These SSCs must be classified at the same level (SC or SS), with the following limitation.

The functional classification designation (SS or SC) extends only to the attributes of the SSC involved in providing the safety function. For example, for an SSC identified as having an SC function based solely on seismic interaction, the only safety requirement the SSC must meet is that imposed by requirements on structural design for the seismic event.

Preventive control SSCs are designated in a judgment-based process involving many factors, such as effectiveness; a general preference of preventive over mitigative and passive over active; relative reliability; and cost considerations.

SSCs that function to monitor initial conditions assumed in the accident analysis are not required to be classified as SS- or SC-based on the monitoring function if all the following conditions are met.

- They do not generate a signal (indication, alarm, or interlock function) that causes action (operator action or equipment change of state) that is required to prevent or mitigate an accident.
- Their failure is not the initiator of an accident.
- Violation of the monitored parameter is not the initiator of an accident.

Those controls required by a Nuclear Criticality Safety Program in accordance with the criteria established in DOE-STD-3007-2007, to prevent, monitor, or detect a nuclear criticality accident, even if that accident would not directly impact worker safety, should be functionally classified as SS.

D.2 Criteria for Selecting SS Major Contributors to Defense-in-Depth

Selecting major contributors to defense-in-depth that will be identified as SS is an integral part of the hazard analysis process. The result of this selection process must be technically defensible. Major contributors to defense-in depth (DID) are identified from the candidate controls in the hazard analyses scenario

documentation. These major contributors to DID should be designated as SS SSCs based on consideration of criteria such as suggested below.

- DID controls that are common to multiple accident scenarios may be considered to provide a significant contribution to DID in the context of all of the scenarios taken together and should be considered for classification as SS. In this evaluation, accident scenarios are scrutinized for common safety control elements that qualify as safety controls across the spectrum of hazards, considering how often a particular potential control appears in different scenarios. For example, if it is determined that the fire suppression system appears in a significant number of scenarios as a potential safety control, then this would be a criterion for elevating the DID fire suppression system to an SS SSC.
- If a support SSC is common to several SS SSCs (but not necessarily required to ensure operability alone of any single SS SSC) then it should be considered, from a reliability perspective, as a candidate for SS classification.
- If a candidate control further significantly reduces the consequences of an accident scenario that has required an SC or SS control, then this control should be considered for designation as an SS SSC.
- If a candidate control that further significantly reduces the frequency of an accident scenario that has required an SC or SS control, then this control should be considered for designation as an SS SSC.
- The control appreciably reduces the risk of significant energetic events that potentially threaten multiple safety systems.
- If the reliability of a single control (preventative or mitigative) is not as high as desired, SSCs designed to increase reliability by providing multiple layers of protection should be identified as SS SSCs.

APPENDIX E
SAFETY DESIGN STRATEGY

E.1 Introduction

The Safety Design Strategy (SDS) is a tool to guide project design, document safety documentation development planning, and allow approving authorities sufficient information on which to make decisions. It provides a single source for the safety policies, philosophies, major safety requirements, and safety goals for the project. The SDS describes the major hazards anticipated in the facility, how those hazards will be addressed using safety structures, systems, and components (SSC) considering natural phenomena, confinement ventilation, and other significant safety needs. Any risks to these decisions from new technology or assumptions should be identified. In addition, the SDS identifies major safety documentation deliverables to be provided within each project phase.

E.2 SDS Format and Content

The SDS should be tailored based on complexity and risk and should reference available information sources where possible. It should also address important aspects that impact the development of the safety basis documentation or the interface with design and operations or areas that require concurrence (assumptions calculations, decisions that affect the technical baseline or the data used to generate hazard and safety analysis required from an Integrated Hazard Analysis). Additionally, the SDS content will vary significantly through the course of a major project that spans several years. As the project moves from conceptual design to preliminary design to final design, construction, and startup, the detailed information within the SDS will change, and the focus of various portions of the SDS will change to be consistent with project needs. The intent of this format and content guidance is to establish the minimum expectation for the types of material that will be addressed in the SDS. The depth of treatment is where tailoring occurs. The intent of the SDS is that it be as detailed as needed to communicate to the decision makers and the Safety-in-Design Integration Team (SDIT) the strategy for successfully integrating safety and design and producing safety basis documentation that will be approved to allow either entry into the next critical decision or into operation.

1.0 Purpose

This section introduces the SDS for the project. Effectively, this section should simply state that the SDS for the specific project will describe the overall safety strategy, the strategy for certain high-cost, safety-related design decisions, identify key assumptions or inputs that may represent

potential risks to those design decisions, and the expected safety deliverables through the project.

2.0 Description of Project/Modification

This section provides a brief description of the project/modification or proposed activity consistent with the level of knowledge of the project phase. Fundamentally, the description should allow the reader to understand the discussion that follows regarding safety strategy. Such details may include: mission; proposed location(s); description of major facilities/processes or changes to existing facilities/processes; and major hazards. Aspects that may be relevant to the overall strategy should also be included, such as storage capabilities of hazardous materials, waste streams and processes, and support systems. Reference to other project documents is acceptable.

3.0 Safety Strategy

This section is the core of the SDS and should present the overall safety strategy for the project. The following topics should be addressed in the section.

3.1 Safety Guidance and Requirements

This section should present the overarching philosophies and goals for the project in approaching the hazards involved in the project. Each of the following topics should be explicitly addressed.

- Describe or define the safety goals and philosophies (e.g., provide assurance that a member of the public will be protected from radiological exposure, minimization of materials-at-risk (MAR), passive controls over active, segmentation of hazards, approach to protection of facility worker).
- Define the criteria or approach to safety functional classification, including evaluation guidelines for both radiological and toxicological hazards and for public and worker protection.
- Identify the safety design criteria to be applied to the project (commitment to DOE G420.1-1, -2; ANS 2.2 and similar standards; DOE O 420.1B for double contingency, etc.). Overarching requirements are sufficient for this purpose.

3.2 Hazard Categorization

This section should provide a logical discussion of the major hazards involved in the project, the possible consequences those hazards may pose, and the resulting DOE-STD-1027 hazard category. An exhaustive list of hazards is not needed; only those that could potentially drive identification of Safety Class or major Safety Significant SSCs need to be listed. Examples would include fissile materials, explosion, and fire. Hazard categorization should be based on initial or assumed hazard inventories, describe results

of initial consequence estimates based on "parking lot" calculations. Inventories should define candidate hazard categorization. Summarize the use of any computer codes in describing the "parking lot" analysis.

3.3 Key Safety Decisions

Key safety decisions are those that potentially result in significant cost or have resulted in costly rework in past projects. These topics must be explicitly addressed and the strategy justified in the context of the hazard categorization and any associated preliminary consequence estimates. Highlight any key inputs or assumptions that influence these decisions.

- Seismic and other natural phenomena design categorization – Define expected facility design categorization based on initial hazard considerations.
- Confinement strategy – Describe overall approach to confinement including use of active confinement system(s); define expected functional classification of any confinement system(s).
- Fire mitigation strategy – Describe overall approach to fire protection including any use of fire barriers, segregation, and similar measures. Fire mitigation strategy may influence confinement strategy significantly.
- Anticipated safety SSCs – Identify major safety SSCs, their safety functional classification (SC, SS), and major safety function (e.g., confinement). Any potential need for emergency power for safety purposes should be identified, particularly with respect to confinement ventilation systems.

4.0 Risks to Project Safety Decisions

Summarize any key risks identified in developing the strategy to the key safety design decisions in Section 3. These should be included in the project Risk Management Plan until appropriate resolution of unknowns or solidification of assumptions. Other factors such as application of new technology, need for additional data to substantiate assumptions (e.g., new material airborne release fraction [ARF]), or hazardous material inventory assumptions should be captured for prominent consideration through the ensuing project steps and potential impact or opportunity to the project.

5.0 Safety Analysis Approach and Plan

This section should describe the safety analysis process and deliverables planned for the project. A summary of the analysis steps and processes to be used with evolution of design should be sufficient. Deliverables

expected to be completed, submitted, and approved should be described for all project phases. Integration with other safety discipline efforts (e.g., Fire Hazards Analysis) is pertinent to describing the project interfaces and synergy. Tailored project approaches (e.g., design/build) should be specifically identified, and safety basis development should be described sufficiently to facilitate concurrence by approving authorities.

Major safety analysis tools (e.g., computer codes) to be used should be identified, and any tools not included in the DOE toolbox should be described and justified.

6.0 SDIT – Interfaces and Integration

This section describes strategy for establishing and employing an SDIT within the project. Discussion should address the primary interfaces within the project team that are specifically aimed at facilitating coordination not only with design functions, but with traditional worker safety disciplines, emergency management, and safeguards and security. This may be accomplished in a number of ways, including appropriate representation on the SDIT directly, periodic coordination, and design review meetings. Ultimately, the goal is to ensure coordination among these various interests to ensure development of a design compliant with the various factional requirements while achieving the overall safety strategy. Also, the role of the SDIT in the broader Contractor Integrated Project Team (CIPT) and Integrated Project Team (IPT) should be described. Often, key project members will comprise more than one of these teams.

The security interface is of particular importance. Competing requirements are not unusual, and important security requirements can often be classified. Engaging security and developing a parallel security strategy is recommended.

It is critical that the various SDIT discipline roles not be “stovepiped.” The SDIT has a significant role in developing both the design/facility modification and the associated safety documentation. However, within that team certain individuals must be the SME or own that portion of the team’s efforts.

7.0 References

APPENDIX F
SAFETY-IN-DESIGN RELATIONSHIP WITH THE RISK MANAGEMENT PLAN

Projects are required to prepare Risk Management Plans to define the roadmap to executing the project within a risk and opportunity environment. DOE O 413.3A and its guidance describe the process for identification, assessment, and mitigation of project risks. Given the potentially significant costs associated with safety decisions, the integration of safety into the design process must also include a strong link between the development of safety-in-design and identification of project technical and programmatic risks. With anticipated risks, early identification of possible opportunities to address potential risks allows the project to define appropriate range estimates. Comprehensive risk identification, coupled with an appropriately conservative safety design posture, afford the project the opportunity to execute within the range estimate with a higher degree of reliability. The identification of risks and opportunities associated with the conceptual design along the appropriate mitigation strategies will be a key component in identifying the contingency cost range for the project in accordance with DOE O 413.3A expectations.

Developing the risk and opportunities assessment is especially important at the conceptual design stage. This assessment is the foundation that will demonstrate the overall technical risk and maturity of the other technical deliverables associated with the conceptual design package. The addition of opportunities is deliberate since the safety-in-design philosophy espoused herein is to make reasonably conservative safety design decisions early in the design process. A conservative posture at the equipment level can sometimes be found later in design to be unnecessarily conservative and lead to avoidable costs. For this reason, opportunities are intended to capture that possible outcome in addition to opportunities for addressing risks in general.

The risk and opportunity assessment of the conceptual design package is the foundation for demonstrating the adequacy of the safety design approach documented in the Conceptual Safety Design Report (CSDR) and overall technical risk and maturity of the other technical deliverables included in the conceptual design package. To be of value to the approval authorities, the risk and opportunity evaluation must be robust in identifying unknowns and potential technical issues related to the results of the preliminary hazard analysis; specifically, the selection of safety controls. Consideration of the risks and opportunities completes the risk “picture” upon which decision makers can appropriately evaluate the proposed project. The risk process should demonstrate prudent conservative decision making approaches were applied in the conceptual design. As such, it is imperative that all pertinent subject matter experts (SME), such as safety personnel, including criticality experts; engineering designers; and security personnel participate in this evaluation process to properly portray the level of technical maturity in the conceptual design and appropriate mitigation strategies.

If the guidance in this Standard is followed, the hazards analysis process should drive conservative decision making to envelope the bounding case effects of the risks

associated with these unknowns and technical issues. Prudent conservative decision-making approaches applied in the conceptual design should ensure that final project cost and schedule baseline are within the range estimate established in the Conceptual Design Report (CDR) or Critical Decision-1 (CD-1) package.

In developing input for the risk and opportunity assessment, all risks that could impact the safety-in-design strategies delineated for hazard category 1, 2, and 3 nuclear facilities should be specifically considered in the analysis. In determining the overall risk and opportunities for the project, technical risks must be given at least equivalent weight to programmatic considerations. Risks and opportunities associated with safety-in-design issues should be specifically annotated in the risk assessment process as such to enable an understanding of all risks associated with the safety strategy for the facility (versus programmatic and operational non-safety risks that may be in the risk assessment). This approach will help establish clear definition of safety-in-design risks and will enable demonstration of selected mitigation strategies. All risks that impact the safety basis should be specifically annotated as such in the Risk Management Plan. For each risk and opportunity delineated, an appropriate identification of the necessary mitigation strategies should be provided as recommended in the DOE O 413.3A guidance. This will enable improved management by the project managers as well as improved demonstration of the maturity and risk of the projects for approval authorities. The summary of the Risk and Opportunities associated with the safety-in-design strategies should be discussed in the Conceptual Safety Design Report (CSDR).

Table F-1 provides a list of typical factors that may be considered in identifying and developing risks and opportunities. This list is not exhaustive and the specific project applications should be considered on their own issues. As the project life cycle progresses, the risks and opportunities should be periodically revisited as the design matures and the project moves into different phases. A solid foundation at conceptual design is vital to ensuring risks and opportunities can be managed through the project.

Where risks and opportunities are identified, appropriate mitigation strategies must be developed to address them. The goal should be to appropriately define responses to a realized risk or opportunity such that as preliminary and final designs proceed, actions are taken in accordance with planned mitigation strategies versus emergent issue resolution actions.

Table F-1, Safety-in-Design Considerations for Risk and Opportunity Analysis

Functional Areas	
Design	**Technology**
Undefined, Incomplete, Unclear Process or Safety Functions or Requirements • Potential impact to confinement ventilation strategy • Potential impact to functional classification of SSCs	New Technology application or new application or existing technology • hazards and upset conditions may not be well understood • material form may be one not previously studied for Airborne Release Fraction (ARF) • toxicological effects may not have sound basis
Complex Design Features • Security requirements and impact on safety analysis • Safety-related control system design, interface with safety analysis, and implementation	Unknown or undecided technology • Potential for different materials at risk (MAR) should be assessed with resultant impact to NPH categorization and SSC functional classification • Potential for additional or exacerbated accident scenarios
Assumptions on key utility interfaces • Capacity • Equipment compatibility • Safety precautions in existing utilities • Reliability of existing utilities	Scale-up of bench scale technology or process or technology application maturity • Production quantities could introduce unknowns in hazard behavior or material interactions
Design Basis Threat requirements • Potential for changes affecting seismic design or hazards analysis	
Deferred capability decisions (where hazards could be introduced or increased with added capability in the future) • Potential for added capacity (MAR and SSC functional classification impact) • Potential for addition of significant mass to structure affecting seismic analysis • Potential for impacting confinement ventilation system	
Safety Class SSC selection confidence • Management judgments related to selection of borderline SSC classifications should be identified • Assumptions critical to consequence results with potential for change (e.g., ARF)	
Assumptions regarding production objectives • Increases in production objectives could affect MAR, NPH categorization, and/or SSC functional classification	
Errors and Omissions in Design • Potential for impact to MAR, NPH categorization, and/or SSC functional classification	

Functional Areas	
Seismic design margin • 10-year site hazard reevaluation (e.g., change in seismic hazard curve) requirement may impact NP design basis for long-term design/construct projects Criticality Design Criteria • Ill-defined criteria can result in potential miscommunication between design disciplines and criticality safety	
Fire Protection • Insufficient or untimely Authority Having Jurisdiction (AHJ) interaction can result in design changes • Rigorous fire hazards is necessary to define facility fire mitigation design basis	Field Quality Control • Field installation/Quality Control errors during structure construction can result in design changes to protect seismic basis, separation requirements, etc.

APPENDIX G
HAZARDS ANALYSIS TABLE DEVELOPMENT

This appendix provides an acceptable example of development and documentation of hazard analysis results. A table should be prepared with columns corresponding to the headings of sections F.1 through F.10 of this appendix. Sections F.1 through F.10 describe the content of the corresponding column of the table for each hazard analysis accident scenario. This format can be used to document the Preliminary Hazard Analysis (PHA) developed during the conceptual design, or the Process Hazard Analysis (PrHA) developed during the preliminary design. It should be updated as the design matures through final design and transition to operations.

G.1 Scenario Description

Describe each postulated accident scenario that could lead to the release of hazardous materials. The description should appropriately describe the mechanism(s) that lead to the release of hazardous material. Examples include spills, over-pressurization, deflagration, fire, and similar mechanisms.

The description should also include an explicit description or reference to the material at risk (MAR), chemical or radiological, as appropriate, involved with or potentially affected in the scenario. As appropriate, describe the effect that the initiating event has on the major facility structures, systems, and components (SSC), primarily those that could release energy or radioactive/hazardous material.

It is recognized that the scenarios identified during the Preliminary Hazards Assessment (PHA) process for conceptual design that the scenarios listed will be more facility-level or major MAR location events for the facility. The key at conceptual design is to review the release mechanisms for the major MAR inventory locations sufficiently to ensure that high-cost safety functions have been identified and included in the project design and cost estimates.

G.2 Initiating Event Frequency

Discuss the conservatively assigned frequency of the initiating event or of the accident itself, where a series of events contribute to a release of material, such as fire events or a natural phenomena hazard (NPH) followed by spill or fire. The goal is to qualitatively bin the event frequency sufficiently to aid in event prevention and mitigation strategy selection.

G.3 Unmitigated Consequence Evaluation

Describe the hazardous material release with respect to facility workers,

collocated workers, and offsite personnel who are affected.

Identify the consequence to each receptor for the event. Although detailed knowledge may not be available, it is important to make appropriately conservative determinations of dose consequences so that the safety control selection is also conservative. Wherever possible, quantitative information should be provided for consequences due to chemical or radioactive material releases based on bounding assumptions.

Assumptions established as a part of the consequence determination should be identified providing the technical basis for parameters of interest. Particularly, the hazardous material inventory, airborne release fraction, and damage ratio must be described. Reference appropriate calculations that support the identified consequence when performed.

While an assessment of the level of accident consequences is necessary to determine the need and safety classification of SSCs providing protection of in-facility workers, these assessments should be, at most, "back of the envelope" calculations to give a sense of the order of magnitude of the doses. In the case of in-facility worker doses, especially immediately involved workers ("hazard huggers"), the assumptions that could be made in the course of any more definitive calculations could easily affect the results by orders of magnitude. Thus, such calculations, if used to apply a numerical criterion, would divert attention from good safety decisions to arguments about the calculations and assumptions during the review.

G.4 Safety Functions

Based on the release events that are described, list the safety functions needed to be fulfilled to prevent or mitigate the MAR release event. The safety function is a qualitative statement of a function that prevents an initiating event or mitigates the outcome. The safety function is the desired result from some yet to be identified system, structure, or component. The safety function should be stated in the most general way possible while still describing the preventative or mitigative action. The safety function in this entry shall not specify a system, structure, or component or otherwise state how the safety function is satisfied. This has two purposes: (1) it provides flexibility in SSC selections and (2) it ensures that the specific functional and design attributes for a selected SSC fulfill the defined higher-level safety function identified by the team.

- The safety function statement serves as a link between the hazard analysis and the safety SSCs by defining the overall objective and top-level functional requirements for the SSC. The top-level functional requirements are those performance parameters of special importance because they are specifically relied upon to be met by the safety analysis.
- Safety functions should not be predicated on the SSCs that may be chosen to provide the function. The opportunity for novel and improved solutions

is reduced when the solution drives the requirement.

- The safety function statement for each SSC within a facility should be sufficiently specific to enable assigning appropriate SSCs to fulfill the needed safety function completely.
- Safety functions should include the following:
  - situations and any specific accidents during which the function is required to be met;
  - specific functional needs that prevent, detect, or mitigate an event; and
  - sufficient description to enable clear functional requirements acceptance limits for those SSCs ultimately chosen to meet the top-tier safety function described.

G.5 Preventive Features (Design and Administrative)

List all SSCs and Administrative Controls that have the potential to prevent the initiating event, not the event scenario or progression. In the early stages of the conceptual design process, this listing may include SSCs that are currently not part of the conceptual design; but, if selected, would be added to the conceptual design. Events that cannot be prevented, such as NPH events, should be listed as not applicable (N/A).

SSCs identified that may prevent a release, but cannot prevent the initiating event, should be listed as mitigative features not preventive features.

This listing will be used to select the suite of safety systems, important to safety systems, and/or defense in depth SSCs for the MAR release events. When complete at CD-1, only SSCs actually present in the conceptual design should be included.

G.6 Method of Detection

Identify all SSCs and administrative functions that could detect the event. This would include SSCs that may or may not be selected, as well as direct observation by the operations staff. In the early stages of the conceptual design process, this listing may include SSCs that are currently not part of the conceptual design.

Although the instrumentation systems are generally not well defined at the conceptual design stage, the expected detection methods to be included in the preliminary design should be included in the PHA tables. This provides a means for providing future design guidance and a basis for estimating equipment costs, in particular for systems that may be a high-cost driver for the project. An example of this is when instrument air would be needed to support an SC detection system. This could lead to the compressor systems for the air being SC and ultimately becoming a high-cost impact to the project. Therefore, it is

important in conceptual design to consider this sufficiently to capture any major cost needs at a minimum during conceptual design.

When complete at CD-1, only SSCs in the conceptual design should be included.

G.7 Mitigative Features (Design and Administrative)

List all SSCs and Administrative Controls that potentially could mitigate the event by either preventing the release after the initiating event or by limiting the consequences after the event has happened. In early stages of the conceptual design process, this listing may include SSCs that are not currently part of the conceptual design. Consideration of the following mitigative systems and design features must be included:

- fire suppression/detection;
- confinement ventilation;
- emergency power;
- nuclear criticality design features and/or alarms, consistent with the guidance in DOE-STD-3007-2007 (if the facility will have at least a minimum critical mass of fissionable material);
- seismic design, including addressing level of confinement for primary confinement system (building structure); and
- flammable gas controls.

When complete at CD-1, only SSCs in the conceptual design should be included.

G.8 SSC Safety Control Suite and Safety Functions

This section summarizes the suite of safety controls, including safety SSCs that will be relied upon to detect, prevent, or mitigate each event. Appendices A, C and D, and the requirements in DOE O 420.1B are key inputs to the identification of the safety control suite selected, the functional classification of selected SSCs, and the NPH requirements.

The safety controls identified in the conceptual design PHA are preliminary until accident analysis confirms their need and validates that they are the correct and adequate controls for the event. The identification of the safety controls should be reasonably conservative to establish an appropriate cost and schedule basis for the project. It should be noted that the selection of safety controls is iterative. If, after selecting one or more of the available controls, the mitigated consequence still exceeds the applicable threshold criteria, additional controls must be selected or identified. In some cases, it may be prudent to use multiple controls where only one may be required to effectively prevent or mitigate the event. As an example, multiple hazardous material confinement controls may be appropriate where the

MAR and/or unmitigated release consequences are high. The final list of selected controls should be provided in the PHA tables.

G.9 Mitigated Consequences and Frequency Reduction

The estimated consequences for the identified receptor after applying the safety controls are listed. During conceptual design, the quantitative results for the unmitigated events may not be known. In this case, the mitigated results are qualitatively estimated on the basis of a reduction factor on the unmitigated consequences. Once the accident analysis is performed, this section will be updated with the results of this quantitative analysis. If an event is prevented by application of the safety controls, this result is reported in the mitigated consequence column.

In the case of preventative features, an estimate should be made for the reduced frequency of the event.

This information is important as input to demonstrate sufficiency of the control suite selected in the Conceptual Safety Design Report (CSDR).

G.10 Planned Analyses, Assumptions and Risk/Opportunity Identification

List remaining analysis or assumption validations and risk/opportunities associated with the selected strategies. The bounding events that require further analysis must be identified in the PHA. The events selected are grouped into accidents that are representative of the hazardous conditions. The accidents are defined in such a way as to predict the consequences so as to be bounding for all similar events with the same control suite. Other events, not necessarily bounding events, for which the need for safety controls (or the functional classification or NPH criteria) was not obvious, should also be evaluated quantitatively later in the preliminary design phase. This will ensure that the selection for each safety control has a firm basis and that the assigned functional classifications and design criteria are also based on objective determinations.

Assumptions used in the PHA process must be validated as the design matures. As an example, the facility MAR used in the hazards analysis may have been based on a highly conservative assessment of tank volumes and concentrations. When the final documents and piping and instrumentation diagrams (P&ID) are issued in preliminary design, the actual tank volumes should be used in the accident analyses. Other assumptions concerning the event progression, such as impact to SSCs, should also be validated. This section should capture a listing of the remaining evaluations to be performed.

It is essential for the Integrated Project Team (IPT) to identify potential risks and opportunities to be fed into the formal Risk and Opportunity Assessment as the safety control suite is selected. The presentation of risks and opportunities

associated with the strategies are essential facets for risk-informed decision making by the project approval authority to authorize the project to proceed to preliminary design.

G.11 Hazards Analysis Table

The final hazards analysis table (or equivalent) should include the items discussed above and should portray the hazard scenarios associated with the facility and the safety systems that will detect, mitigate, or prevent unacceptable MAR releases. The table should present the logical binning of events evaluated (e.g. fire, operational events, fire, NPH). In essence, these scenarios are those from which the design basis accidents (DBA) for the facility are selected. The table provides valuable information to be included in the risk and opportunities analysis and needed studies to validate key assumptions. This table portrays the functional safety attributes for the facility safety systems that are to be incorporated into the conceptual design and cost estimates. The final table will be used as the foundation for development of the CSDR, which will describe the events evaluated and the safety control suite in a format that can be used as the foundation for a final Documented Safety Analysis for the facility.

APPENDIX H
Conceptual Safety Design Report

H.1 Introduction

DOE O 413.3A requires a Conceptual Safety Design Report (CSDR) as a part of the approval package for Critical Decision-1 (CD-1) approval of the conceptual design. The purpose of the CSDR is to summarize the hazards analysis efforts and safety-in-design decisions incorporated into the conceptual design along with any identified project risks associated with the selected strategies. The DOE review and approval of the CSDR via a Safety Validation Report (SVR) confirms that the preliminary safety positions adopted during conceptual design constitute an appropriately conservative basis to proceed to preliminary design. These positions include the following:

- preliminary hazard categorization (HC-1, 2 or 3) of the facility;
- preliminary identification of facility design basis accidents (DBA);
- assessment of the need for Safety Class (SC) and Safety Significant (SS) facility-level safety controls based on preliminary hazards analyses of DBAs;
- preliminary assessment of the appropriate seismic design basis (seismic design category and limit state) for the facility structure and major safety controls; and
- position(s) taken with respect to compliance with the safety design criteria of DOE O 420.1B or any alternate criteria proposed.

A major purpose of conceptual design is to propose a design concept and safety strategy that will support the mission to be accomplished by the facility and a conservative cost estimate. The design information that is available at the conceptual design approval stage is very likely to change and mature in various aspects as preliminary design proceeds. The design package may very likely propose several alternative approaches to some aspects of the design and also contain some aspects that require more research and development as part of the preliminary or event final design stage. Therefore, a rigorous safety assessment of the conceptual design is not needed as part of the CSDR approval. That assessment is more properly a part of the more broadly focused design reviews during preliminary and final designs, which should be participated in fully by DOE safety specialists who will be responsible for SVR and Safety Evaluation Reports (SER) for the project. However, part of the CSDR review should assess the implementation of the principles of the hierarchy of safety controls. The review should confirm that the process was implemented (at the facility level of

hazard controls), assess the acceptability of the decisions made, and identify any safety issues that require further study. An important approval basis for the CSDR is that the safety system selection provides an adequate basis for proceeding to the preliminary design stage.

In reviewing the CSDR, DOE must verify that the safety design basis was developed in a reasonably conservative manner and that the risk associated with significant redesign required due to the addition of new or different safety controls is minimal. The review should confirm that the hazards analysis process was complete commensurate with the available detail in the conceptual design, assess the acceptability of the decisions made with respect to safety controls, and include identification of any safety issues that require further study. The Risk and Opportunity Assessment for conceptual design should also be reviewed with the CSDR to verify that the technical uncertainties in the safety basis are identified and that the risk-handling strategy (strategies) for each risk element has bounded the risk for proceeding with the project. The Risk and Opportunity Assessment is essential to enable the project risks to be understood by the project team and the Federal Project Authorization Executives.

H.2 CSDR FORMAT AND CONTENT GUIDE

1. INTRODUCTION

a. Facility and Mission Overview

Identify the facility and present general information on the background of the facility as it relates to the use of the project scope. Present the current mission statement. Present any relevant information (e.g., short facility life cycle, anticipated future change in facility mission, approved DOE exemptions) impacting the extent of safety-in-design approaches documented in the CSDR.

b. Site Location

Provide a description of the facility location, including the physical and institutional boundaries, relationship and interfaces with nearby facilities, facility layout, and significant external structures, systems, and components (SSC) interfaces (e.g., utilities) as they pertain to the hazard analysis.

If multiple sites are under consideration, describe each of them.

2. CONCEPTUAL DESIGN DESCRIPTION

a. Facility Structure and Layout

Provide an overview of the basic facility structures. The structure

description should include information such as basic floor plans, material-at-risk (MAR) locations within the structure, general dimensions, and dimensions significant to the hazard analysis activities. Supply information to support an overall understanding general arrangement of the facility as it pertains to hazard analyses topics to be described in later sections of the CSDR.

b. Process Description

Describe the individual processes within the facility to support understanding of the overall postulated facility level MAR release events and safety-in-design strategies taken to prevent or mitigate the events described. Include details as necessary on basic process parameters, including summary of types and quantities of hazardous materials, energy sources, process equipment, basic flow diagrams, and operational considerations associated with individual processes or the entire facility, including major interfaces and relationships between SSCs. Information is expected only at the level of conceptual design. The intent is to supply information sufficient to understand facility-level MAR release events.

3. PRELIMINARY HAZARD CATEGORIZATION

a. Hazardous Material Inventories

Estimate the total inventory (with associated uncertainties) of radionuclides, hazardous chemicals, and flammable and explosive materials used or potentially generated in facility processes. Present the results either by direct inclusion of or by reference to the hazard identification data sheets in the Preliminary Hazard Analysis (PHA). The attributes of hazards identified in this section are the basis for subsequent hazard evaluation and accident analysis in future project stages.

This inventory should describe the maximum inventories of hazardous materials that are anticipated to be in the facility during its operational life. To the extent possible, the inventory should be specified by component and location within the conceptual designed facility. This should be in sufficient detail to support a facility-level PHA that would, in turn, support the definition of facility-level DBAs or bounding accidents associated with the inventory locations (e.g., tanks, storage, process vessels and the associated preliminary lists of SC and SS SSCs.

b. Comparison of Inventories to Threshold Quantities

Compare the radionuclide and fissile material inventories with the threshold quantities in Table A.1 of DOE-STD-1027-92 and identify the preliminary hazard categorization. When segmentation is proposed, identify segment boundaries and hazard inventories and justify the independence of the segments. Identify the individual segment preliminary hazard categorizations.

The preliminary hazard categorization must be in compliance with DOE-

STD-1027, as required by 10 CFR 830.202. The information compiled in the preliminary inventory of hazardous materials should be used. Note any likely issues that may change final hazard categorization, such as obvious inconsistencies with the basis of the STD-1027 Table A.1. For example, if facility processes include the possibility of vaporization of radioactive materials, for which STD-1027 assumed an airborne release fraction (ARF) of 1 E (-3), it should be noted that final hazard categorization would likely have to be based on an ARF of 1.0. Similarly, if the facility is intended for the storage of vitrified "logs," it should be noted that an ARF of 1 E (-6) might be appropriate in final hazard categorization.

4. DESIGN BASIS ACCIDENTS

a. Facility-Level DBAs

Provide a summary table identifying postulated hazardous material release events. The goal is to provide a perspective on facility hazards by summarizing the major events or hazardous situations (e.g., fires, explosions, loss of confinement) that were postulated in the facility during the PHA activities.

During the conceptual design stage, a facility layout, including process flow diagrams and locations of MAR will be developed. Bounding accident scenarios involving the MAR locations, such as fires, explosions, and seismic induced failures, can be postulated.

b. Unmitigated DBA Analyses

Appendix A and Appendix B of this Standard provides radiological dose and chemical exposure-related criteria and guidance respectively. These are to be used for the classification of SSCs as Safety Class or Safety Significant on the basis of collocated worker unmitigated accident dose analyses and for the application of seismic design guidance of ANSI/ANS 2.26, *Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design*. These criteria address both radiological and chemical hazards. In the guidance below, when the word "dose" is used, it should be understood to apply to radiation dose when the DBA is a nuclear accident and to apply to chemical exposures when the DBA is a chemical release accident.

Application of the criteria requires unmitigated accident analyses for the facility-level DBAs.

For each DBA:

1. Identify the release category by individual title, category (i.e., operational, natural phenomena, external) and general type (e.g., fire, explosion, spill, earthquake, tornado).

2. Describe the source-term determination for the event category. Discuss all parameters used to derive the source term. This definition includes the material at risk (as derived from the hazard identification), the damage ratio (DR) and the ARF. The degree of conservatism believed to be present in the calculation needs to be consistent with DOE-STD-3009, Appendix A, definitions and requirements.
3. Present the results of the DBA analysis, both for the dose to the collocated worker at 100 m and the dose to the public according to the guidance of Appendix A of this Standard.
4. Compare the DBA results to guidance for safety system classification and seismic design criteria of Appendix A of this Standard.

c. Preliminary Selection and Classification of Safety Controls

For each DBA the following information is presented, based on the analyses of the DBAs in the PHA and the safety classification criteria in Appendix A of this Standard:

i. preliminary identification of facility level safety functions, and if proposed, the associated Safety Class and SS structures, systems, and components (safety SSCs) and their necessary support systems'

ii. requirements for the identified safety functions and, if proposed, for the associated safety SSCs; and

iii. applicable structural design basis associated with each system (seismic design criteria and PC categories for other NPH).

Based on unmitigated analyses of the facility DBAs, candidate preventative and mitigative safety SSCs can be identified and classified, according to the guidance of Appendices A through D.

This section should provide a discussion of safety functions and design criteria for safety SSCs; for example, the required safety functions for the confinement, active ventilation, fire protection, and electrical power and distribution SSCs. This section must also describe the rationale from a safety-in-design perspective for the following major systems (including NPH design expectations) recognized as having significant cost impact if changed later in the project cycle:

- facility structure;
- facility hazardous material confinement;
- fire protection; and
- emergency power

As described in Appendix A, DOE is adopting ANSI/ANS 2.26, *Categorization of Nuclear Facility Structures, Systems, and Compon*ents, for the purpose of new facility design. Once the Seismic Design Category is identified for facility SSCs, the appropriate Limit State for those SSCs should be selected, based on their safety function. See Appendix A and ANSI/ANS 2.26 and its appendices for guidance.

5. SECURITY HAZARDS AND DESIGN IMPLICATIONS

This section, depending on security classification considerations, may have to be a placeholder that references a classified report. That report would describe the facility design aspects that respond to Design Basis Threat (DBT) information, and would address how the security design aspects take into account facility safety issues in protection of workers and the public.

DOE Security Orders (i.e.., 470 series) have requirements that may affect design and the safety aspects thereof for some facilities. These directives should be reviewed as part of the design process. In particular, there are requirements regarding the DBT, the implementation of which may have implications regarding public and worker safety. The key concept that must be considered in ensuring that both the security requirements and safety requirements are satisfied for any security installation at a facility meeting the DBT is that the approach must (1) encompass all threats against which security systems must be designed and (2) be employed in an effective manner to assure neutralization and protect the national security.

6. NUCLEAR SAFETY DESIGN CRITERIA

a. Design Criteria and Strategy for Compliance

Provide a listing of the applicable safety design criteria of DOE O 420.1B, *Facility Safety*, and a brief summary of the implementation approach being taken in the project for each design-related criterion. Programmatic criteria are not expected to be discussed. This section is meant to be a description of, or a roadmap to, the specific information that demonstrates the implementation approaches for the various criteria, not a detailed re-write of information included in other sections of the CSDR or other available project documentation.

Note that some of the applicable attributes applicable to the project may not be items that would be addressed by the hazards analysis process (e.g., provisions for decontamination and decommissioning and provisions for radiological controls for ALARA expectations). These items still are expected to be include as applicable criteria and discussed in this section of the CSDR to demonstrate that the key items that will be in the final DSA are being considered appropriately in the conceptual design process.

The nuclear safety design criteria of DOE O 420.1B are primarily located in both the Order and Attachment 2 to the order in Chapter I, “Nuclear and Explosives Safety Design Criteria”; but additional applicable safety design

criteria can be found in Chapter II, “Fire Protection”; Chapter III, “Nuclear Criticality Safety”; and Chapter IV, “Natural Phenomena Hazards Mitigation.” The Implementation Guides for these chapters should also be followed.

b. Exceptions to Design Criteria

Provide, for any exception to the high-level safety design criteria in DOE O 420.1B, or the implementing standards listed in DOE G 420.1-1 and listed in Section 6.a, the project’s alternative criterion and a justification for the alternative. The justification should show why the alternative is an acceptable criterion or standard.

7. OTHER CONSIDERATIONS

a. Planned Studies or Analyses

Describe any key planned technical studies essential for development or validation of the safety design basis that will be accomplished in preliminary/final design. These studies may be necessary to confirm key assumptions or key process component equipment selections that could impact safety. The primary source for this information is the PHA and Safety Strategy.

b. Safety-in-Design Risks and Opportunities

Summarize the safety-in-design risks and opportunities from the CDR. The intent of this summary is to provide an overall perspective of the risks and opportunities associated with the safety-in-design strategies considering the maturity of the project, the remaining technical studies, and the mitigative and preventive strategies selected for the recognized preliminary design basis events. Describe only key risk and opportunities and the associated mitigation strategies that are important to be recognized by the approval authority. These discussions are intended to support a risk-informed decision regarding progressing to preliminary design.

c. Lessons Learned From Previous Experience Involving Major Systems

In this section, discuss the logic used to select the safety-related functions for SSCs that may generate significant cost changes to the project if changed in later stages of the project.

It is important for safety SSCs be identified early in the design process. Otherwise, costly upgrades to the facility design could occur. When a safety classification is unclear for a major SSC (based upon very preliminary analysis) a higher level of categorization should be the default position early on until the analysis progresses to the point that a confident and defensible determination can be made for a lower level.

When followed correctly, the hazard and accident analysis process should supply a reproducible logic for safety SSC choices. Specific examples of potential safety SSCs include the following:

- fire suppression;
- fire detection;
- confinement ventilation;
- emergency power;
- nuclear criticality design features and alarms;
- seismic design, including addressing level of confinement for primary confinement system (building structure); and
- flammable gas controls.

These items have the potential for large cost and schedule impacts if their design expectations are added later in the project life cycle.

APPENDIX I
Preliminary and Final Design Stage Safety Documentation

I.1 Introduction

I.1.1 Preliminary Safety Design Report

The Preliminary Safety Design Report (PSDR) should update the information in the Conceptual Safety Design Report (CSDR), if needed (i.e., if the information has changed). In addition, more detailed site information of the type that can affect safety-in-design should be provided (e.g., location of nearby facilities and external hazards, meteorological information for dispersion analyses, seismic and other natural phenomena information).

PSDR review and approval is very important during the design process. Decisions made and approved as a result of preliminary design reviews and documented in the PSDR will provide the basis for the approach for detailed design and construction. Decisions that are reversed after this stage, for whatever reasons, can have significant impacts on overall project cost and schedule. It is essential that contractor and DOE safety personnel be totally engaged and participate fully in design reviews during this stage, so that their views and advice can be considered in the design in a timely fashion.

There should be a specific crosswalk between the top level safety design criteria of DOE O 420.1B and its Implementation Guides (DOE G 420.1-1 and DOE G 420.1-2), or any approved substitute criteria and implementation, and the specifics of the design description and the specified Safety Class (SC) and Safety Significant (SS) structures, systems, and components (SSC). This should include any SSCs that are intended to become design features in operational technical safety reports (TSR). It is not necessary for the full details of consensus design codes and standards to be listed in the PSDR. These details should be in the documents available for the design reviews and should be fully scrutinized during design reviews as part of safety personnel participation in those reviews. The PSDR should, however, include the identification of any codes and standards used that are not included in DOE G 420.1-1 and DOE G 420.1-2 guidance and a brief description regarding why they are appropriate. The basis for tailoring of codes and standards should be provided when tailoring is required.

The bases of the PSDR approval in a preliminary Safety Validation Report (SVR) should primarily be focused on the adequacy of the hazards analyses and selection and classification of the hazard controls, including consideration of the application of the principles associated with the

hierarchy of controls. Further, it should be concluded that, if carried through in detailed design, the commitments made in the PSDR and design documents would result in a final design and a constructed facility that might result in a facility that could be approved for operations, without major changes. The review and approval should specifically address the acceptability of the design implementation in complying with the nuclear safety design criteria of DOE O 420.1B, or the acceptability of alternate safety design criteria and alternate codes and standards that are proposed and their implementation in design.

Because the design is not complete at this point in the process, adequate safety in design for the preliminary design is based primarily on the identification of viable engineered solutions to nuclear design requirements and the specification of an adequate set of more detailed safety design requirements that are integrated with the safety analysis. The following points are to be demonstrated in the PSDR.

- The design addresses the nuclear facility design requirements of DOE O 420.1 as described in PSDR, Appendix B.
- The design is integrated with safety analyses as described in Section 3.
  - A viable design solution (e.g., safety SSCs) is identified to provide the safety functions required by the hazard analysis.
  - The unmitigated accident consequence assessment properly indicates the required functional classification (i.e., Safety Class vs. Safety Significant) and seismic and other natural phenomena hazard (NPH) design requirements (i.e., the proper seismic design criteria (SDC) for seismic design and PC for other NPH design).
  - The analysis of DBAs identifies the functional requirements and accident conditions (e.g., environmental qualifications) that the safety SSCs must address.
- Appropriate supplemental design criteria (DOE G 420.1-1, Chapter 5) are specified for safety SSCs as described in PSDR Chapter 4.
  - General requirements for safety SSCs are specified (e.g., conservative design features, design against single-point failure, environmental qualification, safe failure modes)
  - Based on the functional classification and the safety SSC design function, appropriate codes and standards are specified and tailored, as needed, or alternate codes and standards are identified and justified.

- Technical studies still needed to complete the safety design are identified and described.
- Safety design risks and risk mitigation strategies for the final design phase are identified.

I.1.2 Preliminary Documented Safety Analysis

The major new content of the Preliminary Documented Safety Analysis (PDSA) as compared to the PSDR is completion of the Documented Safety Analysis (DSA). The DSA, as opposed to the hazards analysis (HA), demonstrates the adequacy of the design from the safety prospective. As with the design, it is not necessary to show the progression of the design that lead to the final choices, only those final choices and the justification for their adequacy. The PDSA format and content discuss how this information is documented.

Demonstrating safety design adequacy for final design is focused on demonstrating that the safety design requirements specified at the end of preliminary design have been satisfied, and describing the mitigated condition for hazards and accidents with the safety controls applied.

To provide a baseline understanding of the adequacy of controls, the accident analysis in the PDSA should describe how the selected controls adequately prevents/mitigates the accidents including how the controls provide defense in depth, if warranted, based on accident frequency and control reliability. The analysis need not be quantitative in either frequency or consequences but should provide an adequate understanding of the base line mitigated risk for the facility. The discussion puts the safety controls' effectiveness in accident context and also provides the base line safety analysis for the evaluation of changes, for example, under the Unreviewed Safety Question (USQ) process, as the facility DSA is developed for the transition to operation. This Standard anticipates that the eventual safety basis for the facility being constructed or modified is based on the methodology of DOE-STD-3009. If a different safe harbor is applicable to the project or modification, the Safety Design Strategy should establish that expectation, and the format of the PSDR/PDSA as provided in this appendix should be modified as appropriate. However, the expectations for integration of safety into the design process and application of nuclear safety design criteria apply to all projects and modifications within the scope of this Standard. Application of an SDS utilizing existing safety documents created under DOE-STD-3009-94, *Preparation Guide for U.S Department of Energy Nonreactor Nuclear Facility Documented Safety Analyses* or DOE STD-3011-2002, *Guidance for Preparation of Basis for Interim Operation (BIO) Documents* or DOE-STD-1120-2005, *Integration of Environment, Safety, and Health into Facility Disposition Activities* could be appropriate for legacy facilities or

departmental D&D activities.

I.2 PSDR/PDSA FORMAT AND CONTENT GUIDE

The project documentation describing the safety-in-design for the preliminary design consists primarily of the Process Hazard Analysis Report (PrHA) and the PSDR. The project documentation describing the safety-in-design for the final design consists primarily of the PDSA. The PDSA is an evolution of the PSDR. The format and content for the PSDR begins to build toward a PDSA, and the PDSA will build toward a DSA that will form a key part of the safety basis for the operating facility. This format and content guide often refers to “the document” meaning the PSDR or the PDSA. It is intended that the content of a PSDR or PDSA be commensurate with the stage of safety in design that it is intended to document. For example, hazards analyses that are documented in a PSDR would not necessarily include process hazards analyses and the in-facility worker safety controls. These would typically be developed during final design and would be documented in the PDSA.

Executive Summary

PURPOSE. The Executive Summary provides an overview of the facility safety-in-design approach and presents information sufficient to establish a top-level understanding of the facility, its operations, and the results of the safety analysis. It summarizes the facility safety-in-design as documented in detail in the remainder of the document. The PSDR may be relatively short and higher level and may not warrant an executive summary whereas the PDSA is more detailed and, therefore, an executive summary is recommended.

E.1 FACILITY MISSION

This section identifies the facility for which the document has been prepared and presents general information on the mission. Clearly present the mission statement for which the PSDR/PDSA documents the safety-in-design approach (e.g., the purpose for which authorization to proceed to final design is sought).

Present any relevant information (e.g., short facility life cycle, anticipated future change in facility mission, approved DOE exemptions) impacting the extent of safety analysis documented in the document and briefly explain its impact in terms of application of the graded approach.

E.2 FACILITY OVERVIEW

This section provides an overview of the facility, including the facility location, physical and institutional boundaries, relationship and interfaces with nearby facilities, facility layout, and significant external interfaces (e.g. utilities, fire support).

E.3 FACILITY HAZARD CATEGORIZATION

This section provides a statement of the facility hazard category as determined in accordance with DOE-STD-1027. If determination of the hazard category relied upon segmentation of facility hazards, then provide a brief explanation of the technical basis for such segmentation.

E.4 SAFETY ANALYSIS OVERVIEW

This section provides an overview of the facility operations and the results of the facility safety analysis to include the following:

- description of the facility operations analyzed in the document;
- summary of the significant accidents resulting from the facility processes, natural events and external man-inducted hazards; and

- summary of the main preventive and mitigative engineered features (SSCs), their functional classification (i.e., Safety Class or Safety Significant), and associated NPH performance category, and seismic design category.

E.5 ORGANIZATIONS

This section identifies the prime contractors responsible for facility design and should also identify participants (including consultants) in the safety-in-design process.

E.6 SAFETY-IN-DESIGN CONCLUSIONS

This section should provide a brief assessment of the appropriateness of the facility safety-in-design approach. As part of this summary, this section would identify any safety-in-design issues significant to project risk (e.g., cost and schedule) and risk mitigation measures applied to address them.

E.7 DOCUMENT ORGANIZATION

This section provides a guide to the structure and content of the document (e.g., a table that indicates where the requirements of this Standard are addressed, its sections, and appendices) if the format in this appendix is not followed. If the main body of the document parallels the format delineated in this Standard, a simple statement to that effect will suffice.

Chapter 1
Site Characteristics

PURPOSE. This chapter provides a description of site characteristics necessary for understanding the facility environs important to integrating safety into the design. Information is provided to support and clarify assumptions used in the hazard analyses to identify and analyze potential external and natural event accident initiators and accident consequences external to the facility. Existing supporting documentation is to be referenced. Include brief abstracts of referenced documentation with enough of the salient facts to provide an understanding of the referenced documentation and its relation to this chapter.

APPLICATION OF THE GRADED APPROACH. Hazard Category 3 facilities may not have the potential for resulting in significant radiological consequences beyond the immediate facility. Therefore, the description of site characteristics, as a minimum, locates the facility on the overall site, shows the facility boundaries, and identifies any other facilities that can significantly impact the facility being examined. For Hazard Category 3 facilities, onsite meteorological conditions, hydrology, population information, and offsite accident pathways may not be required if consequences can be shown to be limited to the facility itself. Note, however, that if chemical hazards are present in a Hazard Category 3 facility that have the potential to cause significant offsite consequences, more information is necessary.

For Hazard Category 2 facilities the emphasis of site characteristics description is focused within site boundaries unless hazards have the potential to cause offsite consequences of concern; that is, can challenge the evaluation guideline. For Hazard Category 2 facilities with the potential for an accident resulting in consequences of concern at the site boundary, site characteristics information is extended beyond the site boundary to support assessment of population dose, land contamination, and emergency planning external to the site.

If the final site selection is not complete, information for siting options may need to be provided.

1.1 INTRODUCTION

This section provides an introduction to the contents of this chapter based on the graded approach and includes objectives and scope specific to the chapter as developed.

1.2 SITE DESCRIPTION

This section describes the site boundary and facility area boundary.

1.2.1 Geography

This section provides basic geographic information, such as the following:

- state and county in which the site is located'
- location of the site relative to prominent natural and man-made features such as rivers, lakes, mountain ranges, dams, airports, population centers;
- general location map to define the boundary of the site and show the correct distance of significant facility features from the site boundary;
- public exclusion areas and access control areas;
- identification of the point where the Evaluation Guideline is applied; and
- additional detail maps, as needed, to present near plant detail such as orientation of buildings, traffic routes, transmission lines, and neighboring structures. (Note: This level of detail is typically not necessary for the PSDR.)

1.2.2 Demography (Not required for PSDR)

Population information based on recent census data is included to show the population distribution as a function of distance and direction from the facility. Demographic information emphasizes worker populations and nearby residences, major population centers, and major institutions (e.g., schools and hospitals) to the degree warranted by potential offsite consequences. The minimum area addressed is defined by the area significantly affected by the accidents analyzed in Chapter 3, "Hazard Analyses, Accident Analysis, and Control Selection."

1.3 ENVIRONMENTAL DESCRIPTION

This section describes the site's meteorology, hydrology, and geology.

1.3.1 Meteorology

This section provides the meteorological information necessary to understand the regional weather phenomena of concern for facility operations and to understand the dispersion analyses performed.

1.3.2 Hydrology

This section provides the hydrological information necessary to understand any regional hydrological phenomena of concern for facility operation and to understand any dispersion analyses performed. Include information on groundwater aquifers, drainage plots, soil porosity, and other aspects of the hydrological character of the site. Discuss or reference, to the degree necessary, the average and extreme conditions as determined by historical data to meet the intent of this section. (Note: Hydrology is not typically a significant input to the safety analysis required for a PDSR. Therefore, this section is not required for the PDSR, unless there are unique features of the proposed facility, such as a high aquifer level that interfaces directly with the building structure.)

1.3.3 Geology

This section provides the geological information necessary to understand any regional geological phenomena of concern for facility operation and possible effects on seismic structural design. Describe the nature of geotechnical investigations performed and provide the results of the investigations. Include geologic history, soil structures, and other aspects of the geologic character of the site.

1.4 NATURAL EVENT ACCIDENT INITIATORS

This section provides identification of specific natural events, such as design basis earthquakes considered to be potential accident initiators. Summarize assumptions supporting the analysis in Chapter 3, “Hazard Analyses, Accident Analysis, and Control Selection.”

1.5 MAN-MADE EXTERNAL ACCIDENT INITIATORS

This section provides identification of specific man-made external events associated with the site (e.g., events such as explosions from natural gas lines or accidents from nearby transportation activities) considered to be potential accident initiators, exclusive of sabotage and terrorism. Summarize assumptions supporting the analysis in Chapter 3, “Hazard Analyses, Accident Analysis, and Control Selection.”

1.6 NEARBY FACILITIES

This section identifies any nearby facilities that could be affected by accidents within the facility being evaluated. Conversely, this section also identifies any hazardous operations or facilities onsite or offsite that could adversely impact the facility under evaluation. Summarize assumptions supporting the analysis in Chapter 3, “Hazard Analyses, Accident Analysis, and Control Selection.”

1.7 EVALUATION OF SITING CRITERIA

This section addresses the siting criteria used in selection of the site. If the siting criteria used in DOE G 420.1-1 are used, discuss how the criteria are met by the site; if they are not met, discuss the impact of not meeting them. If alternative siting criteria were selected, discuss them and explain how well they were met.

Chapter 2
Facility Description – Preliminary Design

PURPOSE. The purpose of this chapter is to provide the facility and process information necessary to support the hazard analysis and also to describe key aspects of safety-in-design. However, this chapter does not include information at the level of functional requirements and performance criteria; that information is provided for safety SSCs only, and the information is provided in Chapter 4. In the basic description of safety SSCs, their categorization as Safety Class SSC or Safety Significant SSC should simply be noted.

Existing supporting documentation is to be referenced. Include brief abstracts of referenced documentation with enough of the salient facts to provide an understanding of the referenced documentation and its relation to this chapter.

APPLICATION OF THE GRADED APPROACH. The development of this chapter for Hazard Category 2 and 3 facilities is an iterative process dependent on the development of the hazard analyses. The facility description should provide a model of the facility that would allow an independent reader to develop an understanding of facility operations and an appreciation of facility structure and operations without extensive consultation of controlled references. The level of detail required in the facility description is based on the significance of subject to hazard analysis. Significant subjects typically include the location, quantity, and nature of radioactive and hazardous materials (MAR); energy sources that could disperse these materials, including combustible or explosive materials; and significant pathways for release. In addition, for aspects that are important to safety-in-design, sufficient description should be provided to demonstrate that the preliminary design addresses the nuclear design requirements of DOE O 420.1B, as appropriate for preliminary design in the PSDR and as appropriate for final design in the PDSA.

2.1 INTRODUCTION

This section provides an introduction to the contents of this chapter based on the graded approach and includes objectives and scope specific to the chapter as developed.

2.2 REQUIREMENTS

This section lists the major design codes, standards, regulations, and DOE Orders that are required for establishing adequate safety-in-design for the facility; however, it is not intended to be a comprehensive listing of all industrial standards or codes or criteria. Project requirement documents (e.g., Functional and

Operational Requirements, Design Criteria documents) may be referenced as appropriate.

2.3 FACILITY OVERVIEW

This section includes a brief overview of the facility mission, facility configuration, and the basic processes performed therein.

2.4 FACILITY STRUCTURE

This section provides an overview of the basic facility buildings and structures, including construction details such as basic floor plans, equipment layout, construction materials, and dimensions significant to the hazard analysis activity. Supply information to support an overall understanding of the facility structure and the general arrangement of the facility as it pertains confinement and the hazard analysis. (Note: Less detail is expected in the PSDR and more detail expected in the PDSA, consistent with the design stage.)

2.5 PROCESS DESCRIPTION

This section describes the individual processes within the facility. Include information on basic process parameters, summary of types and quantities of hazardous materials, process equipment, instrumentation and control systems and equipment, basic flow diagrams, and operational considerations associated with individual processes or the entire facility, including major interfaces and relationships between SSCs. For the PSDR, process flow diagram level of detail is appropriate; for the PDSA, more detailed information is expected (e.g., piping and instrumentation diagram level of detail).

2.6 SUMMARY OF SAFETY CLASS AND SAFETY SIGNIFICANT STRUCTURES, SYSTEMS AND COMPONENTS

This section provides a summary description of safety SSCs. However, this chapter does not include information at the level of functional requirements and performance criteria; that information is provided for safety SSCs only and the information is provided in Chapter 4. Their categorization as Safety Class SSC or Safety Significant SSC should simply be noted.

2.7 UTILITY DISTRIBUTION SYSTEMS

This section provides information regarding basic utility distribution systems, including offsite power supplies and onsite components of the system. For the PSDR the information may be focused more on the need for utilities, whereas the PDSA should provide details of systems, to the level necessary, for understanding

the utility distribution philosophy and facility operations (e.g., schematic outline of power supplies and other utilities).

2.8 AUXILIARY SYSTEMS AND SUPPORT FACILITIES

This section provides information on the remaining portions of the facility that have not been covered by the preceding sections and which are necessary to create a conceptual model of the facility as it pertains to the hazard analyses. For the PSDR, the information may be focused more on the need for auxiliary systems and support systems, whereas the PDSA should provide details necessary to understand the more detailed safety analysis content in the PDSA.

2.9 DESIGN PROVISIONS FOR DECONTAMINATION AND DECOMMISSIONING

This section provides information regarding design provisions for decontamination and decommissioning (see DOE G 420.1-1, Section 3.7).

Chapter 3
Hazard Analyses, Accident Analysis and Control Selection

PURPOSE. The purpose of this chapter is to describe the process used to systematically identify and assess hazards, select and analyze accidents, identify and classify controls for significant hazards, and specify the seismic and natural phenomena design criteria for these hazards. This chapter also presents the results of this hazard and accident analysis and control selection process.

The hazard and accident analyses expected during the preliminary and final design phase are described in this Standard.

APPLICATION OF THE GRADED APPROACH. In general, a graded approach dictates a more thoroughly documented assessment of complex, high-hazard facilities than simple, lower-hazard facilities since grading is a function of both hazard potential and complexity. The graded approach for hazard analysis is a function of selecting techniques for process hazard analysis. The techniques used for hazard evaluation can range from simple checklists or What-If analyses to systematic parameter examinations such as hazard and operating analyses (HAZOP). The technique selected need not be more sophisticated or detailed than is necessary to provide a comprehensive examination of the hazards associated with facility operations. For example, a simple storage operation may be adequately evaluated by a preliminary hazard analysis or a structured What-IF analysis. However, a more complex process facility is expected to use more detailed techniques, such as HAZOP.

The level of analytical effort used for accident analysis (e.g., facility-level accident consequence analysis, analysis of DBAs, and mitigated accident analysis) is primarily a function of magnitude of hazard, but also takes into account system complexity and the degree to which detailed modeling can be meaningfully supported by system definition. The graded approach cannot be based solely on facility hazard categorization because Hazard Category 3 facilities may also have chemical hazards, and the hazard classification mechanism used in DOE-STD-1027 does not consider the potential for hazardous chemical releases. The results of the hazard analysis (e.g., chemical screening) will indicate whether a facility contains significant chemical hazard(s) that may necessitate DBA analysis.

Accident analysis is also inherently graded in terms of the degree of physical modeling and engineering analysis needed to quantify accident consequences. The use of bounding assumptions and less detailed physical modeling in DBA analysis during preliminary design is appropriate.

In addition to analysis of accidents that can affect the public or collocated worker, hazards must be evaluated to determine if safety controls (i.e., Safety Significant SSCs and SACs) are required for significant facility worker hazards, and this would typically be expected to result from Process Hazards analysis in final design. This is a qualitative analysis and uses guidelines and examples for significant facility worker hazards described in Appendix C.

3.1 INTRODUCTION

This section provides an introduction to the contents of this chapter based on the graded approach and includes objectives and scope specific to the chapter as developed.

3.2 HAZARD ANALYSIS, ACCIDENTANALYSIS, CONTROL SELECTION, AND CLASSIFICATION METHODOLOGY

This section summarizes the methodology used to perform hazard analysis, accident consequence analysis, analysis of Design Basis Accidents, and control selection, as applied during preliminary and final design.

3.2.1 Hazard Analysis Methods

This section summarizes the methods used to perform the hazards analysis at the stage of design (preliminary or final) that is being documented. See Vol. 1 and Appendix G of this Standard for more guidance.

3.2.2 Accident Consequence Analysis Methods

This section describes the methods used to identify and analyze accidents for comparison to guidelines established to establish their classification (i.e., Safety Class, Safety Significant) and required seismic and other natural phenomena design criteria. These accidents are analyzed for radiological source terms and toxicological exposures to the public and collocated workers. Expectations for these analyses are described in Appendices A and B. (Note: Safety functions may also be identified and classified based on facility worker hazards as described under control selection and classification below.)

3.2.3 Method for Analysis of Design Basis Accidents

This section describes the methods used to identify and analyze DBAs. DBAs are the minimum set of accidents needed to define safety design requirements for safety SSCs under postulated accident conditions. The DBA analysis should also provide accident environmental conditions for which the safety SSCs must be designed to withstand and perform their

safety function. If the methodology is specific to a particular accident, the methodology may be described as part of the accident description in Section 3.4.

3.2.4. Control Selection and Classification Methods

This section describes the method used to select safety controls. Focus is on the selection method for Safety Class and Safety Significant SSCs. Control hierarchy preferences are described. Methods used to establish a necessary and sufficient set is described. Selected safety SSCs are classified as described in Appendix D based on radiological source terms and criteria described in Appendix A of this Standard, chemical exposures and criteria described in Appendix B of this Standard, and facility worker consequences based on considerations and examples described in Appendix C.

3.3 HAZARD ANALYSIS RESULTS

Provide a high-level summary of the process hazard analysis results. This summary can be short, as key results will be described in later sections. The detailed results of the process hazard analysis are described in the Process Hazard Analysis (PrHA) report.

3.4 FACILITY HAZARD CATEGORIZATION

This subsection presents the results of the hazard categorization activity specified in DOE-STD-1027. Include the facility hazard categorization and, where segmentation has been used, the segment boundaries and individual segment classifications. Justify any segmentation in terms of independence. Where facility segmentation is used, provide the hazard breakdown by segment in the PrHA report.

3.5 RESULTS OF ANALYSIS OF ACCIDENTS

This section describes each accident analyzed. For the PSDR, the focus is on analysis of facility and selected system level accidents, including an unmitigated consequence assessment and an analysis of selected Design Basis Accidents to derive design requirements and accident environmental conditions. The PDSA adds description of mitigated accidents to demonstrate the adequacy of controls.

3.5.1 Accident #1 (e.g., Fires and Explosions)

3.5.1.1 Scenario Development

Describe the scenario including a summary of the MAR (radioactive, chemical, or both), energy source and release pathway. State the qualitative frequency assigned during hazard analysis (i.e., anticipated, unlikely, extremely unlikely). Identify the top-level safety functional requirements that involve responses to fires and explosions.

3.5.1.2 Analysis of Radiological Source Term and/or Chemical Exposure

Describe the MAR, DR, and ARF and bases used to determine the radiological source term. Describe the chemical release rate and concentration, and the bases that were used to determine the toxicological exposures. Describe and justify any adjustments made to respirable fractions, receptor breathing rates, or atmospheric dispersion factors and why such adjustments are warranted. Compare the radiological source terms and/or chemical exposures to classification guidelines. State the results of the hazard evaluation for facility workers (i.e., does the hazard/accident present a significant facility worker hazard, yes or no).

3.5.1.3 Design Requirements

Identify the design requirements that are derived from the DBA. These could include the worst case fire temperature, duration, locations (interior, exterior), type of fuels (to derive soot loading), and other constraints (such as a not to exceed temperature to prevent auto ignition for materials protected by a fire barrier). For explosion events, identify TNT equivalents, overpressures (detonation and deflagration), for the various explosion events. Also identify required protective response associated with secondary events, such as fires or structural failures, pressure relief requirements, and other design aspects needed to meet the functional safety requirements.

3.5.1.4 Control Selection and Classification

Describe the SSCs and SACs selected to prevent or mitigate the accident including the safety function. For SSCs, provide the safety classification, seismic design criteria, and other natural phenomena design criteria. For the PDSA, describe how the selected control suite adequately prevents/mitigates the accident including how the control suite provides defense in depth, if warranted, based on accident frequency and control reliability.

3.5.2 DBA #2

Same format and content as DBA #1

3.5.3 DBA #3

Same format and content as DBA #1

3.6 SUMMARY OF SIGNIFICANT FACILITY WORKER HAZARDS AND CONTROLS

Describe the significant facility worker hazards identified (if not addressed in the accidents described above) and the SSCs and specific administrative controls (SAC) selected to address them. A table identifying the SSC or SAC and its safety function, and for the SSCs the classification, seismic design criteria, and other natural phenomena design criteria is adequate. (Note: For the PSDR, this section may be limited based on the maturity of the design and hazard analysis. The PDSA section would be complete for significant facility worker hazards identified during the design effort. The DSA may address additional significant facility hazards identified during hazard analysis based on a more complete understanding of operations as operating procedures are developed.)

3.7 SUMMARY OF SAFETY FUNCTIONS AND SSCs and SACs

This section provides a summary (e.g., table) listing the safety functions and the SSCs and SACs selected to provide them. For SSCs, provide the safety classification, seismic design criteria, and other natural phenomena design criteria. In addition, SSCs needed to support the identified safety SSCs, or whose failure can prevent operation of the safety SSCs, are identified, along with their safety classification, seismic design criteria, and other natural phenomena design criteria. (Note: The identification of support SSCs and SSCs whose failure can prevent operation of the safety SSCs maybe limited during preliminary design and thus in the PSDR but should be addressed to the extent the design maturity allows.)

3.8 ACCIDENTS BEYOND THE DESIGN BASIS

The Nuclear Safety Management Rule requires consideration of the need for analysis of accidents which may be beyond the design basis of the facility to provide a perspective of the residual risk associated with the operation of the facility. The evaluation of accidents beyond the design basis serves as bases for cost-benefit considerations in determining if the facility design basis should be revised to consider more severe (although less likely) accidents and accident conditions. This evaluation of accidents beyond the design basis establishes the

facility design basis by providing the division between events and conditions the facility will be designed for and those for which it will not be designed. Thus, the selection of facility design basis is established with the concurrence of DOE.

It is expected that accidents beyond the design basis will not be analyzed to the same level of detail as accidents within the design basis. The requirement is that an evaluation be performed that simply provides insight into the magnitude of consequences of these accidents (i.e., provide perspective on potential facility vulnerabilities). This insight has the potential for identifying additional facility features that could prevent or reduce severe accident consequences. For nonreactor nuclear facilities, however, the sharp increase in consequences from accidents within the design basis, to those beyond the design basis, is not anticipated to approach that found in commercial reactors where the beyond the design basis precedent was generated. No lower limit of frequency for examination is provided for accidents beyond the design basis whose definition is frequency dependent. It is understood that as frequencies become very low, little or no meaningful insight is attained.

Operational accidents beyond the design basis are simply those operational accidents with more severe conditions or equipment failures than are estimated for the corresponding accident within the design basis. For example, if an accident within the design basis assumed releases were filtered because accident phenomenology did not damage filters, the same accident with loss of filtration is beyond the design basis. The same concept holds true for natural events, but natural events beyond the design basis are defined by the initiating frequency of the natural event itself (i.e., frequency of occurrence less than the design basis event frequency of occurrence). Accidents beyond the design basis do not consider man-made external events.

Chapter 4
Safety Structures, Systems and Components for Preliminary Design

PURPOSE. This chapter provides details on those facility structures, systems, and components that are necessary for the facility to protect the public, or significantly contribute to worker safety. Similarly, this chapter provides details on Specific Administrative Controls (SAC) that are also necessary for the facility to protect the public or significantly contribute to worker safety. Descriptions are provided of the attributes (i.e., design and functional requirements and performance criteria) required to accomplish the safety functions identified in the hazard and accident analyses and to demonstrate adequacy of the final design of these SSCs. Maximum advantage should be taken of pertinent design and safety design analysis information developed during the project design effort (e.g., structural analysis, safety design analysis). Include a brief summary for each such reference that explains its relevance to this chapter and provides an introductory understanding of the reference.

APPLICATION OF THE GRADED APPROACH. The extent and detail for this chapter is generally graded based on the facility hazard category. Hazard Category 3 facilities will generally not have Safety Class SSCs, and the number of Safety Significant SSCs and SACs, if any, typically would be less than that of a Hazard Category 2 facility due to the reduced magnitude of radiological hazards. However, exceptions to this general guidance pertain to chemical hazards and facility worker hazards. The hazard classification mechanism used in DOE-STD-1027-92 does not consider potential hazardous chemical releases. It is possible that a Hazard Category 3 facility could need Safety Significant SSCs for chemical hazards and significant facility worker hazards (i.e., those that could result in prompt worker fatality, or severe injury or significant radiological or chemical exposure to workers).

4.1 INTRODUCTION

This section provides an introduction to the contents of this chapter based on the graded approach and includes objectives and scope specific to the chapter as developed.

4.2 SAFETY CLASS STRUCTURES, SYSTEMS AND COMPONENTS

Relevant information is provided, in the following SSC specific subsections, for Safety Class SSCs.

Note: The following format is repeated sequentially for each (“X”) Safety Class SSC. The examples provided are for illustration purposes only and should not be

construed as a requirement to designate such systems Safety Class or Safety Significant.

4.2.X [Applicable Safety class Structure, System and Components]

Identify the Safety Class SSC.

4.2.X.1 Safety Function

This subsection states the reason for designating the SSC as a Safety Class SSC, followed by specific identification of its preventive or mitigative safety function(s) as determined in the hazard analysis. Do not discuss nonsafety functions.

Safety functions are top-level statements that express the objective of the SSC in a given accident scenario. For example, the safety function of a hydrogen detector in a dissolver vessel offgas line could be stated as: “To monitor hydrogen concentration in the dissolver offgas and provide a signal to shut down the dissolving operation before explosive concentrations of hydrogen are reached.” The specific accidents associated with the safety function should be identified.

4.2.X.2 System Description

This subsection provides a description of the Safety Class SSC and the basic principles by which it performs its safety function (e.g., sensor and interlock for hydrogen detector discussed in Section 4.3.X.1). Describe its boundaries and interface points with other SSCs relevant to the safety function.

Identify SSCs whose failure would result in a Safety Class SSC losing the ability to perform its required safety function. These SSCs would also be considered Safety Class SSCs for the specific accident conditions for which the Safety Class designation was made originally.

When describing the SSC, provide a basic summation of the physical information known about the SSC, including P&IDs, or a simplified system drawing with reference to P&IDs. If known, abstract and reference pertinent aspects of manufacturer’s specifications. Pertinent aspects are considered to be those that directly relate to the safety function (e.g., diesel generator load capacity, time to load if critical) as opposed to general industrial equipment specifications that fall out from

these capabilities (e.g., starting torque, motor insulation, number and type of windings). Such lower-tier details should be implicitly included only by reference to the overall specifications.

4.2.X.3 Design and Functional Requirements

This subsection identifies requirements that are specifically needed to fulfill safety functions. Such design and functional requirements are specified for both the Safety Class SSC and any needed support Safety Class SSCs.

Limit functional requirement designation to those requirements necessary for the safety function. Functional requirements are provided for Safety Class SSCs for the specific accident(s) where the Safety Class SSC must function (e.g., if that accident is not initiated by an earthquake, the functional requirement does not involve seismic parameters).

Functional requirements specifically address the pertinent response parameters or nonambient environmental stresses related to an accident for which the safety function is being relied upon. In the hydrogen detector example, one obvious parameter would be maintaining hydrogen concentration below the explosive limit. If the offgas temperature was significantly above ambient temperatures, operation at that temperature would be a functional requirement as well. (Note: The level of design maturity at the end of preliminary design may limit the description of safety SSCs to the requirements identified for the SSCs.)

4.2.X.4 System Evaluation

Safety class SSCs must be designed to reliably perform their safety function under those conditions and events for which their safety function is intended. For the PDSA, this subsection summarizes the safety design analysis and other justification for the adequacy of the SSCs ability to reliably perform it safety function. Performance criteria are identified that characterize the specific operational responses and capabilities necessary to meet functional requirements. Evaluate the capabilities of the SSC to meet design and functional requirements. The evaluation of Safety Class SSCs must address the following.

Conservative Design Margins – Safety SSCs must be designed to withstand design basis loadings with an appropriate

margin of safety. The design should incorporate multiple levels of protection against normal, anticipated, and accident conditions. For example, while built-in process controls may maintain pressure within a conservative limit, the design may also require provisions for relief valves, automatic shutdown capability, or other preventive features.

Design Against Single Point Failure – The facility and its systems must be designed to perform Safety Class functions with high reliability. The single-point failure criterion, requirements and design analysis identified in ANSI/IEEE 379 must be applied during the design process as the primary method for achieving this reliability.

Environmental Qualification – Environmental qualification must be used to ensure that Safety Class SSCs can perform all safety functions with no failure mechanism that could lead to common cause failures under postulated service conditions. The requirements from ANSI/IEEE 323 for mild environmental qualification must be used unless the environment in which the SSC is located changes significantly as a result of the DBA(s) for which the SSC must perform a safety function, in which case the requirements for harsh environmental qualification must be used. In general, qualification for mild environments should consist of two elements:

- ensuring that all equipment is selected for application to the specific service conditions based on sound engineering practices and manufacture's recommendations; and
- ensuring that the system documentation includes controls that will preserve the relationship between equipment application and service conditions.

Safe Failure Modes – The design must ensure that more probable modes of failure will increase the likelihood of a safe condition.

Support System – If the Safety Class SSC relies on support systems to perform its safety function, the support system must be classified as Safety Class as well. That is, if a support system failure can prevent the Safety Class SSC from performing its safety function, the support SSC must be classified as Safety Class.

Interface Design – A nuclear safety design goal is to minimize the interfaces between safety SSCs and nonsafety SSCs.

Ideally, safety SSCs would not have any interfaces; however, this is not always practical. Interfaces, such as pressure retention boundaries, integrity of fluid systems, electrical equipment, I&C, and mechanical and support systems exist between Safety Class and non-safety SSCs. These interfaces must be evaluated to identify failures that would prevent the Safety Class SSC from performing its safety function. For these failures, isolation devices, interface barriers or design class upgrades (i.e., upgrade the interfacing SSC to Safety Class) should be provided to protect and ensure the Safety Class SSC reliability. In many cases, systems may consist of a group of subsystems, where each subsystem supports the operation of the whole system. For example, an auxiliary power diesel generator system may consist of lubricating oil, fuel oil, diesel engine, jacket cooling, and room ventilation subsystems. System interface evaluations should clearly define these boundaries. In all instances, a case-by-case evaluation should be performed.

Specific Criteria - A portion of the application of design criteria to safety SSCs entails the selection of appropriate and relevant design codes and standards. The intent is to apply the design codes and standards that will ensure that the safety SSC will perform it required safety function, including due consideration of the intangible areas of influence. Blanket application of national codes and standards is not necessary. Rather, it may be necessary to tailor selections of codes and standards for each specific application based on the safety function. DOE G 420.1-1, Chapter 5, provides specific criteria for various types of Safety Class SSCs. Aspects of these criteria that are key to the Safety Class SSC performing its safety function, when required, should be evaluated and summarized in this section.

4.2.X.5 Controls (TSRs)

This subsection identifies those assumptions requiring TSRs to ensure performance of the safety function. This section is meant to provide the information necessary to ensure that the facility design adequately considers design features that will be needed to implement TSRs required by 10 CFR 830.205 as the facility transitions to operation. Identify, as appropriate, the type of TSR needed to ensure each safety function, in particular:

- Safety Limits (SL);
- Limiting Control Settings (LCS);
- Limiting Conditions for Operation (LCO); and
- Surveillance Requirements (SR).

Identify facility design features included to ensure that the TSRs can be implemented (e.g., instrumentation, equipment accessibility to perform surveillances, sufficient redundancy to allow safety SSC outages for maintenance, if required). Specific TSR values (e.g., setpoints, surveillance limits) are not expected for preliminary design.

For passive design features, identify any required inspections that will be needed during facility operation, and design provisions to support these inspections. (Note: The design maturity during preliminary design may limit the amount of information in the PSRD. However, the PDSA should demonstrate adequacy of the final design to support implementation of expected TSRs.)

4.3 SAFETY SIGNIFICANT STRUCTURES, SYSTEMS AND COMPONENTS

Relevant information is provided, in the following SSC specific subsections, with descriptions sufficiently detailed to provide an understanding of the safety function of Safety Significant SSCs. The content of the following sections is similar to that described under Safety Class SSCs (Section 4.2) except as described below.

4.3.X [Applicable Safety significant Structure, System and Component]

Identify the Safety Significant SSC.

4.4.X.1 Safety Function

This subsection states the reason for designating the SSC as a Safety Significant SSC, followed by specific identification of its preventive or mitigative safety function(s) as determined in the hazard and accident analysis. Do not discuss nonsafety functions.

Safety significant SSCs may designated for overall purposes, such as defense-in-depth, for which even normal operation considerations are involved. There may or may not be a single accident that, by itself, completely defines the safety function.

4.4.X.2 System Description

This subsection provides a description of the Safety Significant SSC and the basic principles by which it performs its safety function (e.g., sensor and interlock for hydrogen detector discussed in Section 4.4.X.1). Describe its boundaries and interface points with other SSCs relevant to the safety function.

4.4.X.3 Design and Functional Requirements

This subsection identifies requirements that are specifically needed to fulfill safety functions. Such requirements are specified for both the Safety Significant SSC and any needed support Safety Significant SSCs. (Note: The level of design maturity at the end of preliminary design may limit the description of safety SSCs to the requirements identified for the SSCs.)

4.4.X.4 System Evaluation

Safety significant SSCs must be designed to reliably perform their safety function under those conditions and events for which their safety function is intended. For the PDSA, this subsection summarizes the safety design analysis and other justification for the adequacy of the SSCs ability to reliably perform it safety function. Performance criteria are identified that characterize the specific operational responses and capabilities necessary to meet functional requirements. Evaluate the capabilities of the SSC to meet design and

functional requirements. The evaluation of Safety Significant SSCs must address the following.

Conservative Design Features — Safety SSCs must be designed to withstand design basis loadings with an appropriate margin of safety. The design should incorporate multiple levels of protection against normal, anticipated, and accident conditions. For example, while built-in process controls may maintain pressure within a conservative limit, the design may also require provisions for relief valves, automatic shutdown capability, or other preventive features.

Safe Failure Modes — The design must ensure that more probable modes of failure will increase the likelihood of a safe condition.

Support System – If the Safety Significant SSC relies on support systems to perform its safety function, the support system may need to be classified as Safety Significant. That is, support SSCs to Safety Significant SSCs that prevent or mitigate accidents with the potential for significant onsite consequences should also be classified Safety Significant if a support system failure can prevent the Safety Significant SSC from performing its safety function. However, support SSCs to Safety Significant SSCs that prevent or mitigate accidents with the potential for only localized consequences (i.e., significant facility worker hazards) need not be classified as Safety Significant.

Interface Design – A nuclear safety design goal is to minimize the interfaces between Safety Significant and nonsafety SSCs. Ideally, safety SSCs would not have any interfaces; however, this is not always practical. Interfaces, such as pressure retention boundaries, integrity of fluid systems, electrical equipment, instrumentation and control (I&C), and mechanical and support systems exist between Safety Class and nonsafety SSCs. These interfaces must be evaluated to identify failures that would prevent the Safety Significant SSC from performing its safety function. For these failures, isolation devices, interface barriers or design class upgrades (i.e., upgrade the interfacing SSC to Safety Class) should be provided to the Safety Class SSC reliability. In many cases, systems may consist of a group of subsystems, where each subsystem supports the operation of the whole system. For example, an auxiliary power diesel generator system may consist of lubricating oil, fuel oil, diesel engine, jacket cooling, and room ventilation subsystems. System interface evaluations should clearly define these boundaries. In all instances, a case-by-case

evaluation should be performed.

Specific Criteria - A portion of the application of design criteria to safety SSCs entails the selection of appropriate and relevant design codes and standards. The intent is to apply the design codes and standards that will ensure that the safety SSC will perform its required safety function, including due consideration of the intangible areas of influence. Blanket application of national codes and standards is not necessary. Rather, it may be necessary to tailor selections of codes and standards for each specific application based on the safety function. DOE G 420.1-1, Chapter 5, provides specific criteria for various types of Safety Significant SSCs. Aspects of these criteria that are key to the Safety Significant SSC performing its safety function should be evaluated and summarized in this section.

4.4.X.5 Controls (TSRs)

This subsection identifies those assumptions requiring TSRs to ensure performance of the safety function. For preliminary design, this section is meant to support and provide the information necessary to ensure that the facility design adequately considers design features that will be needed to implement TSRs required by 10 CFR 830.205 as the facility transitions to operation. Identify, as appropriate, the type of TSR needed to ensure each safety function, in particular the following:

- Safety Limits (SL);
- Limiting Control Settings (LCS);
- Limiting Conditions for Operation (LCO); and
- Surveillance Requirements (SR).

Identify facility design features required to ensure that the TSRs can be implemented (e.g., instrumentation, equipment accessibility to perform surveillances, sufficient redundancy to allow safety SSC outages for maintenance, if required). Specific TSR values (e.g., set points, surveillance limits) are not expected for preliminary design.

For passive design features, identify any required inspections that will be needed during facility operation, and design provisions to support these inspections. (Note: The design maturity during preliminary design may limit the amount of information in the PSRD. However, the PDSA should

demonstrate adequacy of the final design to support implementation of expected TSRs.)

4.5 SPECIFIC ADMINISTRATIVE CONTROL

It is not expected that Specific Administrative Controls (SAC) will be developed in detail during preliminary or final design. However, the safety function of SACs needs to be understood so that the decision to use an SAC rather than a safety SSC can be understood. In addition, any design requirements needed to implement the SACs are identified (e.g., instrumentation, access control provisions, provisions for lock and tag).

4.5.X [Applicable Specific Administrative Controls]

Identify the SAC.

4.5.X.1 Safety Function

This subsection states the reason for designating an administrative control as an SAC, followed by specific identification of its preventive or mitigative safety function(s) as determined in the Chapter 3 hazard analysis. Do not discuss nonsafety functions.

Safety functions are top-level statements that express the objective of the SAC in a given accident scenario. For example, the safety function of a MAR limit could be stated as: "To limit the total quantity of nuclear material present within the facility to no more than 2000 Curies." The specific accident(s) or general rationale associated with the safety function should be identified.

4.5.X.2 SAC Description

This subsection provides a description of the SAC and the basic principles by which it performs a safety function (e.g., nuclear material control procedure for the MAR limit discussed in Section 4.5.X.1). Describe its boundaries and interface points with any SSCs relevant to the safety function, such as procedural actions interfacing with sensors/instrumentation and equipment.

If an SAC is utilized in lieu of the identification of safety SSCs, clearly identify and discuss the rationale for this decision. Engineering controls are preferable over ACs and SACs, and emphasis should be placed on identifying safety

SSCs. Include a discussion regarding why SSC(s) are not plausible or practical for accomplishing the safety function.

Identify SSCs whose failure would result in losing the ability to complete the action required by the SAC. These SSCs would also be considered Safety Class or Safety Significant based on the significance of the SAC safety function.

When describing the SAC, provide a basic summation of the physical information known about the SAC, including tables or drawings showing relevant information, such as instrumentation and other SSCs, physical boundaries, approved storage areas, and operator routes or locations.

4.5.X.3 Functional Requirements

This subsection identifies requirements that are specifically needed to fulfill safety functions. Such functional requirements are specified for both the SAC and any needed support SSCs.

Limit functional requirement designation to those requirements necessary for the SAC safety function. Functional requirements are provided for SACs for the specific accident(s) or general rationales for which the SAC is needed.

For SACs, functional requirements may involve unimpeded access to specific rooms or areas, use of certain instrumentation, written procedures or checklists, and special tooling. The description of the functional requirement must fully address all aspects important for ensuring the SAC can be accomplished.

4.5.X.4 SAC Evaluation

This subsection provides performance criteria imposed on the SAC so it can meet functional requirements(s) and thereby satisfy its safety function. Performance criteria characterize the specific operational responses and capabilities necessary to meet functional requirements.

The formulation of SACs should include a process that validates that plant operators can perform the task(s) called for in an SAC within the timeframes assumed in the safety basis. If SACs require operator action and perform a function similar to a safety SSC, assurance should be provided that the operators can adequately perform their required tasks by analyzing the

following human performance factors to be considered during preliminary design such as the following:

- environmental conditions created by the accident, and in which operators may need to perform a safety task;
- level of difficulty of the task;
- design of the equipment and feedback (e.g. indicators and alarms); and
- time available to do the task or recover from an error;
- stress levels induced by the external environment (e.g., noise, heat, light, and protective clothing worn).

Formal engineering calculations may be necessary to ensure that plant operators have the appropriate time and resources to carry out the required tasks. For example, if it is assumed that operators will take action to detect and isolate a leak, flowrate calculations will need to be performed to substantiate the available time interval necessary to accomplish the task. Consequences of incorrect implementation of the control should be evaluated and measures to prevent control failure should be factored into the design where possible.

Chapter 5
Preliminary Derivation of Technical Safety Requirements

PURPOSE. This chapter builds upon the control functions determined to be essential in Chapter 3, "Hazard Analyses, Accident Analysis and Control Selection," and Chapter 4, "Safety Structures, Systems and Components for Preliminary Design," to derive TSRs. This chapter is not necessary for preliminary design in the PSDR. Necessary description of TSR considerations is provided in PSDR Chapters 3 and 4. For final design, this PDSA chapter is meant to support and provide the information necessary to ensure that the facility design adequately considers design features that will be needed to implement TSRs required by 10 CFR 830.205 as the facility transitions to operation.

APPLICATION OF THE GRADED APPROACH. The majority of Hazard Category 2 facilities are not anticipated to need SLs. Even facilities that designate SLs will not need many. Potential candidates for SL designation are restricted to those controls that protect the public. TSRs assigned for worker safety and Safety Significant SSCs will not use SLs.

For administrative controls designated as Specific Administrative Controls (SAC), the DSA preparer should refer to DOE-STD-1186-2004, "Specific Administrative Controls," for implementing SACs into TSRs.

5.1 INTRODUCTION

This section provides an introduction to the contents of this chapter based on the graded approach and includes objectives and scope specific to the chapter as developed.

5.2 TSR COVERAGE

This section provides assurances that TSR coverage for the facility is complete in relation to the hazard analysis completed for final design. The section lists the features identified in Chapters 3 and 4 that are needed to:

- Provide for significant public safety. These features are Safety Class SSCs or SACs, and assumptions requiring TSR coverage identified in previous chapters.
- Provide for significant worker safety. These features are Safety Significant SSCs or SACs, and assumptions requiring TSR coverage identified in previous chapters.

Presentation of the summary of TSRs could easily become disorganized and difficult to follow. It is recommended that the information be distilled into an organized presentation (e.g., table format) that identifies the relevant hazard and the major features relied upon for protection against that hazard. This presentation will form the basis for organization of the remainder of the chapter. Associated TSR SLs, LCSs, LCOs, surveillance requirements, administrative controls and Design Features identified throughout the remainder of the chapter need to be noted in this presentation for overall clarity. This subsection will specifically note those safety SSCs listed, if any, that will not be provided with TSR coverage and provide accompanying explanation.

5.3 DERIVATION OF FACILITY MODES

This section derives basic operational modes (e.g., startup, operation, shutdown) used by the facility that are relevant to derivation of TSRs are needed to understand the adequacy of design. As such this section may be minimal for final design but developed in detail in the DSA as the facility transitions to operation. The definition of modes required in this subsection expands and formalizes the information provided in Chapter 3, “Hazard Analyses and Control Selection,” regarding operational conditions associated with accidents.

5.4 TSR DERIVATION

Note: This information can be organized by the hazard protected against, the specific features, or even actual TSRs, if desired. The choice of a specific method of organization is left to the discretion of the PDSA preparer. The following format is repeated sequentially for each TSR (“X”).

5.4.X [Applicable Hazard/Feature/TSR “X”]

This subsection identifies the specific feature(s) listed in Section 5.2 and the relevant modes of operation.

5.4.X.1 Safety Limits, Limiting Control Settings, and Limiting Conditions for Operation

This section provides the basis and identifies information sufficient to identify what SLs, LCSs, and LCOs will be needed to support the facility TSR documentation required by 10 CFR 830.205 as the facility transitions to operation. For final design, this chapter is meant to support and provide the information necessary to ensure that the facility design adequately considers design features that will be needed to implement TSRs. Specific limits and setpoints are not expected

at this stage of design. The nature of the TSR, however, may determine facility design requirements.

SLs, if used, are reserved for a small set of extremely significant features that prevent potentially major offsite impact. LCSs are developed for any SL that is protected by an automatic device with set points. LCSs/LCOs act to keep normal operating conditions below the SLs and are developed for each SL identified, thereby providing a margin of safety. Most LCOs are assigned without an accompanying SL.

Generally SLs are applicable only for protection of passive barriers as close to the accident source as possible whose failure, due to the occurrence of a specific event, will result in exceeding Safety Class criteria. Mitigation of releases is generally not amenable to useful definition of SLs. For example, a ventilation system directing airflow through HEPA filters to protect the public from radiological dose during an accident is mitigative and is more appropriately covered by a LCO. Temporary loss of its function during normal operations does not initiate a significant hazardous material release. An LCO on the system would identify the specific responses necessary to compensate for the loss of safety function. Control of the ventilation system via an SL would be academic for preventing accidents that the ventilation system only mitigates. In contrast, consider a tank that acts as a barrier preventing an uncontrolled release of hazardous material that could exceed Safety Class SSC criteria without ventilation mitigation. If that tank could experience a hydrogen explosion and rupture, then the tank hydrogen concentration may warrant coverage by an SL.

5.4.X.2 Surveillance Requirements

This section identifies Surveillance Requirements that address testing, calibration, or inspection requirements to maintain operation of the facility within SLs, LCSs, and LCOs. Specific requirements are not expected for final design, but facility design features required to implement Surveillance Requirements should be identified (e.g., instrumentation, equipment access).

5.4.X.3 Administrative Controls

This section provides the basis and identifies information necessary to derive TSR administrative controls. The rationale

for assigning TSR administrative controls need to be clearly and briefly stated. Specific Administrative Controls (SAC) are developed in Chapter 4. Repeating this information here is of little value. A summary for the SACs is therefore appropriate. Administrative controls that are not developed as SACs will need to described in more detail.

5.5 DESIGN FEATURES

This section identifies and briefly describes the passive design features that, if altered or modified, would have a significant effect on safe operation. Simply reference Chapter 2, "Facility Description," for the descriptions if that chapter contains the desired information.

Chapter 6
Design for the Prevention of Inadvertent Criticality

PURPOSE. The purpose of this chapter is to provide information regarding aspects of the design that are required to support the prevention of inadvertent criticality.

APPLICATION OF THE GRADED APPROACH. Hazard Category 3 facilities, by definition, do not contain sufficient fissionable materials to present a criticality hazard. This chapter, therefore, is not applicable to Hazard Category 3 facilities. Inventory limits specified in the TSRs will control the amount of fissionable materials. This chapter applies only to Hazard Category 2 facilities with inventories of fissionable materials sufficient to present an inadvertent criticality hazard.

6.1 INTRODUCTION

This section provides an introduction to the contents of this chapter based on the graded approach and includes objectives and scope specific to the chapter as developed.

6.2 CRITICALITY CONCERNS

This section identifies the fissionable material available within the facility and provides information on the location of potential criticality hazards (e.g., description, and drawing), the fissionable material form (e.g., chemical and/or physical, including isotopic content, concentration, densities), and the maximum quantities involved.

6.3 CRITICALITY CONTROLS

This section summarizes information relevant to criticality control. Include a general discussion of the criticality safety design limits, their bases, and any design criteria used to ensure subcritical configurations under all normal, abnormal, and accident conditions (i.e., ensure criticality limits are not exceeded); the parameters used for the prevention and control of criticality and the methods for the application and validation of these parameters; and the application of the double contingency principle in criticality safety. It is not the intention of this section to individually list all criticality safety design limits.

6.3.1 Engineering Controls

This section summarizes the safety design approach for engineered

controls, either passive or active, and the bases placed on equipment designs or operations to ensure subcritical conditions under all normal, abnormal, and accident conditions. Include in the summary of these engineered controls use of geometry, spacing, and any other engineered controls (e.g., neutron absorbers, elimination of moderators, storage location limitations, and level detectors). Specific limits are not expected for preliminary design the PSDR. However, the nature of the controls should be described to ensure that the preliminary design includes provisions to implement such controls. The adequacy of the final design to prevent inadvertent criticality needs to be demonstrated in the PDSA.

6.3.2 Administrative Controls

This section summarizes the administrative controls used to prevent accidental criticality. Include in the discussion the administrative controls on nuclear material safety limits, such as mass; moderators; changes in geometry configurations; and provisions for handling, storing, and transporting fissionable materials. Specific limits are not expected for preliminary design or final designs in the PSDR or PDSA. However, the nature of the controls should be described to ensure that the design includes provisions to implement such controls.

6.4.3 Application of Double Contingency Principle

This section summarizes the methods used to ensure that at least more than one unlikely, independent, and concurrent changes in process conditions would be necessary before a criticality accident is possible (e.g., contingency or CSE). The contingency or CSE will identify how the double contingency principle, as defined in DOE O 420.1B, is being met (i.e., control of two independent process parameters). It is not the intention of this section to individually present all facility contingency or CSEs.

The results of the contingency or CSEs helps identify safety SSCs, controls, and the TSR limit designations (safety control parameters). The identification of safety SSCs and safety control parameters for TSR controls should be done as part of Chapter 3, “Hazard Analyses and Control Selection”; Chapter 4, “Safety Structures, Systems and Components” ; and Chapter 5, “Preliminary Derivation of Technical Safety Requirements” in concert with the guidance provided in DOE-STD-3007-2007.

Appendix A
Safety Management Program Roadmap

A chapter-by-chapter description of safety management programs that will used to support safe operation is not necessary for preliminary or final design. The design must, however, include features to implement safety not derived from the nuclear safety analysis and not designated as safety SSCs or provided with specific TSR coverage. Information regarding these design features is included in project design information. This appendix provides a roadmap to such considerations in the project design information.

Table I-1, Sample SMP Roadmap

Safety Management Program	Project Document	Comments
Occupational Radiation Protection Program	ALARA analysis and shielding design, and similar documents	
Worker Safety and Health Program		
Criticality Safety Program	DOE Approved CSP required by DOE O 420.1B	
Radioactive Waste Management Program		
Fire Protection Program	Preliminary FHA (example)	
Environmental Protection Program	Permitting (example)	
In-service Testing, Inspection and Maintenance		
Engineering Program		
Quality Assurance and Performance Assessment		
Emergency Management		

Management, Organization and Institutional Safety Provisions		

Comments section addresses key design consideration included in preliminary design.

Appendix B
Design Approach to Address DOE O 420.1B Design Requirements

This is a facility-level and system-level crosswalk to the nuclear safety design criteria of DOE O 420.1B and its implementing guidance documents or DOE-approved alternate criteria. The crosswalk should have a comment column that would provide a commentary and reference to the PDSA section providing details on how the criteria are satisfied by each design element. Any exceptions should be identified and justified.

APPENDIX J
MAJOR MODIFICATION DETERMINATION EXAMPLES

The following Major Modification Evaluation examples are provided for illustration. Capturing the evaluation in a tabular format provides a concise means of documenting the evaluation results and their bases.

Example 1

Major Modification Evaluation		
Project Information *Waste tank material will be processed in a new Steam Reforming facility in a preexisting building (segmented from other processes in the building) prior to transfer to the permanent disposal facility. The project involves limited design activities and significant physical modifications to support the Steam Reforming process with an estimated cost of greater than $25M.*		
Criterion No.	**Evaluation Criteria**	**Evaluation**
1	Add a new building or facility with a material inventory ≥ HC 3 inventory limits or increase the HC of an existing facility?	*The project does not does not involve the addition of a new building or facility. The project will be housed within a preexisting building, segmented from other processes in the structure. The project involves the processing of the existing waste inventory within a Steam Reforming facility and will not impact the hazard classification of the facility. Steam reforming is a moderate temperature process used to destroy volatile organic chemicals contained in an aqueous solution without vaporizing radionuclides. The process produces durable, solid mineral glass-like material suitable for permanent storage*
2	Change the footprint of an existing HC 1, 2, or 3 facility with the potential to adversely impact any credited safety function?	*The steam reforming process will be housed in a section of an existing building which has not previously been utilized. New equipment will be installed and includes a steam generator and superheater, mix tanks, evaporators, scrubbers, demisters and ventilation equipment.*
3	Change an existing process or add a new process resulting in a Safety Basis change requiring DOE approval?	*The project will introduce a process which is utilized in multiple other locations for processing similar material. However, the steam reforming process is new to the facility and the current facility safety basis does not address steam reforming.*
4	Utilize new technology or GFE not currently in use or not previously formally reviewed / approved by DOE for the affected facility?	*Steam reforming is not new technology and no GFE equipment is utilized in this process. Steam reforming has been licensed by the EPA as a non-incineration method for the destruction of organics and is in use at Erwin, TN and other DOE and commercial locations Steam reforming is utilized in multiple other locations for processing similar material and the technology is not new to DOE facilities. Therefore, the specification of applicable nuclear safety design criteria can be performed with a high degree of certainty. However, the safety basis for this facility does not address steam reforming.*

Major Modification Evaluation		
5	Create the need for new or revised Safety Basis controls (hardware or administrative)?	*Safety basis controls for the facility will require modification. However, steam reforming is utilized in multiple other locations for processing similar material and the required controls are known and have been proven. Therefore, the specification of applicable nuclear safety design criteria can be performed with a high degree of certainty.*
6	Involve a hazard not previously evaluated in the DSA?	*Although steam reforming is utilized in multiple other locations for processing similar material and the hazards of the process are known and understood, the project will introduce hazards which are new to this facility and which are not addressed by the existing facility safety basis.*
Summary and Recommendation: *Three of the six criteria (Criterion 3, 5 and 6) were tripped in this PDSA evaluation. As discussed above, there is no substantial risk involved in changing the footprint of the existing HC 2 facility as a result of this project. The process does not involve new technology and has been proven at other locations. However, the project does introduce a new process and new hazards to the facility and will therefore result in significant impact to the facility safety basis. Per 10CFR830, this qualifies the project as a Major Modification and therefore requires the development of a PDSA.*		

Example 2

Major Modification Evaluation		
Project Information *A proposed project will install new mixing devices and supporting infrastructure in a HC 2 Safety Class radioactive waste storage tank at a TEC of $10,000,000. A similar technology has been used previously to mix radioactive waste in small process tanks located within cell structures at this and other DOE sites. Although the mixing capability of this specific technology has been successfully demonstrated using simulant in a full scale mock-up, it has never been deployed within the DOE complex for mixing the contents of a large radioactive waste tank. Therefore, the current HA and DSA do not address all of the hazards inherent in the use of this technology for this application. The waste to be mixed is bounded in terms of isotopic inventory by the waste analyzed in the facility HA and DSA; however, a preliminary review of the potential application has identified some potential waste-release mechanisms not currently analyze, as well as the potential to release a total quantity of waste in excess of that current analyzed.*		
Criterion No.	**Evaluation Criteria**	**Evaluation**
1	Add a new building or facility with a material inventory ≥ HC 3 inventory limits or increase the HC of an existing facility?	*The project does not does not involve the addition of a new building or facility, nor will it increase the HC of the existing waste tank.*
2	Change the footprint of an existing HC 1, 2, or 3 facility with the potential to adversely impact any credited safety function?	*The project changes the footprint of a HC 2 facility (waste tank) to accommodate the required supporting infrastructure equipment. The existing waste tank structural analysis will be revised as part of the project scope to account for the increased loads due to the mixing device and support equipment. The weight associated with this proposed mixing system exceeds the weight typically associated with typical mixing systems previously used. The ability of the Safety Class tank structure to accommodate this weight or the ability to design a means to support this weight independent of the tank structure is indeterminate at this point in the project.*
3	Change an existing process or add a new process resulting in a Safety Basis change requiring DOE approval?	*Although the new mixing system could potentially be viewed as new process, for the purposes of this evaluation it will not. The consideration of technology application and Safety Basis impact potential will be addressed by criteria 4 and 5. No further assessment of this criterion is therefore required for this evaluation.*

Major Modification Evaluation		
Criterion No.	**Evaluation Criteria**	**Evaluation**
4	Utilize new technology or GFE not currently in use or not previously formally reviewed / approved by DOE for the affected facility?	*The project will utilize a mixing technology that has never previously been formally reviewed / approved by DOE for mixing radioactive waste inside of a large radioactive waste tank. Full scale mock-up testing performed to date using simulant has yield promising results. Additionally, this technology has been successfully used at this site in the past for mixing of radioactive waste in relatively small (< 10,000 gallons) process vessels with minimal operational problems. Based upon the large scale mock-up testing and on the successful application of similar technology on smaller tanks, there is a reasonably high degree of confidence in the ability of the technology to be successfully applied via this project. Uncertainty with the ability to properly specify applicable nuclear safety design criteria will be addressed in Criterion 6.*
5	Create the need for new or revised Safety Basis controls (hardware or administrative)?	*The project will require new or revised Safety Basis controls (hardware or administrative) given the potential failure modes and release mechanisms. At this point in the project, substantial design details have not been completed. Additional design details are expected to identify additional hazards requiring new/revised controls. Given the number of new potential failure modes and release mechanisms, it is reasonable to assume that the number of controls required will be quite significant in scope. Due to the complexity of the project any significant new/revised controls may involve significant redesign with accompanying cost and schedule impacts. Therefore there is a relatively high degree of design and regulatory uncertainty.*
6	Involve a hazard not previously evaluated in the DSA?	*As discussed above, the project will involve hazards not previously evaluated in the DSA and is likely to require additional unidentified controls. In addition the change creates a new condition where the total potential quantity of waste released may be in excess of that currently analyzed. Given this situation, it is expected that the use of the proposed mixing devices will have a substantial impact on the current DOE-approved Safety Basis and precludes the ability to specify applicable nuclear safety design criteria with a reasonable degree of certainty*
Summary and Recommendation: *Three of the six criteria (criteria 2, 5 and 6) were tripped in this PDSA evaluation. The assessment of each of these three criteria identified a high degree of risk inherent in the application of the new mixing technology as proposed by this project. Additionally it is noted that although Criterion 4 was not tripped, the application of this mixing technology to a large radioactive waste tank represents an untried approach despite previous success with similar technology on much small scale tanks and full scale simulant testing. Based on these considerations, it is concluded that this project constitutes a Major Modification and will therefore, require the development, review, and approval of a PDSA. Therefore, it is recommended that the project proceed accordingly.*		

Example 3

Major Modification Evaluation		
Project Information *A proposed project will add a new loading dock to a HC-2 facility. The new loading will not interface with the Safety Class and Safety Significant infrastructure of the existing facility. Estimated TEC is $8,000,000. The types of project and infrastructure equipment are identical to that already used and considered in the facility hazard analysis and DSA with appropriate safety-related controls specified. The material to be processed is bounded by the MAR currently analyzed in the facility hazard analysis and DSA.*		
Criterion No.	**Evaluation Criteria**	**Evaluation**
1	Add a new building or facility with a material inventory ≥ HC 3 inventory limits or increase the HC of an existing facility?	*The project involves the addition of a new loading dock to an existing HC-2 facility. It will not increase the material inventory of the existing facility and will not change the HC.*
2	Change the footprint of an existing HC 1, 2, or 3 facility with the potential to adversely impact any credited safety function?	*The addition of a new loading dock changes the footprint of a HC-2 facility, but it does not have any potential for adverse impacts on credited safety functions The structural qualification, evacuation egress path, fire suppression system performance and other safety analysis assumption are preserved.*
3	Change an existing process or add a new process resulting in a Safety Basis change requiring DOE approval?	*The addition of a new loading dock does not change the existing processes and does not result in a Safety Basis change requiring DOE approval. The current DOE-approved Safety Basis already addresses the use of loading docks.*
4	Utilize new technology or GFE not currently in use or not previously formally reviewed / approved by DOE for the affected facility?	*The addition of a new loading dock will not utilize new technology or GFE not previously formally reviewed and approved by DOE for use in this facility.*
5	Create the need for new or revised Safety Basis controls (hardware or administrative)?	*The addition of a new loading dock does not create the need for new or revised Safety Basis controls due to new processes. The current DOE-approved Safety Basis already addresses the use of loading docks.*
6	Involve a hazard not previously evaluated in the DSA?	*The addition of a new loading dock does not involve a hazard not previously evaluated in the DSA. The current DOE-approved Safety Basis already addresses the use of loading docks.*
Summary and Recommendation: *No criteria were tripped in this PDSA evaluation. Based on this finding, it is concluded that this project does not involve a Major Modification and therefore, no PDSA is required. The changes to the existing DSA/TSR to reflect this project will be made following the normal DSA/TSR change process. Therefore, it is recommended that the project proceed accordingly.*		