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Your engineering career at Fermilab will test your skill at a number of levels. You will undertake routine design tasks, but you will also take on challenging projects at the cutting edge of technology. The engineering process can be dynamic and fluid at the laboratory, involving frequent interaction between you and those for whom you design. The development of specifications can begin as a discussion between scientific staff and the individual engineer or engineers and can evolve into a formal, detailed request. It is your responsibility as a Fermilab engineer to make scientific dreams and what-ifs a reality by providing safe, cost-effective and reliable designs.

Often you will work on projects alone with oversight and mentoring provided by senior engineers or scientists. The lead engineer will determine the degree of oversight you will need using a risk-based graded approach. On other occasions you will do design work as a member of a team.

Management will ask you to participate in project reviews. You will be involved in internal design reviews and may take part in Department of Energy project reviews with formal presentations covering cost and scheduling. You will usually inherit operational responsibility for your designs and will be asked to assist with problem-solving.
Overview: Purpose and Scope

This document provides a manual for properly executing and documenting engineering projects at Fermilab. Anyone undertaking a design effort at Fermilab, regardless of his or her job classification, must follow this document. The specific requirements included in each step of the engineering process differ for projects carrying different degrees of risk, expense or involvement by other departments and institutions. However, for each project, engineers go through the same procedure, a risk assessment, to determine those requirements. This manual explains that procedure. It is important that the risk assessment be completed correctly for all projects at each step as it determines the appropriate level of formality as a project moves forward. Examples in the Appendices demonstrate how Fermilab engineers have conducted more formal processes for past projects.

Engineers at Fermilab must consider quality assurance, potential ES&H issues, reviews and applicable codes and standards for every step in every project.

It is important to note that other processes, programs and manuals, such as the Department of Energy’s Critical Decision Process; Director’s Policy Manual; Fermilab Environment, Safety and Health Manual; Fermilab Project Management System; and the Integrated Quality Assurance Program, include additional requirements not stated in this manual. Managers will note these additional requirements in project specifications.

The authors of this manual believe that the fundamental engineering steps are the same for a project of any size or phase of development. You may need to repeat some of the process steps multiple times as your design matures.

The manual contains nine sections, one for each step in the Fermilab Engineering Process, as depicted on the following page. Chapter 1: Requirements and Specifications explains the first step in the design process, which defines the objectives and requirements of the project. Chapter 2: Engineering Risk Assessment explains the process of determining the level of rigor required for documentation and review of an engineering project based on technical, cost and schedule risks. Chapter 3: Requirements and Specifications Review describes the process of reviewing the adequacy of the resulting specification. Chapter 4: System Design explains the steps of the design phase. Chapter 5: Engineering Design Review describes the required reviews the design must undergo. Chapter 6: Procurement and Implementation explains the process engineers follow to make their projects a reality. Chapter 7: Testing and Validation explains the process of verifying that the design meets the requirements. Chapter 8: Release to Operations describes the operating and maintenance documents the lead engineer must produce before the project is complete and becomes operational. Chapter 9: Final Documentation describes the final documentation the lead engineer must create and archive in order to complete a project.
Fermilab Engineering Process

Requirements and Specifications
↓
Engineering Risk Assessment
↓
Requirements and Specifications Review
↓
System Design
↓
Engineering Design Review
↓
Procurement and Implementation
↓
Testing and Validation
↓
Release to Operations
↓
Final Documentation
The next section defines the responsibilities of those involved in the engineering process. These definitions apply to all chapters of the Engineering Manual.

**Line Management**
Responsibility for the quality and effectiveness of the design and engineering process at the laboratory lies primarily with line management. This is based on the same principles used in the Fermilab Integrated Safety Management System. Line management includes Division/Section/Center heads, their assistants, department heads and supervisors. Members of line management are responsible for adding additional requirements to the engineering process as they see fit to ensure the success and quality of projects executed under their supervision.

**Project and System Managers**
Project and system managers are responsible for ensuring that tasks are completed using good engineering and quality-control methods. These managers should be aware of the design and engineering process requirements outlined in this document and should verify that engineers fulfill these requirements. Project and system managers work with department heads and lead engineers to determine which projects require special design or safety reviews. They work with department heads in setting up those reviews. Project and system managers are ultimately responsible for system integration.

**Department Heads**
The project manager divides some projects into multiple tasks and assigns them to different divisions or sections. When a project is divided, department heads are directly responsible for ensuring that their tasks are completed using good engineering and quality-control methods. These managers should be aware of the design and engineering process requirements outlined in this document and should verify that engineers fulfill these requirements. Department heads are directly responsible for using the graded approach under the guidance of the risk assessment section to determine and implement the proper level of formality for a project. They are directly responsible for determining which projects should have special design and safety reviews. The project manager coordinates with department heads to integrate the tasks.

**Lead Engineers**
Generally, any engineering effort defined by a set of specifications requires the participation of a lead engineer, the engineer responsible for ensuring that the design meets project specifications. The lead engineer has overall responsibility for the efforts of all engineers working on a single project. The lead engineer is responsible for organizing overall project documentation. He or she provides technical leadership and ensures that all engineering, including system integration, is performed according to the provisions of the Engineering Manual.

**Engineers**
Engineers are responsible for following the provisions of the Engineering Manual and for fulfilling any additional requirements established by their Division/Section/Center heads and departments. Engineers must ensure their subsystems comply with project specifications and all applicable standards and safety codes.
Chapter 1: Requirements and Specifications

Purpose and Scope
The purpose of this section is to describe the specification process, which defines the desired project result and enumerates the project requirements.

Engineering departments document their agreements with other organizations in the form of engineering specifications detailing the technical and project requirements of the system to be provided. Larger engineering projects with multiple subprojects require an engineering design project plan. This plan clearly defines the level of subproject subject to a separate engineering risk assessment. Each identified subproject follows the chapters of this manual.

It is important to note that managers and project leaders may introduce additional requirements, such as further reviews or documentation, outside the technical specifications described in this manual. The design engineer must fulfill these requirements during the implementation of the engineering project.

Engineering Specification
In the first step of the design project, the lead engineer prepares the engineering specification based on requirements from the project or system manager. In order to prepare the specification, the lead engineer must consider the elements listed below. For high-risk projects, as determined in Chapter 2: Engineering Risk Assessment, the specification document must include all elements.

- Scope of the work
- Project milestones
- Relevant codes and standards
- Relevant ES&H and QA requirements
- Functional or design technical requirements
- Requirements for interfacing to external systems
- Acceptance criteria included or referenced
- Identification of those characteristics of the design that are crucial to the safe and proper functioning of the project
- Any special requests such as design reviews, DOE reviews or additional documentation requirements

The department head and lead engineer, following the guidance of the graded approach described in the Engineering Risk Assessment section, determine the level of formality the specification document needs. This may result in specifications ranging from a simple e-mail message from the requester to a detailed document that is subject to the change-control process. Change control is the process that ensures design changes achieve the desired result without adversely affecting other aspects of the system.

The department head and project management approve specifications before the lead engineer initiates the design. The department head and project management must agree upon changes to the specification. The lead engineer makes the specification accessible to project management and collaboration members throughout the project.

The Requirements and Specifications Appendix includes example requirements and specifications from previous Fermilab projects. They range in complexity from e-mail correspondence to a more formal document, based on the graded approach applied to each project.
Chapter 2: Engineering Risk Assessment

Purpose and Scope
The purpose of this chapter is to define a risk-based graded approach for use in engineering projects. This process helps the lead engineer and department head evaluate project risks and determine the appropriate level of documentation and review a project needs. The project manager may add additional requirements, as defined in Chapter 1: Requirements and Specifications.

The lead engineer and department head complete the graded approach worksheet as part of the specification process. Completion of the graded approach worksheet is a way to quantify project risk early in a project. If a project carries a high level of risk, the engineer needs to complete further risk analysis based on guidelines from other governing organizations.

Definitions

Graded Approach: A graded approach uses a list of factors to establish the appropriate level of formality a project requires.

Risk-Based Graded Approach: A risk-based graded approach evaluates the level of risk in various risk elements in order to establish the appropriate level of controls a project requires.

Risk Element: A risk element is an aspect of a project that could prevent its successful completion, without appropriate control measures.

Risk Assessment
The Engineering Policy Manual Team has identified 15 potential risk elements to evaluate for each project.

The department head and lead engineer determine the level of risk for each element and document it using the graded approach worksheet. The department head and lead engineer can use the guidelines in this chapter to determine the overall level of risk and to highlight high-risk categories. This risk assessment applies to the engineering subproject at hand, not the overall project. A subproject is a self-contained engineering task, component or system that generally falls under the responsibility of a single department. Subprojects do not take on the risk level of the larger project.

The engineer should record, in Tables 1 and 2 below, risk assessment integer values between 1 and 5, as follows:

1 low risk
2 low to medium risk
3 medium risk
4 medium to high risk
5 high risk

Definitions of the risk levels are given below with criteria for risk levels 1, 3 and 5. Levels 2 and 4 are implied to fall between those provided.
A: Technology
This defines the technical complexity of the project.

1 The project will use off-the-shelf technology.
3 Engineers will purchase and modify off-the-shelf technology.
5 The project will require the development of new technology.

B: Environmental Impact
This defines the potential level of environmental impact.

1 There will be no significant environmental impact.
3 The project may have some environmental impact but will not require an environmental assessment, as determined by FESHM.
5 The project will require an environmental impact statement.

C: Vendor Issues
This defines the expected complexity of working with vendors. Complicating factors may include long lead times and issues with vendor qualification and reliability.

1 Vendors could cause minor issues.
3 Vendors could cause manageable complications.
5 Vendor issues could result in significant schedule delays or cost overruns or could otherwise jeopardize the successful completion of the project.

D: Resource Availability
This defines the availability of internal and external resources to plan and execute the project.

1 Resources will be readily available.
3 Resources could be somewhat restricted.
5 The difficulty of obtaining resources puts the project schedule at high risk.

E: Quality Requirements
This determines the effort required to achieve the quality level the customer assigns to the final product.

1 The quality requirements can be met easily with existing infrastructure.
3 The quality requirements are challenging but can be met with existing infrastructure.
5 The quality requirements are beyond the capability of existing infrastructure.

F: Safety
This defines the safety issues the project team will encounter.

1 The project will require standard safety considerations.
3 The project will require increased diligence due to its location, the configuration of the product or the type of work required. This includes work requiring review according to FESHM.
5 The project will require very restrictive safety considerations. This includes work requiring review and personnel safety systems.
G: Manufacturing Complexity
This defines the expected complexity of combining the elements of technology, operations and schedule in product manufacturing.

1. The manufacturing processes will be routine.
3. The project will require an existing technology that the manufacturer has not previously used.
5. The project will require new or complex manufacturing methods.

H: Schedule
This defines how much time the project team will have to complete the schedule.

1. Time will be unlimited.
3. The schedule will be somewhat constrained.
5. The subproject will be on the overall project critical path and has no schedule contingency.

I: Interfaces
This defines the complexity of integrating multiple subprojects.

1. One department at Fermilab will be involved with a standalone project.
3. Project success depends upon contributions from multiple departments at Fermilab.
5. Project success depends upon contributions from multiple institutions.

J: Experience/Capability
This defines the level of experience and capability project team members will have.

1. Only experts will participate.
3. A blend of experts and inexperienced personnel will participate.
5. Only inexperienced personnel will participate.

K: Regulatory Requirements
This identifies the impact of oversight by governmental or other regulatory agencies on the project.

1. Regulatory agencies will have minor to no involvement.
3. The Department of Energy (DOE) will have direct regulatory involvement.
5. DOE, as well as other state or federal government agencies, will have regulatory involvement.

L: Project Funding
This defines the availability and approval status of project planning and execution funds.

1. A single source within Fermilab will fund the project.
3. A source outside of Fermilab will fund the project.
5. Multiple sources outside of Fermilab will fund the project.

M: Project Reporting Requirements
This indicates the level of reporting to the senior management the project requires.

1. Reports to senior management about the project will not be required.
3. The project will require quarterly performance reports.
5. The project will be highly visible. Top management or outside agencies will schedule visits and issue monthly performance reports.
N: Public Impact
This indicates how much the project will affect the public or public opinion.

1  The public will not be affected.
3  The public may be somewhat affected and should be informed with news releases.
5  The project may have an impact on the public. The public should be involved through public forums and may participate in advisory councils.

O: Project Cost
This defines the projected cost.

1  The project will be within the department operating budget.
3  The project will require divisional budget planning.
5  The project will require laboratory or DOE budget tracking and reporting.
Interpreting the Graded Approach Worksheet

The lead engineer fills out an engineering and project risk element table for his or her project or subproject. If the project or subproject has a risk score of 5 in any engineering risk element (A - G), it requires formal control as described within the Engineering Manual chapters indicated in the table below. If the subtotal of the risk scores for the elements related to one chapter is higher than the high risk score indicated in the table below, the topic covered in that chapter requires formal control. If the project or subproject has a risk score of 5 in any project risk element (A - O), or the project management risk (H - O) subtotal is 25, notify the project manager. The project manager may choose to elevate formal control requirements to address elevated project management risk (H - O).

### Engineering Risk Element

<table>
<thead>
<tr>
<th>Chapter</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>High Risk</th>
<th>Subtotal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>≥ 10</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>≥ 16</td>
<td></td>
</tr>
<tr>
<td>4*</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td>≥ 19</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>≥ 19</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>≥ 16</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>≥ 13</td>
<td></td>
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<td>8</td>
<td></td>
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<td></td>
<td></td>
<td>X</td>
<td>≥ 4</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>≥ 7</td>
<td></td>
</tr>
</tbody>
</table>

*The System Design chapter encompasses several subtopics.

### Project Risk Element

<table>
<thead>
<tr>
<th>Score</th>
<th>H</th>
<th>I</th>
<th>J</th>
<th>K</th>
<th>L</th>
<th>M</th>
<th>N</th>
<th>O</th>
<th>High Risk</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>≥ 25</td>
<td></td>
</tr>
</tbody>
</table>
Sample Risk Assessment Worksheet

A sample risk assessment worksheet is shown below.

Consider a project to design and build a 201 MHz, 5 MW peak power RF source. Past experience with the production of the high-power tubes has shown this to be a high-risk procurement. Only one vendor is capable of manufacturing these tubes, and it is expected that significant vendor oversight will be warranted.

### Engineering Risk

<table>
<thead>
<tr>
<th>Item</th>
<th>Risk Element</th>
<th>Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Technology</td>
<td>2</td>
</tr>
<tr>
<td>B</td>
<td>Environmental Impact</td>
<td>2</td>
</tr>
<tr>
<td>C</td>
<td>Vendor Issues</td>
<td>5</td>
</tr>
<tr>
<td>D</td>
<td>Resource Availability</td>
<td>4</td>
</tr>
<tr>
<td>E</td>
<td>Quality Requirements</td>
<td>3</td>
</tr>
<tr>
<td>F</td>
<td>Safety</td>
<td>3</td>
</tr>
<tr>
<td>G</td>
<td>Manufacturing Complexity</td>
<td>4</td>
</tr>
</tbody>
</table>

### Project Management Risk

<table>
<thead>
<tr>
<th>Item</th>
<th>Risk Element</th>
<th>Risk Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>Schedule</td>
<td>3</td>
</tr>
<tr>
<td>I</td>
<td>Interfaces</td>
<td>3</td>
</tr>
<tr>
<td>J</td>
<td>Experience / Capability</td>
<td>4</td>
</tr>
<tr>
<td>K</td>
<td>Regulatory Requirements</td>
<td>2</td>
</tr>
<tr>
<td>L</td>
<td>Project Funding</td>
<td>2</td>
</tr>
<tr>
<td>M</td>
<td>Project Reporting Requirements</td>
<td>2</td>
</tr>
<tr>
<td>N</td>
<td>Public Impact</td>
<td>1</td>
</tr>
<tr>
<td>O</td>
<td>Project Cost</td>
<td>3</td>
</tr>
</tbody>
</table>
The System Design chapter encompasses several subtopics. The engineer will use the high-risk control measures in Chapter 4: System Design and Chapter 5: Engineering Design Review because the Vendor Issues risk element has a rating of 5 and because the risk element subtotals for those chapters are high. In addition, the engineer will use the high-risk control measures in Chapter 6: Procurement and Implementation because the risk element subtotal for that chapter is high.
Purpose and Scope
The purpose of this section is to describe the steps of the requirements and specifications review process. These reviews use a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment. The project may require only an informal technical review within the engineering department. High-risk projects require formal technical reviews with subject-matter experts from outside the engineering department or laboratory.

Subsequent design reviews could result in changes to the requirements, which would necessitate an additional requirements and specifications review. Managers may call for reviews of the technical aspects or safety of entire systems or of individual components.

Review Documentation
The lead engineer ensures all requirements and specifications reviews are documented. Project documentation includes, at a minimum, a meeting summary describing who attended the review, what issues they discussed, what deficiencies they identified and what recommendations they made. The lead engineer provides a copy of the review results with proposed resolutions to the manager who called the review and files it with the project final documentation. The manager must accept the results of the review before the lead engineer can implement the proposed recommendations or action items. Any additional changes that may arise during implementation require reapproval by the manager.

The lead engineer and the department head determine the type and level of detail of review materials using the graded approach. When documenting a technical review, the lead engineer must consider the elements listed below. For high-risk projects, include all elements in the review documentation.

- Project description
- Project presenters
- Review date
- Review committee members
- Project specification document
- Review findings
- Review recommendations
- Action items

Department Reviews
At the request of the department head, projects undergo department-based requirements and specifications reviews. The extent of a review depends on the complexity of the project as evaluated using the graded approach.

In consultation with the lead engineer and his or her supervisor, the department head selects engineers or subject-matter experts to serve as reviewers. The department head may also invite additional stakeholders. Reviewers may or may not be members of the same department. Smaller departments, for example, need to ask other departments to provide members.

The review focuses on whether the requirements are complete and whether the proposed specifications fulfill the requirements.

Project Manager Reviews
Project management may decide to conduct special targeted requirements and specifications reviews for important subprojects or tasks. The project manager works with the department head responsible for a particular task to arrange these special reviews. Together they assemble the review team and establish the review schedule.
Purpose and Scope
The purpose of this section is to describe the elements of system design, including document numbering, engineering calculations, engineering drawings, software and interlock safety systems.

Document Numbering System
The local design drafting group and the lead engineer assign to a document a project, system and subsystems category number, as defined in the System Design Appendix.

The laboratory plans to replace this system as Fermilab adopts a new electronic document management system. Historical document numbers will still be accessible through local document-control representatives. Historical documents that are ported to the new system will still be identifiable by the original document numbers.


Engineering Calculations
Engineering calculations are an integral part of the engineering process. The rigor with which the engineer performs, checks and documents engineering calculations depends on a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment. Some projects may require a calculation as simple as an analysis in a log book. High-risk projects require detailed calculations that are subject to review and the change-control process. The System Design Appendix gives an example of a formal engineering calculation procedure.

For informal engineering calculations, any format is generally acceptable. The engineer may document calculations in a lab notebook, on a computer spreadsheet or with specialized computer tools. Refer to Chapter 9: Final Documentation for project documentation archival requirements.

Engineering calculations associated with high-risk projects must adhere to the following requirements:

• Engineers must document calculations with sufficient detail so that they are reproducible and peer-reviewable. The documentation should include the methodology, assumptions, input parameters and, if commercial software is used, the software version. If the engineer creates the code, the documentation should include the source code listing.

• Calculation results should be realistic and comparable to results from past experience. For complex analyses or those involving computer software, consider using simplified methods to validate the results.

• If the results of the calculations suggest a problem with the project design, the engineer may need to review or revise the engineering specification or risk assessment.

• The department head or project leader must review and approve calculations.

• As the laboratory moves toward electronic documentation, the lead engineer will scan all log books into the documentation database.
Engineering Drawings
This section describes the basic approach used in the creation and modification of engineering drawings.

In creating or modifying an engineering drawing, the engineer must use applicable drafting standards and requirements, as described in the System Design Appendix. The engineer must follow the proper procedure for assigning a drawing number and must track changes to each version of the drawing.

As engineers create or modify drawings, they may need to hold design reviews to validate progress and address any design, quality or safety concerns. Design iterations take place until the engineering drawings are completed.

The lead engineer ensures that a qualified person, other than the originator of the drawings, has properly reviewed and approved them. Engineers follow the procedures of their local design/drafting groups to create, review, approve and release drawings.

See the System Design Appendix for detailed information.

Software
This section covers software programs and computer configurations designed to operate experiments, tests, accelerator components and associated equipment. Examples include PLC logic, Field Programmable Gate Arrays and embedded software. Commercially purchased software not modified by Fermilab, such as CAD, e-mail, file storage, public displays, etc., is not included in this scope. Fermilab’s Computer Security Policy regulates the use of computers in high-value systems, including personnel safety systems.

Software design and documentation uses a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment. Documentation as simple as inline comments may suffice for some projects. High-risk projects require detailed software documentation that is subject to the change-control process.

The purpose is to ensure that other personnel can review and maintain installed software. Three documents that help others to do this are the design note, operator instructions and system and software maintenance plans. Software projects that are assessed to be high-risk must include these elements in detail.

Design Note
Engineers must prepare a design note describing all software. The note contains:

- System overview and requirements
- Interfacing information
- Primary code and configuration
  (a) Source code or backup code information
  (b) ‘Module’ or program organization description
  (c) 'Build and Boot' information, if applicable
  (d) A change-control plan including security
- System analysis, test results and design algorithms

Operator Instructions
Engineers provide operator instructions that are clear, succinct and readily available. The instructions must include:

- Functional descriptions of all operational modes
- Clear means to display operating status
- The location of default or custom operator settings, if applicable
System and Software Maintenance Plans

Engineers should create maintenance plans that take into consideration:

- Source code or configuration comments in code or logic
- Comments wherever the functions of the software are not reasonably obvious to another programmer

Hardware and software tools should be maintainable for the life of the project. The lead engineer maintains code versions to allow others the ability to fall back to previous operating code should the new code present problems. The lead engineer and department head maintain software security to prevent unwarranted changes.

Interlock Safety Systems

Safety Interlocked Systems, or Interlocks, implemented in software have additional design requirements, which are spelled out in FESHM and in International Electrotechnical Commission (IEC) 61508, “Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems.”
Chapter 5: Engineering Design Review

Purpose and Scope
The purpose of this section is to describe the steps of the engineering design review process. Engineering design reviews use a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment. The project may require only an informal technical review within the engineering department. High-risk projects require a formal technical review with subject-matter experts from outside the engineering department or laboratory. Reviews occur at various stages of the engineering process, such as prototyping, conceptual design, preliminary design and final design. Managers call for design reviews of the technical aspects or safety of entire systems or individual components.

Review Documentation
The lead engineer ensures that all design reviews are documented. Project documentation includes, at a minimum, a meeting summary describing who attended the review, what issues they discussed, what deficiencies they identified and what recommendations they made. The lead engineer provides a copy of the review results with proposed resolutions to the manager who called the review and files it with the project final documentation. The manager must accept the result of the review before the lead engineer can implement the proposed recommendations or action items. Any additional changes that may arise during implementation require reapproval by the manager.

For high-risk projects, include all the following elements in the review documentation:

- Project description
- Project presenters and their presentations
- Review date
- Project requirements
- Documents and calculations reviewed
- Procurement specifications
- Review findings
- Review recommendations
- Action items

The lead engineer returns review results that affect the project specification to the originator of the review for resolution. The engineer may need to ask for reapproval of the project requirements and specifications document.

The lead engineer and the department head coordinate the type and level of detail of review materials using the graded approach.
Department Reviews
At the request of the department head, projects have department-based technical or safety reviews. The extent of the review depends on the complexity of the project as evaluated using the graded approach.

For smaller projects, a single review may address both design and safety issues. Larger projects may require multiple reviews held over multiple sessions.

In consultation with the lead engineer and his or her supervisor, the department head selects engineers or subject-matter experts to serve as reviewers. The department head may also invite additional stakeholders. Reviewers may or may not be members of the same department. Smaller departments, for example, need to ask other departments to provide members.

The review focuses on the project’s ability to meet specifications, ES&H requirements and good engineering practices. The department head and lead engineer jointly determine review content and detail.

Project Manager Reviews
Project management teams oversee progress and coordinate the project phases for all major projects at Fermilab. Project management may decide to conduct special targeted technical or safety reviews for important subprojects or tasks. The project manager works with the department head responsible for a particular task to arrange these special reviews. Together they assemble the review team and establish the review schedule. They also establish the required documentation. The lead engineer must provide this documentation to reviewers, allowing them ample time for study before the review.

Division/Section/Center Head Reviews
Division/Section/Center heads are responsible for all of the activities occurring in their areas. This includes the engineering efforts of their own personnel as well as any outside activities that affect their areas. Division/Section/Center heads may decide to conduct technical or safety reviews of any engineering project executed within their areas of responsibility. Project managers and the Division/Section/Center heads work with the department head responsible for the task in question to arrange these special reviews. Together they assemble the review team and establish the review schedule. They also establish the required documentation. The lead engineer must provide this documentation to reviewers, allowing them ample time for study before the review.
Purpose and Scope
The purpose of this section is to describe the steps of the procurement and implementation process. With appropriate approval, an engineer or member of the technical staff may procure materials, services, fabrication and construction elements. The implementation process involves many elements of project management as they apply to an engineering project. Procurement and implementation processes together represent the realization of the project.

Procurement
Engineers should use a purchase requisition, which can include a list of suggested vendors, to initiate the procurement of goods or services. Purchases at a cost above the amount specified in the Fermilab Procurement Policy and Procedures Manual require competitive bids or sole-source justifications. The System Design Appendix includes examples of completed sole-source justifications.

Technical personnel send purchase requisitions to the department administrative personnel. They can assist in tracking the status of the procurement.

Technical personnel cannot directly solicit competitive quotes from vendors or enter into binding agreements on behalf of Fermilab. They must work with the Procurement Department of the Business Services Section.

See the Fermilab Procurement Policy and Procedures Manual for more information about the procurement process.

Procurement Department of the Business Services Section
The Procurement Department of the Business Services Section buys standard or off-the-shelf items and establishes service agreements for the maintenance of equipment. The department can assist in obtaining product availability information and information about vendors, including procurement history.

The Procurement Department contracts for items to be built to Fermilab design or performance specifications, including all construction projects. The Procurement Department also procures all services. The department offers assistance in the preparation of specifications and the review of specifications and drawings. Engineers should discuss fabrication issues with the Contracts Group. The Contracts Group should be included in resolving any problems with outside manufacturers or subcontractors.

Procurement Credit Cards
Laboratory management issues procurement credit cards, Procards, to a limited group of employees. They use Procards to buy most commercial goods and off-site services priced up to $2,500 per transaction. Business Services restricts the purchase of some items with Procards. Fermilab encourages Procard use, as it accelerates the procurement process and minimizes paperwork. Administrative personnel know which cardholders can assist with purchasing for their departments.

Communications to Vendors and Subcontractors
Engineers must keep records of all vendor and subcontractor communications. Refer to Fermilab’s records-retention policy for additional information.

Procurement documentation may be as simple as a purchase requisition description. Other projects may require documented vendor communication and detailed, multipage specifications that are subject to the change-control process. The Procurement and Implementation Appendix gives multiple examples of formal procurement specifications.

Task Management
The lead engineer requests the aid of qualified Fermilab task managers when employing workers in contracted trades. The lead engineer communicates special project requirements to the task managers and ensures that tasks are completed properly.
Technical Specifications for Procured Materials or Services

The lead engineer ensures that technical specifications are developed for items that require engineering, design, procurement or custom fabrication effort by outside vendors and contractors. The issuing department approves and controls the specifications.

The lead engineer retains specifications in a file accessible to project and collaboration members. For high-risk procurements, the lead engineer assigns an appropriate document number and record revision dates, keywords and authors. He or she also keeps a record of any change-control documents.

A procurement specification must include, at a minimum:

- Scope of the work
- Performance requirements
- Applicable standards
- List of required submittals
- Quality-assurance plan
- Acceptable products or acceptable substitutions
- Expected execution of the specified product or service

In addition, consider including the following items:

- Design approval
- Interface points
- Applicable codes and standards
- Inspection and test requirements
- Installation requirements
- Documentation and training requirements
- Spare or replacement part requirements
- Safety and health plan
- Project management plan
- Warranty terms and conditions

The design review for high-risk projects must include technical specifications for procured materials or services.
Civil Construction Specifications

Civil construction specifications follow the Construction Specifications Institute’s Master Specification Format numbering system.

The content of a civil construction specification must include, at a minimum:

- Scope of the work
- Performance requirements
- List of required submittals
- Quality-assurance plan
- Acceptable products or acceptable substitutions
- Expected execution of the specified product or service

The Procurement and Implementation Appendix includes several sample specifications, sole-source justifications, and bid evaluation sheets.

Implementation

In the implementation phase, the lead engineer is responsible for providing cost and schedule progress updates to project management. The department head and, for large projects, the project manager inform engineers of any additional requirements associated with project management.

Listed below are actions that the lead engineer must complete during the project implementation.

- Track financial and personnel resources and ensure they are sufficient to meet the project schedule.
- Assess progress and discuss quality, safety and technical concerns at regular meetings with key personnel.
- Integrate changes resulting from design reviews.
- Track delivery dates and identify items critical to maintaining the schedule.
- Perform quality-assurance verification of delivered parts and subcomponents.
- Verify the requirements, connections and interfaces between the project and all external systems.
- Work with groups involved with or affected by the installation to reserve space and to coordinate work activities.
- Coordinate with support staff to ensure proper fabrication and installation of the project components.

For high-risk projects, the department head or project manager ensures that the lead engineer develops, reviews, approves, implements and controls implementation procedures. Implementation procedures include quality-assurance, fabrication, assembly and installation procedures. In some cases, Fermilab or Division/Section/Center policy may require additional levels of approval for a particular procedure or set of procedures.
Purpose and Scope
The purpose of this section is to describe the testing and validation process. This process uses a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment. Testing and validation demonstrate that the component or system satisfies the project requirements and component specifications. The lead engineer should use standard test methods from national standards organizations when available.

The lead engineer must consider taking the steps listed below to validate a device or system. For high-risk projects, include all steps in the testing process.

- Devise a strategy for testing the device or system.
- Document the testing plans, processes and procedures.
- Conduct the tests.
- Analyze the test results and compare them to system requirements.
- Document the test results.

The test documentation must include the following elements:

- Descriptive title and scope of the test
- Date of the test
- Designation of the last revision
- Name of the individual responsible for testing the system, updating the testing procedure, and documenting exceptions
- Description of the test plan, including a list of equipment and instruments required to conduct the test
- Brief description of the importance of the test and its intended use
- Test acceptance criteria
- Safety precautions and hazard analysis
- Environmental concerns and considerations
- Required instrumentation calibrations
- Calculations and analysis of test results

The test documentation may also include the following elements:

- Definitions of terminology
- Description of sampling procedures and data-logging
- Detailed description of testing procedures
- Environmental conditions, such as temperature, pressure and humidity, under which the test was conducted
- Any required concurrence of safety professionals
- Start-up checklists
- Accuracy, precision, systematic bias, repeatability, reproducibility and uncertainty of test results
If the device or system meets requirements, the lead engineer should continue to the next step in the engineering process.

If the device or system fails to meet requirements, the lead engineer must conduct a special requirements and specifications review with those affected. He or she uses the review to determine the implications for the overall project and to determine the next course of action.

The lead engineer must include test methods, procedures and reports in the project’s final documentation.
Purpose and Scope
This section describes the operating and maintenance documents the lead engineer must produce before the project is complete and becomes operational. This process uses a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment.

Operating Documents
The department head and lead engineer determine which operating procedures are required. The lead engineer compiles any required operating procedures, which may be developed by vendors or by Fermilab project engineers. The lead engineer archives the documents, which the department head or designee then controls and distributes.

The operating procedures should describe steady-state and transient operating conditions.

Maintenance Documents
The department head and lead engineer determine which maintenance procedures are required. The lead engineer compiles any required maintenance procedures, which may be developed by vendors or by Fermilab project engineers. The lead engineer archives the documents, which the department head or designee then controls and distributes.

The maintenance procedures should include any required written lock-out tag-out (LOTO) or other ES&H procedures related to maintenance.

Consider the following items while preparing written LOTO procedures:

• An explanation of special precautions
• Checklists of steps to be taken and acknowledged in a prescribed order
• A description of normal and current conditions
• An explanation of the approval process for exceptions to or deviations from the procedure
• A determination of whether a controlled copy needs to be present during use

For additional information, read FESHM Chapter 5120, Fermilab Energy Control Program.
Chapter 9: Final Documentation

Purpose and Scope
The purpose of this section is to describe the final documentation the lead engineer must create and control in order to complete a project. This process uses a graded approach as determined by the department head and lead engineer following the guidance of the Engineering Risk Assessment.

The final documentation includes all documents from prior steps in the process. This section of the manual describes additional documents the lead engineer must produce before archiving final documentation for the project.

Project Documentation
All projects require a final written Project Report. The detail of the report depends on the complexity of the project. The report consists of system diagrams, explanations of important technical decisions, and explanations of how to operate and maintain the system. The report includes an explanation of how the project interfaces with other systems, if applicable.

The final documentation incorporates all documents required by this manual. This must include the following documents:

- Project report
- Requirements and specifications
- Engineering risk assessment with design project plan
- Calculations with evidence of reviews

In addition, the department head or project manager will decide whether to include the following documents:

- Software documentation
- List of part and subassembly numbers with titles
- List of drawing numbers with revision levels and titles
- Results of design and safety reviews with a list of identified issues and their resolutions
- Procurement documents, which may include:
  - specifications
  - statements of work
  - technical change orders
  - supplier quality plans
  - inspection and test results
  - material certifications
  - nonconformance reports
  - deviation request reports
  - other relevant supplier data
- Fabrication and assembly documents
- Testing and validation documents, including test results and, where necessary, corrections made to the system as a result of testing
- Approved operations and maintenance manuals and procedures
- Lessons learned
• References
• Copies of any published papers, technical memos, reports, etc.

Archiving and Control
The lead engineer stores engineering documents to allow future engineering teams to review the history of a project.

A project might require formal archival and control of documentation within a Division/Section/Center or within an overall project document management system. In other cases, archiving may be as simple as saving the project notebook.

In the future, Fermilab will implement a labwide Electronic Document Management System (EDMS). This will provide a central location and common method for document storage, document identification, workflow, configuration control, change management and document retrieval.
No matter whether this is your first pass through the Fermilab Engineering Manual or only your latest, the Engineering Team hopes your project has been successful. We want you to remember that the manual is a living document and will be updated as engineering processes evolve at the laboratory.

“Engineering is not merely knowing and being knowledgeable, like a walking encyclopedia; engineering is not merely analysis; engineering is not merely the possession of the capacity to get elegant solutions to non-existent engineering problems; engineering is practicing the art of the organized forcing of technological change… Engineers operate at the interface between science and society…”

Gordon Brown, Dean of the MIT School of Engineering from 1959–1968

“Engineering is the art of organizing and directing men and controlling the forces and materials of nature for the benefit of the human race.”

Henry G. Stott, President of the American Institute of Electrical Engineers from 1907–1908

“Engineering is a great profession. There is the satisfaction of watching a figment of the imagination emerge through the aid of science to a plan on paper. Then it moves to realization in stone or metal or energy. Then it brings homes to men or women. Then it elevates the standard of living and adds to the comforts of life. This is the engineer’s high privilege.”

Herbert Hoover, President of the United States from 1929–1933 and professional mining engineer
This engineering manual was initially released in 2010 at the request of the laboratory director, Dr. P. J. Oddone. It was developed by a team composed of engineers from across the laboratory representing the major engineering disciplines and an editor from the Office of Communication. The team members were:

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Appendices to this manual are collected in a separate document titled Engineering Manual Appendices. This document, which is available online, provides example documents for many chapters of this manual. It gives examples of documents with varying levels of formality as determined by a graded approach.

You will no doubt face issues similar to those addressed in the Appendices. We encourage you to add to the Appendices by submitting additional examples.

Appendices