



GOOD PRACTICE GUIDE:

Management of Engineering Standards





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ISBN 978-1-936379-85-9

Preface

This ISPE Good Practice Guide on the Management of Engineering Standards has been developed and published by ISPE with the aim to provide to the industry a common understanding and approach to the management of Engineering requirements (Standards) typically set at the corporate level for manufactures, designers, and builders of Pharmaceutical plants and processes. This Guide is a unique opportunity to integrate in a single document the complex body of knowledge required by all professionals involved in the highly regulated pharmaceutical market.

The Guide is intended to promote excellence and knowledge within the pharmaceutical Engineering enterprise and systems. The Guide addresses the knowledge management needs associated with the identification of content, creation, review and approval of Engineering Standards. In addition, the process of keeping content current and compliant through periodic review, as well as successful integration with third party designers/integrators are also addressed.

The Guide is a reference source of good practices covering in a structured way a wide variety of themes, subjects, problems and issues faced across the realm of pharmaceutical design, maintenance, and operation. This Guide is intended to be read in conjunction with other ISPE guidance, International Council for Harmonisation (ICH) guidelines, and industry recognized standards.

Acknowledgements

The Guide was produced by a Task Team led by Jeffrey S. Fluharty (Eli Lilly and Co.) and Frank J. Smith (Merck & Co., Inc., Kenilworth, NJ, USA). The collaboration of knowledge is based on the learnings from the former ISPE Engineering Standards Benchmarking Community of Practice (COP).

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Special Thanks

The Task Team wishes to thank all the former members of the Engineering Standards Benchmarking COP for their participation, input, and sharing via the community and for the numerous responses to the multiple surveys issued over the years the COP was active. The Task Team also wishes to expressly thank the former COP Steering Team members listed below for their vision and efforts to bring the COP into existence to provide the inspiration for this Good Practice Guide:

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The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

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1 Introduction and Business Value

The *ISPE Good Practice Guide: Management of Engineering Standards* is intended to provide guidance on how to establish and maintain an Engineering Standards Program. It covers the entire life cycle of an Engineering Standard, from chartering to retirement. In addition, it includes a description of the governance process for the Engineering Standards Program.

Although it is intended for an Engineering Standards Program, the principles would apply to other document programs.

The application of the recommendations in this Guide are scalable, based upon the size of the organization, number, and type of documents to be managed. For example, a smaller organization may not have Engineering Standards, but could apply the concepts to the maintenance and use of specifications.

Some of the topics in this section will be discussed in more detail in later chapters.

1.1 Business Value

The goals of the Engineering Standards Program should be determined and documented as part of the program charter. Depending upon the size of the program, the resources needed can be several Fulltime Equivalents (FTEs), including the Subject Matter Experts (SMEs), the program management, and governance. The costs to establish and maintain an Engineering Standards Program should be offset by the benefits. Key benefits of having an Engineering Standards Program include:

- Assures the appropriate level of quality, safety, and regulatory compliance is incorporated into engineering designs
- Improves the effectiveness and efficiency of the asset delivery process
- Reduce costs and time to conceptualize, engineer, specify, design, commission, and qualify engineering solutions
- Assures the design solution provides optimal operability and maintainability
- Streamlines engineering information gathering processes by providing a roadmap for engineers to follow to be in compliance with requirements
- Increases productivity by avoiding “reinventing the wheel”. Engineers can focus time on systems that require unique definition
- Reduces cost of new facilities by limiting Architect/Engineer (A/E) firm cost and project time associated with designing every system from scratch
- Reduces variability by documenting proven requirements and driving improvements in facilities and equipment operability and maintainability
- Provides an effective knowledge capture and dissemination process (Knowledge Management System) that is integrated into the engineering process
- Preserves know-how and increases efficiency by retaining reasons of why a specific technical solution has been performed

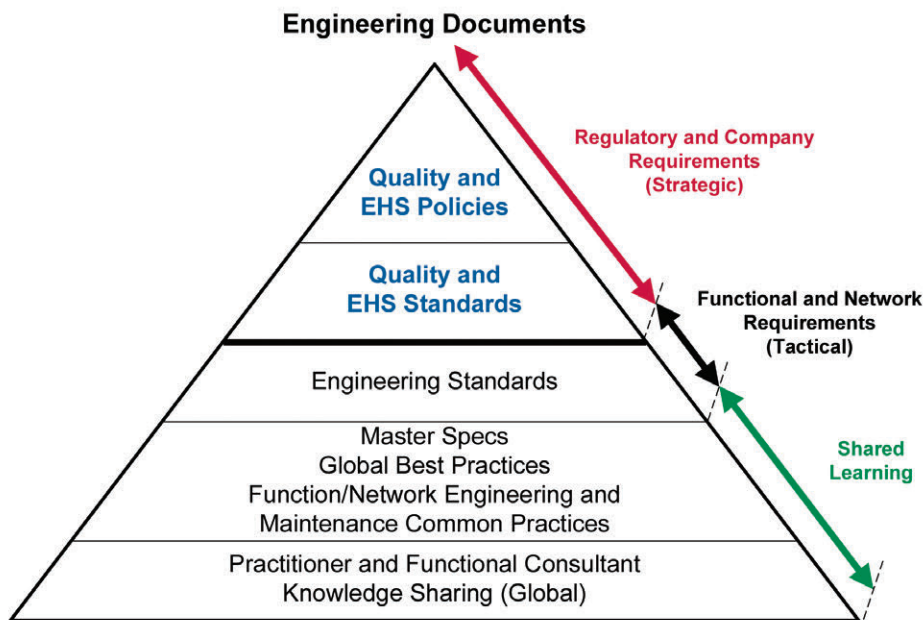
1.2 Relationship to Other Documents

The relationship of Engineering Standards should be established to:

- Quality
- Environmental, Health, and Safety (EHS)
- Automation
- Maintenance
- Other corporate policies and guidance documents

Typically, Engineering Standards are technical requirements established to support regulatory and company requirements (Quality, EHS, Strategic Initiatives such as life cycle costs, operational performance, etc.). In addition, there may be other company guidance documents that are subordinate to the Engineering Standards such as best practices, specifications, etc. Figure 1.1 illustrates this concept.

Figure 1.1: Positioning of Engineering Standards



When establishing the relationship of the Engineering Standards to the other documents, considerations include:

- Are the Engineering Standards part of the Quality System, i.e., they use the Quality System processes and governance? This may impact the level of detail and approval.
- Is the intention to audit compliance to the Engineering Standards?
- Will references be bi-directional or one-way between quality documents and Engineering Standards?
- The relationship to other documents may have an impact on the variance process
- How will the standard structure around the organizational design or other systematic considerations be built?

When setting up an Engineering Standards Program consideration should be given to the scope of the program and how it will interface with any site/local standards. This may be particularly significant when mergers and acquisitions take place. If there are local standards, the “corporate standard” should state how it interfaces with the local one (i.e., supersedes local standards, used only if local standard does not exist, should comply with more stringent requirements, etc.).

1.3 Program Foundational Principles

There are several high level foundational principles that should be addressed when establishing an Engineering Standards Program, including:

- Engineering Standards contain the “How”. Higher level documents such as Policies and other Standards (Quality, EHS, etc.) contain the “What is required”
- The Engineering Standards Program should have sponsorship from the highest levels within the organization
- There should be a robust process to communicate new and updated Standards
- The Engineering Standards Program should address document control (numbered, revision control, periodic review, retention, etc.)
- Governance of the program should be within the Engineering Organization and Quality
- The boundaries of the Engineering Standards Program should be established with regards to activities such as designing, commissioning, maintaining, and retiring
- Engineering Standards should be aligned with (supports the requirements of) Quality, EHS and other Corporate Policies and external regulatory and legal requirements to ensure compliance
- The Engineering Standards Program should be documented in a way which ensures compliance with Standard Operating Procedures (SOPs), Policies, etc.
- All new projects should utilize the appropriate Engineering Standards, based upon the scope of the project
- How Engineering Standards will apply to existing assets and newly acquired sites/facilities should be determined:
 - Expect to come in alignment through gap assessments over time
 - Apply only to new/renovation projects
 - Or combination of these aspects
- Standards should be reviewed periodically, based upon supporting document updates (Quality, EHS, etc.) and new technology availability

For further information on Operating Level Principles concerning the Steering Committee and the documents see Section 3.

1.4 Governance Body

The Governance Body plays a key role in the Engineering Standards Program. Deliverables, milestones, decision rights, and membership should be established early.

Key deliverables and milestones of Governance Body:

- Focused decision making authority to drive problem resolution and remediation
- Decision based upon experience, regulatory, and engineering knowledge
- Identify appropriate individuals/teams with the capabilities and assign them to the appropriate roles with the authority to make decisions
- Structured library for engineering knowledge management
- Reviews process metrics and takes appropriate action

Decision rights of Governance Body:

- Approves Committee Procedures and work practices
- Influences the resources for document development
- Approves the scope of Engineering Standards and charters the team to develop and update specific Engineering Standards
- Approves Engineering Standards and effective dates, ensuring that all decisions provide optimal business solutions
- Authorizes development of training to support documents, identification of any training gaps, and recommends additional training
- Governs the Variance Process

When establishing the Governance Body, the appropriate functional areas should have representation, directly or indirectly. Where there are other document governance/Steering Committees within other functional areas, there should be some collaboration to assure alignment. Functional areas may include:

- Quality
- EHS
- Operations
- Maintenance
- Facilities Management
- Corporate/Global Engineering
- Site Engineering
- Automation and Control

- Maintenance/Reliability
- Other areas when deemed necessary (such as Regulatory Affairs, Security, Legal, IT, etc.)

Once Standards are developed, the application, Variance Process, and Maintenance Process become key to having a robust program.

1.4.1 *How Standards Apply to Existing Systems or a Project in Implementation*

- Establish milestones for compliance on projects underway
- Establish an effective date of Engineering Standards
- Consideration should be given to the application of Engineering Standards to the installed base:
 - “Grandfathering”, not applying new Engineering Standards to existing assets. If the Standards are meant to apply to existing assets, then some justification should be provided when “grandfathering”.
 - Gap assessments and a risk based compliance plan
 - “100%” compliance over time
 - Immediately apply everywhere due to EHS or quality concerns

For further information on Engineering Standards Program Governance, see Section 4.

1.5 Variances

A Variance Process that is transparent and robust can help to assure compliance with Engineering Standards. It also is a means to keep Engineering Standards up to date (i.e., they are healthy challenges that will over time improve Engineering Standards). For further information on the Variance Process see Section 8.

1.6 Review Cycle

The Governance Body determines a set minimum review cycle time for all Engineering Standards. Consideration may be given to impact on Quality, EHS, stability of the technology, etc. In addition, there are key inputs that need to be monitored (Code of Federal Regulations, EU Annex Documents, etc.) that will influence the content and frequency of update. A process should be established to achieve this. For further information on the Review Cycle see Section 6.1.

2 Key Terms/Document Types

Engineering Document	Description
Engineering Standard	• Mandatory minimum requirements that apply to facilities and equipment covering aspects of design, construction, and/or commissioning/validation (including operational requirements, e.g., gowning, pest management) • Typically, minimum requirements are described in Standards, however, on some occasions an Upper Limit may be described to set standardization or to limit costs. • Requirements can be functional and performance related • There are several types of Engineering Standards such as: - design - functional - equipment • EHS Standards may be included or follow similar process • Quality Standards/Policy are not included as the process may not be as rigorous as required
Engineering Best Practice	• Established design guidance and methods that are applied throughout a project's "life cycle" to deliver appropriate, cost-effective solutions. The use of Best Practices is highly encouraged, but not compulsory • Use with existing assets/facilities and for maintenance over asset life cycle • Best practices also contain: - Instructions to project design teams concerning editing of specifications for project use, and - Application tables to assist the design team in the selection of the appropriate materials specifications • Best Practice examples: engineering disciplines such as process, maintenance reliability, packaging, controls
Engineering Specification	• A contractually binding document covering requirements to procure equipment, materials and construction for projects. The document that can be tailored by the designer (unless prohibited by an Engineering Standard mandatory requirement) to meet individual project needs.

