Get Excellent Performance

from

Good Engineering Practice

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Process, CRB

Agenda

Part 1: Engineering Practice

good engineering practice

Part 2: Good Engineering Practice

Part 3: Getting Alignment

What is an Engineer?

"The scientist seeks to understand what is; the engineer seeks to create what never was"

-Theodore von Kármán

The Consultant's Job

- Understand the Client's Needs

CHAPTER 1200-3-24
GOOD ENGINEERING PRACTICE STACK HEIGHT REGULATIONS

(c) **"Good engineering practice" (GEP) stack height** means the greater of:

1. 65 meters (213 feet), measured from the ground-level elevation at the base of the stack:

2. Considering other stack criteria the following formulae apply:

   (i) For stacks in existence on January 12, 1979 and for which the owner or operator had obtained all applicable permits or approvals required,

   $$H_g = 2.5\ H,$$

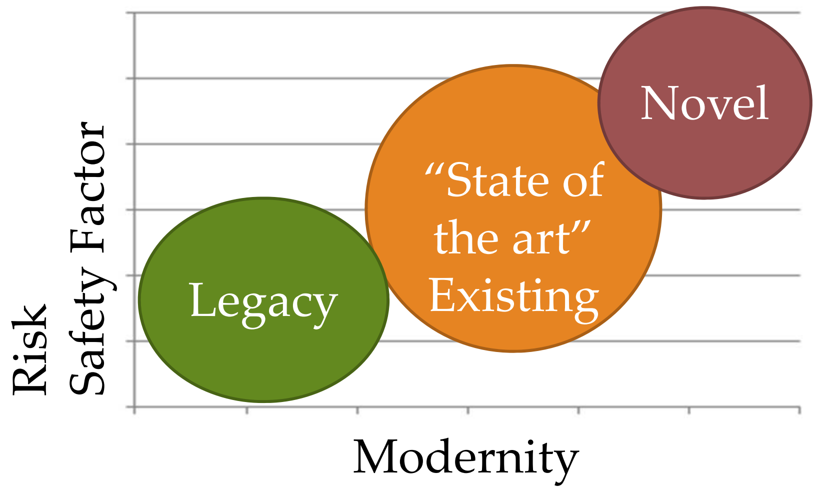
…

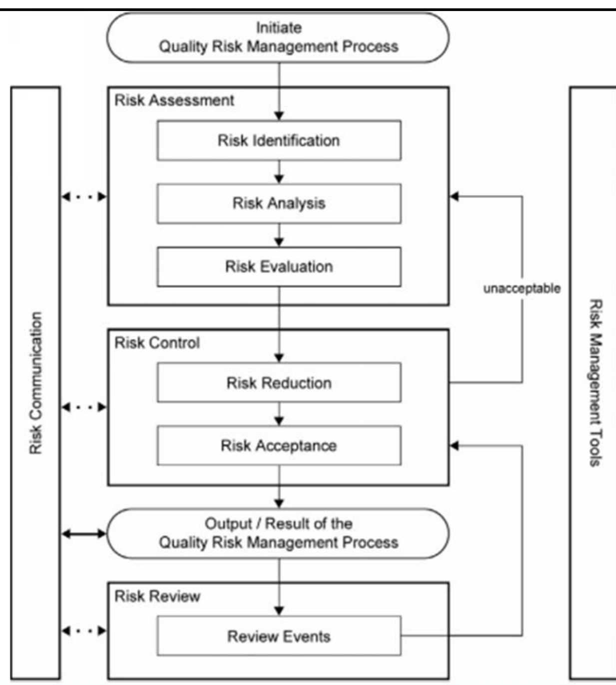
3. The height demonstrated by a fluid model or a field study approved by the Technical Secretary, which ensures that the emissions from a stack do not result in excessive concentrations of any air pollutant as a result of atmospheric downwash, wakes, or eddy effects created by the source itself, nearby structure or nearby terrain features.

The Consultant's Job

- Understand the Client's Needs
  - Design Constraints
  - Design Assumptions
  - Design Loads

Modernity, Risk and Safety





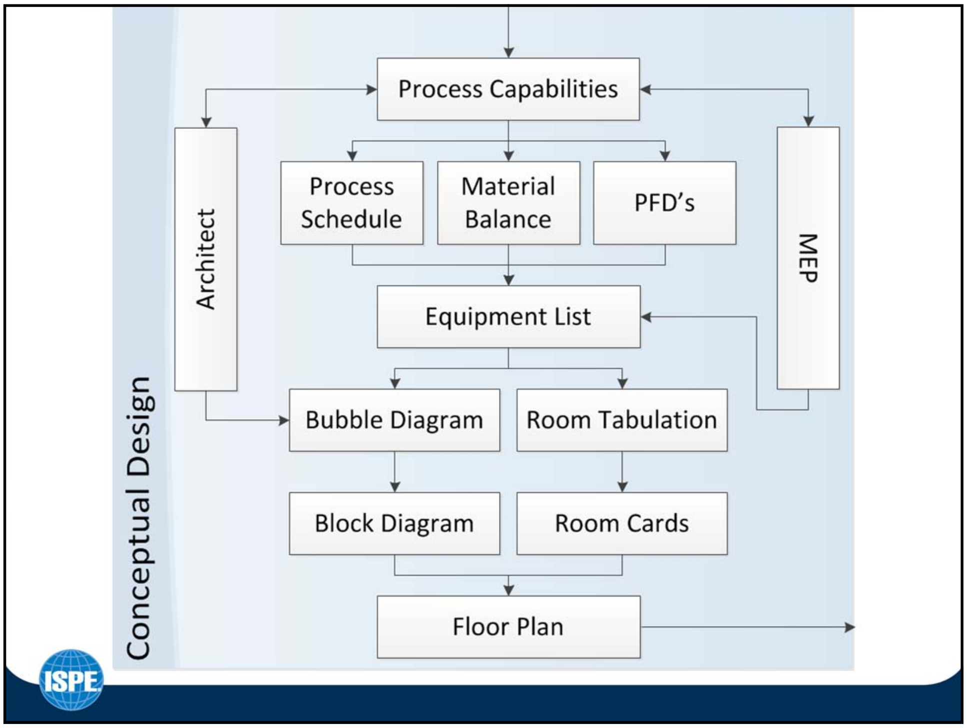
The Engineering Method

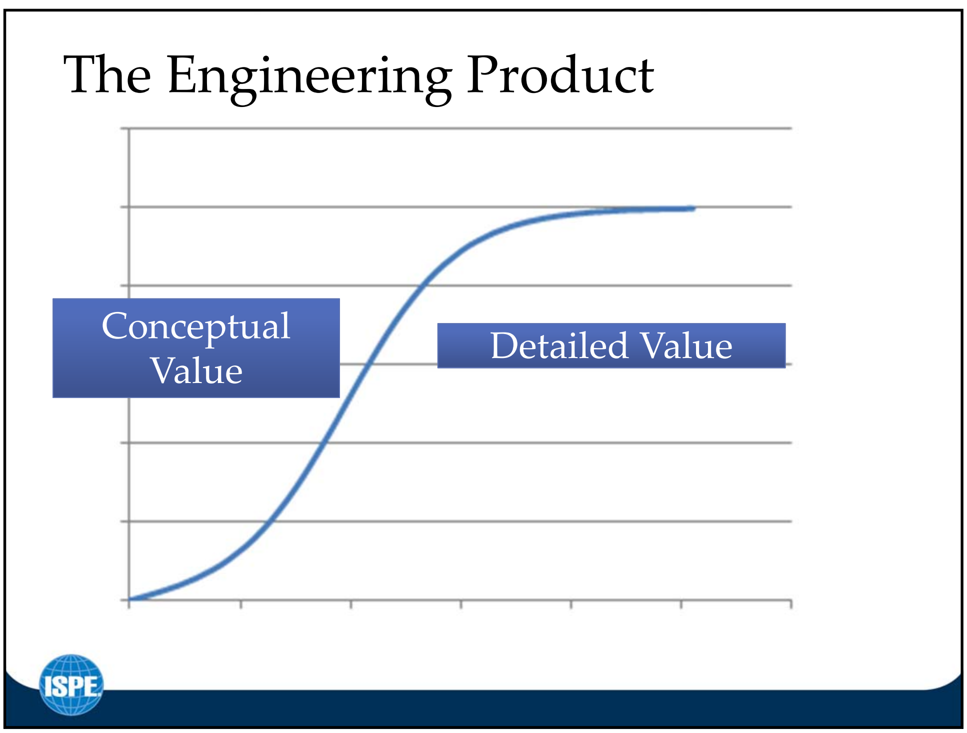
- Define the Problem
- Do Background Research
- Specify the Requirements
- Conceptual Design
- Detailed Design
- Bidding
- Construction Administration

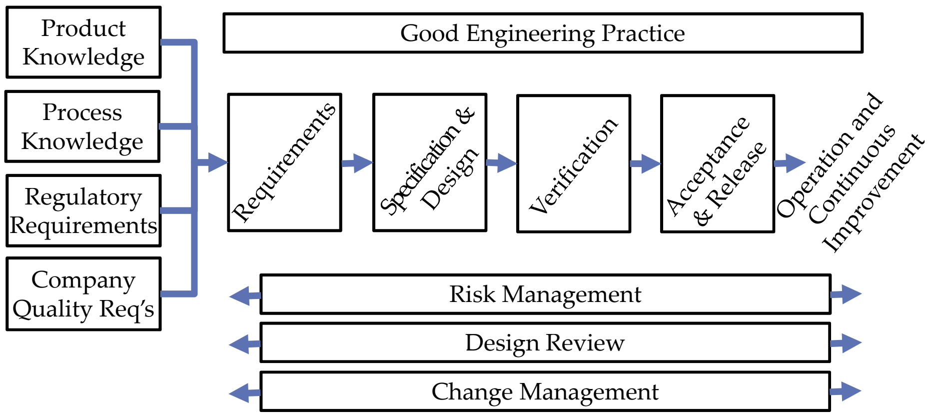
- Consider Options
- Develop Solution
- Test Solution Meets All Requirements
- Repeat as Needed

The Consultant's Job

- Communicate those needs by **generating documents** a contractor/fabricator can understand to **design and construct** the required equipment and facility.


Conceptual Design
Process Capabilities
Architect
MEP
Process Schedule
Material Balance
PFD's
Equipment List
Bubble Diagram
Room Tabulation
Block Diagram
Room Cards
Floor Plan


The Engineering Product
Conceptual Value
Detailed Value



6.6.2 Good Engineering Practice is defined as those established engineering methods and standards that are applied throughout the life cycle to deliver appropriate and effective solutions.

6.6.3 Examples of Good Engineering Practices include:

6.6.3.1 Specification, design, and installation activities should take full account of all applicable requirements, including GxP, safety, health, environmental, ergonomic, operational, maintenance, recognized industry standards, and other statutory requirements.

6.6.3.2 Adequate provisions related to quality should be included in specification, design, procurement, and other contractual documents.

6.6.3.3 Life-cycle documentation covering planning, specification, design, verification, installation, acceptance, and maintenance should be produced.

6.6.3.4 An appropriate degree of oversight and control should be achieved by suitable verification of execution, construction and installation activities.

"…deliver appropriate and effective solutions."

"… take full account of all applicable requirements…"

"…quality should be included…"

"Life-cycle documentation… should be produced."

"…verification of…activities."

User Requirement Brief

- Executive Summary
  - Purpose
  - Project Rationale and Background
  - Goals and Priorities
  - Scope Overview
- Capacity
  - Capacity Requirements and Basis
  - Process Design Basis
  - Flexibility
  - Plant Capacity and Batch Sizes
  - Expandability/Phasing Strategy
  - Capacity Utilization Targets
  - Yield Targets
  - Modeling
- Operational Strategies
  - General
  - Manufacturing Plant Configuration
  - Maintenance and Reliability
  - Staffing
  - Production Support Services
- Automation and Controls
  - Automation Strategy
  - Level of Automation
  - Conceptual System Architecture
- Business Systems
  - ERP
  - Batch Records
  - DMS
  - LIMS
  - Maintenance Systems
  - EDMS
  - Other Systems
- Validation
  - Validation Involvement and Responsibilities
  - General Approach
  - Validation of Automation
- Cost
  - Capital Cost
  - Cost of Production
- Revision History

Engineering Change Management

Documentation Review

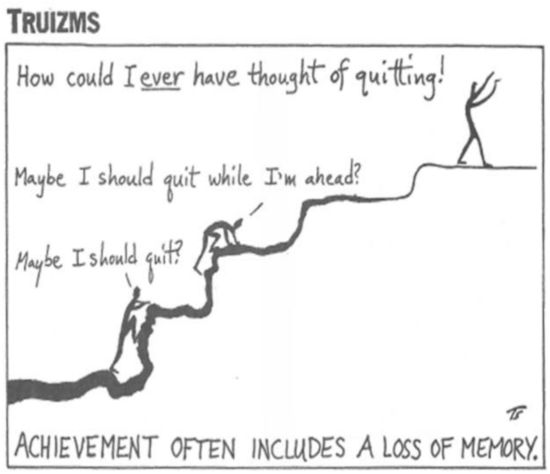
Design Risk Assessment

Work-Flow Management

Design Review

Automation Reviews

Lessons Learned Should be Learned NOW



Todd Siler