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  - Hazards and Risk Assessment ------Schuste Engineering
  - Failure Modes and Effects Analysis FMEA -----Dr. Timothy Cyders, Ohio University,
- Product Liability Concepts ------Schuste Engineering
- Codes and Standards ------Varun Patel

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What is Risk Assessment?

A structured approach to:

- Identify Hazards
- Assess the severity and likelihood of exposure
- Identify techniques to reduce Risk
- Monitor safety improvements

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Hazards and Risks

- Hazards are…
  - Unsafe conditions
  - Often unavoidable
- Risks are …
  - Exposures of people to hazards
  - Adjustable by designs and processes

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What is the Risk Assessment process?

- Identify all users who interact with your product/process
  - For each user … define tasks/activities
    - For each task … define the Hazards
- For each Hazard … estimate the risk
- For each Hazard … implement processes to reduce risk
- For each Hazard … track implementation

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Sound familiar?

Failure Mode & Effects Analysis	Risk Assessment
Identify *Failures* & Causes Assess Severity & Likelihood Prioritize Actions Implement *Preventative* Actions	Identify *Hazards* & Causes Assess Severity & Likelihood Prioritize Actions Implement *Protective* Actions
Focus on product issues Use early in design process Primarily Design Modifications	Focus on user injuries Use late in design process Primarily Process Improvements

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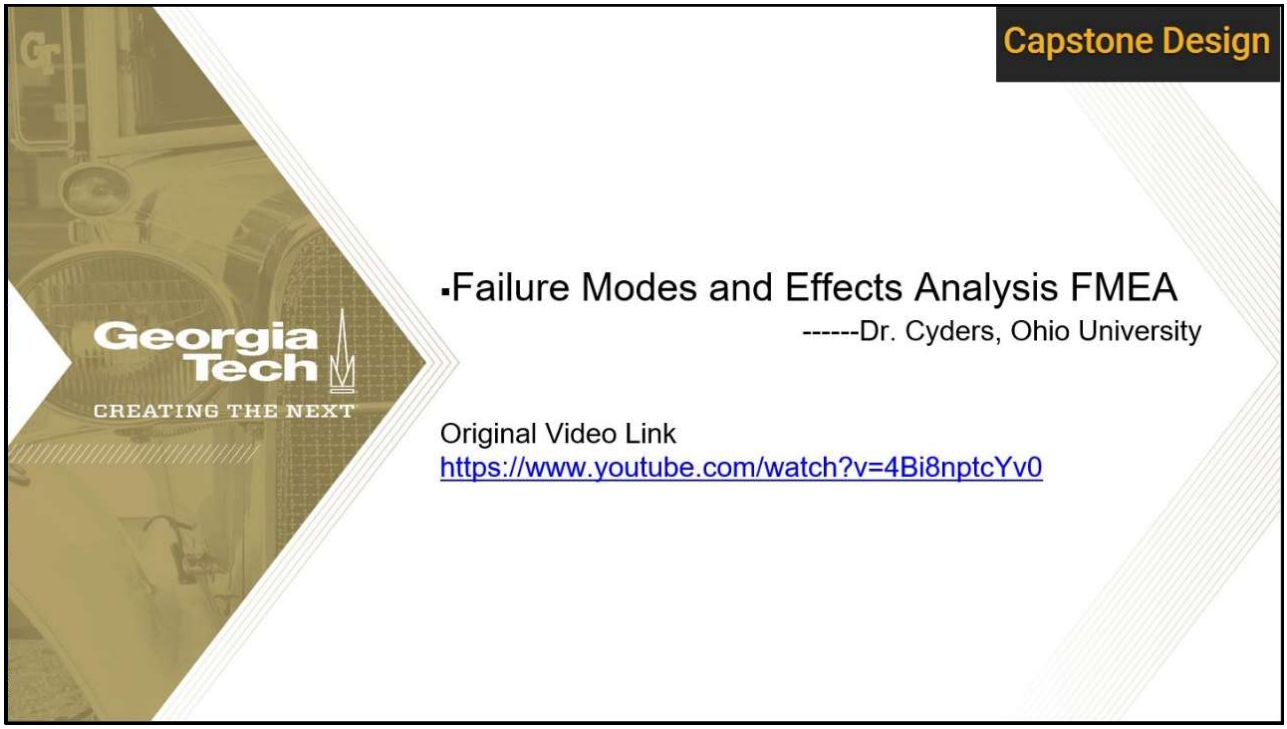

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Failure Mode and Effects Analysis (FMEA)

FMEA is a design tool for assessing risk associated with the different ways (modes) in which a part or system can fail, identifies the effects of those failures, and provides a structure for revising the design to mitigate risk where necessary.

- Inductive process, asks question 'If this failure occurred, then what could happen?'
- Provides a method for quantitative analysis of risk
- Useful for comparing design concepts and refining designs
- Documents safety review in an easy-to-read format

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Process Steps:

- 1: Identify modes of failure (e.g.: car won't stop)
- 2: Identify consequences & related systems for each mode
- 3: Rate the *Severity* (S) of each effect
- 4: Identify potential root causes for each failure mode
- 5: Rate the *Probability of Occurrence* (O) of each root cause
- 6: Identify process controls and indicators (e.g.: brake squeal)
- 7: Rate *Detectability* (D) of each mode/root cause
- 8: Calculate risk priority (S*O*D) and criticality (S*O)
- ***9: Use design to mitigate high-risk or highly critical failures, and re-assess to ensure goals have been achieved***

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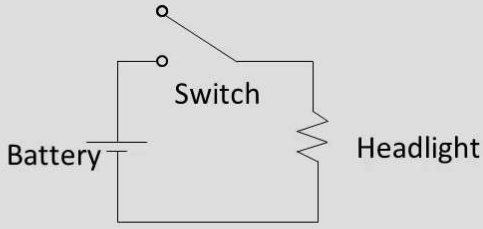
Example:

Possible Failure Modes:

- Light doesn't turn on
- Light doesn't turn off



Possible Consequences:

- *Light doesn't turn on*
  - Driver can't see obstacles
    - Car inoperable at night (8)
- *Light doesn't turn off*
  - Battery dies
    - Car won't start (10)

Possible Root Causes:

- *Light doesn't turn on*
  - Battery dead (8)
  - Broken wire (3)
  - Headlight out (10)
  - Switch corroded (2)
  - Switch broken (3)

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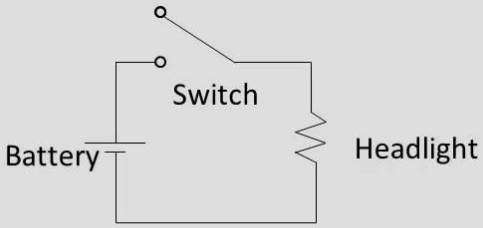
Example:

Possible Failure Modes:

- Light doesn't turn on
- Light doesn't turn off



Possible Consequences:

- *Light doesn't turn on*
  - Driver can't see obstacles
    - Car inoperable at night (8)
- *Light doesn't turn off*
  - Battery dies
    - Car won't start (10)

Possible Root Causes:

- *Light doesn't turn off*
  - Short circuit in switch (2)
  - Operator error (left on) (8)

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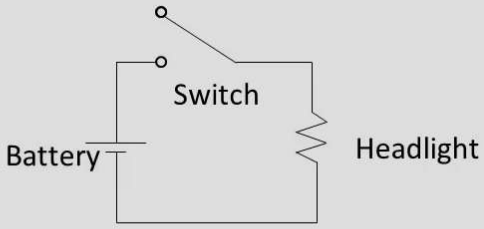
Example:



Controls/indicators:

- *Light doesn't turn on*
  - User notices lights on in dark
- *Light doesn't turn off*
  - User notices lights on in dark

Detectability:

- *Light doesn't turn on (6)*
  - User notices lights on in dark
  - User doesn't notice lights not on during day
- *Light doesn't turn off (6)*
  - User notices lights on in dark
  - User doesn't notice lights not on during day

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Example:

Failure Mode: *Light doesn't turn on*

Possible Effect	Root Cause	S	O	D	RPN	Crit.
Car inoperable at night	Battery dead	10	8	6	480	80
	Broken wire	8	3		144	24
	Headlight out	8	10		480	80
	Switch corroded	8	2		96	16
	Switch broken	8	3		144	24

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Example:

Failure Mode: *Light doesn't turn on*

Possible Effect	Root Cause	S	O	D	RPN	Crit.
Car inoperable at night	Battery dead	10	8	2	160	80
	Broken wire	8	3		60	30
	Headlight out	6	10		120	60
	Switch corroded	8	2		40	20
	Switch broken	8	3		60	30

Redesign: Use two headlights instead of one, add visual lights-on display in console.

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Example:

Failure Mode: *Light doesn't turn off*

Possible Effect	Root Cause	S	O	D	RPN	Crit.
Car won't start	Short circuit in switch	10	2	7	140	20
	Operator error		8		560	80

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Example:

Failure Mode: *Light doesn't turn off*

Possible Effect	Root Cause	S	O	D	RPN	Crit.
Car won't start	Short circuit in switch	10	2	2	40	20
	Operator error		8		160	80

Redesign: Add audible indicator when driver's door is opened while lights are on, add visual lights-on display in console.

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SAFETY IS YOUR DUTY
INCLUDED IN ENGINEERING CODES OF ETHICS

NSPE Rule of Practice #1:

Engineers shall hold paramount the safety, health, and welfare of the public.

- If engineers' judgment is overruled under circumstances that endanger life or property, they shall notify their employer or client and such other authority as may be appropriate.

NSPE NATIONAL SOCIETY OF PROFESSIONAL ENGINEERS

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DESIGN FOR SAFETY

- Paramount Issue in Product Design
- Safe by DESIGN – goal is ZERO injury, property loss, or damage to environment
- This takes conscious focus during design
- Three Levels of Product Safety Design:
  1. Make the product safe by eliminating all hazards.
  2. Reduce risks by adding specific guards, screens, etc.
  3. Warn user with labels, flashing lights, sounds, etc.

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1. DESIGN FOR SAFETY
THE BEST APPROACH

- Focus on safety during design
- Design product to be "fail-safe"
- Eliminate hazards in the design.

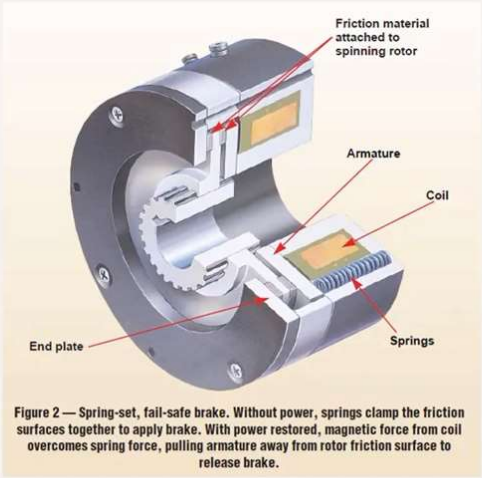

Figure 2 — Spring-set, fail-safe brake. Without power, springs clamp the friction surfaces together to apply brake. With power restored, magnetic force from coil overcomes spring force, pulling armature away from rotor friction surface to release brake.

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DESIGN FOR SAFETY

- Avoid pinch points
- Automatic shutoff
- Mechanical overrides
- Latch switches

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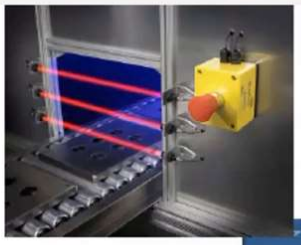
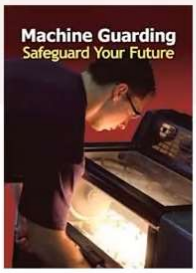
2. ADD PROTECTIVE FEATURES
FOR RISKS THAT CAN'T BE AVOIDED





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3. LABEL & PROVIDE TRAINING
WEAKEST APPROACH

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CAUTION LABELS

- All three of these labels are on the same dumpster!

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WARNING LABELS

Label standards at ANSI.org and ISO.org

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Wacky Warning Label Contest Finalists

CenterforAmerica.org

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Wacky Warning Label Contest Finalists

CenterforAmerica.org

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Wacky Warning Label Contest Finalists

CenterforAmerica.org

Second place: An iron-on T-shirt transfer that warns: "Do not iron while wearing shirt."

Grand Prize: A label on a small tractor that warns: "Danger! Avoid Death."

Third place: A baby stroller featuring a small pouch for storage that warns: "Do not put child in bag.

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AS AN ENGINEER HOW DO YOU REDUCE SAFETY RISKS?

- Include "safety" in your primary criteria
- Design to nationally recognized standards
- Communicate "design considerations" completely and accurately throughout the design process
- Select materials properly
- Test the product under real world conditions
- Document the development of the product

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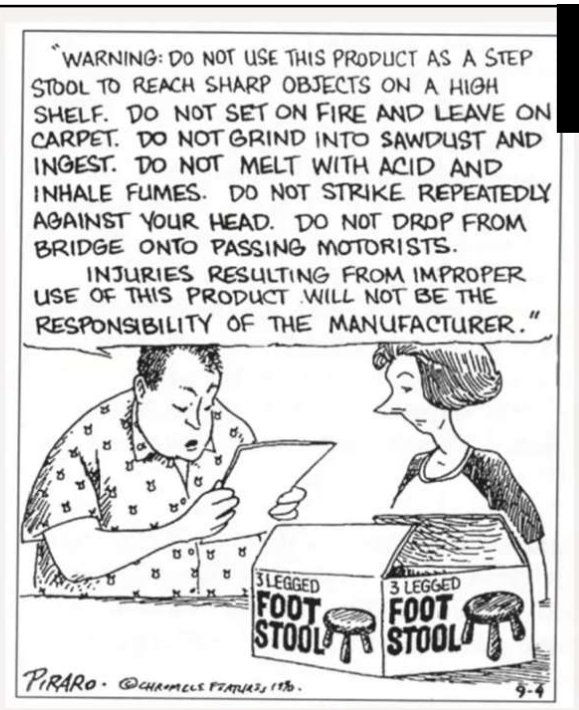
SAFETY

...

or Liability?



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PRODUCT LIABILITY

- Product liability identifies who is responsible for damage caused by a product (manufacturer, seller, consumer).
- There have been changes in product liability over the years: from one extreme to the other
  - 100 years ago the individual was responsible: "let the buyer beware"
  - Now, the majority of liability is put on the manufacturer
- What is a designer's liability when a product fails to perform as expected?

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LEGAL SYSTEMS

Common Law vs. Civil Law Systems

- In common law, court decisions become part of the law (this is known as judicial precedence)
- In civil law, statutes & codes are updated by legislature, not courts

U.S. and most other English-speaking countries use common law

Criminal Law vs. Civil Law

- Criminal – government brings suit against a person
- Civil – suit is filed by party against another

Product liability claims can be pursued in both criminal and civil courts

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PRODUCT LIABILITY CLAIMS

- Negligence – A judgment of fault. May include criminal charges. When a manufacturer failed to use a reasonable level of care.
- Strict Liability – A judgment of liability regardless of fault. A manufacturer is liable even if high level of care was taken.
- Warranty of fitness – A breach of contract. If a product doesn't work properly, it violates an implied contract.
- In California, defendants must prove that a product is NOT defective (in 47 states, plaintiff must prove it is).

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POTENTIAL PRODUCT DEFECTS

- Product Design
  - Concealed danger (design has flaws)
  - Material failure
  - Failure to consider misuse
- Manufacturing and Materials
  - Packaging, transportation, installation, application
- Marketing / Warnings and Labels
  - Must be clear & easy to understand
  - Appropriately placed
  - Secure & lasts the life of the product
- Disposal and the Environment
  - What happens when consumer is done with it?

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CHARGES OF NEGLIGENCE

- The product was defectively designed
  - Includes claims of improper calculations, poor materials, insufficient testing, not following standards, etc
- The design did not include proper safety devices
  - Comparisons to state of the art, competitive products, standards
- The designer did not foresee possible alternative uses
  - What would a reasonable person think/do?
- The product was defectively manufactured
- The product was improperly advertised
- Instructions for safe use of the product were not given.

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HOW TO PROTECT YOURSELF
(FROM PRODUCT LIABILITY)

"The product was defectively designed"
- Keep good records of all considerations, including calculations, standards, test results, etc.
- Use commonly accepted standards when available
- Use state of the art evaluation techniques
- Follow a thorough, rational process.

"The design did not include proper safety devices"
- Try to design-in safety (eliminate hazards)
- If not, then add safety in the form of guards
- Lastly, add warnings (this is not as effective)

"The designer did not foresee possible alternative uses of the product"
- Must imagine all possible misuse
- Product should be difficult to use improperly
- Try to make things "idiot proof"

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Capstone Design

Georgia Tech
CREATING THE NEXT

- Codes and Standards

------Varun Patel, HardHat Engineering

Original Video Link:
https://www.youtube.com/watch?v=yBnlOWMhovE

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ASME
SETTING THE STANDARD
ASTM
INTERNATIONAL
Standards Worldwide
Code, Standard & Specification
1

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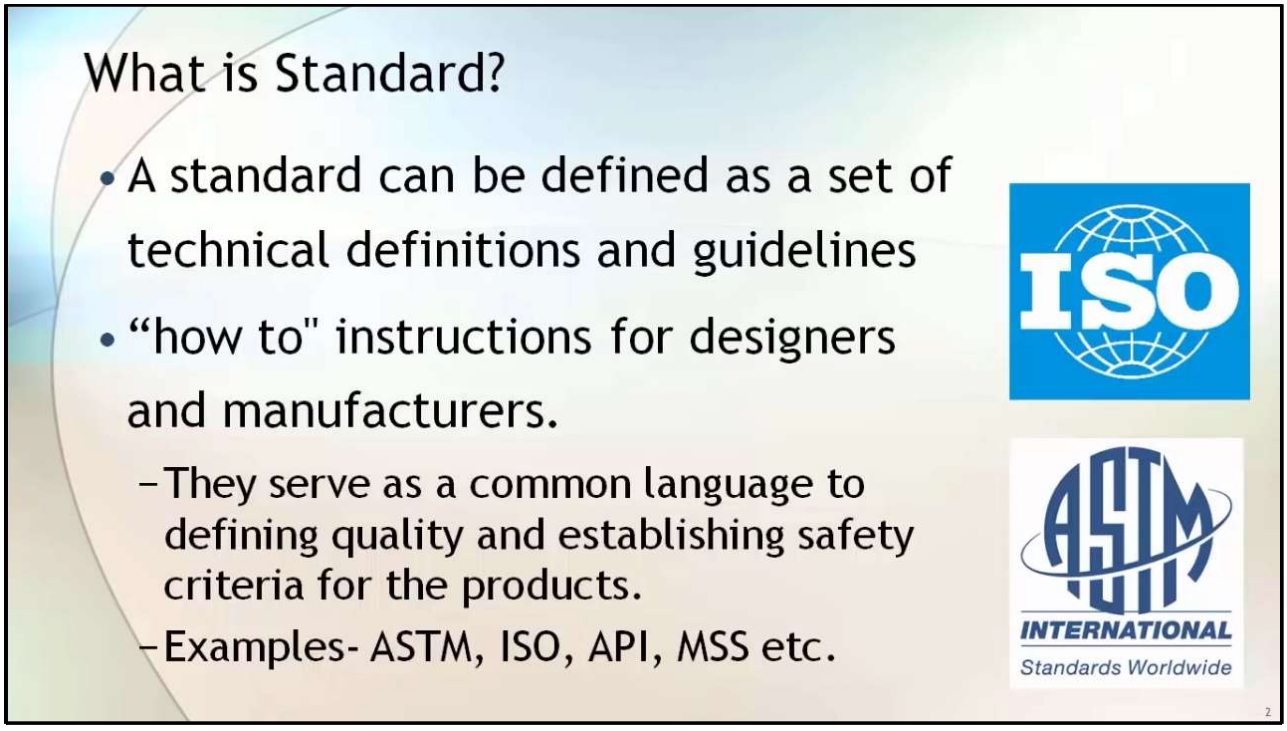
What is Standard?
• A standard can be defined as a set of technical definitions and guidelines
• "how to" instructions for designers and manufacturers.
– They serve as a common language to defining quality and establishing safety criteria for the products.
– Examples- ASTM, ISO, API, MSS etc.
ISO
ASTM
INTERNATIONAL
Standards Worldwide
2

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Why Standard is required ?

- Standards are documents that establish engineering or technical requirements for products, practices, methods or operations.
  - Build confidence about quality in users
  - Lower the cost of production as requirements are standardize

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What is Code ?

- A code is a standard that has been adopted by one or more governmental bodies and can be enforced by law or
- When it has been incorporated into a business contract

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Why Code is required ?

- Provide a set of rules that specify the minimum acceptable level of safety & quality for manufactured, fabricated or constructed objects.
- Also refer out to standards or specifications for specific details on additional requirements not specified in the Code itself.

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What is Specification ?

- Specifications provide specific / additional requirements for materials, components or services beyond the code or standard requirements
  - Often generated by private companies to address additional requirements applicable to a specific product or application

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Why Specification required?

- Allow purchaser to include special requirements as per design and service condition
- Must meet requirements
  - Examples- Product specification

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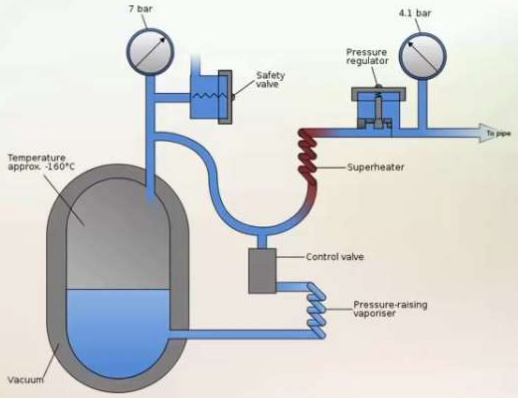
Code & Standard grouping

- System Design Code
  - ASME B31 series, ASME Section XIII
- Material Standard
  - ASTM, ASME Section II
- Dimensional Standard
  - ASME B16 series



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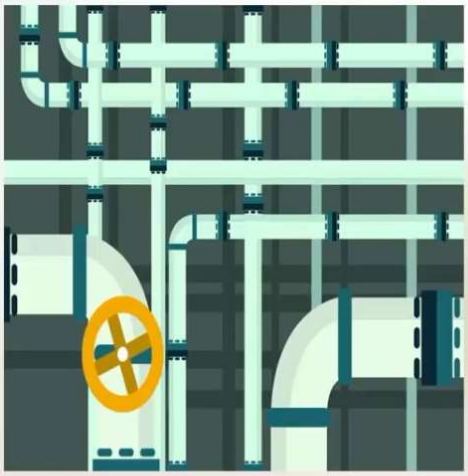
System Design Code Covers

- Requirements for materials
- Types of Components
- Design requirements
- Fabrication, assembly, Installation requirements
- Inspection and testing requirements



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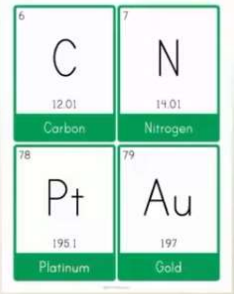
Material standard covers

- Manufacturing process
- Chemical Property
- Mechanical Property
- Heat treatment requirements
- Mechanical testing requirements
- Non-destructive Testing and inspection requirements



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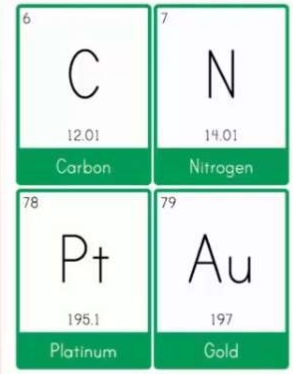
Material standard covers

- Acceptable tolerance for imperfection
- Defect repair and acceptance
- Marking requirements
- Supplementary requirements
- General requirements



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Dimension standard cover

- Different standard for different components gives product specific requirements in general
- Standard Sizes
- Inside and outside diameters
- Wall thickness (schedule no.)
- Pressure Temperature ratings

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Dimension standard cover

- Bolting dimensions
- Threading requirements
- Gasket thickness & finishing requirements
- End types for pipe & fittings
- Permissible variance in dimensions

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