

# Challenges in Conducting Safer Technologies and Alternatives Analysis (STAA) Studies for the Revised EPA RMP Rule

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# Agenda

- Inherently Safer Design / Inherently Safer Technology
- STAA Requirements
- Issues with Implementation
- Questions & Answers

# Fundamentals of Inherently Safer Design

- Inherently Safer Design - a holistic approach to making the development, manufacture, and use of chemicals safer.
- Focuses on first reducing or eliminating hazards rather than adding more safeguard barriers.
- Involves such practical applications as:
  - substituting less hazardous chemicals at the development stage,
  - using less intense process conditions and safer processing methods at the manufacturing stage,
  - and simplifying processes to avoid human errors.
- It has been mostly voluntary, except for local regulations such as the NJ Toxic Catastrophe Prevention Act and the Contra Costa County Industrial Safety Ordinance.



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# Inherently Safer Design

- Industry developed the concept of inherently safer design
- Now EPA is requiring consideration of Inherently Safer Design on a national scale for the first time
- Why?
  - Longstanding concern that process safety incidents continue
  - Public safety – concerns that large-scale impact incident potential exists
  - Perception that inherent safety is the most reliable means of risk reduction and isn't being voluntarily practiced universally
  - Social justice – eliminating/modifying chemical manufacturing in highly populated areas with inequitable risks

# Background on Inherent Safety

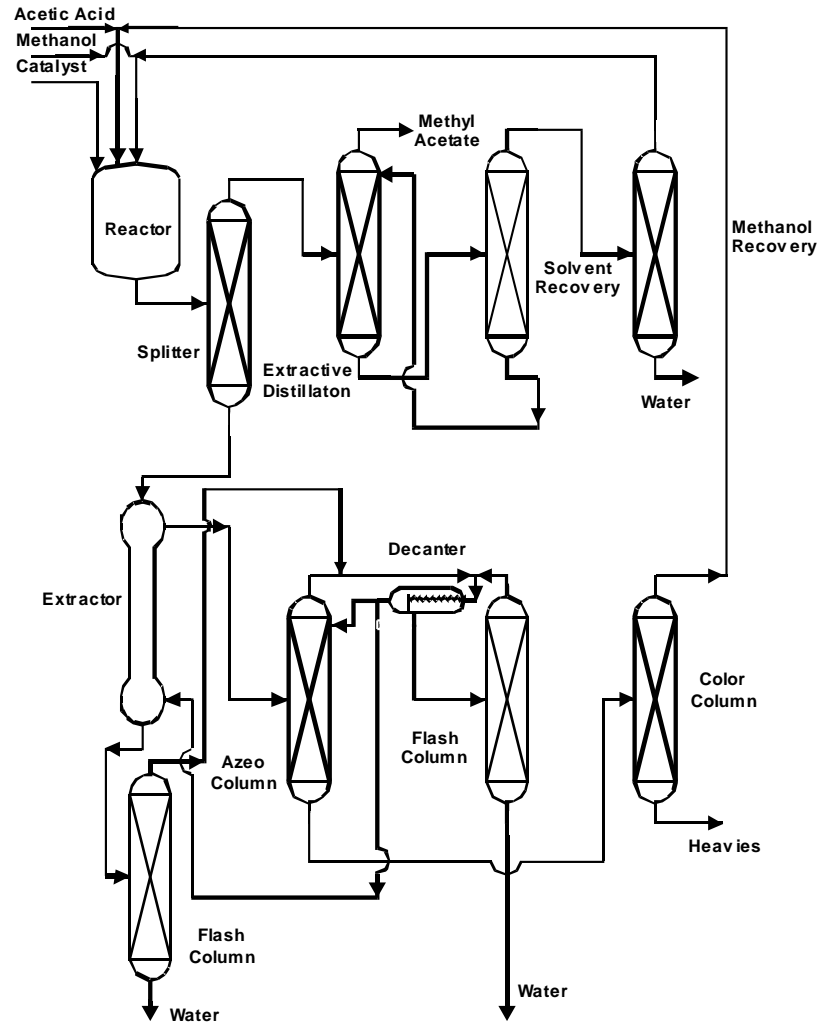
- The history of inherent safety as a documented strategy for loss prevention is rather recent, but the concept is very old.
  - On December 14, 1977, Trevor Kletz (ICI Chemicals, UK) presented “**What You Don’t Have, Can’t Leak,**” the first clear and concise documentation of the concept of inherently safer chemical processes and plants.
  - ICI had been working on inherent safety since the late 1960’s.
  - They wanted to reduce the complexity and scale of their plants to be in better control and have fewer catastrophic releases with lower consequences.



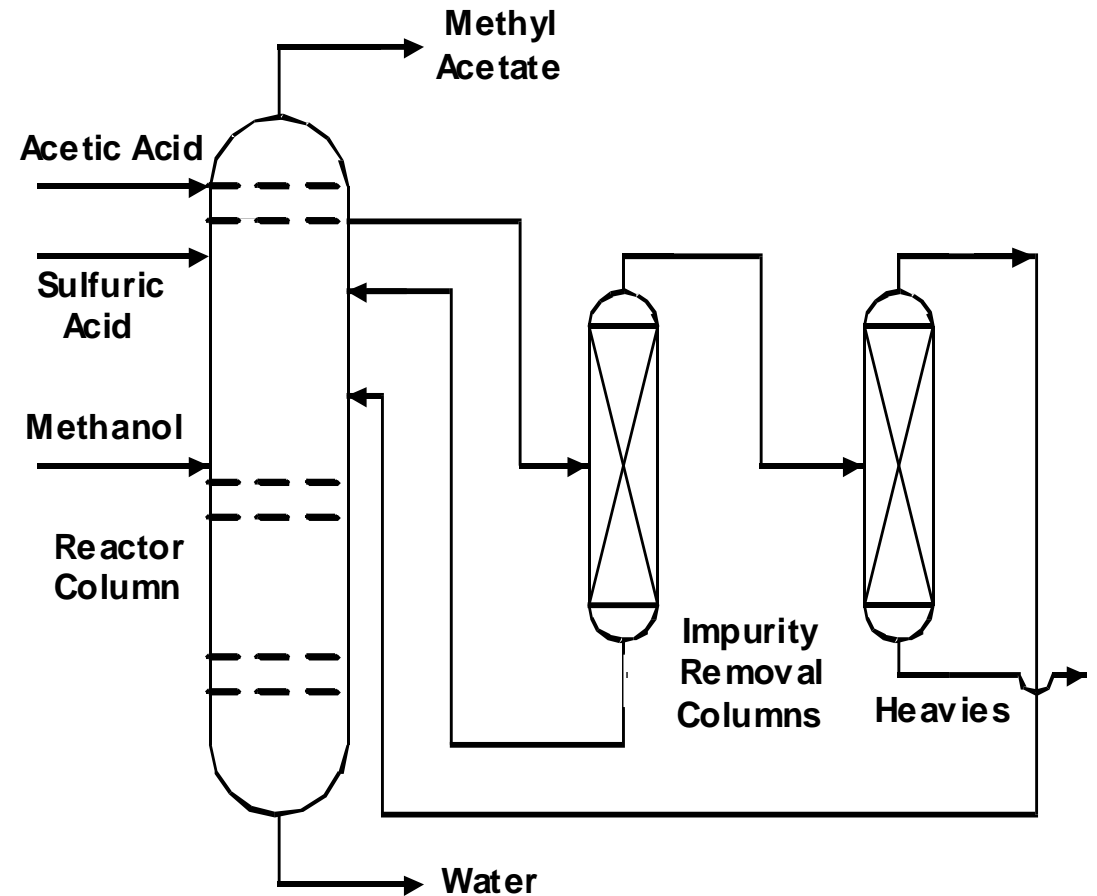
# Terminology for Inherent Safety

- “Inherently Safer Technology (IST),” or “Inherently Safer Design (ISD)”
  - **Inherently Safer Technology (IST):** The hazards of the technology of the process is modified, eliminated, or substituted
  - **Inherently Safer Design (ISD):** Any aspect of the process (technology, component equipment, operating procedures, administrative controls) is modified, eliminated, or substituted
  - CCPS guidance refers to ISD, and the EPA RMP accepted IST or ISD
    - This is important since the “technology of the process” cannot always be modified to be inherently safer without considerable disruption
    - Design (including operating features) may be more feasible to modify

# Minimization Example: Technology of the Process - Methyl Acetate Production



Conventional Process – 10 Major Vessels



Reactive Distillation Process – 3 Major Vessels

# Chemical Hazard

- An inherent physical or chemical characteristic that has the potential for causing harm to people, the environment, property, operations/business, and/or security.
- Onsite and offsite is within EPA scope of authority
- Examples
  - Chlorine - toxic by inhalation
  - Hydrogen - flammable gas/explosion overpressure
- Which hazards might EPA be most concerned with?
  - List of Regulated Substances under the Risk Management Program
  - Those that were reported in the Offsite Consequence Analysis (WCS/ARS)
  - Those where accident history shows a significant reportable release or trend

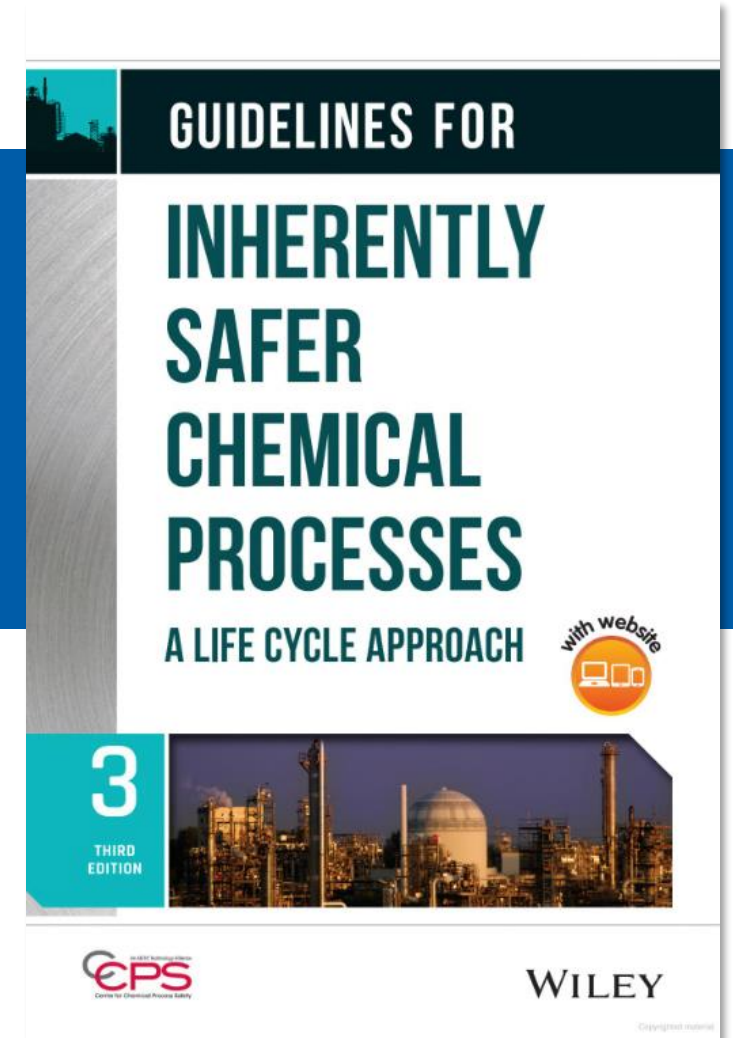
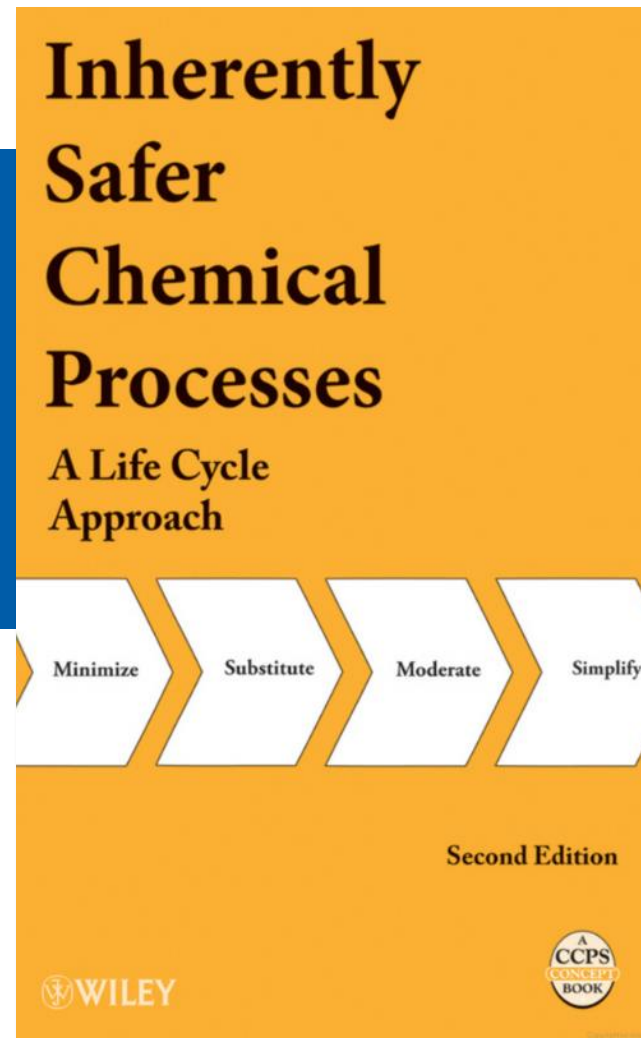
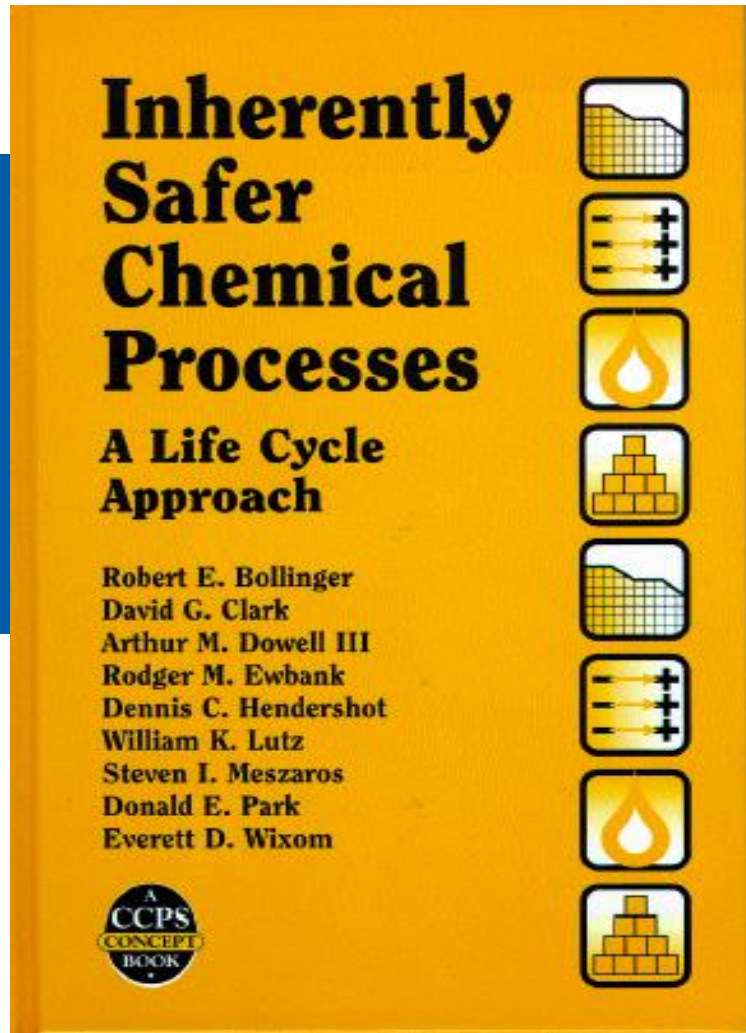


# Definition of Inherently Safer Design

- "Inherently Safer Design (ISD) means Inherently Safer Design Strategies as discussed in the Center for Chemical Process Safety (CCPS, 2019) Publication "Inherently Safer Chemical Processes"\* , which AcuTech prepared for AIChE.
  - "Inherent safety is a concept, an approach to safety that focuses on eliminating or reducing the hazards associated with a set of conditions. A chemical manufacturing process is inherently safer if it reduces or eliminates the hazards associated with materials and operations used in the process and this reduction or elimination is permanent and inseparable."
- **USEPA RMP Definition 68.3: "Inherently safer technology or design means risk management measures that minimize the use of regulated substances, substitute less hazardous substances, moderate the use of regulated substances, or simplify covered processes in order to make accidental releases less likely, or the impacts of such releases less severe."**

\*Center for Chemical Process Safety, "Guidelines for Inherently Safer Chemical Processes: A Life Cycle Approach," 3rd edition, CCPS, AIChE, New York, NY (2019)

# Inherent Safety References



# Definition of Inherently Safer Technologies

- The term inherently safer implies that the process is safer because of its very nature and not because equipment has been added to make it safer.<sup>[1]</sup>

[1] Process Plants: A Handbook for Safer Design, 1998, Trevor Kletz.”

# Inherently Safer Design Strategies

Strategy	Examples
Minimization (Intensification)	Use smaller quantities; eliminate unnecessary equipment; reduce size of equipment or volumes processed.
Substitution	Replace material with a less hazardous substance.
Moderation (Attenuation)	Use less hazardous conditions, a less hazardous form of material or facilities which minimize the impact of a release.
Simplification (Error Tolerance)	Design facilities which eliminate unnecessary complexity and make operating errors less likely.

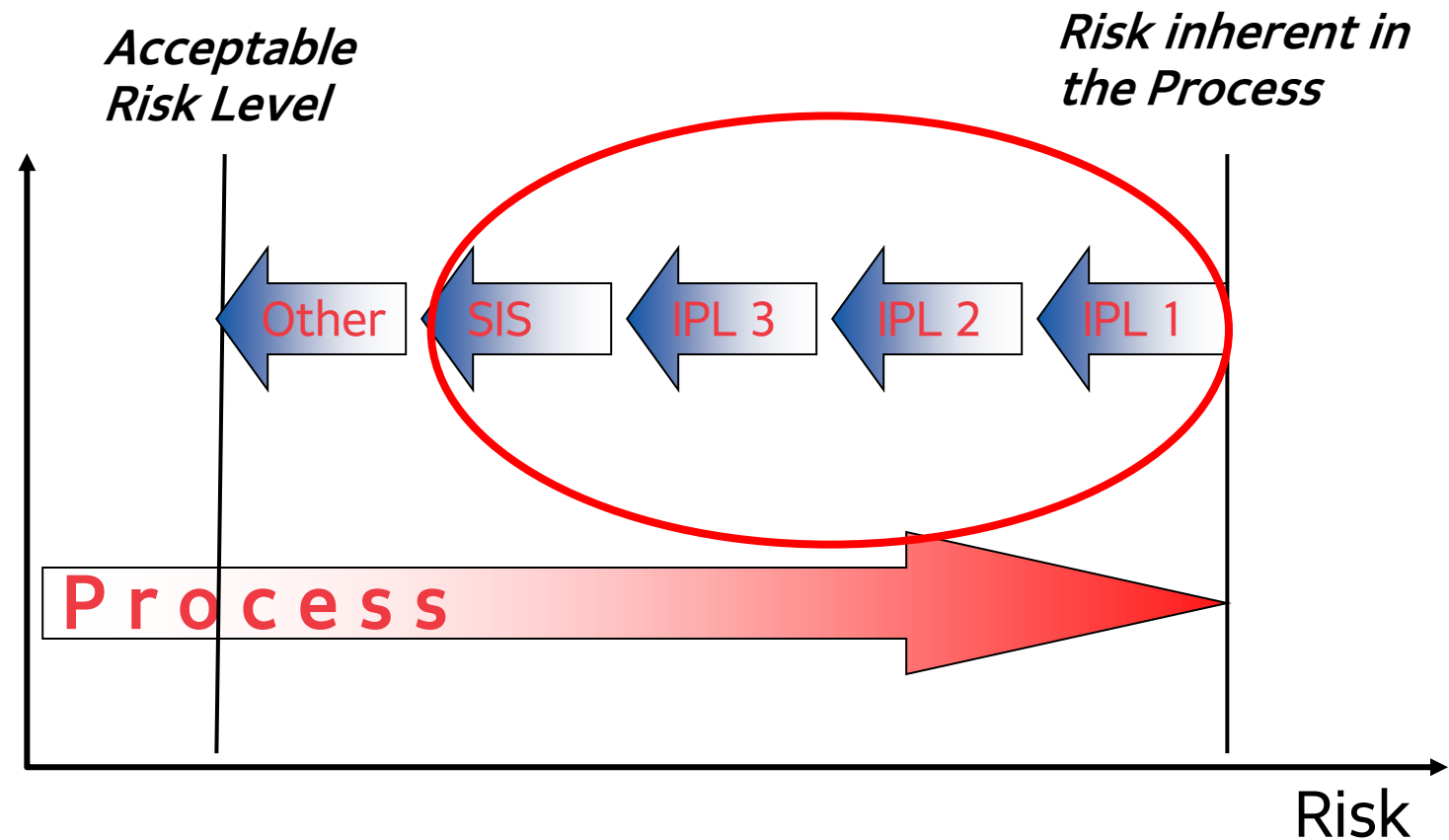
# Process Risk Management Strategies (Hierarchy of Controls)

- **Inherent**
  - Eliminate or modify the hazard and/or risk by employing one of four strategies of minimization, substitution, moderation, simplification
- **Passive**
  - Minimize the hazard by process and equipment design features which reduce either the frequency or consequence of the hazard without the active functioning of any device.
- **Active**
  - Using controls, safety interlocks, and emergency shutdown systems to detect and correct process deviations.
- **Procedural**
  - Using operating procedures, administrative checks, and emergency response to prevent incidents or to minimize the effects of an incident.

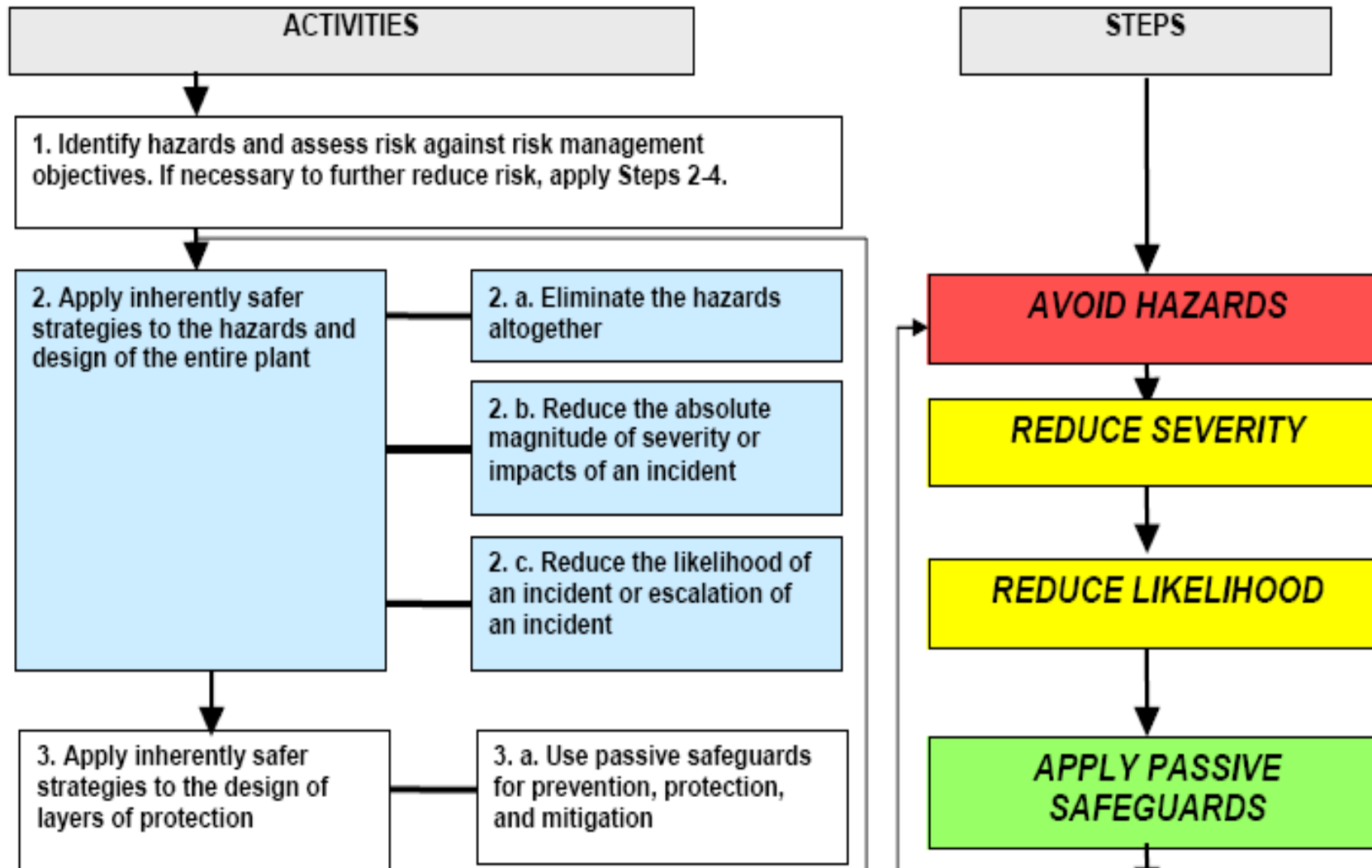
Source: CCPS

# Traditional Risk Management

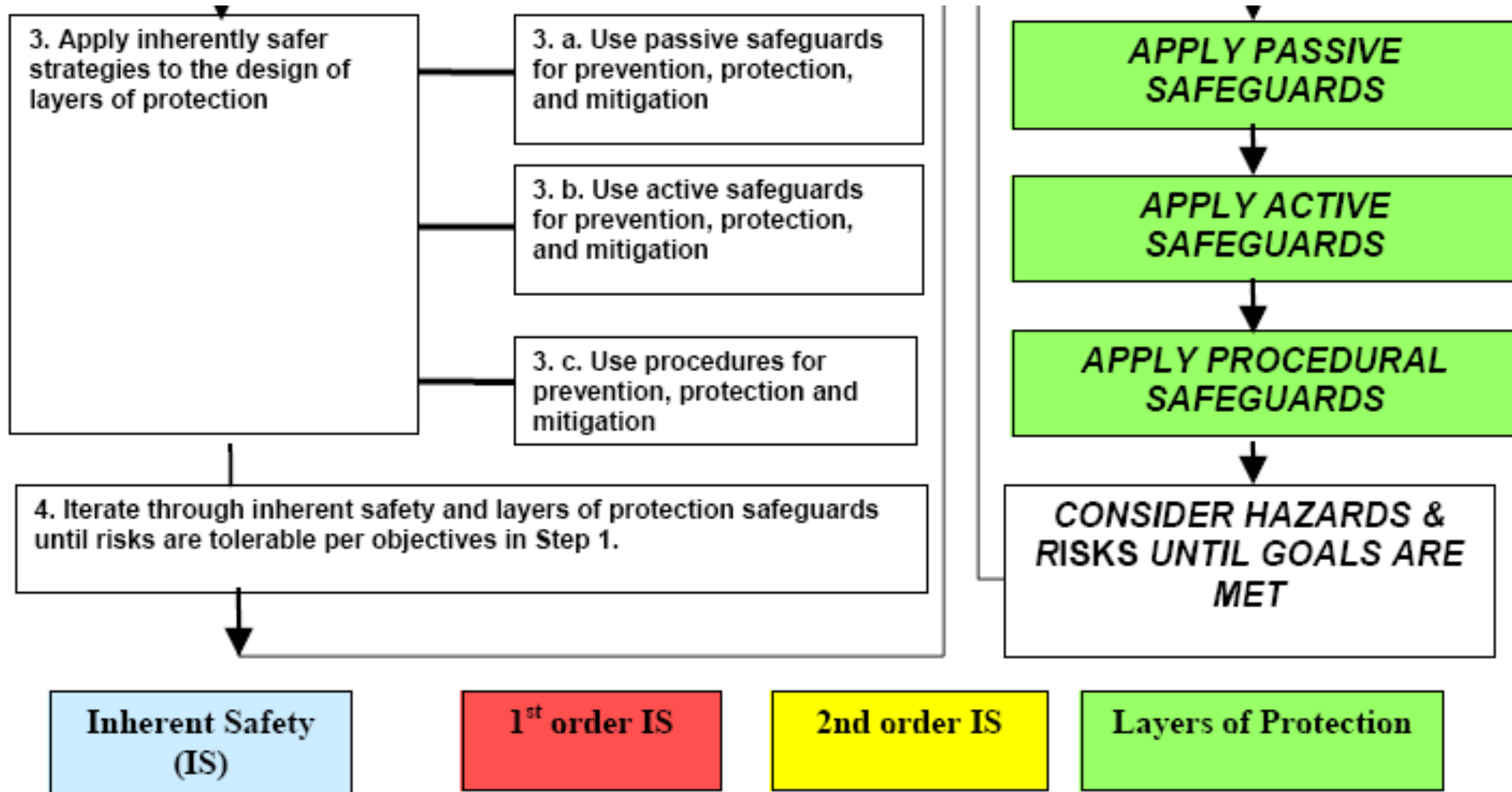
- Typical risk management practices focus on managing the inherent risk of the process to achieve an acceptable risk level using layers of protection
- Applying ISD allows options to lower the inherent risk, and reduce/eliminate need for additional levels of risk mitigation



# Practical Application of Inherent Safety



# Practical Application of Inherent Safety





# EPA RMP PHA: STAA - Requirements

- STAA = Inherently Safer Technologies/Inherently Safer Design Assessment
- Criteria for performing an STAA:
  - **NAICS codes 324** (petroleum and coal products manufacturing), and **325** (chemical manufacturing) with Program 3 processes that are located **within 1 mile of another** RMP-regulated facility with these same processes (classified in NAICS 324 and 325).
  - Refineries (NAICS 324) with **hydrofluoric acid (HF) alkylation units** (currently approx 45 refineries) consider safer alternatives to liquid HF acid alkylation, regardless of proximity to another NAICS 324- or 325-regulated facility.
  - Facilities in NAICS codes 324 and 325 that have had **one accident that meets the RMP accident history reporting requirements** since the most recent PHA.

# PHA: STAA - Requirements

- STAA analysis required as part of the PHA.
- STAA team must include (with documentation) one member who works in the process and has expertise in the process being evaluated.
- However, the typical PHA team may not be qualified to answer all the ISD considerations such as alternative technologies or practicability.

# Applications of ISD - Process Hazards Analysis

- Inherently Safer reviews can be conducted as:
  - Independent ISD studies
  - Incorporated into HAZOP studies or revalidations
  - If the PHAs are done thoroughly, following the PHA is another approach to then base the hazards to be reduced on the findings of hazard scenarios from the HAZOP/LOPA or other methodology used for the base PHA.
- Methodology:
  - An Inherent Safety Checklist can be used to supplement the analysis.
  - A strategy-based ISD study can be used as a methodology for analysis of options

# PHA – STAA

- The additional safety measures are to be implemented in the following hierarchical manner:
  - inherently safer technology or design, then
  - passive measures, then
  - active measures, and procedural measures.
- Must implement at least one passive measure, or an IST/ISD measure, or a combination of active and procedural measures equivalent to or greater than the risk reduction of a passive measure.
- Note: This is the first regulation requiring implementation of a safeguard (by class) for process safety

# PHA – STAA – Analysis/Insights

- EPA is not requiring owners or operators to implement identified IST/ISD measures, but this is the first time that any federal, state, or local process safety regulator has required any sort risk reduction measure be implemented because of a hazard evaluation.
- Shall document sufficient evidence to demonstrate that implementing the passive and active measures is not practicable and the reasons.
- What are the implications of that?
  - Incident investigations
  - Public information sharing
  - Legal proceedings liability

# PHA – STAA – Practicability Assessment

- STAA must include a more comprehensive practicability assessment, including documenting the practicability of publicly available safer alternatives.
- Practicability” is the “capability of IST/ISD measures being successfully accomplished within a reasonable time, accounting for technological, environmental, legal, social, and economic factors”.
- A claim of impracticability shall not be based solely on evidence of reduced profits or increased costs.
- Shall document any methods used to determine practicability.

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# Example of an Inherent Safety Checklist

No.	Inherently Safer Design Alternatives	Applicable (Y/N)?	Opportunities/ Applications	Feasibility	Recommendation	Action Plan
1.0	SUBSTITUTE					
1.1	Is this (hazardous) process/product necessary?					
1.1	Is it possible to completely eliminate hazardous raw materials, process intermediates, or by-products by using an alternative process or chemistry?					
1.2	Is it possible to completely eliminate in-process solvents and flammable heat transfer media by changing chemistry or processing conditions?					
1.3	Is an alternate process available for this product which eliminates or substantially reduces the need for hazardous raw materials or production of hazardous intermediates?					

# Typical Industry Inherent Safety Study of an Inherent Safety Checklist

**Figure 1**  
**Inherent Safety Analysis – Checklist Process Hazard Analysis (PHA)**

Location: Orange, New Jersey						Risk Ranking			Unit: Hydrofluoric Acid Alkylation unit	Analysis Date: April 1, 2008
PFD No.: 1234-5678										
Node:: Isobutane Storage										
Design Conditions/Parameters: Storage of isobutene in five bullets and two process vessels near the unit										
	QUESTION	POTENTIAL OPPORTUNITIES	FEASIBILITY	CONSEQUENCES	EXISTING SAFEGUARDS	S	L	R	RECOMMENDATIONS	COMMENTS/STATUS
1	Reduce hazardous raw materials inventory	Lower storage tank volume or eliminate some storage if possible.	Lowering tank volumes is already done. There may be one tank that could be eliminated.	Potential release from storage and exposure to south plant from unconfined vapor cloud explosion.	1. Administrative controls limit fill level of the five tanks.	4	1	3	1. Eliminate one of five flammable storage bullets to reduce potential releases from storage. <sup>1</sup>	In review.
2	Reducing in-process storage and inventory	Interim storage adds to inventory and could be eliminated.	Will require engineering analysis to evaluate.	Potential leak, fire and explosion.	1. High level alarms 2. Flammable gas detectors	4	1	3	2. Consider eliminating interim storage and providing a continuous flow operation <sup>2</sup>	In review
3	Reducing finished product inventory	Not applicable (NA) <sup>3</sup>								
4	Reduce hazardous material by using alternate equipment		No alternatives available or feasible <sup>4</sup>							



Node Name: 1. Flammable Liquid Storage Tank T-100

Design Intent:

Drawing:

Scenario	Unmitigated Risk			Safeguards	Mitigate Risk Safety/ Health			ISD Strategies	Question/Opportunity	ISD Consideration	Practicality Analysis
	S	L	RR		S	L	RR				
1. Potential for overfill of T-100 due to human error in operation. Potential impact to the public from offsite consequence release.	4	D	4D	1. 10PT-100 high level alarm on tank which stops the feed pump (A)	4	B	4 B	1. Minimize	1. Can hazardous raw materials inventory be reduced?	1. Consider reducing the inventory in the tank 2. Review if a smaller tank can be used.	Document the "capability of the IST/ISD measures being successfully accomplished within a reasonable time, accounting for technological, environmental, legal, social, and economic factors". If not implemented, then hierarchy of controls or other ISD/IST)
				2. The normal maximum operating level of T-100 is 95% of the tank level capacity. (AD)							
				3. The tank has a dike with 100% volume capacity (P)							
				4. The tank has a fixed firefighting foam system (A)							
1. Potential for overfill of T-100 due to human error in operation. Potential impact to the public from offsite consequence release.	4	D	4D	1. 10PT-100 high level alarm on tank which stops the feed pump (A)	4	B	4 B	2. Substitute	1. Is there a substitute chemical for the system	3. Consider changing to a different solvent that has a lower flash point	No other solvent will suffice....(then hierarchy of controls or other ISD/IST)
				2. The normal maximum operating level of T-100 is 95% of the tank level capacity. (AD)							
				3. The tank has a dike with 100% volume capacity (P)							
				4. The tank has a fixed firefighting foam system (A)							
1. Potential for overfill of T-100 due to human error in operation. Potential impact to the public from offsite consequence release.	4	D	4D	1. 10PT-100 high level alarm on tank which stops the feed pump (A)	4	B	4 B	2. Is it possible to completely eliminate hazardous raw materials, process intermediates, or by-products by using an alternative process or chemistry?	4. No ISD/IST consideration is identified	If so, then hierarchy of controls or other ISD/IST for other benefits	
				2. The normal maximum operating level of T-100							

# What Accidents Must Be Reported?

- “Facilities in NAICS codes 324 and 325 that have had **one accident that meets the RMP accident history reporting requirements** since the most recent PHA.”
- **The five-year accident history covers only certain releases:**
  - The release must be from a covered process and involve a regulated substance held above its threshold quantity in the process.
  - The release must have caused at least one of the following:
    - On-site deaths, injuries, or significant property damage (§68.42(a)); or
    - Known offsite deaths, injuries, property damage, environmental damage, evacuations, or sheltering in place (§68.42(a)).
- What if below threshold quantity?
  - The release does not need to be reported even if the release caused one of the listed impacts or if the process is covered for some other substance.
  - A site may choose to report the release in the five-year accident history but is not required to do so.

# Inherently Safer Viewpoints

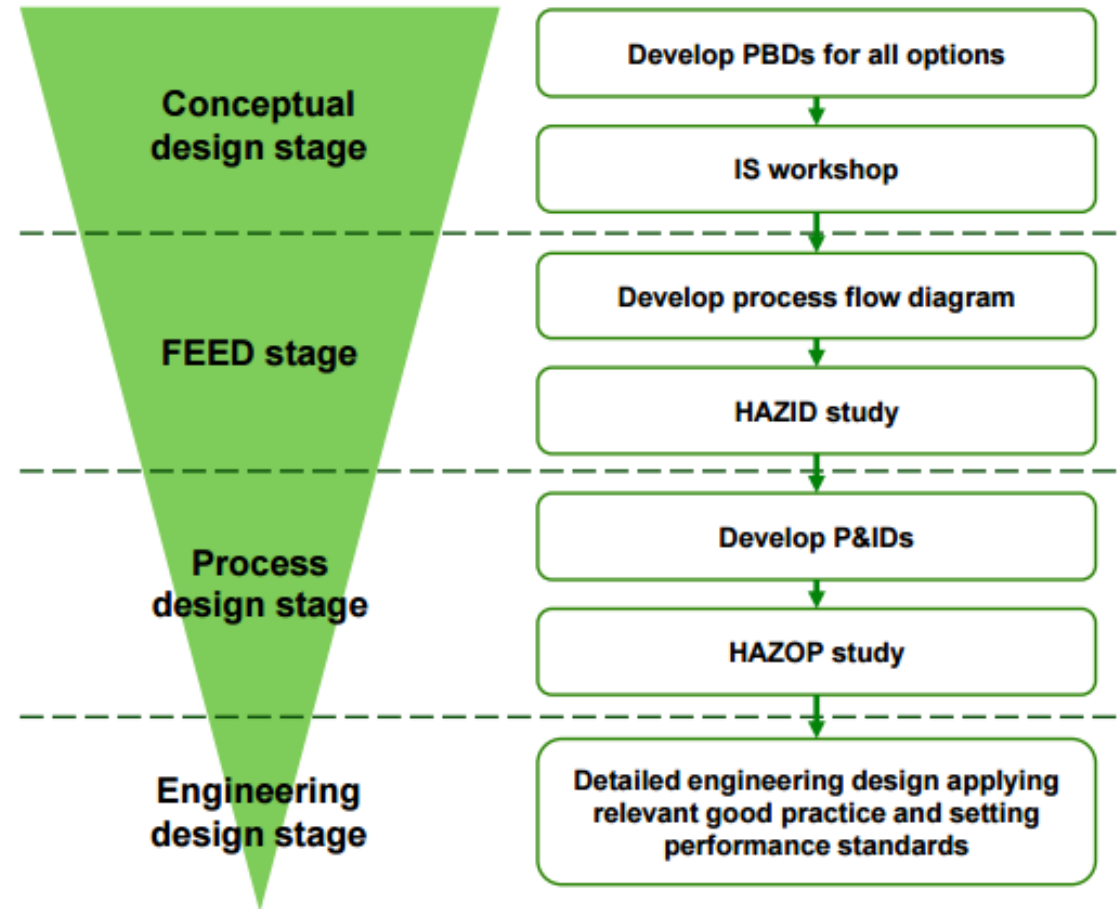
Viewpoint	Examples
<p data-bbox="417 486 924 682"><b>Macro</b> (community-based &amp; strategic)</p>	<ul data-bbox="1161 451 2364 719" style="list-style-type: none"><li data-bbox="1161 451 2249 568">• Use alternative technology that has a lower operating pressure</li><li data-bbox="1161 589 2364 639">• Substitute feed stocks with less toxic substance</li><li data-bbox="1161 661 2097 719">• Substitute entire process technology</li></ul>
<p data-bbox="387 965 952 1096"><b>Micro</b> (plant-based &amp; tactical)</p>	<ul data-bbox="1161 865 2351 1196" style="list-style-type: none"><li data-bbox="1161 865 2351 982">• Reduce the size of a particular vessel or line in a process</li><li data-bbox="1161 1003 1944 1053">• Use a catalyst that is less toxic</li><li data-bbox="1161 1075 2333 1196">• Simplify DCS controls and/or control/operating procedures</li></ul>

# Inherently Safer Design (ISD) - First Order vs Second Order

- Use ISD “order” to set priorities for evaluation.
- **First Order** is a change that results in the highest degree of risk reduction possible by employing an ISD strategy
  - For example, elimination of a material from site with no need for substitution. The hazard is completely eliminated.
- **Second Order** is risk reduction that is less than First Order and varies in risk reduction.
  - Substitute a less hazardous material that reduces hazard and risk levels. Minimizes inventory but does not eliminate the hazard entirely.
- Bottom line – Any level of ISD may be a valuable idea.

# Implementation of Inherent Safety

- While conception of Inherent Safety for the chemical process industries has been around for nearly 40 years, it is still rarely employed to its full potential.
- Misconceptions
  - Only for new facilities
  - Once missed in the process design only traditional means of risk management can be applied – layers of protection
  - Lifecycle possibilities
- Inherent Safety Regulations – new or existing processes



# ISD Regulatory Issues\*

- **Very challenging** - Inherent safety is a challenge for all parties to understand and consider – the owner, design engineer, regulator, and the public.
- **Limitations** - There are limitations of inherent safety and technical and business constraints to its usage.
- **Inherent in codes, standards and typical practice** - ISD is not new but regulation of ISD is new. Most of industry is already practicing it but not formally documenting how they use inherent safety as a strategy for risk management.
- **Judgmental and Subjective** - Requires judgment and is potentially subjective. It is precisely because ISD can be vague and involves considerable judgment that it is very difficult to define and implement to any degree of uniformity and objectivity.
- **How ‘safe is safe enough’** - a decision of the analyst conducting the study. There are no clear and objective guidelines on how to make these decisions as it is considered both a concept to apply as one sees fit and as opportunities arise.
- **Risk conflicts** - there is an entire section of the CCPS guidelines explaining the numerous conflicts and risk:risk tradeoff problems of ISD.

\*Testimony of David A. Moore before the Senate Environment and Public Works Committee on Inherently Safer Technology in the Context of Chemical Process Security, June 21, 2006

# ISD Pitfalls

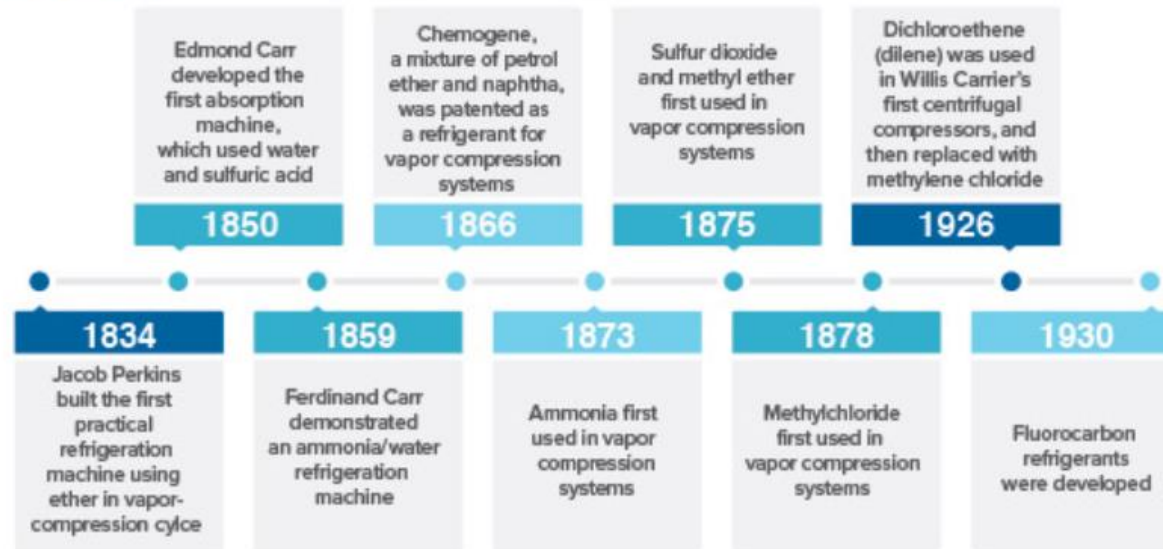
*“When we try to pick out anything  
by itself, we find it hitched to  
everything else in the universe.”*

- John Muir, 1911  
in *My First Summer in the Sierra*

# ISD Pitfalls

- Creating a completely new and unforeseen risk
  - e.g., replacing toxic or flammable refrigerants with chlorofluorocarbons (CFCs)
  - Later it recognized they cause harm to the environment when released (depletion of ozone layer and global warming as greenhouse gases).

FIGURE 1. Timeline of Refrigerant History.





# ISD Pitfalls – Squeezing a Balloon Theory

- Transferring the risk to other industrial sectors or to other parts of the value chain for the same sector
  - e.g., minimization of onsite inventory that requires many more shipments – transfers risk to the transportation sector
  - Nothing is “risk-free”



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- Join us on:  
**Monday, June 3, 2024**  
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