New Final RMP Rule

Safer Technology and Alternatives Analysis

Webinar · May 1, 2024

Farley & Partners LLP
Workplace Safety and Incident Response

AcuTech
Process Risk Management

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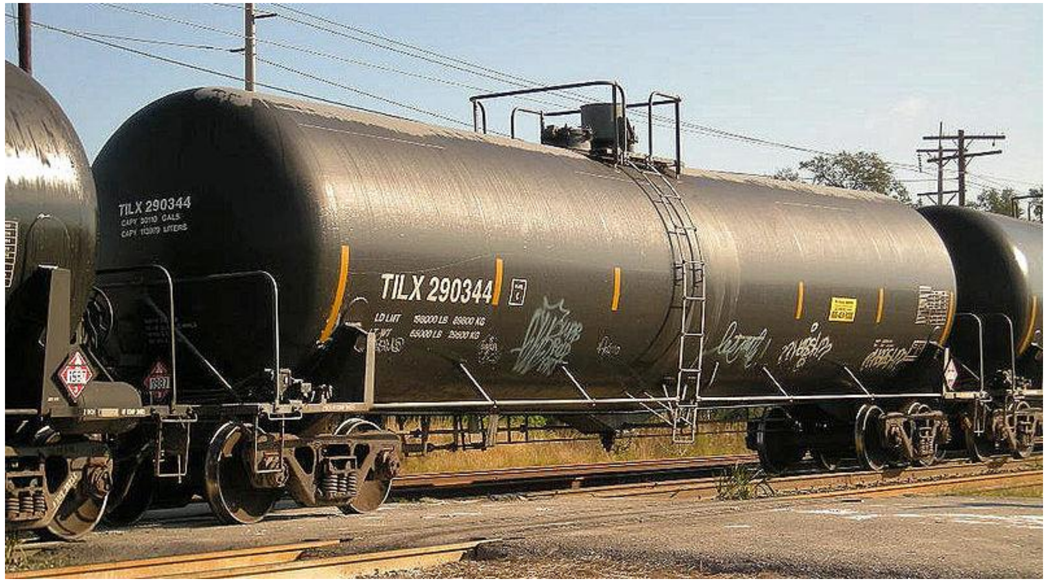
Agenda

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

Fundamentals of Inherently Safer Design

- Inherently Safer Design presents a holistic approach to making the development, manufacture, and use of chemicals safer.

- It focuses on first reducing or eliminating hazards rather than adding more safeguard barriers.



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- 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.

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.
- 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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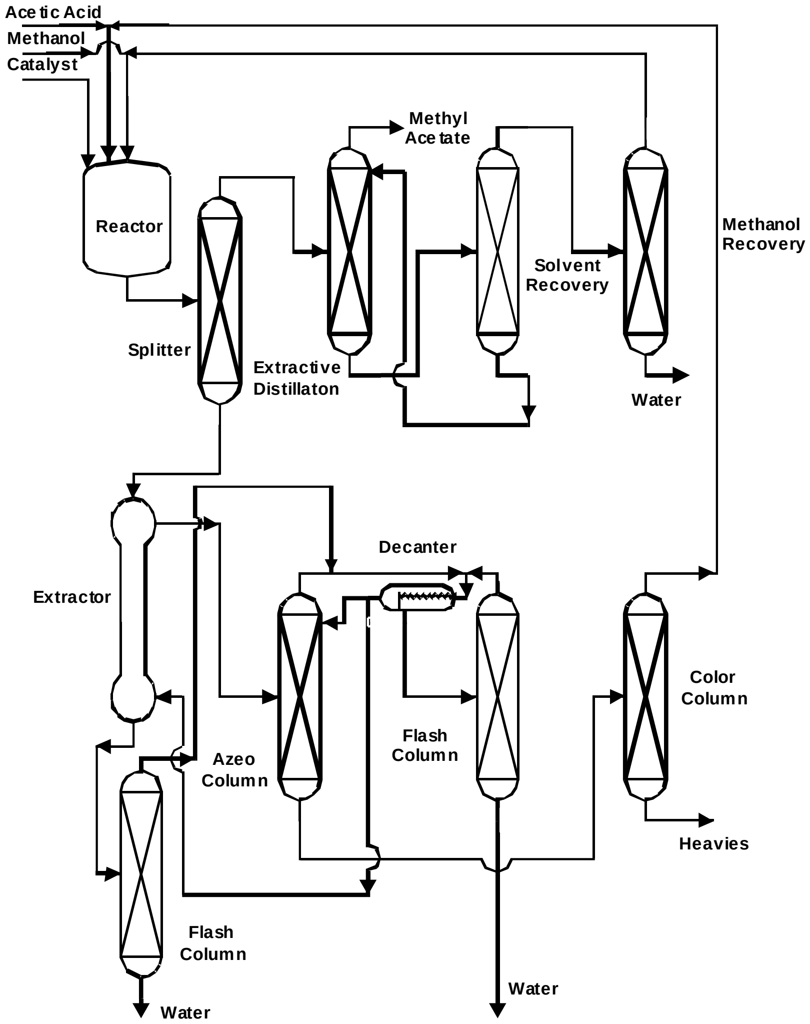
Terminology for Inherent Safety

- "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

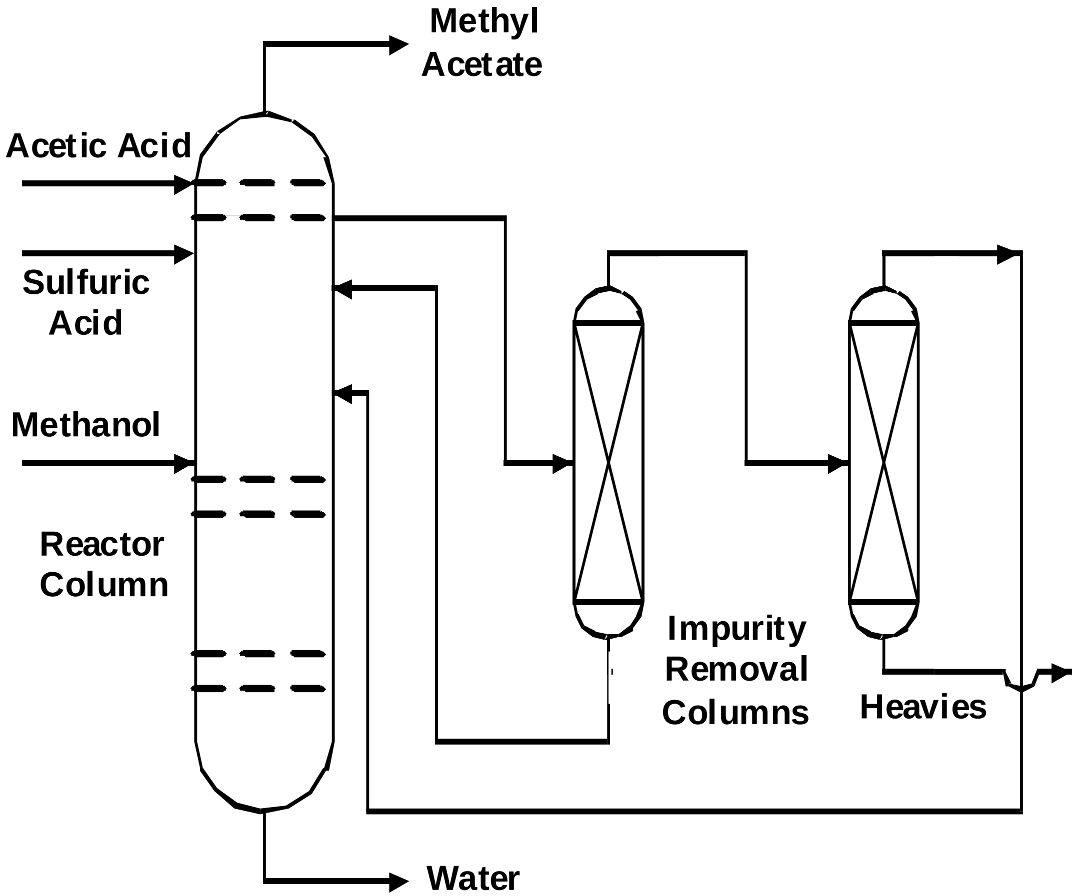
Background on Inherent Safety

- 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 of elimination is permanent and inseparable (CCPS).
- Any move in an inherently safer direction may be beneficial, so not only wholesale changes in technology or chemicals should be considered.
  - Incremental ISD/IST changes have been acceptable to industry.
  - By referencing ISD, it appears EPA is also amenable to incremental ISD

Minimization Example: Technology of the Process - Methyl Acetate Production



Conventional Process – 10 Major Vessels



Reactive Distillation Process – 3 Major Vessels

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Chemical Hazard

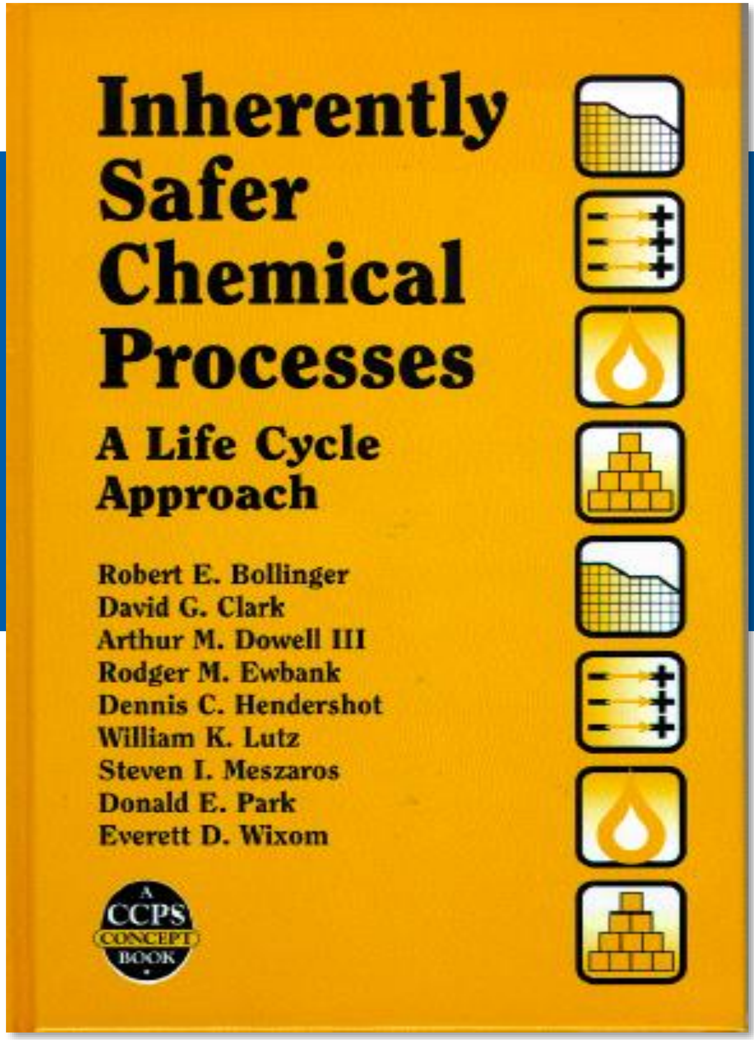
- An inherent physical or chemical characteristic that has the potential for causing harm to people, the environment, property, operations/business, and/or security.
- Hazards are intrinsic to a material, or its conditions of use.
- Examples
  - Chlorine - toxic by inhalation
  - Hydrogen – flammable gas
  - High pressure steam - potential energy due to pressure, high temperature
- 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

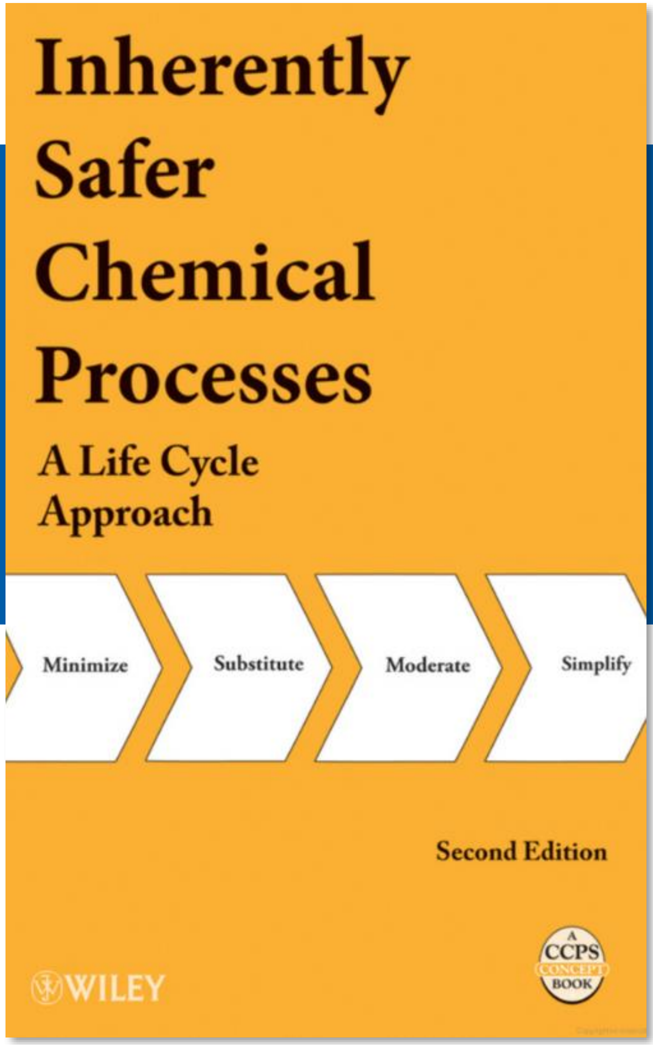
Definition of Inherently Safer Design

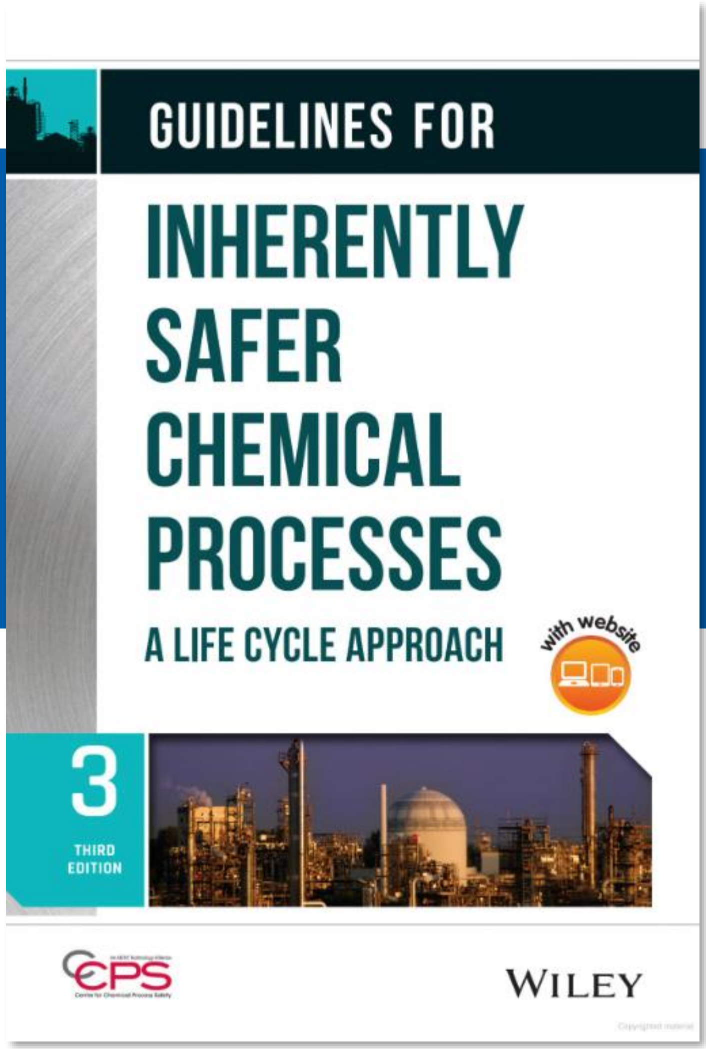
- "Inherently Safer Design (ISD) means Inherently Safer Design Strategies as discussed in the Center for Chemical Process Safety (CCPS, 2019) Publication “Inherently Safer Chemical Processes”*, which AcuTech prepared for AIChE. “Inherent safety is a concept, an approach to safety that focuses on eliminating 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







CCPS Definition of Inherently Safer Design*

- "Inherently Safer Technology (IST), also known as Inherently Safer Design (ISD), permanently eliminates or reduces hazards to avoid or reduce the consequences of incidents."
  - "IST is a philosophy, applied to the design and operation life cycle.… IST considers options, including eliminating a hazard, reducing a hazard, substituting less hazardous material, using less hazardous process conditions, and design a process to reduce the potential for, or consequences of, human error, equipment failure.…
  - IST's are relative. A technology can only be described as inherently safer when compared to a different technology, including a description of the hazard or set of hazards being considered, their location, and the potentially affected population.…
  - IST's are based on an informed decision process. Because an option may be inherently safer with regard to some hazards and inherently less safe with regard to others, decisions about the optimum strategy for managing risks from all hazards are required. The decision process must consider the entire life cycle, the full spectrum of hazards and risks, and the potential for transfer of risk from one impacted population to another."

*CCPS, 2010, prepared for the US Department of Homeland Security

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.[1]

[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.

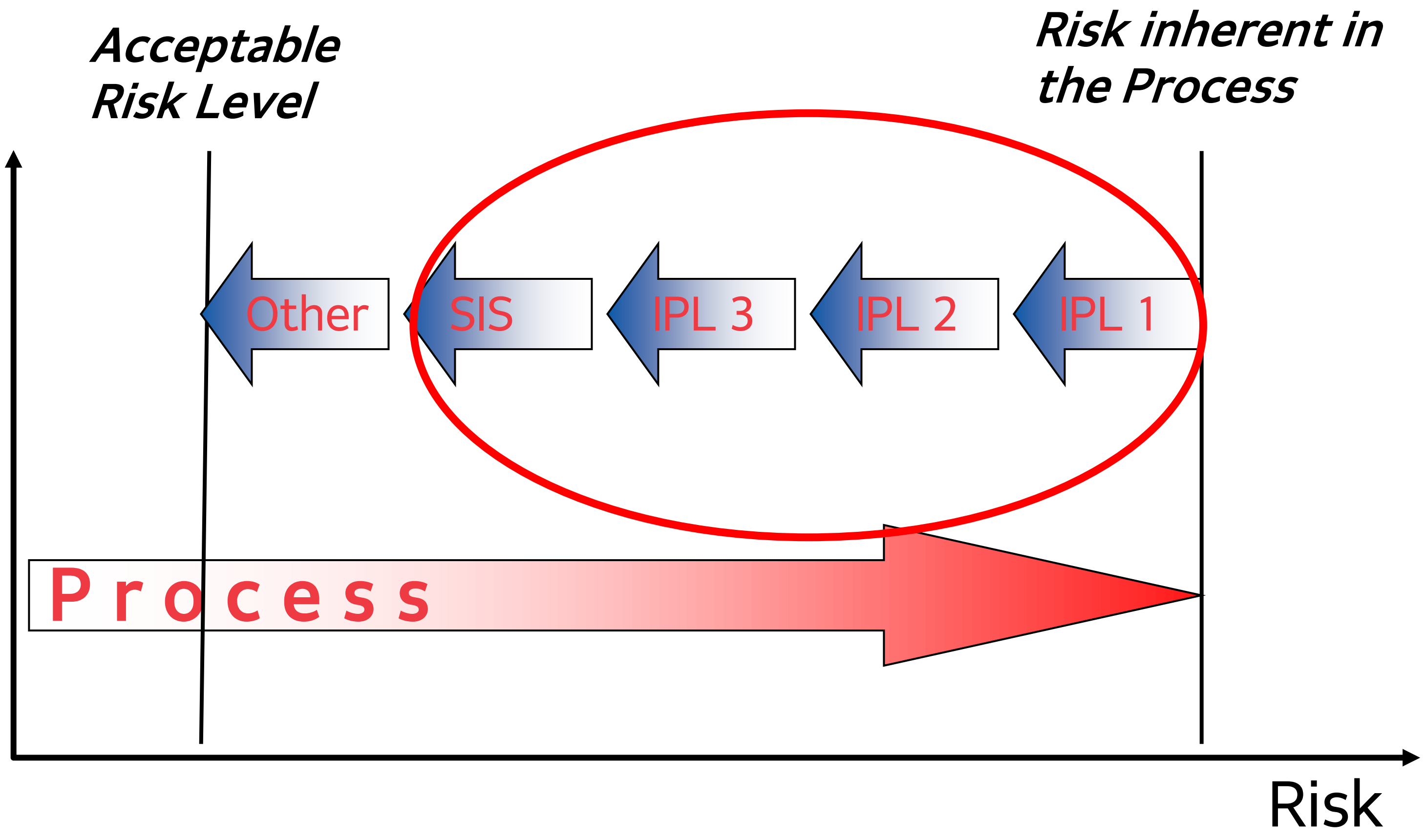
Process Risk Management Strategies (Hierarchy of Controls)

- **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.

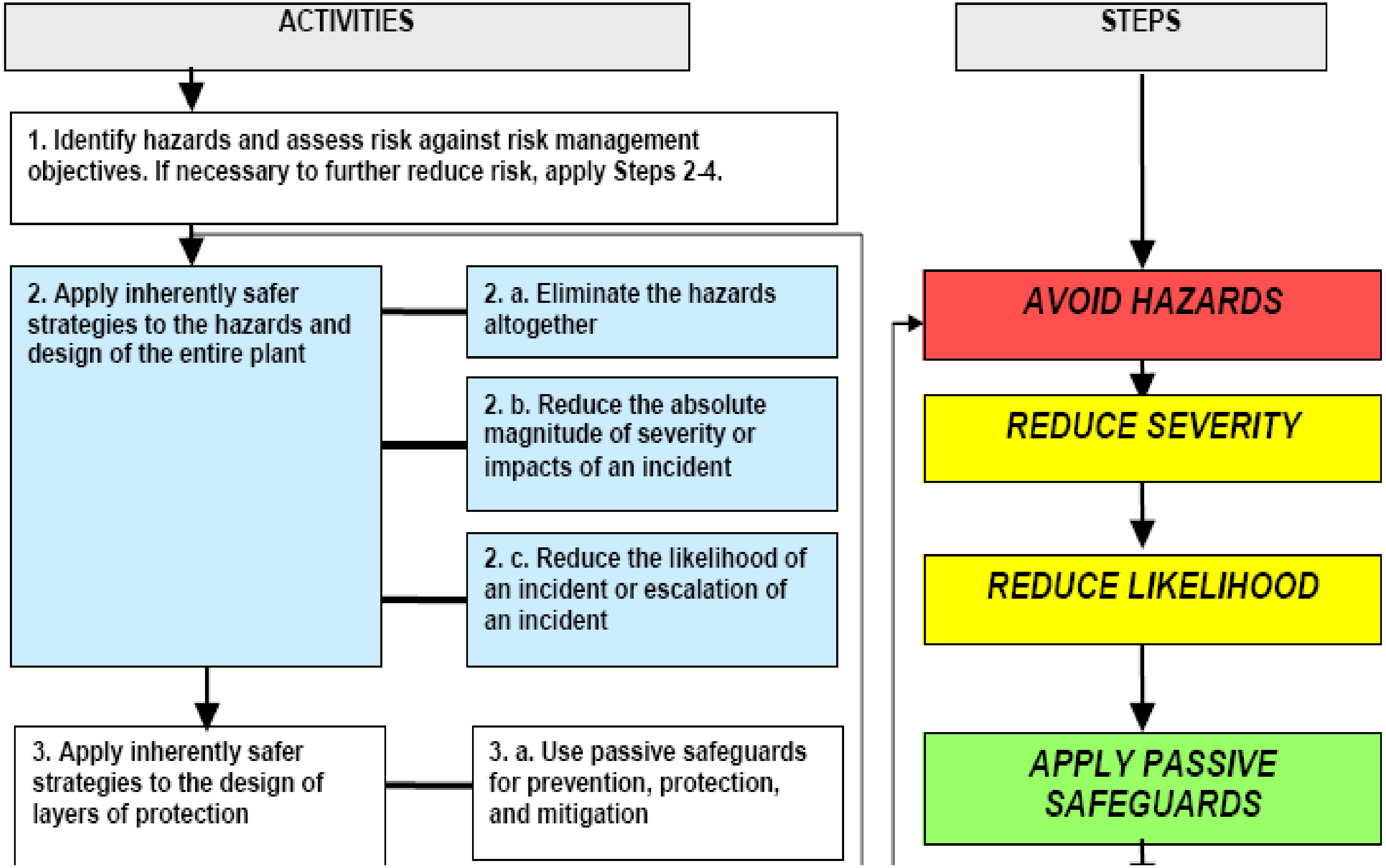
Source: CCPS

Traditional Risk Management

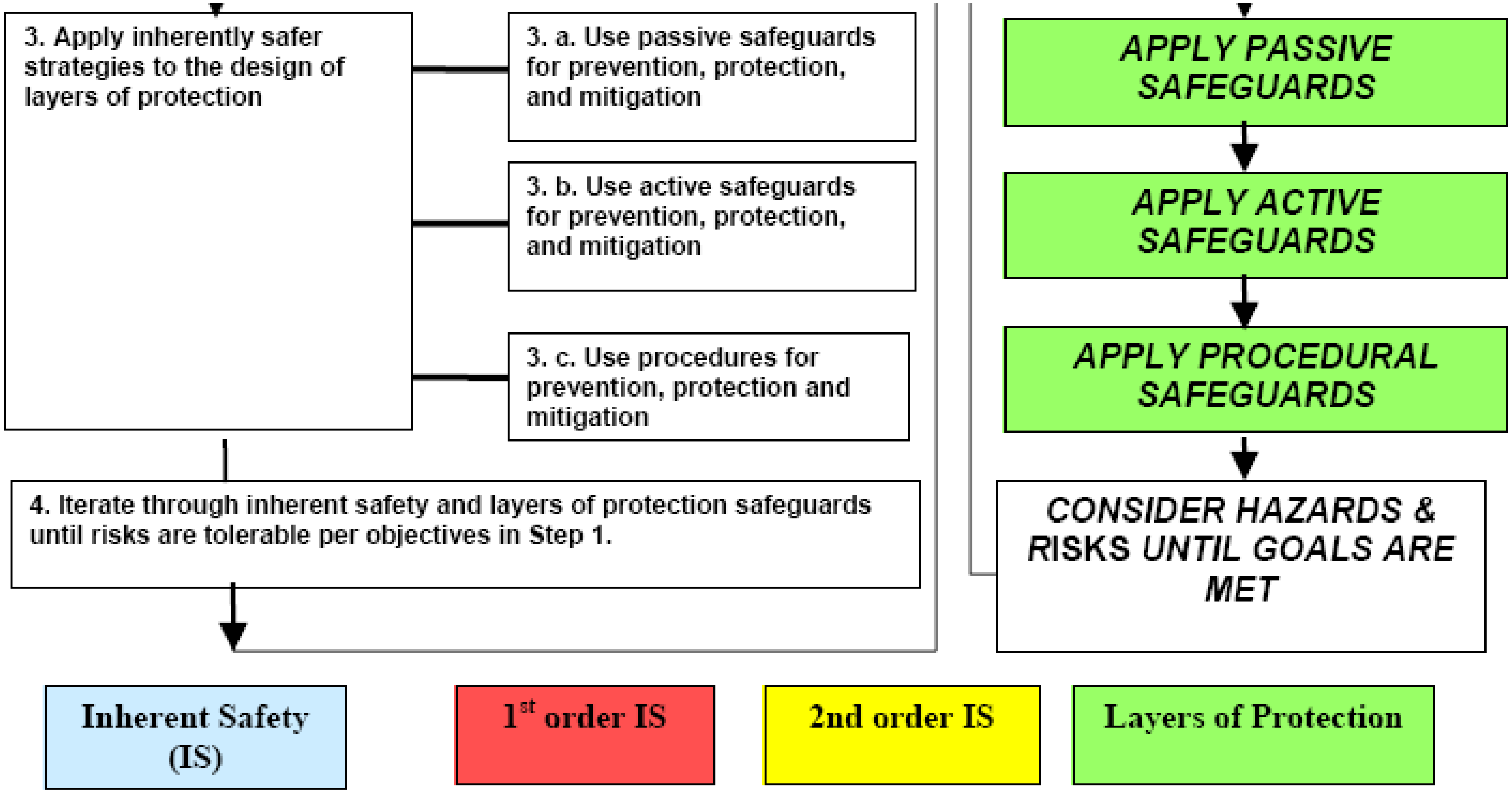
- Typical risk management practices focus on managing the inherent risk of the process to achieve an acceptable risk level using layers of protection
- Applying ISD allows options to lower the inherent risk, and reduce/ eliminate need for additional levels of risk mitigation



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.

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.

PHA – STAA – Analysis/Insights

- Shall document sufficient evidence to demonstrate that implementing the passive and active measures is not practicable and the reasons.
- 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.

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
PFD No.: 1234-5678
Node:: Isobutane Storage
Design Conditions/Parameters: Storage of isobutene in five bullets and two process vessels near the unit

Risk Ranking

Unit: Hydrofluoric Acid Alkylation unit

Analysis Date: April 1, 2008

	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.[1]	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[2]	In review
3	Reducing finished product inventory	Not applicable (NA)[3]								
4	Reduce hazardous material by using alternate equipment		No alternatives available or feasible[4]							

PHA-Pro 8 - [AcuTech - STAA Webinar Example 5-1-2024 *]

File Edit View Insert Format Tools Data Window Help

Administration | Nodes | Deviations | PHA-LOPA Worksheets | **IST Review** | Settings | Data Check

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

Scenario	Unmitigated Risk S	Unmitigated Risk L	Unmitigated Risk RR	Safeguards	Mitigate Risk Safety/ Health S	Mitigate Risk Safety/ Health L	Mitigate Risk Safety/ Health RR	ISD Strategies	Question/Opportunity	ISD Consideration	Practicality Analysis
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) 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)	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)
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) 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)	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)
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) 2. The normal maximum operating level of T-100	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

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PHA: STAA - EPA's Perception of Benefits of STAA

- The Agency assumes owners and operators will likely explore specific benefits to their facility when making decisions and expects the evaluation to consider several factors, such as:
  - Operating and Maintenance (O&M) costs reduction
  - Productivity improvements
  - Capital/facility reduced losses reduction

PHA: STAA – Preparation, Methodology, and Documentation Efforts (and Regulatory Compliance and Legal Risks)

- Learning to conduct and justify decisions for Safer Technology Alternatives Analysis (STAA)) if applicable.
- Will require training, development of a methodology, and efforts to review PHA studies for additional ISD/IST safeguards.
- Typical PHA teams do not have the expertise to evaluate technological, environmental, legal, social, and economic factors.
- Documentation may create liabilities to the owner before or following an incident.
- Additional regulatory burden and risks of noncompliance.

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.

When Are RMP Accidents Reported?

- When an RMP is updated as required by section 68.190 of the rule, it must contain an updated five-year accident history including all the accidents that meet the reporting criteria and that occurred within five years of the date on which the updated RMP is submitted.
- If an accident occurs that meets the reporting criteria, it must be reported in the RMP five-year accident history within six months of the accident, as required by section 68.195 of the rule, unless it is included in an RMP update prior to that time.

RMP Accident Reporting - Issues

- If a facility has recently changed ownership, the new facility owner is required to include accidents which occurred prior to the transfer of ownership in the accident history portion of the RMP submitted for the facility.
- If there is a large on-site incident, but no offsite impact, the site still must report the incident in the five-year accident history if there were onsite deaths, injuries, or significant property damage.
- If there was a release where several people were treated at the hospital and released; and they attributed their symptoms to exposure, but the site doesn't believe that their symptoms were in fact the result of exposure to the released substance, it is still required to report these as offsite impacts.

PHA – STAA – Analysis/Insights

- Shall document sufficient evidence to demonstrate that implementing the passive and active measures is not practicable and the reasons.
- *What is not clear: Are these in addition to existing passive, active, and procedural measures, or can existing measures be credited for this requirement?*
- 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.
- *Define "practicability" as the capability of IST/ISD measures being successfully accomplished within a reasonable time, accounting for technological, environmental, legal, social, and economic factors, with cost being last.*

Inherently Safer Viewpoints

Viewpoint	Examples
Macro (community-based & strategic)	• Use alternative technology that has a lower operating pressure • Substitute feed stocks with less toxic substance • Substitute entire process technology
Micro (plant-based & tactical)	• Reduce the size of a particular vessel or line in a process • Use a catalyst that is less toxic • Simplify DCS controls and/or control/operating procedures

Inherently Safer Design (ISD) – First Order vs Second Order

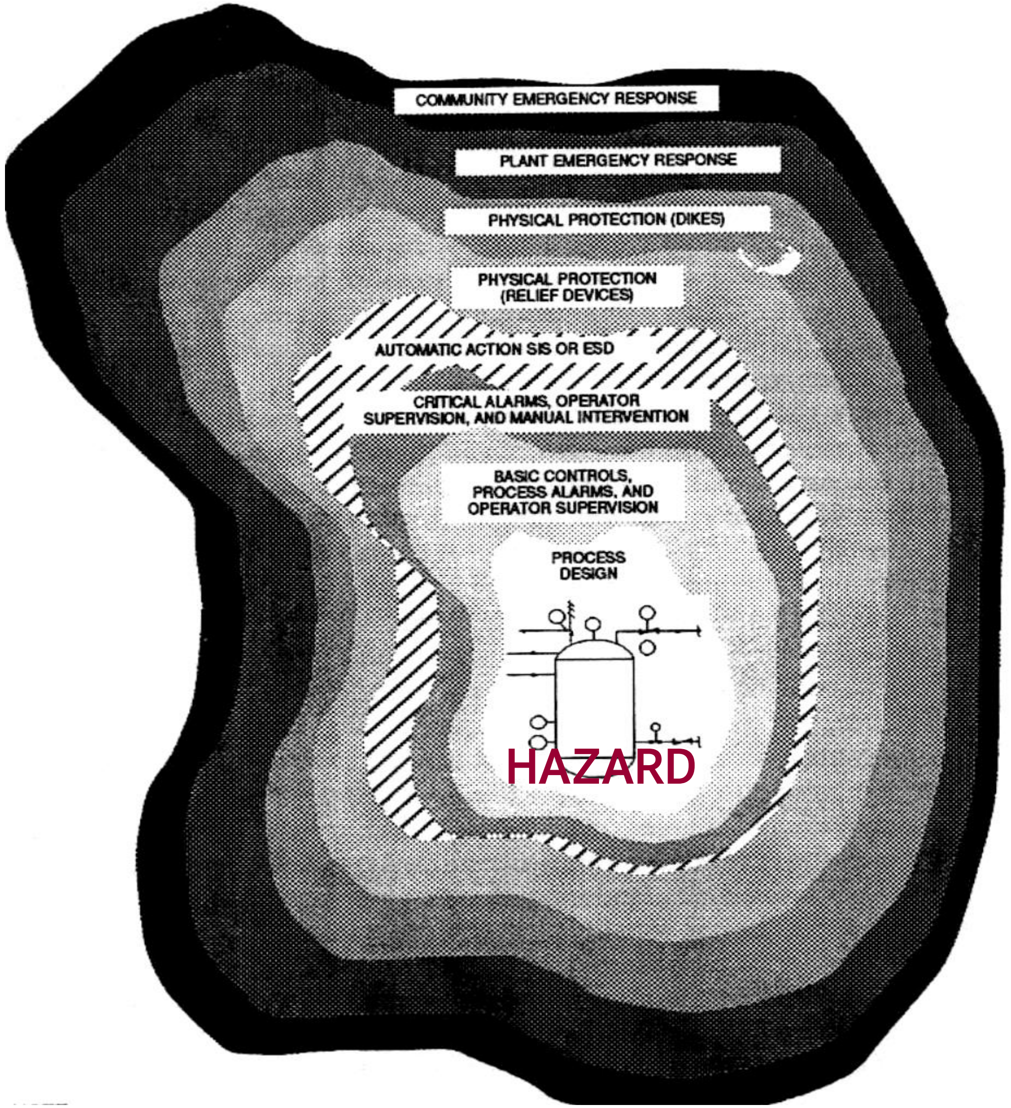
- Use ISD "order" to set priorities for evaluation.

- **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.

Layers of Protection Strategy



Conflict –
LOPA standpoint, no further safeguards required, acceptable risk

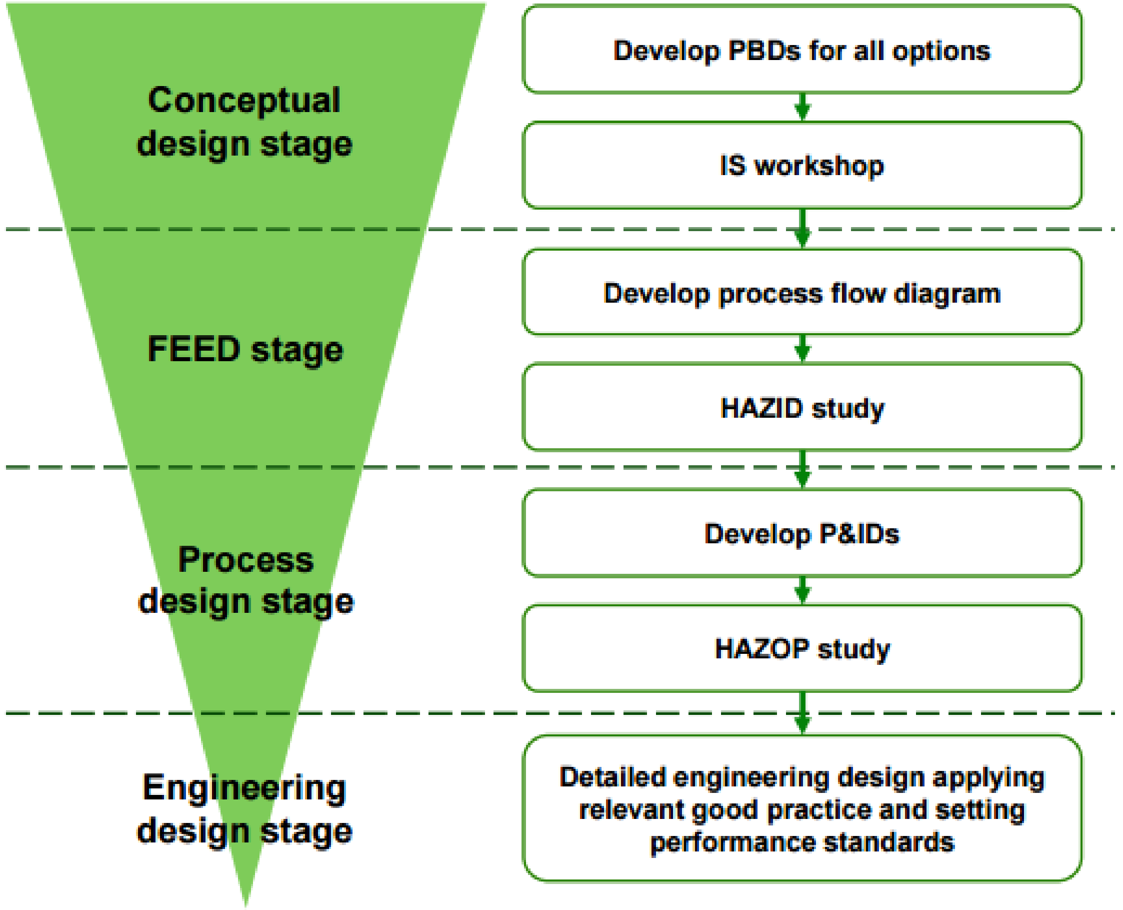
ISD Concept –
Continue to try to reduce the hazard, regardless

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 it's 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 Study Documentation

- A report of the review should be prepared to document the study that includes, at minimum, the following information:
  - A summary of the approach used for the IS review (i.e., methodology, checklist used, etc.).
  - Names and qualifications of the team facilitator/leader and team makeup, including positions, names, and any relevant experience or training.
  - ISD alternatives considered, as well as those already implemented or included in the design.
  - The method used for the analysis, what inherently safer systems were considered, and the results of each consideration.
  - Document the reasons why items were not considered, for example, if they were not applicable or other reasons.
  - Documentation of rationale for rejecting potential IS opportunities (practicability" as the capability of IST/ISD measures being successfully accomplished within a reasonable time, accounting for technological, environmental, legal, social, and economic factors).
  - Recommendations/action plans for further evaluation or implementation of IS alternatives identified during the study.

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

https://www.epw.senate.gov/public/_cache/files/e/2/e2d92204-e2e3-441a-9519-63184d611d90/01AFD79733D77F24A71FEF9DAFCCB056.062106moore-testimony.pdf

ISD Pitfalls

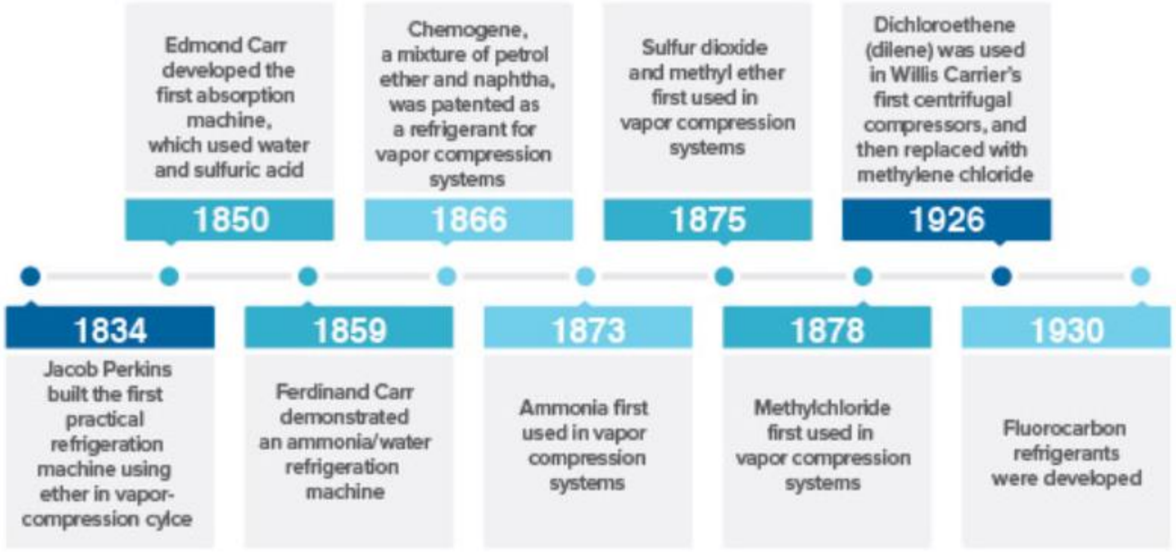
"When we try to pick out anything by itself, we find it hitched to everything else in the universe."

- 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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