Back to Basics: Foundation Setting for Successful Regulatory Compliance

Anaheim, CA
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PHA BASICS

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AGENDA

• Brief History and Regulatory Basis for PSM/RMP
• What is a PHA?
• Overview of Contemporary PHA Techniques
REGULATORY & PHA OVERVIEW
NOTABLE EVENTS
FLIXBOROUGH - 1974

- Cyclohexane vapor cloud generated
  - Cracked reactor vessel
  - Temporary bypass fabricated in plant
  - Bypass failed
  - Significant explosion
NOTABLE EVENTS
TEXAS CITY - 2005

- Hydrocarbon Vapors Released from Raffinate Splitter Tower, and Ignited
  - Start-up Procedure Step Inadvertently Omitted
  - Failure of Safety Alarm Systems
  - Siting Issues
Industry Initiatives drove first Process Safety improvements but were later absorbed into Performance/”Management System”-Based Federal Regulatory Requirements (United States/California)

- **1997** - 19 CCR Division 2, Chapter 4.4 - “California Accidental Release Prevention (CalARP) Program”
PROCESS SAFETY MANAGEMENT (PSM)

• Purpose
  ▪ To recognize, understand, and control deviations from design and operating intent
  ▪ Management systems - No accident repeats itself
  ▪ Non-prescriptive - look for root issue

• Characteristics
  ▪ “Performance-based”, not “rule-based” (represents an evolution in industry control and regulatory strategies)
  ▪ Proactive approach to the management of safety
PROCESS SAFETY MANAGEMENT (RMP/CALARP PROGRAM 3)

- Employee Participation
- Safety Information
- Process Hazard Analysis
- Operating Procedures
- Training
- Contractors
- Pre-Startup Safety Review
- Mechanical Integrity
- Hot Work Permit
- Management of Change
- Incident Investigation
- Emergency Planning & Response
- Compliance Audits
- Trade Secrets
PROCESS SAFETY MANAGEMENT (RMP/CALARP PROGRAM 2)

- Employee Participation
- Process Safety Information
- **Hazard Review**
- Operating Procedures
- Training
- Maintenance
- Compliance
PHA OBJECTIVES

• 29 CFR 1910.119(e) & 40 CFR 68.67 (P3) – The PHA shall be appropriate to the complexity of the process and shall:
  ▪ Identify hazards
  ▪ Evaluate hazards
  ▪ Control hazards

• Note: CalARP/RMP Program 2 Hazard Review requirements are less stringent. This workshop will focus on PHA.
PHA OBJECTIVES

• The PHA shall address:
  ▪ Hazards of the process
  ▪ Previous incidents
  ▪ Engineering and administrative controls
  ▪ Consequences of failure of controls
  ▪ Facility siting
  ▪ Human Factors
  ▪ Qualitative evaluation of potential safety and health effects on employees
  ▪ For CalARP, external events
Each of these tools provides a different perspective & different insights.

- Checklist
- What-If/Checklist
- API RP 14C Review
- FMECA
- HAZOP
- LOPA
- ETA
- FTA

Less Effort vs. Increased Effort, with Increased Insights
A key objective of the PHA is to uncover vulnerabilities by evaluating:

- Causes
- Consequences
- Safeguards
OTHER PHA REGULATORY REQUIREMENTS

- Team composition
- System to promptly address Team findings & recommendations
- Five-year updates/revalidations
- Retention of PHAs and updates/revalidations for the life of the process
CONTEMPORARY PHA TECHNIQUES
HAZOP STUDY CHARACTERISTICS

• Creative & Systematic Deductive Method
• Identifies/Examines Both Causes & Consequences (i.e., scenario) of a Hazard or Operability Concern
• General Objective - Identify Facility Design or Operations Recommendations
• Team Approach Makes Effective Use of Multiple Talents & Experience
  ▪ Can be Expensive if Misused
  ▪ HAZOP Can Provide One of Best PHA Values
HAZOP STUDY CHARACTERISTICS

- Comprehensive & Thorough
- Flexible Technique
  - Applicable to Many Phases of Facility Life Cycle
  - Used for Hazard Identification and Qualitative Engineering Reliability Evaluation
  - Screening Prior to More Intensive Analysis
- Self-Contained, Documented, Formalized Study
- A quality HAZOP Study can provide many intrinsic benefits to reliability & operability.
WHAT-IF/CHECKLIST
CHARACTERISTICS

• Similar to HAZOP Study:
  ▪ Examines Both Causes & Consequences
  ▪ Identifies Design or Operations Vulnerabilities
  ▪ Applied at the Equipment or Procedural Level
  ▪ Team Approach
  ▪ Self-Contained, Documented, Formalized Study
WHAT IS CHECKLIST REVIEW?

• Uses of a list of specific questions to identify known types of hazards or design deficiencies, which may result in potential accident or incident scenarios
FAILURE MODES, EFFECTS, AND CRITICALITY ANALYSIS (FMECA) CHARACTERISTICS

• FMECA is a component-based process hazard analysis methodology that can be conducted at any stage in the life of a system.
  ▪ Component-by-component analysis of a system
  ▪ Focused on the immediate effects of component failure modes
  ▪ Can be conducted individually or by a team of experts

• The objectives of FMECA are to . . . .
  ▪ Identify all possible failure modes of a component.
  ▪ Identify the effects of the failure modes.
  ▪ Recommend modifications.
FMECA CHARACTERISTICS

• A FMECA has the following key elements:
  ▪ Component
  ▪ Failure modes
  ▪ Causes of each failure mode
  ▪ Effects of each failure mode
  ▪ Limiting safeguards
  ▪ Recommendations

• These are typically documented in tabular form
# FMECA Example

## Potential Failure Mode and Effects Analysis

**FMEA Type:** Front Door L.H.

**Model Year(s)/Vehicle(s):** 20XX/Lion 4dr/Wagon

**Key Date:** 3/10/2015

**Key Team:** A. Tice Body Engr, J. Smith - QC, R. James - Production, J. Jones - Maintenance

### Name / Function

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>SVI</th>
<th>Classification</th>
<th>Potential Cause(s) of Failure</th>
<th>OCC</th>
<th>Current Process Controls (Prevention)</th>
<th>Current Process Controls (Detection)</th>
<th>DEFI</th>
<th>RPN</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Planned Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Op. 70 Manual</td>
<td>Insufficient wax</td>
<td>7</td>
<td>8</td>
<td>Allows integrity</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td>Add positive depth stop to sprayer.</td>
<td>7</td>
<td>2</td>
<td>5 70</td>
<td>Mfg Engr - 3/10/2009</td>
<td></td>
</tr>
<tr>
<td></td>
<td>application of wax</td>
<td>coverage over</td>
<td></td>
<td></td>
<td>breach of inner</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td>Mfg Engr - 3/10/2009</td>
<td></td>
<td></td>
<td></td>
<td>Stop added, sprayer checked on line.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>inside door,</td>
<td>specified surface</td>
<td></td>
<td></td>
<td>door panel.</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td>Automate spraying. Mfg Engr - 3/10/2003</td>
<td></td>
<td></td>
<td></td>
<td>Rejected due to</td>
<td></td>
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<td></td>
<td>lower surfaces with</td>
<td></td>
<td></td>
<td></td>
<td>corroded interior</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>complexity of</td>
<td></td>
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<tr>
<td></td>
<td>wax to specification</td>
<td></td>
<td></td>
<td></td>
<td>lower door panels,</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>different doors on</td>
<td></td>
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<tr>
<td></td>
<td>thickness.</td>
<td></td>
<td></td>
<td></td>
<td>Deteriorated life of</td>
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<td>Visual check each hour - 1/sh for</td>
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<td></td>
<td></td>
<td></td>
<td>same line.</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>door leading to:</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Unsatisfactory</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>appearance due to rust</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>through paint over time</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td></td>
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<td></td>
<td></td>
<td>- Impaired function of</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>interior door hardware</td>
<td>5</td>
<td>Visual check each hour - 1/sh for</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Source:** [WEIBULL.com](http://WEIBULL.com)
FAULT TREE ANALYSIS
CHARACTERISTICS

• A Fault Tree graphically represents the logical combinations of possible occurrences within a system, which can result in a predefined “Undesired Event.”

• Uses:
  ▪ Calculation of Standby System Unavailability
  ▪ Calculation of Frequency of Accident Initiating Event or Other Undesired Event
FAULT TREE ANALYSIS
CHARACTERISTICS

• **Results** - Provides the Likelihood of the “Undesired Event” and identifies and ranks “Weak Links” of the system.

• **Process**
  - Define Clearly and Precisely the Top Event (e.g., HAZOP, FMECA)
  - Construct the Fault Tree
  - Qualitatively Analyze the Fault Tree
  - Quantitatively Analyze the Fault Tree
FAULT TREE ANALYSIS CHARACTERISTICS

- Use to Determine All Ways a System May Fail
- Deductive Logic
  - Work Backwards from Results to Cause
  - One Step at a Time
- Start with a Top, “Undesired Event”
- Use Two Main Logic Gate Types – causes and protections
LOPA is designed as a screening tool. Evaluates the safety integrity of process operations in a semi-quantitative manner. To support this objective, inherently conservative failure probabilities are deliberately used from industry data. Usually used in conjunction with a HAZOP Study.

- If HAZOP Study “safeguards” are clearly identified, they will have a direct application as a LOPA “independent protection layer” (IPL).
LAYER OF PROTECTION ANALYSIS

CHARACTERISTICS

• IPLs reduce the likelihood of an event occurring.
  ▪ IPLs are given risk reduction factors (RRF) which are numerical values associated with risk reduction.

• Lowering likelihood lowers risk.
  ▪ The goal is to lower risk to an acceptable tolerance.
    – Risk tolerance is usually identified within company/corporate policies
A initiating event has a frequency e.g. BPCS error (transmitter fails once every 10 years based on industry data).

Need to reduce the risk to acceptable levels (by decreasing likelihood).
LAYERS OF PROTECTION ANALYSIS
CHARACTERISTICS

• LOPA can provide a vehicle for assimilating additional details, if needed, e.g.:
  ▪ More accurate failure rates & probabilities
  ▪ Results of detailed human error probability calculations, based on specific task analysis
  ▪ More accurate consequence modeling
TYPICAL APPLICATIONS

- Process Systems/Equipment (HAZOP, What-If/Checklist)
- Oil and Gas Production (HAZOP, LOPA, What-If/Checklist)
- Pipelines (What-If/Checklist, FMECA, HAZOP)
- Standalone Instrumentation, Communication, and Power Systems (FMECA, What-If/Checklist)
- Utility Systems (What-If/Checklist, HAZOP, FMECA)
- Procedures (What-If/Checklist, HAZOP)
- Structures (What-If/Checklist, FMECA)
COMPARISON OF HAZARD IDENTIFICATION & QUALITATIVE RISK ASSESSMENT TECHNIQUES

• HAZOP
  ▪ Deductive Method
  ▪ One of the Most Effective Hazard Identification Techniques
  ▪ Comprehensive Investigation of Potential Hazard & Operability Problems - Provides Greatest Assurance that All Hazards have been Identified
  ▪ Future Efforts can Build on Previous HAZOP Study
  ▪ Complex Scenarios are more Likely to be Uncovered
  ▪ More Usable for Subsequent Fault Tree Analysis & Other Quantitative Techniques
COMPARISON OF HAZARD IDENTIFICATION & QUALITATIVE RISK ASSESSMENT TECHNIQUES

• What-If/Checklist
  ▪ Straightforward & Structured, but Idea-Restrictive
  ▪ Not As Likely to Identify New Potential Hazards
  ▪ Easy to Use - Faster than FMECA and HAZOP, but Provides Less Detail
  ▪ Fewer Resource Requirements
  ▪ Provides the Minimum Level of Information
  ▪ Use May Provide a False Sense of Security
  ▪ Better Applied at Early Stage of a Project or as a Precursor to a Later Analysis
HAZOP STUDY EXAMPLE

Conditions: 2-50% capacity relief valves exist to provide overpressure protection for downstream LP vessel during gas blowby.
# HAZOP Study Deviation Matrix

<table>
<thead>
<tr>
<th>DESIGN/OPERATIONS PARAMETER</th>
<th>GUIDE WORDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No/Low</td>
</tr>
<tr>
<td>Pressure</td>
<td>Lower Pressure</td>
</tr>
<tr>
<td>Level</td>
<td>No/Lower Level</td>
</tr>
<tr>
<td>Other/General</td>
<td>Composition, Maintenance, Start-up/Shutdown, Heat Tracing, Piping Specifications, Phase, Viscosity, Density, Reaction, Corrosion, Erosion/Fatigue, Sampling, Service Loss, Duration, Sequence, Human Factors, Safety/Health, Instrumentation, Agitation, Speed</td>
</tr>
</tbody>
</table>
# RISK RANKING

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>LIKELIHOOD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>A</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>1</td>
</tr>
<tr>
<td>C</td>
<td>2</td>
</tr>
<tr>
<td>D</td>
<td>3</td>
</tr>
</tbody>
</table>
## HAZOP STUDY EXAMPLE

<table>
<thead>
<tr>
<th>Deviation</th>
<th>Cause</th>
<th>Consequences</th>
<th>Safeguards</th>
<th>S</th>
<th>L</th>
<th>R</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| More Flow   | LV-1 malfunctions open, possibly due to a failure of LT/LIC-1, or bypass valve inadvertently open. | Gas blow-by resulting in overpressurization of downstream equipment and resultant release of hydrocarbons and H2S, Potential for severe injury or fatality. | - LAL-1, if LT/LIC-1 is not the cause of the malfunction.  
- 2-50% capacity relief valves on downstream LP vessel | B | 3 | 2 | Consider evaluating the merits of:  
- Installing a separate level transmitter and low alarm  
- Installing a separate emergency isolation valve fed by an independent level transmitter  
- Reconfiguring LV-1 to include a separate SIS closure feature |
AGENDA

• HAZOP Best Practice Example
• Maximizing the Future Usefulness of PHAs
• Quality Tips for PHAs
HAZOP BEST PRACTICE EXAMPLE
HAZOP STUDY EXAMPLE

**Conditions:** 2-50% capacity relief valves exist to provide overpressure protection for downstream LP vessel during gas blowby.
<table>
<thead>
<tr>
<th>Deviation</th>
<th>Cause</th>
<th>Consequences</th>
<th>Safeguards</th>
<th>S</th>
<th>L</th>
<th>R</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>More Flow</td>
<td>LV-1 malfunctions open, possibly due to a failure of LT/LIC-1, or</td>
<td>Gas blow-by resulting in overpressurization of downstream equipment and</td>
<td>- LAL-1, if LT/LIC-1 is not the cause of the malfunction.</td>
<td>B</td>
<td>3</td>
<td>2</td>
<td>Consider evaluating the merits of:</td>
</tr>
<tr>
<td></td>
<td>bypass valve inadvertently open.</td>
<td>resultant release of hydrocarbons and H2S, Potential for severe injury or</td>
<td>- 2-50% capacity relief valves on downstream LP vessel</td>
<td></td>
<td></td>
<td></td>
<td>- Installing a separate level transmitter and low alarm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>fatality.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Installing a separate emergency isolation valve fed by an independent level</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- Reconfiguring LV-1 to include a separate SIS closure feature</td>
</tr>
</tbody>
</table>
HAZOP STUDY EXAMPLE – BEST PRACTICES

• Key to a well documented PHA – details, details, details.
• Consequences:
  ▪ Which downstream equipment?
    – Tag number? Located on which P&ID?
  ▪ Overpressure ratio?
    – What is the maximum pressure of the gas blow-by case?
      • Necessary information to have to determine Severity of the event.

<table>
<thead>
<tr>
<th>Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas blow-by resulting in overpressurization of downstream equipment and resultant release of hydrocarbons and H2S, Potential for severe injury or fatality.</td>
</tr>
</tbody>
</table>
CONSEQUENCES – BEST PRACTICES

• Specific to the Scenario
• Determine Consequences w/o “existing systems/practices” (safeguards) - e.g., no credit for Operator action, controls, or alarms
• “Ultimate”/global consequences can have effects outside of the node – e.g., offsite injuries
HAZOP STUDY EXAMPLE – BEST PRACTICES

- Safeguards:
  - Level Transmitter/Alarm:
    - Located on which P&ID? What is the alarm setpoint? Is there enough time after the alarm and before the consequence to make corrective action?
  - Relief Valves:
    - Implied, but do they have to work together? Which vessel are they on? Located on which P&ID

<table>
<thead>
<tr>
<th>Safeguards</th>
</tr>
</thead>
<tbody>
<tr>
<td>- LAL-1, if LT/LIC-1 is not the cause of the malfunction.</td>
</tr>
<tr>
<td>- 2-50% capacity relief valves on downstream LP vessel</td>
</tr>
</tbody>
</table>
CONTROL/PROTECTION SYSTEM SPECTRUM – BPCS & SIS

Increasing Reliability & Larger SIL (SIS-Only, ANSI/ISA-S84.01)

- Smart Sensors
- Redundancy
- Diversity
- High Pedigree Devices
- Voting Logic
- Electronic Sensing & Sig. Processing
- Separation of Control & Protection
- Single-Element Analog Devices

Decreased Cost

Increased Redundancy, Diversity, Pedigree
PHA STUDY PRIORITY FOR SAFEGUARDS

• “Cause Elimination” Then “Consequence Mitigation”
• Active Safety Features
• Alarms
  ▪ Generally, it is good practice to list alarms in the order they will appear
• Written Procedures:
  ▪ Operations
  ▪ Maintenance/Inspection/Testing
  ▪ Emergency
• Training
• Emergency Response Mitigation Features
• History
HAZOP STUDY EXAMPLE – BEST PRACTICES

- Recommendations should be logical and easily understood on their own.
  - Second Level Transmitter/Alarm:
    - Where would the new transmitter and alarm be located? What is the justification?

<table>
<thead>
<tr>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider evaluating the merits of:</td>
</tr>
<tr>
<td>- Installing a separate level transmitter and low alarm</td>
</tr>
<tr>
<td>- Installing a separate emergency isolation valve fed by an independent level transmitter</td>
</tr>
<tr>
<td>- Reconfiguring LV-1 to include a separate SIS closure feature</td>
</tr>
</tbody>
</table>
PHA RECOMMENDATIONS

• The employer shall establish a system to:
  ▪ Promptly address the team’s findings & recommendations
  ▪ Assure that the recommendations are resolved in a timely manner and that the resolution is documented
  ▪ Document what actions are to be taken
  ▪ Complete actions as soon as possible
  ▪ Develop a written schedule for completion
  ▪ Communicate the actions to operating, maintenance, and others who may be affected by the recommendation
PHA RECOMMENDATION TRACKING

- Many Acceptable Approaches (e.g. spreadsheets, etc.)
- Consistency with Plant Culture is Helpful
- PHA Software Packages – some include Recommendation tracking and closeout logs
MAXIMIZING PHA
FUTURE USEFULNESS
TIPS TO MAXIMIZE THE FUTURE USEFULNESS OF THE PHA

- Scenarios should be understandable.
- Recommendations should be sensible and cost-effective.
- Standardize PHA approach – have set likelihood and severity rankings and describe the levels.
- Apply standardized risk-rankings.
- The Team’s evaluation and basis for conclusions should be readily understood (Leave notes if necessary!!).
- Group information sensibly.
- Qualifications and experience of Facilitator and Team.
TIPS TO MAXIMIZE THE FUTURE USEFULNESS OF THE PHA (CONT.)

• Nodes can be made as large as can be thoroughly examined through the use of the guide word technique.
  ▪ Pre-causing will maximize the effectiveness of PHA time.
  ▪ Prolific use of equipment tag numbers and referencing.

• Strive to be always up-to-date
• Consider long-term use of PHA
• Software
  ▪ Optimize Usage, Storage, and Retrieval
  ▪ Compatibility, Compatibility, Compatibility !!
QUALITY PHA TIPS
QUALITY TIPS

• Resources and Approach
  ▪ Use of a Qualified, Experienced, and Prepared Facilitator
  ▪ Use of Qualified and Experienced Technical Experts who Participate in all Phases of the PHA
  ▪ Ensuring Access to All Necessary Information (e.g., PSI)
  ▪ Use of Appropriate PHA Technique
QUALITY TIPS (CONT.)

• Session Dynamics
  ▪ Team Interaction & Professionalism
  ▪ Understanding of the PHA - Initial synchronization training is typically provided by the Facilitator.
  ▪ Involvement by All Participants, as Appropriate
  ▪ Team Understanding of Process Design & Equipment Configuration
  ▪ Consideration of All Salient Perspectives & Input
  ▪ Importance of Objectivity
QUALITY TIPS (CONT.)

• Session Dynamics (continued)
  ▪ Consideration of Recommendations, as Appropriate, Whether or Not Driven by Risk-Ranking
  ▪ Follow-through of Information Requirements and Action Items – Many Teams retain a running list of actions (e.g., using Flipchart, PC-Based Notepad) that are resolvable during the PHA, sometimes avoiding significant follow-up efforts.
  ▪ Management Endorsement and Commitment of Resources
• Session Dynamics (continued)
  ▪ Facilitator Periodically Reminding the Team of the Basis for Scenario Documentation and Scenario Ranking (e.g., Frequency being the Frequency of the Cause, with credit for safeguards, and Consequence Ranking reflecting the Ultimate Consequences w/o pre-credit for Safeguards) – As appropriate, the Facilitator can show the link between Quantitative Risk Assessment (QRA) and Risk Ranking.
QUALITY TIPS (CONT.)

• Documentation
  ▪ Completeness
    − The entire deviation list should be considered for each node.
    − Development of scenarios should be consistent with their importance.
    − If required by the agreed-upon risk-ranking criteria, Recommendations should be created, or a suitable justification provided.
    − Siting issues should be considered.
    − Security issues should be considered.
QUALITY TIPS (CONT.)

− Human factors, training, maintenance, testing, and inspection, and start-up/shutdown issues should be considered.
− Safeguards must be reliable, e.g., if personnel would not have time to take corrective action, alarms should not be credited.

*Consistency*

− Risk-ranking should be consistently applied and be synchronized with the scenario.
− Documentation level of detail should be consistent, adjusted for scenario importance.
QUALITY TIPS (CONT.)

- **Reporting**
  - Recommendations should be self-standing, logical, and complete.

- **Traceability**
  - Scenarios should be logically developed, complete, and relatively easy to understand.
  - Sensible and consistent grouping of information.
  - If there appear to be inconsistencies, suitable clarifying comments should be documented.
  - The Team’s evaluation and basis for conclusions should be readily understood to support future revalidation efforts.
QUALITY TIPS (CONT.)

- A description of how applicable regulatory requirements are met should be provided in the cover report.
- The scope and boundaries of the study should be clear.
- Risk-ranking guidelines and criteria for requiring recommendations should be clearly identified.
- Team composition and experience should be documented, clearly depicting that regulatory requirements were met.
- The Team’s evaluation and basis for conclusions should be readily understood.
- Recommendations should be sensible & cost-effective.
- Equipment tag numbers should be used prolifically.
QUESTIONS?

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