Process Hazard Analysis and Automation

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Process Safety

- Main objective is to prevent unwanted release of hazardous chemicals through a proactive approach of identification, evaluation and mitigation of hazards.
- An effective process safety management program requires a systematic approach to evaluating the whole process:

Process Hazard Analysis

- PHAs are one of the most important elements of the Process Safety Management Program
- PHAs are
  - An **organized and systematic effort to identify and analyze** potential hazards associated with chemical processing and handling
  - A tool to assist in making decisions for **improving safety and reducing the consequences** of unplanned releases of hazardous chemicals
  - Directed toward **analyzing potential causes and consequences** of fires, explosions, releases of toxic/flammable chemicals
  - Focused on **equipment, instrumentation, utilities, human actions** and external factors that may impact the chemical process

These considerations assist in determining the hazards and potential failure points of failure modes in a process

PHA Methodology

- Selection of a PHA tool will be influenced by many factors, such as knowledge of the process (e.g. new vs experienced), size and complexity of the process
- Examples: What-if checklist, Hazard and Operability Study (HAZOP), Failure Mode and Effect Analysis (FMEA), Fault Tree Analysis
- Need an appreciation of the advantages and disadvantages of each method

Supporting Tools for PHAs

- Process flow Diagrams that show main flow streams that help PHA teams understand the process (Pressures, Temperatures, MOC, Pump Capacities, Alarm Sequencing, etc)
- P&IDs that describe the relationship between equipment and instrumentation
- Teams – comprehensive team with operational and technical skills
  - Team members: expertise in PHA methodology, process technology, process design, instrumentation, maintenance, alarms, emergency procedures, safety and health

Regulatory Requirements for PHAs

- 20CFR 1910.119
- Scope:
  - A process which involves a chemical at or above the specified threshold quantities listed in Appendix A to this section;
  - A process which involves a flammable liquid or gas on site in one location, in a quantity of 10,000 pounds or more except for hydrocarbon fuels used solely for workplace consumption as a fuel (e.g., propane used for comfort heating, gasoline for vehicle refueling)

Regulatory Requirements for PHAs

- Written Plan
- PHA evaluates initial start-up, normal operation and temporary operation
- Must use recognized PHA methodology
- Training
- Emergency Shutdown Procedure

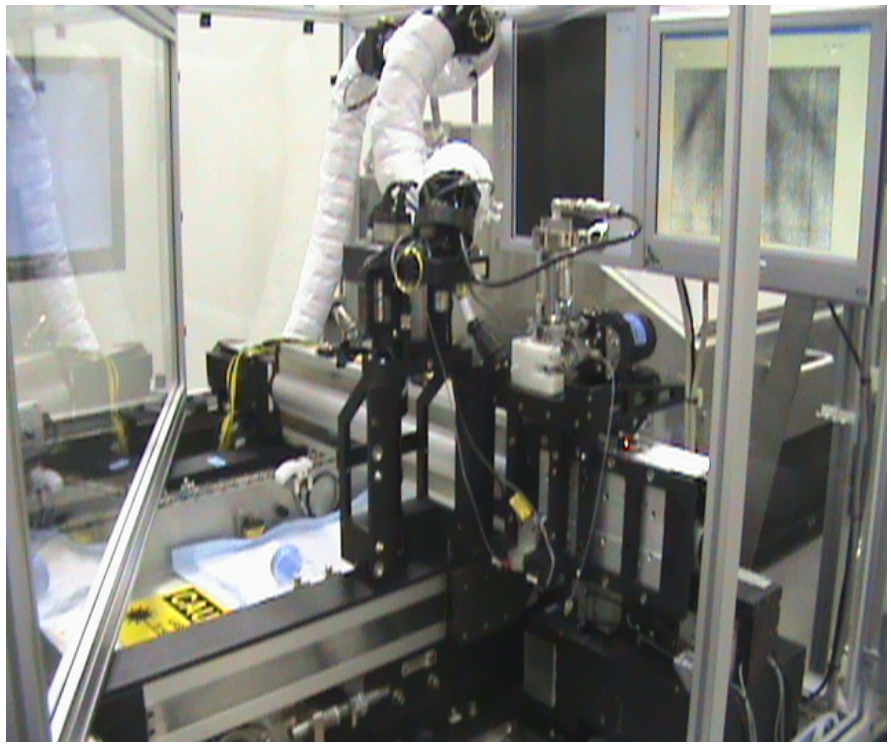
General Review of Automation and Human Exposure to Chemicals

- Prior to 1980s, automation of hazardous processes was rarely economically feasible
- Automation is typically necessary for isolation or separation controls
  - Hierarchy of controls:
    - Engineering
    - Administrative
    - PPE
- Automation decreases routine employee exposure to chemicals, physical agents and ergonomic hazards
- Automation does not alleviate maintenance duties and sometimes delays them to after hour shifts or increases maintenance frequency
- Increases product precision and accuracy, decreases failure rate, and can operate more hours/day
- Limitations – difficult to reprogram to meet change in needs, capital costs and indirect costs associated with programming, present additional hazards (e.g. pinch points)

An Undesirable Outcome

- http://www.chemsafety.gov/videoroom/detail.aspx?vid=16&F=0&CID=1&pg=1&F_All=y

Pharma Liquid Dose Technology



Case Study with Desirable Outcomes

- Liquid Dose Technology (LDT)
  - Used to make tablets that contain potent pharmaceutical ingredients
  - Lab and Manufacturing scale units
- Oral Solid Dose – negative impact on cost time, money, safety, quality and morale

Desirable Outcomes from LDT

- Respiratory protection not required !!!!!! (containment improved 100 fold)
  - Preparing drop solution*
  - Charging solution and operating LDT*
  - Disassembly and Cleaning*
- Traditional Oral Solid Dose Processing
  - Blending*
  - Granulation*
  - Milling*
  - Drying*
  - Compress*
- Exposure levels were greatly improved with the LDT. Contact the presenter for additional information.

LDT

- PHA Outcomes
  - Assisted in flagging PM schedule items
  - During oven does not exceed Operating Temp
  - Trip Test, ensuring drying oven heater turns off
  - Machine guards, E-Stops, LOTO, Safe Work Practices, Training
  - UL Compliant
  - MOC compatibility with solvents used
  - UV Light and Class 2 Laser
  - Thermal Gloves near oven
  - Spill Clean up

Desirable Outcomes from Automation

- Robotic Submarine (Solex Robots) - inspects the bottom of underground storage tanks
  - Saves labor and health risks
  - Avoids costs to transfer fuel and have standby tank, the emissions of tons of purge gas

Desirable Outcomes from Automation- TECANs

- DNA Extraction
- Multichannel pipetting (384 channel)
- Storage, Retrieval, and reformatting of samples
- Microplate washer and incubation
- Volume checking, centrifuge and aliquoting