PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

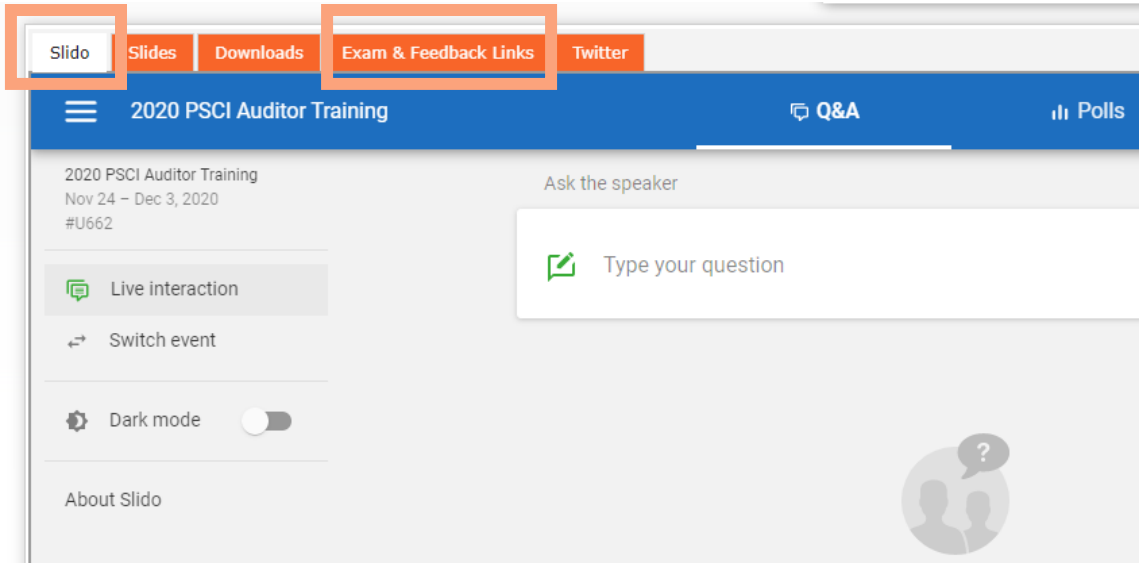
PSCI Auditor Training 2020

General Safety; Occupational Health and Industrial Hygiene; High Risk Work and Red Flags for Dangerous Working

Day 4 December 03, 2020

Practicalities

- Switch to audio feed only for better connection. Chinese attendees click at Live Stream (China)
- Break
- We'll be using Slido for Q&As, please click Slido tab to enter your questions or go to https://www.sli.do/ to pose questions with the code **#U662**
- Exam
- Certificates
- Feedback survey



Anti-Trust Statement

While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

i. Price fixing;
ii. Product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation;
iii. Standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete);
iv. Codes of ethics administered in a way that could inhibit or restrict competition;
v. Group boycotts;
vi. Validity of patents;
vii. On-going litigation;
viii. Specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information.

Agenda

General Safety; Occupational Health and Industrial Hygiene; High Risk Work and Red Flags for Dangerous Working	
13:15 – 13:30	**Registration**
13:30 – 14:15	**Plant General Safety (30 mins)** The presentation will discuss general plant safety topics such as personal protective equipment (PPE), safety training, chemical storage & handling, emergency response, accident/incident investigation, hazard communication (HAZCOM), process hazard analysis (PHA), safety equipment (fire extinguishers, water sprinklers), etc. It will focus more on six (6) life-critical safety topics – lock out tag out (LOTO), confined space entry (CSE), hot work (HW), machine guarding (MG), respiratory protection (RP), and fall protection (FP). **Pratap Padalkar**, Associate Director, Chemical Development & Manufacturing, Gilead *Q&A (15 mins)*
14:15 – 15:00	**Occupational health and industrial hygiene in plants (30 mins)** The presentation will discuss chemical exposure, noise exposure, radiation/bio safety, occupational exposure limits (OELs), safety data sheets (SDSs), respirator types, medical clearance, fit-testing, laboratory safety and engineering controls, emergency preparedness, etc. **Pratap Padalkar**, Associate Director, Chemical Development & Manufacturing, Gilead *Q&A (15 mins)*
15:00 -15:10	**BREAK (10 mins)**
15:15 – 16:15	**High risk work and red flags for dangerous working (45mins)** High risk work, including confined spaces, hot work, working at heights, lockout/tagout and electrical work accounts for the majority of serious workplace accidents and injuries (in some cases fatalities) at a site. In many cases, these incidents can be prevented. Therefore, the session will give an overview of areas to focus on during a site assessment and commonly observed gaps in these programs. **Roberta Haski,** HSE Leader, External Manufacturing & Commercial, Asia Pacific, Japan, ANZ *Q&A (15 mins)*
16:15 – 16:45	**Exam (20 mins)** **Closing comments / end of day 4**

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General Safety

Pratap N. Padalkar

Associate Director, EH&S

Gilead Sciences

Speaker Bio

- Pratap N. Padalkar
- Current Position - Associate Director, Gilead Sciences
- Location - Foster City, U.S.A.
- Qualifications: M.S. Environmental Engineering, Texas Tech University, U.S.A.
  M.E. Environmental Engineering, University of Bombay, India
  B.E. Civil Engineering, University of Bombay, India
- Credentials: Professional Engineer (P.E.)
  Registered Environmental Manager (R.E.M.)
  Certification in Hazardous Materials Management (Univ. of California Irvine, U.S.A.)
  Certification in Environmental Auditing (Univ. of California Irvine, U.S.A.)
  OSHA Authorized General Industry Trainer
- Professional Experience: 30+ years in EH&S compliance and risk management, mostly in chemical industries in Southern California, U.S.A. Current role & responsibilities include: Lead EH&S auditor at Gilead Sciences for the past five (5) years. Responsible for world-wide supply chain reliability for Gilead Sciences, ensuring compliance and reduction of EH&S risks at contract manufacturing sites (supplier facilities) located in Asia, Europe, North America, and U.S.A.
- Contact Information – pratap.padalkar@gilead.com

AGENDA

Training and Personal Protective Equipment

Incident Management, Reporting, Recordkeeping

Life Critical Topics

Important Areas of Plant

Miscellaneous Safety Topics

PSCI Questions

Questions & Answers

Training and PPE

- Initial and Periodic Training
- Employee Training Matrix
- Contractor Training

QUALITY COMAPNIES TRAINING MATRIX
Minimum Training Requirements

Company	Classification	Quality CORE	PEC / SafeGulf / SafeLand	Crane Operator	Electrical Qualified Person	Forklift Operator	Fall Protection / Rescue	Incipient Fire / Fire Watch	First Aid / CPR / BBP / AED	Hazardous Materials Shipping (HM126	Marine Trash & Debris	NORM Awareness	PSST / T2 / Subpart O	Rigging / Material Handling	Scaffolding	Water survival / HUET
Training class expriation interval →		Once	Once	4 years	Once	3 year	4 years	2 years	2 years	3 years	Annual	Once	3 years	4 years	Annual	4 years
REQUIRED FOR ALL OFFSHORE																
QPM	Field Supervisor / Foreman	X	X	X			X	X	X	X	X	X	X	X	X	X
	Lease Operator															
	Lead Operator	X	X	X			X	X	X	X	X	X	X	X	X	X
	A Operator	X	X	X			X	X	X	X	X	X	X	X	X	X
	B Operator	X	X	X			X	X	X		X		X	X	X	X
	C Operator	X	X	X			X	X	X		X		X	X		X
	D Operator (Roustabout)	X	X					X			X		X	X		X
	Operator 1	X	X													
	Operator 2	X	X													
	Gas Operations	X	X													
	Electrician / Operator	X	X		X		X	X	X		X		X	X		X
	Mechanic / Operator	X	X				X	X	X		X		X	X		X
	I&E / PLC	X	X		X		X	X	X		X		X	X		X
	Offshore Clerk	X	X						X	X	X					X
	Pipeline Technician															
	Truck Rack Technician															
QCP	Superintendent	X	X				X	X	X		X			X	X	X
	Welder	X	X				X	X			X			X		X
	Fitter	X	X				X	X			X			X		X
	Rigger	X	X				X	X			X			X		X
	Crane Operator	X	X	X							X			X		X
	Blaster / Painter	X	X				X	X			X			X	X	X
	Helper	X	X													
	Onshore Shipping & Receiving	X	X							X				X		
	Onshore Shop Personne	X	X											X		
	Onshore Equipment Operator	X	X	X		X								X		

Training and PPE (continued)

- Types of PPE provided to employee for usage is based upon:
  - Hazard assessment (Job Hazard Assessment)
  - SDS information
  - Training provided on proper usage and care

- Types of PPE
  - Head protection (helmet or hard hat), types 1 & 2, classes C/G/E
  - Eye protection (safety glasses, goggles), use of protective filter lenses
  - Face protection (face shield, welding shield)
  - Respiratory protection (half face and full face respirators with cartridges, SAR – supplied air respirator, SCBA – self contained breathing apparatus, PAPR – powered air-purifying respirator)
  - Hearing protection (ear plugs, ear muffs, molded hearing bands with chords), 85 dB/8-hr TWA hearing conservation, 90 dB/8-hr PEL
  - Hand protection (neoprene/butyl/rubber/leather/nitrile/latex gloves)
  - Body protection (lab aprons, coveralls, jackets)
  - Knee and shin protection (knee pads, shin guards)
  - Foot protection (boots, steel-toed safety shoes)

Incident Management, Reporting & Recordkeeping

- Standard Operating Procedure for Accidents/Incidents
  - fire, explosion, release, spill, earthquake, medical emergency, workplace violence, etc.
  - audio/visual alarm system and radio communication
  - emergency contact numbers for reporting
  - nearest hospital location
  - fire dept. and rescuers
  - CPR & first-aid trained first responders
- Injury and Illness
  - recordable incident rate (RIR), lost time accidents (LTA), days away & restricted time (DART)
  - trending rates (200,000 x no. of injuries sustained/no. of hours worked), rates comparison
  - near miss reporting
- Drills
  - emergency response (in conjunction with Fire Dept.)
  - evacuation (map of evacuation routes & exits, staging/assembly areas, head count including visitors, contractors)
  - critique and communication of drills
- SIN: S - safety first, I - isolate, N – notify

Life Critical Topics

- Lock Out Tag Out
  - Safe work permit, SOP, Training (authorized/affected/other), Different types of hazardous energy, Special locks & tags, One key per lock, Annual review of actual LOTO work, Steps for putting equipment back in service, Employer & employee responsibilities
- Confined Space Entry
  - Safe work permit, SOP, Training (entrant/attendant/supervisor), 3 Criteria for meeting definition of CS, Permit-required & non-permit required confined spaces, Rescue team (CPR & FA trained) for permit-required CS, Continuous monitoring of O_2/LEL
- Hot Work
  - Safe work permit, SOP, 35-Feet clearance around flammable materials, Proper PPE usage, Fire extinguisher availability, 30-Minute fire watch, Adequate ventilation, LEL monitoring, Escape route & fire alarm, Designated hot work area in plant
- Machine Guarding
  - Pinch points, Rotating parts, Guidance document, Training, No loose clothing/hanging jewellery/long hair, Use of interlocks
- Fall Protection
  - Hierarchy of fall protection: eliminate/prevent/control, Personal fall arrest system (PFAS): full body harness with lanyard, 5,000 Pounds anchorage point capacity, Fall restraint system, Pre-use inspection, Proper maintenance, Guardrail for 4 feet or higher working surface, 3-Point contact on ladders, Metal/fiberglass/wooden ladders, Weight capacity on ladders, Monthly ladder inspection
- Respiratory Protection
  - SOP, Medical clearance, Fit-test, Training on proper donning, doffing & storing, Half face and full face respirators, Negative & positive testing, SCBA, PAPR,
- Electrical Safety
  - 1000 Volts (high voltage), PPE for arc flash hazard (NFPA 70E), Trained & qualified personnel, Signs/labels for Arc-flash and High Voltage Danger, 36-Inch clearance, Labelling of circuit breakers, GFCI near water sources, Grounding & bonding, Frayed extension chords, Missing prong on chord, Multiple extension chords, Circuit overload

Important areas to visit in plant when conducting Audits

- Important areas to visit within plant:
  - Workshop (production area)
  - Hazardous Materials Storage (includes Finished Products Storage)
  - Tank Farm
  - Main Electrical Room (MCC)
  - Solid/Liquid Hazardous Waste Storage
  - Fire Fighting Pump System
  - QC/R&D Laboratory
  - Generator Room
  - Maintenance Yard
  - Air Emissions Control Area
  - Wastewater Treatment Area

Miscellaneous Safety Topics

- Written Environmental Health & Safety Policy and Program
- Business Licenses and Permits
- EH&S Trained Staff on Site
- Safety Committee and Safety Audits/Inspections
- Forklift Safety
- Job Safety Analysis (JSA) & Process Hazard Analysis (PHA)
- Preventive Maintenance (PM) Program
- Process Safety Management (PSM), if applicable
- REACH (Registration, Evaluation, Authorization & Restriction of Chemicals), if applicable
- Good Housekeeping
- Adequate Ventilation, Lighting, Walkways, Designated Smoking Areas
- Neighboring Facilities

PSCI General Safety Questions

- 47. Does the facility have a written Health & Safety policy, procedures, and practices?
- 48. Does the facility have any documented Health & Safety objectives and targets or goals for performance improvement, including metrics?
- 49. Indicate the number of significant Health & Safety incidents (serious injuries, fatalities, fires, explosions, fines or violations) that occurred at this facility over the past three years? – Last Year, Two Years Ago, Three Years Ago.
- 50. Does the facility provide HSE (Health, Safety & Environment) training to employees (full-time, temporary, or contractor)? – New employee orientation, Periodic refresher training, Pre-start up process specific HSE training, Employee emergency response action training, Hazard communication, Process safety management, Environmental practices
- 51. Does the site have a program for improving safe behaviors?
- 52. Does the facility ensure the provision of safe and potable drinking water and hygienic facilities to all employees?

PSCI General Safety Questions(continued)

- 53. Does the company provide adequate sanitary facilities (e.g. clean toilets, possibilities for hand-washing)?
- 54. If living accommodation (e.g. dormitories) are provided to employees or contractors, are they safe and clean, and do they meet the relevant basic requirements (e.g. fire protection and emergency)?
  - If housing is provided, who has responsibility for maintenance and general HSE?
  - Is it ensured that housing for workers and families is not in the vicinity of production areas or with uncontrolled access to operational facility?

PSCI General Safety Questions (continued)

- 55. Does the facility have a safe work permit system for the following? – Hot Work, Confined Space Work, Lock Out Tag Out, Line Breaking, Work at Height, General Permit, Other.
- 56. Has the facility developed and implemented an Electrical Safety Program that includes: Installation of lockable disconnect interlocks and emergency stop devices, Labeling of switches/outlets, breakers, panels and disconnects, Designation to keep clear areas around electrical equipment for safe work practices, Locking of electrical cabinets, Arc flash analysis?
- 57. Has the facility developed and implemented machine guarding procedures (including conveyor systems or other overhead equipment conveying materials (side rails, netting, etc.)) with proper hazard symbols?
- 58. Does the facility use any of the following processes for managing risks related to contractor activity onsite? – Contractor pre-approval, Training orientation before entry, Electronic access control, Drug/alcohol testing, On-going recurrent safety training, Mandatory accident reporting, Other
- 59. Are the facility's pedestrian and material handling equipment aisles marked or designated?

PSCI General Safety Questions

- 60. Has the facility developed and implemented a formal program to provide for the selection and maintenance of Material Handling Equipment? – Does it include: Operation by trained persons, Periodic inspection and maintenance by qualified personnel, Fall protection equipment and rescue plan in place for elevated work?
- 61. Are the facility receiving and/or shipping docks equipped with wheel chocks, dock locking systems or other means of trailer restraint to prevent trailers from moving during loading/unloading?
- 62. Is product stored overhead in pallet racking stretch wrapped or secured by some means to prevent it from falling?
- 63. Does the facility have practices to ensure pallet racking is maintained in good condition and regularly inspected (no obvious damages to components – especially uprights – cross beams locked in place, foot plates secured to floor, and capacity posted)?

PSCI General Safety Questions

- 64. Does the facility have a system to evaluate stored materials to ensure that special storage requirements are identified (e.g. flammable storage, segregation of non-compatible materials, containment, etc.)?

Questions and Answers

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About the Secretariat
Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

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Occupational Health & Industrial Hygiene

Pratap N. Padalkar

Associate Director, EH&S

Gilead Sciences

Speaker Bio

- Pratap N. Padalkar
- Current Position - Associate Director, Gilead Sciences
- Location - Foster City, U.S.A.
- Qualifications: M.S. Environmental Engineering, Texas Tech University, U.S.A.
  M.E. Environmental Engineering, University of Bombay, India
  B.E. Civil Engineering, University of Bombay, India
- Credentials: Professional Engineer (P.E.)
  Registered Environmental Manager (R.E.M.)
  Certification in Hazardous Materials Management (Univ. of California Irvine, U.S.A.)
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AGENDA

PSCI Industrial Hygiene Principles

Good Industrial Hygiene Program

Occupational Exposure Limits

Sampling, Monitoring and Hierarchy of Controls

PPE Program Elements

Respirators & Respiratory Protection Factors

Laboratory Controls

Biosafety and Radiation Safety

OEL Banding

IH Audit Red Flags

PSCI Questions

Questions & Answers

What are PSCI Health & Safety Principles applicable to IH?

1. Worker Protection (similar to OSHA General Duty Clause)
Suppliers shall protect workers from over-exposure to chemical, biological, physical hazards and physically demanding tasks in the work place, and in any company provided living quarters.

3. Emergency Preparedness and Response
Suppliers shall identify and assess emergency situations in the workplace and any company provided living quarters, and minimize their impact by implementing emergency plans and response procedures.

4. Hazard Information
Safety information relating to hazardous materials - including pharmaceutical compounds and pharmaceutical intermediate materials - shall be available to educate, train, and protect workers from hazards.

What does a good Industrial Hygiene program look like?

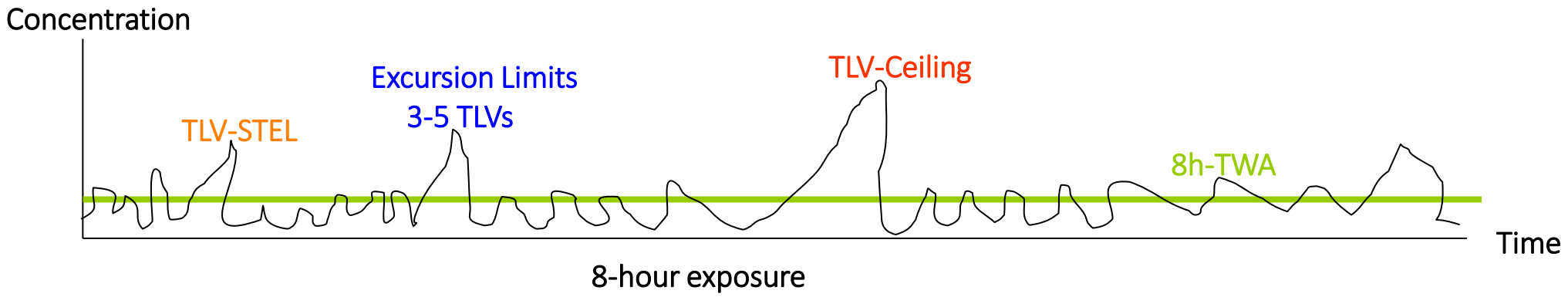
- An onsite person who has had training in control of hazardous agents
- Access to expert (e.g. certified industrial hygienist, qualified consultant)
- Inventory of hazardous chemicals, in particular potent materials (<10mcg/m^3 OEL), sensitizers, carcinogens and reproductive hazards
- Information on chemicals from customers & suppliers, and use of a banding system
- Access to SDS and communication of risks, procedures, and controls to employees that handle the hazardous chemicals
- Chemical risk assessments for chemicals handled, operations performed, and assessment of control measures (including non-production tasks such as equipment maintenance, waste handling)
- Procedures and training on storage, use, and cleaning of PPE
- Exposure sampling and monitoring data as appropriate
- Risk based health surveillance
- Incident/exposure records and accident investigations
- IH program rules for handling unknown chemicals
- Training and emergency response plan for worst-case scenarios for off-site consequences

Occupational Exposure Limits (OELs)

- OEL (mg/m^3) = $\frac{\text{NOEL (mg/kg/day) x BW (kg)}}{\text{BR } (m^3/\text{day}) \text{ x SF}}$

  - NOEL = no-observed-effect-level (mg/kg/day or mg of chemical administered per kg of body weight per day)
  - BW = average human body weight (70 kg for adult male)
  - BR = typical human breathing rate in an 8-hr work day (10 m^3/day)
  - SF = safety factor (1 to 100)

- Occupational Exposure Limits (OELs)
  - A numerical air concentration limit expressed as ppm or mg/m3 over a stated time duration (8hr, 12hr, 15 min, Ceiling) which nearly all adult workers may be exposed to during their working lifetime without adverse effects. The OELs may be established by a government or a company
  - OELs can be found in SDSs
  - Several chemicals do not have OELs



Occupational Exposure Limits (continued)

- Legal exposure limits exist for many chemical compounds
  - OSHA – Permissible Exposure Level (PEL)
  - ACGIH – Threshold Limit Value (TLV)
  - NIOSH – Recommended Exposure Limit (REL)
  - OEL – Occupational Exposure Limit

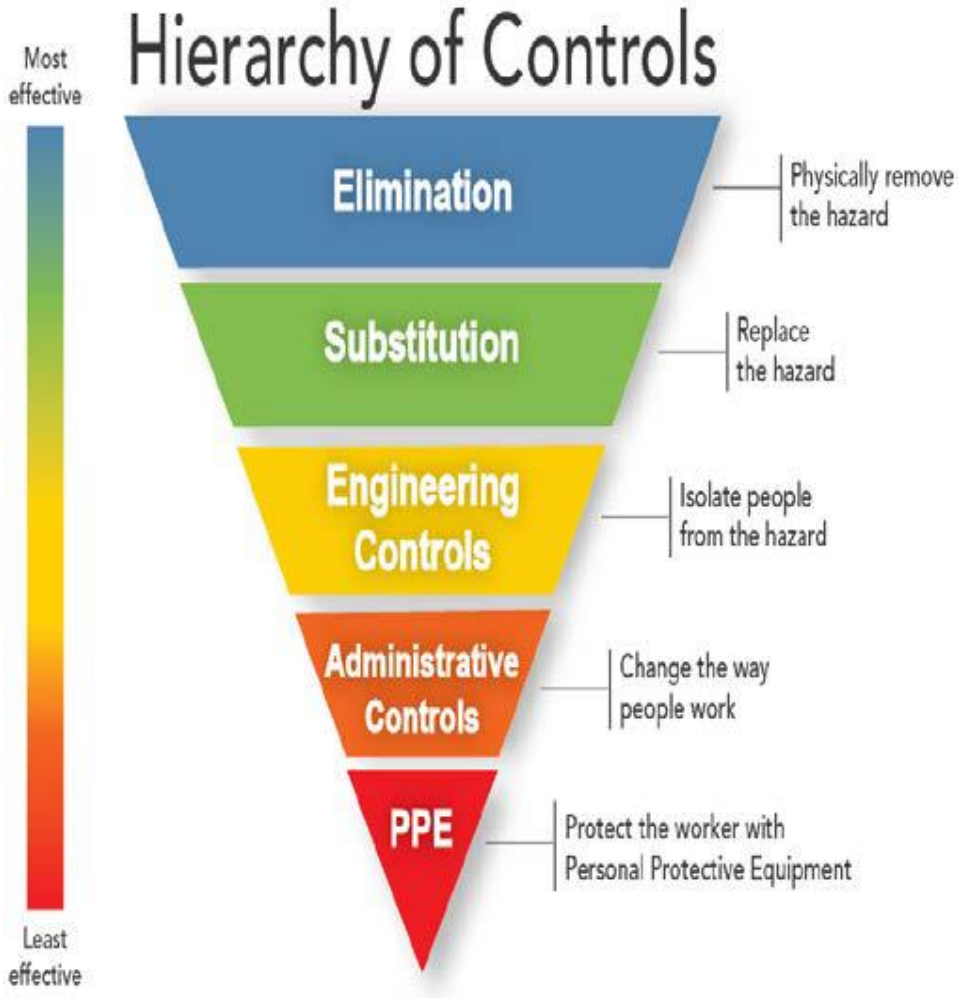
- Exposure limits
  - PEL – Permissible Exposure Limit (OSHA), maximum time-weighted 8-h exposure limit for worker
  - TWA – Time Weighted Average, typical for 8 hours (one shift)
  - STEL – Short time Exposure Limit, acceptable average exposure over short period, usually 15 min, as long as the TWA exposure is not exceeded
  - C – Ceiling, maximum level of exposure without suffering any adverse effects
  - TLV – Threshold Limit Value (ACGIH) ceiling, time-weighted average concentration of exposure over 8-h workday and 40-h workweek to which nearly all workers may be repeatedly exposed every day without adverse health effects
  - REL – Recommended Exposure Limit (from NIOSH to OSHA, not a regulatory requirement)
  - Maximum concentration of a chemical in the air without a health hazard
  - ppm = (mg/m^3 x 24.45 L/mole) / (Mol Wt. in g/mole)

Occupational Hygiene Sampling/Monitoring & Hierarchy of Controls

Pollutants:

- Particulates
  - filters
- Gases and Vapors
  - adsorption tubes or badges

1. Does the facility perform exposure monitoring for health and safety risks? Is there a procedure to inform employees of the results of exposure evaluations and monitoring results?
2. Is the facility more heavily reliant on PPE and work procedures and does NOT use Hierarchy of engineering controls?.....Do these adequately protect worker health & safety?
3. Does the facility provide adequate Respiratory Protection to employees?
4. Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up?



PPE Program should cover these elements

PPE Types and Hazards

- Head Protection
- Eye Protection
- Hearing Protection
- Respiratory Protection
  - Respiratory Protection Fit Testing
  - Filters/Cartridges (Use & Replacement)
- Hands Protection
  - Based on chemical compatibility data
- Body Protection
- Feet Protection

Inspection of PPE

- Use of PPE
- Cleaning
- Storage
- Maintenance
- Training

Respirators

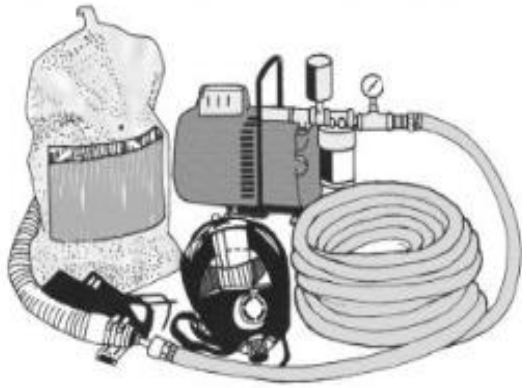
Two types of Respiratory Protection:
Negative Pressure
Positive Pressure

Negative Pressure:
Half Face Mask, Tight Fit
Full Face Mask, Tight Fit

Positive Pressure:
Powered Air Purifying Respirator (PAPR)
Supplied Air Respirator (SAR)
Self Contained Breathing Apparatus (SCBA)

- Fit Check is conducted prior to use
  - Negative Pressure & Positive Pressure Seal Checks
- Cannot be used with beard or other interferences on respirator seal
- Training is needed
- Use of appropriate filtration media is in accordance with the chemicals present

In the US, Fit Testing and medical clearance are key requirements. Qualitative and quantitative fit testing might be a legal requirement to adequately set protection factors.



- Fit Test is not needed
- Prior to use inspection is required (physical condition, battery, airflow, filtration media)
- Training is needed

Respiratory Protection Factors Enforced in US

According to OSHA

Assigned Protection Factor (APF) of masks:

Type of Respirator[1] [2]	Half Mask	Full Facepiece	Helmet / Hood
Air Purifying Respirator	10[3]	50**	-
Powered Air Purifying Respirator (PAPR)	50	1,000	25 / 1,000*
Supplied Air Respirator (SAR) -Demand Mode -Continuous Flow Mode -Pressure Demand	10 50 50	50 1,000 1,000	- 25 / 1,000* -
Self Contained Breathing Apparatus (SCBA) -Demand Mode -Pressure Demand	10 -	50 10,000	50 10,000

[1] Employers may select respirators with higher protection.
[2] an effective respiratory program must be implemented.
[3] includes filtering facepiece respirators.
* Manufacturer must provide test data to demonstrate an APF of 1,000 is achieved.
** Per (Canada) CSA Z94.4-02, the APF for a full face mask is 100.

RPF (Respirator Protection factor - as defined by OSHA):
"… workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section…."
https://www.osha.gov/pls/oshaweb/

The level of protection offered by Respirators is defined by the Assigned Protection Factor (APF) or Nominal Protection Factor (NPF)

- Usually, each country establishes its own APF or NPF
  APF or NPF x OEL for substance = Max Use Concentration (MUC)

Laboratory Controls

FUME HOOD

- Average face velocity 100 fpm
- Max sash height should be demarked (18 inches)
- Alarm (face velocity loss)

BIOLOGICAL SAFETY CABINET (Class 1, 2, 3)

- Face velocity varies between 75 -100 fpm depending on the cabinet type
- Alarm (face velocity loss)
- HEPA filtration or ducted models available
- Filter integrity testing

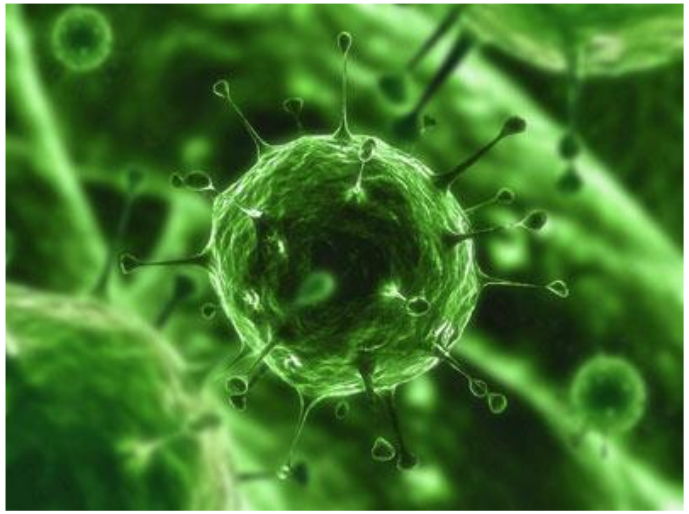
VENTILATED ENCLOSURE CABINET FOR WEIGHING

GLOVE BOX

- Provides high containment capability
- Requires detailed procedure that includes
  - Pre-inspection verification
  - Practices for removing material after its use
- Requires routine maintenance (gloves & filter replacement, pressure test)

Biosafety & Radiation Safety

- Just as there are control bands for chemicals, there are risk groups for biosafety hazards and established Biosafety Control Bands for biologicals.
- In bio laboratories, there are four Biological Safety Levels (BSLs) – 1, 2, 3, 4.
- If sites have products with ionizing radiation and/or BSL 3 or 4 operations, special government licenses are required.



OEL Banding Concept - Criteria

- Occupational Exposure Banding – Pharmaceutical Industry Method

  - An established set of recommended engineering and control strategies for handling chemicals within a chemical exposure band. Companies that set OELs generally have these bands. Banding is NOT typically found on a SDS.
  - Default Band: The method a company establishes to set rules for identifying a control strategy for handling chemicals with limited toxicology data for safe handling. The bands may be created using set of rules, limited toxicology, and phrases from the Global Harmonization Standard typically found on a SDS. The site classifies the Hazard Bands and chooses the most relevant/appropriate band.

OEL Category	1 Low toxicity or pharmacological activity	2 Moderate toxicity or pharmacological activity	3 Medium toxicity or pharmacological activity	4 High toxicity or pharmacological activity	5 High/ Very high toxicity or pharmacological activity
OEL [µg/m^3]	≥ 1000	100 – <1000	10 - <100	1 - <10	<1
Therapeutic dose* [mg]	≥ 200	20 - 200	2 - 20	0.2 - 2	<0.2
Repeat-dose toxicity	Low	Moderate	Severe systemic effects	Severe systemic effects	Very severe
Reproductive Hazard	No	No	No or only at high doses	Reproductive effects	Severe reproductive effects
Mutagenicity	No	No	No	Mutagenic	Highly mutagenic
Carcinogenicity	No	No	No or only at high doses (threshold)	Carcinogenic	Potent carcinogen
Sensitisation	Not sensitising	Not sensitising	Sensitizer	Sensitizer	Highly sensitising

* depending on the mode of action and adverse effects, a higher or lower classification might be adequate

When doing a PSCI audit for a member company – obtain their banding categories and tools

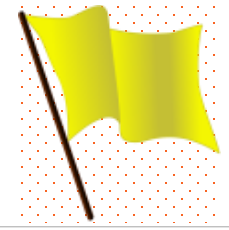
SAMPLE: Control Banding Implementation

Band	PPE	Facility Design	Engineering Controls	Equipment Cleaning and Maintenance
Level 1	•Gloves •uniforms	•General Ventilation •Shared HVAC •General Filtered Exhaust •Recirculate Permitted •Common Gowning & De-gowning	•Passive Ventilation/Dilution •Open Mat'l Conveying and/or Mat'l Transfers •Open Process Equipment	•Open Process Equipment Transport to Cleaning Area •Manual Cleaning
Level 2	•Respirators •Tyvek coveralls	•Pressure Differential To Selected Adjacencies •Open Process Area •Closed Building •Process segregation with doors •Gowning/De-gowning Room	•Standard Equipment Design (Normally Closed) •Local Exhaust Ventilation •Mat'l Conveying Essentially Open with Hardware Remediation •Pressure Convey •Laminar flow	•Open Process Equipment Cleaned In-Situ
Level 3	•Maximum PF (protection factor) respirator	•HEPA Filtration •Room Finishes and Utilities Are Designed for Ease of Cleaning •Process segregation with airlocks •Decontamination Shower	•Standard Equipment Design with Separate Mechanical Space •Glovebox or Glovebag •Closed Material Conveying •Minimize Make/Break Connections •Split butterfly valves (SBV)	•Provide cleaning-in-place (CIP) with Rinse Water Capture •Closed equipment maintenance capability
Level 4	•Seek expert assistance •Respirators not adequate for "open" processing •Redundant PPE with engineering controls	•Seek expert assistance •Dedicated HVAC •HEPA Filtration w/Safe Change •No Exhaust Return •Closed Process Area •Closed Building •Separate Gowning & De-gowning •Automation	•Seek expert assistance •Process Equipment iDesigned for Total Containment •Closed Mat'l Transfers with Barrier Add-ons •Vacuum Convey •Minimize Mat'l Conveying Steps •Minimize Material Transfer Connections •Isolator with continuous liner •Enhanced/purgeable SBV	•Seek expert assistance •Minimize Waste via Process and Formula Optimization •Protective barriers for laptops, paperwork, documents

Red Flags to watch out for in IH Audits

- Site is handling their API as Nuisance Dust because there is no regulatory limit. APIs are NOT Nuisance Dust. We know APIs do not have regulatory exposure limits. Agree with site on the required exposure limit and control banding. If none exists – Red Flag.
- Site is handling potent pharmaceuticals but there is no banding.
- Site has never seen the OEL for API from the PSCI member company's SDS.
- IH monitoring has had faulty interpretation of results – there are clear overexposures and no action is taken.
- Highly potent pharmaceuticals (<10 mcg/m3 OEL) are being handled, operation is open, respirator required by SOP is not provided at the site or completely inappropriate respirator provided for the hazard class (e.g. clearly not a respirator or the respirator protection factor is too low). There is no segregation of chemicals.
- During tour of site that handles highly toxic gases/solvents, you smell strong odors, experience irritation, observe incorrect PPE worn and no alarm or shut-offs. Dust masks are being used for handling gases/solvents. Process venting is directed into the room where employees work.
- The site lacks any data to justify that their workers are protected. This may relate to poor HAZCOM and PPE practices.
- There is no local exhaust ventilation (LEV) in the centrifuge unloading or dryer loading rooms where wet cakes are being handled. Limited PPE is being worn.
- No capable resources are being used to manage IH issues/concerns.
- Site performs QC sampling in warehouse on the open floor for all chemicals.
- There is no IH sampling data for any process or chemical on record.

IH Red Flags (continued)



- IH Program is in place but some differences exist between OELs and associated protection factors for respirators.
- PPE and IH Programs are written at corporate level (central location) by API company – instructions on posters, SOPs, etc., do not match what is available at the site. Need to confirm that the PPE requirements indicated in SOPs are clearly explained and understood by workers so they can be protected.
- Site does not perform respirator fit testing.
- Site has not linked occupational workplace exposure to worker health surveillance program.
- Production/Manufacturing process is highly dependent on PPE and administrative controls but not on engineering controls. Engineering improvements to improve exposure control are strongly recommended.
- Site has not assessed exposure risk to workers in lab areas.
- IH data collected is very limited (only area samples taken, no personal monitoring conducted).
- Local exhaust ventilation (LEV) exists, but designs and photos show it is most likely ineffective to control exposure risks since there is no (or very minimal) PPE being used. The site needs to review its engineering control strategy and data collected on LEV performance.

PSCI Occupational Health/IH Questions

- 65. Does the facility perform risk assessments for chemicals handled? Do they consider pregnant women?
- 66. Does the facility have occupational exposure level (OEL) values for all Active Pharmaceutical Ingredients (API) and hazardous substances (including intermediates and solvents)? If yes, explain how OEL values are obtained?
- 67. Has the facility established exposure control capabilities for handling pharmaceutical compounds? Please specify the lowest control range of containment for dust/powder handling that has been achieved.
- 68. Does the facility perform risk-based medical monitoring or employee health surveillance which includes recording, investigation and follow-up? Pre-employment physicals, Routine blood monitoring, Routine urinalysis, Lung function testing, Hearting test, Other.
- 69. Has the facility developed and implemented a plan to protect First- Aid Responders and Medical Professionals from exposure to body fluids? Does the program include: Training, Exposure response kits regular checking, Hepatitis B vaccination offerings?
- 70. Does the facility perform exposure monitoring for the following health and safety risks? – Solvent vapors, Workplace noise levels, Pharmaceutical powders, Radiation levels, Oxygen-deficient atmospheres (e.g. nitrogen, inert gases), Ergonomics (height-lifting, illumination, vibrations).

PSCI Occupational Health/IH Questions (continued)

- 71. Is there a site procedure to inform employees of the results of exposure evaluations and monitoring results?
- 72. Does the site provide Personal Protective Equipment (PPE) for face, eye, foot, head, body and hand protection?
- 73. Does the facility rely primarily on respiratory protective devices and/or engineering controls to protect employees who handle chemicals to achieve exposure levels below the exposure limit? – Respiratory protective devices used? Engineering controls used?
- 74. Does the facility use any of the following respiratory protection equipment for worker protection against exposure to chemicals or pharmaceutical compounds – Supplied air breathing systems, powered air purifying respirators, full face respirators, half face respirators, filtering face masks, other?. What criterial are used to select respiratory protection devices?
- 75. Are there provisions for fit testing, training, use, cleaning, inspecting, storing, and maintenance of respirators?

Questions and Answers

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BREAK

It is break now. Please come back in 10 minutes.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

SIF (Serious Injury or Fatality) High Risk Safety Programs

Roberta Haski

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Speaker Bio

Roberta Haski

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- 2015 – present: HSE Consultant, Elanco External Manufacturing, Asia-Pacifc
- 2012 – 2015: Legal work and practice
- Prior to 2012: Variety of positions in HSE and HR senior management at global pharmaceutical company, university, hospital. Variety of consulting work.
- 2011 - 2007: Admitted to practice law, graduated JD from UT; MLLR – Sydney Uni
- Prior to 2007: MSc – UNSW; BSc – Sydney Uni

Agenda

Introduction to SIF Programs

Examples of SIF Programs

References

Examples of High Risk Safety Programs

Why the Focus on SIF programs?

- High risk work – but risks can be controlled;
- One of main causes of serious injuries & fatalities in the workplace;
- Applicable to all workplaces;
- Focus of HSE regulatory requirements;
- PSCI focus;
- Information readily available for workplace improvements;

Why the Focus on SIF programs?

55	Does the facility have a safe work permit system for the following?	Hot Work: Yes No NA Confined Space Work: Yes No NA Energy Isolation or Lock Out/Tag Out: Yes No NA Line Breaking: Yes No NA Work at Height: Yes No NA General Permit Yes No NA Other: Yes No Please describe:	Yes No Comments

Why the Focus on SIF programs?

56	Has the facility developed and implemented an Electrical Safety Program that includes:	Installation of lockable disconnects interlocks, and emergency stop devices? Yes No Labeling of switches, outlets, breakers, panels, and disconnects? Yes No Designating keep clear areas around electrical equipment for safe work practices? Yes No Electrical cabinets are locked? Yes No Arc Flash Analysis? Yes No	Yes No Comments

Why the Focus on SIF programs?

57	Has the facility developed and implemented machine guarding procedures (including conveyor systems or other overhead equipment conveying materials (side rails, netting, etc.)) with proper hazard symbols?	Yes No NA Comments:	Yes No NA Comments

Why the Focus on SIF programs?

58	Does the facility use any of the following processes for managing risks related to contractor activity onsite?	Contractor pre-approval: Yes No Training/orientation before entry: Yes No Electronic access control: Yes No Drug/alcohol testing: Yes No On-going recurrent safety training: Yes No Mandatory accident reporting: Yes No Other: Yes No If yes, please describe:	Yes No Comments

Confined Spaces

- India Factories Act – s36
- What is a confined space?
  - Enclosed or partially enclosed space;
  - Intended or likely to be entered – but not designed for continuous human occupancy;
  - Limited means of entry & exit;
  - Contains or likely to contain:
    - Atmosphere with harmful level of contaminant;
    - Atmosphere that does not have safe oxygen level;
    - Stored substances (except liquids) that could cause engulfment;
  - Entry permit req'd for potentially hazardous confined spaces.

Examples of Confined Spaces

1. Is it enclosed, partially enclosed? Y/N
2. Is it likely to be entered or partially entered? Y/N
3. Is it at normal atmospheric pressure? Y/N
4. Is there limited or restricted entry/exit? Y/N
5. Does the space contain:
   - Atmosphere with harmful level of contaminant? Y/N
   - Harmful oxygen levels? Y/N
     - Safe range oxygen: 19.5% – 23.5%
   - Substances that could cause engulfment? Y/N

- If answer YES to 1,2,3,4 and at least one part of 5, then it is more than likely a Confined Space (ref: based on WorkSafe Victoria – *Compliance Code, Confined Spaces* (2008)

- Examples include: blenders, reaction vessels, duct or pipe work, tanks, pits, underground sewer or well – many other examples

Why are accidents and fatalities so common?

- Unaware of potential hazards – no risk assessment carried out;
- Inadequate controls in place;
- Inadequate isolation of energy, utilities – require LOTO procedure
  - Identify, isolate, verify
- Atmosphere not monitored;
- Inadequate means of communication or rescue;
- No emergency plans in place.
- Consider – does the confined space need to be entered or is there an alternative?
  - Egs. – spray ball cleaning for tanks;
  - High pressure hose inserted through hatch to clean tank;
  - Remote cameras or mirror attachments;
  - Use of hook, long handle clasp, magnet to retrieve fallen objects

Minimum Requirements for CS Program include
(but not limited to):

- Confined spaces have been identified, labelled;
- Confined space entry procedures are in place:
  - Completed permits;
  - LOTO;
  - Atmospheric testing;
  - Calibrated meter for testing atmosphere;
  - Permit displayed in work area;
  - Rescue and emergency procedures, including rescue equipment;
- TRAINING, including practical training for entrants, supervisors, standby persons, rescue team;
- Red flag: “This is not applicable to us – we have no confined spaces”;

Permit to Enter Confined Space

- Provides formal check for safe system of work;
- Means of communication between management, supervisors, those carrying out work, prior to entry;
- Ensure responsible person has checked & authorised confined space entry and safe to proceed;
- Permit posted at entrance to confined space and remains till work completed and people have exited the confined space;
- Elements include:
  - Description of confined space – eg. tank no. 2, production room 3;
  - Purpose for entry – eg. cleaning procedures;
  - Date and time permit issued and how long it is valid for;
  - Name of entrants, monitors, standby persons;
  - List of hazards;
  - List of PPE req'd;
  - Oxygen monitoring results;

CS program – Common Observations

- Confined spaces have not been fully identified;
- Missing labels;
- Unaware of potential hazards – no risk assessment carried out;
- Inadequate controls in place;
- Inadequate isolation of energy, utilities – require LOTO procedure
  - Identify, isolate, verify
- Atmosphere not monitored -
  - Check calibration of meter used;
- Permits not fully completed or signed;

CS program – Common Observations

- Training not extended to contractors;
- Adequate rescue equipment is not available, not maintained;
- Inadequate means of communication or rescue;
- No emergency plans in place or plans have not been simulated;
- Consider – does the confined space need to be entered or is there an alternative?
  - Egs. – spray ball cleaning for tanks;
  - High pressure hose inserted through hatch to clean tank;
  - Remote cameras or mirror attachments;
  - Use of hook, long handle clasp, magnet to retrieve fallen objects

Lockout Tagout (LOTO) or Energy Isolation

- India - Electricity Act and Indian Electricity Rules;
- LOTO applies to all equipment and plant except just cord and plug equipment;
- Major cause of serious injuries, fatalities:
  - Work carried out and equipment is still electrically active;
    - Especially if cleaning by spaying water
  - Work carried out and equipment has inadvertently activated;
  - Work carried out and stored energy is released;
  - Work has been completed and safety devices have not been replaced.

Minimum Requirements for LOTO Program Include: (but not limited to)

- Procedure for energy isolation – include instructions for various equipment, plant;
  - Some sites use pictures, photos
- Permit for energy isolation;
- Plan for energy isolation, inform affected persons;
- Shutdown the equipment, plant;
- Isolate energy/energies from equipment, plant;
- Use of lockout devices and tags;
- Verify the isolation
  - Confirm the correct equipment, plant has been isolated;
  - Ensure the switches used for isolation are for the correct equipment
  - **Lockout, Tagout, Try out**
- TRAINING of operators, supervisors

LOTO – Common Observations

- Lack of LOTO procedures for specific equipment;
- Lack of permit or permit not adequately completed or signed;
- Tags used but not locks;
- Each person working on the equipment does not use an individual lock;
- Gaps in training – especially for third party contractors, supervisors;

Electrical Safety - Issues

- Events that have caused fatalities:
  - Objects/equipment not grounded;
  - Stored electrical energy;
  - Arc Flash;
  - During service/maintenance – “Energy not disconnected, locked out and verified”

- Effects of electricity:
  - Electric shocks;
  - Electric burns;
  - Loss of muscle control;
  - Thermal burns

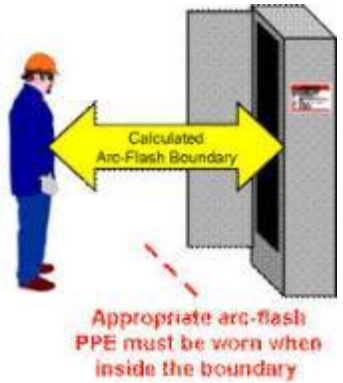
(ref: based on data in “Electrical Safety in the Workplace” - https://www.osha.gov/dte/grant_materials/fy09/sh-18794-09/electrical_safety_manual.pdf)

Minimum Requirements for Electrical Safety Program include (but not limited to):

- Identifies hazards, assesses risks and specifies work practices;
- Require safe work practices during applicable work activities such as: electrical installation, inspection, operation, maintenance and removal of electric conductors and equipment.
- Provides guidance for selection of appropriate PPE and tools, including electrically rated PPE, insulated tools, multi meters and other related equipment;
- Provides training for workers exposed to electrical hazards and general awareness training for all;
- Ensures workers/third party contractors are qualified and trained for the tasks they will perform;
- Requires regular supervision or regular (at least) annual inspections to ensure safety.

Minimum Requirements for Electrical Safety Program include (but not limited to) cont:

- Emergency stops, interlocks as red;
- Labelling of electrical cabinets, high voltage areas;
- Rated equipment for flammable areas, combustible dust areas, wet areas;
- Grounding , bonding – ensure regular testing;
- Locked/secure electrical cabinets, clear space around them;
- Regular inspection of electrical equipment and ensure maintained in good working order;



Electrical Safety – Common Observations

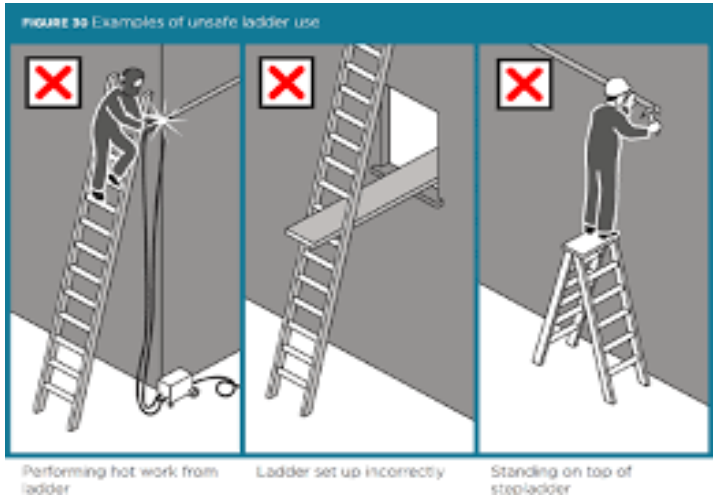
- Site has not identified high risk electrical work;
- Site is unaware / not complying applicable legal requirements for electrical work;
- Site is lacking electrical safety programs, or major parts of programs;
- Lock out, Tag Out, (LoTo) not applied (or not fully applied).
- No documented programs – or worse – what is documented is not what is implemented;
- Workers not trained in these programs;
- Programs not applied to third party contractors;
- High voltage areas not secured for unauthorized access;
- No special procedures for high voltage.
- No Arc Flash Analysis is available.
- Changes done in electrical system are not governed through Management of Change.
- Emergency stops when necessary not available, not identified or not readily accessible to operators

Electrical Safety – Common Observations contd..

- Field Observations;
  - No tagging of electrical equipment.
  - Damaged Cables, Damaged grounding
  - Resistance for grounding is higher than threshold.
  - No maintenance program for checking effectiveness of grounding.
  - Electrical equipment installed (including in Ex-Zone) don't comply to standard OR not maintained.
  - Electrical work done by non-certified electricians.
  - Open / accessible electrical terminals.
  - No PPE's / damaged PPE's used.
  - LoTo is not followed by electricians while doing maintenance work.
  - Use of temporary installations / connections.

Working at Heights

- Usually involves potential falls when working approx. 2m from floor;
- Also include any fall hazards in floor/ground area;
- Remember ladders:
  - Ladder safety program – includes safe use of ladders;
  - Correct ladder for the job;
  - Ladder regular inspections.

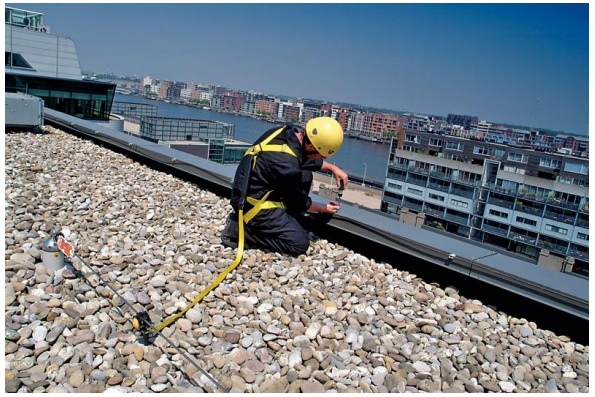


Working at Heights – Minimum Requirements Include (but not limited to)

- Identify if fall hazards exist. Assessment should include all areas including roof, elevated locations with open-sided floors, platforms and areas near floors and wall openings;
- Assess fixed ladder access openings, pits, vats, ditches, etc. must be adequately protected (i.e., cover, protective screen, guardrail or barricade);
- Conduct inspection of the scaffold system (if in use) by a competent person before each shift, or before use if scaffolding is not used each shift;

Working at Heights – Minimum Requirements Include (but not limited to)

- A personal fall arrest system, fall restraint system, or a means to prevent a fall (e.g., guardrail, parapet) should be in place – as required by work being performed – ensure inspection, maintenance program in place;
- Identify what current controls are in place;
- Identify the gaps and plan to close gaps;
- Ensure training provided – esp. for fall arrest and restraint systems



Hot Work – Minimum Requirements include (but not limited to)

- Hot work – fire prevention;
- Hot work includes any work that uses or can create open flame, sparks – eg. welding, grinding;
- Hot work procedures – usually include permit;
- Provisions for a trained fire watch to be present during and after hot work activities;
- Designated post-hot work monitoring period following the fire watch mandatory observation period – usually 30 mins;
- Training for personnel responsible for and involved in Hot Work program.

Third Party Contractor and Labour Hire Management Program – HSE Considerations

- Definition of third party contactors and labour hire – identify;
- How does the site manage these people?
- Are the third party contractors/labour hire utilised by the site qualified to carry out the required work?

Minimum Requirements for Contractor Safety and Labour Hire Program Include: (but not limited to)

- Supervision of third party contractors and labour hire;
- Contractor and labour hire access requirements;
- Contractor and labour hire site orientation and training requirements;
- Communicating hazards to contractors and labour hire – is specific training req'd;
- Consider pre-qualification if frequent contractor or labour hire;
- Incident reporting, investigation;
- Emergency response planning;
- Training – especially induction, orientation to site

Any Questions??

References

- Govt of India – Ministry of Labour & Employment - http://www.labour.nic.in/industrial-safety-health
- UK Health and Safety Executive - http://www.hse.gov.uk/index.htm
- US Occupational Health & Safety Administration - https://www.osha.gov/
- SafeWork Australia - http://www.safeworkaustralia.gov.au/sites/SWA
- Canadian Centre for Occupational Health and Safety - https://www.ccohs.ca/

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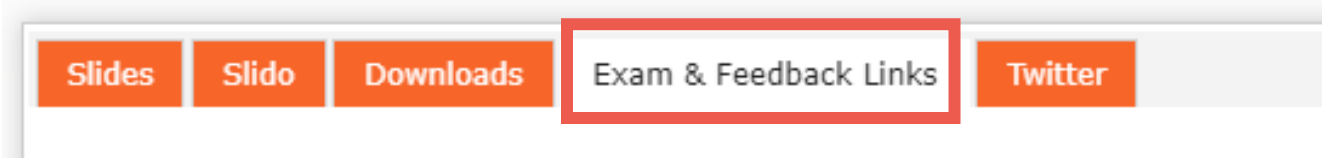

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