Pfizer

Working together for a healthier word

Laboratory Safety
AT QUALITY CONTROL SCENARIO

43RD IUPAC WORLD CHEMISTRY CONGRESS
AUGUST 1,2011

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PFIZER PHARMACEUTICALS

AGENDA

- Who we are?
- Laboratory Safety Program Main Aspects
- Laboratory Safe Work Practices
- Hazards vs Risks
- Risk Assessments
- Pfizer Laboratory Safety Initiatives

PFIZER: Who We Are?

Ethic and Transparency

Quality and Innovation

Principles part of the responsibility of being leaders

Collaboration and Partnership

Person Centrality

For over 150 years our aim is to improve the quality of people health and life

OSHA Voluntary Protection Program

A Partnership for Excellence in Safety

- Incident Rates
- Management Leadership and Employee Involvement
- Work Site Analysis
- Hazard Prevention and Control
- Safety and Health Training

VPP

Partners in Safety and Health
OSHA – Management – Labor

Our values are a declaration of our core beliefs and the defining features of a culture that breeds achievement. These crystallize who we are—who we have always been—and what we stand for. They reflect the enduring character of Pfizer and its people.

Pfizer colleagues worldwide are the cornerstone of our success — and we are dedicated to providing a safe and healthy workplace. We focus continuous improvement initiatives on minimizing illness and injury and benefiting from a worldwide driver safety program.

safety

Laboratory Safety Program Main Aspects

Key Elements :

- Active Participation
- Responsibilities
- Risk Identification/Management
- Communication
- Procedures/Management of Change

Laboratory Safety Program Main Aspects

Compliance with local and federal regulations

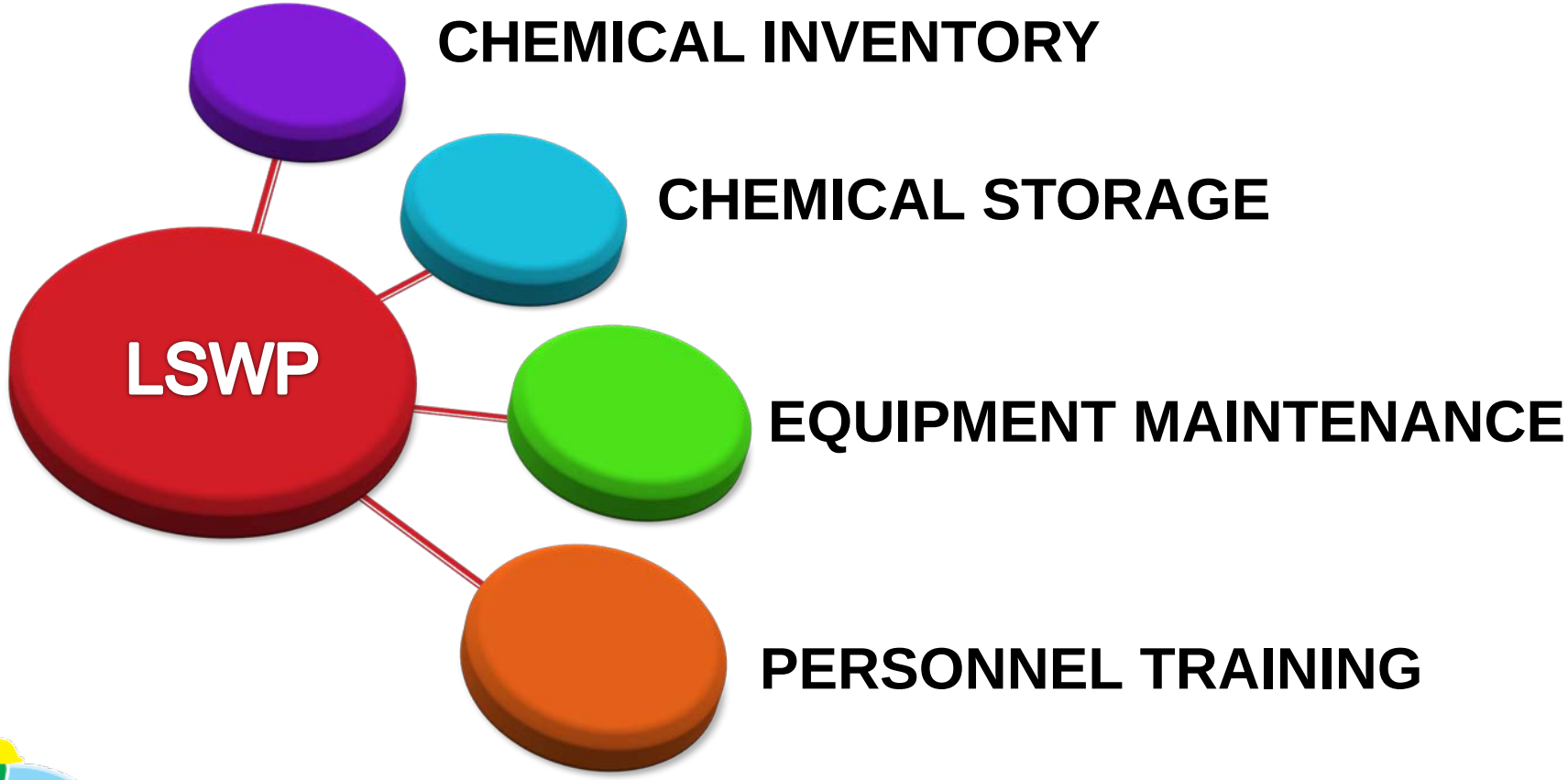
- Subpart Z- Toxic & Hazardous Substances
  - 29 CFR 1910.1000- Air Contaminants
  - 29 CFR 1910.1003- OSHA 13 Carcinogens
  - 29 CFR 1910.1096 Ionizing Radiation
  - 29 CFR 1910.1200- Hazard Communication
  - 29 CFR 1910.1450- Occupational exposure to hazardous chemicals in laboratories
  - Specific Substances Standards
- Subpart G – Occupational Health & Environmental Control
  - 29 CFR 1910.1097- Non-Ionizing Radiation

Laboratory Safety Program Main Aspects

Compliance with local and federal regulations (cont.)

- Subpart H- Hazardous Materials
  - 29 CFR 1910.101- Compressed Gases
  - 29 CFR 1910.119 – Process Safety Management of HHS
- Nuclear Regulatory Committee 10 CFR part 19
- Protection Against Radiation 10 CFR part 20
- PR Explosives Law # 134 of June 28 1969
- PROSHA Regulation # 17 – Boilers & Pressure Vessels

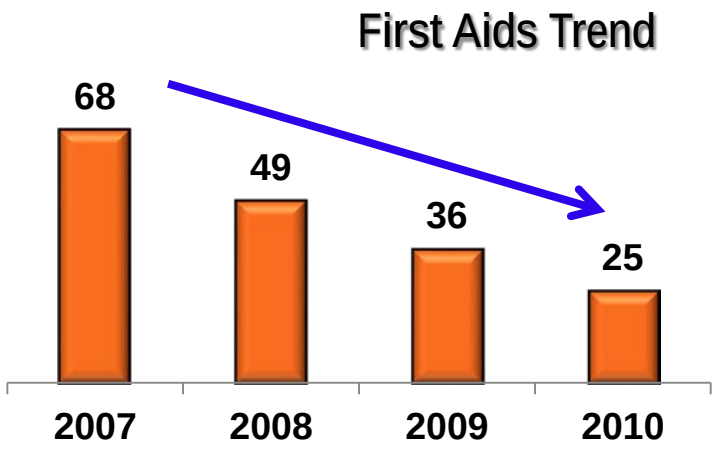
LABORATORY SAFE WORK PRACTICES (LSWP)



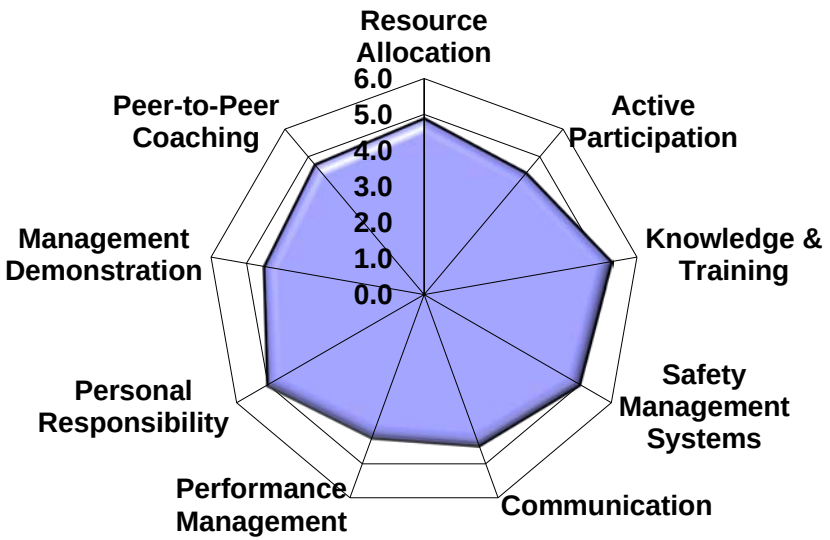
LABORATORY SAFE WORK PRACTICES

IS MY PROGRAM EFFECTIVE?

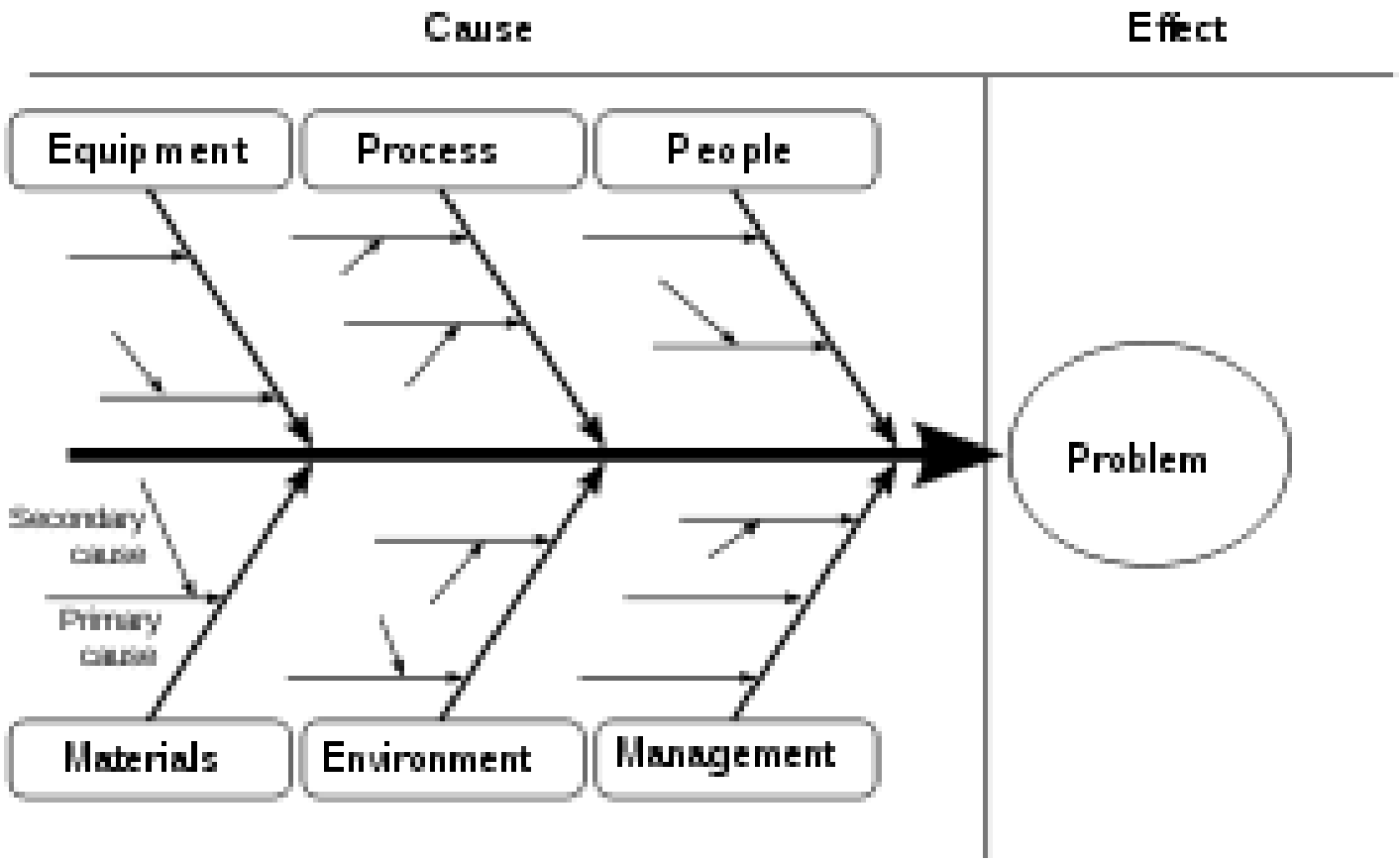
- Measure (incident rates, trends)
- Assess (people participation, unsafe conditions and near misses)
- Review & Update



"You get what you measure, not what you expect."



Incident Analysis



IS AN OBJECTIVE ANALYSIS…

Glassware Incident

Fact: Accidents involving glassware are the leading cause of lab injuries

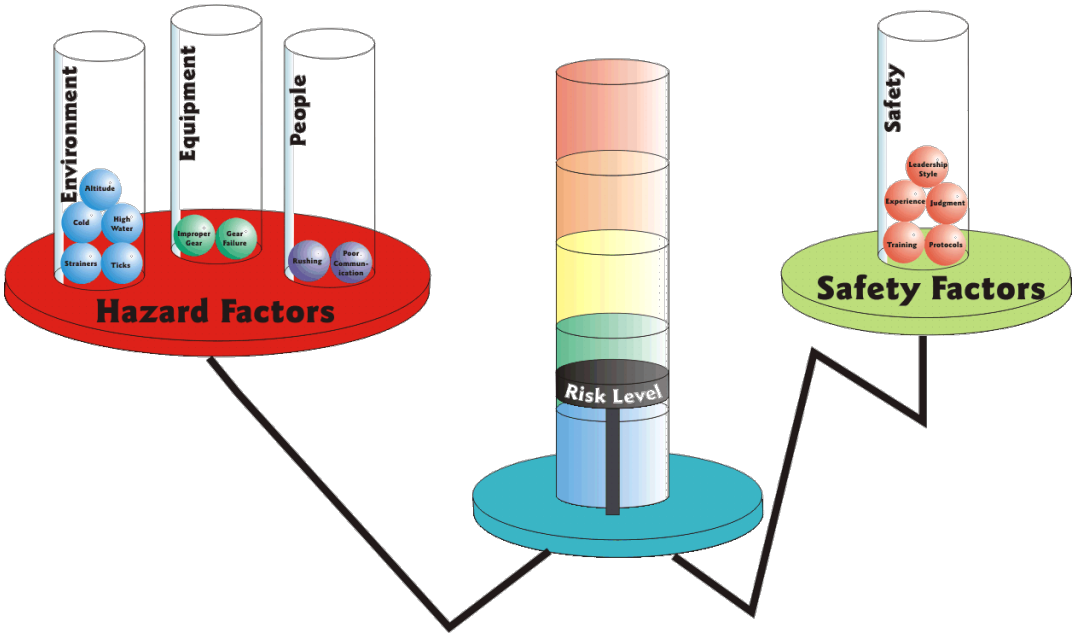
LABORATORY SAFE WORK PRACTICES

CHEMICAL STORAGE ASSESSMENTS

HAZARDS VS. RISKS

- Hazard– the capacity to cause adverse health effects, an inherent property.
- Risk– the probability of such effects occur do to exposure.

"Everything we do exposes us to hazards. However, it is HOW we do things that determines the risk."



HAZARDS VS. RISKS

WHAT AREA LAB HAZARDS?

- Chemical
- Physical (noise, vibration, temperature, pressure)
- Biological (biohazardous agents and microorganism)
- Mechanical
- Radiation (X,α, β rays, atomic particles, lasers, microwaves, UV, IR)
- Electrical
- Stress

HAZARDS VS. RISKS

DEFINING RISK LEVEL

- Risk Assessment is…
  - Evaluation of Exposure Potential, Reactions, Equipment and Handling Requirements
- Risk = **(Probability of Harm)** X **(Severity of Consequences)**

HIGH
MEDIUM
LOW

- Factors affecting risk:
  - Route of exposure
  - Physical properties
  - Operations and handling scenario
  - Controls
  - Human variability
  - Pre-existing Conditions

RISK ASSESSMENT

"LABORATORY ENVIRONMENTS ARE UNDERGOING CONTINUOUS CHANGES"

PREHS

RISK ASSESSMENT

What is a risk assessment?

Risk assessment is the process where you:

- Identify hazards,
- Analyze or evaluate the risk associated with that hazard, and
- Determine appropriate ways to eliminate or control the hazard.

RISK ASSESSMENT

- Catastrophic events do not occur only if the Threshold Quantity are exceeded

- Example PS threshold quantity in pounds for highly hazardous materials:

  Acetaldehyde 2,500

  Ammonia, Anhydrous 10,000

  Ethylene Oxide 5,000

  Formaldehyde (Formalin) 1000

  Sulfur Pentafluoride 250

  Sulfur Tetrafluoride 250

  Thionyl Chloride 250 (Water Reactive Material)

BC STUDENT HURT IN LAB ACCIDENT
June 26, 2011
Globe Correspondents

A Boston College chemistry student was injured when **a beaker exploded** during an experiment yesterday morning, cutting her face and **forcing the evacuation of Merkert Chemistry Center**, officials said.
The chemistry student was working alone in the lab with a small amount of **thionyl chloride**, a substance commonly used in organic chemistry experiments, when it exploded, according to fire department spokesman Steve MacDonald.
The student received cuts on her face and minor burns on her hands.

RISK ASSESSMENT

- **Do we understand the Reactive Chemistry Hazards?**

RISK ASSESSMENT

Explosion due to Hydrogen tank left open and explosive limits exceed. H2 was used to supply an anaerobic hood.

RISK ASSESSMENT
CONSIDER OVEREXPOSURE

- **In 2008 two fatal events related to TrimethylSilyl Diazomethane (TMSD):**

-New Jersey lab worker dropped a container of TMSD and spilled on his clothing. Person died in hospital due to a "massive“ pulmonary edema.

-Nova Scotia, Lab worker was exposed to fumes of while conducting a d-malic acid tests developing breathing problems and died 18 hours later.

FACT: Before the incident no clear warning in the MSDS about risk of pulmonary edema

RISK ASSESSMENT
IS REALLY THE QUANTITY AN ISSUE?

Fact: Handling of 2 ounces of T-butyl Lithium kill a lab worker in 2009 at California

Causes:

- Human Errors: No using PPE, Delayed response by nervousness.

- Management Errors:
  - Poor training
  - Poor technique
  - Lack of Supervision
  - Improper Method
  - *No clear procedures for pyrophoric compounds
  - Previous safety inspections not corrected

References: Memorial Wall - The Laboratory Safety Institute.htm
H2Incidents Settings–Laboratory.htm

RISK ASSESSMENT
OCCUPATIONAL EXPOSURE LIMIT ANALYSIS

29 CFR 1910.1000- Air Contaminants

Table Z-1

Sulfuric Acid: 1mg/m³

Nitric Acid: 2 ppm

Chloroform: (C) 50 ppm

Table Z-2: Toluene

8hr TWA: 100 ppm

Ceiling: 200 ppm

Peak: 500 ppm for 10 min.

Specific OSHA Standards

Ethylene Oxide 1910.1047- 8hr TWA: 1 ppm, Action Level: 0.5 ppm, Excursion Limit: 5 ppm

Formaldehyde 1910.1040- 8hr TWA: 0.75 ppm, Action Level: 0.5 ppm, Excursion Limit: 2 ppm

Methylene Chloride 1910.1052- 8hr TWA: 25 ppm, Action Level: 12.5 ppm, Excursion Limit: 125 ppm

RISK ASSESSMENT

Occupational Exposure Limits / PFIZER

There are many dangerous substances for which there are no formal occupational exposure limits. In these cases, **CONTROL BANDING** strategies can be used to ensure safe handling.

Property Airborne Level Equivalency (µg/m^3) or OEL range	OEB 1 >1000 ug/m^3	OEB 2 100-1000 ug/m^3	OEB 3 10-100 ug/m^3	OEB 4 1-10 ug/m^3	OEB 5 <1 ug/m^3
Potency (mg)	> 500	50 – 500	5 – 50	5 – 0.5	< 0.5

RISK ASSESSMENT
Pfizer Exposure Control Practices & Handling Guidelines

Default Compound Handling Guidelines (Laboratory Scale)					
Goal: To minimize potential exposures to Discovery compounds (solids) of unknown hazard, primarily through engineering controls; and also to minimize potential contamination of the laboratory. **These guidelines provide only general information regarding the minimum requirements for employee protection during most procedures. Department SOPs for specific procedures are strongly recommended**.					
General Expectations	**Engineering Controls – General Ventilation**	**Engineering Controls – Fume Hoods, Local Exhaust Ventilation, Vented weighing stations**	**Administrative Controls**	**Personal Protective Equipment**	**Decontamination**
• No open handling on bench	• No air recirculation permitted. • Air flow in work area must be negative to surrounding area	• Dry material must be handled in a vented containment hood or equivalent. • Containment device must be verified as operational prior to use. • Certification sticker on device must be valid. • All unnecessary equipment in containment device must be removed to encourage best performance of device	• Minimize traffic through designated work area(s). • Clean up spills immediately. Work surfaces must be cleaned of any visible residue at completion of task. • Keep work area free of visible contamination at all times. • Secondary containment is required during transportation of the compound.	• Eye protection, lab coat or disposable lab coat • Gloves • Tyvek sleeves, if appropriate	• Equipment exteriors mustbe visually clean of product residue after use. • Any tools, exposed equipment or work area surfaces must be cleaned with damp cloth immediately after use to avoid spread of contamination. • Reusable PPE must be visibly clean; • Disposable PPE must be disposed of after each use or completion of unit operation. • Wash hands and any exposed skin after removal of PPE

PONTENT COMPOUND HANDLING AT PFIZER

RISK ASSESSMENT
IMPORTANT ELEMENTS

- **Hazard Analysis / Methodologies**
  - **What –If**
  - **Checklist**
  - **What-If/ Checklist**
  - **Hazard and Operability Study (HAZOP)**
  - **Failure Mode and Effects Analysis (FMEA)**
  - **Fault Tree Analysis**
- **Pre-Start-Up and Modifications Safety Review**
- **Mechanical Integrity**

RISK ASSESSMENT
MECHANICAL STRESS

- Is you lab equipment reliable?
- Do you have a Preventive Maintenance Program in place?

PFIZER LABORATORY SAFETY INITIATIVES

NEAR MISS COMMUNICATION

Description of near miss:

A “T connect” on an Argon Gas pipeline in a laboratory burst. The noise was heard throughout the room

Contributing & Root Causes:

The argon pipeline was designed for 12 bar, but received a pressure of 22 bar.

1° why: Gas pressure that broke the T connect;

2° why: The first stage reducer did not regulate the pressure as set.

3° why: The shutter control was damaged.

4° why: The sealing of the shutter was not acting in the minimum flow to maintain pressure causing leakage at low/zero flow rates.

Gas reducer dissembled to verify the components

Corrective / Preventive Actions:

- Replacement of the pressure reducer.
- Installation of a second safety valve on the Argon pipeline.
- Verification of all the pressure regulators on lab gas lines.
- Installation of a second safety valve on the other gas lines.

HIGH REACTIVE CHEMICALS SPECIFIC TRAINING

CHEMICAL STORAGE/CONTAINMENT

3R: Review, Revise, Reinforce
Remember Peroxides forming compounds

VOLATILE CHEMICALS STORAGE

- Volatile materials (ether, hydrocarbons) must be stored in an explosion-proof refrigerator.
- The thermostat switch or light switch in a standard refrigerator may spark and with the fumes inside may explode.
- Local fire code requires that vents in the cabinets should be connected into a fume hood that runs continuously, or into a ventilation system designed specifically for the purpose, or should be kept plugged.

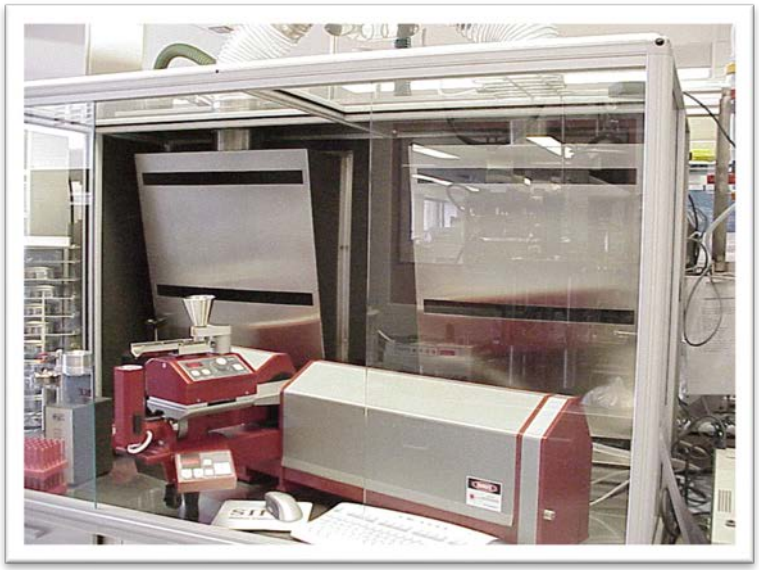
WASTE CONTAINER CONTROLS

Phase 1: Safety Waste Funnels

Phase 2: Exhaust Ventilation

Vapors Control for HPLCs

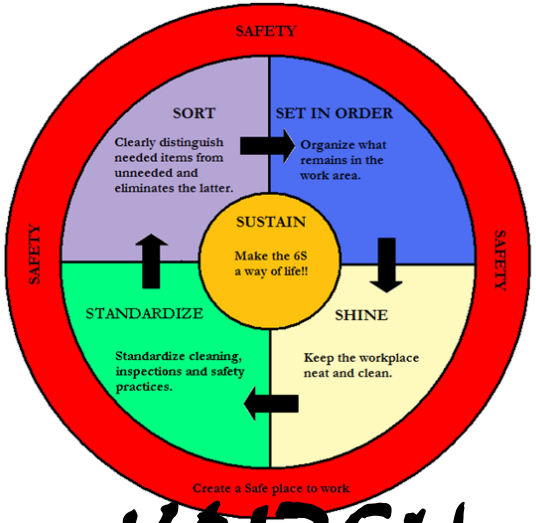
Engineering Controls



Lean Six Sigma / Kaizen: Laboratory Initiatives

- **Transformation drivers:**
  - Automation
  - Organization
  - Standardization
  - Simplification
  - Efficiency
  - Cost improvement

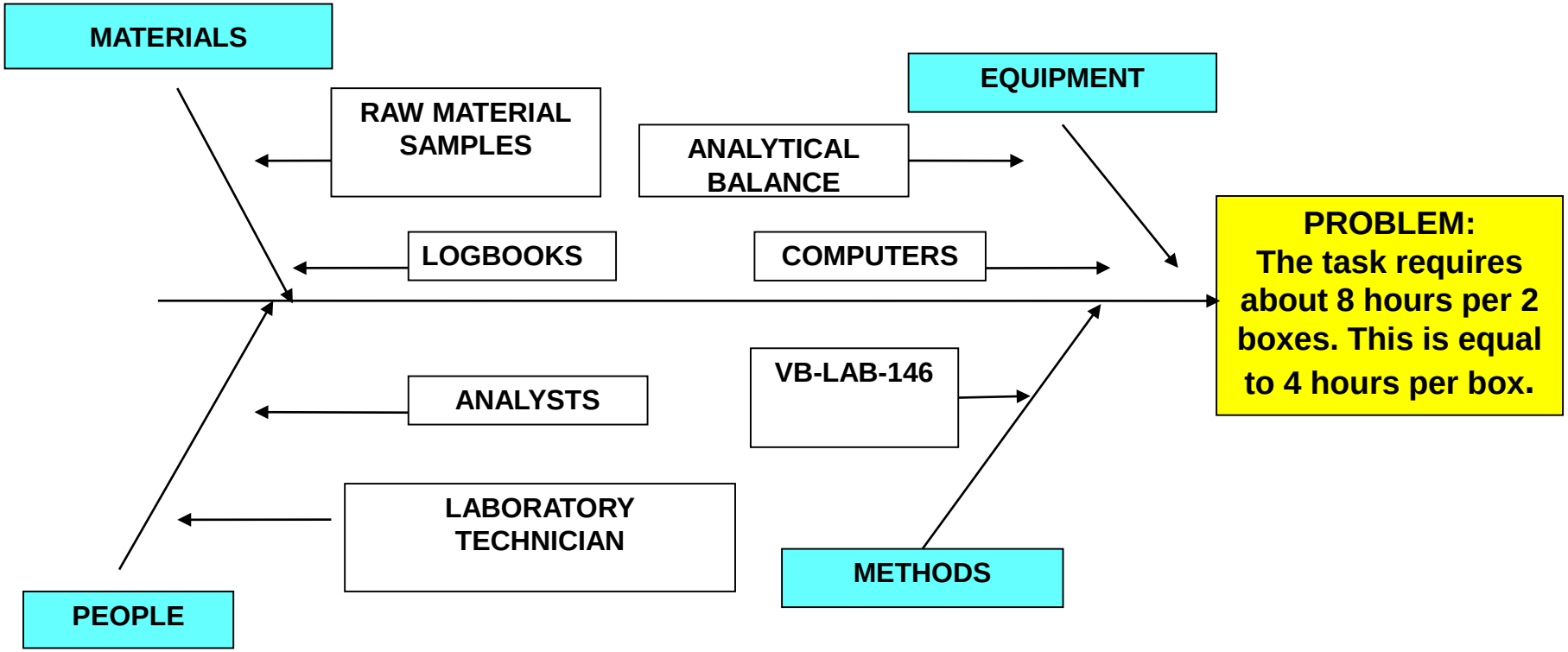
- Lean/six sigma projects:
  - Lab Optimization: Reduction of waste and increase speed of lab activities.
  - Lab re-organization based on analysis complexity.
  - Analyses Rationalization (First level of Lean lab house).



KAIZEN

EMBRACE LEAN INITIATIVES

Raw Material Samples Disposition Time Reduction Project



Results: Increased efficiency, reduction by half of the time required for Raw Material Samples Disposition.

KAIZEN: 6S LABORATORY PROJECTS

	Chromatography/Spectroscopy
	Sample Preparation
	Glassware
	Equipment Position/Parts
	General
	Documentation Area
	Safety
	Office Supplies
	Metrics

Before

After

6S LABORATORY PROJECTS

PREHS

6S LABORATORY PROJECTS

Before

After

PFIZER SITUATIONAL AWARENESS

Ask
3 Questions

Take
Action

1. **What am I doing?**
   - **Be mindful of the environmental conditions surrounding the activity.**

2. **How can I be injured?**
   - **Think about the future situation.**

3. **What can I do to prevent injury?**
   - **Take action to prevent an injury from occurring.**

Injury Free – Easy as 1, 2, 3

PREHS

PEOPLE PARTICIPATION / RISK IDENTIFICATION

Pfizer

Dímelo

Tarjeta de Observación de Condiciones Inseguras

Fecha: _____ Observador: _____

Departamento: _____ Tipo de Observación: ☐ EHS ☐ GMP ☐ SECURITY

Describa la situación o condición insegura:

_____

_____

_____

Describa la acción inmediata tomada o recomendación para solucionarla:

_____

_____

Instrucciones:
En las áreas que hayan "Visual Boards" las tarjetas deben ser llenadas y dejadas en las mismas para ser recogidas por el "EHS Rep". En otras áreas, las mismas pueden entregarse al "EHS Rep", a un integrante de EHS. Puede utilizar la versión electrónica localizada en la siguiente dirección: http://pgmsharepoint.pfizer.com/region/PR/PREHS/Vega%20Baja1/Dimelo-Forma.xsn

PREHS

Our priority is to provide a safe and healthy work environment for every Pfizer colleague, contractor, and visitor, and for the communities where we work and live.

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