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The Value of an EHS Management of Change Process

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Agenda



- ▶ MOC Process Rationale, Definitions, Principles
- ▶ Real Life Scenarios
- ▶ MOC Types and Workflow
- ▶ Introducing Chemicals, Processes, Equipment, Personnel
- ▶ EHS MOC Process Examples
- ▶ Conducting an EHS Review: 10 Simple Steps
- ▶ Levels of Change - Examples
- ▶ Key MOC Processes, Tools, Learnings, Benefits

Why Manage Change?

- ▶ **Uncontrolled change** is a frequent contributor to incidents, and can result in injury to personnel, damage to the environment, and loss of quality.
- ▶ **Managing change** is essential to maintaining and improving the EHS controls of existing operations, and for the safe startup and operation of a new process or facility.

Management of Change (MOC)

▶ Management of Change (MOC) Process

- ▶ A system to assess and address the EHS impacts of change to a process, equipment, facilities, procedure, personnel or organization, **before the changes are made.**

▶ Key Principles

- Every change must be managed
- Changes must not be made without an appropriate review
- The type of review should be consistent with the complexity of the change
- MOC system should be simple to use

Scenario - Polymerization Example



July 20, 1988: Tank-car of acid-washed MAA polymerized violently in Houston rail yard. MAA put in car had low inhibitor. Car was stainless, not normal lined car for this grade. H_2SO_4 reacted with car walls.

Waste Water Tank *Flashback*

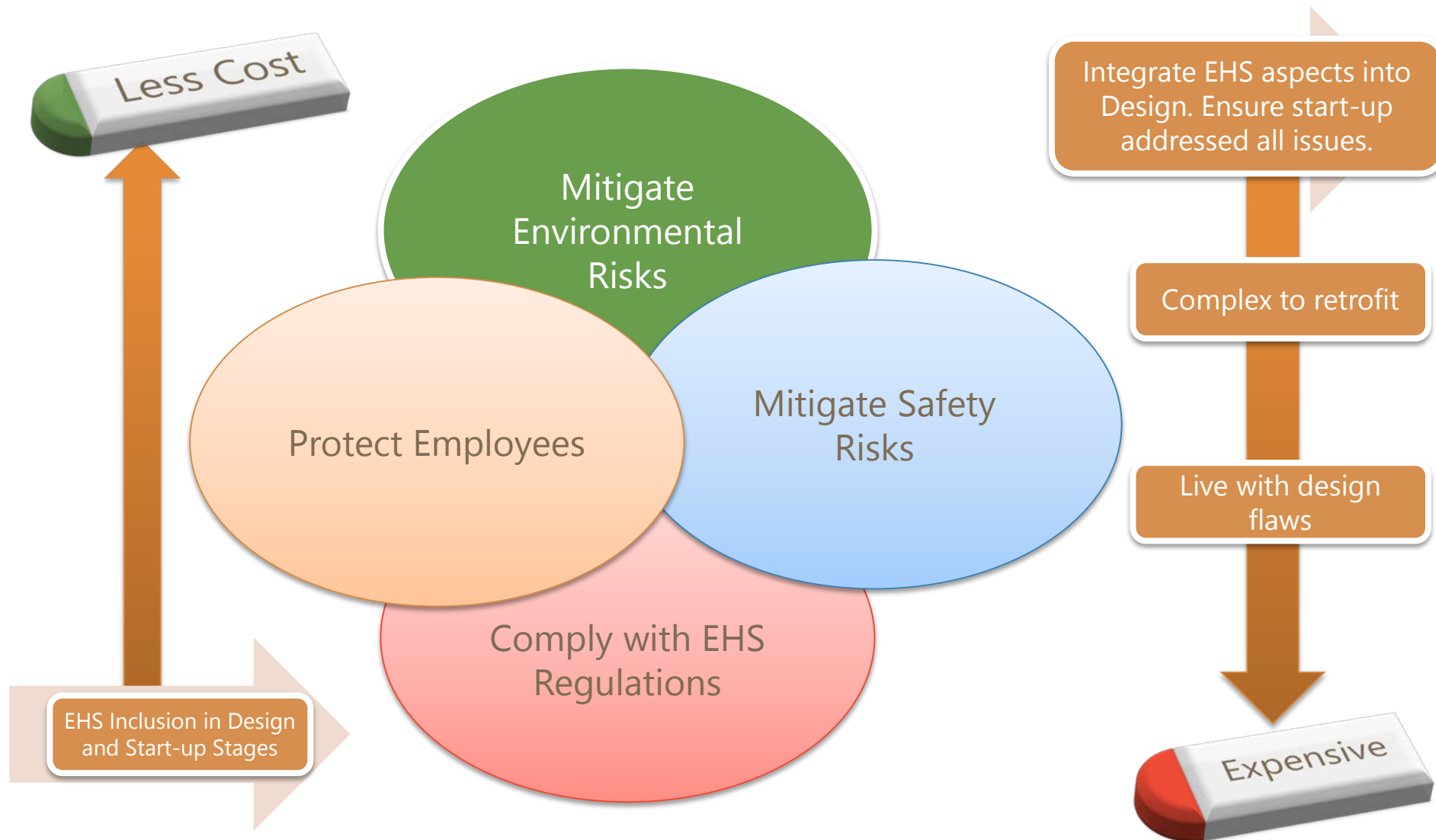


1988: Organic layer floating on water in tank. Tank draining to sewer trench. Welding overhead. Tank emptied. Welding spark to trench. Flashback into tank. Tank launched and turned upside down.

Other Real Life Scenarios

- ▶ New -80C freezer requires 208V
- ▶ Ammonia added to 4L DCM bottle
- ▶ Ventilated enclosure installation
- ▶ Switched HPLC solvent to DMF
- ▶ Filtering “non-hazardous” product
- ▶ Sub-contractor pouring wet cement
- ▶ Runaway glacial acrylic acid polymerization
- ▶ Heptane tanktruck explosion
- ▶ Employee sprayed with hot 3,4-dichloropropionanilide

Why EHS inclusion is essential in both the design and start-up stages?



MOC Types and Workflow

- ▶ MOC Process needs to address Permanent, Temporary, Emergency Changes
- ▶ Description, Justification, Impact on EHS
 - What, Where, When, Who, and Why?
- ▶ Initiating Changes:
 - Reduce the risk of unintended consequences due to change
 - Seek and maintain records of technical and financial input to a change
 - Provide visibility to changes being planned or already underway
- ▶ Approving Changes
 - Review the change request to gain an understanding of the proposed change and its impacts
 - Indicate what changes to the initial request are necessary, if any, in order for the change request to be approved
 - Indicate support for proceeding with the proposed change

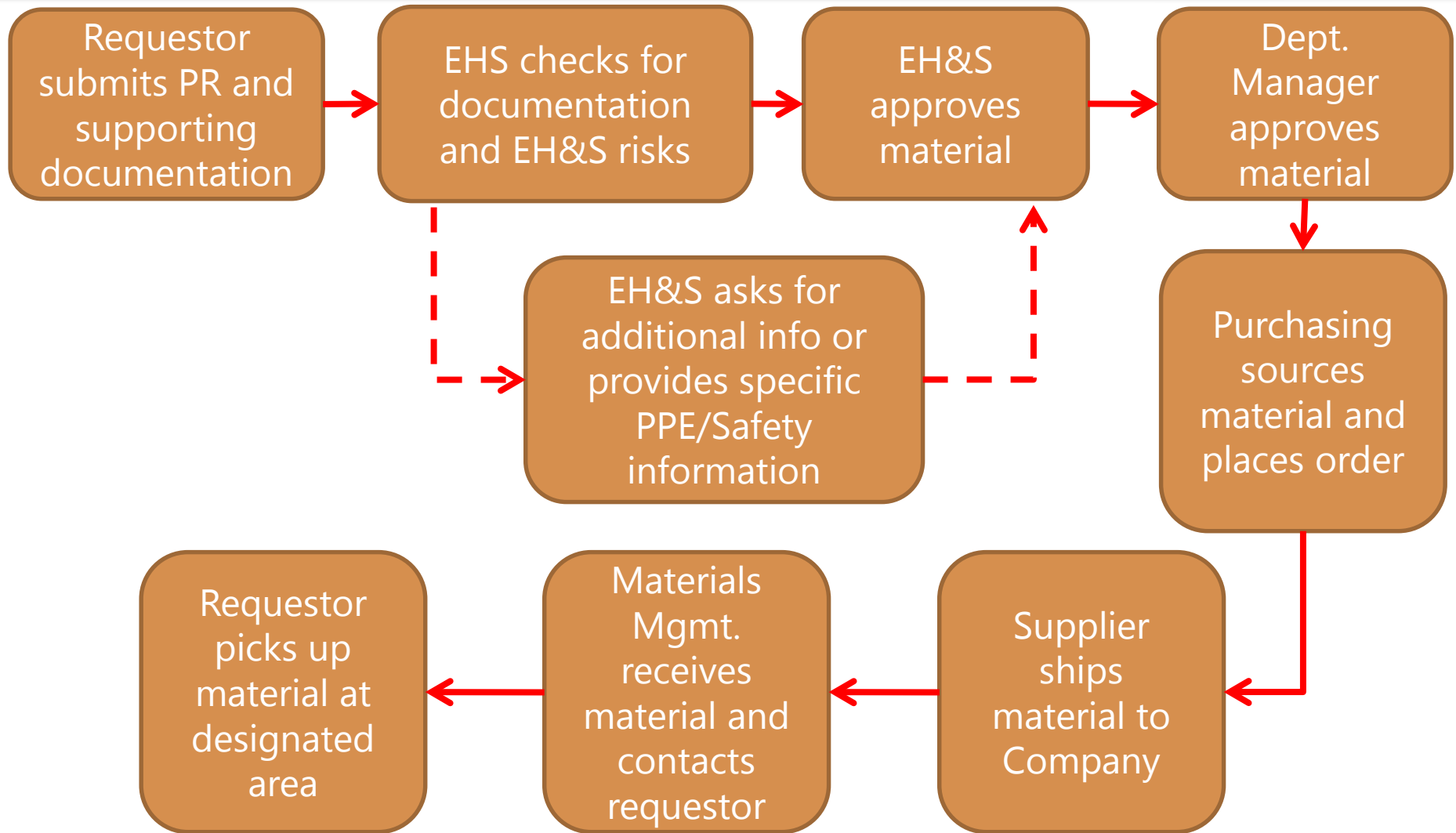
Introducing a New Chemical

- ▶ Hazardous Material Business Plan updated?
- ▶ Which work areas/employees will be handling this material?
- ▶ What other employees might be affected (e.g. maintenance, waste handlers)
- ▶ Safety Data Sheet?
- ▶ New Hazards Presented?
- ▶ OSHA regulations? Fire Code? OELs? Monitoring method? Exposure potential?
- ▶ How will chemical be stored and used?
- ▶ Training?
- ▶ Medical surveillance?
- ▶ Engineering controls? PPE? Respiratory Protection?
- ▶ Waste Stream?

Example: Ordering Chemicals

- ▶ How does the ordering process work?
- ▶ New material or used before? Any adverse incidents or institutional knowledge that needs to be integrated?
- ▶ What documentation is needed and how do I find it?
- ▶ How much do I need to order?
- ▶ Is there sufficient storage space?
- ▶ Do we have a waste stream designated?
- ▶ What do I do if there is a spill of this material?

Example of how this process work?



MOC Example: Introducing an Active Pharmaceutical Ingredient into R&D

- ▶ Proactive Quarterly Dept Mgr Meetings to anticipate and prepare for new API introductions
- ▶ Chemical Review and Approval Process
- ▶ Occupational Health Categorization (1-4); Default Cat - 3
- ▶ SOP, Training, Exposure Assessment, Engineering Controls
- ▶ Sample Shipment triggers SDS development
- ▶ Phase 2B Clinical Trials triggers OEL/Monitoring and Analytical Method Development

New Processes

- ▶ Major new installations or process changes involving hazardous chemicals. Examples: addition of a new reactor; addition of a new process that uses a hazardous chemical.
- ▶ Requires HAZOP and formal EHS reviews in design, construction and before startup.

Introducing a New Process

- ▶ Batch or continuous process?
- ▶ Operating pressures/temperatures?
- ▶ Exothermic reaction steps?
- ▶ Process flow?
- ▶ Charging/removing materials from containment?
- ▶ Open handling vs closed system?
- ▶ Materials of construction?
- ▶ Process hazard analysis?

Introducing New Equipment

- ▶ Robotic?
- ▶ Ergonomics?
- ▶ What materials will be in contact with equipment?
- ▶ Magnetic fields?
- ▶ Ionizing or non-ionizing radiation?
- ▶ Exposed moving parts?
- ▶ Is noise generated?
- ▶ Air emissions?
- ▶ Waste generation?
- ▶ Access by maintenance staff for repairs, PM?

Introducing New Equipment

For New Construction, Renovations and Remodels:

- ▶ Storage, handling, release of potentially hazardous materials (chemical, biological, physical hazards)?
- ▶ Installation/removal of safety showers/eyewashes?
- ▶ Permit required confined spaces or machine guarding issues?
- ▶ Impacts on LEV or other control equipment?
- ▶ Wastewater discharge?
- ▶ Will project affect Life Safety issues?
 - Installation/modification of fire alarm or suppression systems
 - Installation of elevators or other lift devices
 - Change of egress routes, exit signage
 - Access/egress restrictions

Introducing New Personnel

- ▶ Essential experience, skillsets and training to do the job?
- ▶ Training curricula/assignments?
- ▶ Evacuation roster?
- ▶ Workstation ergonomics evaluation?
- ▶ Medical surveillance program?
- ▶ Respirator clearance and use?
- ▶ Prescription safety glasses?
- ▶ Clearly defined roles and responsibilities?

Example of an MOC Process – Before Change Happens

- Identify the level of change and type of review needed
- Gather the information needed to identify hazards
- Gather the people needed for the review
- Include additional internal or external experts if needed
- Conduct the EHS review
- Classify actions by priority
- Assign responsibilities and due dates for actions
- Follow-up on actions
- Document actions to closure

Levels of Change - Examples

▶ **Identical Change**

- Same material, same quality, same concentration, same everything

▶ **Like for Like (Replacement in Kind)**

- Same material, same quality, same concentration, almost same everything, exception, ex. different supplier

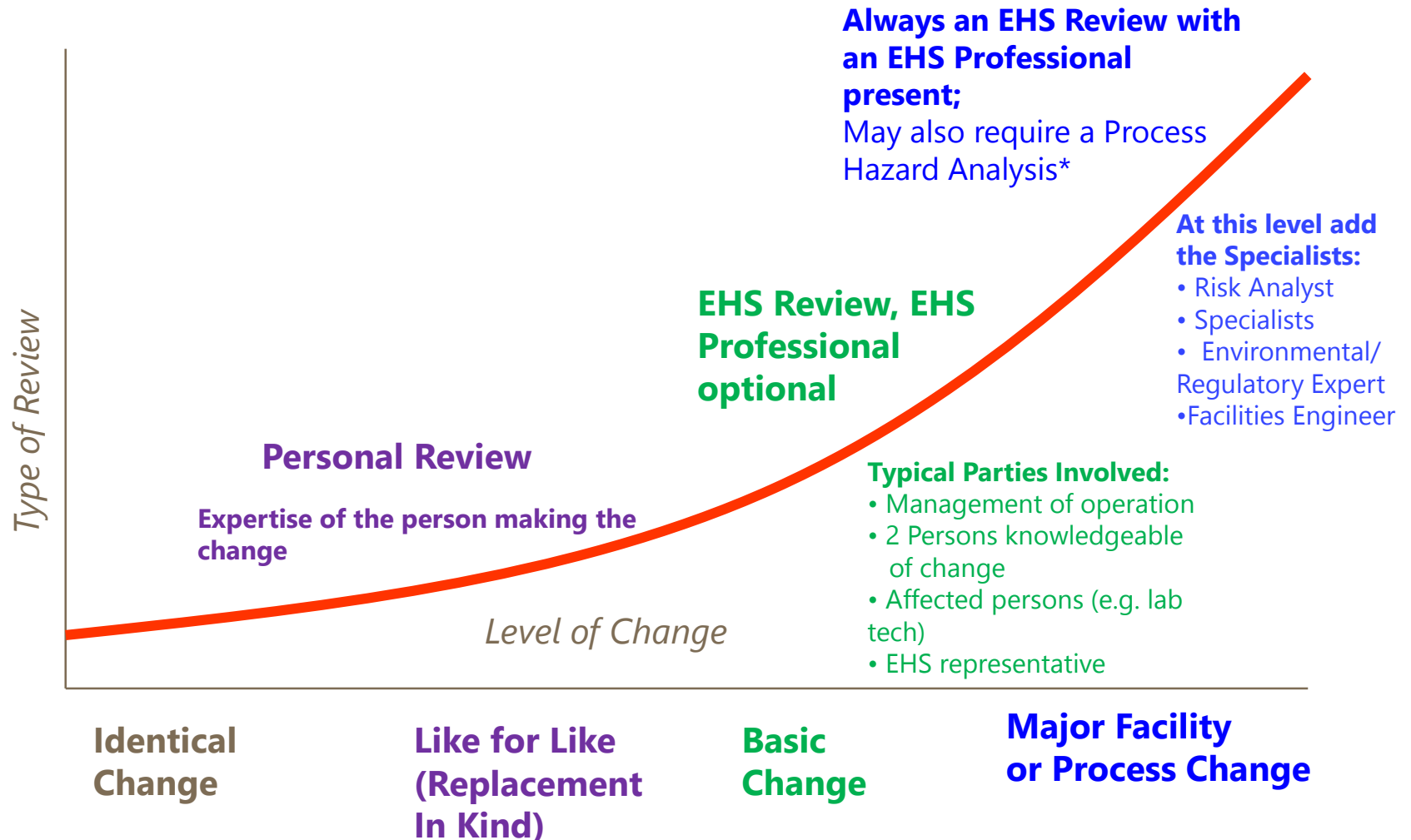
▶ **Basic Change**

- Same or different material, same quality, different concentration outside the scope of the original review

▶ **Major Change**

- New or unfamiliar material or equipment where no review has been conducted

Example of How EHS Reviews Match the Complexity of Change



Personal EHS Review - Example

- ▶ **The personal EHS review is used when you are making an identical substitution. Verify that nothing is being changed.**
- ▶ **Documentation:** none required
- ▶ **People involved:** the person making the substitution

Simple EHS Review - Example

- ▶ **Documentation:** recommended but not required
- ▶ **People involved:** the person who knows about the effects of the change, and the owner of the equipment. Always have two areas of responsibility involved.
- ▶ **The simple EHS review is used when you are making the same general type of substitution, but not an identical substitution.**

Formal EHS Review - Example

- ▶ **The formal EHS review is used when you are making a basic change and when introducing new processes.**
- ▶ **Documentation:** minutes from the formal EHS meeting and action points.
- ▶ **People involved:**
 - Originator of the change,
 - Person(s) who will be affected by the change;
 - Person who knows about the effects of the change;
 - Management representative from the area that is affected;
 - EHS representative;
 - Person who will maintain the equipment.

Formal EHS Review - Example

- ▶ Designed to identify, evaluate and eliminate potential hazards by people who understand the hazards and necessary safeguards for the change
- ▶ Proposed change meets the criteria for Basic Change or Major Process or Facility Change
- ▶ Meeting with department management designee and personnel responsible for proposed change, affected personnel, EHS Professional
- ▶ Documentation is required
 - Classify actions by priority
 - Assign responsibilities and due dates for actions
 - Follow-up on actions
 - Document actions to closure

PHA/HAZOP Review - Example

- ▶ **The PHA/HAZOP review is used when you are adding a major new facility or new processes**
- ▶ **Documentation:** minutes from the PHA/HAZOP meeting, action points and changes to P&ID's.
- ▶ **People involved:** a PHA/HAZOP expert is the leader, and the team is made up of site personnel including those affected by the changes being considered.

Major Accident Prevention Plan Study

- ▶ **A MAPP study is performed for process changes and new processes involving bulk chemical quantities above the minimum storage amounts.**
- ▶ **Documentation:** minutes and action points from the MAPP study.
- ▶ **People involved:** a MAPP expert is the leader, and the team is made up of site personnel.

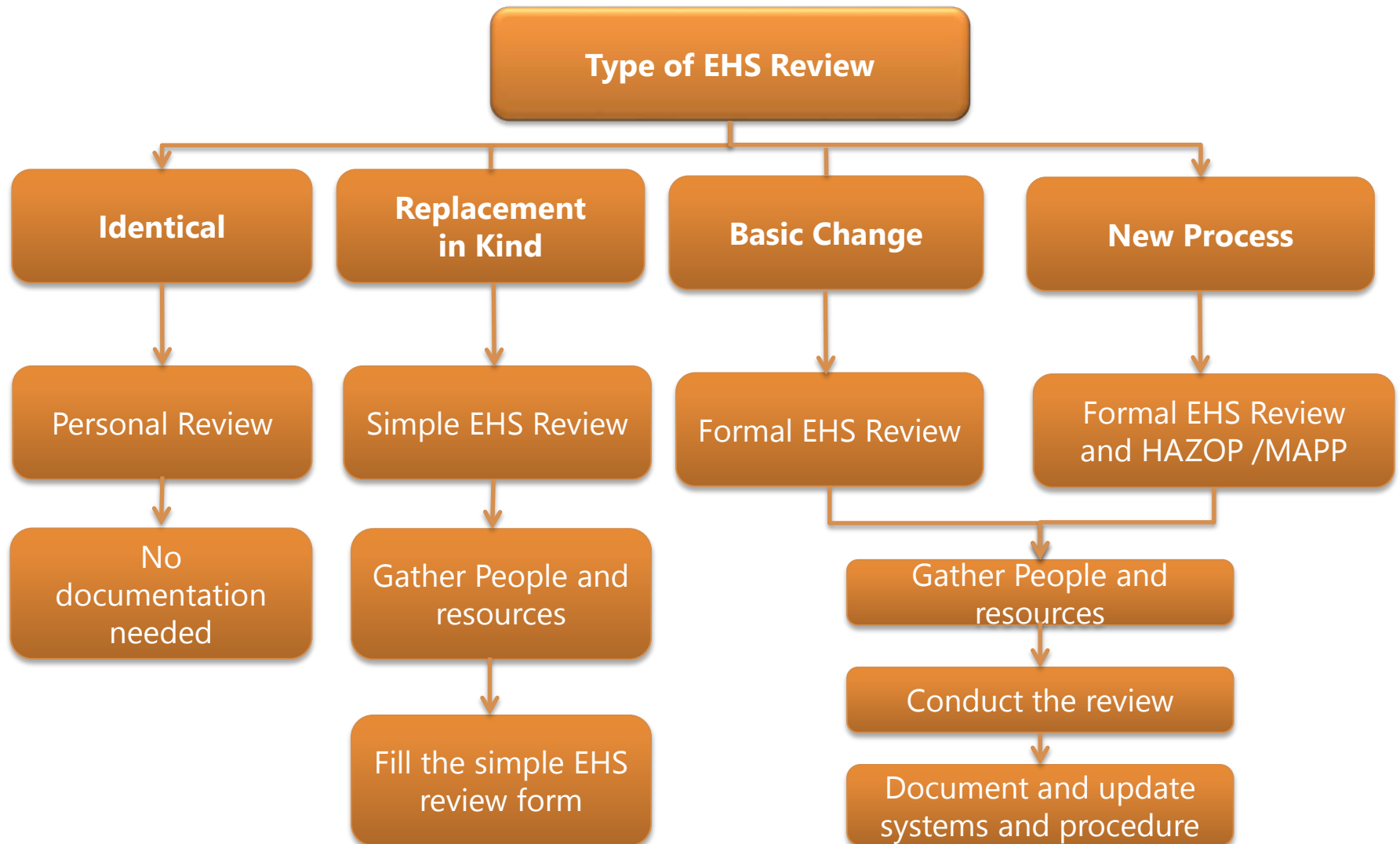
Example of Conducting an EHS Review: 10 Simple Steps

1. Select a **leader**. This is usually the person who initiated or knows the most about the change.
2. Appoint someone to take **meeting minutes**.
3. Agree on the **purpose** of the EHS Review.
4. Define **scope and explain** the proposed change.
5. If appropriate, **review flow sheets, plans or other drawings** that shows the change being proposed.
6. If appropriate, **visit the location** of the change and review each part of the change.

Example of Conducting an EHS Review: 10 Simple Steps

7. People **ask questions** to understand the change and discuss the EHS aspects and **potential impacts** of the change. At this point, it is useful to use an EHS review **checklist**.
8. During the review, the person taking notes **records action items**.
9. After visiting the location of the change, the people return to the meeting room. They review the action points and **assign completion dates, priorities and responsibilities** for the action points.
10. A system is used to **track action points to closure**. The EHS review is finished when all action items have been closed.

EHS Review Summary



Key Management of Change Processes

▶ **Chemical Review and Approval Process**

- In the Pharma World this would include APIs, Biologics and Chemicals

▶ **Capital Requests – EHS Review**

- new project/ new equipment \geq \$5000

▶ **Employee On-boarding/Off-boarding**

- Training, ergonomics assessments, facility access/security, risk assessments, medical surveillance

▶ **Workflows and Approvals for New Equipment Design and Start-up Reviews**

▶ **Technology Transfer between sites/partners**

▶ **Emergency Changes – Non-Routine Tasks!**

▶ **Process Hazard Analyses**

Key MOC Tools and Learnings

- ▶ EHS Management of Change SOP
- ▶ Training on MOC Processes
- ▶ Proactive Quarterly Dept. Meetings with EHS, Facilities and Affected Department Managers
- ▶ Defining Acceptable Process Parameters/Boundaries beyond which the MOC Process is triggered
- ▶ Leveraging Software Tools

Management of Change Benefits

- ▶ **Involves affected employees** - *Two heads are better than one*
- ▶ **Identifies:**
 - Hazards before they become incidents
 - Problems when they are least expensive to fix
 - Safeguards and actions to reduce risk
 - Training and procedures that are needed
- ▶ **Reduces risk of:**
 - Injuries and illnesses
 - Environmental spills and releases
 - Catastrophic events (e.g. fire / explosion)
- ▶ **Confirms *built-as-designed*, avoids rework, and verifies EHS requirements for safe operations**

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*Thank
you*

