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| Eli Lilly and Company |
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| **Document Number:** **GPME-SOP-SAF-CPHP-1017** |
| **Category: Industrial Safety** |
| **Name: Catastrophic Potential Hazards Program** |

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| Title | Catastrophic Potential Hazards Program |

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| Procedure number | GPME-SOP-SAF-CPHP-1017 |

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| Purpose | This program identifies requirements that protect operations and maintenance employees working in areas with catastrophic potential hazards (CPH). |

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| Scope | This program applies to the following groups of employees, who operate or maintain catastrophic potential hazards processes;   1. Lilly site employees 2. Integrated Facilities Management Provider (IFMP) employees 3. Contract firms supervised by Lilly personnel on a daily basis (Temporary (D62) Contract Workers) 4. Outsourced (D63) contractors 5. Independent (D61) contractors. |

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| Areas impacted | This program covers all site facilities. |

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| Reason for Revision | This document has been revised for:   * Section 1.4: Add Qualitative Risk Evaluation * Section 2.5 and 4.2: For CPH assessment, use Guideline and tools to track action plans. |

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| Acronyms | Terms specific to this document:   * OHS – Occupational Health and Safety * OSHA – Occupational Safety and Health Administration |

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# Definitions

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| Catastrophic Consequences | The potential harm to people, property, community, or the environment that includes death, permanent disabling injuries, significant physical damage, huge economic loss, or severe long-term effects caused by the loss of containment of highly hazardous chemicals/materials from a process or from natural disasters. |
| Catastrophic Potential Hazards (CPH) Process | Physical and Chemical operations that potentially have 3-4 Catastrophic Consequences of Interest, as identified by the Lilly Catastrophic Hazard Identification Tool. (e.g. Steam Letdown Stations, Dust Collectors, Ozone Generators, Flammable Waste Solvent, etc.) |
| Personal Injury hazards (Chemical or Energy Release) Catastrophic Consequence of Interest | Lilly onsite Employee - Permanent Disabling Injury/ Fatality  &/or  External Injury or Fatality |
| Environmental hazards (Air, Water, Waste, Soil) Catastrophic Consequence of Interest | Environmental Damage – Onsite or Offsite – Acute or Toxic  or  Offsite Evacuation/ Offsite Shelter in Place/ Offsite Property Damage |
| Financial hazards Catastrophic Consequence of Interest | Revenue Loss/ Business Interruption  or  Onsite Assets/ Property Damage  or  Reputation & Fines/ Regulatory Action &/ Adverse Publicity |
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## APPLICABILITY

* 1. Each business area must determine if any process/operation (routine and non-routine) has hazards that could lead to potential Catastrophic Consequences. Evaluation shall be determined by completing the Lilly Catastrophic Hazard Identification Tool.
  2. Conformance to requirements in this program is required for:
     + - New equipment, existing equipment, facilities, or utilities that are designed after the effective date of this program, with the potential for catastrophic hazards.
       - Introduction of new products (or processes) into existing equipment or facilities with the potential for catastrophic hazards, when conformance is warranted, based upon a risk assessment or is required by local regulations.
       - Modifications and/or subsequent changes to these systems (based upon a risk assessment).
  3. Catastrophic Potential Hazards processes shall be:
* Declared and documented as an aspect on the HSE Management System collabsite
* Documented in Lilly Catastrophic Hazard Identification Tool documents, located in the Process Safety Management or various HSE Support Services Steering Team collabsites
* Boundaries and process descriptions are documented in the PSM and CPH Applicability Declaration document, located in the CPH collabsite.
  1. A Qualitative Risk Evaluation shall be used to determine priority for CPH Assessments, (an optional template is available in the CPH Assessment Guideline) based as a minimum on the following criteria;
* Process Safety Information (PSI) in place and available
* CPH Assessments/ Process Hazard Reviews completed and recommendations resolved
* Chemical or Physical Hazards involved understood &/or communicated
* Procedures and Training for process in place and up to date
* Automated Control Systems in place and up to date
* A Maintenance List in place and up to date for CPH equipment (see 4.1)
* Upcoming major Projects/ Changes being planned requiring analysis
* Lessons Learned from Events in similar processes (External or Lilly)

## CPH Assessment

2.1 A CPH Assessment must be performed and revalidated at least every 8 years for CPH processes, that have been determined to have at least 3 catastrophic consequences of interest. Note; CPH Assessments are intended to drive PSI packages, Procedures, Training and Maintenance Lists. These may not be available until CPH Assessments are scheduled and/or completed.

2.2 A CPH assessment must identify hazards and propose recommendations that resolve the following Catastrophic Consequences of Interest:

1. Personal Injury hazards (Chemical or Energy Release)

2. Environmental hazards (Air, Water, Waste, Soil)

3. Financial hazards

2.3 The assessment must be performed by a team which at a minimum includes;

* an engineer/operations/maintenance person knowledgeable of the process and operations
* an additional operations/ maintenance person knowledgeable of the specific material &/or processing hazards
* an individual trained and familiar with performing risk assessments.

2.4 CPH assessments shall follow a recognized and generally accepted good engineering practice (i.e. PHR, LOPA, JSA, Dust Hazard Assessment, etc.), utilizing appropriate Process Safety Information pertinent to the process.

2.5 Recommendations and the action plans stemming from CPH assessments shall be reviewed and approved by management. Action plans shall be resolved and tracked to completion, using the CPH Assessment Guideline, located on the CPH collabsite.

2.6 Documentation for completed CPH Assessments (i.e. assessment documents, PSI, tracking documents, etc.) shall be located on the Process Safety Management or the HSE Support Services Steering Team or HSE Support Services Steering Team collabsites

## Training and Procedures

3.1 Upon completion of a CPH Assessment, Operating Procedures must address CPH processes catastrophic consequences of interest, where applicable.

3.2 Upon completion of a CPH Assessment, initial and refresher procedures training must be provided to employees, who operate CPH processes and their immediate supervision.

## Maintenance Strategy

4.1 Upon completion of a CPH Assessment, a list of PM’s with a short description of the PM, the frequency of the PM and the reason for the frequency (i.e. reliability data, Codes & Stds., Lilly MITI Guidelines, etc.) shall be created and kept on the PSM or Support Services or HSE Support Services collabsites. A Maintenance List template located on the CPH collabsite can be used.

4.2 Records of maintenance and repairs performed per Lilly record retention guidance shall be retained in GMARS databases for CPH processes.

## changes in CPH processes

When a process involving a CPH process is to be changed, including changes to materials, technology, equipment and procedures, the safety and environmental implications of the change shall be evaluated and approved prior to implementation of the change, utilizing Change Management Program, GPME-SOP-ADM-IN-CHGMGMT-3005.

## cPH Processes and investigations

If a HSE Level 2 or 3 event or a Level 2 Near Miss event occurs in a CPH process;

* a team-based root cause analysis (RCA) investigation must be initiated within 48 hours of the event, per Managing Health, Safety & Environmental Events Procedure, GPME-SOP--ADM-HSEEVENTS-6002
* the process where the event has occurred must not be restarted until the investigation has identified the root cause(s) and actions have been implemented to resolve the cause(s), unless authorized by the or P Director of the area.

# References and Approvals

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| **References** | * Eli Lilly HSE Management System Standard, HSE-STD-100 * Change Management Program, GPME-SOP-ADM-IN-CHGMGMT-3005 * Managing Health, Safety & Environmental Events Procedure, GPME-SOP--ADM-HSEEVENTS-6002 |

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| **Contacts** |  |

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| **Reviewers** | Reviewer completion of GPME-SOP-SAF-CPHP-1017 requires the signatures of:   * Consultant/ Associate Consultant, Health and Safety * Consultant/ Associate Consultant, Environmental |

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| **Approvals** | Approval of GPME-SOP-SAF-CPHP-1017 requires the signatures of:   * Manager, Health and Safety * Manager, Environmental |