

# PSCI - HSE Checklist

Status: Feb 2012

## for use with API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers

HSE = Health, Safety, Environment

TOPIC	Requirements
Basic Hygiene Practices	General hygiene practices with regard to smoking and eating at the workplace, washing hands, changing work clothes are implemented.
Basic Hygiene Practices	The work environment and equipment give an orderly and neat impression (good housekeeping practices are applied).
Basic Hygiene Practices	The organization has developed and implemented an action plan to ensure compliance with the requirements of the local legislation.
Carcinogen control program	A risk assessment has been completed for all activities with known human carcinogens on site.
Carcinogen control program	Exposure monitoring has been conducted for those employees identified by the risk assessment as having potential exposures for known human carcinogens.
Carcinogen control program	The results of the baseline sampling are used to develop an action plan to control exposure risks of known human carcinogens.
Chemical Hazard Assess & Communicat.	Employees receive general safety training related to chemicals (hazard symbols, basic physico chemical properties, link to health effects).
Chemical Hazard Assess & Communicat.	Employees received training in the hazards, handling, personal protective equipment (PPE), storage and disposal of chemicals and mixtures in their workplace or area. Specific focus is put on human carcinogens (if applicable) and API/IPI (active product ingredient/inactive product ingredient).
Chemical Hazard Assess & Communicat.	Safety Data Sheets (SDS) are available for chemicals and mixtures in use and stored.
Chemical Hazard Assess & Communicat.	Each chemical and mixture container (tank, drums, pail, bag, bottle, ...) has a label that identifies the contents and lists specific safety information (at least hazard symbols).
Chemical Hazard Assess & Communicat.	Each pipe is labeled with the chemical name of their content or identified by a site specific color code and the flow direction is indicated. Each dispensing valve dedicated to a chemical agent is labeled with the chemical name.
Chemical Hazard Assess & Communicat.	A formal procedure (process) must be in place to ensure that all new chemicals or mixtures are evaluated to their physical and health hazards before introduction on site (known human carcinogen, permit required, banned, explosive, impact on environment).
Chemical Hazard Assess & Communicat.	The organization has developed a process to assure proper storage of chemicals (incompatible chemicals, avoid contact water, temperature conditions, ventilation).
Chemical Hazard Assess & Communicat.	An inventory of chemicals and mixtures is available and up to date.
Chemical Hazard Assess & Communicat.	Employees are trained and know how to react in case of a chemical exposure with specific signs & symptoms (e.g., irritation eye or skin, burns, inhalation - difficult breathing).
Chemical Hazard Assess & Communicat.	A system is in place to periodically check if the safety data sheets (SDS) are still up to date.
Chemical Risk Assess & Exposure Monitoring	The organization has gathered all the information necessary to perform a detailed IH (industrial hygiene) theoretical risk assessment using the Risk Based Exposure Assessment Process methodology unless the organization can demonstrate this has been done by an equivalent methodology. Each activity with potential exposure to chemicals needs to be split up in basic steps. Each step needs to be evaluated as follows: - identification of the chemicals involved. For each chemical the following should be available: - the physical/chemical properties (operational exposure limits (OEL), routes of exposure, vapor pressure, dustiness, specific hazards e.g. known human carcinogens, very toxic compounds,...) - circumstances work conditions (quantity, aggregation, process conditions) - exposure controls (Containment technology, local exhaust ventilation (LEV), administrative controls).
Chemical Risk Assess & Exposure Monitoring	The organization has performed the IH (industrial hygiene) theoretical risk assessment for all the activities with potential exposure to chemicals. Exposure severity rating is defined for each activity without taking in consideration the use of personal protection equipment (PPE). If there is reason to believe that the exposure might exceed the operational exposure limit (OEL) then a quantitative risk assessment (monitoring) is required to determine the exposure levels and the subsequent controls.
Chemical Risk Assess & Exposure Monitoring	A risk assessment has been completed on all activities with active pharmaceutical ingredients (API) and inactive pharmaceutical ingredients (IPI) on site using the product information provided by operational exposure limits (OEL), performance-based operational exposure limits (PBOEL), analytical method, monograph, ...
Chemical Risk Assess & Exposure Monitoring	A Medical Surveillance Program is in place to periodically evaluate the employees exposed to chemicals (severity rating high or extreme).
Chemical Risk Assess & Exposure Monitoring	The results of the baseline sampling are used to develop an action plan to control exposure risks of chemical agents above the operational exposure limit (OEL). Risks can safely be controlled by using respiratory protective equipment (RPE) if the exposure is below protection factor. If the protection factor does not provide a safe level of exposure and if there is extensive use of RPE then engineering controls should be implemented.
Chemical Risk Assess & Exposure Monitoring	Monitoring equipment is available to measure the exposure of chemicals in case of a spill (acute exposure).
Controlling chemical exposures	Periodically measure engineering controls. If exhaust systems are in place, airflow rates (at laboratory hoods, general & local exhaust systems and dust collection systems) are measured periodically.
Controlling IPI & API (active pharmaceutical ingredient (API) & inactive pharmaceutical ingredient (IPI) )	Exposure monitoring has been conducted for those employees identified by the risk assessment as having potential exposures for API/IPI using total dust monitoring and if possible specific active pharmaceutical ingredient (API) and inactive pharmaceutical ingredient (IPI) monitoring.
Noise & Hearing Conservation	Hearing protection is mandatory in areas with high noise levels (> 85 dBA). If no measurements are executed, hearing protections needs to be worn, based on qualitative assessment (=normal conversation not possible).
Noise & Hearing Conservation	Noise level surveys of production operations that reflect current exposure conditions are performed.
PPE & Respiratory Protection Program	Employees wearing personal protective equipment (PPE) for protection against chemical agents are properly trained. Specific focus should be on Respiratory Protection (use, donning and doffing, maintenance, storage, cartridge change schedule, condition, inspection).
PPE & Respiratory Protection Program	Written documents & procedures are in place that specify the required personal protective equipment (PPE) and respiratory protective equipment (RPE) based on the exposure of the activities (proper selection).
PPE & Respiratory Protection Program	Employees received training on the proper use of personal protective equipment (PPE) and respiratory protective equipment (RPE).
INCIDENT INVESTIGATION	A procedure for promptly reporting and investigating incidents, accidents and non-conformances, and ensuring that corrective action is taken to prevent recurrence is in place.
PSI (Process Safety Information)	Employees receive training on the proper handling of flammable liquids and explosive dusts, avoidance of ignition sources (static electricity, inertization, etc. ).
TRAINING	General safety practices with regard to smoking, open flames, sparks (phones), safety and antistatic shoes, work clothes and safety glasses, access to buildings, traffic on site are documented and implemented.
STATIC ELECTRICITY	Necessary grounding & bonding is implemented.
ERP (Emergency Response Procedures)	Emergency notification, evacuation, planning and response etc. are documented and implemented: - emergency number is in place - there are sufficient emergency exits which are clearly indicated and illuminated - clear emergency maps with routes and emergency equipment are posted at strategic places - fire extinguishers are readily available and of the appropriate type (ABCD)
ERP (Emergency Response Procedures)	Employees are trained and know how to react in case of a fire or explosion, or a chemical toxic release. Employees have a profound understanding of what potentially can result in fire and explosion or toxic releases (flammable liquids, dust) and the preventive measures related with these risks.
ERP (Emergency Response Procedures)	The organization must have an established program and procedures for reporting emergencies, and an internal alarm system for alerting those who may be affected by the emergency. The alarms shall be audible through the facility and tested at appropriate intervals.

PSI (Process Safety Information)	A formal procedure (process) must be in place to ensure that all new chemicals or mixtures are evaluated to their hazards (flammability, risk of explosion and toxic release potential, water sensitive, shock sensitive, carcinogens, impact on the environment, etc.) before introduction on site.
STATIC ELECTRICITY	Employees receive advanced training on static electricity (inertization and grounding) and fire and explosion risks, including information on technical and administrative protection measures, prior to any process related activity.
TRAINING	All PSM (Process Safety Management) related training of employees is documented, and basic understanding is evaluated and documented. Initial and refresher training records exist and identify the employee, the date of the training, and the means used to verify that the employees understand the training.
OPERATING PROCEDURES	Step by step instructions for basic safety operations must be documented. This includes: inertization of reactors and centrifuges, grounding of mobile equipment containing flammable liquids, adding of powders to reactor (by funnel or other means), etc.
PHA (Process Hazard Analysis)	Pressure indication, relief systems and temperature control are implemented and maintained.
CONTRACTORS	All contractors involved in in-process work or close proximity or performing work in interaction with process work must receive basic training on hazards (fire, explosion, toxic release, etc.) of process/installation and be continuously supervised.
LEGAL COMPLIANCE	A list of local legislation is kept up to date and related process safety management (PSM) requirements are identified and implemented.
SAFE WORK PERMITS	Safe Work Permits for Hot Work, Cold Work, Confined Spaces, Line Breaking, Confined Spaces, Electrical Safety are implemented and actively used.
PHA (Process Hazard Analysis)	The PHA (process hazard analysis) shall include: The hazards of the process; engineering and administrative controls, human factors (e.g., alarm handling, communication during shift change, ergonomic design of interfaces, staffing levels, etc.), qualitative evaluation of a range if possible.
MOC (Management of Change)	The Management of Change (MOC) process shall identify, evaluate and document the potential health and safety impact associated with the new project/process, the current situation and the proposed changes utilizing a "Management of Change Impact Checklist".
PSI (Process Safety Information)	The process safety information contains the following information pertaining to the technology of the process: block flow diagram or simplified process flow diagram, process chemistry, maximum intended (up to date) inventory, safe upper and lower limits (pressures, temperatures, etc..) an evaluation of the consequences of deviations, including those affecting the safety and health of employees.
OPERATING PROCEDURES	Operating procedures (and all relevant health, safety, environment (HSE) changes to them) must be trained before start of the process to all involved persons (operators, supervisors, etc.). Retraining must be done for all changes to the procedure and prior to start up.
OPERATING PROCEDURES	Operating procedures should include operating limits and outline the consequences of process deviation and steps required to correct or avoid deviations. Operating procedures must be available in the local language (understood by all operators and supervisors).
MECHANICAL INTEGRITY	Written procedures shall be established and implemented that specify the maintenance required to ensure the ongoing integrity of process equipment.
MECHANICAL INTEGRITY	Deficiencies in equipment shall be identified and corrected before further use.
ERP (Emergency Response Procedures)	Yearly emergency drills are conducted with the local fire brigade and first aid, hospital services. Exercises are conducted that involve the local community (local authorities, police, major, adjacent industry, etc.).
INCIDENT INVESTIGATION	Causes of accidents, incidents and non-conformances shall be identified through a root cause analysis and classified and shall be analyzed on a regular basis (as a minimum annually). Incident frequency and severity rates shall be calculated in accordance with accepted guidelines.
COMPLIANCE AUDITING	Periodic process safety management (PSM) training is provided to the all employees and contractors. Training packages are periodically updated. Periodic inspections are frequently done. Process hazard analysis (PHA) and process safety information (PSI) are periodically updated.
WASTE WATER TREATMENT	The waste water treatment (WWT) station is fully permitted.
WASTE WATER TREATMENT	The organization fully understands where its waste water ultimately flows to (surface water or municipality).
WASTE WATER TREATMENT	The waste water treatment (WWT) effluent characteristics is monitored on at least a monthly basis.
WASTE WATER TREATMENT	A process is in place to report and ensure appropriate management action is taken in case of deviations (exceedances) of the effluent limits.
WASTE WATER TREATMENT	The organization knows the total amount of yearly waste water discharged.
WASTE WATER TREATMENT	Storage tanks of hazardous chemicals are secondarily contained.
WASTE WATER TREATMENT	An effective communication is in place between the production and the waste water treatment plant (WWTP) concerning incoming off spec wastewater, also in case of calamity.
WASTE WATER TREATMENT	A calamity tank and a procedure are available to store calamities, e.g. wastewaters with extreme pH or toxicity.
WASTE WATER TREATMENT	The sludge is at least monthly characterized and controlled. If not, it should be understood what the sludge characterization could indicate and a good rationale is available for not checking sludge quality.
WASTE WATER TREATMENT	The sources of wastewater to the waste water treatment plant (WWTP) are known and a waste mass balance is made.
WASTE WATER TREATMENT	Rainwater is discharged in a separated sewer system.
WASTE WATER TREATMENT	In case there is toxicity the toxic compounds are identified.
WASTE WATER TREATMENT	Water saving projects are carried out.
WASTE WATER TREATMENT	The equipment of the waste water treatment plant (WWTP) installation (pumps, tubing, tanks, aerators, mixers, ...) is maintained on routine basis per manufacturer specifications.
WASTE WATER TREATMENT	The most important influent / effluent parameters are identified and trended.