**Chemical Safety Committee (CSC) Charter**

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# **Purview of the Wayne State University Chemical Safety Committee**

## **Purpose**

The Wayne State University (WSU) Chemical Safety Committee (CSC) focuses on creating and nurturing a **laboratory chemical safety culture** to protect research personnel, general public and the environment from exposure to hazardous laboratory chemicals during each step of the chemical life cycle, which includes chemical:

* Acquisition
* Storage
* Usage
* Transfer
* Disposal

## **Aim and Scope of Work**

The overall aim of this committee is to streamline the existing chemical safety processes without unnecessary additional administrative burden to WSU research personnel. To achieve this, the committee will:

1. Provide required scientific knowledge and guidance to the WSU Office of Environmental Health and Safety (OEHS), which establish safe chemical work practices/procedures.
2. Serve as a resource for OEHS to develop, review, and approve:
	1. Laboratory chemical safety procedures, guidelines, and policies.
	2. Standard Operating Procedures (SOPs)
	3. WSU Chemical Hygiene Plan (CHP)
3. Ensure that protocols in research and teaching handling hazardous chemicals are conforming with recommendations and guidelines from various regulatory agencies (e.g., NIH, OSHA, MIOSHA, NIOSH, ACS).
4. Address chemical safety problems where applicable and as forwarded from WSU-OEHS.
5. Recommend necessary consultation and educational (training) activities to assist the WSU research/teaching laboratories in the performance of safe chemical handling techniques and procedures while assuring their awareness to OEHS chemical safety requirements.
6. Prioritize the highly hazardous chemicals used in WSU research laboratories based on:
	1. Quantity
	2. Form/State
	3. Concentration
	4. Frequency of use
	5. # of potential exposures
7. Develop a method to monitor and record novel hazardous chemicals either synthesized or purchased by WSU research facilities. including but not limited to:
	1. Carcinogens
	2. Chemotherapeutics
	3. Toxins
	4. Nanoparticles
8. Develop a Quantitative Risk Assessment model to efficiently (e.g., RAMP)
	1. Identify
	2. Evaluate
	3. Respond

to chemical exposure incidents throughout the chemical life cycle based on RAMP concept: (**R**ecognize the hazards; **A**ssess the risks of the hazards; **M**inimize the risks of the hazards; **P**repare for emergencies from uncontrolled hazards.)

1. Advises and recommends strategies to Associate Vice President for Research (AVPR) to enhance WSU’s Chemical Safety Program.

## **CSC Authority**

The AVPR has charged the WSU-CSC with the role of supporting the Office of Environmental Health and Safety (OEHS) Chemical Hygiene Program in their goal of enhancing chemical safety and, in turn, the safety of the WSU community and visitors. This will be accomplished via:

1. **Establishing safe working practices for research involving the use of hazardous chemicals.** The WSU-CSC will contribute expertise, experience and knowledge to the development and maintenance of:
	1. Chemical safety programs and guidance documents for the education of the WSU research community
	2. Standard Operating Procedures (SOP) templates for the use of hazardous chemicals
	3. Review of SOPs for use of hazardous chemicals designated by the WSU-OEHS as requiring institutional oversight.
2. **Review of compliance issues identified by the WSU Chemical Hygiene Officer (CHO).**
	1. WSU-CSC will review and act upon potential safety violations or non-compliance issues reported to the committee by the WSU CHO. This includes violations of WSU-CSC safety requirements or of any applicable federal, state or local health and safety standards.
	2. The WSU-CSC will provide recommendations to the Office of the AVPR based upon the outcomes of the review.
	3. Violations of any applicable federal, state and local health and safety standards that require expedited reporting will be reviewed by the CHO, Chair of the CSC, and the AVPR.

## **CSC Responsibilities**

The WSU CSC responsibilities include:

1. Serve as a resource for WSU Office of Environmental Health and Safety (OEHS) to develop, review and approve laboratory chemical safety practices, standard operating procedures (SOPs) and WSU Chemical Hygiene Plan (CHP).
2. Support OEHS to establish safe chemical work practices /procedures to properly manage hazardous laboratory chemicals during its acquisition, storage, use, transfer and disposal.
3. Develop, recommend, update, and maintain compliance procedures, guidelines and policies applicable to laboratory chemical safety.
4. Review annually, the CHP and other safety guidelines and training programs as required, and advise the AVP and OEHS regarding its effectiveness, and propose improvements.
5. Investigate/review chemical safety incidents as forwarded by OEHS and recommend or initiate remedial actions when safe procedures are not followed or when procedures are not in compliance with regulations or the CHP.
6. Review requests for variances from established safe chemical work practices/procedures and make recommendations to the OEHS on accepting or not accepting these requests.
7. Where applicable, generate reports/summaries on WSU chemical incident investigations, chemical safety policy and procedural changes (federal, state and WSU) to inform WSU community, federal, state and local agencies.
8. Investigating and reviewing potential violations of other state or federal regulations.
9. Reporting to institutional officials and relevant regulatory agencies of any significant violations
10. Performing such other functions as may be delegated to the WSU-CSC

# **Principal Investigator (PIs) Responsibilities**

The PI is responsible for providing guidance on the safe conduct of research in her or his laboratory in compliance with the federal (e.g., EPA, OSHA), state (e.g., MIOSHA, MDEQ) and local (e.g., WSU- OEHS) chemical safety regulations and guidelines. **A major responsibility of the PI is to promote a laboratory culture where safety is a valued component of research**.

PIs responsibilities related to chemical safety includes the following:

1. Research Procedures/Protocols
	1. Identify hazardous laboratory procedures.
	2. Implement and enforce standard safety procedures for laboratory work associated with hazardous materials/conditions.
	3. Analyze proposed standard safety procedures to determine the appropriate controls (engineering, administrative, and PPE) needed to sufficiently mitigate the hazards.
	4. Be trained and available, as needed, to engage, review and correct the routine operations of the laboratory research procedures to ensure staff are performing the research in compliance with the safe handling guidelines.
	5. Ensure that laboratory staff receive instruction on how to follow safe work practices and specific Standard Operating Procedures (SOPs) for:
	6. use of highly hazardous chemicals
	7. proper use of engineering, administrative, and PPE controls
	8. spill clean-up
	9. emergency procedures
	10. Notify OEHS and/or Facilities Planning and Management (FP&M) at WSU as soon as possible when workplace engineering controls (e.g., chemical fume hoods) and safety equipment (e.g., emergency showers, eyewashes, etc.) become non- operational.
2. Laboratory Safety Training
	1. Provide the required safety training to laboratory staff on handling hazardous chemicals/equipment.
	2. Maintain written or electronic records of laboratory-specific training.
	3. Ensure easy access to adequate safety information for laboratory staff based on the hazardous chemicals/equipment with which they work with or is in their workspace.
3. Personal Protective Equipment (PPE)
	1. Ensure all PPE is available, maintained and properly used by each lab employee and visitor.
	2. Provide training on use and maintenance of required PPE.
4. Health Screens for Laboratory Staff
	1. Inform the laboratory staff on any precautionary medical examinations.
	2. Request/ advise laboratory staff on exposure monitoring relevant to laboratory work practices and encourage them to report any changes or suspected changes in their health status.
	3. Facilitate funding for medical surveillance and/or medical consultation/examination for laboratory personnel, as required.
5. Laboratory safety Inspections
	1. Provide regular, formal chemical hygiene and housekeeping inspections of emergency and personal protective equipment.
	2. Assist the Chemical Hygiene Officer (CHO) and Office of Environmental Health and Safety (OEHS) chemical safety group in fulfillment of their laboratory safety inspections / duties with respect to PI’s laboratory/facility.
	3. Correct deficiencies identified during laboratory safety inspections, as directed.
	4. If research conducted in PI’s laboratory is subject to WSU-CSC review/ investigation, the PI must remain in communication and cooperate with the committee throughout the duration of the process to report:
		1. Significant problems pertaining to the operation and implementation of containment practices and procedures.
		2. Violations of the Federal, state, and regulatory guidelines or standards
		3. Significant research related accidents and/or illnesses
6. Laboratory Accidents and Emergencies
	1. Report all accidents or near misses (which are unplanned events that did not result in injury, illness, or damage but had the potential to do so) that occur in their laboratory to OEHS.
	2. Reach out to support personnel (e.g., CHO) and subject matter experts (e.g., OEHS, WSU-CSC) for assistance, as needed to take corrective measures to prevent accidents or near misses.
	3. Adhere to OEHS approved emergency plans for handling accidental spills and personnel chemical exposure.
7. Chemical Inventory
	1. Ensure the integrity of chemical containment.
	2. File a chemical inventory with OEHS listing all chemicals present in the laboratory/work area.
	3. Report any significant changes in the use or new use of Specific High-Risk Chemicals (refer to section IV of this document, Chemical Safety Protocol (CSP) review for more information) to OEHS.
	4. Comply with permit and shipping requirements for regulated hazardous chemical materials.
8. Laboratory Waste Management
	1. Ensure proper identification and labeling of chemical waste.
	2. Oversee the chemical wastes collection process and good housekeeping in waste generation areas.
	3. Ensure all hazardous materials/waste must be disposed of through OEHS.
9. Laboratory Visitors
	1. Assume responsibility for laboratory visitors. Inform them of potential laboratory hazards and how to mitigate the hazards before accessing the laboratory/facility.
	2. Ensure visitors follow laboratory safety guidelines and regulations when they are required to work in the laboratory environment.

# **CSC Membership**

## **CSC Composition**

1. Full Members:
	1. “Eleven Full Members” appointed to the CSC will include:
		1. One CSC Chair
		2. One CSC Vice Chair
		3. One Chemical Hygiene Officer
		4. One member of the Department of Laboratory Animal Resources (DLAR) veterinarian staff.
		5. WSU faculty members with sufficient expertise to evaluate the range of research activities typically performed at WSU.
2. Ex Officio Members (without vote):
	1. Associate Vice President for Research (AVPR), Division of Research
	2. Director, Office of Environmental Health and Safety
	3. Associate Director, Research Safety, Office of Environmental Health and Safety
3. Alternate Members:
	1. Individuals may be appointed to the committee as alternates who serve in place of a specific CSC member or multiple members in their absence.
	2. Alternate members must be discipline-matched and have similar expertise, including the same scientific or non-scientific status.
	3. Alternate members may vote in the absence of the member they are assigned to as an alternate. If assigned to multiple members, an alternate may only represent a single vote and only counts once towards quorum.
	4. If both the member and their designated alternate member are present at a convened meeting of the CSC, the alternate member may not vote unless they are the primary or secondary reviewer on a specific protocol. In these instances, the alternate member will vote in place of the full member.
	5. Alternate members are encouraged to attend all CSC meetings and contribute to the discussion process.
4. Ad-Hoc Members:
	1. Individuals with specialized knowledge/experience in specific research fields may be invited to serve as ad-hoc members.
	2. These individuals will provide adequate expertise for chemical safety issues and/or research activities that require expertise beyond that included within the current CSC membership.

## **Quorum Requirements**

All full members, or in their absence their designated alternate, have voting rights at each WSU-CSC meeting. A quorum constitutes more than 50% of the full members rostered on the committee. A majority vote is the majority of the quorum of full members, or in their absence their designated alternate, present at the meeting.

## **Conflict of Interest**

No member of the WSU-CSC may be involved in the review or approval of a project in which they have been, or expect to be engaged, or in which they may have a professional or financial interest, except to provide information requested by the WSU-CSC. The conflicted CSC member must abstain from voting. The conflicted CSC member cannot contribute towards quorum under these circumstances.

## **CSC Appointments**

The AVPR will serve as an ex-officio member and will not be a voting member of the CSC. The AVPR Research Integrity is responsible for appointing members to the CSC.

* Members will be appointed by the AVPR for three-year terms.
* New members will be appointed for an initial one-year term, followed by a two- year appointment.
* Returning members will be appointed for three years unless a term of less than three years is agreed upon prior to appointment.
* Members may be re-appointed at the end of each three-year term.
* A member who cannot serve a complete term (e.g., sabbatical or separation) may be replaced by a new member who will be expected to serve the remainder of the initial member’s term, unless the initial member plans to return and complete their term.
* Removal of a member from the CSC typically requires documented and substantiated "just cause" that demonstrates the member to be unfit or unable to serve on the CSC. "Just cause" for removal may include, but is not limited to, lack of participation in CSC related activities (including attendance at meetings, number of reviews completed) a finding of misconduct, or an unresolved conflict of interest. Members may also be removed to allow for fresh perspectives on the committee. The ultimate decision to remove a member is made by the AVPR.

## **CSC Member Training**

All newly appointed members should complete the following training required by WSU OEHS.

* Collaborative Institutional Training Initiative (CITI) training module on laboratory safety (Initial and annually required refresher)
* Collaborative Institutional Training Initiative (CITI) training module on Hazard Communication
* Collaborative Institutional Training Initiative (CITI) training module for CSC Members and Researchers working with Nano Materials

These training must be completed before a new member participates in committee activities (e.g., convened meetings, review and approval of Chemical safety protocols, procedures and/or documents, and voting). The CITI training module on laboratory safety covers topics that will enhance members understanding of general lab and chemical safety issues. Hazard Communication Training provides a common and coherent approach on classifying chemicals and communicating hazard information. CITI training module for CSC Members and Researchers working with Nano Materials offers basic awareness and understanding of nanoparticles, and the unique safety issues associated with their handling. The Chemical Hygiene Officer and/or the CSC Chair will facilitate this training.

## **CSC Member Responsibilities**

The **AVPR** shall:

1. Ensure that CSC meets the requirements set forth by federal and state regulations and guidelines pertaining to chemical safety.
2. Determine the responsibilities of the CSC beyond non-compliance chemical safety issues.
3. Appoint members as described in section D above.
4. Ensure appropriate training for the CSC Chair, Members, and Chemical Hygiene Officer is available.
5. Report any significant non-compliance chemical safety issues, or any significant chemical research-related accidents or illnesses to OVPR as stated in the WSU Laboratory Safety Compliance Procedure for Chemical Hazards (Appendix A).

The **Chemical Hygiene Officer** shall:

1. Serve as the CSC coordinator and understand all functions, policies, and procedures of the CSC and the University’s chemical safety program conducted by OEHS.
2. Report to the CSC and the AVPR any significant non-compliance chemical safety issues, chemical research-related accidents or illnesses identified/reported to OEHS.
3. By instruction from the AVPR, serve as liaison with federal and state regulatory agencies.
4. By instruction from the AVPR, coordinate with the WSU Department of Marketing and Communications regarding media relations and public disclosures.
5. Schedule and attend meetings of the CSC.
6. Set meeting agendas and assist the CSC Chair with reviewer assignments.
7. Distribute review assignments (e.g., Chemical safety protocols, procedures and/or documents) to designated reviewers.
8. Review chemical safety protocols, procedures and/or documents at convened meetings of the CSC.
9. Assist the CSC Chair with the drafting of letters from the CSC regarding CSC decisions and actions.
10. Sign CSC letters, as needed.
11. Make decisions about researcher responses to CSC conditions for chemical safety protocols/procedures approval, in collaboration with the CSC Chair
12. Assist in the development and implementation of new chemical safety protocols, procedures and other required CSC documentation.
13. Provide advice on laboratory chemical safety.
14. Assist with periodic reviews of CSC policies, procedures and documentation.
15. Participate in periodic review of the CSC Charter and update as necessary.
16. Develop and complete required chemical safety training and provide advice to PIs and the CSC on research safety procedures.
17. Perform Chemical Safety inspections to individual PIs laboratories prior to full approval of their lab specific procedures/chemical safety protocols by CSC and report on these visits at scheduled CSC meetings.

The **CSC Chair** shall:

1. Serve as a member of the CSC and understand all functions, policies, and procedures of the CSC and the University’s chemical safety program directed by OEHS.
2. Review and make recommendations on any significant non-compliance chemical safety issues, chemical research-related accidents or illnesses reported by the Chemical Hygiene Officer
3. Attend scheduled meetings of the CSC.
4. Direct the proceedings of convened meetings of the CSC.
5. Review chemical safety protocols, procedures and/or documents at convened meetings of the CSC.
6. Assist in setting meeting agendas.
7. Designate reviewer assignments.
8. Provide written communication regarding CSC decisions to PIs.
9. Sign CSC letters, as needed.
10. Make decisions about researcher responses to CSC conditions for chemical safety protocols/procedures approval, in collaboration with the Chemical Hygiene Officer
11. Assist in the development and implementation of new chemical safety protocols, procedures and other CSC documentation.
12. Assist with periodic reviews of CSC policies, procedures, and other CSC documentation.
13. Ensure member training (this task may be delegated to the Chemical Hygiene Officer)
14. Participate in periodic reviews of the CSC Charter and update as necessary.
15. Complete required chemical safety training

The **CSC Vice-Chair** shall:

1. Serve as a member of the CSC and understand all functions, policies, and procedures of the CSC and the University’s chemical safety program.
2. Review and make recommendations on any significant non-compliance chemical safety issues, chemical research-related accidents or illnesses reported by the Chemical Hygiene Officer
3. Attend scheduled meetings of the CSC.
4. Perform duties of the Chair in the Chair’s absence or in instances where the Chair has a conflict of interest.
5. Participate in periodic review of the CSC Charter and update as necessary.
6. Assist with periodic reviews of CSC policies, procedures and other CSC documentation.
7. Complete required chemical safety training

**WSU CSC members** shall:

1. Understand all functions, policies, and procedures of the CSC and the University’s chemical safety program.
2. Review and make recommendations on any significant non-compliance chemical safety issues, chemical research-related accidents or illnesses reported by the Chemical Hygiene Officer
3. Attend scheduled meetings of the CSC.
4. Notify the CSC Coordinator when unable to attend CSC meetings.
5. Complete required chemical safety training
6. Review protocols as requested and provide feedback to the CSC Chair, and/or the Chemical Hygiene Officer
7. Assist with periodic reviews of CSC policies, procedures and other CSC documentation.

## **CSC Meetings**

Meetings are held monthly with the schedule being published online on Microsoft Teams group “WSU-CSC” and/or WSU OEHS website. Members must be either physically present or connected to the meeting virtually (via phone or internet service) in order to count towards quorum.

CSC meeting minutes are provided to CSC members at the following monthly meeting and are approved by committee vote. Members may attend any CSC meeting or review meeting minutes with prior notification of the Chemical Hygiene Officer, who serve as the CSC Coordinator.

Upon request, the CSC minutes shall be made available to the public. When possible and consistent with protection of privacy and proprietary interests, meetings are open to the public.

Comments from the public will be recorded in the meeting minutes and either addressed during the course of the meeting or reviewed and discussed with the relevant institutional representatives.

# **Chemical Safety Protocol (CSP) Review**

## **CSP Approval Procedures**

Specific High-Risk Chemicals (SHRCs) are chemicals which require prior approval by the Wayne State Chemical Safety Committee (WSU CSC) to be used in a procedure either in the form of a reactant or a product.

WSU CSC must approve the use of the following SHRCs:

* Globally Harmonized System (GHS) category 1 acute toxins (dermal and/or inhalation)
* Other high-risk chemicals referred to WSU-CSC by Chemical Hygiene Officer

WSU labs/facilities intending to use SHRCs, must submit a Chemical Safety Protocol (CSP) to the CSC for review prior to initiating work.

**Steps for Chemical Safety Protocol (CSP) approval by CSC:**

1. For the SHRCs identified, the principal investigator/laboratory supervisor must complete the following documents of the CSP package (Appendix C)
* Risk Assessment Form

This form communicates to the WSU CSC relevant hazard information associated with a particular SHRC.

* Lab Specific Standard Operating Procedure

Upon approval by WSU CSC, this Lab Specific Standard Operating Procedure (SOP) will be used to communicate hazard information to the lab personnel handling SHRC.

Risk Assessment Form (Appendix C) and WSU Lab Specific SOP template along with guidance documents (Appendix C: Instructions, Risk Assessment Matrix) are available on- line or will be emailed to the PI.

1. All personnel listed on the protocol must have completed required training modules. In addition to the laboratory safety modules, all personnel listed in the CSP must complete the CITI training course entitled “Hazard Communication”. This module will help personnel understand the key elements of hazard communication and how they apply in their workplaces.
2. Each CSP must be supported by the applicants Departmental Chair.
3. Once the Risk Assessment Form and Lab Specific SOP are ready, submit the CSP documents to the Department Chair to acquire departmental approval.
4. Once departmental approval is obtained, submit the CSP to the WSU Chemical Hygiene Officer. The CSP must be received by the Chemical Hygiene Officer on or before the first day of the month for inclusion in that months CSC meeting. Upon receipt, Chemical Hygiene Officer will complete a pre-review of the protocol for completeness. If CSP is incomplete, Chemical Hygiene Officer will communicate with the PI for necessary changes to the protocol. All corrections and recommended changes to the protocol must be made and returned to the Chemical Hygiene Officer one week prior to the meeting. If the protocol is complete, the Chemical Hygiene Officer will submit the protocol to the CSC.
5. The CSC Chair will assign two CSC members to each protocol one week prior to the meeting date. A review outline (Appendix C) is provided to assist reviewers with approval criteria.
6. The CSC may communicate with PIs and applicants via the Chemical Hygiene Officer to clarify details, specify experimental approaches, advise safe practices, or request further information. Additional forms may be requested, including access to IACUC, IBC or IRB forms to ensure consistency.
7. The designated primary reviewer presents each protocol to the committee for discussion. The primary and secondary reviewers are responsible for providing motions on approval, tabling, or denial of approval following completion of CSC deliberations.
8. Each eligible committee member votes to determine the outcome of the review.
9. For each protocol reviewed, designated reviewers must send their comments to the Chemical Hygiene Officer. This should be done immediately after the CSC meeting is concluded (within 24 hours). Comments are used by the Chemical Hygiene Officer to draft the outcome of the protocol reviewed by CSC, which will be sent out to PIs within 4 business days of meeting completion.
10. A chemical safety visit will typically be completed prior to CSC approval being granted. This will be conducted in accordance with the OEHS Chemical Hygiene Inspection program and the [MIOSHA Part 431 Hazardous Work in Laboratories Standard](https://www.michigan.gov/leo/-/media/Project/Websites/leo/Documents/MIOSHA/Standards/Combined/CS_GI_431/CS_GI_431__12-12-2018.pdf?rev=4aedae899e4f4bcd969ff2e493243b79&hash=975CB73897A3D191B73A87D1AF1F53BE). Final CSC approval is contingent on a satisfactory chemical safety visit.

**Notes**:

* CSC approval is independent of other oversight committees (e.g., IACUC, IBC and IRB).
* OEHS approval does not equate to CSC approval for the use of particularly hazardous substances and other hazardous chemical agents.
* Expedited reviews of new protocol submissions are not possible. Full committee review is necessary; therefore, all CSC Chemical Safety Protocols will be handled as described above.
* Approval is given for three years unless otherwise indicated in the CSP approval letter (Appendix C).

## **CSP Review Outcomes**

The outcome of the Chemical Safety Protocol review process by CSC depends upon the quality of the information provided in the documents submitted. The CSC is required to assess the risk associated with each experimental design.

Potential outcomes:

1. **Approval**

Full CSC approval is granted when there are no additional chemical safety concerns raised by the CSC in addition to those identified by the PI.

1. **Conditional Approval**

Conditional approval is granted when committee members raise minor issues associated with the protocol that must be addressed before the protocol is approved. Review of the modified documents is performed administratively by the CSC Chair, the Chemical Hygiene Officer, and any additional CSC members identified during the meeting. In circumstances where either the CSC Chair or Chemical Hygiene Officer is unable to complete the review of the modified documents, the original primary reviewer will be asked to perform this function. Once conditions are deemed to have been met, the protocol can be approved without further review by the full committee.

1. **Tabled**

A protocol may be tabled for the following (but not limited to) reasons:

* 1. Failure to complete all required documents.
	2. Poor quality of written documents
	3. Failure to supply sufficient information in order for the CSC members to complete the risk assessment.
	4. Identification of potential issues during chemical hygiene inspections
1. **Denial of approval**

Denial of approval may occur for the following (but not limited to) reasons:

* 1. Excessive risk of proposed activities
	2. Inadequate containment facilities (e.g., work involves glove box, chemical fume hoods with specific duct systems to handle highly corrosive materials)
	3. Excessive health risk due to acute or chronic exposure to highly hazardous chemical concentrations
	4. Lack of experience associated with proposed research activities (PI’s may be required to provide curriculum vitae if concerns are raised by the CSC during protocol review)

In the event of a protocol being tabled or denied approval, the CSC will work with the PI to address the issues raised and to seek solutions.

Should the PI fail to respond to the requirements of the CSC within 3 months of the meeting in which it was reviewed, the protocol will be removed from the review process and a new application will be required.

## **Chemical Safety Visits**

A chemical safety visit is typically required for full CSC approval of a Chemical Safety Protocol. Inspections are conducted by the WSU Chemical Hygiene Officer. Under certain circumstances, the CSC Chair may appoint selected members of the CSC to accompany an OEHS staff member on chemical safety visits.

Exceptions can be made to perform chemical safety visits, at the discretion of the Chemical Hygiene Officer, if a recent chemical hygiene inspection has been performed for the spaces indicated in the protocol.

This visit provides an opportunity for the Chemical Hygiene Officer/CSC members to:

* Assess the research facilities selected for use in specific research activities.
* Address any questions researchers may have regarding the review process.
* Address any areas of the research protocol that require clarification prior to the CSC meeting.
* Assess the knowledge of research personnel who are involved in the CSC related work with regard to protocol specifics and procedures and practices associated with the chemical safety level.
* Inform the CSC members of any facility issues that need to be addressed prior to approval being granted.

## **Maintenance of CSP Approval**

1. **Protocol amendment**

It is the PI’s responsibility to maintain the Chemical Safety Protocol (CSP) approved by the CSC and ensure that it accurately reflects work that is being performed. If an amendment is required to an approved CSP within the 3-year approval window, the PI must complete the following actions prior to initiating the changes:

* 1. Complete the Protocol Amendment Form (Appendix C) in the CSP package. Revise the protocol to include new information and details. Submit the amendment to Chemical Hygiene Officer. Amendments will initially be reviewed by the CSC Chair and Chemical Hygiene Officer.
	2. Protocol Amendments are required for any of the following examples:
		1. Change in personnel
			1. Training modules offered by OEHS is required.
			2. New personnel should read and sign the CSC approved lab specific chemical SOPs related to the protocol.
		2. Change in research location
		3. Change in chemical agent being utilized
		4. Change in procedures

**Note**: Administrative approval by the CSC Chair and/or Chemical Hygiene Officer may be granted if response indicates no major change to the chemical safety risk associated with the project. More substantial changes will require full committee review and approval.

* 1. CSPs found to differ significantly from the previously approved work may require a new protocol submission.
1. **Protocol expiration**

If work is planned past the expiration date of the approved Chemical Safety Protocol, the PI must submit a new CSP for review by the full committee; no work can be performed in the absence of a current and approved protocol.

# **Unexpected Problems Reporting**

## **Background**

This section outlines the reviewing and reporting (to regulatory authorities) criteria for any unexpected chemical safety problems forwarded to the CSC. Unexpected problems constitute chemical safety issues that are outside of the scope of the regular chemical hygiene inspections (CHIs) conducted by OEHS chemical safety group and are not covered by WSU laboratory safety compliance procedure (LSCP). LSCP only covers non-compliance issues found during routine CHIs.

Forwarding of unexpected problems to the CSC is initiated at the discretion of the WSU CHO. Upon notification by the CHO, the CSC Chair will initiate the review process as detailed in the section B and, if necessary, will report to the institutional official. In their role as Institutional Official, the AVPR is then responsible for any reporting requirements to supporting agencies and appropriate regulatory authorities.

The timeline for reporting unexpected problems to the CSC will depend on the nature, severity, or associated regulatory reporting requirements of the problem, but will be no later than the next scheduled CSC meeting.

Unexpected problems forwarded to the CSC include:

1. Items which do not require immediate corrective actions and require the expertise or support of the CSC.

Upon notification by CHO, the CSC will initiate a review on these problems and implement corrective action plans. Examples of such problems include, but are not limited to:

* SOP violations (No SOP, deviation from SOP)
* Chemical safety violations identified outside of routine chemical hygiene inspection.
* Non-compliance issues: minor, serious, continuing.
* Failure to obtain CSC approval to work with Specific High-Risk Chemicals
1. Items which require immediate action due to associated adverse health, physical and environmental effects and are initially addressed by other WSU groups such as Enterprise Risk Management, Fire safety, OEHS Emergency response team, WSU police etc.

The CSC will be notified about the outcome of these problems by the CHO to determine if further review and reporting is required. Examples of such unexpected problems include, but are not limited to:

* Hazardous Chemical Spills
* Chemical Fires
* Life threatening laboratory injuries

## **Procedure to Review and Report Unexpected Problems by CSC**

1. The WSU Chemical Hygiene Officer will notify PIs and their Department Chair when unexpected problems are identified that need to be reported to the WSU CSC for further review.
2. The PI is required to complete the “Unexpected Problems Report Form” and return to the CHO within 3 business days of the notification.
3. The information in the report will be provided to the CSC Chair by CHO for review.
4. The CSC Chair's review will determine if the problem requires full CSC review. This will be based primarily on the nature, severity, or associated regulatory reporting requirements of the incident.
5. If full review is required, CSC members will be asked to determine if they agree with the PI’s corrective actions outlined in the “Unexpected Problems Report” and determine if WSU needs to implement any corrective actions at the institutional level.
6. Due to the time sensitive nature of the CSC reporting responsibilities, full CSC review of these reports does not need to be conducted during the regularly scheduled meetings.
7. Information provided in the form completed by the PI, supported by information provided by the CHO and CSC, will be utilized to complete any official reports that need to be submitted by the Institutional Official.
8. PI and their Department Chair will be informed on the outcome of the review, provided with a copy of the official report, and if any supporting agencies and/or appropriate regulatory authorities have been notified.
9. Official reports will be presented to the CSC at the next convened meeting, along with any information received from supporting agencies and regulatory authorities.

## **Appealing Corrective Actions Implemented By CSC**

If the PI disagrees with the outcome of the CSC review and any corrective actions proposed, in whole or in part, they may submit a written appeal to the CSC. Committee will review the PI’s appeal and inform the PI with the committee decision within 14 business days. If required, committee may meet the PI in person or may visit the problem site prior to taking the final decision.

# **References**

1. [NIH Chemical Safety Guide (2015)](https://www.ors.od.nih.gov/sr/dohs/Documents/ChemicalSafetyGuide.pdf)
2. [NIH guidelines for the laboratory use of chemical carcinogens](https://catalog.hathitrust.org/Record/007419033)
3. [Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards,](https://www.ncbi.nlm.nih.gov/books/NBK55878/)
4. [Prudent Practices in the Laboratory: Handling and Disposal of Chemicals (1995)](https://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals)
5. [OSHA Laboratory Safety Guidance](https://www.osha.gov/Publications/laboratory/OSHA3404laboratory-safety-guidance.pdf)
6. [OSHA's Occupational Exposure to Hazardous Chemicals in Laboratories standard (29 CFR 1910.1450)](https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1450)
7. [MIOSHA Laboratory Safety regulations (general lab safety and bloodborne infectious disease standard),](https://www.michigan.gov/documents/CIS_WSH_part554_35632_7.pdf)
8. Safety in Academic Chemistry Laboratories - American Chemical Society
9. [Guidelines for Chemical Laboratory Safety in Academic Institutions-American Chemical Society](https://www.acs.org/content/dam/acsorg/about/governance/committees/chemicalsafety/publications/acs-safety-guidelines-academic.pdf)
10. [Chemical Laboratory Safety and Security: A Guide to Developing Standard Operating Procedures](https://www.ncbi.nlm.nih.gov/books/NBK379131/)

# **Appendices**

## **WSU Laboratory Safety Compliance Procedure for Chemical Hazards**

**Laboratory Safety Compliance Procedure for Chemical Hazards**

The Wayne State University (WSU) Office of the Vice President for Research (OVPR) has charged the Wayne State University Chemical Safety Committee (WSU-CSC) to develop, recommend, update, and maintain procedures applicable to chemical hazards and safety practices at WSU in order to promote safe research practices. In an effort to ensure that safety issues related to chemical hazards in WSU laboratories are addressed and corrected within a timely manner, the committee has established a 3- tiered Laboratory Safety Compliance Procedure (LSCP) for Chemical Hazards. This procedure outlines the process for remedial actions for non-compliance chemical safety issues identified during routine chemical hygiene inspection (CHI) or during follow-up spot check inspections.; a physical re-inspection of a space following CHI. These non-compliance issues emerge when safety procedures are not followed, or when procedures are not in compliance with federal, state, or local regulations. Laboratory safety compliance issues related to biological and radioactive hazards are covered by separate institutional oversight committees.

While the 3-tiered procedure is designed to provide a progressive compliance process, it may be by- passed in the event of an egregious finding that endangers the safety of employees or the environment. Any egregious findings will be reported to OVPR immediately for review at the discretion of The Office of Environmental Health & Safety (OEHS) Chemical Hygiene Officer (CHO). This may result in suspension of the Principal Investigator (PI)’s laboratory activities, in whole or in part, by OVPR, and the OEHS Director. Should this occur, the PI will be required to appear before the WSU-CSC (or an appropriate subcommittee) before laboratory activities may resume.

**Tier One**

The LSCP for Chemical Hazards is initiated at the discretion of the CHO when an issue of noncompliance is identified by OEHS and a suitable plan of action (corrective action plan, CAP) to resolve it is not in place or corrective actions described in the CAP are found not to have been performed during the follow-up spot check inspections. The CHO provides the Chair of the WSU-CSC with a report indicating the issue(s) of noncompliance, the date(s) the issue was identified, and the time frame over which the issue has not been resolved.

Note: Corrections that require infrastructure upgrades will be considered on a case-by-case basis and alternative risk mitigation strategies may be approved by the WSU-CSC (or a Subcommittee consisting of at a minimum, the Chair, the CHO, and a third committee member to be appointed by the Chair) and the OEHS Director or designated alternate OEHS representative.

Once a report is issued to the WSU-CSC, the committee may move to issue a Tier One Memorandum or defer issuance of the memorandum. If the committee wishes to defer, it must establish a rationale for deferring issuance and set a time for re-evaluation.

A Tier One Memorandum will be sent to the PI and their Departmental Chair from the WSU-CSC Chair informing them of the noncompliance issue(s); the risks associated with these issues; consequences of safety violations; and of the potential for suspension of operations. The memorandum will indicate the item(s) of noncompliance and indicate a new time frame for implementing corrective action.

A written response to the Tier One Memorandum is required. The response should contain details regarding either the corrective action taken or plans to take corrective action. Failure to respond within the stated time period (15 calendar days or a time frame determined by the committee) will escalate the memorandum level to Tier Two. Lack of corrective action within the prescribed problem-resolution period following a Tier One Memorandum will result in the issuance of a Tier Two Memorandum. If the committee wishes to defer issuance of a Tier Two Memorandum, it must establish a rationale for deferring issuance and set a time for re-evaluation.

When the item(s) of noncompliance are corrected within the specified time frame the WSU- CSC will issue a Resolution Memorandum indicating that corrective action has been taken and verified by OEHS. Since corrective action must be verified by OEHS, labs should provide sufficient time for OEHS to respond to claims of corrective action.

**Tier Two**

A Tier Two Memorandum will be sent to the PI, Department Chair, Collegiate Dean, and Associate Vice President for Research (AVPR) informing them of the noncompliance issue(s); the risks associated with these issues; consequences of safety violations; and of the potential for suspension of operations. This notice will be sent to the PI informing them that this is a repeat item of noncompliance that was not resolved in response to the Tier One Memorandum. The PI, or their representative, must provide a formal written response to the WSU-CSC and OEHS as to the reasons for a second instance of non- compliance specifying the specific barriers to complying with best practices, and/or why the previous corrective action(s) was/were ineffective and what further corrective action(s) will be implemented to prevent recurrence. In addition, the PI (or other responsible manager) will be asked, along with their Department Chair, to appear before the WSU-CSC to discuss the proposed corrective action plan. Additionally, members of the WSU-CSC may determine that a site visit of the laboratory space(s) is required. The Committee will offer recommendations and/or additional requirements to the PI to ensure future compliance.

Failure to respond within the stated time period (15 calendar days from the date of issue or as determined by the committee) will escalate the memorandum level to Tier Three.

Lack of corrective action within the prescribed problem-resolution period following a Tier Two Memorandum will result in the issuance of a Tier Three Memorandum. If the committee wishes to defer issuance of a Tier Three Memorandum, it must establish a rationale for deferring issuance and set a time for re-evaluation.

When the item(s) of noncompliance are corrected within the specified time frame the WSU- CSC will issue a Resolution Memorandum indicating that corrective action has been taken and verified by OEHS. Since corrective action must be verified by OEHS, labs should provide sufficient time for OEHS to respond to claims of corrective action.

**Tier Three**

A Tier Three Memorandum will be sent to the PI, Department Chair, Collegiate Dean, AVPR and the Vice President of Research informing them of the continuing noncompliance and recommending that the PI’s operations be suspended until corrective action is taken. The OVPR will decide on the course of action following consultation with the WSU-CSC and the Director of OEHS and will provide authority and instruction on enacting suspensions. During the suspension period, the PI and Department Chair will be instructed to appear before the WSU-CSC to explain why the operation should be reinstated and concurrently present a formal written corrective action plan.

Adapted from:

University of California, Los Angeles, [Laboratory Safety Compliance Procedure (LSCP) Implementation Plan](http://rsawa.research.ucla.edu/cpsc/laboratory-safety-compliance/)

University of Iowa, [Laboratory Safety Compliance Policy for Chemical and Physical Hazards](https://ehs.research.uiowa.edu/sites/ehs.research.uiowa.edu/files/CompliancePolicyforChemicalandPhysicalHazards.pdf)

## **Summary of WSU Laboratory Safety Compliance Procedure for Chemical Hazards**

**Laboratory Safety Compliance Procedure (LSCP) for Chemical Hazards**

**SUMMARY**:

Wayne State University Chemical Safety Committee (WSU-CSC) has established a three-tiered Laboratory Safety Compliance Procedure (LSCP) to address non-compliance chemical safety issues. WSU Office of Environmental Health and Safety (OEHS) identified these issues during Chemical Hygiene Inspections (CHIs) or during follow-up spot check inspections; physical re-inspection of laboratories following CHIs. The sections below provide a summary of the actions taken to mitigate non-compliance issues for each Tier of this LSCP. A full description of the LSCP can be found on-line.

**Note. The LSCP will be applied to laboratories that:**

1. **Fail to provide a corrective action plan (CAP) in a timely manner to the non-compliance issues identified during CHIs performed by the (OEHS): Steps 1-4**
2. **Fail to complete steps described in the CAP submitted to OEHS: Steps: 2-4**

| **Laboratory Safety Compliance Procedure** |
| --- |
| **Step 1: Chemical Hygiene Inspection (CHI) Report**:* **Individuals notified**: Principal Investigator (PI) and Department Chair
* **Time frame for corrective action(s)**: Unless otherwise indicated, the PI must return the completed corrective action plan (CAP) to OEHS within 30 calendar days of date indicated on the report.
* **Consequence of non-response**: WSU Chemical Hygiene Officer reports non-compliance occurrence to WSU-CSC and initiates Tier One review.
 |
| **Step 2: Tier One Review and Memorandum**:* **Individuals notified**: PI and Department Chair
* **Time Frame**: Unless otherwise indicated, a response is required within 15 calendar days.
* **Response Required**: Written response to CSC outlining corrective action(s) or planned corrective action(s).
* **Consequence of non-response**: WSU-CSC elevates non-compliance issue to Tier Two of the LSCP.
 |
| **Step 3: Tier Two Review and Memorandum**:* **Individuals notified**: PI and Department Chair, Collegiate Dean, Associate Vice President for Research (AVPR)
* **Time Frame**: Unless otherwise indicated, a written response is required within 15 calendar days.
* **Response Required**:
	+ Written response to CSC outlining corrective action(s) or planned corrective action(s) and reasons for failure to respond to the Tier One memorandum.
	+ PI and Department Chair will be asked to appear before the WSU-CSC to discuss the non-compliance issue.
* **Consequence of non-response**: Elevation of non-compliance issue to Tier Three of the LSCP.
 |
| **Step 4: Tier Three Review**:* **Individuals notified**: PI and Department Chair, Collegiate Dean, Associate Vice President for Research (AVPR), Vice President of Research
* **WSU-CSC recommends to the VP of Research that PI’s operations be suspended until corrective action is taken**.
* **Response Required**:
	+ OVPR determines the response required following consultation with the WSU-CSC and Director of OEHS
	+ PI and Department Chair are instructed to appear before the WSU-CSC to present a formal written corrective action plan.
 |

## **Chemical Safety Protocol (CSP) Package**

**CSP Document 01- Instructions**

**Review and Approval Procedure for Specific High-Risk Chemicals**

**Instructions**

Specific High-Risk Chemicals (SHRCs) are chemicals which require prior approval by the Wayne State Chemical Safety Committee (WSU CSC) to be used in a procedure either in the form of a reactant or a product. SHRCs include:

* Globally Harmonized System (GHS) category 1 acute toxins (dermal and/or inhalation). Refer to the Safety Data Sheet section 2 for chemical hazard information.
* Other high-risk chemicals identified by WSU Chemical Hygiene Officer (CHO)

WSU labs/facilities that intend to use SHRCs, must submit a Chemical Safety Protocol (CSP) to the CSC by following the guidelines detailed below.

1. **Complete the Chemical Safety Protocol (CSP)**

For the SHRC(s) identified, the principal investigator/laboratory supervisor must complete the following documents of the CSP.

* 1. **Risk Assessment Form**

This form communicates to the WSU CSC on hazard information associated with a particular SHRC.

* 1. **Lab Specific Standard Operating Procedure**

Upon approval by WSU CSC, this Lab Specific Standard Operating Procedure (SOP) will be used to communicate hazard information to the lab personnel handling SHRC(s).

1. **Acquire departmental approval**

Once the Risk Assessment Form and Lab Specific SOP are completed, submit to the department chair for the signature on section 13 of the Risk Assessment Form.

1. **Submit the signed CSP to the Chemical Hygiene Officer**

Once the departmental approval is obtained, submit the CSP to the WSU CHO for an initial review of the protocol for completeness. If the protocol is complete, CHO will then submit the CSP to the CSC.

Review and approval of the CSP by the CSC

1. **Typically, your CSP will be reviewed within 30 days of submission to the CHO. Committee will** either approve or recommend changes. The outcome of the review will be communicated to the principal investigator by the CHO.
2. **Renewal of approved protocols**

Each CSP must be resubmitted and reviewed every three years.

**CSP Document 02 - Risk Assessment Form**

**Wayne State University Chemical Safety Committee (WSU CSC) Chemical Safety Protocol (CSP) Review and Approval Procedure**

**Risk Assessment Form**

**Purpose**

This form is to perform a risk assessment by WSU CSC on the Specific High-Risk Chemicals (SHRCs) used in chemical procedures conducted at WSU labs/ facilities. Specific High-Risk Chemicals (SHRCs) are the chemicals which require prior approval by the WSU CSC to be used in a chemical procedure either in the form of a reactant or a product. As outlined in the document “WSU Step by Step Guide on Standard Operating Procedures (SOPs) and Animal Hazard Agent Form II Chemical (AHAF II) requirements for Chemicals Use in Research”, WSU research labs/facilities MUST obtain the CSC approval prior to using following SHRCs:

* GHS category 1 acute toxins (dermal and/or inhalation)
* Other high-risk chemicals referred to WSU-CSC by Chemical Hygiene Officer

**Procedure**

Please complete this form for any experimental procedure using SHRCs. The CSC will review this form and corresponding SOP(s) included in the CSP to determine if any additional procedures, health and safety measures or equipment are required to mitigate the potential exposure risks associated with the experimental procedure using SHRCs.

For more information, /questions on the WSU CSC Chemical Safety Protocol (CSP) Review and Approval Procedure:

* Refer to the Instructions guide included in the CSP package.
* or Contact Sandamali Ekanayaka, WSU Chemical Hygiene Officer (sekanayaka@wayne.edu 313-993-6614)

**Note: DO NOT** combine SHRCs from multiple procedures to one CSP. If lab uses multiple chemical procedures involving use of SHRCs, separate CSP must be submitted to each procedure.

1. **Principal Investigator (PI) Information**
	1. PI Name:
	2. Department:
	3. Campus Address:
	4. Phone number(s):
	5. Email:
2. **Chemical Safety Protocol (CSP) Title:**
3. **Date CSP submitted to the CHO:**
4. **Status of the CSP (New / Renewal):**
5. **Previously Approved by Chemical Safety Committee? (Yes/No):**
	1. If yes, approval #:
6. **IRB/IACUC/IBC/RSC Protocol # (If applicable):**
7. **SHRCs used in this CSP which require CSC approval.**

Use the table below to complete the quantity, physical form, hazards and exposure routes of SHRCs used. Note: SHRCs listed in the table should associate with an individual experimental procedure.

Use a continuation sheet if necessary. If applicable, provide a copy of the Safety Data Sheet (SDS) for each SHRCs listed in Table 01. Note: Each CSP review use of SHRCs specific to individual experimental procedures.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SHRC[name and CAS number (if applicable)] | Quantity/ Concentration (if applicable) | Physical form (powder, vapor, volatile liquid, gas, etc.) | Hazards (Physical or Health) | Exposure route(s)e.g., skin, eyes |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Experimental procedure

Please provide a brief summary of the experimental procedure which use SHRCs in the form of a reactant or a product. If applicable include experimental/reaction conditions (e.g., temperature, pressure) and potential outcomes (e.g., explosive, exothermic, release gas/ vapor, pressurization, generate unstable products etc.)

1. Risks associated with potential exposure to SHRCs.

Briefly describe the known and anticipated risks (e.g., fire, explosion, leaks, spills etc.) associated with the potential exposure to each SHRCs (reactants or products) used in this CSP.

For each SHRC used also Include: \*

* 1. What is the likelihood of the exposure? (Unlikely, Likely, Very Likely)
	2. What is the severity of the exposure? (Low, Medium, High)
	3. What is the risk level of the exposure? (Insignificant, minor, moderate, major, intolerable)

*\* To answer the items 9.a to 9.c please refer to the risk assessment matrix included in the CSP package.*

1. Control measures to mitigate the risks associated with SHRCs.
	1. Elimination, Substitution and Administrative Controls

|  |  |
| --- | --- |
| **Control measures** | **Yes/ No? (Provide detail answers)** |
| Can any of the SHRCs be substituted by a less hazardous chemical? |  |
| Can the amount of SHRC used be reduced |  |
| Is there an area dedicated to performing the experiments/ procedures using SHRCs? |  |
| What warning signage is posted on areas where SHRCs are used? |  |
| Can the experimental procedure be modified to reduce the risk of exposure? |  |
| Can different laboratory equipment can be used to reduce the risk? |  |

* 1. **Engineering Controls:**
* Chemical fume hood (Provide certification date):
* Glove box
* Other local exhaust ventilation (describe):
* Blast guard/shield
* Other (specify):
	1. **Personal Protective Equipment:**
* Lab coat (type):
* Chemical apron
* Gloves (type):
* Eye protection (type):
* Full Face shield
* Respiratory protective equipment (type):
* Other (specify):
	1. **Chemical Transportation:**

Describe transportation methods to be used to prevent risks associated with the transportation of SHRCs used in this CSP.

* 1. **Chemical Storage:**

List storage methods to be used to prevent risks associated with the storage of SHRCs used in this CSP (e.g., chemical incompatibility, storage cabinet type, storage temperatures etc.)

* 1. **Waste Disposal:**

Describe disposal measures to be used during and after the procedures to prevent exposure to hazardous waste.

* 1. **Other Laboratory Equipment:**

If applicable, list any major laboratory equipment (other than engineering controls) used to process the SHRCs in Table 03. Include associated risks and control measures implemented to mitigate these risks.

|  |  |  |
| --- | --- | --- |
| **Major Laboratory Equipment Used** | **Potential Risks****(i.e., electric shock, temperature extremes, pressure, chemical exposure)** | **Risk Control measures** |
|  |  |  |
|  |  |  |
|  |  |  |

* 1. **Safety Training:**

Select all the applicable safety training programs required to safely handle the SHRCs used in this CSP.

* Laboratory Safety Training (general lab and chemical safety issues)
* Laboratory-Specific Safety Training (link to Word Doc checklist)
* Biosafety/Bloodborne Pathogens Training
* Shipping Biological Substances & Dry Ice Refresher Training
* Controlled Substance Training
* Radiation Safety Training
* Hazard Communication
* Other training
	1. **Other Control measures:**

If available, list any additional control measures, which can be used to reduce the risk of exposure to the SHRCs listed in this protocol.

1. **Emergency procedures (emphasize any special hazards, check SDS further information):**
2. Shut down Procedures:
3. Action in the event of Fire (type of extinguisher):
4. Action in the event of spillage or uncontrolled release (chemical specific spill control kit etc.):
5. Emergency first aid treatment (s) for personnel in the event of contamination, exposure to vapors or other adverse effects.
6. **Principal Investigator’s Agreement**

I acknowledge responsibility for this project, and I agree to fully comply with all pertinent Wayne State University Chemical Safety Committee (CSC) and the Office of Environmental Health and Safety (OEHS) guidelines and policies. I assure that all faculty, staff and students involved in this project will be trained and qualified to carry out the research in a responsible manner in accordance with all applicable federal and state regulations, WSU policies and procedures.

Date:

Principal Investigator Signature

1. **Department Chair’s Agreement**

In signing this Risk Assessment Form, I certify that I am aware of the proposed research project using Specific High-Risk Chemicals and that the department is able to provide the facilities described in this application (space, equipment, etc.).

Date:

Department Chair Signature

1. **Following section is for use of WSU CSC ONLY**
2. Date CHO received CSP:
3. Date CSC received CSC:
4. Chemical Safety Protocol #:
5. Type of CSP approval
6. Approved
7. Denied: Reason for denial
8. Date CSP approved by CSC:

**CSP Document 03 - Risk Assessment Matrix**

**Wayne State University Chemical Safety Committee (WSU CSC)**

**Chemical Safety Protocol (CSP) Review and Approval Procedure**

**Risk Assessment Matrix**

|  |  |
| --- | --- |
|  | **Severity of Exposure** |
| **Likelihood of Exposure** |  | **Low****(Less hazardous)** | **Medium****(Hazardous)** | **High****(Highly hazardous)** |
| **Unlikely** | **1** | **2** | **3** |
| **Likely** | **2** | **3** | **4** |
| **Very likely** | **3** | **4** | **5** |

**Risk Level**

**1** – Insignificant. No further action needed.

**2** – Minor. Monitor and review the risk control procedure. No further risk control measures required.

**3** – Moderate. If possible, modify existing or implement new risk control measures to mitigate the risk. Monitor, review and document the risk control procedures.

**4** – Major. Must modify existing or implement new risk control measures to mitigate the risk. Monitor, review, document and strictly managed the risk control procedure.

**5** – Intolerable: Cease the chemical procedure, until existing risk controls measures are modified, or new control measures implemented. Monitor, review, document and strictly managed the risk control procedure.

**CSP Document 04 - WSU Lab Specific Chemical SOP Template**

*Contact WSU Chemical Hygiene Office for a copy of this template.*

**CSP Document 05 - CSP Review Outline**

**WSU Chemical Safety Committee (CSC) Chemical Safety Protocol (CSP) Review Outline**

|  |  |
| --- | --- |
| **Reviewer Name**:  | **PI Name:**  |
| **Chemical Safety Protocol** (CSP) #:  | **Date:**  |
| **Protocol Title:**  |
| **Reviewer recommendation and comments:** |
|[ ]  **Approved** |  |
|[ ]  **Conditionally approved** |  |
|[ ]  **Tabled for approval** |  |
|[ ]  **Denied** |  |
|  |
| **Issue** | **YES** | **NO** | N/A | **Comments** |
| **Completeness** |
| Is the Chemical Safety Protocol (CSP) package complete? (All documents: Risk assessment form and SOP attached.) |[ ] [ ] [ ]   |
| Is the information provided on Risk assessment form and the SOP consistent? |[ ] [ ] [ ]   |
| **Experimental Procedure** |
| Is the Specific High-Risk Chemicals (SHRCs) listed in the CSP associated with an individual experimental procedure? |[ ] [ ] [ ]   |
| Is the information provided on physical form, hazards, and exposure routes of SHRCs accurate? |[ ] [ ] [ ]   |
| Does the summary of the experimental procedure provide sufficient detail? |[ ] [ ] [ ]   |
| **Risks associated with potential exposure to SHRCs** |
| Is the information provided on known and anticipated risks of exposure to SHRCs adequate?  |[ ] [ ] [ ]   |
| Is the information provided on likelihood, severity, and risk level of exposure to SHRCs acceptable? (Refer to risk assessment matrix included in the CSP package)  |[ ] [ ] [ ]   |
| **Control measures to mitigate the risks associated with SHRCs**  |
| Are any of the control measures taken to substitute, reduce the amount or the level of exposure to SHRCs adequate?  |[ ] [ ] [ ]   |
| Does the protocol use proper administrative controls to mitigate the risks?  |[ ] [ ] [ ]   |
| Are the selected engineering controls sufficient to mitigate the exposure to SHRCs? |[ ] [ ] [ ]   |
| Does the experiment use adequate PPE? |[ ] [ ] [ ]   |
| Are the chemical transportation methods described in CSP sufficient to prevent risks associated with the transportation of SHRCs? |[ ] [ ] [ ]   |
| Are the chemical storage methods described in CSP sufficient to prevent risks associated with the storage of SHRCs?  |[ ] [ ] [ ]   |
| Are the waste disposal/decontamination measures taken during and after the experimental procedures adequate to prevent exposure to hazardous waste? |[ ] [ ] [ ]   |
| Do any major laboratory equipment (other than engineering controls) used to process the SHRCs, (Table 03 risk assessment form) use adequate control measures to mitigate the exposure risks of SHRCs? |[ ] [ ] [ ]   |
| Are safety training programs chosen by the researchers adequate to provide guidance on safe handling of the SHRCs? |[ ] [ ] [ ]   |
| Are the additional control measures listed appropriate to reduce the risk of exposure to the SHRCs? |[ ] [ ] [ ]   |
| If no additional control measures listed, does this procedure require any additional control measures to mitigate the exposure risk to SHRCs? |[ ] [ ] [ ]   |
| **Emergency procedures** |
| Are appropriate emergency shut down procedures correctly identified? |[ ] [ ] [ ]   |
| Is the correct fire extinguishing method and/or the type of fire extinguisher described in the CSP?  |[ ] [ ] [ ]   |
| Are the methods mentioned in CSP appropriate to respond to spillage or uncontrolled release of SHRCs? |[ ] [ ] [ ]   |
| Are first aid treatments correctly described in the CSP documents? |  |  |  |  |
| **Additional issues** |
| Does the protocol contain issues that require subcommittee discussion or specialist input? |[ ] [ ] [ ]   |
| Any other issues of concern? |[ ] [ ] [ ]   |
| **Reviewer Comments (summary to send to the applicant)** |
|  |

**CSP Document 06 - CSP Approval Letter Template**

[CHAIR NAME]

Chair - Wayne State University Chemical Safety Committee

[Chair department]

Wayne State University

[Chair building and office address]

Detroit, MI 48202

(Date)

(Name) (Address)

Dear Dr. (name)

Thank you for submitting your Chemical Safety Protocol (CSP) for review by the WSU Chemical Safety Committee (CSC). I am pleased to inform you that the WSU CSC has approved your CSP (title and number) as of the date of this letter.

This approval is valid for three years and will expire on (expiration date). Please note that each CSP must be resubmitted and reviewed by CSC in order to continue any activities described in this protocol beyond its expiration date (date). In addition, any new changes to this CSP must be reviewed and approved by the WSU CSC prior to its implementation.

I wish you good luck with your research.

Sincerely

[CHAIR NAME]

Chair - Wayne State University Chemical Safety Committee

CC: Sandamali Ekanayaka, WSU Chemical Hygiene Officer

## **WSU CSC** **Unexpected Problems Reporting**

**Unexpected Problems Reporting**

**BACKGROUND:**

Unexpected problems constitute chemical safety issues that are outside of the scope of the regular chemical hygiene inspections (CHIs) conducted by the Office of Environmental Health and Safety (OEHS) chemical safety group and are not covered by Wayne State University (WSU) laboratory safety compliance procedure (LSCP). LSCP only covers non-compliance issues found during routine CHIs.

The Wayne State Chemical Hygiene Officer (CHO) is required to promptly report unexpected problems to the Wayne State university Chemical Safety Committee (WSU CSC) and appropriate institutional officials.

Upon notification by the CHO, CSC Chair will initiate the review process and act upon potential safety violations or non-compliance issues associated with the unexpected problems reported. If necessary, CSC Chair will report and provide recommendations to the Institutional Official on the outcomes of the review. At WSU, the Institutional Official for the CSC is the Associate Vice President for Research (AVPR). In their role as Institutional Official, the AVPR is then responsible for any reporting requirements to supporting agencies and appropriate regulatory authorities.

The timeline for reporting unexpected problems to the CSC will depend on the nature, severity, or associated regulatory reporting requirements of the problem, but will be no later than the next scheduled CSC meeting.

Unexpected problems forwarded to the CSC include:

1. Items which do not require immediate corrective actions and require the expertise or support of the CSC.

Upon notification by CHO, the CSC will initiate a review on these problems and implement corrective action plans. Examples of such problems include, but are not limited to:

* SOP violations (i.e., no SOP, deviation from SOP).
* Chemical safety violations identified outside of routine chemical hygiene inspection.
* Non-compliance issues: minor, serious, continuing.
* Failure to obtain CSC approval to work with Specific High-Risk Chemicals.
1. Items which require immediate action due to associated adverse health, physical and environmental effects and are initially addressed by other WSU groups such as Enterprise Risk Management, Fire safety, OEHS Emergency response team, WSU police etc.

The CSC will be notified about the outcome of these problems by the CHO to determine if further review and reporting is required. Examples of such unexpected problems include, but are not limited to:

* Hazardous Chemical Spills
* Chemical Fires
* Life threatening laboratory injuries

**Procedure to Review and Report Unexpected Problems by CSC:**

1. The WSU CHO will notify PIs and their Department Chair when unexpected problems are identified that need to be reported to the WSU CSC for further review.
2. The PI is required to complete the “Unexpected Problems Report Form” and return to the CHO within 3 business days of the notification.
3. The information in the report will be provided to the CSC Chair by CHO for review.
4. The CSC Chair's review will determine if the problem requires full CSC review. This will be based primarily on the nature, severity, or associated regulatory reporting requirements of the incident.
5. If full review is required, CSC members will be asked to determine if they agree with the PI’s corrective actions outlined in the “Unexpected Problems Report” and determine if WSU needs to implement any corrective actions at the institutional level.
6. Due to the time sensitive nature of the CSC reporting responsibilities, full CSC review of these reports does not need to be conducted during the regularly scheduled meetings.
7. Information provided in the form completed by the PI, supported by information provided by the CHO and CSC, will be utilized to complete any official reports that need to be submitted by the Institutional Official.
8. PI and their Department Chair will be informed on the outcome of the review, provided with a copy of the official report, and appropriate regulatory authorities have been notified. For protocols in which animal models are used, the IACUC Chair and Attending Veterinarian will also be notified.
9. Official reports will be presented to the CSC at the next convened meeting, along with any information received from regulatory authorities.

**Instructions to Complete the Unexpected Problem Report.**

1. Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident. Include the following information as applicable.

A description of:

* The incident/violation location (e.g., laboratory, vivarium, non-laboratory space)
* Who was involved in the incident/violation, including others present at the incident location?
* Note – please do not identify individuals by name. Provide only gender and position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker)
* Actions taken at the time of the incident and by whom, to limit any health or environmental consequences of the event.
* The training received by the individual(s) involved and the date(s) the training was conducted.
* The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.
* Any deviation from the CSC approved containment level or other CSC approval conditions at the time of the incident/violation.
* The personal protective equipment in use at the time of the incident/violation.
* The occupational health requirements for laboratory personnel involved in the research.
* Any medical surveillance provided or recommended after the incident.
* Any injury or illness associated with the incident.
* Equipment failures
* The scope of the incident – was it restricted to the designated laboratory space and approved personnel or were other, non-approved areas and personnel involved in the incident? Note – please do not identify individuals by name. Provide only gender and position titles such as custodian, student, salesperson, etc.
1. Describe corrective actions taken by the Principal Investigator to mitigate any problems identified. Please provide a list of key occurrences/circumstances that led to the unexpected problem and under each one, provide a corrective action intended to prevent further such incidents. For measures identified but not yet taken, please include a timeline for their implementation.
2. Please complete all relevant sections of the form below and submit the completed document to the WSU CHO within 3 days of receipt. Forms can be submitted via e-mail to Dr. Sandamali Ekanayaka, az9749@wayne.edu.
3. Additional information may be requested by the WSU CSC after review of this report depending on the nature of the problem.

| **UNEXPECTED PROBLEMS REPORT FORM**This form is intended to facilitate the reporting of problems that occur during the conduct of research and subsequent notification of appropriate regulatory authorities. |
| --- |
| **Date of Report:** |  |
| **Name of Principal Investigator:** |  |
| **E-mail address:** |  |
| **Phone Number:** |  |
| **Date problem occurred/identified:** |  |
| **What was the nature of the problem:****(More than one answer may apply)** | [ ]  Failure to follow / deviations from the approved SOP.[ ]  Failure to obtain CSC approval.[ ]  Loss of hazard containment[ ]  Personnel exposure[ ]  Spill[ ]  Uncontrolled experiment [ ]  Other (please describe):  |
| **Did the WSU Chemical Safety Committee (CSC) approve this research?** | [ ]  Yes [ ]  NoIf yes, date of approval: Date of expiration:  |
| **Please describe the root cause of the problem:** |  |
| **Description of the incident** *(To be completed by the PI/lab manager. Use additional**space as necessary, refer to section C.1 for instructions)* |  |
| **Corrective actions recommend by the PI** *(To be completed by the PI/lab manager. Use additional space as necessary, refer to section C.2 for instructions)* |   |
| **Corrective actions recommend by the OEHS and WSU CSC** *(To be completed by the CSC Chair/Administrator).* |   |