UBC BIOSAFETY COMMITTEE
POLICY 001
Non-Compliance Procedures

Date Approved: May 17, 2016

POLICY

All individuals involved in the use of Biohazardous materials for research, teaching or testing at the University of British Columbia must follow their approved biosafety permit, as well as meet all requirements set out by the various regulations overseen by: Public Health Agency of Canada, Canadian Food Inspection Agency, Environment Canada, Health Canada, and WorkSafe BC. The Principal Investigator (PI) named on a biosafety permit is ultimately responsible for all work performed under this permit. Non-compliance with these guidelines and regulations could lead to permanent suspension of all permits held by the PI responsible, and could lead to a finding of scholarly misconduct against the PI (see UBC Policy #85).

PURPOSE and SCOPE OF THE POLICY

This policy will apply to all users of biological materials which includes faculty, postdoctoral fellows, students and research staff.

The purpose of this policy is to detail the course of action to be taken when an Investigator or any of his/her trainees or staff (students, graduate students, post-doctoral fellows, technicians, etc) is found in violation of the UBC Biosafety program.

These violations may be a serious one-time incident or repeated less-serious incidents indicating a more chronic issue with biosafety compliance.

PROCEDURES

A) Serious Incidents of Non-Compliance in Regards to Biological Materials

2. If such an incidence of non-compliance occurs requiring a suspension of the permit(s), the Biosafety Committee has a duty to act as expeditiously as possible. For a non-compliance issue, the Biosafety Officer or the Biosafety Committee will provide written notice to the PI and his/her delegates, and the Biosafety Committee as soon as possible (within 1 working day). The Committee will then communicate to the PI within 72 hours whether such suspension is confirmed beyond this initial period.

3. The Risk Management representative and the Chair, Biosafety Committee will arrange to meet with the investigator at the earliest possible time to conduct a fact-finding meeting and to determine an initial course of action to address the situation, its causes and consequences. An initial course of

action will be developed at the first meeting, and may be elaborated at subsequent meetings or as additional facts concerning the incident emerge (see step 3 in Procedures, Section B (below). If the risk of repeated non-compliance is considered to be high, the initial course of action may include temporary suspension of the active permit. This means that the investigator cannot conduct any new research work under the suspended permit until the incident is reviewed by the full Biosafety Committee. A quorum of the Biosafety Committee will make the final determination of the seriousness of the incident and of subsequent courses of action.

B) Chronic Problems Contravening Biohazardous Materials or Use Standards

1. Chronic problems of non-compliance are normally reported through Risk Management site visits or local health and safety committee inspections, but can be reported by anyone.

2. The details of the chronic issue(s) will be discussed by the Biosafety Committee at the next meeting. The Committee will notify the PI in writing of the reported non-compliance. An initial meeting of the Biosafety Committee Executive with the PI will be arranged as soon as possible to resolve the problem. If there is a subsequent recurrence of problems either associated with one particular permit or with several permits involving the same PI, a letter will be sent to the PI outlining the concerns and the Committee will arrange to meet the investigator at the earliest possible time to conduct a fact finding meeting.

In the event that a member of the Biosafety Committee is the PI named in the incident, the Committee will arrange to meet the investigator at the earliest possible time to conduct a fact finding meeting. However, any subsequent discussion of the issue and the course of action to be taken will be conducted confidentially by the Committee in the absence of that member.

3. The Biosafety Committee may recommend one or more courses of action in dealing with the resolution of chronic non-compliance issues. Measures must be taken by the Committee to ensure that issues are effectively resolved and will not reoccur. These may include, but are not limited to: a) temporary suspension of an active permit, b) permanent suspension of a single permit, or c) temporary or permanent suspension of all permits held by the PI.

DOCUMENTATION

1. Verified details of the circumstances of serious incidents of non-compliance or chronic non-compliance will be retained on file with the Biosafety Committee Administration and the investigator in question will receive a copy.

2. A formal letter containing the details of the Committee recommendations will be sent to the PI with copies to the Chair, Head or Dean of the investigators academic unit. If the Committee permanently suspends an investigator's research permits, copies will also be sent to the VP Research & International and the University Counsel, and this could lead to initiation of a scholarly misconduct investigation process for the PI (see UBC Policy #85).

REACTIVATION OF A SUSPENDED PERMIT

1. Depending on the nature of the non-compliance incident(s), suspension of a permit (temporary or permanent) means that the investigator is either prohibited from conducting any *further* research work under the suspended permit or any *new* research work under the suspended permit (one of these two options will be identified in the meeting with, or letter to, the PI).

2. In all cases where a permit is suspended, a quorum of the Biosafety Committee will outline the steps that must be taken to have the permit reinstated. Requirements for reactivation of a suspended permit will vary depending on the nature of the incident(s).

3. In some cases, reactivation can occur once the Biosafety Committee receives a letter indicating that the PI will comply with the recommendations. In other cases, the Committee may require that the PI and/or members of their lab receive further training, either didactic or hands–on, to ensure competency, prior to or in conjunction with resumption of permit activities.

4. The Biosafety Committee may also require follow-up visits and reports on the conduct of the reinstated research permit. The PI may also be asked to meet with the full Committee or subset of the Committee to discuss the noncompliance situation and corrective measures, and to provide further information in the form of a follow up report or visit.

5. In some cases, reactivation may not be advised. In some cases, after permanent suspension an investigator may only be permitted to transfer grants and activities to another lab which may continue to conduct his/her research with no hands on, direct involvement by the PI or his/her personnel

6. PIs are expected to fully and sincerely cooperate in the review process. In the event of non – cooperation by the investigator with the Biosafety Committee Executive and Risk Management Services, the Biosafety Committee will revoke all permits belonging to a PI until the cooperation is received.

RECOURSE

1. The investigator may request to meet with the full Biosafety Committee to review the facts and, if there is dispute about acceptable practice, to introduce documentation in support of the practices in question. The investigator may be accompanied by his/her Department Head.

2. An investigator may seek recourse in the form of a written request to the Vice President, Research, for a full review of the Biosafety Committee recommendations and the reasons that led to them. The written decision of the VP Research, copied to the Biosafety Committee, Risk Management Services, the PI and his/her Head, Dean or Chair, on the final disposition of the incident is binding and final.

Appendix F Graduated Enforcement of Non-Compliance

Issues of non-compliance are normally noted, but not restricted to, discovery by the biosafety office staff in the execution of their duties. The follow steps shall be taken to ensure the shortcomings are addressed fully and in a timely manner.

1. Informal compliance inspections conducted by BSO staff are normally performed in laboratories designated as RG1. The hazards in these areas is generally low and when issues of non-compliance such as shortcomings in record keeping are noted, often verbal notification of the issue to the permit holder will be considered appropriate with the expectation the issue will be resolved. Such instances will normally be recorded in the RMS database for future reference. Written response by the permit holder to oral guidance from BSO staff is not required. Should the issue be deemed to be significant, i.e. repeated findings by BSO staff of unidentified mid or high level removable surface contamination, the BSO may choose to inform the licensee in writing with a requirement that a written response of correction be supplied to the BSO by a specific date. The BSO may also choose to forward the issue to the Committee for resolution.

2. Formal compliance inspections conducted by BSO staff are normally performed in laboratories designated as RG2 or higher. An inspection form is utilized to document the findings. A detailed written summary of the findings from this form will then be forwarded to the permit holder. This notification shall include recommendations to resolve the issues of non-compliance with a requirement that a written response of correction be supplied to the BSO by a specific date. Failure to provide proof that the shortcomings have been addressed within the required time limit may result in the BSO choosing to forward the issue to the Chair of the IBC for resolution.

3. The IBC Chair shall be informed when BSO staff become aware of the following issues of non-compliance:

    a. Willful violation of policies, license conditions or the applicable regulations regarding the use of biological materials.
    b. Loss or inability to account for biological material.
    c. Repeated findings by BSO staff of unidentified mid or high level removable surface contamination.
    d. Biological exposures
    e. Improper use of biological materials that results in significant endangerment of the safety of personnel or the environment.
    f. Use of biological materials not authorized by the permit.
    g. Repeated findings by BSO staff of eating/drinking/or smoking in permitted laboratories.

4. Upon notification of non-compliance, the Chair of the IBC shall initiate an investigation into the circumstances of the incident. Information collected from relevant individuals shall be reviewed and a written directive shall be issued to the permit holder. This directive will include a requirement that a written response of correction be supplied to the IBC by a specific date. At the discretion of the IBC Chair, the issue may be brought to the attention of the full Committee for discussion and resolution.

5. All issues brought to the attention of the full IBC shall be documented and a copy of the written notice of correction shall be forwarded to the Vice-President of Research.

6. Given that immediate hazards to health, safety and security are resolved, at the request of the permit holder, the Chair of the IBC shall review all remedial actions recommended by BSO staff.

7. Given that immediate hazards to health, safety and security are resolved, at the request of the permit holder, the full IBC shall review all remedial actions recommended by the IBC Chair.

8. Given that immediate hazards to health, safety and security are resolved, at the request of the permit holder, the Vice-President Research shall review all remedial actions recommended by the full IBC. The recommendations of the Vice-president Research are final.