HARVARD MEDICAL SCHOOL

HMS Primary Responsible Office: Office of Biological Safety
Approval Body: Committee on Microbiological Safety (COMS)
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Incident Reporting Policy

Purpose

This policy outlines the incident reporting requirements for Principal Investigators, Biosafety Officers, and institutions who possess COMS Regulated Materials ("CRM"), as defined in the COMS Policy Introduction.

Scope

Any COMS application that is approved by the committee must follow this policy and the recommendations in the NIH Guidelines.

Policy

1. Responsibilities
    A. Principal Investigator (PI):
    As stated in the Memorandum of Understanding and Agreement, signed by the Principal Investigator (PI) of COMS-approved research, PIs are required to report potential or overt exposures to CRM to COMS, via their Institutional Biological Safety Officer (BSO). Additionally, the NIH Guidelines state that reporting of accidents or illnesses to the NIH is the responsibility of the PI, the BSO and the Institutional Biosafety Committee (IBC). This policy mandates the reporting through the BSO. The following excerpts from the COMS application memorandum highlight the PI requirements under this policy:

    > *By signing this document, I agree to immediately notify COMS if a member of the laboratory staff develops symptoms of illness related to an agent involved in this study and if there is accidental release of a biohazardous agent into the environment.*
    >
    > *And in a separate paragraph, "By signing this document I accept full responsibility for laboratory biosafety training, for the maintenance of a safe workplace and for immediate reporting of accidental exposures to biohazardous agents."*

    B. Biosafety Officer (BSO) and/or duly designated representative:
    As stated above, upon becoming aware of an incident involving CRM, the biosafety officer is responsible for reporting said incident to COMS and to the appropriate

government agencies. In some cases, an entity may designate an institutional responsible official other than the BSO to complete said reporting. The BSO is also responsible for presenting any incident and corrective action plans that have preceded each COMS meeting.

C. COMS:

The committee is responsible for reviewing and discussing incidents at each committee meeting (including determining whether the recommended corrective action plan is appropriate or not) and ensuring the reporting institution has complied with all applicable regulations for incident reporting. The committee also requires that each Principal Investigator comply with all applicable regulations for incident reporting.

2. Reporting Considerations
   A. Procedure
      i. Personnel involved in any personal potential or overt exposure must be provided with all appropriate medical evaluation and surveillance.
      ii. The BSO or duly designated representative will notify the Director of COMS and/or the COMS Chair or Vice Chair with the initial details of the incident. The BSO, or duly designated institutional official, will then notify all appropriate regulatory agencies. Notification of the agencies should take place in accordance with reporting requirements as specified in Appendix A.
      iii. BSO should investigate the incident to identify route cause, training needs, and corrective action measures.
      iv. A verbal summary of the incident shall be provided by the BSO at the next scheduled COMS meeting and will be recorded in the meeting minutes.
      v. For incidents involving laboratory acquired infections, breach of containment or overt exposures, and/or violations of the COMS approval (or lack thereof), PIs must prepare a written response detailing the laboratory event and actions taken to mitigate future reoccurrence. The letter should be submitted to COMS one week prior to the next scheduled COMS meeting so that it can be discussed during the meeting. COMS will document its review in the meeting minutes.
   B. Reporting of Significant reporting events:
      i. Harvard personnel must immediately report all workplace accidents (or near misses), injuries, and illnesses to their supervisors or managers.
      ii. PI must report to BSO. The BSO will report to COMS and to regulatory agencies if necessary.
      iii. Reporting timeframes dictated by regulatory bodies take precedence, and the reports must be submitted in accordance with those requirements first and foremost.
      iv. Illnesses and/or symptoms potentially related to CRM in use in the BL3 laboratory must be immediately reported.
      v. Breach of BL3 containment which results in potential or overt exposures to organisms containing CRM released into the environment must be immediately reported.

vi. Breach of containment resulting from failure of mechanical systems (e.g., HVAC, loss of power) and laboratory equipment (Biosafety cabinet, centrifuge, ventilated animal cages) must be immediately reported.
vii. BSOs should report incidents to COMS as soon as they become aware of the incident.
viii. COMS Office will report the incident to COMS Leadership.
ix. Incident is discussed at the next scheduled COMS meeting.

C. Reporting of Incidents at the COMS meeting:
BSO should provide verbal report, which shall include, but not limited to, the following:
i. The nature of the incident (e.g., personnel exposure, spill, loss of containment, loss of transgenic animal, failure to obtain IBC approval, failure to follow approved containment conditions, etc.)
ii. The COMS approval number (if incident occurred while conducting activities associated with a COMS approved protocol)
iii. Federal, state or local agencies to which incident is being reported
iv. A description of the incident, including the following information:
a. The recombinant agent or material involved. (If applicable)
b. The incident/violation location (e.g., laboratory biosafety level, vivarium, non-laboratory space).
c. The person(s) involved in the incident/violation, including others present at the incident location. [position title only] (e.g., graduate student, post doc, animal care worker, and facility maintenance worker).
d. Actions taken immediately following the incident/violation to limit any health or environmental consequences of the event, as well as the [position titles] of the individual(s) who took those actions.
e. The training received by the individual(s) involved and the date(s) the training was conducted.
f. The institutional or laboratory standard operating procedures (SOPs) for the research and a determination of whether there was any deviation from these SOPS at the time of the incident/violation.
g. Any deviation from the COMS-approved containment level or other COMS approval conditions at the time of the incident/violation.
h. The personal protective equipment in use at the time of the incident/violation.
i. The occupational health requirements for laboratory personnel involved in the research.
j. Any medical treatment/surveillance provided after the incident.
k. Any injury or illness associated with the incident.
l. Any equipment failures that occurred.
m. Any other relevant information identified during the review/investigation of the event

n. Measures taken by the Institution to mitigate identified problems (e.g., review by COMS, root cause analysis)

D. Multi-institutional research:

i. There may be circumstances where Principal Investigators are collaborating with other institutions that are not covered by COMS. The Principal Investigator must report to their BSO any incident that occurs under a COMS protocol. PIs should be aware that they may have additional reporting obligations to other institutions should their work be registered at other Institutional Biosafety Committees (IBCs).

Definitions

1. *CRM incident:* Any incident involving a CRM. These incidents must be reported to COMS. Local health departments (Boston Public Health Commission and/or Cambridge Biosafety Committee) may also require the reporting of a CRM.
2. *Recombinant DNA incident:* Section IV-B-2-b-(7) of the NIH Guidelines states that IBCs must report "...any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses" to NIH OSP within 30 days. Appendix G of the NIH Guidelines specifies certain types of accidents that must be reported on a more expedited basis. According to NIH Guidelines Appendix G-II-B-2-k, spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA (as well as the IBC). According to NIH Guidelines Appendix G-II-C-2-q and Appendix G-II-D-2-k, spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OSP (as well as the IBC, and BSO). COMS expects that even incidents that do not fall into one of these expedited reporting categories will be reported to NIH OSP as soon as possible. Local health departments under COMS (City of Boston and Cambridge) also require reporting recombinant DNA incidents *Potential exposure:* A possible personal contact with a Biosafety Level Three (BL3) recombinant or synthetic CRM. According to the NIH guidelines, this contact would be reportable to NIH Office of Science Policy (NIH OSP). Examples of potential exposures to a BL3 agent are any accidents, equipment failure, or splash to intact skin.
3. *Overt exposure:* A definitive contact with a Biosafety Level Two or Biosafety Level Three recombinant or synthetic CRM. According to the NIH guidelines, this contact would be reportable to NIH Office of Science Policy (NIH OSP). Examples of overt exposures are needle sticks and splashes of recombinant or synthetic nucleic acid molecules agent on personnel.

Related Materials/ References

- NIH Guidelines
- CDC/NIH BMBL 6th edition