A. PURPOSE

This SOP describes the procedures that will be applied when a PI or laboratory is found to be out of compliance with biosafety practices mandated in federal, state, local, and institutional regulations, policies, and procedures.

B. POLICY

To protect the campus community, the IBC is tasked with evaluating research, teaching, and diagnostic testing involving biological hazards and constantly monitoring safety and compliance. Should an individual (faculty, staff, student, etc.) commit or attempt to commit any inappropriate action as determined by the IBC, UTC Safety and Risk Management, or other UTC personnel, every effort will be taken to resolve issues with the involved individual(s) and laboratory leadership. However, refusal or failure to correct identified concerns will prompt the following escalation procedures (summarized in Appendix A).

C. FIRST LEVEL*

A first-level event occurs when:

1. a deviation from federal, state, local, or institutional regulations, policies, or procedures poses a risk to human health, the environment, or the compliance integrity of the University of Tennessee;
2. an individual flagrantly refuses to follow biosafety principles and practices; or
3. a laboratory inspection identifies minor findings that trigger the audit escalation procedure.

A noncompliance notification letter from the IBC Chair (or Vice-Chair) and Designated Official will be immediately sent to the principal investigator (PI)/laboratory supervisor and Department Head stating that inappropriate action has taken place and the consequences if such action continues. A copy of the current escalation procedures will be provided.

The PI is required to submit a Corrective Action Plan to the IBC within three business days. Unless deficiencies are sufficiently critical to the life and health of the lab workers or the regulatory status of the laboratory, laboratories will be given a minimum of 10 business days to correct deficiencies. Corrective action status reports are required every 10 business days until all corrective actions have been completed. Re-inspection will occur upon completion of corrective actions or during the next inspection cycle as warranted by risk.

D. SECOND LEVEL*

If a first-level event remains unresolved after the deadline set for corrective action has passed, it is escalated to the second level. A follow-up letter from the IBC Chair (or Vice-Chair) and Designated

Official will be immediately sent to the PI/laboratory supervisor, Department Head, and Dean stating that that event has taken place and the consequences if noncompliance continues and/or occurs again. A copy of the current escalation procedures as well as a copy of the initial noncompliance notification letter will be provided.

Unless the deficiencies found are sufficiently critical to the life and health of the lab workers or the regulatory status of the laboratory, laboratories will be given five business days to correct deficiencies. Corrections will be verified by a follow-up audit.

E. THIRD LEVEL*

Purchasing and research will be suspended immediately if the following occurs:

- After five business days from escalation to the second level, the lab is still out of compliance or the hazardous condition or action remains unmitigated; or
- A third noncompliance event is documented for an individual or lab in a 12-month period.

A follow-up letter from the IBC Chair (or Vice-Chair) and Designated Official will be immediately sent to the PI/laboratory supervisor, Department Head, Dean and Vice Chancellor for Research stating that the suspension has occurred. Copies of all prior correspondence will be provided. Suspension of purchasing and research will remain in effect until the Department Head, Dean, and Designated Official approve reinstatement in cooperation with the IBC and research administrators. Discretion regarding the lifting of a suspension ultimately rests with the IBC.

Teaching and diagnostic testing laboratories will follow a similar communication/escalation scheme; however, resolution is at the discretion of the respective department and/or college administration. Resolutions must be communicated to the IBC/Office of Research Integrity in a timely manner.

F. SERIOUS ACTIONS

Serious actions include those that:

- pose an immediate threat to the life or health of students, faculty, staff, and/or visitors,
- pose an immediate risk of harm or damage to property of the University;
- are in violation of Federal, State or local laws and may be subject to legal action or civil fines;
- demonstrate (through documentation) an unwillingness to take corrective actions and/or repeated failure to follow programmatic and institutional policy; or
- defy the University Code of Conduct.

Serious actions may result in the suspension of research; total shutdown of a lab or office; notification of local, state or federal regulatory and/or funding agencies (as required); or referral of the individual(s) for disciplinary action, as determined by University administration in cooperation with the IBC.

The IBC, Director of the Department of Safety and Risk Management, and Designated Official reserve the right to immediately stop work and/or shut down a laboratory for serious actions. To ensure prompt remediation, such orders may be issued irrespective of the escalation process and communicated in writing by the IBC Chair (or Vice-Chair), Director of the Department of Safety and Risk Management, or Designated Official to any or all administrative levels.

For Serious Actions that can be remedied (e.g., major findings identified during a laboratory inspection), the PI is required to submit a Corrective Action Plan to the IBC within three business days. Corrective action status reports are required every 10 business days until all corrective actions have been completed and verified.

G. CONTACTS

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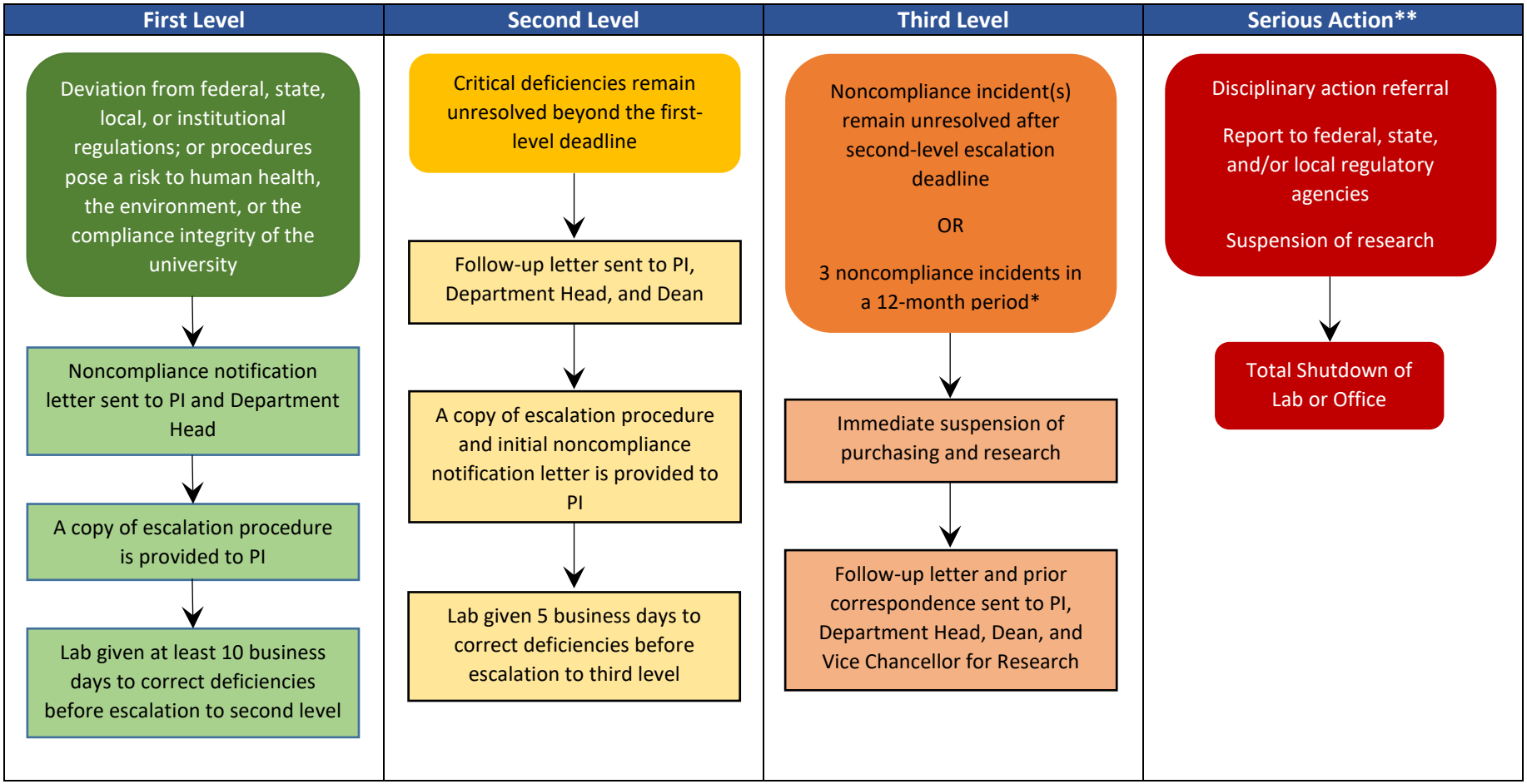
UTC Institutional Biosafety Committee SOP #5, Appendix A:

Escalation Levels and Process



*Three distinct events that suggest a pattern of noncompliance or carelessness about safety and the environment. For example: one lab inspection result that triggers the escalation process (regardless of the number of deficiencies requiring corrective action), plus one independently reported major finding, plus discovery that untrained or inadequately supervised personnel are participating in biohazardous activities.

The IBC, Director of the Department of Safety and Risk Management, and Designated Official reserve the right to immediately stop work and/or shut down a laboratory for serious actions. To ensure prompt remediation, such orders may be issued irrespective of the escalation process and communicated in writing by the IBC Chair (or Vice-Chair), Director of the Department of Safety and Risk Management, or Designated Official to any or all administrative levels.