Institutional Biosafety Committee (IBC) Handbook

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Purpose

The Rutgers Institutional Biosafety Committee (IBC) shall serve as the primary oversight administrative unit for environmental and occupational health and safety matters related to the safe use of recombinant DNA/and synthetic DNA molecules, nucleic acid molecules, microbial pathogens, toxins of biological origin, select agents and toxins, human and non-human primate cell lines, tissue and body fluids in research and teaching laboratories.

Responsibilities

The Rutgers University IBC will:

1. Provide an open forum for the discussion of biosafety concerns and resolve biosafety issues brought before the Committee.

2. Ensure Principal Investigators achieve compliance with applicable local, state and federal biological safety regulations.

3. Review and approve research and teaching lab proposals involving pathogenic microorganisms or potentially infectious materials requiring work at the Biological Safety Level 2 or higher as classified in the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories.

4. Review and approve recombinant/and synthetic nucleic acid research and ensure compliance with the latest National Institutes of Health (NIH) Guidelines for Research Involving the Use of Recombinant and/ or Synthetic Nucleic Acids (from here referred to as the NIH Guidelines). This review shall include:

    - Committee determination of the containment levels required by the NIH Guidelines for the proposed research;
    - Review, assessment and follow up on any proposal that may constitute a Major Action as described in the NIH Guidelines;
    - Assessment of the facilities, procedures, practices, training and expertise of personnel involved in recombinant or synthetic nucleic acid research;
    - Ensure that any protocols involving the transfer of recombinant/ synthetic nucleic acid molecules into one or more human research participants comply with the NIH Guidelines; and
    - Ensure compliance with surveillance, data reporting, and adverse event reporting requirements set forth in NIH Guidelines through establishment of institutional procedures that apply to those requirements.

5. Set containment levels for recombinant and synthetic nucleic acid and pathogenic microorganism research as specified in the NIH Guidelines, and the current CDC/NIH Biosafety in Microbiological and Biomedical Laboratories. The IBC may, at its discretion, adjust containment level requirements depending on the circumstances presented by a specific project.

6. Periodically review recombinant/synthetic nucleic acid research conducted at the institution to ensure compliance with current NIH Guidelines.

7. Ensure that any problems with, or violations of, the NIH Guidelines and any significant research related accidents or illnesses are reported to the appropriate institutional official(s) and the NIH within 30 days.

8. Notify Principal Investigators of the results of the Committee's reviews within 5 business days.

9. Create and maintain awareness of Dual Use Responsibility in Research throughout the University community.

10. Perform Dual Use Research of Concern (DURC) reviews for all IBC protocols, including but not limited to, those outlined in the Federal Policy for Dual Use oversight at the Institutional Level.

The Principal Investigator (PI) will:

1. Be familiar with the most recent NIH Guidelines for Research Involving Recombinant DNA and Synthetic Nucleic Acids.
2. Obtain the necessary approvals from the IBC as well as Institutional Animal Care and Use Committee (IACUC) and/or the Institutional Review Board (IRB) prior to beginning work involving rDNA or synthetic nucleic acids.
3. Maintain the biosafety protocol in a current manner and share the contents of the protocol with all lab members. The biosafety protocol registration form is complete with the information required to serve as the laboratory's Biosafety Manual. Protocol specific training must be conducted and documented for any personnel listed for that protocol.
4. Conduct a comprehensive risk assessment that includes identifying: a) the hazardous characteristics of known infectious or potentially infectious agents or materials; b) the activities that can result in personnel's exposure to the agent/material; c) the likelihood that such an exposure will cause a laboratory acquired infection (LAI) and the consequences of such an infection.
5. Use the information obtained from the risk assessment to determine the appropriate biosafety levels and microbiological practices, safety equipment and facility safeguards needed to prevent LAIs.
6. Ensure personnel are informed of the hazards of working with infectious agents/materials and the need for developing proficiency in the use of safe work practices and containment equipment.
7. Ensure that personnel receive appropriate training through REHS, and ensure and document all personnel receive appropriate hands-on training.
8. Report accidents/exposures to the IBC through the University Biosafety Officer and ensure proper documentation of any incidents by using the Accident Database.
9. Maintain awareness of Dual Use Responsibility in Research by reporting unanticipated results or other safety-related concerns to the IBC through the University Biosafety Officer.

10. Amend and renew previously approved IBC protocols within the indicated timeframes.

Rutgers Environmental Health and Safety (REHS) will:

1. Adopt and revise when necessary, an institutional biosafety manual that, in conjunction with the Chemical Hygiene Plan, establishes policies, practices and procedures that support the safe use of biological materials and comply with the most recent NIH Guidelines as well as with federal and local regulations.

2. Ensure that the institution's biosafety manual includes appropriate emergency procedures covering accidental spills and personnel contamination resulting from recombinant and synthetic nucleic acid and pathogenic microorganism research.

3. Conduct investigations and follow-up of any significant accidents or illnesses related to biological research and inform the IBC of findings and recommendations, as necessary.

4. Address biosafety issues as requested and as reported by the committee membership and the PI. Ensure knowledge of committee activities by maintaining communication with the appropriate institutional officials.

5. Serve as liaison with the Rutgers University IBC and the NIH Office of Science Policy (OSP), including the submission of the annual IBC registration to the NIH.

6. Report immediately, on behalf of the IBC, any overt exposure at BSL2, or potential exposure incidents at BSL3 to the NIH OSP as required in the NIH Guidelines. The IBC will also be notified and the incident presented in the following meeting.

Occupational Medicine/Employee Health Services will:

1. Assign a designee to serve as a participating member of the Rutgers University IBC.

2. Provide medical clearance (for respirator wearers), medical surveillance, vaccinations, and other occupational health-related services as necessary.

3. Provide post-exposure prophylaxis and medical follow-up in the event of an exposure incident.

4. Maintain medical records as required by Occupational Health and Safety Administration (OSHA) 29 CFR 1910.120 and 29 CFR 1910.134 and 42 CFR 73 and the NIH Guidelines for recombinant or synthetic nucleic acids.

Composition and Membership

An executive committee composed of the IBC administrators and the standing committee chairs will be formed. The committee is comprised of two standing committees; North and Central.

There is a chair for each standing committee. The chairs and administrators meet as needed to discuss IBC related issues and to ensure consistency across standing committees.

The Executive Vice President for Academic Affairs appoints the chairperson of each standing committee. In accordance with NIH Guidelines, committee members are drawn from each represented school's research departments, functional units, and other non-affiliated institutions. Each department that conducts research reviewed by the IBC should have at least one representative on the committee. Membership will include personnel with infectious disease expertise, both clinical and experimental, experience in recombinant and synthetic nucleic acid technology, knowledge of biological safety and containment, proficiency in plant and animal containment, and a representative of the laboratory technical staff. At least two members who are not affiliated with the institution will sit on each standing committee to represent the interest of the surrounding community with respect to health and protection of the environment.

Recruitment of new members is conducted by the IBC chairperson and/ or the IBC administrator. The need for new members are identified through feedback from the chairperson, administrator or other pathways. When candidates for membership are identified, the IBC administrator reaches out to the individual to explain the function of the committee and to request their participation.

Members are formally appointed by the Executive Vice President for Academic Affairs. Appointments are renewed annually in September and are for a two year term. Terms are renewable as desired by members.

A separate, permanent/standing committee for dual use research review will be established. A second permanent /standing committee will be established for ethical review for the use of human embryonic stem cells. Membership for these committees will include members from both the North and Central standing committees. This group will review for dual use research of concern (DURC) for all protocols containing agents outlined in the Federal Policy and any select agent proposed protocols.

Removal of a member from the IBC requires documented and sustained "just cause" that demonstrates the member to be unfit or unable to serve on the IBC. Just cause may include lack of regular attendance at meetings, a finding of misconduct, or an unresolved conflict of interest. The decision to remove a member is made by the Institutional Official after a motion recommending removal receives a majority vote at a convened IBC meeting.

Ex-officio non-voting members may include representatives from the administrative offices for the Institutional Review Board and Institutional Animal Care and Use Committee. Additionally, other members may be from Enterprise Risk Management and the ESCRO committee. Additional non-voting members may be added as requested. Ex-officio voting members include the biosafety officers from REHS, Veterinarians, Employee Health and Student Health (as applicable).

Quorum

For regularly scheduled (e.g., monthly) meetings of IBC-North and IBC-Central, a quorum is defined as greater than 50% of the number of voting members of the individual IBC standing committee. As needed, voting members from the other standing committee can be counted towards quorum. Up to two biosafety officers from REHS will be counted towards quorum. The University Biosafety Officer, or designee when absent, plus one additional BSO will comprise the REHS voting members.

For emergency and ad hoc meetings, a quorum is defined as greater than 25% of the total number of voting members from IBC-North and IBC-Central combined.

Meetings

Meetings occur every month, rotating between the Newark and New Brunswick campuses, and committee members may attend via phone and/or video conference. Additional meetings (e.g., ad hoc and emergency meetings) may occur at the discretion of the chairperson or co-chairs. The IBC administrator, in conjunction with the campus IBC Standing committee chair, schedules meetings, prepares the agenda and documents meeting minutes.

Subcommittees

The North and Central standing committees can establish subcommittees in order to review and resolve specific issues. Subcommittees must have at least three voting members. One member must represent the biosafety staff from REHS.

Criteria for Principal Investigators for IBC related projects conducted at Rutgers

Definition of a Principal Investigator:

A principal investigator is the individual who assumes full responsibility for a research project, including the supervision of any co-investigators, research staff, house staff, interns, volunteers, visitors and students. The Institutional Biosafety Committee recognizes one principal investigator per protocol, other individuals may be listed as co-investigators. The principal investigator must possess the expertise, time and commitment to conduct and provide the necessary oversight for all aspects of the experiments, and must be willing to accept full responsibility for the research covered in the application.

Who may be a Principal Investigator for IBC related projects at Rutgers:

1. Individuals with a paid faculty appointment at a Rutgers school, other than visiting and per-diem faculty, with the approval of the department chair; unpaid (volunteer) faculty at a Rutgers school by exception only, with written justification by the Department Chair and Research Dean, and case-by-case approval by the Institutional Biosafety Committee.

2. Individuals in permanent, non-faculty staff positions at Rutgers, with the approval of the department chair or pertinent Vice President.

3. Students enrolled in a Rutgers School or Program or postdoctoral fellows by exception only, with the approval of their Principal Investigator, who will be listed as a co-Investigator, with the

approval of the department chair and the Research Dean or Program Administrator (where appropriate). Approval by the IBC will be on a case-by-case basis, and will include procedures to ensure that appropriate close out of the research is in place when the postdoctoral fellow or student leaves the University.

Responsibilities of a Principal Investigator for IBC related research:

1. Ensure that research receives IBC review and approval before any activity begins.

2. Ensure all co-investigators and research staff comply with the conditions, findings, determinations and requirements of the IBC.

3. Ensure that all pertinent regulations, laws, guidelines and procedures are observed by all co-investigators and research staff involved in the conduct of the study.

4. Ensure that all IBC projects receive timely continuing review and approval.

5. Obtain prior IBC review and approval for all changes, including that of personnel, to the protocol.

6. Report to the IBC any serious hazards or findings from the research protocol that could necessitate increased biosafety precautions.

Protocol Review

Protocols, renewals and amendments are submitted online via the biosafety database located at http://myrehs.rutgers.edu. New protocols are assigned the next number in a series consisting of the last two digits of the current year, followed by a dash, followed by the next protocol submission number in the series (e.g. 13-001 is the first protocol received in 2013). Renewal of protocols occurs every 3 years for biosafety level (BSL) 1 and BSL2 and annually for BSL3 protocols. Annual review occurs for protocols involving administration of recombinant materials to human subjects. The committee reserves the right to change the cycle for renewals if warranted by the risk and type of research performed. Amendments to protocols can be submitted by clicking on the amendment option within the protocol and describing the amendment. Once submitted, protocols and amendments become locked and cannot be edited until they are unlocked by the REHS biosafety staff.

The administrator or Biosafety Officer conducts a pre-review to ensure the application is completed properly and to identify any deficiencies that are noted prior to committee review. If necessary, the pre-review comments are returned to the submitter for action. The administrator will then unlock the protocol to allow changes to be made. Once changes are made in the protocol and it is resubmitted, the protocol is deemed ready for review by the committee. The administrator assigns a primary and secondary reviewer for the protocol in the REHS Admin section of the protocol. Protocols are also assigned to either the North or Central standing committee for their review and approval, but reviewers could be from either standing committee depending on expertise. Primary reviewers must have a scientific background sufficient to

understand the proposed experiments and potential hazards that could arise from the conduct of this research.

Criteria for Reviewing Protocols

The IBC reviews the safety of the proposed experiments. Scientific merits of a protocol are not reviewed by this body unless they impact on the safety of procedures. Significant revisions (as mentioned below) cannot be addressed by administrative review and require additional information for a thorough review.

Potential risks to study personnel (staff and students), animal caretakers, facility and custodial personnel, and the community at large are considered. Primary reviewers must assess the use of engineering controls (biosafety cabinets, containment labs, safety needles, etc.), administrative controls (hazard warning signage, training of staff, etc.), and personal protective equipment (respirators, gloves, lab coats, etc.) to verify that the protocol adequately addresses safety requirements.

Projects involving the administration of recombinant materials, or potentially infectious material, to human subjects require a drug specific SOP to be created (using provided template by REHS, and at the discretion of the IBC) and uploaded to the file cabinet of the protocol registration document with signatures providing evidence of training for all staff on the drug specific requirements and potential hazards.

Experiments performed at BSL3 have additional SOP requirements that are reviewed by the laboratory specific Risk Assessment Committees after IBC approval is granted.

All protocols submitted to the IBC will be reviewed for DURC. The IBC will act as the Institutional Review Entity (IRE) and its procedures will be fully outlined in a separate document. The IRE will follow the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern. Specifically, all protocols containing work with agents specified in this policy will be reviewed by a special standing committee of the IBC (the Dual Use Standing committee), and if DURC is determined, the funding agency or NIH will be notified within 30 calendar days. Minutes and reviews by the IRE will be maintained separately from the IBC minutes. The biosafety group at REHS will work with the PI to develop a risk mitigation plan. This plan will be reviewed by the Dual Use standing committee and will be submitted to the funding agency or NIH within 90 days of the determination of DURC within that protocol application.

Protocols will be reviewed for the 7 main categories of DURC experiments:

1. Enhances the harmful consequences of the agent or toxin;
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification;
3. Confers the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies;

4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin;
5. Alters the host range or tropism of the agent or toxin;
6. Enhances the susceptibility of a host population to the agent or toxin;
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed within the federal policy.

Reviewers must also consider the use of disinfectants, potential risks posed by experimental materials (i.e., pathogens or recombinant materials) and the potential for adverse events if an individual were to be exposed to experimental materials or infected animals.

If a protocol specifies or requires medical surveillance, the IBC must verify with appropriate physicians that listed project personnel meet the requirements.

Approval of Protocols

Administrative Review

Protocol amendments and renewals that do not involve ***significant changes*** (see Figure 1) to the experimental procedures and do not present an increase in risk to personnel may be administratively approved on a case-by-case basis by the IBC Administrator. Examples include changes to personnel or locations, the addition of new cell lines and/or strains (of the same or lower Risk Group) not involved in recombinant work, or a volume change that will not alter the hazards of the experiment. Previously approved protocols that are combined (or separated) with no change in materials or risk, may be eligible for this level of review.

The IBC Administrator will send the approval letter and will include in the next meeting agenda a list of protocols that were administratively approved since the last IBC meeting.

Designated Member Review

Designated Member review will occur only for protocols *not subject to the NIH Guidelines* such as work involving risk group 1 agents, human/non-human primate materials (including body fluids, cell lines and tissues), non-select agent biological toxins and agents of the same or lower risk group as previously approved. The review process will be conducted as described in the Criteria for Reviewing Protocols section above but once the reviewers have no additional concerns, the protocol will be approved by the IBC Administrator. Protocols approved by this process will be reported on the agenda presented at the committee meeting.

Biosafety Officer (BSO) review

Protocol renewals with changes or amendments that involve work that *1)* is covered under NIH Guidelines Sections III-E, or; *2)* has been previously approved by the IBC under NIH Guidelines section III-D *and* does not involve ***significant changes*** (see Figure 1) will undergo a review and risk assessment by the BSO. Examples include:

- change in cell line used as host for gene expression
- addition of a viral serotype
- changes to promoter, enhancer and/or marker genes
- addition of gene targets that are of the same family/class/function as those previously approved

- new strain of a previously approved pathogen
- new non-rodent transgenic animals obtained from outside institution/vendor

Upon notification by the Biosafety Officer, the IBC Administrator will issue an Approval Letter and report the review outcome at the next IBC meeting. The BSO Report will include the PI name, project title, biosafety level, brief description of changes and the applicable section of the NIH Guidelines.

Figure 1

Significant changes include the addition of *previously unapproved work* with recombinant/synthetic nucleic acids covered under the NIH Guidelines or procedural changes that present new or increased risks. Examples include:

- Modifications/genetic manipulations that are anticipated to increase pathogenicity, oncogenicity and/or resistance to known therapeutics/drugs
- Use of new equipment/techniques that have greater potential to generate aerosols, splashes and/or spills
- Order of magnitude increase in volume or pathogen concentration
- Addition of pathogens of a higher risk group

All ***significant changes*** to protocols are processed through normal review pathways leading to full IBC review.

Full Committee Review

Committee members are given 5 working days to review and comment on a protocol. The IBC administrator will perform a pre-review of the application to be sure all sections are completed before sending it to the reviewers. Comments are submitted online through the comment link. All comments are available for the committee members to review for all protocols. The administrator will send reminders to reviewers if comments are not posted by day 5. The administrator compiles the comments and returns them within five business days of posting to the PI via a question request in the online database. The PI will then respond within the database to the question and make the requested changes in the protocol.

Primary reviewers present a brief overview of the protocol during the committee meeting. The reviewer's comments and concerns are documented, the protocol is opened for discussion and any concerns are also recorded for the minutes. A motion to approve, require modification, or to table the protocol is made and a second is recorded. Following the motion, a vote of the members present is taken and the number of yea, nay and abstaining voters is recorded. A majority vote constitutes committee action on that protocol. Protocols in which both assigned

reviewers are absent at the time of the IBC meeting will be Tabled until the next scheduled IBC meeting.

After the meeting, the administrator contacts the PI with any additional comments and a summary of the committee's action on each additional reviewed protocol. All communication shall be through the online biosafety database so all concerns are captured in the protocol history.

When all issues are satisfactorily addressed by the investigator, and the reviewers have no additional concerns, the protocol can be approved. Reviewers will indicate their approval decision in the Submission Summary tab. The approval letter is automatically generated in the online database and specifies the protocol registration number, title, approval date, and biosafety level. The approval letter also stipulates that it represents solely IBC approval and not approval from other committees such as the Institutional Review Board or the Institutional Animal Care and Use Committee. Additional provisions can be added to each approval letter.

Types of Approvals for Protocols

Approved

Protocols and significant amendments that are not subject to the designated member review process are approved by a vote of the quorum of the IBC Standing Committee. Designated member reviewed protocols can be approved if none of the reviewers have concerns. If there are concerns by any of the assigned persons, it can be brought to the full committee for review and approval. Approved protocols may begin research. The IBC administrator or Biosafety Officer will approve the submission in the database. The approval letter will be automatically generated, using the biosafety database, indicating the effective date of the approval. The PI will receive an email indicating the protocol has been approved. After approval, protocols and amendments become locked in the biosafety database and cannot be changed or edited until they are unlocked by the REHS biosafety staff.

Conditional Approval

When a protocol requires minor or major revisions, the committee may conditionally approve the protocol. Conditional approval is granted by a vote of the full IBC. The conditions are communicated to the Principal Investigator, who must respond to the conditions. Once the primary and secondary reviewers and biosafety officer acknowledge satisfactory response to requested modifications, an approval letter is prepared and distributed by the IBC administrator or Biosafety Officer. The project cannot be initiated until the approval letter is granted.

Tabled Protocols

Protocols may be tabled when there are significant concerns, or if the procedures or risks involved are unclear or not adequately described. In this case the Principal Investigator is required to address the IBC's concerns by resubmitting a revised application for full committee review. In some cases, the Principal Investigator may be invited to the IBC meeting to make a personal presentation of the protocol and/or to respond to questions.

Periodic Protocol Review

Protocols are renewed every 3 years for BSL1 and BSL2 and annually for HGT and BSL3, even if there are no changes. Renewal emails are sent through the biosafety database and PIs update their protocols accordingly. New protocols do not need to be submitted for continuation of an approved project. Personnel changes and amendments can be submitted at any time during the life of a protocol. Renewals without changes are administratively reviewed. Only amendments that meet the requirements above must go to full committee for review/ approval.

Withdrawal of Protocol Applications

In the event that a researcher wishes to withdraw an application (that has not been approved) from review by the committee, the researcher must send a written message to the IBC administrator formally withdrawing the application. If a PI does not respond to comments within 3 months, the protocol will be automatically withdrawn. The IBC Administrator will follow up with the PI, at a minimum, at least once prior to the three-month mark.

Expired Protocols and Lingering Protocols

The biosafety protocol management system sends automated reminders to PIs and persons designated as Assistant PIs regarding protocol renewal two (2) months prior to protocol expiration. These reminders go out on a weekly basis. Additionally, protocols in process, that are unlocked, are also sent reminders weekly to complete the changes required to their protocols. There are times when a PI fails to respond to these reminders. In addition to the reminders, REHS will send emails to the PI, copying their Chair and Dean as necessary to elevate. The reminders will go out over approximately two month period (including two IBC meetings). This will allow ample opportunity for the lab to respond to questions, to renew or terminate a protocol. In the event of no action on this protocol after two meetings, the Office of Research and Sponsored Programs and department administrator will be notified and asked to suspend all funding to the laboratory. Additionally, the biosafety officers will pay a visit to the lab to ensure that there is no work in progress with materials requiring IBC registration. If the lab still continues work with the experimental materials in question, the University BSO will contact the Chairs of the IBC to discuss experimental material in question and an action plan will be developed and disseminated to appropriate persons.

Conflicts of Interest

The IBC relies on a two-fold system for dealing with conflicts of interest. First, the IBC administrator does not assign protocol reviews to committee members who have conflicts of interest with a particular protocol or researcher.

The second method for identifying conflicts of interest is through self-disclosure from committee members. Committee members may contact the administrator or chairperson to recuse themselves from reviews on a particular protocol if they have a real or perceived conflict.

In all cases where conflicts of interest are identified the committee member involved is recused from reviewing and voting on the protocol.

Collaboration with the IRB and IACUC

Communication between the IRB, IACUC and IBC is critical to the success of research at the university. The IBC will provide at least one ad hoc member to the IACUC. This individual is responsible for reviewing IACUC protocols for the safe use of biological materials. The IBC provides confirmation of IBC approval when a research project involves the use of materials subject to IBC review in animals.

The IBC provides at least one member to sit on the IRB. This individual is responsible for reviewing IRB protocols for the safe use of biological materials in humans as well as the safe use of human materials in research. Representatives from IACUC and IRB are members of the IBC Standing Committees and provide reciprocity to the IBC review process.

Public Access to IBC Meetings and Minutes

The IBC will post meeting dates on the REHS biosafety website annually in the event a member of the public would wish to attend. Anyone may request to attend an IBC meeting but must send their request via email to biosafety@rutgers.edu at least 48 hours in advance, and the biosafety officers will liaise with the IBC chair/co-chairs to determine which portions of the meeting will be closed to the public. As a general rule, only protocol actions subject to the NIH Guidelines will be open to the public.

Minutes will be available to the public upon request. Minutes include the write up of the general meeting and a list of protocols reviewed. These minutes will be redacted according to the policy below.

If a member of the public submits comments regarding an IBC action, the comments and the response will be sent to the NIH Office of Science Policy as outlined in the NIH Guidelines Section IV-B-2-a-(7).

Redaction Policy

The redaction policy of the IBC is in spirit with the NIH Guidelines requirements for transparency and redactions will be kept to a minimum. The IBC will redact only security information and information that is private personnel information such as medical requirements and training requirements. Upon request confidential information will be redacted, as documented in lease agreements and other contracts. The committee will be able to review all information, and the redaction will only occur in the public distribution. In the redacted materials, the building and room numbers and personnel names in the comments will be redacted (but the requirements for medical surveillance and training would remain).