The Cleveland Clinic Experience of Using Audits as a Key Component of an Effective Biosafety Program

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Abstract

Objective: To strengthen the biosafety program, an annual audit has been instituted for research studies that require IBC approval. The goal of the audit is to be a positive tool to engage key stake holders. The audit provides further understanding that Biosafety is a team effort between the research personnel, the IBC, and the Biosafety Officers.

Method: The Biosafety Officers and IBC Chairman developed a checklist of items that are evaluated when the annual audit is performed. This checklist is based on information extracted from the section by Peterson and Hashimoto (2006) in the textbook **Biological Safety Principals and Practices**[1].

Results: The Principal Investigator and key research personnel are informed two weeks in advance of the upcoming audit. The audit involves a direct meeting between individuals on the IBC approved protocol and an Environmental Health and Safety Associate who is part of the Biosafety program. There are two key components to the audit: 1. Determine if there have been any program changes, including change in personnel, change in recombinant DNA inserts or agents, change in location, or change in title or funding. 2. A physical plant assessment to ensure that the Biological Safety Cabinet has been certified in the past 12 months, appropriate PPE is present, pipets, centrifuges, and other tools are in good working order, appropriate signage is present, and, if research animals are being used, the location at which the experiments are conducted has been approved.

Conclusion: The Biosafety audit is an opportunity to gauge the work environment and provide an opportunity for discussion and education.

Outcomes: The Biosafety audit program has increased effective engagement with the Principal Investigators and research personnel. It has provided an avenue for further discussion and education. Also, by identifying deficiencies, the Cleveland Clinic Biosafety program has used this information to be more proactive to prevent potential issues.

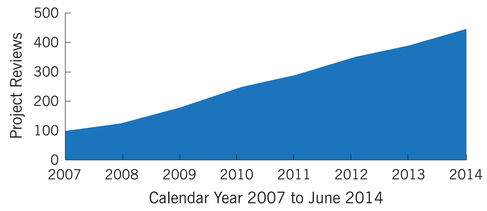
[1]Peterson JS, Hashimoto RJ. Measuring Biosafety Program Effectiveness. In: Fleming DO, Hunt DL, editors. Biological Safety: Principals and Practices, 4th edition. Washington, DC: ASM press; 2006 p. 445-457.

Introduction

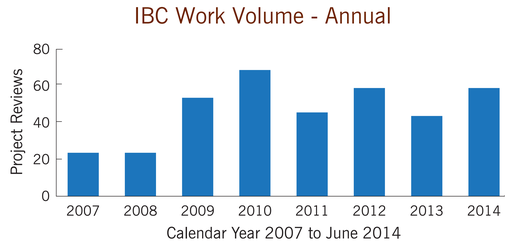
- In order to ensure that researchers are compliant with proper use of biohazard agents and NIH guidelines, an in-depth audit process was required.
- A checklist was developed to capture common clerical and physical deficiencies that are present in the lab.
- The checklist is sent ahead of the inspection so that the lab can be prepared for the audit.
- Using the checklist allows for researchers to have a better understanding of what is required to be in compliance.
- The main objective of the audit is to identify which deficiencies are happening in the labs.
- The audit is not meant to be punitive but is intended to serve as a means to prevent identified issues from happening again in the future.
- Copies of the checklist can be requested from Nick Tripoulas (tripoun@ccf.org).

Biosafety Program Overview

IBC Project Review Volume - Cumulative

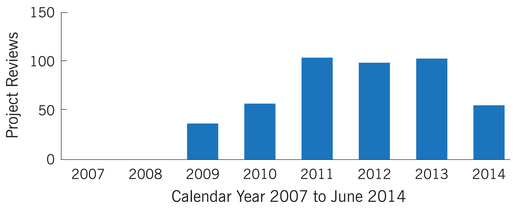


IBC Work Volume - Annual



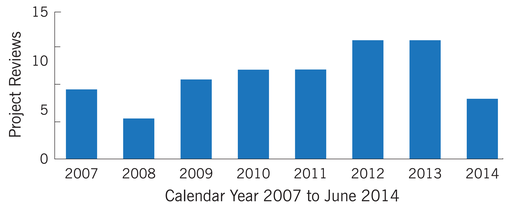
The Cleveland Clinic Biosafety Program has undergone a significant increase in work load over the past 7 years. This has led to need to have an established method to monitor the work to assure safe practices and congruence with the IBC-approved protocols.

Biosafety Audits



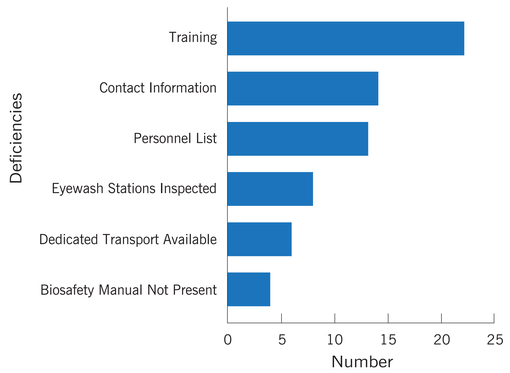
As the audit process was implemented, the goal was to have six audits performed per month. Due to the increase in applications, the new goal is eight audits per month. If a PI has multiple IBC approved protocols, they are all covered during a single audit.

IBC Meetings - Annual



As the amount of applications have increased, so have the number of IBC meetings. The IBC committee is now meeting monthly. Topics covered include but are not limited to: new applications, amendments to existing protocols, renewals, new personnel added to protocols, educational materials for the committee and the results of biosafety audits performed that month.

Total Deficiencies CY 2013



The deficiencies that are found during the annual biosafety audit are grouped into two categories: clerical and physical. An example of a clerical deficiency would be not having an up-to-date personnel list while a physical deficiency would be a biological safety cabinet not being certified annually. The number of deficiencies has gone down significantly, especially in lab members not completing their CITI™ training as labs understand what is expected to be compliant.

How Clinical Trial Audits are Performed

- There are several clinical trials that have been approved by the IBC.
- On the day of the procedure, the Biosafety team will be with the agent from the time that it is removed from storage and transported to the Operating Room (OR)/ procedure room to ensure proper handoff and transport.
- Once the agent has been delivered to the OR/procedure room, the Biosafety team will observe the procedure to assure proper handling and disposal of the agent.
- After the procedure is complete, they will meet with the nurse manager to review how the procedure was carried out.
- A memo is submitted to the Principal Investigator (PI) and nurse manager which will present the audit findings and any required changes to the procedures. This provides an opportunity for discussion about the study.

Conclusion

- As a result of the audit and using the checklist, we have observed a reduction in observed deficiencies and an increase in the number of labs that are in compliance.
- By using the checklist, we observed that researchers are more willing to have a discussion about what is required and how they can improve their work practices.
- Also, by having clear requirements, lab members are more willing to take ownership of the protocol and work with the Biosafety team.
- If there are deficiencies identified during the audit, the Biosafety team will work with the lab to correct the deficiencies within 30 days of identification.
- If any serious items are identified, a meeting will be held between the Biosafety team, the lab manager, and the P.I. to get the items corrected as soon as possible.
- By taking this approach, the lab members see that the Biosafety team is willing to work with them to prevent accidents in an environment that emphasizes cooperation and collegiality.