BioRAFT Inspection Module Guide
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Overview

This guide serves as an introduction to the BioRAFT system that will be used as a web-based safety and compliance management platform to support academic, clinical, and research operations.

The purpose of the BioRAFT laboratory inspection system is to assist supervisors in maintaining compliance with regulatory agencies and to ensure a safe and healthy work environment for students, faculty and staff.

In addition to inspections, BioRAFT will also be used for self-inspections, training, and correspondence with Drexel supervisors.

BioRAFT Inspection Module Features

- BioRAFT uses wireless technology to access the Environmental Health and Safety (EHS) online inspection system and may be accessed anytime at https://drexel.bioraft.com.
- Electronically sends inspection reports immediately upon completion of the inspection. Automatically emails reminders and follow-up notices to the supervisor and compliance liaisons. Department Head will be notified of unresolved findings.
- The supervisor may designate one or more group compliance liaisons to receive and access inspection reports and other compliance related notifications.
- The supervisor and group compliance liaisons are able to document corrective actions for inspection findings. This record can be accessed by the supervisor, the group compliance liaison, the department head, and Environmental Health and Safety.
- The system tracks all correspondence between the supervisor and inspector.
- The system tags and tracks findings that have been observed at least once within the last 18 months.
- Supervisors, group compliance liaisons and department heads are able to search inspections by inspection type, status, and date.
- The supervisor and group compliance liaison can conduct self-inspections.
Compliance dashboards can be accessed by the compliance liaison, supervisor, department head, and Environmental Health and Safety.

**BioRAFT Terminology**

*Laboratory or Lab* – this term is used to designate the supervisor, principal investigator, or clinical practice manager. For example, Martin Bell would be designated as the Bell Lab. Laboratory in this system is not associated with a physical space.

*Space* – this term is used to identify physical spaces (i.e. room 153).

*Group Compliance Liaison* – this term is used to designate individuals responsible for a specific laboratory’s compliance. The supervisor or principal investigator can delegate the responsibility to individuals working for them. For example, Joe Nihill is the group compliance liaison for the Bell Lab.

**Laboratory Profile**

The Lab Profile provides the following:

- Lab contact information.
- List of members.
- List of spaces associated with the lab.
- Compliance Dashboard.
- Training records.
- Documents, notes or forms uploaded by the supervisor or group compliance liaison.
- Lab inspection log.
- Correspondence.
- Lab Categories.
- Hazard Categories.

The supervisor can manage and review all information in the profile.
Inspections

The inspections will cover but not limited to the following topics:

- Biological Safety
- Chemical Safety
- Compressed Gas Cylinder Safety
- Fire and Life Safety
- General Laboratory Safety
- Hazard Communication
- Personal Protection
- Radiation Safety
- Training
- Waste Handling
• Mechanical Safety
• Machine Safety
• Equipment Safety

The inspector will be able to:

• Include other comments, recommendations, or corrective actions not directly covered in the above topics.
• Input severity level in the comment section. These levels are initially set to low priority. The inspector will use his or her judgment to determine the severity level.
• Include pictures to help identify any findings.
• Include attachments for missing or helpful documents.
• Identify repeated findings.
Severity Levels

Findings noted during an inspection will be classified using a 4-point scale, with Level 4 indicating the greatest severity. The severity level will be included with the description of any findings during the inspection. The severity level of the finding will be assessed by the inspector and documented using the following definitions:

• Severity Level 1 – Notice
  • Situation is a minor departure from Standard Operating Procedures (SOPs), common sense, best practices and/or housekeeping standards.
  • Action – All findings will be noted on the inspection. The supervisor must address the inspection findings and update the inspection platform within thirty (30) days.

• Severity Level 2 – Moderate
  • Situation is not life threatening, and does not pose risk of serious illness or injury, and/or significant damage to property. The violation may also be an infraction of EPA, OSHA, and/or local (state, city, institutional) regulations.
  • Action – All findings will be noted on the inspection. The supervisor must address the inspection findings and update the inspection platform within fifteen (15) days.

• Severity Level 3 – Important
  • Situation is potentially life threatening, with an associated danger that may pose a risk of serious illness or injury, and/or significant damage to property. The violation may also be an infraction of EPA, OSHA and/or local (state, city, institutional) regulations.
• Action – Operations may be discontinued and the occupants evacuated from the room until the situation is resolved. All findings will be noted on the inspection. The supervisor must address the inspection findings inside the laboratory within five (5) days and update the inspection platform within ten (10) days.

• Severity Level 4 – Critical

  • Situation is life threatening with an imminent danger that poses an immediate risk of serious illness or injury, and/or significant damage to property.

  • Action - Operations will be discontinued and the occupants evacuated from the room until the situation is resolved. All findings will be noted on the inspections. The supervisor must immediately address the inspection findings and update the inspection platform within five (5) days.
Inspection Work Flow

EHS Performs Inspection
- EHS sets the inspection due date and status to "Pending Resolution".
- EHS sends inspection to the lab (i.e. supervisor and group compliance liaison).

Lab receives Inspection
- Lab logs into the system to review and confirm receipt the inspection.

System sends reminder and follow up emails to the lab.
- Reminders and follow-up message timing are set by the inspector.

Lab corresponds with the inspector
- Lab logs into the system to indicate whether or not the findings are addressed.
- Lab can contact EHS to discuss the report findings.

EHS is notified by the system
- If lab indicates the findings are addressed the inspector will set the status to "Follow-up".
- If the inspector determines all the findings are addressed the inspection status is set to "Finalized".
Email Inspection

To:
Martin W Bell - Principal Investigator

CC:
Martin W Bell - Principal Investigator
James R Klinger - Technician
Jeffrey D Nemetz - Technician
Joseph R Nihill - Technician

Subject:
Drexel EHS - Lab Inspection Report - 09/07/2016

Body:
Drexel EHS has performed an inspection on 09/07/2016 for Bell Lab,
Academy of Natural Science - Research - 218,
Academy of Natural Science - Research - 218.5,
New College Building - B42,
Queen Lane - G92B,
Queen Lane - G92E,
Stratton Hall - 145. The PI or compliance liaison must review and confirm the inspection report. Please use the link below to login, view and confirm receipt of the inspection report.
https://drexel.bioroad.com/nede/886667

Inspection Report:

Corrective Action(s): Remove all food and drink from the laboratory. Please inform all personnel of this requirement.
Contact EHS at safehseal@drexel.edu for further assistance.

*Space(s):
Academy of Natural Science - Research - 218, Academy of Natural Science - Research - 218.5, New College Building - B42, Queen Lane - G92B, Queen Lane - G92E, Stratton Hall - 145

*See Attachment(s):
- Discus.215 Drinks-3.1473277261.42269.jpg
This finding has been recorded 3 times in the past 18 months.

2 Compressed gas cylinders are not capped when not in use

*Comments/Corrective Action(s):
Compressed gas cylinders are not capped when not in use: Compressed gas cylinders must be capped when not in use or if not hooked up to an experimental process; Cylinder regulators must be removed when not in use. Protective cap must be in place when transporting compressed gas cylinders. Store only cylinders needed for immediate use in the lab; excess...
Inspection Status

The inspector sets the inspection status and follow-up due date prior to sending the report to the Laboratory. There are three stages for an inspection:

- **Pending Resolution**: Report has been sent to the Laboratory. The inspector is waiting for a response from the Laboratory. The Laboratory has four options to report to the inspector.
  - All audit findings have been resolved.
  - Audit findings have been resolved except those noted below in comments.
  - Corrective actions have not yet been put in place.
  - Please have the auditor contact me to discuss this report.

- **Pending Inspector Review**: The inspector must confirm that all of the findings have been resolved before the report can be finalized. The Laboratory may arrange a time to meet with the inspector to review the corrective actions.

- **Finalized**: Findings have been resolved and verified by the inspector. No further activity for this report is required. The Laboratory will need to arrange to review the corrective actions before Finalizing the report.
**Inspection Email**

Inspection reports will be sent via email from support@bioraft.com or no-reply@bioraft.com on behalf of the inspector. The supervisor or group compliance liaison must confirm the receipt of the report. Log into the system to confirm the receipt of the report using your Drexel credentials. The system will send a reminder email if you do not confirm the receipt within one week.
Drexel EHS has performed an inspection on 09/07/2016 for Bell Lab,
Academy of Natural Science - Research - 216,
Academy of Natural Science - Research - 216.5,
New College Building - B42,
Queen Lane - G92B,
Queen Lane - G92E,
Stratton Hall - 145. The PI or compliance liaison must review and confirm the inspection report. Please use the link below to login, view and confirm receipt of the inspection report.
https://drexel.berkley.com/node/886697

Click to review and confirm

The report includes comments that have also been included below for your convenience.

Inspector Report

Inspected Date: 09/07/2016
Inspection Type: Spot Inspection

Inspected By: Martin W Bell
Status: Pending Resolution

Primary Contact: Martin W Bell
James R Klinger

Inspected Group/Space:
Bell Lab
Academy of Natural Science - Research - 216
Academy of Natural Science - Research - 216.5
New College Building - B42
Queen Lane - G92B
Queen Lane - G92E
Stratton Hall - 145

Rating: N/A

Summary

Spot inspection


Inspection Report View Inside the System

Bell Lab Inspection 09/07/2016

Attention: Your response is required to this Inspection Report.

Groups/Spaces:
- Bell Lab
- Academy of Natural Science - Research - 216
- Academy of Natural Science - Research - 216.9
- New College Building - 842
- Queen Lane - G320
- Queen Lane - G32E
- Stanton Hall - 146

Primary Contact: Martin W Bell
Compliance Liaison: James R Kinney, Jeffrey D Nemetz, Joseph R Nihill
Inspection Type: Spot Inspection
Inspected By: Martin W Bell

Status: Pending Resolution
Last Emailed: 05/07/2016
Respond By Date: 10/07/2016
Confirmed: -

Findings:
- Personnel are eating and/or drinking food in the laboratory
- Compressed gas cylinders are not capped when not in use

Repeat finding within the last 18 months

Summary
Spot Inspection

Findings

1. Personnel are eating and/or drinking food in the laboratory

Comments/Corrective Action(s):

Personnel are eating and/or drinking for in the laboratory. Eating and/or drinking food in the laboratory is strictly prohibited. Food is not to be stored within the lab or lab refrigerators. Food and drink is not permitted in laboratory even if kept closed and in book packs. Food items used strictly for research purposes must be labeled as such. Eating, drinking, or storing food in the laboratory creates an unnecessary exposure risk. The storing food in Smoking, chewing gum and applying cosmetics in the laboratory is prohibited.

Corrective Actions(s): Remove all food and drink from the laboratory. Please inform all you personnel of this requirement. Contact EHS at ehs@drexel.edu for further assistance.

Space(s):
- Academy of Natural Science - Research - 216
- Academy of Natural Science - Research - 216.5
Inspection Report Confirmation

Reminders and Follow-up Notifications

The system sends the following reminders and follow-up notifications:

- **Inspection Confirmation Reminder** – This message is sent to a Laboratory (i.e. supervisor, principal investigator, or clinical practice manager) to remind them that an inspection has been performed and receipt of the report must be confirmed. This reminder is sent if the lab has not confirmed receipt after one week.
**Inspection Follow-up Reminder** – This message is sent to remind the Laboratory (i.e. supervisor, principal investigator, or clinical practice manager) that an inspection report is pending resolution and follow-up is required. This message is sent to the lab and the group compliance liaison. The reminder message is sent three (3) days after the inspection has been placed in the pending resolution state, and will continue to send every three (3) days following the initial message until the status is moved out of the pending resolution state.

From: no-reply@bioraft.com
Subject: Drexel EHS - Inspection Report - Follow Up Required

**Message Body:**

**ACTION REQUIRED: Follow Up Required for Inspection Report**

The inspection carried out on [Inspection Date] requires an update or resolution from your group. Please respond within the inspection report to the corrective actions outlined at the following URL: [URL]

Thank you.

Responses to this automated message will not be received. If you have any questions, or believe you received this message in error, please contact support@bioraft.com.
Inspection Report Due Notification – This message is sent as a reminder to push the inspection to a finalized state. All inspection findings on the report must be resolved by the due date on the report. This message is sent two (2) weeks before the inspection is due, and will continue on a weekly basis until the due date, or until the inspection is finalized.

From: no-reply@biocraft.com
Subject: Drexel EHS - Inspection Report Receipt Confirmation Required

Message Body:

Our records indicate that you have not confirmed receipt of an inspection report that was emailed to you. Please review the inspection report below and click on the link at the bottom to confirm receipt.

You may also view the report and confirm receipt by logging in here: [URL]

[Inspection Report]

Responses to this automated message will not be received. If you have any questions, or believe you received this message in error, please contact support@biocraft.com.

Inspection Overdue Notification – This message is sent when an inspection is overdue. The recipients of this message are the department head, the lab, the group compliance liaisons, and the inspector. This message is sent one (1) day after the due date has passed and continues to send every three (3) days until the report is finalized.
** ACTION REQUIRED: Inspection Report is now Overdue **

The inspection carried out on [Inspection Date] required resolution to finalize the report by [Inspection Response Date].

As the due date has passed, please respond using the inspection link below IMMEDIATELY. Failure to respond will result in this inspection report being escalated to your Department Head.

Please follow the link below to contact your EHRS inspector via the correspondence section to resolve this matter.

You may view and add comments to the inspection at the following URL:
[URL]

Thank you.

Responses to this automated message will not be received. If you have any questions, or believe you received this message in error, please contact support@biolabt.com.

➢ **Inspection Overdue Escalation Notification** – This message is sent when an inspection is overdue, and is being escalated to the department head. The recipients of this message are the department head, the lab, the group compliance liaison, and the inspector. This message is sent when an inspection is fourteen (14) days overdue, and will continue to send every day until the report is finalized.
Inspection Correspondence

E-mails will automatically be sent out to notify the respective parties when comments and responses are added to the inspection report. These notifications will also be available in the Compliance E-Mail Inbox when you log into BioRAFT. All correspondence must be done within the BioRAFT platform. The system will track all comments.
From: no-reply@bioraft.com
Subject: Drexel EHS - Inspection Report - [Inspection Date] - Response

Message Body:

A new comment has been added by [sender name] to the Inspection Report performed on [Date]:

[Comment]

Please respond to the comment at the following URL:
[URL]

Thank you.

Responses to this automated message will not be received. If you have any questions, or believe you received this message in error, please contact support@bioraft.com.

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Correspondence

Submit Response

Require Follow Up

Response:

- All audit findings have been resolved.
- Audit findings have been resolved except those noted below in comments:
  - Corrective actions have not yet been put in place.
  - Please have the auditor contact me to discuss this report.

Additional Comments:

I am in the process of purchasing a new cap for the compressed gas cylinder. The cap will be in next week.

On posting, notify these people:

- James R Klinger
- Jeffrey D Nemetz
- Joseph R Nihill

Select: All None

Submit
Audit findings have been resolved except those noted below in comments:

I am in the process of purchasing a new cap for the compressed gas cylinder. The cap will be in next week.

Follow up required by October 7, 2016

Response:
- All audit findings have been resolved.
- Audit findings have been resolved except those noted below in comments:
  - Corrective actions have not yet been put in place.
  - Please have the auditor contact me to discuss this report.
Pending Inspector Review

The inspection report will be set to Pending Inspector Review when the lab indicates all findings have been resolved.
Inspection Report Finalized

The inspection report will be set to Finalized upon confirmation that all findings have been resolved. The report will not be finalized if some of the findings are still open.
Access Recent Laboratory Inspections

Compliance Inbox

Inspection reports that have been recently updated will be sent to your email address and will be available in your Compliance Inbox in BioRAFT. The Compliance Inbox
is available in the top right corner of your homepage. This page can be accessed at any time by clicking on the “Home” link in the top right corner of any page in BioRAFT.

Lab Inspection Log

The Lab (supervisor, principal investigator, clinical practice manager, or group compliance liaison) can view all recent inspections by accessing the Lab Inspection Log on your Profile Page. Click on “View Lab Profile” to open the profile page. Click on the “Lab Inspections” tab to open the log.
View an Inspection Report

To view all recent inspections reports, select the “View” link next to the corresponding inspection in the log. You may search through inspections by Inspection Type, Status, or by Dates, to review desired reports accordingly. The list will provide you with the following:

- Date of Inspection.
- Inspection Type.
- Name of Inspector.
- Number of Findings.
- Status.
- List of type and frequency of findings found during the inspections in the past 18 months.
Self-Inspections

Self-Inspection Log

To view all recent self-inspections performed, visit the self-inspection log by view your Lab Profile, then clicking on the “Self Inspections” tab. On this page you will also be able to review items found during self-inspections in the past 18 months.
Add a New Self-Inspection

From your self-inspection log, select the “Add a New Self Inspection” link. You will then be asked to identify the spaces you are inspecting. Where applicable, add additional spaces using the “Lookup” box.
On the subsequent page, you will walk through the list of items EHS has identified as relevant for the self-inspections. In the “Summary” box, please feel free to take note of any relevant details or overall observations regarding items identified during the inspection. By default, when you select a response of “No” to an inspection question, the corrective action text defined by EHS will be pre-populated to guide you in making the necessary corrections.
To add additional information or comments to an item with an answer of “Yes” or “N/A”, select the “Add Details” link to the right of the question.

Review Completed Self-Inspection

In the final step, you will be able to review your report and make any necessary edits before submitting.