Calling Critical and/or Corrected Values

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 12/1991
CLIA Lab Director: Gregory Pomper, MD	**LAB DEPARTMENT: QUALITY, SAFETY & ACCREDITATION**	**CONTACT:** Quality, Safety & Accreditation

APPLICABLE LABORATORY(S)):

☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is

SCOPE

This policy applies to all WFBMC Department of Pathology employees, faculty and staff.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
C. Critical Test: a value at such variance with normal as to represent a pathophysiologic state that may be life-threatening unless some action is taken in a very short time for which an appropriate action is possible.
D. Corrected Value: any change in a previously reported value.
E. Urgent Diagnosis*:* are considered medical conditions that, in most cases, should be addressed as soon as possible.
F. Significant/Unexpected Diagnosis: are considered medical conditions that are clinically unusual, or unforeseen and should be addressed
G. EHR – Electronic Healthcare Record

POLICY GUIDELINES

A. Critical Value (NPSG.02.03.01)

1. The Department of Pathology will notify immediately, by telephone, a responsible nurse, physician assistant, physician, or other healthcare provider (as defined by the CMO) of any test result which must be corrected or any test value that falls outside the established critical limits established for certain tests. Exceptions to this procedure must be agreed to, in writing, by the CLIA Laboratory Director, Chief Medical Officer (CMO), and chief(s) of the involved service(s).

2. Critical laboratory results shall be reported within 30 minutes after results are available.

3. For inpatients, the alert call may be communicated to the unit charge nurse or the nurse taking care of the patient. The call must be identified as a Critical Value/Corrected Value call.

4. For outpatients and Outreach, the physician alert/call(s) should be made to the clinic or practice and given to the responsible nurse, physician assistant, physician, or healthcare provider. For WFBH practices, phone numbers can be found in the intranet and on Wake On-Call. For Outreach, the list of Outreach Phone Numbers is available on the Pathology SharePoint site:

   https://wakehealth.sharepoint.com/teams/Pathology

5. For clinics that perform their own point of care testing or have laboratory services provided for them onsite, critical or corrected values may be presented directly to the authorized provider on paper instead of the required alert/call. The laboratory is still responsible for documenting the date and time the information was presented to the provider, the name of the provider the information was given to and the name of the lab staff responsible for the transaction.

6. After-hours, the physician alert call(s) should be made to a responsible nurse, physician assistant, physician, or healthcare provider in the clinic or practice. If no one is available, follow the phone message instructions given for after-hours calls.

7. Discharged patient physician alert calls should be made to the hospital operator to obtain the name of the person on call for the discharged patient's service.

8. For the list of values defined as critical, see Policy: List of Critical Laboratory Values. The list is also published in the *Online Test Directory (Pathology Handbook).*

9. Point of Care Testing Results:
   Refer to each Point of Care Testing procedure for the critical value of each test.

10. Anatomic Pathology Results: (ANP.12175; CYP.06450)

    Certain Surgical Pathology and Cytopathology diagnoses may be considered urgent, significant or unexpected. These are not considered critical values under this policy. Urgent diagnoses are considered medical conditions that, in most cases, should be

addressed as soon as possible. Significant, unexpected diagnoses are considered medical conditions that are clinically unusual or unforeseen and should be addressed at some point in the patient's course.
Policy: Communication of Significant or Unexpected Findings.

B. Infectious Disease Reporting (GEN.41316)

Communication of infectious diseases procedures is located in the microbiology document control system.
Procedure: MB-SOP-0053 Infectious Disease Reporting

C. Corrected Result

1. For **ANY** change in a previously reported value, follow the same steps above as calling a critical value.

D. Documenting Critical Values or Corrected Results (COM.3000)

1. When a critical value is obtained, **STOP**. Call the responsible nurse, physician assistant, physician, or healthcare provider. Identify the patient by name and medical record number or use two (2) unique patient identifier. Additional information such as date and time of sample collection should be given as appropriate.

2. Any critical value called must be documented in the patient medical record. The person called should be asked to read back the result and patient information to verify accuracy. The caller will append or type in the appropriate verbal verification code (Smart text Code), ***CTRB*** (Called To And Read Back By) or any Smart Text Code specific to their department, along with the following information:
    - The date of the call
    - The time of the call
    - The full name of the person you notified and who read back the result(s).
    - The name of the responsible laboratory individual who called the result(s).

3. For patients seen in the 3rd floor Cancer Center, Absolute Neutrophil and Platelet Critical value results are printed and hand delivered to the 3rd floor nurses' desk. Append Smart Text Code ***GTN*** (Given to Nurse) and/or ***ANCN*** (≤0.5 Absolute Neutrophils Notification Given to Nurse) to these results. Read back is not required if the report is given in this manner. All other critical values should be called and the appropriate verification code ***CTRB*** (Called To And Read Back By) or any Smart Text Code specific to their department must be appended to the result, along with the following information:
    - The date of the call
    - The time of the call
    - The full name of the person you notified and who read back the result(s).
    - The name of the responsible laboratory individual who called the result(s).

4. If it is a point of care test performed in the same clinic as the provider, the critical value can be given to the provider on paper. Read back is not required if the result is given in this manner. Critical result documentation is site specific and includes but is not limited to recording in the "Provider Notification" flowsheet in the EHR, appended as a comment

to the result in EHR, recording in the "Critical Value Call report Form Sticker" during downtime, recording in a Critical Value Sticker by Outreach, or recording in the Critical Results log sheet. Regardless of how it is documented, it should include the following information:

- The date the result was given.
- The time the information was given.
- The full name of the provider the result was given to.
- The name of the personnel responsible for the transaction.

5. ANY change in a previously reported value must be called to the responsible nurse, physician assistant, physician, or healthcare provider. (COM.30100)

   Read back is required and Smart text Code ***CTRB*** (Called To And Read Back By) must be appended to the corrected value along with the following information:

   - The date of the call
   - The time of the call
   - The full name of the provider the information was given to.
   - The name of the responsible laboratory individual who gave the result.

6. Three (3) attempts should be made to report the critical or corrected results. If you receive no response after 3 attempts, document the attempts by appending all three phone calls along with the numbers and the time last call was made to the reported value.

7. After 3 attempts have been made to give the results, contact the section Medical Director between 8am-5pm or the Clinical Pathologist on-call after hours (found on the Wake On-Call portal).

LITERATURE REFERENCES:

A. COM.30000, COM.30100 and GEN.41316. CAP Accreditation Program, All Common and Laboratory General Checklist, 06.204.2020.
B. National Patient Safety Goals - NPSG.02.03.01. The Joint Commission E-dition © 2020.
C. 493.1291(g) - Standard: Test Report. Clinical Laboratory Improvement Act of 1988 (CLIA), Rev. 166, 02-03-17.

RELATED POLICIES/PROCEDURES IN NAVEX:

Critical Results of Tests and Diagnostic Procedures

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

QUAL-SOP-0005: Communication of Significant or Unexpected Findings
QUAL-POL-0008: Critical Laboratory Values
QUAL-POL-0007: List of Critical Laboratory Values
MB-SOP-0053 Infectious Disease Reporting

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Contaminated Requisition Handling

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 1/2021
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** QUALITY, SAFETY & ACCREDITATION	**CONTACT:** QUALITY, SAFETY & ACCREDITATION

APPLICABLE LABORATORY(S)):

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☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to minimize the risk to all employees of contamination from blood and/or other body fluids from soiled requisitions.

SCOPE

This policy applies to all staff in the Department of Laboratory & Pathology.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

POLICY GUIDELINES

A. Process

    a. It is the responsibility of the person first encountering the contaminated requisition to prevent any other person from being exposed.
    b. Handle contaminated requisitions in one of the following ways:

- Copy
    - Place the contaminated requisition in a plastic sheet cover.
    - Make a copy of the contaminated requisition.
    - Discard the contaminated requisition.
    - Use the requisition copy.
- Decontaminate
    - Place the contaminated requisition on a dry paper towel.
    - Soak the spot on the requisition with a decontaminating solution such as 1:10 Clorox.
    - Allow the requisition to dry.
    - Beside the spot, write “decontaminated” – date and initial.
- Replace
    - If the requisition is saturated with blood and/or body fluids or so contaminated that it cannot be easily handled, a new requisition should be requested.

LITERATURE REFERENCES:

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 4/2021
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** **QUALITY, SAFETY & ACCREDITATION**	**CONTACT:** **QUALITY, SAFETY & ACCREDITATION**

APPLICABLE LABORATORY(S)):
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POLICY PURPOSE

The purpose of this policy is to standardize the maintenance of all general laboratory equipment used within the Department of Pathology. This standardization should fulfill regulatory requirements for records and functionality of laboratory equipment.

SCOPE

This policy applies to all faculty, residents and employees in the Department of Lab & Pathology.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
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POLICY GUIDELINES

Maintenance must be performed at minimum based on the manufacturer's manual requirements for defined intervals, however, a more stringent maintenance schedule may

be performed at the discretion of the laboratory Section Director and/or the CLIA Laboratory Director.

Maintenance may be performed by appropriately trained laboratory staff, members of the Clinical Engineering department, or in situations where agreements with secondary contractors are in place, technical service representatives from instrument/equipment vendors.

A. Responsibilities

a. Responsibilities of the Laboratory Staff

i. It is the responsibility of the laboratory section managers to make sure all new equipment is registered with Clinical Engineering and is appropriately labeled with a "green or purple tags".

NOTE: In 2021, all green tags will be transitioned to purple throughout the year by Clinical Engineering.

ii. The laboratory managers are responsible for ensuring that out of service equipment is also "de-tagged" so that Clinical Engineering can appropriately record this information in their records as well.

iii. As a safeguard for our patients, staff, and laboratory equipment, it is also the responsibility of laboratory Section Managers to know when all preventative maintenance of green or purple tagged equipment is due within their designated section and communicate this frequency to Clinical Engineering.

iv. For pieces of equipment that have certifications with expiration dates such as NIST certified SPOT tags and thermometers, it is the responsibility of the Section Manager to monitor and track these expiration dates and ensure that re-certification or replacement of the device occurs prior to its expiration.

v. The laboratory, not Clinical Engineering, is ultimately responsible for ensuring that all preventative maintenance is performed in a timely manner in accordance with CLIA and CAP standards.

b. Responsibilities of Clinical Engineering

i. Maintain agreements with secondary contractors for coverage provided for certain pieces of laboratory equipment beyond their scope of service.

ii. Maintain records of services performed by secondary contractors for the Laboratory Department.

iii. Be responsible for all equipment tagged with a green labels.

iv. Maintain and complete all required services for "green or purple tagged equipment" with as little disruption to laboratory operations as possible within defined timeframes that meet CAP and CLIA standards.

v. Assist the laboratory as needed in securing purchase orders for vendor covered maintenance or equipment repairs.

vi. Serve as the point between the laboratory and vendor for any service related interactions.

B. Equipment covered under this policy:

Autoclaves: All autoclaves used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Balances*:* All balances used in the Department of Pathology laboratories will have annual preventative maintenance with calibration performed by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Centrifuges: All centrifuges used in the Department of Pathology laboratories will have annual preventative maintenance to include RPM evaluations performed by Clinical Engineering. Weekly, monthly or as needed maintenance defined by the manufacturer is performed by the laboratory staff. Official records of annual maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager. All other maintenance records are maintained within the section.

Electron Microscopes: Preventative maintenance and repairs for the electron microscopes are completed as part of the manufactures' service contract with Thermo-Fisher Scientific. Records of these activities are maintained jointly by Clinical Engineering, Electron Microscopy Section Manager and Thermo-Fisher Scientific.

Freezers: Most freezers are continually monitored with NIST certified SPOT tags. Electronic notifications of range failures are also monitored and recorded by SPOT, sending immediate notification to an individual designated responsible for the laboratory section (i.e Section Manager). The Section Manager or designated laboratory staff in their absence are responsible for reviewing SPOT generated, electronic temperature logs daily to check for shifts or trends in the freezer temperature. All other freezers not on SPOT are monitored manually by the laboratory staff daily using NIST certified thermometers and records are maintained by the section manager. All -80°C freezers are maintained and by Clinical Engineering. Conventional freezers are maintained through Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Fume Hoods: All fume hoods used in the Department of Pathology laboratories have preventative maintenance performed at least annually to include functionality testing by Precision Air. Official records of maintenance are maintained by Precision Air with a copy of services performed forwarded to the Section Manager.

Hotplates: All hotplates used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager. Any maintenance other than annual maintenance recommended by the manufacturer is the responsibility of the laboratory. Those records will be retained in the section.

Incubators: All incubators used in the Department of Pathology laboratories will have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager. Any maintenance other than annual maintenance recommended by the manufacturer is the responsibility of the laboratory. Those records will be retained in the section.

Microscopes: All microscopes used in the department of Pathology laboratories have annual preventative maintenance performed by a certified outside vendor.

Present vendors include:

- Southern Microscope
- JP Optical Consulting Inc.

Daily or routine maintenance is performed by the laboratory staff with those records maintained in the section.

Microwaves: All microwaves used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Ovens: Most ovens are continually monitored with NIST certified spot tags and records and notifications can be obtained from SPOT. All other ovens are monitored by the laboratory staff daily using NIST certified thermometers and records are maintained by the Section Manager. All services performed by Clinical Engineering are maintained by them with a copy forwarded to the laboratory Section Manager. Any services performed by laboratory staff will be retained in the laboratory section.

pH Meters: All pH meters used in the Department of Pathology laboratories have preventative maintenance with calibrations performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Refractometers: All refractometers used in the Department of Pathology laboratories have preventative maintenance with calibrations performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager. Any maintenance other than annual maintenance recommended by the manufacturer is the responsibility of the laboratory. Those records will be retained in the section.

Refrigerators: Most freezers are continually monitored with NIST certified SPOT tags. Electronic notifications of range failures are also monitored and recorded by SPOT, sending immediate notification to an individual designated responsible for the laboratory section (i.e Section Manager). The Section Manager or designated laboratory staff in their absence are responsible for reviewing SPOT generated, electronic temperature logs daily to check for shifts or trends in the refrigerator temperature. All other clinical refrigerators not on SPOT are monitored

manually by the laboratory staff daily using NIST certified thermometers and records are maintained by the section manager. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Safety Hoods: All safety hoods used in the Department of Pathology laboratories have preventative maintenance performed annually to include functionality testing by Precision air. Official records of maintenance are maintained by Precision Air with a copy of services performed forwarded to the Section Manager.

Shaker/Rockers: All shakers/rockers used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Stirrers: All stirrers used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager.

Thermometers: All thermometers used in the Department of Pathology laboratories are NIST certified. Once the original NIST certifications expire, they must be reverified on a yearly basis. Reverifications must be completed in the same location where the thermometer is in service. Records of reverifications must be kept by laboratory Section Managers and thermometers labeled with reverification dates, expiration of reverification and initials of person who completed the task. NIST certified thermometers to be used in reverifications are located in the Laboratory Compliance office on the Main floor of the South Building. Managers can check these thermometers in and out as needed. The Laboratory Compliance thermometers are reverified yearly by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to Lab Compliance

> **Note:** In lieu of reverification section managers may choose to purchase new NIST certified thermometers to replace the existing thermometers in use before their expiration date. Managers must keep records of the current in use thermometer and its current NIST

certificate. These records must be kept for 2 years after the thermometer has been removed from service.

Thermometers should be periodically evaluated for damage (e.g. separation of columns). Thermometers with obvious damage must be replaced or rechecked before continued use.

Timers: All timers used in the Department of Pathology laboratories are NIST certified. Once the original NIST certifications expire, they must be reverified on a yearly basis. Records of reverifications must be kept by laboratory Section Managers and timers labeled with reverification dates, expiration of reverification and initials of person who completed the task.

Note: In lieu of reverification section managers may choose to purchase new NIST certified timers to replace the existing timers in use before their expiration date. Managers must keep records of the expiration date of the timer and its current NIST certificate. These records must be kept for 2 years after the timer has been removed from service.

Timers should be periodically evaluated for damage. Timers with obvious damage must be replaced or rechecked before continued use.

Volumetric Pipettes: All volumetric pipettes used in the Department of Pathology laboratories have preventative maintenance with calibrations performed annually by Bio-Matrix. Records are maintained by Section Managers.

Vortex Mixers: All vortex mixers used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager..

Water baths: All water baths used in the Department of Pathology laboratories have preventative maintenance performed annually by Clinical Engineering. Official records of annual maintenance are maintained by Clinical Engineering with a copy of services performed forwarded to the Section Manager. Any maintenance other than annual maintenance recommended by the manufacturer is the responsibility of the laboratory. Those records will be retained in the section. Temperatures must be recorded daily when in use.

LITERATURE REFERENCES:
CAP standards: GEN.41017, GEN.41042, COM.04200, COM.30600, COM.30625, COM.30675, COM.30680, COM.30685, COM.30700, COM.30725, COM30750, COM.30775, COM.30800.

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Wake Forest Baptist Medical Center	**Laboratory Operations System Delay Notification Procedure**	**Dept:**	**Pathology**
		Origin Date:	**7/2020**
		Contact:	**Lab Safety**
CLIA Lab Director: Gregory Pomper, MD		**Signature on file**	

1. **General Procedure Statement:**
   It is the policy of the Department of Lab & Pathology that known delays in results of laboratory tests for inpatients be communicated across the medical center.

2. **Purpose:**
   The purpose of this policy is to provide a structure for lab sections to communicate an unplanned and unexpected delay in patient results in order to minimize the impact to patients. Planned delays or short term equipment failures that can be compensated by incorporating onsite backup instrumentation will not be communicated across the medical center as there should be no impact to turnaround times on posting results. System-wide downtime delays will not follow this process.

3. **Responsible Department/Scope:**
   a. Procedure Owner/Implementer: Department of Lab & Pathology
   b. Procedure Originator: Lab Safety
   c. Scope: Clinical Laboratory Medical Directors, Lab Managers and Lab Staff

4. **Procedure**
   a. It is the responsibility of the Department of Lab & Pathology to notify inpatient providers and patient care teams of an unexpected, unplanned delay in laboratory testing that will affect turnaround times as soon as possible after the delay has been identified.

   b. Notification of delayed testing should follow these steps:

      Step 1: Lab Staff Member

      - Identifies an unplanned delay in testing
      - Immediately notifies the Lab Section Manager, Lab Manager on-call or delegate if after hours or on weekends. A Lab Section Manager must be notified in order to initiate the system notification process.
      - NOTE: In some situations, the initiation of the system notification process may be delegated by the Section Manager or Section Medical Director to a laboratory staff member meeting CLIA and CAP's personnel standards as a Technical Supervisor. This is at the discretion of the Lab Manager and/or Section Medical Director

Step 2: Lab Section Manager/Assistant Lab Manager or Delegate

- The Lab Section Manager or their delegate will verbally notify the lab section Medical Director. If the Lab Section Medical Director cannot be reached, the Clinical Pathologist on-call should be notified.
- The Lab Section Manager will email the following script to the Lab Medical Director or the Clinical Pathologist on-call with the blanks completed as soon as possible.

  Laboratory Delay WINSTON Campus: Results of (affected test) will be delayed (time frame).

Step 3: Lab Section Manager/Assistant Lab Manager

- Communicate the delay in testing to Charge Nurses, Nursing Operations Supervisors and the Network group (if applicable).
- Charge Nurses:
  - Go to the Net Page link (http://netpage.wakehealth.edu) to send a message to all Charge Nurse ASCOM's, to include the Adult/Pediatric Emergency Departments.
  - Click "send message"
  - Click "Use Group" and choose "All CHG/RES RN's" in the common group list.
  - Type this message in the "message test" box:
    Laboratory delay Results of (affected test) will be delayed (time frame).
- Nursing Operations Supervisors and Nursing Management
  - Page the Nursing Operations Supervisor (NOS) at 336-806-9647 and/or 336-806-9648. Tell them of the delayed tests and an estimation of how long.
  - Email the Nursing Operations Supervisors and nursing management with this message
    Laboratory delay Results of (affected test) will be delayed (time frame). **Email** nur_house_supervisor_wfbmc_dl@wakehealth.edu
- Network
  - If the testing involved in the delay will affect others in our Network, send an email to the Network group. Network_Pathology_Laboratory_Leaders_DL@wakehealth.edu
  - Nur_management_team_WFBMC_dl@wakehealth.edu

Step 4: Lab Section Medical Director or Clinical Pathologist on-call

- At the discretion of the Laboratory Medical Director or Clinical Pathologist on-call, notify CMO on-call and request approval for the Message of the Day and for the Intranet post. Email this script with the blanks completed. Alternate notifications may be utilized at the discretion of the Laboratory Medical Director.

  Laboratory Delay WINSTON Campus: Results of (affected test) will be delayed (time frame).

Step 5: Delay Resolved

- When the delay in testing has been corrected and tests are being processed according to the expected TAT, the Lab Manager/Assistant Manager or a lab delegate should call the help desk @ 6-HELP (6-4357) and request the Wake One team to deactivate the Laboratory Message of the Day.

c. The timeframe of the delay is determined based on the Lab Section Manager's best estimate of the situation. Messages and time frames will be updated as changes or new information is learned. If updates are needed, the Lab Section Manager will provide the update to the Lab Section Medical Director or the Clinical Pathologist on-call until the issue has been resolved.

5. Review/Revision/Implementation:
   a. All laboratory procedures are reviewed every 2 hours at a minimum.
   b. All new procedures and procedures that have major changes in the process must be signed by the CLIA Laboratory Director.
   c. Reviewed procedures and procedures with minor process revisions may be signed by the Lab Section Medical Director.
6. Related Procedures: N/A
7. References: N/A
8. Attachments: N/A

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 10/2020
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** QUALITY, SAFETY & ACCREDITATION	**CONTACT:** QUALITY, SAFETY & ACCREDITATION

APPLICABLE LABORATORY(S)):

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POLICY PURPOSE

The purpose of this policy is to create, maintain, and enhance a safe and healthful environment. This Laboratory Safety & Chemical Hygiene Plan provides information regarding protection from health hazards associated with the laboratory environment in accordance with the governing bodies that apply; including but not limited to CAP, OSHA, ANSI, EPA, CDC & FDA.

SCOPE

This policy applies to all employees in the WFBMC, LMC and DMC Clinical Laboratories, including students, faculty, staff, hospital patients, and visitors. The scope of this policy does not cover research laboratories but could be used as a guide.

DEFINITIONS

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C. Acronyms:

    1. ACR: Annual Chemical Review

2. ANSI: American National Standards Institute
3. CAP: College of American Pathologists
4. CAPA: Corrective Action/Preventative Action
5. CDC: Centers for Disease Control and Prevention
6. CHP: Chemical Hygiene Plan
7. EH&S: Environment, Health & Safety
8. EVS: Environmental Services
9. EPA: Environmental Protection Agency
10. FDA: Food & Drug Administration
11. LN2: Liquid Nitrogen
12. LSM: Laboratory Safety Manual
13. OSHA: Occupational Safety & Health Administration
14. PPE: Personal protective equipment
15. PPM: parts per million
16. PSI: pounds (force) per square inch
17. RCA: Root Cause Analysis
18. SDS: Safety Data Sheets
19. SGC: Safety Governance Committee
20. STEL: Short term exposure limit
21. TB: Tuberculosis

POLICY GUIDELINES

A. Responsibilities

1. CLIA Laboratory Director

    a. Reviews and approves all changes to the safety policies and procedures before implementation. (GEN.73200)
    b. Ensures implementation of a safe laboratory environment in compliance with good practice as well as OSHA and national, federal, state (or provincial), and local laws and regulations, as well as other applicable safety regulations as evidenced by the following:
        i. Records of review of safety procedures AND
        ii. Records of safety audits with corrective action taken to correct violations, as applicable, AND
        iii. Safety meeting minutes AND
        iv. Chemical hygiene plan up to date with annual evaluation for effectiveness AND
        v. Records of periodic on-site assessment of physical and environmental conditions by the laboratory director. (DRA.11400)

2. Safety Governance Committee (SGC)

    a. Membership: Lab & Pathology Department Chair, CLIA Lab Director, AP Medica Director; Laboratory Program Directors; Lab Quality, Safety & Accreditation Director; and others as deemed necessary.

    b. Purpose:
        i. Provide leadership, guidance and structure to the department's safety program.
        ii. Review and address RL6 submissions and resolutions as appropriate

iii. Review and approve all safety related CAPAs.
iv. Oversight of Lab & Pathology specific safety policies
v. Oversight of the Laboratory Safety Manual

c. Meeting Frequency: Quarterly; more frequently if needed.

3. Laboratory Quality, Safety & Accreditation Director

a. Review and revise the Laboratory Safety Manual as needed.
b. Oversight of quarterly safety inspections in each lab section. (GEN.73400)
c. Complete and/or oversee CAPAs for occupational injuries or accidents when indicated.
d. Reports an evaluation of laboratory accidents and occupational injuries/illnesses to the laboratory's quality management program to avoid reoccurrence. (GEN.73700)
e. Reviews national, federal, state and local laws for hazardous waste management compliance with EH&S at a minimum of every 2 years or as changes occur and document that review. (GEN.77800)

4. Laboratory Section Medical Director

a. Ensures that the laboratory has a written chemical hygiene plan that defines safety policies for all chemicals used in the laboratory. (GEN.76000)

5. Laboratory Employees & Faculty

a. Comply with all safety and health standards within the policies and procedures that apply to their job responsibilities to maintain a safe environment.
b. Completes the New Employee Checklist upon hire.
c. Completes all safety training assigned via MTS in a timely manner.
d. Report all occupational illnesses and injuries, no matter how minor, to his/her supervisor and complete an incident occurrence report.
e. Participate in the safety program and attend Error Prevention training.
f. Report all unsafe conditions to his/her supervisor.
g. Use all instrumentation/equipment minding manufacturer recommendations.
h. Keep all work areas clean, uncluttered, disinfected and/or decontaminated daily.

6. Laboratory Safety Team
a. Membership: sharp-end team members from each Lab & Pathology section
b. Purpose:
i. Determine compliance and discuss the environment of care standards in each section for employee safety and safe laboratory practices.
ii. Process improvement for laboratory specific safety and operations, complaints, discrepancies and deficiencies, to include but not limited to: safety prevention and equipment, chemical handling, fall and trip hazards, fire hazards, etc.

iii. Discuss patient safety events as reported via RL6.
iv. Determine RL6 eligibility of events not reported and discuss why events are not reported.
v. Understand the safety focus and the employee hazard awareness topic of the month and how to use them in each specific section.
vi. Oversight of the compliance of laboratory procedures described at the organizational level and the Lab Safety Manual
vii. Communicate this information back to their team members.

c. Meeting frequency: Monthly

d. Facilitator: Laboratory Safety Coordinator and/or Laboratory Quality, Safety & Accreditation Director

e. Reports to: Safety Governance Committee

7. Environmental Health & Safety (EH&S):

a. Review national, federal, state, and local laws for compliance with Laboratory Safety Coordinator at a minimum of every 2 years and document that review.
b. Serve as a resource for safety, including chemical hygiene for the laboratory.
c. Perform and document hazard assessments in accordance with EH&S, OSHA, ANSI, etc. standards deem it necessary and required.
d. Report all summaries and findings associated with the lab hazard assessments to the Lab Section Manager and the Lab Safety Manager.
e. Serve as a resource and support to all labs pertaining to PPE/Hazard Risk Assessment

B. **Chemical Hygiene Plan** (CHP) (GEN.76000)

The CHP is a written program that defines standards of practice, protocols and responsibilities that are intended to protect laboratory employees from harm due to hazardous chemicals in the workplace. (OSHA 29 CFR 1910.1450(b))

The purpose of the CHP is to ensure that all hazards of all chemicals are evaluated and that information concerning their hazards is transmitted to laboratory personnel.

1. CHP elements: (CAP GEN.76000) (OSHA 1910.1450(e)(3))

a. Responsibilities within Lab & Pathology:
i. Lab Section Medical Director Responsibilities:
- Ensure that the laboratory has a written chemical hygiene plan that defines safety policies for all chemicals used in the laboratory. (GEN.76000)

ii. Lab Section Manager Responsibilities:
- Annual Chemical Review:

Maintain a current chemical inventory and specify the maximum amount normally kept in the lab. The inventory is reviewed and updated annually at a minimum. Review and update inventories annually, when moving a laboratory, when starting a new project, or whenever there are significant changes in the chemical inventory. Document the chemical inventory on the Annual Chemical Review (ACR) form.

- Ensure that all hazards of all chemicals are evaluated and that information concerning the hazards is transmitted to laboratory personnel before they work with the chemical.
- Ensure that this CHP is always accessible to laboratory employees and students in all laboratory sections the laboratory is occupied. (OSHA 1910.1450(e)(2))
- Ensures PPE and other necessary supplies are available in accessible locations and used as outlined in this policy.

  Lab Policies: PPE/Hazard Assessment Policy; DMC PPE Hazard Risk Assessment Policy

- Evaluates compliance by:
  a) Initiates re-training or education for non-compliance.
  b) Initiates and documents disciplinary action for continued non-compliance.
  c) Reviews the currently available departmental-specific engineering controls annually with frontline employees.
  d) Evaluates circumstances surrounding exposure incidents in collaboration with the Chemical Hygiene Officer

iii. Lab Employees Responsibilities

- Awareness of the specific laboratory tasks that may result in occupational exposure in the role.
- Conduct all tasks with potential occupational exposure risk in accordance with this CHP.
- Report all chemical exposures by completing occurrence reports, informing their supervisor, and undergoing evaluation by Employee Health when applicable.

  http://intranet.wakehealth.edu/Tools/Occurrence-Reporting/Occurrence-Reporting.htm
- Voice issues or concerns regarding PPE and/or engineering controls to their manager.
- Participate in the identification, evaluation, and selection of effective PPE and engineering controls when applicable.

iv. Lab Safety Coordinator Responsibilities

In the Department of Lab & Pathology the Laboratory Safety Coordinator serves as the chemical hygiene officer in collaboration with EH&S.

- Provides consultation to department managers to determine job classifications with occupational exposure.
- Assists with compliance evaluation.
- Makes recommendations for occupational chemical exposure prevention.
- Completes CAPAs in collaboration with lab section manager when exposure occurs.
- Chemical Hygiene Officer consults with EH&S for chemical exposure monitoring.

v. EH&S Responsibilities

- Monitors trends in injuries and near-miss incidents.
- Works with management and front-line staff to identify opportunities to minimize risk of exposure when appropriate.
- Collaborates with the Chemical Hygiene Officer as a resource to the Department of Lab & Pathology
- EH&S will provide chemical exposure monitoring in coordination with the Lab Section Manager and Chemical Hygiene Officer.

2. Policies for all operations that involve chemicals are maintained in each lab section. Policies from each lab section on maintained and available for all lab employees on Title 21.

3. Criteria for the use of personal protective equipment (PPE) and control devices
    a. A PPE hazard risk assessment is performed in each lab section annually.
    b. Laboratory Policies: PPE/Hazard Assessment Policy; DMC PPE Hazard Risk Assessment Policy

4. Criteria for exposure monitoring when permissible levels are exceeded (OSHA 1910.1450(d))
    a. The Department of Lab & Pathology will ensure that laboratory employees' exposures to the OSHA regulated substances (Xylene and formaldehyde) do not exceed the permissible exposure limits.
    b. Initial monitoring: WFBMC will measure an employee's exposure to Xylene and formaldehyde which requires monitoring if there is any reason to believe that exposure levels for that substance routinely exceed the action level.

c. Periodic monitoring: If the initial monitoring discloses employee exposure over the action level, the laboratory will immediately comply with the exposure monitoring provisions of the relevant standard.
d. Termination of monitoring: Monitoring may be terminated in accordance with the relevant standard.

5. Provisions for medical consultations and examinations (OSHA 1910.1450(g))
    a. WFBMC provides all employees who work with hazardous chemicals an opportunity to receive medical attention, including follow-up examinations which the examining physician determines to be necessary under these conditions:
        i. Whenever an employee develops signs or symptoms associated with a hazardous chemical to which the employee may have been exposed in the laboratory
        ii. When exposure monitoring reveals an exposure level routinely above the action level for an OSHA regulated substance for which there are exposure monitoring and medical surveillance requirements
        iii. Whenever an event takes place in the work area such as a spill, leak, explosion, or other occurrence resulting in the likelihood of hazardous exposure.

6. Provision for training personnel on the elements of the CHP
    a. Employees are trained upon hire and annually by their laboratory section manager.
    b. Laboratory managers retain documentation of compliance.

7. A copy of the OSHA Laboratory Standard 1910.1450 is available for laboratory employees.
8. Evaluation of the carcinogenic potential, reproductive toxicity and acute toxicity for all chemicals used in the laboratory. The product label and safety data sheets (SDS) and the Annual Chemical Review (ACR) are used for this evaluation.
    a. SDS are documents that describe the physical and health hazards of chemicals. Manufacturers of chemicals must provide SDSs for chemicals they sell. Electronic or paper copies of the SDS for all hazardous chemicals are available to all employees in the laboratory. (OSHA CFR 1910.1200(g)) (GEN.76100).
    b. The ACR is used as an annual evaluation tool; is completed by the lab manager; submitted to the Laboratory Safety Manager.

C. Chemical Safety Document Access (GEN.76100)

All lab personnel have access to the following documents:

a. Current SDS and other references that list the details of the hazards and precautions for the safe handling and storage are located electronically via the EH&S SharePoint site and within the lab sections. https://wakehealth.sharepoint.com/sites/ehs/Environmental/ChemicalSafety/SDS/Forms/AllItems.aspx
b. Safety Governance Committee - noncompliance

c. Chemical Hygiene Plan: CHP is located within the LSM.
d. The Code of Federal Regulations, Title 29 part 1910.1450 and its appendices are linked to the LSM.

B. Chemical Labels
   a. Precautionary Labels (GEN.76200)
      Precautionary labels are present on the containers of all hazardous chemicals, indicating the type of hazard and what to do if accidental contact occurs.
   b. Each lab section will ensure that labels on incoming containers of hazardous chemicals are not removed or defaced. (OSHA CFR 1910.1200(b)(3)(i))
   c. Laboratory Policies: Reagent Labeling Policy; DMC Reagent Labeling Policy

C. PPE and Hazardous Materials (GEN.76300)
   a. Laboratory personnel use the proper protective devices when handling corrosive, flammable, biohazardous, and carcinogenic substances. PPE Hazard Risk assessments are completed annually to determine the proper protective devices.
      Laboratory Policies: PPE/Hazard Assessment Policy; DMC PPE Hazard Risk Assessment Policy
D. Chemical Hazard Emergencies (GEN.76400)

Explicit instructions are posted and appropriate supplies available for the emergency treatment of chemical splashes and injuries and the control of chemical spills wherever major chemicals exist.

   a. Chemical Spills Reporting and Responding:
      i. If the spill is greater than 300 ml, do not attempt to clean up the spill. Immediately report to WFBMC Security, 6-9111
      ii. If the spill is considered a carcinogen, reproductive toxin or a highly toxic chemical call 6-9111 and evacuate the immediate area.
      iii. If you are unsure of the type of chemical that spilled call 6-9111
      iv. If the spill is less than 300 ml and non-toxic, contact EH&S at 6-9375 and clean up the spill using the spill kit.
         1. Wear appropriate PPE during the spill response. At minimum wear a lab coat, gloves, safety goggles or face shield, closed toe shoes and long pants.
         2. Spill kits are located in the lab sections and contain directions for cleanup.
         3. Contact EH&S, 6-9375, for proper disposal of spill materials.

4. Contact Environmental Services, 6-1111, to request final cleaning of surfaces.

b. Spill kits are checked for patency per the manufacturer's instructions.
    i. Shake the SPILL-X shaker(s) to determine if the product remains is acceptable for use. If the product remains unopened and free flowing in its granular form, the product can remain in use.
c. Reference EH&S SharePoint site: https://wakehealth.sharepoint.com/sites/ehs/Environmental/ChemicalSafety/Pages/Spill.aspx
d. Notify Lab Safety Manager for any chemical hazard exposure, spill or emergency.
e. Replace spill kit whenever it is opened from EH&S @ 6-9375.

E. Chemical Storage
    a. Evaluate Chemical Hazards for Storage
        i. Maintain the lowest possible quantities of chemicals
        ii. Separate chemicals into compatible groups.
        iii. Prioritize multiple hazards as follows:
            1. Flammability
            2. Reactivity
            3. Corrosives
            4. Toxicity
    b. Safe Storage Practices
        i. Provide an appropriate storage place for each chemical and return the chemical to that location after use.
        ii. Store in compatible containers that are chemically resistant.
        iii. Avoid storing chemicals on bench tops.
        iv. Avoid storing chemicals in laboratory fume hoods.
        v. Store volatile toxics and odoriferous chemicals in a ventilated cabinet (if available).
        vi. Do not expose stored chemicals to heat or direct sunlight.
        vii. Storage shelves should be level, stable, and secured to the wall or stable surface.
        viii. Shelves should be kept free of chemical contamination and dust sources.
        ix. Containers should not protrude over shelf edges.
        x. Store heavy bottles on lower shelves; store corrosives below eye level; ideally, cabinets and shelves should be sturdy and low to the floor and constructed of material that is impervious (i.e., non-reactive) with the corrosive; they should also be ventilated or located near the ventilation system.
        xi. Containers of chemicals must be capped when not in use; make sure that caps on containers are secure; replace damaged caps.
        xii. Chemicals should not be stored under, near, or in the sink to minimize the chance of accidents and improper discharges to the sanitary sewer. Any vapors of corrosive materials and bases will

cause corrosion of the plumbing fixtures under the sink. Some chemicals, including many corrosives, are water reactive and in the event of a water leak, there can be unanticipated and unfortunate consequences.

xiii. If chemicals must be stored adjacent to each other on a benchtop, use secondary containment to prevent incompatible chemicals from mixing and reacting with each other.

xiv. Use secondary containment or spill control, such as placing the container on an absorbent pad (generally required for containers on the floor).

xv. Signs should be posted indicating toxic chemical location and unique hazards.

xvi. Chemicals with a high degree of toxicity should be doubly contained and stored in a locked area accessible only by authorized personnel.

xvii. If containers are placed in refrigerator/freezer door shelves, use secondary containers, additional barriers, or other protective measures to keep them from falling out when the door is opened.

xviii. If chemicals are stored in a shared area or room, the storage space, cabinet or container should be labeled with the responsible party's name so that ownership can easily be identified.

c. Storage Recommendations

Flammables	Store in a separate, ventilated room or enclosure. Cylinders are positioned well away from open flames or other heat sources, not in corridors and not within exhaust canopies. (GEN.76900) Safety cans for storage should be used instead of glass bottles if the purity required does not mandate glass storage. (GEN.76500) In Lab & Pathology, flammables are secured in an upright position in flammable cabinets in the lab sections. WFBH Policy: Compressed Gas, Flammable Liquids, Storage and Issuing
Acids/Bases	Store below eye level, near the floor is recommended. Do not store under sinks where contamination by moisture may occur. Storage of acids and bases should be adequately separated to prevent chemical reaction in the event of an accident/spill/leak. Bottle carriers are used to transport all glass containers larger than 500 ml that contain hazardous chemicals. (GEN. 76700)
Volatile Solvent	Store in areas or rooms that are adequately ventilated. (GEN.76600)
Light Sensitive	Store in amber bottles in a cool, dry, dark place
Nitrated Compounds	Nitrated compounds can be considered explosive; special care and handling may be required. Refer to SDS.
Oxidizers	Store in a cool, dry place away from flammables and

	reducing agents. Oxidizers must not be stored on wooden shelves or in cardboard boxes.
Pyrophoric Substances	Store in a cool, dry place, making provisions for an airtight seal. Materials (e.g., tert-butyl lithium) will react with the air to ignite when exposed
Toxic Chemicals	Store according to the nature of the chemical, using appropriate security where necessary. Generally, store in a ventilated, dry, cool area in a chemically-resistant secondary container
Water-Reactive Chemicals	Store in a cool, dry location away from any water source, including sprinkler systems. Have a Class D fire extinguisher available in case of fire
Compressed Gas Containers	Store upright in a cool, dry place, outside of the building when possible and secured to prevent accidental falling and damage to the valve or regulator. (GEN.76800)
General Chemicals	Store on shelves with like chemicals.

III. Specific Hazards

A. Xylene (CAP GEN.76720)

a. Hazard:
Xylene - Breathing xylene vapors in small amounts can cause headache, dizziness, drowsiness, and nausea. With more serious exposure, xylene can cause sleepiness, stumbling, irregular heartbeat, fainting, or even death. Xylene vapors are mildly irritating to the skin, eyes, and lungs. If liquid xylene is held against the skin, it may cause burning pain. Liquid xylene splashed in the eyes can damage the eyes.
https://www.atsdr.cdc.gov/

b. Handling:
   i. WFBMC shall assure that no employee is exposed to an airborne concentration of xylene which exceeds 100 parts xylene per million parts of air (100 ppm) as an 8-hour weighted exposure limit. (EH&S)
   ii. WFBMC shall assure that no employee is exposed to an airborne concentration of xylene which exceeds 150 parts xylene per million parts of air (150 ppm) as a 15-minute short-term average exposure limit. (EH&S)

c. Monitoring Exposure:

Initial monitoring involves the following in collaboration with EH&S:
   i. Identifying all personal who may be exposed at or above the action level (8-hour time-weighted exposure) or at or above the STEL.
   ii. Accurately determining the exposure to each individual identified, either through measurement of exposure or through a representative sampling strategy

iii. Xylene must be monitored initially, but there is no requirement for periodic monitoring of xylene. Repeat monitoring should be considered when there is a change in physical location of a lab, change in production, equipment, process, personnel, or control measures likely to increase exposure levels.

B. Formaldehyde (GEN.76720) (OSHA 1910.1048(c))

a. Hazard:
Formaldehyde is classified as a human carcinogen. Short-term exposure to formaldehyde can be fatal. Long-term exposure to low levels of formaldehyde may cause respiratory difficulty, eczema, and sensitization.
https://www.osha.gov/SLTC/formaldehyde/hazards.html

b. Handling:
   i. WFBMC shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 parts formaldehyde per million parts of air (0.75 ppm) as an 8-hour weighted exposure limit.
   ii. WFBMC shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds two parts formaldehyde per million parts of air (2 ppm) as a 15-minute short-term average exposure limit.

c. Monitoring Exposure:
   i. Initial monitoring involves the following:
      1. Identifying all personnel who may be exposed at or above the action level (8-hour time-weighted exposure) or at or above the STEL.
      2. Accurately determining the exposure of everyone identified, either through measurement of exposure to each employee or through a representative sampling strategy.
   ii. Formaldehyde vapor concentrations must be monitored in all areas where these reagents are used.
   iii. The results of formaldehyde monitoring must be made available to personnel, either in writing or posted in an accessible area, within 15 days of receipt of results. If results are above the permissible exposure limit, personnel must be provided with a description of the corrective actions being taken to decrease exposure.
   iv. Initial formaldehyde monitoring must be repeated any time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.
   v. If exposure levels are at or above the action level or STEL, the laboratory will institute engineering control and work practices to reduce and maintain employee exposures below these limits.

vi. If any personnel report signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the laboratory will promptly monitor the affected individual's exposure.

vii. Additional periodic formaldehyde monitoring is required if personnel are shown by initial monitoring to be exposed at or above the action level or at or above the STEL. This includes:

1. Repeat monitoring of the personnel at least every 6 months if the results are at or above the action level.
2. Repeat monitoring of the personnel at least once a year under worst conditions if the last monitoring results are at or above STEL.
3. Periodic monitoring of personnel may be discontinued if results from two consecutive sampling periods taken at least 7 days apart show that personnel exposure is below the action level and the STEL.

d. Observation of Monitoring (OSHA 1910.1048(d)(7))

i. WFBMC shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde.

ii. When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the laboratory shall provide the clothing and equipment to the observer, require the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

C. Radioactive Material Handling - Specimens (GEN.77100)

a. The OR Path Lab and Autopsy Lab have specific policies and procedures for the safe handling of specimens that may contain radioactive material.
b. Radiation Safety Officer Contact information: 716-1202, cell# 336-624-1463; alternate numbers: 716-1201 or 704-881-2264; 716-1207 or 505-709-7445; 713-2855 or 336-413-8944.
c. Lab Policies: AUT-SAFE-0005 Autopsy Radioactive Cases; ORPAT-SOP-0047 Procedure for Handling Specimens Containing Radioactive Materials

D. Dry Ice (GEN.77500)

a. Hazards

i. Contact: skin contact with dry ice is can lead to severe frostbite; skin cells freeze and become damaged very quickly

ii. Asphyxiation: Dry ice will sublime (change from solid to gas) at any temperature above -109 °F. This releases potentially substantial volumes of CO_2 (1 pound solid = 250 liters gas), which can displace oxygen quickly in the air around the dry ice, causing difficulty

breathing, loss of consciousness and death. This is especially of concern in nonventilated or confined spaces.

iii. Explosion: Due to the rapid emission of large volumes of CO2 gas, any dry ice that is stored in a closed container can pressurize the container. Given enough time at normal room temperature, such a container may explode if the gas is not able to escape.

iv. Occupational Exposure: Eight-hour, time-weighted average is 5,000 parts per million (ppm); 15-minute, short-term exposure limit is 30,000 ppm.

b. Handling

i. Dry ice can come in flake, pellet or block forms.

ii. Use the following precautions when handling dry ice in any form:

1. Wear appropriate eye protection, including goggles and/or a face shield, as well as a laboratory coat.
2. Use dry ice tongs or scoop.
3. Use loose-fitting, thermally insulated gloves to manually handle dry ice. Never handle dry ice with bare hands.

c. Storage

i. Always store dry ice in a well-ventilated location.

ii. Do not store dry ice in confined areas with limited ventilation. This includes cold rooms, walk-in refrigerators, and environmental chambers.

iii. Never store dry ice in a tightly sealed container, such as a plastic or glass bottle, or any container with a screw-top lid that will not vent. Styrofoam is an appropriate storage material since it is both insulated and not airtight.

iv. To dispose of dry ice, place it in a well-ventilated area at room temperature; the remainder of the ice will sublimate away.

v. Never dispose of dry ice in a trash can, chemical waste container or other garbage/waste can.

vi. Never dispose of dry ice in a sink, toilet or other fixture; the temperature difference can destroy the plumbing.

vii. Do not leave dry ice unattended in open areas.

E. Liquid Nitrogen (LN2) (GEN.77500; 77550)

a. Hazards

i. Contact: Liquid nitrogen is extremely cold and may cause severe frostbite

ii. Asphyxiation: Liquid nitrogen may vaporize into a large amount of nitrogen gas that may displace atmospheric oxygen and lead to asphyxiation.

b. Handling

i. Wear insulated gloves, a face shield, lab coat and close-toed shoes when dispensing liquid nitrogen. Do not allow the liquid nitrogen to contact any unprotected part of the body

ii. Always use liquid nitrogen in a well-ventilated area.

iii. Leave the door to the liquid nitrogen storage room open while dispensing liquid nitrogen.

c. Storage
    i. Hanes 2032 and BMT is equipped with an oxygen monitor which will emit both a visual and audible alarm if oxygen levels fall to a dangerous level.
d. Monitoring
    i. Oxygen monitoring devices are maintained and calibrated following manufacturer instructions. Device display/readout should be visually checked following a defined schedule to ensure proper operation.
e. Laboratory Policies: Safe Handling and Use of Liquid Nitrogen Electron Microscopy; Liquid Nitrogen Handling-MD-IHC; Handling of Liquid Nitrogen for Neuro Lab Histology; Liquid Nitrogen Use, Precautions and Exposure (BB).

F. UV Light (GEN.77600)

a. Hazard
    i. Corneal or skin burns
b. Handling
    i. Biological Safety Cabinet: Lights are operated only when laboratory personnel are not present in the room. A biological safety cabinet (BSC) is the primary means of containment developed for working safely with infectious microorganisms. (CDC)
    ii. Ceiling Fixture: Lights are operated when laboratory personnel are not present, only during non-operational hours
c. Signage
    i. A sign is placed on the door to inform technical personnel, as well as outside personnel, such as housekeeping or security, that the light is on and not to enter without first turning off the light.
d. Laboratory Policy: Ultraviolet Light Exposure; DMC Ultraviolet Light Safety

G. Latex (GEN.77700)

a. Hazard
    i. Allergic reaction ranging from skin irritation to anaphylaxis.
b. Lab & Pathology employees are encouraged to report any latex allergy symptoms to their immediate supervisor and be evaluated in Employee Health for additional guidance.
c. The Department of Lab & Pathology encourages the use of nitrile gloves in place of latex gloves. Nitrile gloves are extremely durable, puncture resistant and can withstand exposure to oils, solvents, and chemicals. Nitrile gloves carry a very low allergy rate of less than 1%.
d. Lab employees with a confirmed latex allergy should follow these steps to minimize risk of latex exposure:
    i. Use non-latex gloves only.
    ii. Avoid areas where powdered latex gloves or other latex products are used and dispensed.
    iii. Wear a latex alert medical bracelet.

iv. Seek treatment for allergy.

IV. Waste Disposal

A. Hazardous Waste Disposal (GEN.77800)
   a. EH&S has oversight of waste disposal at WFBMC, including the Department of Lab & Pathology. The Laboratory Safety Officer will review national, federal, state, and local laws for compliance with EH&S every 2 years and will document that review.
   b. WFBH Policy: Management of Regulated and Non-Regulated Medical Waste (Biological Waste)
   c. Laboratory Policies Department of Pathology Laboratory Waste Disposal Policy; DMC Laboratory Waste Disposal Policy

B. Hazardous Waste Registration and Regulations (GEN.77825)
   a. WFBH is registered with the Environmental Protection Agency (EPA). EH&S updates and maintains the EPA registration documents.

C. Biohazard Disposal Containers (GEN.77900)
   a. All infectious wastes (glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse are discarded into biohazard-labeled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and disposal.
   Laboratory Policies: Department of Pathology Laboratory Waste Disposal Policy; DMC Laboratory Waste Disposal Policy
   WFBH Policy: Management of Regulated and Non-Regulated Medical Waste

D. Sharps Disposal (GEN.78000) (OSHA 1910.1030(d)(2)(vii))
   a. Sterile syringes, needles, lancets, or other blood-letting devices (“sharps”) that are capable of transmitting infection are used only once.
   b. All waste sharps should be discarded in containers that are:
      i. Closeable; leak-proof on sides and bottom; puncture-resistant
      ii. Easily accessible to personnel and located in areas where needles are commonly used.
      iii. Maintained in an upright position.
      iv. Replaced before the level of sharps passes the maximum fill line.
      v. Properly labeled to warn handlers of the potential hazard.
   c. Shearing or breaking contaminated sharps is prohibited.
   d. Any manual manipulation of sharps such as bending, recapping, or removing contaminated needles is prohibited as a general practice.
   e. Needles are expected to be used and immediately discarded, un-recapped, into accessible sharps containers.
   f. When moving containers of contaminated sharps from the area of use, the containers should be:

i. Closed immediately prior to removal or replacement to prevent spills or protrusion of contents.
ii. Placed in a secondary container; the second container must meet the same requirements described in D above (part b). Full containers are picked up by Environmental Services.

g. WFBH Policy: Blood and Body Fluid Exposure Control Plan
WFBH: Management of Regulated and Non-regulated Medical Waste

V. Reagents

A. Reagent Labeling (COM.30300)
   a. Reagents, calibrators, controls, stains, chemicals, and solutions are properly labeled, as applicable and appropriate with the following elements:
      i. Content and quantity, concentration or titer
      ii. Storage requirements
      iii. Date prepared, filtered or reconstituted by lab.
      iv. Expiration date (no requirement to label the date opened)
   b. Laboratory Policies: CCL Reagent Receipt and Handling; Reagent Labeling Histology; Reagent Labeling Policy; DMC Reagent Labeling Policy

B. Reagent Storage and Handling (COM.30350)
   a. All reagents are stored and handled as defined by the laboratory and following the manufacturer's instructions.
   b. Records of reagent storage and handling consistent with manufacturer's instructions, including refrigerator, freezer and room temperature monitoring are in each lab section.

C. Reagent Expiration Date (COM.30400)
   a. All reagents (chemicals, stains, media, and antibodies) are used within their indicated expiration date. Expiration dates assigned by the manufacturer must be observed.
   b. Laboratory Policies: Reagent Labeling Policy; Use of Expired Reagents (Autopsy); Quality Assurance Program (Micro); Detecting Expired Supplies & Reagents (Blood Bank); Chemical Expiration Protocol (Electron Microscopy); Weekly Expiration Date Assessment of Reagents (IHC); Monthly/Annual Assessment of Stains and Reagents (Cytology); Quality Assurance Program (Hematology); Expired Reagent Tracking System (PCR); Histology Lab Management Procedure for Checklists and Tasks; Reagent Labeling Policy; DMC Reagent Labeling Policy

D. New Reagent lot/Shipment Confirmation of Acceptability (COM.30450)
   a. New reagent lots and shipments are checked against previous reagent lots or with suitable reference material before or concurrently with being placed in service to confirm that the use of the new reagent lots and shipments do not affect patient results.

b. Manufacturer's instructions for reagent is required and at a minimum the following must be checked:
    i. Qualitative: For qualitative nonwaived tests, minimum cross-checking includes retesting at least one positive and one negative sample with known reactivity against the new reagent lot.
    ii. Quantitative: For quantitative nonwaived tests, patient specimens should be used to compare a new lot against the previous lot, when possible.
c. Laboratory Policy:
    i. Each lab section has a policy addressing this standard.
    ii. Each lab section has records for the introduction of new lots and shipments, including lot number(s) tested and comparison of results to the acceptability criteria.

E. Reagent Kit Components (COM.30500)
    a. When there are multiple components of a reagent kit, the laboratory uses components of reagent kits only within the kit lot unless otherwise specified by the manufacturer.
    b. Laboratory Policy: Each lab section has a policy addressing this standard.

VI. Transporting Specimens (GEN.74500)

All patient samples are submitted in an appropriately labeled and well-constructed container with a secure lid to prevent leakage during transport.

a. WFBH Policy: Specimen Transport Guidelines (IPP#)
b. WFBH Policy: Handling of Specimens in the Operating Room
c. WFBH Policy: Blood and Body Fluid Exposure Control Plan
d. DMC Policy: Medical Center Transport Policy

VII. Spill Handling of Blood & Other Potentially Infectious Materials (GEN.74600)

The Department of Lab & Pathology follows a written policy that includes handling of spills of blood and other potentially infectious materials.

A. Small spills are cleaned by wiping up the spill then using disinfectant.
B. Large spills of blood or other potentially infectious materials are cleaned by EVS. 336-716-1111 or 336-716-0007.
C. WFBH Policy: Blood and Body Fluid Exposure Control Plan

VIII. Sterilizing Device Monitoring (GEN.75000)

A. All sterilizing devices are monitored periodically with a biologic indicator (or chemical equivalent) for effectiveness of sterility under conditions that simulate actual use.
B. The Department of Lab & Pathology does not use sterilizing devices. Outside vendors are used for sterilization.

IX. Environmental Safety

A. Emergency Eyewash (GEN.77400)
    a. Each lab section has adequate plumbed eyewash.

b. Each lab section is responsible for monitoring the following criteria on each eyewash station in their laboratory section:
    i. No greater than 10 seconds travel distance from areas in the laboratory where hazardous chemicals are present to the eyewash stations.
    ii. Signage for location of eyewash
    iii. Unobstructed path with unlocked doors opening in the direction of the eyewash.
    iv. Tepid fluid temperature (between 15 C and 37 C or 60 F and 100 F). Actual recording of the temperature is not required.
    v. Plumbed systems are activated weekly.
    vi. Capable of delivering 1.5 L per minute for 15 minutes
    vii. Flow is provided to both eyes simultaneously.
    viii. Nozzles or covers to protect from airborne contaminants.
    ix. Hands-free flow once activated.
    x. Plumbed systems are protected from unauthorized shut off.
    xi. Self-contained or disposable bottled eyewash units are visually examined weekly.

B. Showers (ANSI Z358.1-2014)
    a. Each lab section, as applicable based on hazard risk assessment, has adequate plumbed shower facilities.
    b. The safety showers are designed, manufactured, and installed in such a manner that, once activated, they can be used without requiring the use of the operator's hands.
    c. Safety showers are visually checked weekly to determine if flushing needs to be changed or supplemented.
    d. The safety shower should be activated weekly for a period long enough to verify operation and ensure that flushing fluid is available.
    e. Safety showers must be located in areas that are accessible within 10 seconds.
    f. Safety showers must be located on the same level as the hazard and the path of travel must be free from obstructions.
    g. Safety showers are installed in well-lit areas and identified with a highly visible sign.
    h. The water supply line must meet the minimum flow requirement of 30-90 PSI.
    i. The water temperature must be tepid. Tepid is described by ANSI as "A flushing fluid temperature conducive to promoting a minimum 15-minute irrigation period. A suitable range is 60 – 100 F."

C. Ergonomics (GEN.77200)
    a. The Department of Lab & Pathology follows the WFBMC Ergonomics Program. The program investigates the design of workspace arrangements and tools that can help employees do their jobs comfortably and safely, increasing job satisfaction and improving performance.
    b. EH&S oversees the Ergonomics Program at WFBMC. Contact EH&S for additional information at 336-716-9375.

D. Excessive Noise (GEN. 77300)
    a. The laboratory protects personnel from excessive noise levels. Protection will be provided against the effects of noise exposure when sound levels equal or exceed an 8-hour time-weighted average sound level of 85 decibels.
    b. The laboratory should monitor noise exposure if there is an indication that excessive noise levels are present or upon request of an employee.
    c. Noise mapping documents are maintained in EH&S.

E. Laboratory Ventilation
    a. Fume Hoods and biological cabinets are required to function properly, and specific measures must be taken to ensure proper and adequate performance of the fume hood and biological cabinets. (OSHA 1910.1450(e)(3)(iii))

    b. Fume hoods receive a face velocity check on an annual basis. Fume hoods that experience malfunction should be removed from service and Engineering then contacted for assessment and repair.
    c. Biosafety cabinets are recertified annually by an external vendor, according to NSF 49 standard. If a Biosafety Cabinet is malfunctioning, Lab Safety personnel should be contacted to arrange for vendor assessment and repair.

F. Safety Inspections (GEN.73400)
    a. The Department of Lab & Pathology's Safety Section completes quarterly safety audits on all laboratory sections to include blood hazard control and chemical hygiene.
    b. CAPAs are completed on identified problems as applicable.
    c. Safety inspection reports and CAPAs are reported at the SGC.

X. Fire Prevention and Protection

A. Fire Prevention (GEN.75100)
   Policies and procedures are written and adequate for fire prevention and control.
   WFBH Policy: Fire and Life Safety Management Plan

B. Fire Separation (GEN.75200)
   The lab is properly separated from inpatient areas and /or provided with automatic fire extinguishing (AFE) systems or the laboratory is separated by two-hour construction and class B self-closing doors. The Critical Care Lab on 4th Floor Reynolds is separated from inpatients by self-closing doors.

C. Fire Exit (GEN.75300)
   Each room larger than 1000 ft or in which major fire hazards exist, has at least two exit access doors remote from each other, one of which opens directly into an exit route.

D. Fire Safety Training (GEN.75400)
   New personnel are trained in fire safety, with a fire safety review conducted at least annually via a Health Stream module where records of compliance are stored.

E. Fire Detection/Alarm (GEN.75500)
   There is an automatic fire detection and alarm system.

F. Fire Alarm Station (GEN.75600)

There is a fire alarm station in or near the laboratory.

G. Fire Extinguishers (GEN.75700)
Appropriate portable fire extinguishers are provided for all areas in which flammable and combustible liquids are stored.

H. Fire Extinguisher Training (GEN.75800)
Personnel are instructed in the use of portable fire extinguishers via a Health Stream module where records of compliance are stored.

I. Laboratory Policy: DMC Fire Evacuation Plan

XI. Electrical Safety

A. Electrical Grounding (GEN.75900)
There are records that all laboratory instruments and appliances are adequately grounded and checked for current leakage before initial use, after repair or modification and when a problem is suspected. Engineering and/or Trimedx provide assessments of electrical grounding when new instruments are installed, after repairs and when problems are suspected.
WFBH Policy: Electrical Safety for Patients, Staff, Employees and Visitors

B. If a manufacturer of an instrument sets a parameter that requires extra precautions for electrical grounding, the laboratory should follow those recommendations.

XII. Vendor Notifications (GEN.20340)

A. The laboratory manages notifications from vendors of defects or issues with reagents, supplies, instruments, equipment or software that may affect patient care/client services.

B. MD Buyline is the organization used by the Department of Lab & Pathology to meet this standard. Lab managers, their delegates and the safety section receive alert notifications. Lab managers or their delegates are responsible for responding to those that apply to their lab.

C. Laboratory Policy: Product Recall and Alert Notifications (MD Buyline).

XIII. Device-Related Adverse Event (GEN.20351) (FDA 21CFR Part 803)

A. Facilities that use medical devices must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

B. In the Department of Lab & Pathology accidents are reported through an electronic event reporting system. Risk Management receives and reviews the report of adverse events that are device related. They determine if a full investigation is necessary. If so, a Risk Management Investigator is assigned to complete the investigation. At the conclusion of the investigation and based on FDA criteria under the Safe Medical Device Guidelines a MedWatch report is complete. The MedWatch report is sent to the FDA and the manufacturer for cases that involve death of a patient. In the case of a serious injury the MedWatch is sent only to the manufacturer.

XIV. Lab Accidents (GEN.73500)

A. There are written policies and procedures for the reporting and recording of all laboratory accidents resulting in property damage.
B. WFBH Policy: Event Reporting

XV. Manual Manipulation of Needles (GEN.74300)

A. Laboratory personnel are prohibited from recapping, purposefully bending, breaking, removing from disposable syringes or other manual manipulations of needles.
B. WFBH Policy: Blood and Body Fluid Exposure Control Plan

XVI. Personal Protective Equipment (CAP GEN.74100)

A. Appropriate personal protective equipment is provided and maintained in a sanitary and reliable condition in all work areas in which blood and body substances are handled and in circumstances during which exposure is likely to occur.
Laboratory Policy: PPE/Hazard Assessment Policy, DMC PPE Hazard Assessment Policy

XVII. **Laboratory Employee Safety**

A. Personal Protective Equipment (GEN.74100)
    a. Appropriate personal protective equipment is provided and maintained in a sanitary and reliable condition in all work areas whenever blood and other potentially infectious materials are handled and in circumstances during which exposure is likely to occur. PPE must be made available to laboratory visitors, as applicable.
    Laboratory Policy: PPE Hazard Assessment Plan
    b. After removing gloves use an effective antimicrobial method following contact with blood or other potentially infectious materials or after each patient contact. (GEN.74250)

B. Hepatitis B Vaccinations (GEN.74700)
    a. Personnel reasonably expected to have direct contact with blood and other potentially infectious materials are identified and are offered hepatitis B vaccinations free of charge. Personnel that decline the vaccine sign a declination form. Employee Health administers the vaccine and maintains documentation of administration.
    b. WFBH Policy: Blood and Body Fluid Exposure Control Plan

C. Viral Exposure (GEN.74800)
    a. There is a policy for follow up after possible and known percutaneous, mucus membrane or abraded skin exposure to HIV, HBV or HVC.
    b. Employee Health is responsible for viral exposure follow up.
        i. Communicable disease resource: http://intranet.wakehealth.edu/Departments/Employee-Health/Resources/Communicable-Disease.htm
D. TB Exposure Plan (GEN.74900)

a. The Department of Lab & Pathology follows a written TB exposure control plan that includes the following:
    i. TB exposure screening at defined intervals for all personnel who may have occupational exposure to tuberculosis.
    ii. Use of engineering and practice controls for hazardous activities that may potentially aerosolize Mycobacterium tuberculosis.
b. WFBH Policy: Tuberculosis Control Plan

E. Bloodborne Pathogens (GEN.74000) (OSHA 29CFR.1910.1030)
a. WFBH Policy: Blood & Body Fluid Exposure Control Policy
b. Records of training are in the employees' personnel file.

F. Occupational Injuries and Accidents (GEN.73600)
a. Procedure for reporting occupational injuries or illness that require medical treatment except first aide.
    i. Report all injuries to your supervisor, even if it appears minor. Occurrence Reports should be completed electronically. The report can be found on the intranet site under the Tools tab.
    ii. Employees should go to Employee Health during the hours of 7 a.m. - 4:30 p.m., Monday - Friday. If the severity of the injury requires immediate attention, the employee should be directed to go to the Emergency Department.

Emergency Department is appropriate when:
i. The injury is life-threatening.
ii. There is excessive bleeding.
iii. Head injury
iv. Compound fractures
v. Serious allergic reactions
vi. Ingestion or inhalation of toxic substances
vii. Lacerations of the eye
viii. Evenings or weekends

XIII. General Safety Practices

A. Do not use mouth suction for pipetting or starting a siphon. (GEN.74400) (OSHA 1910.1030(d)(2)(xii)
B. Confine long hair and loose clothing.
C. No sandals, open-toe, open-heel, open-side or open-weave shoes are permitted.
D. Food and beverages are not to be stored in refrigerators where chemicals, reagents or specimens are stored. (OSHA 1910.1030(d)(2)(x)
E. Do not eat, chew gum, drink, smoke, vape, apply cosmetics (including lip balm) or handle contacts in the laboratory. (GEN.74400) (OSHA 1910.1030(d)(2)(ix)

XIX. Non-conforming Events

A. Identifying Errors and Adverse Event Reporting (GEN.20208)
a. It is the policy of Wake Forest Baptist Health (WFBH) that employees are expected to report all occurrences that cause harm or that have the potential to cause harm through an electronic event reporting system (RL6).

Hospital Policy: Event Reporting

B. Corrective Action/ Preventative Action (CAPA) (GEN.20318)
    a. The Department of Lab & Pathology uses CAPA as the process to identify, prevent or eliminate the cause of actual or potential nonconformity and evaluate the effectiveness of the actions taken using risk management principles.
    b. CAPAs are used when non-conforming events represent a risk to patients or employees for errors, incidents or quality indicators that do not meet defined targets.
    c. Laboratory Policy: CAPA; DMC – Procedure for Completing CAPA
C. Root Cause Analysis (GEN.20310)
    a. RCA is a process for identifying the causal factors underlying a variation in performance, including the occurrence or possible occurrence of a Serious Safety Event and/or Sentinel Event. The analysis focuses primarily on systems processes, not on individual performance.
    b. At WFBMC, oversight of RCA is by the medical center's Patient Safety Department and utilizes a multi-disciplinary approach, including key stakeholders.
    c. RCAs are required when a non-conforming event occurs that results in death, permanent harm or severe temporary harm.
    d. Hospital Policy: Event Reporting
D. Promotion of a Just Culture
    a. Wake Forest Baptist Health embodies has a Just Culture that supports a fair and just work environment that supports and encourages the reporting of all Patient Safety Events. This environment holds individuals accountable for their own performance in accordance with their job responsibilities, but not for system/process failures or flaws over which they have no control. A "performance management" algorithm has been developed to guide this decision-making process based on best practices utilized throughout the United States.
    b. Hospital Policy: Event Reporting

XX. Safety Training

A. Safety Training Requirements (GEN.73300)
    a. All laboratory personnel are trained in safety policies and procedures upon hire and prior to the implementation of new policies and procedures.
    b. Each lab section manager or their delegate is responsible for completing the New Employee Safety Checklist (attached) and placing it in the employee file.
    c. Prior to the implementation of a new policy or procedure, employees are trained via Medtraining.org (MTS). Documentation of compliance of this training is retained in MTS.
B. Chemical Training
    a. Chemical training is provided at the time of an employee's initial assignment to a work area where hazardous chemicals are present and prior to assignments involving new exposure situations. (OSHA 1910.1450(f)(2)(3))

i. New employees complete chemical training (SDS) including the department's chemical hygiene plan at the time of hire.
ii. Documentation of this training is on the New Employee Safety Checklist that is maintained in the employee file.
iii. New chemicals are added to the lab section's SDS library and are signed off by employees that will use the chemical prior to implementation. Documentation of compliance is maintained in the lab section.

b. Laboratory employees will be trained on the chemical hygiene plan upon hire. (OSHA 1910.1450(f)(4))

C. Liquid Nitrogen and Dry Ice
   a. Employees that work with liquid nitrogen and/or dry ice are trained in the safe handling of these hazards upon hire.
   b. Records of liquid nitrogen and dry ice training are maintained in the employees' personnel file on the New Employee Safety Checklist.
   c. Laboratory Policies: Safe Handling and Use of Liquid Nitrogen Electron Microscopy; Liquid Nitrogen Handling-MD-IHC; Handling of Liquid Nitrogen for Neuro Lab Histology; Liquid Nitrogen Use, Precautions and Exposure (BB).

D. PPE (CAP GEN.74200)
   a. Employees should be instructed in the proper use of PPE. Required elements of training:
      i. Proper fitting of gloves
      ii. Replacing gloves immediately when torn or contaminated
      iii. Do not wash or disinfect gloves for reuse.
      iv. Use hypoallergenic gloves when indicated by patient or health care provider history.
      v. Decontamination of hands after glove removal using an effective antimicrobial method (GEN.74250)
   b. Records of PPE training are maintained in the employees' personnel file upon hire. The annual task-based risk assessment is assigned to employees via MTS where records of completion are maintained.
   c. Laboratory Policy: PPE/Hazard Assessment Policy; DMC PPE/Hazard Assessment Policy

E. Latex Allergy (GEN.77700)
   a. Employees are trained on latex allergies upon hire.
   b. Records of latex allergy training are maintained in the employees' personnel file on the New Employee Safety Checklist.

XXI. Records

A. Records Maintained in the Laboratory Section
   a. Laboratory Safety Manual & Safety Policies & Procedures (CAP GEN.73300) in Title 21.

b. Annual Chemical Inventory is maintained in each lab section.
c. Safety Data Sheets (SDS)
d. Hazard Based Risk Assessment

B. Records Maintained in the Department of Lab & Pathology
a. CAP Self-inspections
b. Safety Self-inspections
c. Noise Assessments when applicable
d. Ergonomics Assessments when applicable
e. Chemical monitoring/exposure records when applicable
f. Safety Training Records

C. Records Maintained in Employee Health
a. Employee Immunization Records
b. Safety Training Records

XXII. Emergency Preparedness and Response (GEN.73800)

A. The Department of Lab & Pathology, including all staff, will be notified of a disaster or emergency via the MIR-3 mass notification system. Additional notification will be via overhead page announcements, alpha-numeric paging, radios, telephones, and other means as necessary.
Medical Center Policy: Comprehensive Emergency Operations; Mass Casualty Plan
Laboratory Policy: Mass Casualty Plan; DMC Lab Disaster Plan

XXIII. Evacuation Plan (GEN.73900)

A. Written comprehensive and workable plan specific for the laboratory. Plan must cover all personnel, patients and visitors and must address the special needs of persons with disabilities. Evacuation routes must be clearly marked (Posting evacuation routes is optional)

B. Each lab section will complete a specific evacuation plan for their section using the medical center's Fire and Life Safety Management Plan.
Hospital Policy: Fire and Life Safety Management Plan
Laboratory Policy: DMC Fire Evacuation Plan

BUILDING / AREA EVACUATION PLAN			
EFFECTIVE DATE		**REVISED DATE**	
CAMPUS		**PRIMARY AREA EVACUATION COORDINATOR**	<position>
BUILDING			
LOCATION		**ALTERNATE AREA EVACUATION COORDINATOR**	<position>
DEPARTMENT			

REPORTING AN EMERGENCY
From any telephone, call:

On Campus	**716-9111**
Off Campus	**911**

FIRE (Code Red)

In the event of fire, smoke, or any emergency that requires evacuation from the building, please do the following:

P A S S

PULL • Pull the pin on the extinguisher
AIM • Point the nozzle at the base of the fire
SQUEEZE • Squeeze the lower grip to the handle, discharging the extinguishing agent.
SWEEP • Move the nozzle from side to side in a steady motion until the fire has died down or the extinguisher is empty • If the fire has gone out, back away from the site and exit…shutting the door if possible. • If the fire has died down but flames are still visible, use an additional extinguisher if available. If no additional extinguisher is available, back away and shut the door. Communicate that the fire is still active and evacuate the area immediately.

R A C E

R	**RESCUE** Rescue persons in danger.
A	**ALARM** **1.** Pull the fire alarm. Pull stations are located within 10 feet from each exit/entrance. **2.** Call the Emergency Number: **6-9111/911**. You should remain in communication with the emergency operator providing as much detailed information as possible i.e.: address and location of fire or smoke.
C	**CONTAIN** **1.** Contain the fire. **2.** Do not break windows. **3.** Close but DO NOT lock any doors.
E	**EXTINGUISH/EVACUATE** 1. If smoke or fire is visible, close the door(s) to that area and verbally notify everyone in the immediate area. 2. Notify Emergency Communications. 3. Exit the floor in a quick, orderly fashion via the nearest exit, (*APPENDIX A & B*). 4. Never allow the fire to get between you and the nearest exit. 5. Stay low to the ground to avoid smoke. 6. Proceed to the assigned emergency assembly point. *7.* ***EXTINGUISH*** *For Ambulatory Healthcare Occupancies only*

THE DEPARTMENT'S EMERGENCY ASSEMBLY POINT IS…

_____

(The designated emergency assembly point location for the occupants of the Department/Unit)

Horizontal Evacuation Route	
Primary	
Secondary	

Vertical Evacuation Route	
Primary	
Secondary	

If you have visitors, escort them to the closest unaffected exit and/or instruct them to meet in the designated assembly point. You are responsible for the safety of visitors in your area.

AREA EVACUATION COORDINATOR RESPONSIBILITIES

1. Check all rooms to ensure that all persons are evacuated.
2. Direct persons evacuating to the designated emergency assembly point.
3. Once all personnel are evacuated, move to the assigned assembly point.
4. Be able to provide an accurate head count of all assigned personnel and visitors/patients.

SPECIAL NOTES

1. Procedures for moving or evacuating disabled employees and or non-ambulatory patients should be determined prior to any emergency.
2. The building will not be reoccupied until the Authority Having Jurisdiction (AHJ) provides information that the building is in a safe condition for re-entry.
3. For unit specific evacuation plan, please contact the supervisor.

DEPARTMENT/ UNIT SPECIFIC EVACUATION PLAN

Building Location:		**Department/ Unit:**		**Floor:**		**Manager:**	
Contact Number:		**Effective Date:**		**Last Reviewed:**			

The manager or designee is responsible for the execution of the evacuation plan.

This plan is to be used in conjunction with the attached checklist.

I. Establish Evacuation Route:

A. Determine Destination or Assembly Area

1. Emergency Assembly Point Location:
2. Area of Refuge:
3. Alternate Assembly Points:

B. Horizontal Evacuation Route

1. Primary Route:
2. Secondary Route:

C. Vertical Evacuation Route

1. Primary Route
2. Secondary Route

II. Establish Priorities:

A. Logistical Needs (Portable O_2, Wheel Chairs, Blankets, Office Supplies, Communication Devices, etc.) After evacuation

B. Notification of evacuation to: Other:

III. Determine Additional Staffing Needs:

A. During Evacuation:

B. At the Assembly Point:

IV. A. Specific Information:

DEPARTMENT/ UNIT SPECIFIC POWER FAILURE PLAN

Unit: | **Building:** | **Floor:** | **Unit Mgr.**

Asst. Unit Mgr. | **Effective Date:** | **Last Reviewed:**

THIS SECTION TO BE COMPLETED AT THE TIME OF THE POWER FAILURE:

1. Are the **RED OUTLETS** functioning:

   If **YES**, refer to **Section A** of the Emergency Power/Power Failure Utility Matrix to determine availability of utilities.

   If **NO**, refer to **Section B** of the Emergency Power/Power Failure Utility Matrix to determine availability of utilities.

2. What is the current total unit bed census?
3. What is the current bed census of patients on critical life support?
4. Based on the answers to questions 1, 2, and 3, is there sufficient power available to sustain critical life support?

   If **YES**, defend in place

   If **NO**, begin unit specific evacuation procedures (Refer to Unit Specific Evacuation Template)

THIS SECTION TO BE COMPLETED PRIOR TO THE POWER FAILURE

1. Who (what position) will be assigned to survey adjoining units to determine the extent of the power failure?
2. Who (what position) is authorized to order a unit evacuation?
3. Where is the closest unit, not on the same generator, that this unit can evacuate to? (See Engineering Policy WFBMC-ENG. PROTOCOL-58: Emergency Power Summary)
4. Where is the next closest unit, not on the same generator, that this unit can evacuate to?
5. Where will this plan be located for quick reference?
6. Who (what position) will be responsible for making notifications?
7. Who must be notified? Number

8. What additional personnel (by position) will be needed and how many?

Personnel	How Many?

9. Who is responsible for maintaining power failure related equipment? (IE: ensuring rechargeable battery operated devices such as portable suctions, transport vents, portable monitor/defibrillators, are plugged into red outlets and are always operable)

10. What power failure equipment is available, and where is it stored? (IE: Ambu bags, flashlights and batteries, paper charts, manual sphygmomanometers, portable suctions, transport vents, portable monitor/defibrillators etc.)

Equipment	Location

11. Who is responsible for maintaining the Unit's Business Continuity Recovery Box. (See unit specific INTERNAL DISASTER RESPONSE AND RECOVERY PLAN)

12. Where is the Unit's Business Continuity Recovery Box located?

13. In the event of a total power failure that includes total HVAC failure, what additional precautions should be taken for immuno-compromised patients?

14. Who will be responsible for manually unlocking automated drug supply cabinets?

15. What critical refrigeration is located on the unit, and where, i.e. lab specimens, research experiments, etc?

Refrigerator Contents	Location

16. Are those refrigerators marked or identified for responding personnel? | |

17. What power failure telephones are available on the unit (extension) and where are they located?

Extension	Location
777-	
777-	
777-	

Comprehensive List of Power Failure Emergency Phones
http://intranet.wakehealth.edu/Departments/Help-Desk/Software-and-Services/Power-Failure-Phone-List-Distribution.htm

(Link also found on the Intranet: Click on Help Desk, then scroll to bottom of page and find “Power Failure Phones

REFERENCES

College of American Pathologist Laboratory General Checklist 06.04.2020
College of American Pathologist All Common Checklist 06.04.2020
Occupational Safety and Health Administration Regulations Standard 29 CFR 1910
American National Standards Z358.1-2014
Food & Drug Administration 21 CFR Part 803

ATTACHMENTS

Occupational Exposure to Hazardous Chemicals in Laboratories
Eyewash/Shower Flush and Maintenance Record
Fire Evacuation Plan & Unit Specific Form
Power Failure Unit Specific Plan
Laboratory Safety Inspection Tool

MEDICAL CENTER POLICY LINKS

Management of Regulated and Non-Regulated Medical Waste
Blood and Body Fluid Exposure Control Plan
Specimen Transport Guide Lines (IPP#)
Handling of Specimens in the Operating Room
Blood and Body Fluid Exposure Control Plan
Fire and Life Safety Management Plan
Electrical Safety for Patients, Staff, Employees and Visitors
Tuberculosis Control Plan
Event Reporting
Comprehensive Emergency Operations
Mass Casualty Plan

LABORATORY DOCUMENT LINKS

Annual Chemical Review
PPE Hazard Risk Assessment
Autopsy Radioactive Cases
Procedure for Handling Specimens Containing Radioactive Materials
Safe Handling and Use of Liquid Nitrogen Electron Microscopy
Liquid Nitrogen Handling-MD-IHC
Handling of Liquid Nitrogen for Neuro Lab Histology
Liquid Nitrogen Use, Precautions and Exposure
Ultraviolet Light Exposure
Department of Pathology Laboratory Waste Disposal Policy
CCL Reagent Receipt and Handling
Reagent Labeling Histology
Reagent Labeling Policy
Use of Expired Reagents (Autopsy)
Quality Assurance Program (Micro)
Detecting Expired Supplies & Reagents (Blood Bank)
Chemical Expiration Protocol (Electron Microscopy)
Weekly Expiration Date Assessment of Reagents (IHC)
Monthly/Annual Assessment of Stains and Reagents (Cytology)
Quality Assurance Program (Hematology)
Expired Reagent Tracking System (PCR)
Histology Lab Management Procedure for Checklists and Tasks

Product Recall & Alert Notifications (ECRI Alerts)
CAPA
Mass Casualty Plan

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Laboratory Waste Disposal Policy

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 3/2021
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** QUALITY, SAFETY & ACCREDITATION	**CONTACT:** QUALITY, SAFETY & ACCREDITATION

APPLICABLE LABORATORY(S)):

☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to explain the categories of waste generated and to standardize how it is handled for proper disposal according to local, state, and federal regulations.

SCOPE

This policy applies to all WFBMC Department Laboratory Medicine and Pathology employees, Faculty and staff.

DEFINITIONS

A. **Policy**: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services, or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.

B. **WFBH Lab System**: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

C. **EH&S**: Environmental Health and Services

D. **Regulated Waste**: Liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and can release these materials during handling;

contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. (OSHA 1910.1030(b))

E. **Non-regulated medical waste**: Any materials that are not considered to be regulated medical waste or OPIM such as blood product transfusion bags and tubing containing < 20ml bloody fluid, exam gloves, and empty urine containers.

F. **Other Potentially Infectious Materials:**
   1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, anybody fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
   2. Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
   3. HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. (OSHA1910.1030(b))

POLICY GUIDELINES

A. EH&S has oversight of waste disposal at WFBMC, including the Department of Lab & Pathology. The Quality, Safety and Accreditation Director or their delegate will review national, federal, state, and local laws for compliance with EH&S every 2 years and will document that review. (GEN.77800)

B. Laboratory sections should place their regulated medical waste or OPIM in appropriate receptacles (see table at the end of this policy) in such a manner as to not over fill the container.

C. All infectious wastes (glassware, blood collection tubes, microbiologic and tissue specimens) and other solid or liquid waste or refuse are discarded into biohazard-labeled containers that do not leak and have solid, tight-fitting covers that are applied before transport from the laboratory work area for storage and disposal. (GEN.77900)

D. Sharps Disposal (GEN.78000) (OSHA 1910.1030(d)(2)(vii))
   1. Sterile syringes, needles, lancets, or other blood-letting devices (“sharps”) that are capable of transmitting infection are used only once.
   2. All waste sharps should be discarded in containers that are:
      a. Closeable; leak-proof on sides and bottom; puncture-resistant
      b. Easily accessible to personnel and located in areas where needles are commonly used.
      c. Maintained in an upright position.
      d. Replaced before the level of sharps passes the maximum fill line.
      e. Properly labeled to warn handlers of the potential hazard.
   3. Shearing or breaking of contaminated sharps is prohibited.
   4. Needles are expected to be used and immediately discarded, un-recapped, into accessible sharps containers.

E. Regulated Medical waste and OPMI is removed from each lab section by EH&S.

F. Large OR Pathology waste, such as amputated extremities, is placed in red biohazard bags. The red biohazard bag is placed in a closable plastic bin for pickup by EH&S.

G. Batteries must be placed into universal battery waste receptacles “sealed buckets” and will be picked up and replaced on request by EH&S.

Type of Waste	Regulated Waste	Non-regulated Waste	
	Incineration (red trash bag)	Sanitary Sewer	Sanitary Landfill (white trash bag)
Mycobacterial isolates / select agents of bioterrorism after steam sterilization			X
All other microbiological waste	X		
Anatomical pathology	X		
Blood, small volumes ≤ 20 mL/container ***from hospital laboratory***	X		
Blood, small volumes ≤ 20 mL/container ***NOT from hospital laboratory***			X
Bulk blood, blood products > 20 mL/container that cannot be emptied	X		
Bulk blood, blood products > 20 mL discarded/poured down clinical sink		X	
Blood contaminated items			X
Blood product transfusion bags and tubing containing > 20 mL bloody fluid	X		
Blood product transfusion bags and tubing containing ≥ 20 mL bloody fluid			X
Suction canister waste		X	
Emptied suction canister			X
Sharps (e.g., needles, scalpels, etc.) in an appropriate locked container	X		
Other non-regulated medical waste, including waste from isolation rooms, ORs and ICUs			X
Hazardous drug supplies (e.g., IV bags, tubing, gloves)	X		

LITERATURE REFERENCES:

Environmental Health and Safety department of Wake Forest Baptist Health
OSHA 1910.1030(b)

RELATED POLICIES/PROCEDURES IN NAVEX:

Management of Regulated and Non-regulated Medical Waste

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21

PPE/Hazard Risk Assessment

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 7/2020
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** QUALITY, SAFETY & ACCREDITATION	**CONTACT:** QUALITY, SAFETY & ACCREDITATION

APPLICABLE LABORATORY(S)):

☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to protect employees within the AH WFBMC Department of Lab & Pathology from exposure to workplace hazards and the risk of injury by utilizing engineering controls, process changes, administrative controls and personal protective equipment (PPE). PPE should not be a substitute for more effective control methods and its use will be considered only when other means of protection against hazards are not adequate or acceptable.

This policy addresses general PPE requirements including eye and face, head, foot and leg, hand and arm, body (torso) as well as engineering controls in some locations. Hazard assessments within this policy also include respiratory and hearing.

SCOPE

This policy applies to all employees, faculty and staff in the Department of Lab and Pathology.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

C. CLIA: Clinical Laboratory Improvement Amendments. Federal laws governing laboratory testing.

D. OSHA: Occupational Safety and Health Administration

E. ANSI: American National Standards Institute, a nonprofit, voluntary membership organization that coordinates the U.S. Voluntary Consensus Standards System. Their standards have been adopted throughout government and industry for various types of personal protective equipment.

F. Hazards: Blood, blood substances, and chemicals

G. Face shield: A protector intended to shield the wearer's face, or portions thereof from certain hazards, as indicated by the face shield's markings. (ANZI Z87.1-2015)

H. Goggle: A device with contour-shaped eyecups or facial contact with glass or plastic lenses, worn over the eyes and held in place by a headband or other suitable means for the protection of the eyes and eye sockets.

I. PPE: Personal protective equipment are items worn by an individual such as an apron, face shield, gloves, respirator or hearing protective devices, to prevent exposure, illness or injury.

J. Hazard Assessment: The first critical step in developing a comprehensive safety and health program is to identify potential physical and health hazards in the workplace. Investigating the work environment for potential dangers that could result in an injury or illness. (OSHA)

K. Hierarchy of Control: A means of determining how to implement feasible and effective control solutions to protect employees from occupational hazards.

1) Elimination – physically removing the hazard from the lab is the most effective option to protect employees if it is possible
2) Substitution – replace the hazard when possible
3) Engineering Controls – isolate the hazard from the employee. Engineering controls are designed to remove the hazard at the source before it comes in contact with the worker. Examples: local exhaust ventilation, splash shields.
4) Administrative Controls – change the way people work, revise policies to add in safety features. These controls are less effective and require significant effort by the lab technician.
5) PPE – personal protective equipment such as gloves, gowns, masks, eye protection, shoe covers. These controls require significant effort by the lab technician and should be used as the last resort.

Content source: National Institute for Occupational Safety and Health National Institute for Occupational Safety and Health

POLICY GUIDELINES

I. Responsibilities

A. CLIA Laboratory Director, Department Chair and Lab Administration

1) CLIA Lab Director is ultimately responsible for the overall administration, operation and compliance oversight of all things related to the lab.
2) Maintains documentation of periodic on-site assessment of the physical and environmental conditions of the laboratory. (CAP DRA.11400)
3) Designate and empower individuals who will be responsible for the preparation and implementation of the Personal Protective Equipment Program.
4) Provide administrative and financial support for this policy within individual departments.

B. Laboratory Quality, Safety &Accreditation
1) Review and revise the PPE program, as needed for compliance with applicable regulations as needed and at a minimum of every 2 years.
2) Serve as a resource and support to all labs for any questions or needs they may have pertaining to PPE and/or hazard assessments as they relate to CLIA, CAP, TJC, ASHI, etc. standards.
3) Assist managers with hazard assessment annually.
4) Perform Safety Inspections and Audits to determine overall compliance with the PPE Policy Plan as well as any regulatory standards that apply.
5) Receive and submit completed Hazard Assessments to the Safety Governance Committee for approval. Once approved, submit a copy to the Lab & Pathology SharePoint site and a copy to the lab section manager.

C. Environmental Health & Safety
1) Perform and document hazard assessments in accordance with EH&S, OSHA, ANSI, etc. standards deem it necessary and required.
2) Report all summaries and findings associated with the lab hazard assessments to the lab section manager and to Lab Safety.
3) Serve as a resource and support to all labs for any questions or needs they may have pertaining to PPE and/or hazard assessments.

D. Laboratory Management (Section Managers and/or Network Site Directors)
1) Perform and document an annual hazard assessment in the lab areas of the manager's responsibility.
2) Based on the hazards identified as part of the annual assessment, in conjunction with EH&S, Lab Safety Compliance and Section Medical Director, determine if the hazard can be eliminated or reduced by methods other than PPE.
3) If hazards cannot be eliminated, appropriate PPE will be identified.
4) Provide appropriate PPE and make it available to employees.
5) Ensure that PPE training occurs for all employees that will use PPE per Section 9 and that the Laboratory Safety Training form has been signed and placed in the employee file.
6) Annually review and document the review of the hazard assessment with the lab section employees.
7) Ensure that employees properly use and maintain PPE and are following PPE policies and rules.
8) Notify Laboratory Compliance and the Safety Officer when new hazards are introduced into the lab or when processes are added or changed.
9) Ensure that defective or damaged PPE is immediately disposed of and replaced.
10) Follow organizational procedures for reporting an accident or injury.

E. Staff/Employees

1) Adhere to PPE and hierarchy of controls per risk assessment.
2) Attend required training sessions.
3) Appropriately care for, clean, maintain and inspect PPE as required.
4) Follow PPE policies and rules.
5) Report PPE malfunctions or failures immediately to the lab manager.
6) Report perceived new risks or hazards to the lab manager.

II. Hazard Assessment Process

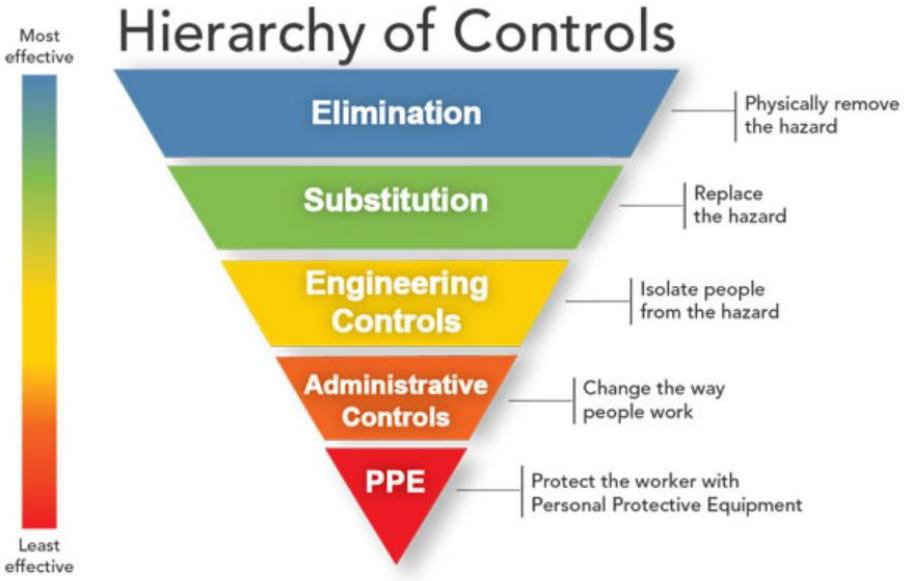
1) Each lab section manager in collaboration with laboratory employee(s) if needed will complete a hazard assessment annually and when changes in the lab occur, such as new tasks, new equipment, new chemicals.

   CAP GEN.73400; OSHA 1910.132(d)(2)
2) Laboratory Safety Manager will assist at the request of the lab manager or a laboratory employee.
3) EH&S will assist with lab section hazard assessments on a consultation basis and/or when changes in the lab occur such as new tasks, new equipment, or new chemicals at the request of the Lab Manager.
4) When performing the hazard assessment, the team will use the hierarchy of control to determine the most effective and applicable protection to the employee.
5) Hazard assessments will be documented using the PPE Hazard Assessment Risk Form.
6) PPE Hazard Assessment Risk Form will be signed off by the lab manager, a representative from the lab quality and safety section and the CLIA LD.

A. Conducting the Hazard Assessment

The hierarchy of controls will be utilized when conducting the hazard assessment. "The idea behind this hierarchy is that the control methods at the top of graphic are potentially more effective and protective than those at the bottom. Following this hierarchy normally leads to the implementation of inherently safer systems, where the risk of illness or injury has been substantially reduced."

Content source: National Institute for Occupational Safety and Health National Institute for Occupational Safety and Health



1. Investigate (either by direct observation, direct knowledge of the task or involvement with employees that perform the task) each task/job duties performed in the lab section during the annual hazard assessment. Identify hazards and potential hazards associated with each task.

2. Hazard assessments may be conducted on:
    1) single employees
    2) single tasks
    3) a group of employees if all are performing an *identical task*.

    Example of a Task Hazard Assessment:
    Lab techs are required to use an aliquot of acetic acid during the steps of a particular testing procedure performed in the lab section. The hazard assessment could be at the single task level because everyone does the same thing in respect to that procedure (task).

    In this example the hazard assessment focuses on a distinct single procedure (task) and that due to the use of the acetic acid aliquot the task has the following hazards or potential for hazards:
    - Chemical spill of the acetic acid
    - Chemical exposure of the acetic acid to the skin
    - Chemical splash of acetic acid to the eyes

    After reviewing the hierarchy of control, the hazard assessment team determined that the use of PPE was the only option for this procedure/task. The lab technician is at risk for injury due to a spill, exposure or splash of acetic acid so the designated PPE must provide protection for those risks.
    Of note: The suitability of any existing PPE in the lab section, including an evaluation of its condition and age should also be assessed at the annually hazard assessment.

3. At least one individual conducting the hazard assessment should have an intimate knowledge of each job/task performed in the area. The lab section manager may have this level of knowledge therefore direct observation of a task may not be required. The Lab Safety representative and/or EH&S representative may not be familiar with the task and request direct observation of the task to determine if any hazards are present. The hazard assessment team will decide if hazards or potential hazards are present.

4. The comprehensive hazard assessment should include an assessment of all potential hazards/risks to the lab technician to include at a minimum the following:
    1) Biological BBP
    2) Eye/face shield
    3) Respiratory/Aerosolization
    4) Skin splash
    5) Physical/projectile
    6) Electrical
    7) Chemical

5. The comprehensive hazard assessment should include a detailed inspection of the lab environment with a focus on hazard sources that include but are not limited to the following:
    1) High or low temperatures
    2) Chemical exposures or spills (use SDS for guidance)
    3) Flying particles or other eye, face or skin hazards
    4) Light radiation, e.g., heat treatment, lasers, UV exposure
    5) Falling objects or potential for dropping objects or spilling
    6) Sharp objects
    7) Rolling or pinching that could crush the hands or feet
    8) Electrical hazards
    9) Biologic hazards such as blood or other potentially infected material

6. For each hazard or potential hazard source identified, the hazard assessment team will use the hierarchy of controls graph to identify the most appropriate protection for the lab personnel.

7. The Hazard Assessment Form (Attachment B) will be used to document the hazards or potential hazards identified along with the appropriate protection. EH&S and Laboratory Quality & Compliance staff are resources for hazard assessments.

8. The Hazard Assessment Form must be complete to include the following information:
    1) Identification of the lab section evaluated and it's physical location
    2) Signature of the person(s) conducting the assessment
    3) Date of the assessment
    4) Identification of each hazard and the appropriate hazard protection

B. PPE Section Guidelines

1. For each hazard identified, select personal protective equipment that will protect the employee by creating a barrier against workplace hazards.

2. All lab section personnel should become familiar with the potential hazards within their lab and know the type of protective equipment that is available as well as the level of protection that is provided by that equipment, i.e., splash protection, impact protection, etc.
3. Appropriate PPE is provided and maintained in a sanitary and reliable condition in all work areas whenever blood and other potentially infectious materials are handled and in circumstances during which exposure is likely to occur. (CAP GEN.74050)
4. Each lab section is responsible for purchasing and providing PPE as identified by the Hazard Assessment.
5. Employees should have input in the PPE selection process. The PPE selected should appropriately fit the employee to optimize hazard protection.
6. Damaged or defective protective equipment should be immediately taken out of service to be repaired or replaced.
7. Consider a disposable lab coat when using high hazard materials. Lab coats made of cotton fabric are recommended for general lab use. Flame resistant fabric (e.g., Nomex) or flame-resistant cotton fabrics are required if there is a significant fire potential.
8. The following resources are available to assist with the proper selection of PPE:
    - OSHA https://www.osha.gov/SLTC/personalprotectiveequipment/hazards_solutions.html
    - Technical assistance from EH&S
    - The manufacturers of PPE
    - SDS for chemicals

Eye and Face Protection (Goggles/Face Shields/Splash Guards)

Eye and face protection should be used per the hazard risk assessment recommendations and in the absence of engineering controls. Proper eye protection should always be utilized with contact lenses per hazard risk assessment.

All eye protection equipment must be American National Standards Institute (ANSI) approved and appropriate for the work being done. ANSI A87.1

Selecting the most suitable eye and face protection for employees should take into consideration the following elements:

1. Ability to protect against specific workplace hazards.
2. Should fit properly and be reasonably comfortable to wear.
3. Should provide unrestricted vision and movement.
4. Should be durable and cleanable.
5. Should allow unrestricted functioning of any other required PPE.

Foot Protection (Shoes/Footwear)

The need for shoe covers will be determined at the hazard risk assessment where splashing is expected. If shoe covers are recommended, they must protect the entire foot. (CAP Standard GEN.76300)

Closed-toed shoes should be worn at all times in the laboratory and the outer material of the shoe should be non-permeable to any type of fluid.

Hand Protection (Gloves)

Selection of gloves will be based upon the hazard risk assessment and glove manufactures guidelines. There is a wide assortment of gloves available for protection against various hazardous situations. No single glove will protect you from all hazards.

When putting gloves on, ensure that there are no tears, holes, or split seams. If there is any damage, replace the gloves immediately and notify the lab manager.

Gloves must be removed before leaving the work area.

Do not eat, drink, or smoke while wearing gloves.

Gloves should be removed properly. Follow these procedures for removal of one-time disposable gloves:

1. Pinch the glove only just below the wrist and pull it off slowly, allowing it to turn inside out as it is pulled off.
2. Use the inside of the first glove to grasp the second glove and pull off slowly, allowing the glove to turn inside out as you go.
3. Place the gloves in an appropriate trash container and handle the same as other hazardous waste in your area.
4. Never re-use disposable gloves.
5. Wash your hands after having removed and disposed of the gloves.

All personnel should remove gloves and clean hands using an effective antimicrobial method following contact with blood or other potentially infectious materials or after each patient contact. (CAP GEN.74250)

Skin (other than hands) and Body Protection (Lab Coats)

The need for lab coats will be determined at the hazard risk assessment.
Lab coats are an important part of personal protective equipment that serve to:

1. Provide protection of skin and personal clothing from incidental contact
2. Prevent the spread of contamination outside the lab.
3. Provide a removable barrier in the event of an incident involving a spill or splash of hazardous substances.

There should be no exposed skin per the hazard risk assessment. Lab coats, coveralls, aprons, or protective suits be utilized to cover exposed skin per the task-based hazard assessment.

Lab coats must be appropriately sized for the individual and be fastened (snap buttons are recommended) to their full length. Lab coat sleeves must be of a sufficient length to prevent skin exposure while wearing gloves. Sleeves are never to be worn "pushed up" on the arms.

1. Length - At least knee length or longer is recommended for most effective coverage.
2. Wristband - It is recommended that a lab coat with a fitted wristband/cuff be used to reduce the potential for splashes up the arm and fire hazards.
3. Top button - It is best to use a lab coat that provides a high top button at the neck to provide most effective protection. Keep lab coats completely "buttoned" up. Snap closures are preferred over buttons or zippers to keep the body covered and allow quick removal in an emergency.

Lab Coat Use – DO's and DON'Ts

- **DO's**
  - wear a lab coat when a Hazard Assessment of the laboratory determines hazards to the body are present or likely to be present. A good rule of thumb is to always wear a lab coat when working in a lab.
  - wear a lab coat of appropriate size.
  - **we**ar a lab coat based on the types of work hazards as determined on the hazard risk assessment.
  - wear lab coats that cover the knees and have full-length sleeves and with a fitted wristband/cuff.
  - immediately remove a lab coat if there is obvious hazardous contamination.
  - attempt to extinguish a fire from your lab coat; use showers as appropriate.
  - consider the addition of a chemical splash/resistant apron and sleeves when there is a significant chance of exposure to corrosive materials.

- **DON'Ts**
  - wear lab coats that have noticeable wear or are contaminated.
  - wear lab coats made of synthetic fabrics if there is a potential for fire. Synthetic fabrics burn, melt, shrink and stick to the skin.
  - roll up the sleeves on lab coats.
  - wear lab coats in common places including break or office areas.

Emergency spill or splash: In the event of a significant spill of a hazardous material on the lab coat, it should be immediately removed. If skin or personal clothing is impacted proceed to an emergency shower. Any contaminated clothing should also be removed. Guidance should be sought from EH&S about whether the coat and clothing should be cleaned or discarded as hazardous waste. See policy, Cleaning of Contaminated Personal Uniforms Policy.

III. Initial Training Guidelines

Employers are required to train each employee who must use PPE. Employees must be trained to know at least the following: (OSHA Standard CFR 1910.132 f)

- when PPE is necessary
- what PPE is necessary
- how to properly don, doff, adjust, and wear PPE
- the limitations of the PPE
- proper care, maintenance, useful life and disposal of PPE
- proper fitting of gloves
- replacing gloves immediately when torn or contaminated
- not washing or disinfecting gloves for reuse
- using hypoallergenic gloves when indicated by patient or by health care provider history
- decontamination of hands after glove removal using an effective antimicrobial method

Each employee should demonstrate an understanding of the PPE training as well as the ability to properly wear and use PPE before they are allowed to perform work requiring the use of the PPE. (OSHA Standard CFR 1910.132 f)

This training should be documented on the Laboratory Safety Training Form and maintained in the employee's personnel file.

When there is reason to believe that an employee who has already been trained does not have the understanding and skill required in the use of PPE, the employee should be retrained to include all the elements of Section III.

Circumstances where retraining is required include, but are not limited to, situations where:

1. Changes in the workplace render previous training obsolete
2. Changes in the types of PPE to be used render previous training obsolete
3. Inadequacies in an affected employee's knowledge or use of assigned PPE indicate that the employee has not retained the requisite understanding or skill. (OSHA Standard CFR 1910.132 f)

IV. Staff Training

All employees required to wear PPE will be trained per Section III of this SOP.
Training will occur:

1. upon hire
2. annually if the risk assessment changes the requirements for PPE for the task
3. when an off-cycle hazard risk assessment leads to a change in the PPE, such as new equipment, CAPAs, accidents, etc.

Records of the employee training and retraining should be documented on the Laboratory Safety Form and entered in the employee's personal file.

V. Review/Revision/Implementation:

Review Cycle: 2 years
Office of Record: Department of Pathology

VI. References, National Professional Organizations, etc.:

CLIA Regulations Section 493
CAP Standards
OSHA 1910.132, the general standard on PPE requirements
OSHA 1910.1450, the standard on occupational exposure to hazardous chemicals in laboratories,
ANSI/ISEA Standards for Occupational and Educational Eye and Face Protection Z87.1-1989 or Z87.1- 2010 (General Industry)

LITERATURE REFERENCES:

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 2/2019
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** QUALITY, SAFETY & ACCREDITATION	**CONTACT:** QUALITY, SAFETY & ACCREDITATION

APPLICABLE LABORATORY(S)):
☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to provide guidelines for correctly labeling reagents, calibrators, controls, stains, chemicals, and solutions.

SCOPE

This policy applies to all faculty, residents and employees in the Department of Lab & Pathology.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

POLICY GUIDELINES

A. Reagent Labeling (COM.30300)

    1. All reagents, calibrators, controls, stains, chemicals, and solutions must be properly labeled as applicable and appropriate with the following elements:

a. Primary Container:

i. Content and quantity
ii. Concentration or titer
iii. Storage requirements
iv. Date prepared, filtered, aliquoted, or reconstituted.
v. Expiration date
vi. Preparer's initials
vii. Safety/Hazard information (GHS) (GEN.76200)

b. Secondary Container:

i. Identity/description of contents
ii. Quantity/concentration or titer if applicable
iii. Storage requirements
iv. Date prepared, filtered, aliquoted, reconstituted, etc.
v. Expiration date
vi. Lot # if applicable
vii. Preparer's initials
viii. Safety/Hazard information (GHS)

2. Information on the label that a user would need to know to properly use a solution should be included.

   Examples:

   Silver Nitrate Stain: *Minimize light exposure* may be written on the label in addition to the other information.

   Glucose Control: You must **change** the *expiration date* once you open the bottle. The new expiration date should be written on the label.

3. All primary and secondary container labels are neat and legible at all times. Replace labels that are stained, faded or begin to peel. Labels that are not legible are safety issues that could lead to harm to employees and/or patients.

4. Each lab section will ensure that labels in incoming containers of hazardous chemicals are not removed or defaced. (OSHA CFR.1910.1200(b)(3)(i))

B. Expiration Dates (COM.30400)
   1. All reagents, chemicals, controls, media, antibodies and stains are only used if in-date (not expired). Unless an exception has been preapproved for the use of expired products.
   2. Each lab section has a section specific policy defining their process for utilizing in-date products only for clinical testing. Unless an exception has been preapproved for the use of expired products.

3. If an expiration date has not been assigned by the manufacture, the Department of Lab & Pathology assigns an expiration date based on known stability, frequency of use, storage conditions and risk of deterioration.

4. Unless it is indicated that the manufacturer issued expiration date changes when opened, the lab must use the manufacturer's expiration. If the expiration changes once opened, then the lab will assign a new expiration date based on either guidance from the manufacturer's instruction or laboratory policy.

C. Labeling of Expiration Dates on Container Types

1. Primary Container
   - Addition of the expiration date is required if opening the container changes the expiration date.
   - If opening the container does not change the expiration date, the expiration date remains the same as it was issued by the manufacturer.
   - If there is no expiration date given on the primary container, use 12 months from the date opened as the expiration date.

2. Aliquots and Secondary Container
   - If a manufacturer's expiration date is given on the primary container or solution, use this as the expiration date on the aliquot label.
   - If the expiration date on the primary container changed after opening, then the expiration date for the aliquot will follow suit and use the same expiration date that was used for the primary container.
   - If there is no manufacturer-provided expiration date, use 12 months from the date aliquoted as the expiration date.

3. Reconstituted Reagents, Calibrators, Controls, Stains, Chemicals, and Solutions
   - If there is a manufacturer-recommended expiration date for reconstituted and prepared reagents, calibrators, controls, stains and chemicals, use it as the expiration date on the label.
   - If there is no expiration date given, use 6 months from the date prepared or reconstituted as the expiration date.

4. Reagents that are prepared daily (10% bleach, KOH, saline, water, etc.)
   - Label the container "**Prepared Daily**."
   - Expiration date is not required if container is label as directed above.
   - All other labeling requirements as directed in 3(A) above will also apply.

5. Test Kits and components
   - Components of a test kit should never be separated.
   - Although the individual components of the kit do have individual expiration numbers, each of these are traceable back to the original, single expiration number of the entire kit found on the outer container/packaging.

- The single kit expiration number on the outside packaging should be used for expiration tracking purposes.

B. Disposal of Expired Reagents

1. It is the responsibility of every laboratory staff member and testing personnel working in a clinical laboratory area within the Department of Pathology to check expiration dates before using any reagent, calibrator, control, stain, test kit or chemicals of any kind.
2. Under normal circumstances, expired reagents should never be used for clinical patient testing.
3. Expired reagents will be properly disposed of. Reagent disposal will be conducted according to established laboratory chemical safety procedures. Contact EHS or the laboratory safety office for questions.

LITERATURE REFERENCES:

CAP All Common Checklist, College of American Pathologists, 325 Waukegan Road Northfield, IL 60093-2750, www.cap.org © 06.04.2020
https://www.osha.gov/Publications/OSHA3636.pdf
https://www.osha.gov/dsg/hazcom/

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Specimen Transportation Policy

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 3/5/2021
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** **QUALITY, SAFETY & ACCREDITATION**	**CONTACT:** **QUALITY, SAFETY & ACCREDITATION**

APPLICABLE LABORATORY(S)):

☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to maintain and facilitate safe transport practices for specimens and/or specimen containers transported within Wake Forest Baptist Medical Center and to outside clinics, offsite laboratories and other hospitals. Practices should meet the requirements of appropriate accrediting agencies such as OSHA, TJC, CAP, AABB and FDA regulations and with Universal ("Standard") Blood and Body Fluid Precautions. It is the policy of WFBMC to require complete labeling of patient specimen containers that may contain harmful additives such as acids or other chemical preservatives. Appropriate PPE should be worn when handling such specimen containers during transport. All employees who are required to transport specimens and/or specimen containers must complete appropriate Safe Handling and Biohazard training offered through Environmental Health and Safety, prior to transport. (GEN.40515)

Wake Forest Baptist Health discourages the use of personal vehicles for the transport of biohazardous specimens.

SCOPE

This policy applies to all faculty, residents and employees in the Department of Lab and Pathology.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.

B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.
C. CLIA: Clinical Laboratory Improvement Amendments
D. CAP: College of American Pathology
E. AABB: American Association of Blood Banks
F. TJC: The Joint Commission
G. OSHA: Occupational Safety and Health Administration

POLICY GUIDELINES

A. Specimen Transportation:

1. Specimens of blood or other potentially infectious materials shall be placed in a well-constructed container with a secure lid which prevents leakage during handling, storage, transport of shipping. If outside contamination of the primary container occurs, then a second leak proof container shall be placed over the outside of the first and closed to prevent leakage during handling, storage, or transport. Specimens which leave the hospital must be labeled with a biohazard label or Biohazard specimen bag. (GEN.74500)

2. When transporting multiple specimens of blood or other potentially infectious materials within the facility, a biohazard labeled transport container (i.e., pail or cooler) shall be used.

3. Special precautions should be taken when transporting specimens for 24 Hour Urine Collection. These jugs typically contain a chemical preservative, either Boric Acid in the form of a tablet or in some cases 6N HCL, which is a liquid acid. Gloves should be worn at all times when handling these containers for transport to or from the laboratory. Before placing the jugs in a compliant transport container/bag always check the lid to make sure it is closed and sealed appropriately and there is no visible evidence of leakage. If a leak is visible, notify a supervisor in the main lab before transporting or handling.

4. Chemical spill kits should be readily available in areas of the laboratory where specimens are received or dropped off in the laboratory.

5. For transport of specimens using the Pneumatic Tube System, refer to policy: Safe Transportation of Biohazard Materials Using the Pneumatic Tube System.

LITERATURE REFERENCES:

CAP, Lab General Checklist; 10.24.2022

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE** 3/2021
CLIA Lab Director: Greg Pomper, MD	**LAB DEPARTMENT:** **QUALITY, SAFETY & ACCREDITATION**	**CONTACT:** **QUALITY, SAFETY & ACCREDITATION**

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☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

POLICY PURPOSE

The purpose of this policy is to provide guidelines for staff and ensure they are compliant with state and federal regulations in monitoring temperature and humidity to assure optimal performance of reagents, instruments/analyzers, and equipment.

SCOPE

This policy applies to all WFBMC Department of Laboratory Medicine and Pathology employees, Faculty, and staff.

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
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C. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all laboratory testing performed on humans.
D. College of American Pathologists (CAP): An association composed of pathologists, certified by the American Board of Pathologists, who is responsible for enforcing standards of quality

assurance through the accreditation of laboratories under authority of The Centers for Medicare and Medicaid Services (CMS).

E. National Institute of Standards and Technology (NIST): A measurement standards laboratory and a non-regulatory agency of the United States Department of Commerce.
F. Intelligent InSites (Cetani): A WFBMC centralized temperature, humidity, and environmental continuous monitoring system.

PROTOCOLS

A. Temperature Checks Phase II:
Temperatures are checked and recorded each day of use for all temperature-dependent equipment and environments using a calibrated thermometer. (COM.30750)

B. Temperature Range Phase II:
Acceptable ranges have been defined for all temperature-dependent equipment and environments (including test-dependent ambient temperature) in accordance with the manufacturer's instructions. (COM.30775)

C. Temperature Corrective Action Phase II:
There is evidence of corrective action taken if acceptable temperature ranges for temperature-dependent equipment and environmental temperatures are exceeded, including evaluation for adverse effects. (COM.30800

POLICY GUIDELINES

A. Temperature and humidity readings are checked and recorded at a minimum of once each day for all temperature dependent reagents, equipment, and environments, using either a calibrated Min/Max thermometer or electronically through Cetani. (COM.30750) Manufacturer requirements must be followed. A complete inventory list along with the optimal temperature and humidity for all temperature dependent reagents, equipment, and environments is maintained and reviewed annually.

    1. All temperature ranges are either specified by the manufacturer or set by the laboratory will be recorded and documented, indicating that an appropriate temperature is maintained (COM.30775) and corrective action is taken when tolerance limits are exceeded. (COM.30800)
        a. Monitoring may be achieved by using a Minimum/Maximum thermometer/hygrometer or through Cetani.
        b. If a minimum/maximum thermometer is used to perform continuous monitoring of temperatures, both the low and high temperatures must be recorded as well as the actual temperature.
            i. After reading and recording these 3 temperatures, the min/max thermometer must be reset. To reset the min/max thermometer, press and release the "reset" button once.
            ii. The lab manager or designee should review and sign all applicable temperature logs at least once per month.
        c. If using the Cetani system, emails and /or calls alerts are sent to key individuals within the department and the Service Response

Center when readings fall outside of predefined limits of acceptability.

d. When setting up a Cetani tag, it is recommended that all labs set the Cetani alert range one degree prior to "going out" for a buffer. Consult all manufacturer recommendations to set this appropriately. This may not be possible for some instruments.
e. This will be the "caution" temp on both the high and low end. This is necessary to allow time for decision making and/or movement of product.
f. ALL Cetani tags/probes are to be set up to ALERT the department IMMEDIATELY in the case that a temperature or humidity reading goes into "caution" range.
g. See section below for setting up Cetani alerts.

i. The lab manager or designee reviews alerts and responds accordingly. Temperature alerts are rounded to the nearest whole number when evaluating an out-of-range event.
ii. The lab manager or designee should review all applicable Cetani temperature logs at least once per month and document review in Cetani.

2. In the event the temperature or humidity exceeds the manufacturer requirements, investigative and corrective actions will be taken and documented. Refer to the CAPA Procedure for any temperature and/or humidity variances. (COM.30800)

B. Thermometric Standard Device

1. An appropriate thermometric standard device of known accuracy (guaranteed by manufacturer to meet NIST Standards or traceable to NIST standards) is available and used when necessary.
    a. Minimum/maximum thermometers/hygrometers and Cetani are traceable to NIST standards.
2. Thermometric standard devices, including Cetani tags, must be recalibrated, recertified, and/or replaced prior to the date of expiration of the guarantee of calibration. The WFBMC Cetani team will annually calibrate all CETANI tags; however, it is also the responsibility of the lab manager or designee to ensure that reagents, equipment and/or environments are not in use if the Cetani tag has expired.
3. Thermometers and Cetani tags should be periodically evaluated for damage, and if damage is present, be rechecked before continued use. See Cetani set up and information below for troubleshooting contact information.

C. Cetani Set-Up and Information: Intelligent InSite's software

1. URL: http://spotm.wakehealth.edu (From a Wake browser, using either Internet Explorer or Google Chrome)
2. Contact information: SPOTSupport_DL@wakehealth.edu or 336-716-8899
3. When requesting Cetani monitoring for reagents, equipment, and/or environment, contact Cetani Support with locations and temperature ranges

for alerts (including optimal range and range tolerance), and alert contact names and contact information (required for 24/7/365 coverage to address and resolve out of range issues).
    a. There is a HELP tab on the home page which has information to assist with daily Cetani system use.
4. When requesting Cetani access for new staff members, email a Cetani Support Specialist with their email information and the Tag numbers they will need to receive alerts on. Cetani Support will respond with username and password, a link to the Cetani website, and, if necessary, a tutorial of temperature monitoring.

LITERATURE REFERENCES:

CAP, All Common Checklist; 10.24.2022

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Policy	**ORIGIN DATE**
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POLICY PURPOSE

The purpose of this policy is to establish guidelines for staff to ensure traceability and/or calibration of thermometers, hygrometers and timers that are used in monitoring temperature and humidity in the laboratory setting as well as time intervals for laboratory procedures. This policy also describes the steps used to point-check the accuracy of laboratory thermometers and timers against a NIST thermometer and timer and the steps to take in case re-calibration is necessary.

SCOPE

This policy applies to

DEFINITIONS

A. Policy: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBH. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBH, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
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POLICY GUIDELINES

A. NIST

1. Thermometer: At least two appropriate thermometric standard devices of known accuracy (certified to meet NIST Standards or traceable to NIST Standards) are available. Thermometric standard devices must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration, or they are subject to requirements for noncertified thermometers. Thermometers should be periodically evaluated for damage (e.g., separation of columns). Thermometers with obvious damage must be rechecked before continued use. The NIST traceable thermometers should be certified annually. (COM.30700)

2. Timer: Multiple NIST certified timers of known accuracy are available throughout the laboratory. NIST certified timers must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration or they are subject to requirements for non-certified timers. Timers should be periodically evaluated for damage. Timers with obvious damage must be rechecked before continued use. NIST timers must be certified annually.

3. Hygrometers: NIST certified hygrometers are available in the laboratory. NIST certified hygrometers must be recalibrated, recertified, or replaced prior to the date of expiration of the guarantee of calibration, or they are subject to requirements for noncertified hygrometers. Hygrometers should be periodically evaluated for damage. Hygrometers with obvious damage must be rechecked before continued use. NIST hygrometers must be certified annually.

B. NIST Thermometers

    1. When purchased, NIST thermometers have been calibrated against NIST traceable instrumentation and are accompanied with certification indicating so.

    2. Once the NIST certification that originally came with the thermometer has expired, the thermometer will either need to be recalibrated against a NIST certified thermometer or removed from use in the clinical laboratory and labeled as such or discarded.

    3. The thermometers that are taken out of use are replaced by new NIST certified thermometers that are within certification expiration.

C. Calibration of Non-NIST Thermometers

    1. All in use non-certified thermometers, or thermometers who's original NIST certification has expired, are calibrated against an appropriate thermometric standard device at least annually and before being placed into use. (COM.30725)

    2. Follow all site-specific procedures when placing a non-NIST thermometer into use, ensuring to include the following:
        a. All thermometers are calibrated using a NIST traceable thermometer.
        b. Allow the non-certified thermometer and the NIST thermometer to equilibrate with the solutions before taking the temperature reading. The temperature reading of the non-certified thermometer must fall within ±2°C of the NIST thermometer.
        c. Once the thermometer has passed calibration, a label is applied to the thermometer displaying "name/number" and date of calibration.

d. If the non-certified thermometer does not pass calibration, it should be removed from the laboratory and marked as out of use.
e. Record calibration information on the Laboratory Thermometers Calibration Log, or other site-specific log.

D. Calibration of Non-NIST Digital Timers

1. All non-NIST timers are calibrated against an appropriately calibrated NIST timer or stopwatch before being placed into use as well as annually.

2. Follow all site-specific procedures when placing a non-NIST timer into use, ensuring to include the following:

a. All timers must be calibrated using a NIST traceable timer or stopwatch.
b. Calibration against a NIST certified traceable timer:
    i. Turn both timers on.
    ii. Set timers to specific length of time and start simultaneously.
    iii. Stop the non-NIST timer when the NIST timer alarms.
    iv. Record the time for both timers. Values must fall within 10% of each other.
c. Calibration against a NIST certified stopwatch
    i. Set non-certified timer to specific length of time.
    ii. Start stopwatch and timer simultaneously.
    iii. Stop the stopwatch when the timer alarms.
    iv. Record time displayed on the stopwatch and the time that the timer was set for. The values must fall within 10% of each other.
d. All timers must be calibrated for all time increments used in the laboratory.
e. Once the timer has passed calibration, a label displaying the timer "name/number" and date of calibration is placed on the non-NIST timer.
f. If the non-NIST timer does not pass calibration, it should be removed from the laboratory and marked as "out of use".
g. Record calibration information on the Laboratory Thermometer/Timer Calibration Log, or other site-specific log.

LITERATURE REFERENCES:

40 CFR 160.63 - Maintenance and calibration of equipment.
https://www.law.cornell.edu/cfr/text/40/160.63

CAP, All Common Checklist; 10.24.2022

RELATED POLICIES/PROCEDURES IN NAVEX:

ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21.

Department of Pathology and Laboratory Services Business Continuity Playbook and Guidelines

Department Address: Medical Center Boulevard, Winston-Salem, NC

Recovery Team Leader Primary Contact (I)	Lauren Elmore Administrative Director
Recovery Team Leader Primary Contact (II)	Dr. Eric Hsi Professor and Chair, Department of Pathology
Recovery Team Leader Primary Contact (III)	Dr. Gregory Pomper Vice Chair of Clinical Pathology, Medical Director, Clinical Laboratories
Plan Version Date	August 31, 2021

Plan Instructions: Formal Business Continuity Playbook/Plan (BCP) activation must be issued and communicated by a member of the Emergency Management Team. Upon notification to a Recovery Team Leader, the applicable BCPs will be activated in the event of an unplanned disruption or other large-scale event affecting a Wake Forest Baptist Health facility.

Refer to Section I for BCP Activation and Recovery Strategies

Table of Contents

INTRODUCTION:

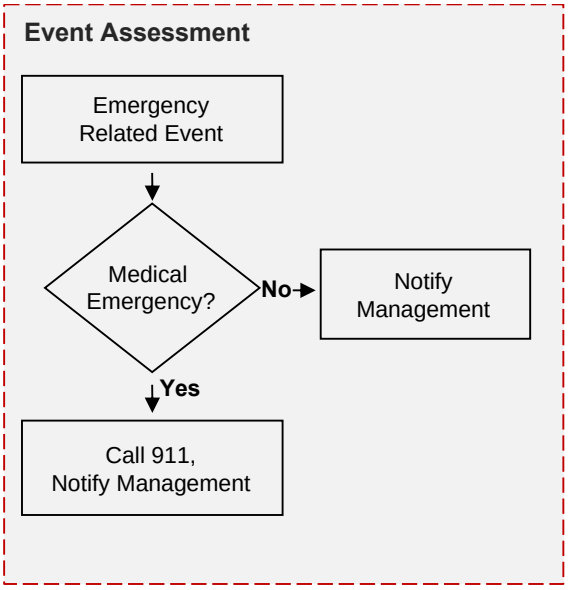
As part of disaster planning, lab employees need immediate guidelines for next steps. The intent of this page is to provide the immediate next step which is focused around communicating the disaster to the leaders of the department.

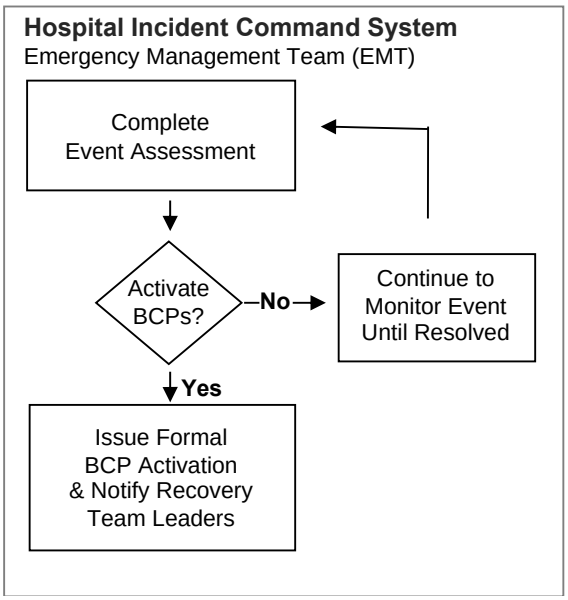
When there is a need to activate the department's business continuity plan, please refer to these tips and tricks to assist with activation.

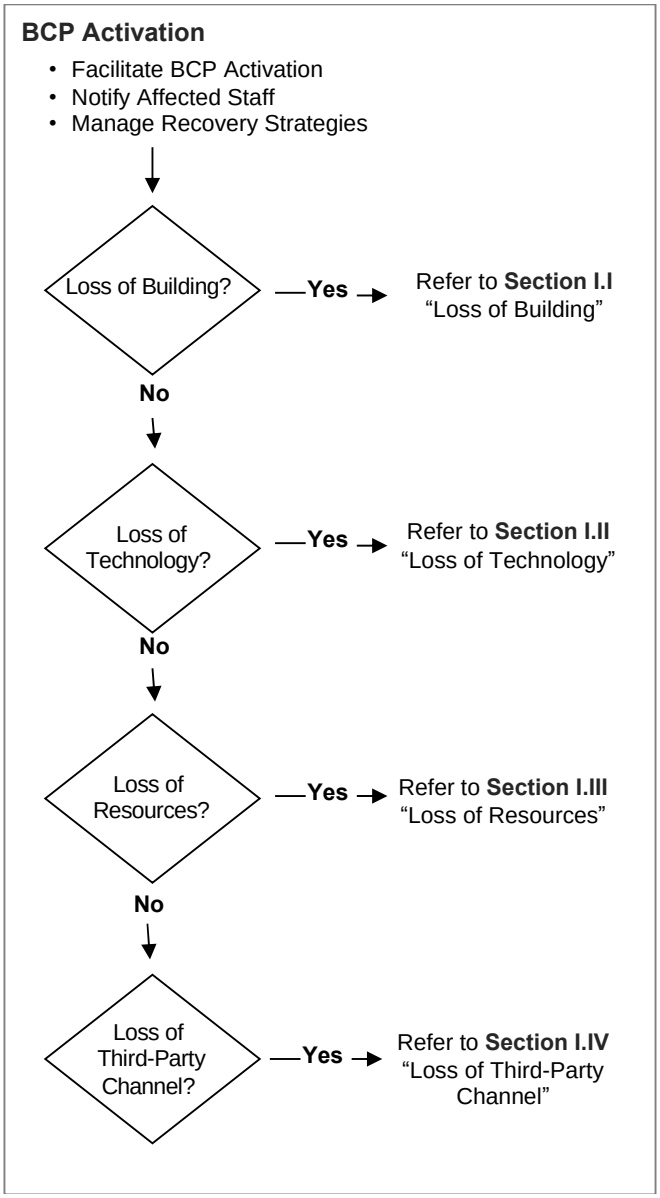
1. Refer to page 43. Section III. Essential Staff Roles and Responsibilities. This section outlines department specific information to make critical communications that will rapidly activate the plan. Coordination and communication in the early stages of a disaster will ensure the mobilization of needed resources and timely coordination of laboratory services. It is important to contact Drs. Eric Hsi (336-813-9651) or Greg Pomper (336-831-6552) and Lauren Elmore (336-816-3109) via phone text message or pager to ensure rapid notification. Associate directors: Nate Weaver (704-650-9183), Julie Simmons (336-978-8974) and/or Sheryl Livecchi (336-423-3603) should also be notified depending on the nature of the event. Use one's best judgement for rapid initial contact based on the emerging crisis.
2. After hours: If a disaster occurs after hours, it is recommended to notify the Clinical Pathologist On-Call, especially if there is difficulty reaching anyone in laboratory leadership. There is always an on-call attending clinical pathologist available to receive and disseminate information. To reach the Clinical Pathologist On-Call, go to the AH WFB Intranet page. From the drop-down box located on the top toolbar, select "Wake On-Call." On the ON-Call Schedule Search, type in "Pathology" and enter; click on "on-call now."
3. Phone Tree: The department of pathology maintains a phone tree of pathology and clinical staff for emergency response. The afterhours phone number list for pathology leaders is on the Pathology SharePoint site's home page, under the phone list section. https://wakehealth.sharepoint.com/teams/Pathology
4. Pager Contact Lookup: Pager contacts can be looked up online: http://spokwebxchg.wakehealth.edu/webxchange/ and one can always call the Winston campus physician access line (PAL) at: 336-716-7654 to use the phone to page someone on-call.
5. The Department of Pathology and Laboratory Services Business Continuity Playbook and Guidelines serves as the department of pathology's disaster plan.

Section I. BCP Activation and Recovery Strategies

The Emergency Management Team (EMT) in collaboration with department leadership will assess the disruption, severity level and impacts to essential services, prior to formally activating department Business Continuity Plans. (BCPs). All measures will be taken to prepare and pre-position resources to ensure continuity of essential services and activities. The following actions will be considered when responding to an emergency and/or event requiring BCP activation.







Department leadership will ensure that all staff are aware of their role and responsibilities in an emergency and/or business continuity incident. Department staff will be prepared to fulfill their duties and responsibilities as part of a team effort to provide the best possible emergency care in any situation.

Section I. BCP Activation and Recovery Strategies (continued)

The tasks, arrangements, and considerations identified within **Sections I.I – I.IV** of this document are intended as **guidelines** and do not provide for all eventualities. The RTL or designee must exercise sound judgement and may need to modify recovery strategies and identify other actions required to effectively respond to and recover from an event.

Loss of a Geographic Region
The EMT in coordination and collaboration with department management will provide direction and strategic oversight in the event of an incident that disrupts a geographic region. The EMT will work closely with and coordinate all phases of emergency and response operations with the applicable Government Agencies, Emergency Responders and other applicable third-party provider(s).

Catastrophic Event
The Emergency Management team in collaboration with department leadership will identify the best relocation site and/or recovery strategies based on the severity of the event. Disasters or other catastrophic related incidents are managed using a variety of pre-established emergency plans, policies, and procedures and are implemented based on the EMT's assessment of the (emergency response) event and out of scope for purposes of this document. In the event of an official emergency declaration, efforts may be made to relocate the department, however, this effort could take multiple weeks/months.

Department Relocation
The EMT in collaboration with department leadership will determine the best recovery strategy given the severity of the disruption. Every effort to stay in place should be considered. Moving the department even a short distance on campus will require a substantial effort and/or would not be a feasible solution. Working in a reduced capacity may be a better choice than a relocation. If the answers to all of the following questions are, "Yes", the EMT will make every attempt to ensure staff and patients stay in the department to ensure continuity of operations. However, if all of the answers are, "No", relocation efforts will be considered.

		Yes	No
✓	Can the damage be contained to one half or less of the affected site?		
✓	Are all utilities and functional abilities still available the affected site?		
✓	Can the repairs needed to make the department viable be completed in a reasonable amount of time to prevent impacts to essential services?		

If relocation or partial relocation is the only option, on-campus locations are preferred for many logical reasons. It is important to note when choosing the off-campus location, the reason will likely be a catastrophic loss of building and services at the main campus or non-emergent procedures.

Shelter-In-Place
The EMT will provide oversight, safety and support to department staff in the event of a shelter-in-place situation. The department may be required to provide services out of the existing location with whatever limitations, moving some processes to manual instead of automated, and potentially relocating select services to other locations within the WFBH network and/or specialty third-parties.

I.I. Loss of Building or Geographic Region

Loss Type Definition: The main facility where the business area resides is not accessible for an indefinite period of time, barring the retrieval of any items.

Recovery Team Leader Task List
The following Task List includes response, recovery, and reconstitution guidelines that need to be considered when managing a Loss of Building scenario. All tasks should proceed from the RTL's assessment of the event, may be performed concurrently and not taken in the order presented.

#	Phase I. Response Tasks & Guidelines	Completed		
		Yes	No	N/A
1.	**Response.** Leverage existing protocols to ensure department staff are notified of the event. • Notify Lab Section Manager • Lab Manager on-call or delegate if after hours/weekends			
2.	Activate essential staff (e.g., Laboratory Management) to participate in the initial assessment of the event and implementation of recovery strategies. Consider: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			
3.	Ensure notification to inpatient providers and patient care teams of the unexpected, unplanned delays in laboratory testing.			
4.	Complete a preliminary assessment of the environment based on the information available at the time of notification. Consider: • Affected Area, Equipment, and Supplies ○ Impacts to Patient Care • Severity and Duration of Building Disruption			
5.	Refer to existing emergency procedures (Unit Specific Fire and Evacuation Plan, etc.) to ensure staff is following safety protocols in responding to the disruption.			

Event Notification

The EMT will coordinate and ensure ongoing and timely notification to internal and external stakeholders (e.g., regulatory agencies, etc.) throughout the disruption to include temporary modifications to department activities and estimated time of resolution.

Stakeholder notifications will be issued using one or more of the following tools: Emergency Notification System, Email, Corporate Website, Front-End Messages, Phone Calls, and other methods as determined by the EMT.

Loss of Building or Geographic Region (continued)

Space Usage and Considerations

Relocation On | Off Campus

The EMT will leverage existing emergency plans and protocols and work with the affected department to determine the best recovery strategy and relocation based on the specifics of the emergency incident. Every effort will be made to ensure ongoing patient care and safety with minimal disruptions where possible. Department staff may need to shelter-in-place, relocate to one or multiple locations within the WFBH network to support continuity of patient-facing activities.

Due to limited space on campus and other logistics required to support essential activities, a relocation strategy to support continuity of essential department activities has not been identified. Refer to page 57 for additional information related to this opportunity.

Partial Damage or Building Closure

Leverage existing department guidelines when selecting non-clinical staff to work from remote locations (home-based office, other) in the event of a partial and/or full building closure.

- Non-exempt employees may not work from home
- Managers must ensure that a remote arrangement do not have a negative impact on patient care or on other departments

Non-Clinical Staff

With Warning	Without Warning
• Instruct staff to take essential items required to work from remote locations. ☑ Laptops (mouse, power cords, headset parts, cell phones and chargers) ☑ Monitors, Keyboards, Docking Station ☑ Special Supplies (check stock, other) • Consider the duration of disruption when identifying essential items (short/long term).	• Determine the number of staff that have (and do not have) laptops available. • Assess immediate impacts to service levels due to limited equipment. • Contact the IT Service Desk for a loaner (or replacement) laptop and other equipment. • Consider duration of disruption when identifying essential items (short/long term).

Loss of Building or Geographic Region (continued)

Recovery Strategies

Recovery strategies should allow for flexible and scalable responses to a complete or partial building disruption that occurs with or without warning. The following guidelines may be modified based on the severity and duration of the building disruption.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
6.	**Recovery.** The recovery strategies identified in this section are representative of the following essential functions: • Clinical Lab and Pathology Tests and Interpretation (<4 Hours) • Equipment Maintenance and Repair (<4 Hours) • Supply Orders (<24 Hours) • Staff Scheduling (<72 Hours)			
7.	Staff Assignments. At the onset the emergency incident, department staff will be provided with specific instructions: • Report to their lab section or an alternate (temporary) site • Obtain immediate instructions and/or assignments from supervisor/manager • Place non-essential staff on stand-by until further notice			
8.	Consult and secure approval from senior leadership prior to closing any department section. • Notify Incident Commander if a laboratory section is closed • EMT will ensure messaging to all providers informing them of the situation and recovery guidance			
9.	Identify and implement the applicable recovery strategies required to support essential activities. Consider: • Status of work in progress, timing and duration of event • Integrity of services, limitations and impacts to patient care • Department capabilities and regulatory obligations			
10.	Coordinate the integration of recovery strategies and downtime procedures across the WFBH network to include but not limited to the following areas: • Clinical Areas, Network Laboratories, BioMed Engineering, Medical Records, Phlebotomy, Information Technology, Outreach clients			

Call Forwarding

The IT Service Desk will be tasked with managing the main incoming line by ensuring the required call-forwarding to the relocation site and/or placing front-end emergency placement messaging on affected lines via the Hijack process.

Loss of Building or Geographic Region (continued)

Department Relocation and Logistics

The EMT in coordination with department leadership will provide oversight and assist with the logistics related to shelter-in-place or relocation activities (on/off campus). The EMT will work with the applicable departments or third-parties to ensure a safe relocation of staff, equipment and supplies. Once the relocation site(s) is available to support essential activities, the EMT will notify senior leadership.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
11.	Upon notification from the EMT of the relocation site(s): • Re-direct select staff to relocation site(s) to ensure ongoing support of essential activities • Provide date, time, location, and changes in work schedules • Ensure oversight to relocated staff and activities			
12.	Leverage additional staff and/or specialized third party agencies to assist in relocating essential equipment or to coordinate logistics at the designated relocation site.			
13.	Re-deploy specialty services to third-parties to ensure minimal disruption to patient care where possible.			
14.	Deploy staff to alternate location for receiving, unpacking, and setting up logistics at the temporary site.			
15.	Ensure tracking of assets that are removed from the department. • Collect data using the Office Relocation Tracking Form			

Scenario: Power Outage in Laboratory Section

16.	Leverage existing policies and procedures and ensure the following tasks: • Notify clinical engineering to report the outage • Continue testing as long as the temperature and humidity stay in acceptable range for all pieces of equipment, test kits and reagents. • Report test values using downtime processes.			
17.	Consider additional measures to maintain temperature and humidity levels (e.g., deploy fans in testing areas, other).			
18.	Discontinue testing that involves analyzers/equipment, test kits, or reagents that are affected by temperature or humidity failure.			
19.	Notify lab leadership of the situation and make arrangements to refer testing to a different lab.			

Loss of Building or Geographic Region (continued)

Scenario: Instrumentation not Operational

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
20.	Discontinue all testing at the location where this occurs.			
21.	Notify Lab leadership of the situation and make arrangements to refer testing to a different lab location.			

22.	Ensure notification to couriers and/or any other third parties.			
23.	Refer to the existing department EOP procedure and implement the tasks required to recover from this scenario.			

Staffing Management and Oversight

24.	Identify staff from other Labs that are able to assist with recovery strategies (relocation, other). • Ensure work schedules adhere to the applicable regulatory requirements			
25.	Evaluate current staffing levels and explore alternative options to ensure ongoing support of essential activities. Consider: • Scheduled staff will work the shifts as previously planned • Adjust or extend shifts (hours of operations)			
26.	Instruct staff to track all items (equipment, supplies) that are removed from the department. • Leverage the Office Relocation Tracking Form			
27.	Suspend processes that are deferrable and reassign staff to assist with essential activities and recovery strategies, where applicable. • Department Administration (<7 Days) • Lab Training (<7 Days)			

Talking Points

The EMT in coordination with department leadership should develop Talking Points to include information related to the building closure and/or relocation of patients. Consider what WFBH staff should (or should not) relay to patients or other third parties regarding the situation. Ensure all staff are provided with this information to ensure consistency is messages being relayed to internal and external sources.

Loss of Building or Geographic Region (continued)

Equipment and Supplies

The EMT in collaboration with department leadership and third-party vendors will ensure the receiving site(s) have the space, technology infrastructure (system access) and equipment established prior to relocating staff and/or essential activities.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
28.	Assess the department's essential equipment and supplies required to support essential activities.			
29.	Determine essential needs required to support ongoing activities at the relocation site(s).			
30.	Consider the need for temperature sensitive items to be transferred to an alternate Lab and/or location within hospital.			
31.	Contact Clinical Engineering and/or Vendor Technical Support to repair or replace required equipment. • Refer to the Equipment Service Procedure for additional tasks and related information			
32.	Instruct staff to track all items (equipment, supplies) that are removed from the department. • Leverage the Office Relocation Tracking Form			

Assessment Checklist

Assess the condition of essential items located within the department if safe to do so. Determine which items can be relocated to an alternate (temporary) site and those that need to be replaced upon restoration.

- Short-Term. Assess the current condition of equipment located within the department to ensure it is in working order and determine which services could be re-directed to other Labs (onsite) and/or outsourced to a specialty third-party service provider.
- Long-Term. A relocation would have to be discussed with regulatory bodies (e.g., CLIA), senior leadership and any other applicable stakeholders followed by the implementation of a relocation plan.

Loss of Building or Geographic Region (continued)

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
33.	**Ongoing Activities.** Ensure Section Managers facilitate frequent meetings with department staff to obtain and provide status updates throughout the disruption. • Instruct staff to track operational status, risks, modifications to service levels, and other notable incidents. • Refer to **Appendix C** (Event Reporting & Tracking) • Note: The EMT will work with the applicable stakeholders to submit documentation to insurance carrier(s) for potential reimbursement of losses incurred as a result of the event.			
34.	Provide ongoing department oversight to staff at all locations to ensure adherence to service levels, regulatory requirements and department policies throughout the event. • Escalate exceptions to department leadership or the EMT • Obtain approval for exceptions to department protocols • Ensure ongoing tracking and reporting of impacts			
35.	Refer to the Emergency Operations Plan or any other applicable WFBH policies and implement the tasks and strategies required to recover from a Loss of Building scenario.			

Signature Requirements

- Continue to obtain signatures from the applicable leadership.
- If wet-signatures are required:
  - Meet the applicable leadership at a central location
  - Send an Email with the attached document(s) and include instructions
  - Mail a hard copy of the document(s) with specific instructions
- Leverage couriers to ensure ongoing delivery of time sensitive correspondence.

Loss of Building or Geographic Region (continued)

Relocation Back to Primary Location

Emergency Management will ensure notification to the affected departments of when the essential infrastructure is available, and services may resume at the primary location. The following tasks need to be considered to ensure a seamless transition back to a business as usual position. Preparations to initiate these actions should be taken at the earliest time possible and various activities need to be completed prior to relocating staff back to the primary site.

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
36.	**Reconstitution.** Assemble essential staff to assist with BCP termination activities to include but not limited to: • Ensure department staff (all shifts) are notified of the BCP termination • Provide date, time, and other information required to prepare staff for relocation back to the primary site • Identify temporary modifications to department policies and procedures			
37.	Instruct staff to assess the primary site and determine if any additional items (equipment, supplies) are required prior to relocating staff and activities back to the primary site. • Escalate issues to the applicable department for resolution (IT, Clinical Engineering, Facilities Management, etc.) • Determine if third-parties are required to assist with reconstitution activities			
38.	Coordinate the integration of reconstitution activities with all applicable stakeholders across the WFBH network to include but not limited to: • Clinical Areas • Network Laboratories • BioMed Engineering • Medical Records • Phlebotomy • Information Technology • Outreach clients			
39.	Work with the EMT to ensure internal and external stakeholder notification as the department returns to a business-as-usual position. • WFBH Network • Regulatory Agencies [e.g., Clinical Laboratory Improvement Amendments (CLIA), Food & Drug Administration (FDA), etc.] • Third-Party Vendors			

Loss of Building or Geographic Region (continued)

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
40.	Identify (temporary) changes to department services and ensure notification to the appliable areas. Modifications may include: • Limited or changes to essential services • Services being conducted by a third-party until further notice			
41.	Implement a process to ensure any manually tracked data is entered online, brought current, and reconciled. • Prioritize work based on operational and service level impacts			
42.	As test begin to be processed according to the expected TAT: • Contact Help Desk @ 6-HELP (6- 4357) and request deactivation of front-end messaging and/or the Laboratory Message of the Day			
43.	Provide oversight to ensure adherence to regulatory and contractual requirements and WFBH policies as BCP activities are terminated.			

Equipment and Supplies. Clinical Engineering, Facilities Management and other select departments may be tasked with preparing the primary site for re-entry to include but not limited to sanitizing the applicable areas, relocating equipment, supplies, and other assets.

44.	Coordinate efforts with the applicable staff to account for all items that were taken offsite or purchased to support recovery strategies. • Establish a process to account for all items upon return • Leverage the Office Relocation Tracking Form that were completed during the relocation			
45.	Replenish inventory required to support essential activities from the primary location (equipment, supplies, other).			
46.	Leverage existing processes and ensure adherence to WFBH procurement policies.			

Loss of Building or Geographic Region (continued)

Post Reconstitution Activities

The following tasks need to be considered by the RTL and department leadership following the termination of BCP activities and the resumption of business-as-usual operations.

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
47.	Facilitate a lessons-learned session with select staff to identify risks, opportunities and how the department can best prepare for similar events in the future. • Assess the need for changes in department policies • Identify select staff to participate in the development of an Enterprise-Wide Relocation Plan with the EMT • Develop an Action Plan, establish target dates, and ensure resolution			
48.	Collect Event Reporting forms and supporting reference that includes modifications to essential functions and costs associated with BCP activation. • Prepare a summary of results to include an evaluation of department performance and areas of opportunity • Participate in post recovery review sessions with the EMT			
49.	If needed, facilitate post recovery sessions with Laboratory Management: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			

50.	Update the required documents based on the event and notify or re-distribute items to select staff.
	• Department of Pathology & Laboratory Services BCP
	  ○ Loss of Building Recovery Strategies
	  ○ Contact Listings
	• Department Policies and Procedures
	  ○ Obtain signature from the CLIA Laboratory Director for major revisions to policies and procedures
	• Minor revisions to policies and procedures can be signed by the Lab Section Medical Director			

I.II Loss of Technology

Loss Type Definition: The main facility where the business area resides has suffered a partial and/or full technology, telecommunication, and/or critical equipment interruption that impacts the business for an indefinite period of time.

Recovery Team Leader Task List

#	Phase I. Response Tasks & Guidelines	Completed		
		Yes	No	N/A
1.	**Response.** Leverage existing protocols to ensure department staff are notified of the event. • Notify Lab Section Manager • Lab Manager on-call or delegate if after hours/weekends			
2.	Activate Laboratory Management and/or other essential staff to participate in the initial assessment of the event and implementation of recovery strategies. Consider: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			
3.	Ensure notification to inpatient providers and patient care teams of the unexpected, unplanned delays in laboratory testing.			
4.	Provide staff with information regarding changes in department priorities based on the severity of the event and affected system.			

The Department of Pathology and Laboratory Services has a critical degree of dependence on technology to meet WFBH's mission, ensure ongoing service delivery and patient care. Manual workarounds for essential technology and activities is limited or cannot be used for any extended period of time without impacting the accuracy of data and impacts to patient care.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
5.	**Recovery.** The recovery strategies identified in this section are representative of the following essential functions: • Clinical Lab and Pathology Tests and Interpretation (<4 Hours) • Equipment Maintenance and Repair (<4 Hours) • Supply Orders (<24 Hours) • Staff Scheduling (<72 Hours)			
6.	In the event the testing involved in the delay will affect others in the network, notify the Network Group. • Network_Pathology_Laboratory_Leaders_DL@wakehealth.edu			

Loss of Technology (continued)

Event Notification

The EMT will provide oversight in the event of a significant (enterprise) technology interruption that impacts the business for an indefinite period of time. The EMT will also ensure ongoing communication to internal and external stakeholders via email blasts, corporate website, and other applicable tools.

Downtime Procedures

Administrative responsibility of the downtime procedures resides with each (Wake Health) department. This includes maintenance of the downtime procedures, which specifies the alternative processes that are to be activated to assure continuity of essential activities during a downtime event to ensure that patient care is not compromised. Each downtime situation will be unique; therefore, tasks and strategies will need to be adjusted in order to ensure minimal disruption to patient care where possible.

The Department of Pathology and Laboratory Services must ensure the continuity of essential activities during any computer downtime event so that essential activities, patient care, etc., is not compromised. Refer to the applicable Downtime Procedures that provide the framework for the activities performed before, during and after an essential system downtime incident.

Laboratory Operations System Delay Notification Procedure

The Laboratory Operations System Delay Notification Procedure provides a structure for lab sections to communicate an unplanned and unexpected delay in patient results in order to minimize the impact to patients. Planned delays or short term equipment failures that can be compensated by incorporating onsite backup instrumentation will not be communicated across the medical center as there should be no impact to turnaround times on posting results. System-wide downtime delays will not follow this process.
Source: Laboratory Operations System Delay Notification Procedure (5/2021)

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
7.	Prioritize key deliverables and implement recovery strategies based on risk and impacts to patient care, testing, etc. Consider: • Timing and duration of event • Status of work-in-progress • Department recovery capabilities • Regulatory, legal and service levels			
8.	Identify and implement the applicable recovery strategies required to support essential activities. Consider: • Status of work in progress, timing, and duration of event • Integrity of services, limitations and impacts to patient care • Department capabilities and regulatory (e.g., CLIA, etc.) obligations			

Loss of Technology (continued)

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
9.	Coordinate the integration of recovery strategies and downtime procedures across the WFBH network to include but not limited to the following areas: • Clinical Areas • Network Laboratories • BioMed Engineering • Medical Records • Phlebotomy • Information Technology • Outreach clients			

10.	Assess staffing levels and determine if additional staff will be required to support (manual) activities.
	• Suspend processes that are non-essential and re-assign that staff to support manual activities
	  ○ Department Administration (<7 Days)
	  ○ Lab Training (<7 Days)			

11.	Consider adding front-end messaging to incoming lines re-directing callers to the corporate website or an emergency number to obtain additional information. • Request assistance from the IT Service Desk, if needed • Provide the EMT with department specific workaround strategies to ensure placement on the corporate website			
12.	Coordinate efforts with the EMT to ensure ongoing notification to affected areas regarding modifications to essential services. • Delays in testing across the WFBH network • Other modifications to essential activities			
13.	Ensure Section Managers facilitate frequent meetings with department staff to obtain and provide status updates throughout the disruption. • Instruct staff to track operational status, risks, modifications to service levels, and other notable incidents. Refer to **Appendix C** • Note: The EMT will work with the applicable stakeholders to submit documentation to insurance carrier(s) for potential reimbursement of losses incurred as a result of the event.			
14.	Provide ongoing department oversight to staff at all locations to ensure adherence to service levels, regulatory requirements and department policies throughout the event. • Escalate exceptions to department leadership or the EMT • Obtain approval for exceptions to department protocols • Ensure ongoing tracking and reporting of impacts			

Loss of Technology (continued)

IT Service Desk

The IT Service Desk or other applicable IT resources will coordinate technology, telecom, and equipment recovery efforts with the applicable third-party provider(s) to ensure the timely resolution and restoration of services. IT will also provide status updates to the EMT and other internal stakeholders throughout the event

(e.g., estimated time of resolution, other) and ensure front-end messaging is placed on the applicable incoming telecom lines.

Technology Recovery Strategies

The following manual workarounds need to be considered in the event that any of the following enterprise and/or department specific **essential** systems/applications are off-line for an indefinite period of time. All recovery strategies should proceed from the RTL's assessment of the event and may be adjusted as needed to respond to and recover from the disruption.

Enterprise-Wide Technology & Workaround Strategies
Affected Technology: Internet, Outlook, Shared Drives, and Cloud-Based Systems

Consider and apply one or more of the following items based on the affected system/application.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
15.	Retrieve data available in unaffected systems, email attachments, hard copy, or other sources.			
16.	Leverage existing downtime forms or create checklists required to support manual tracking of essential activities. • Ensure tracking of information is sufficient to support an audit trail (e.g., dates, times, other). • Maintain paper/downtime forms in a central location by area			
17.	Notify affected staff of manual workarounds, provide downtime or manual tracking sheets and any other special instructions.			
18.	Coordinate efforts with IT to ensure an Email Blast is sent to affected areas providing (temporary) downtime activities: • Send requests via unaffected systems • Call department directly • Fax requests • Hand deliver			
19.	Contact third-party directly to obtain the required information based on data that may have been submitted prior to disruption.			
20.	Maintain data that was entered prior to the system going down. • Check the data upon system restoration when the system comes back up to make sure the information was not lost.			

Loss of Technology (continued)
Affected Technology: Internet, Outlook, Shared Drives, and Cloud-Based Systems

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
21.	Coordinate recovery efforts with the applicable third-party stakeholders to ensure restoration of affected components.			
22.	Make all attempts to ensure adherence to regulatory, legal requirements and department policies.			
23.	Approve items in hard copy as opposed to electronic signature.			
24.	Ensure notification to affected stakeholders of delays or modifications to service			

	levels until technology is restored.			
25.	Adjust manual workarounds and strategies throughout the disruption and ensure minimal disruptions where possible.			
26.	Refer to the Emergency Operations Plan or any other applicable WFBH policies and implement the tasks and strategies required to recover from a Loss of Technology scenario.			

Department Technology & Workaround Strategies
Affected Technology: LIS and/or EMR

It is the responsibility of the Department of Lab & Pathology to notify inpatient providers and patient care teams of an unexpected, unplanned delay in laboratory testing that will affect turnaround times as soon as possible after the delay has been identified. The following is a **summary** of tasks and guidelines as identified in the System Delay Notification and Epic Downtime Procedures.

27.	Refer to System Delay Notification Procedure. • Implement the applicable escalation and notification processes as identified in (Steps 1 – 3)			
28.	Ensure ongoing notification to all applicable areas throughout the disruption. • Charge Nurses, Nursing Operations Supervisors o Net Page link (http://netpage.wakehealth.edu) o Send a message to all Charge Nurse ASCOM's, to include the Adult/Pediatric Emergency Departments • Message: o **Laboratory Delay** Results of (affected test) will be delayed (time frame)			

Loss of Technology (continued)
Affected Technology: LIS and/or EMR

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
29.	Ensure the Laboratory Medical Director or Clinical Pathologist on-call considers the following: • Notify CMO on-call and request approval for the Message of the Day and for the Intranet post. • Alternate notifications may be utilized at the discretion of the Laboratory Medical Director.			

Source: Laboratory Operations System Delay Notification Procedure (5/2021)

Affected Technology: Epic WakeOne

30.	Refer to the Downtime: Electronic Health Record (EHR) Procedure. • Implement manual workaround for the applicable tests and procedures utilizing the appropriate paper forms			
31.	Reference the two BCA reports that indicate outstanding labs house-wide and in all clinics. • Nursing must determine lab needs for their patients and complete paper lab requisitions for both nursing & phlebotomy. • Lab draw requisitions should be placed in the unit lab collection box			
32.	Labs/Pathology specific to the OR case (intraoperative nursing): • Submit with corresponding downtime lab paperwork and documentation via the Nursing Intraoperative Document			

Source: Downtime Electronic Health Record (3/2021)

Time Management, Payroll, Purchasing
Affected Technology: Core Connect (7/2/2021)
Finance (Payroll) will coordinate, communicate, and provide instructions to support manual tracking based on the severity of the disruption, estimated time of resolution, and other contributing factors.

33.	Implement manual tracking activities as directed by Finance (Payroll). Consider: • Hours worked, date, overtime, and other information • Submission of data via unaffected systems			
34.	Implement the strategies, as directed by Finance, to ensure ongoing submission of files for payment processing (e.g., invoices).			
35.	Contact Purchasing directly (phone, Email) to ensure emergency purchases continue throughout the disruption.			

Loss of Technology (continued)

Telecommunications & Essential Equipment
Affected Component: Telecommunications

The IT Service Desk will coordinate recovery efforts with the applicable third-party provider(s) to ensure the timely resolution and restoration of services.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
36.	Coordinate efforts with the IT Service Desk to ensure front-end (emergency) messaging is placed on incoming lines until telecom is restored. Messaging can include: • Requesting caller to call back at a later time • Direct caller to corporate website for additional information			
37.	Continue internal communications via all available tools/sources: • Email, Cell Phones, Video Conference, Face-to Face			
38.	Consider re-directing lines to unaffected hospitals within the network to ensure ongoing message taking activities, if needed.			
39.	Provide the designated operator or recipient of forwarded lines with a contact list of department cell phone numbers. • Designated operator/recipient will triage calls and re-direct to the correct party (cell number).			

Department of Pathology Laboratory Equipment Service Procedure. Wake Forest Baptist Health has an agreement in place with a secondary contractor to service and maintain its laboratory equipment. The following is a **summary** of tasks and guidelines as identified in the department's Equipment Service Procedure.

40.	Refer to the Equipment Service Procedure • Follow existing escalation protocols to arrange for repair or replacement of affected items. • Ensure the safety precautions throughout the disruption ○ Compliance with OSHA requirements			
41.	Coordinate recovery strategies with the applicable stakeholders to include but not limited to the following: • BioMed, Clinical Engineering, Environmental Health & Safety • Section Medical Directors, Section Managers, CLIA Lab Director			
42.	Contact Clinical Engineering, Section Manager and/or Vendor Technical Support to ensure timely resolution and restoration of services. Provide the following: • Hospital Name, Your Name/Telephone Number, Department • Equipment ID/Asset Tag • Equipment Description-Including status (Critical or Not Critical) • Brief Description of Problem			

Loss of Technology (continued)

Affected Component: Laptops, Printers, Scanners

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
43.	Follow existing protocols (e.g., contact IT Service Desk) to arrange for repair or replacement of affected items. • Laptops, printers, scanners, etc. • Allocation of equipment may be prioritized based on the criticality of the affected activities and service levels			
44.	Determine if IT can establish connectivity to non-clinical staff via personal computers until replacement or loaner equipment is available.			

	• Consider lead-time required to configure and re-deploy equipment			

Note: There wasn't any essential equipment identified as single points of failure. The risk of essential machines and equipment being off-line (long-term) is low based on the ongoing pre-tentative maintenance provided by the Clinical Engineering and/or the applicable third-party vendors to ensure all components are maintained at an optimal working condition.

Reconstitution. The EMT will notify department leadership when the technology infrastructure is restored. The following tasks need to be considered to ensure a coordinated return to a normal mode of operations.

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
45.	**Reconstitution.** Assemble essential staff to assist with BCP termination activities. • Ensure department staff (all shifts) are notified of the BCP termination and modifications to department priorities. ○ Changes in work schedules • Identify temporary modifications to department procedures			
46.	Instruct department staff to test and validate restored technology and equipment. Upon validation: • Implement a plan to ensure all manually tracked data is entered online, brought current, and reconciled • Prioritize work based on risk and service level impacts			
47.	As test begin to be processed according to the expected TAT: • Contact Help Desk @ 6-HELP (6- 4357) and request deactivation of front-end messaging or the Laboratory Message of the Day			

Loss of Technology (continued)

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
48.	Identify loss of data and recreate where possible leveraging other systems and/or data that was manually tracked. • Determine impacts in the event data cannot be recreated (for regulatory purposes) and escalate to department leadership • If needed, obtain approval for exceptions from laboratory management and/or the applicable regulatory agencies			
49.	Coordinate the integration of reconstitution activities with all applicable stakeholders across the WFBH network to include but not limited to: • Clinical Areas • Network Laboratories • BioMed Engineering • Medical Records • Phlebotomy • Information Technology • Outreach clients			
50.	Work with the EMT to ensure stakeholder notification as activities return to a business-as-usual position. • WFBH Network • Regulatory Agencies (e.g., CLIA, etc.) • Third-Party Vendors			
51.	Identify (temporary) changes to department services and ensure notification to the appliable areas.			
52.	Provide oversight to ensure adherence to regulatory requirements and WFBH policies as BCP activities are terminated.			

Post Reconstitution Activities

The following tasks need to be considered by the RTL and department leadership following the termination of BCP activities and the resumption of business-as-usual operations.

53.	Facilitate a lessons-learned session to identify opportunities and how the department can better prepare for similar events in the future. • Assess the need to document additional manual workarounds for essential systems and activities • Implement training on manual workarounds to essential staff • Develop an Action Plan, establish target dates, and monitor for resolution			

Loss of Technology (continued)

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
54.	Collect Event Reporting forms and supporting reference that includes modifications to essential functions and costs associated with BCP activation. • Prepare a summary of results to include an evaluation of department			

	performance and areas of opportunity • Participate in post recovery review sessions with the EMT			
55.	If needed, facilitate post recovery sessions with Laboratory Management: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			
56.	Update the required documents based on the event and notify or re-distribute items to select staff. • Department of Pathology and Laboratory Services BCP ○ Loss of Technology Recovery Strategies ○ Contact Listings • Department Policies and Procedures ○ Obtain signature from the CLIA Laboratory Director for major revisions to policies and procedures ○ Minor revisions to policies and procedures can be signed by the Lab Section Medical Director			

I.III Loss of Resources

Loss Type Definition: The main facility where the business area resides has suffered a major disruption resulting in a significant loss of resources (40% or greater) for an indefinite period of time.

Recovery Team Leader Task List

#	Phase I. Response Tasks & Guidelines	Completed		
		Yes	No	N/A
1.	**Response.** Leverage existing protocols to ensure department staff are notified of the event. • Notify Lab Section Manager • Lab Manager on-call or delegate if after hours/weekends			
2.	Activate Laboratory Management and/or other essential staff to and complete a preliminary assessment. Consider: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			
3.	Consider the following to determine the level of risk and impacts to essential services: • Affected Staff and Specialty • Severity and Duration of Disruption			
4.	Ensure notification to inpatient providers and patient care teams of the unexpected, unplanned delays in laboratory testing.			
5.	Provide department staff with information regarding impacts and changes in priorities based on affected resources and processes.			

At the time of disruption, the highest level of Laboratory Management available in the department will be responsible for providing oversight to capacity planning, staff augmentation, and re-distribution of workloads required to support ongoing operations.

As part of the Department of Pathology Emergency Operations Plan, all staff will initially perform their normal daily assignments during a time of emergency or crisis unless otherwise assigned by their immediate supervisor/manager or a member of the Laboratory Administration.

Event Notification

The EMT will provide oversight in the event of a significant (enterprise) resource interruption that impacts WFBH for an indefinite period of time. The EMT will also ensure ongoing communication to internal and external stakeholders via email blasts, corporate website, and other applicable tools.

Loss of Resources (continued)

Staffing

Staffing inventories will be monitored by the EMT throughout the emergency incident. Resources will be replenished as quickly as appropriate from any appropriate source (i.e., subsidiary hospital sites, specialty

third-party service providers and regional/state/federal caches, etc.).

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
6.	**Recovery.** The recovery strategies identified in this section are representative of the following functions: • Clinical Lab and Pathology Tests and Interpretation (<4 Hours) • Equipment Maintenance and Repair (<4 Hours) • Supply Orders (<24 Hours) • Staff Scheduling (<72 Hours)			

7.	Determine Succession Planning in order of availability to ensure oversight of recovery strategies, tracking and reporting. Consider:
	• Primary and Alternates (Laboratory Management)
	  ○ Section Medical Director
	  ○ Pathology and Lab Medicine Director
	  ○ Administrative Director
	  ○ CLIA Lab Director
	  ○ Department Chair
	  ○ Vice President of Laboratory Operations
	• Other: Select department staff based on specialty and specific work required (e.g., Lab Managers, Lab Staff, etc.)			

8.	Evaluate testing capacity and sample stabilities. Manage both incoming orders (demand) and seek alternative testing support via other laboratories (supply).
	• Communicate to clinical teams that non-critical test orders should be minimized and turnaround times will be delayed
	• Determine critical test menu that can be offered and communicate to clinical team.
	• Communicate with network labs/reference lab to determine their capacity to complete testing.
	• Redirect testing to network labs and or reference lab (i.e. Lab Corp)
	  • Refer to procedure: CP12 Creating Packing Lists or Manifests for Specimen Transport of Clinical Lab Specimens
	  ○ Quick training on packing lists and specimen packing.
	  ○ Leverage available staff from unaffected areas to facilitate
	• Communicate with courier (i.e., DOT) for frequent pick-ups/delivery			

Loss of Resources (continued)

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
9.	Assess immediate and ongoing staff needs based on existing and predicted levels of resources available. • Scheduled staff will work the shifts as previously planned • Prepare and implement contingency staffing schedule • Adjust staffing requirements to ensure adequate coverage • Place additional staff on stand-by			
10.	Suspend non-essential work, prioritize, and implement recovery strategies based on risk and impacts to essential services. Consider:			

	• Status of essential Work-in-Progress • Regulatory, Contractual Obligations and Service Levels			
11.	Coordinate the integration of recovery strategies and downtime procedures across the WFBH network to include but not limited to the following areas: • Clinical Areas • Network Laboratories • BioMed Engineering • Medical Records • Phlebotomy • Information Technology • Outreach clients			
12.	Work with the EMT to ensure ongoing notification to affected areas regarding modifications to essential services. • Delays in testing across the WFBH network and other changes			
13.	If needed, add front-end (emergency) messaging to incoming lines until capacity planning is implemented. Messaging can include: • Request callers to call back at a later time, estimated time of resolution, and/or any other special instructions			
14.	Provide ongoing department oversight to staff at all locations to ensure adherence to service levels, regulatory requirements and department policies throughout the event. • Escalate exceptions to department leadership or the EMT • Obtain approval for exceptions to department protocols • Ensure ongoing tracking and reporting of impacts			

Loss of Resources (continued)

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
15.	Ensure Section Managers facilitate frequent meetings with department staff to obtain and provide status updates throughout the disruption. • Instruct staff to track operational status, risks, modifications to service levels, and other notable incidents. Refer to **Appendix C** • Note: The EMT will work with the applicable stakeholders to submit documentation to insurance carrier(s) for potential reimbursement of losses incurred as a result of the event.			
16.	Refer to the Emergency Operations Plan or any other applicable WFBH policies and implement the tasks required to recover from a Loss of Resources scenario.			

Refer to the Mass Casualty Preparedness Plan for the Department of Pathology and implement the applicable tasks and strategies required to recover from a Loss of Resources scenario. The following is a **summary** of tasks and guidelines identified in this Mass Casualty Preparedness Plan.

- WFBH will respond to a mass casualty incident by activating Phase 3, Medical Surge Plan.
- Laboratory Administration will further assess the type of event and potential of additional laboratory requests based on hospital needs.
  - Based on this assessment, Lab Administration may initiate an internal lab notification process to disseminate further lab specific guidance.
  - On site staffing needs will also be assessed by Lab Administration.
- Department staff will initially perform their normal daily assignments during a time of emergency or crisis unless otherwise assigned by their immediate supervisor/manager or a member of the Laboratory Administration.

Overtime Considerations

Coordinate efforts with the EMT and/or department leadership if approval of overtime is required to support business recovery strategies

- Who has the authority to authorize emergency overtime?
- In what order staff will be called up or have overtime authorized to them?
- Any limits to the amount of overtime that can be authorized without special permission?
- Any limits to how long staff may consecutively work?
- How much time must elapse between shifts?
- How or will exempt staff will be compensated for overtime hours?

Loss of Resources (continued)

Delegation of Authority

The following Delegation of Authority provides successors the legal authority to act on behalf of department leadership for specific purposes, and to carry out specific duties. Delegations of Authority will take effect when normal channels of direction are disrupted and will terminate when these channels are reestablished.

Essential Task	Authority	Delegated Authority
Evacuate the department	• Department Director	• Managers and Supervisors
Allow staff to leave work	• Managers	• Supervisors
Purchasing	• Dictated by Policy	• Department Leadership

Orders of Succession

During a disaster event, it's critical to know which resources have the authority to take action on required decisions. Succession plans will identify who has the authority to step into various roles immediately to avoid a breakdown in operations.

Consider the following Orders of Succession in the event that the principal of an essential position is unable or incapable of performing authorized duties. The department should also consider job knowledge and tenure when identifying successors for affected positions.

Positions	Successors or Sources of Additional Staff
Laboratory Management	In order of availability: • Section Medical Director, Pathology and Lab Medicine Director, Administrative Director, CLIA Lab Director, Department Chair, VP of Laboratory Operations
Essential Staff	Non-Leadership: • Select department staff based on specialty and specific work required (e.g., Lab Managers, Lab Staff, etc.) • Aureus Temporary Agency (Lab Staff)

Pandemic Scenario and Considerations

According to the World Health Organization, a pandemic is declared when a new disease for which people do not have immunity spreads around the world beyond expectations. Social distancing measures are most often thought about as a way to slow the spread of infection and steps are implemented to restrict where people can gather to stop or slow the spread of infectious diseases. The EMT in coordination with department management will lead and provide oversight to all response and recovery efforts during a pandemic related event to include but not limited to the following:

- Modifying company practices
- Closing buildings and implementing telecommuting
- Canceling any large meetings, conferences, events, and implementing travel restrictions
- Other measures as deemed appropriate to support continuity of operations

Loss of Resources (continued)

Reconstitution. The EMT will notify department leadership when to terminate BCP activities. The following tasks need to be considered to ensure a coordinated return to a normal mode of operations.

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A

17.	**Reconstitution.** Assemble essential staff to assist with BCP termination activities.
	• Ensure department staff are notified of the BCP termination and modifications to department priorities
	  ○ Changes in work schedules
	  ○ Plans and approach to bring work current
	• Identify temporary modifications to department processes and ensure notification to the applicable staff and affected areas			

18.	Coordinate the integration of reconstitution activities with all applicable stakeholders across the WFBH network to include but not limited to: • Clinical Areas • Network Laboratories • BioMed Engineering • Medical Records • Phlebotomy • Information Technology • Outreach clients			
19.	Work with the EMT to ensure stakeholder notification as activities return to a business-as-usual position. • WFBH Network • Regulatory Agencies (e.g., CLIA, etc.)			
20.	Provide oversight to ensure adherence to regulatory, contractual and department policies as BCP activities are terminated.			

Loss of Resources (continued)

Post Reconstitution Activities

The following tasks need to be considered by the RTL and department leadership following the termination of BCP activities and the resumption of business-as-usual operations.

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
21.	Facilitate a lessons-learned session to identify opportunities and how the department can better prepare for similar events in the future. • Implement additional cross-training within the department for specialized positions • Identify modifications to Delegation of Authority • Develop an Action Plan, establish target dates, and monitor for resolution			
22.	Collect Event Reporting forms and supporting reference that includes modifications to essential functions and costs associated with BCP activation. • Prepare a summary of results to include an evaluation of department performance and areas of opportunity • Participate in post recovery review sessions with the EMT			
23.	If needed, facilitate post recovery sessions with Laboratory Management: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			

24.	Update the required documents based on the event and notify or re-distribute items to select staff.
	• Department of Pathology and Laboratory Services BCP
	  ○ Loss of Technology Recovery Strategies
	  ○ Contact Listings
	• Department Policies and Procedures
	  ○ Obtain signature from the CLIA Laboratory Director for major revisions to policies and procedures
	  ○ Minor revisions to policies and procedures can be signed by the Lab Section Medical Director			

I.IV Loss of Critical Third-Party Vendor

Loss Type Definition: An essential Vendor and/or Service Provider has suffered a major disruption and will not be available for an indefinite period of time.

Recovery Team Leader Task List

#	Phase I. Response Tasks & Guidelines	Completed		
		Yes	No	N/A
1.	**Response.** Leverage existing protocols to ensure department staff are notified of the event. • Notify Lab Section Manager and/or Lab Manager on-call or delegate if after hours/weekends			
2.	Activate Laboratory Management and/or other essential staff to participate in the initial assessment of the event and implementation of recovery strategies. Consider: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			
3.	Consider the following to determine the level of risk and impacts to essential services: • Service provided by affected Vendor or Service Provider • Severity and Duration of Disruption			
4.	Ensure notification to inpatient providers and patient care teams of the unexpected, unplanned delays in laboratory testing.			
5.	Provide department staff with information regarding impacts and changes in priorities based on affected resources and processes.			

The Supply Chain Services EOP provides specific emergency guidelines for all departments when conducting business operations and supporting patient care when the HICS has been activated and/or when patient capacity demands/exceeds the current and available resources.

The EMT maintains Memos of Understanding for emergency re-supply with critical vendors as well as copies of those vendor's emergency contingency plans.

Loss of Critical Third Party Vendor (continued)

Event Notification

The EMT will provide oversight in the event of a significant third-party interruption that impacts WFBH for an indefinite period of time. The EMT will also ensure ongoing communication to internal and external stakeholders via email blasts, corporate website, and other applicable tools.

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
6.	**Recovery.** The recovery strategies identified in this section are representative of the following functions: • Clinical Lab and Pathology Tests and Interpretation (<4 Hours) • Equipment Maintenance and Repair (<4 Hours) • Supply Orders (<24 Hours) • Staff Scheduling (<72 Hours)			
7.	Consult with department leadership to ensure the following: • Assess recovery strategies based on impacts to patient care • Identify potential impacts to regulatory requirements			
8.	Leverage stock on hand and/or emergency supplies to maintain an adequate level of services across essential areas.			
9.	Coordinate the integration of reconstitution activities with all applicable stakeholders across the WFBH network to include but not limited to: • Clinical Areas, Network Laboratories, BioMed Engineering, Medical Records, Phlebotomy, Information Technology, Outreach clients			
10.	Provide oversight to ensure adherence to department policies and procedures throughout the disruption. • Escalate exceptions to department leadership or the EMT • Obtain approval for exceptions to department policies			
11.	Facilitate frequent sessions with department staff to obtain and provide status updates. • Instruct staff to track issues, modifications to service levels, and other notable incidents. Refer to **Appendix C** (Event Reporting & Tracking) • Note: The EMT will work with the applicable stakeholders to submit documentation to insurance carrier(s) for potential reimbursement of losses incurred as a result of the event			
12.	Refer to the Emergency Operations Plan or any other applicable WFBH policies and implement the tasks and strategies required to recover from a Loss of Third-Party Vendor scenario.			

Loss of Critical Third-Party Vendor (continued)

Third-Party Dependencies

Redundant Vendors

☑ Pre-Approved Specialty Vendors and Suppliers

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
13.	Follow existing department protocols and leverage redundant vendors and service providers to ensure continuity of operations.			
14.	Consider lead time required for the redundant vendor or service provider to be notified and available to support recovery strategies.			
15.	Coordinate efforts with the EMT to ensure ongoing notification as the department switches to a redundant vendor or service provider.			

Single Source Vendors

☑ LabCorp ☑ Mayo ☑ Medline

16.	Consult with department staff to determine the applicable recovery strategy based on the department's reliance and type of service provided by the affected third-party. Consider: • Obtain assistance from WFBH network of specialized third party vendors/service providers • Suspend or modify affected activities until the third-party is restored			
17.	Determine if bringing work in-house is a feasible solution (short-term) based on the department's capacity to handle additional (specialty) work.			
18.	Work with WFBH network to re-direct work to established third-parties. • Specialty vendors that currently provide preventative maintenance on special equipment and/or other essential services			
19.	Identify if a redundant vendor needs to be established based on the type of service provided (e.g., essential vs non-essential support).			
20.	If needed, provide the EMT with new vendor requirements and ensure the new vendor be brought on-line in an expedited manner. • Obtain the required approval from the EMT or other stakeholders			
21.	Coordinate efforts with the EMT to determine vendor replacement from available sources (e.g., subsidiary specialty third-party service providers and regional/state/federal caches, etc.).			

Loss of Critical Third-Party Vendor (continued)

Third-Party BCP Activation

Consider the following options when a Business Continuity Plan has been activated by a third-party

#	Phase II. Recovery Tasks & Guidelines	Completed		
		Yes	No	N/A
22.	Leverage redundant vendors/providers, where applicable, to ensure ongoing support of essential activities.			
23.	Implement recovery strategies as directed by the affected vendor. • Hold data or re-direct to alternate (URLs, websites, etc.) until further notice • Work with replacement vendor/service provider as determined by the affected third-party			
24.	Bring work in-house, where applicable, on a short-term basis or until a redundant vendor/provider is operational.			
25.	Coordinate efforts with the EMT to determine vendor replacement from available sources (i.e., subsidiary specialty third-party service providers and regional/state/federal caches, etc.).			

Reconstitution. The EMT will notify department leadership when to terminate BCP activities. The following tasks need to be considered to ensure a coordinated return to a normal mode of operations.

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A

26.	**Reconstitution.** Assemble essential staff to assist with BCP termination activities.
	• Ensure department staff are notified of the BCP termination and modifications to department priorities
	  ○ Changes in work schedules
	  ○ Plans and approach to bring work current
	• Identify temporary modifications to department processes and ensure notification to the applicable staff and affected areas			

27.	Coordinate the integration of reconstitution activities with all applicable stakeholders across the WFBH network to include but not limited to: • Clinical Areas • Network Laboratories • BioMed Engineering • Medical Records • Phlebotomy • Information Technology • Outreach clients			

Loss of Critical Third-Party Vendor (continued)

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
28.	Work with the EMT to ensure stakeholder notification as activities return to a business-as-usual position. • WFBH Network • Regulatory Agencies			
29.	Provide oversight to ensure adherence to regulatory, contractual and department policies as BCP activities are terminated.			
30.	Ensure stakeholder notification by providing the EMT with modifications to activities as the department returns to a business-as-usual position.			

Post Reconstitution Activities

The following tasks need to be considered by the RTL and department leadership following the termination of BCP activities and the resumption of business-as-usual operations.

31.	Facilitate a lessons-learned session to identify risks, opportunities and how the department can better prepare for similar events in the future. • Ensure copies of BCPs are on file for essential vendors and providers • Establish a process to review third-party BCPs on a regular basis to ensure the provider meets Supply Chain requirements • Identify mitigating controls that need to be considered and/or implemented • Develop an Action Plan, establish target dates, and monitor for resolution			
32.	Establish and enter into Memorandums of Understanding, Agreement (MOUs/MOAs) with partners and service providers required to support essential functions.			
33.	Collect Event Reporting forms and supporting reference that includes modifications to essential functions and costs associated with BCP activation. • Prepare a summary of results to include an evaluation of department performance and areas of opportunity • Participate in post recovery review sessions with the EMT			

Loss of Critical Third-Party Vendor (continued)

#	Phase III. Reconstitution Tasks & Guidelines	Completed		
		Yes	No	N/A
34.	If needed, facilitate post recovery sessions with Laboratory Management: • Section Medical Director • Pathology and Lab Medicine Director • Administrative Director • CLIA Lab Director • Department Chair • Vice President of Laboratory Operations			

35.	Update the required documents based on the event and notify or re-distribute items to select staff.
	• Department of Pathology and Laboratory Services BCP
	  ○ Loss of Technology Recovery Strategies
	  ○ Contact Listings
	• Department Policies and Procedures
	  ○ Obtain signature from the CLIA Laboratory Director for major revisions to policies and procedures
	  ○ Minor revisions to policies and procedures can be signed by the Lab Section Medical Director			

Third-Party BCP Assessment – Snapshot

If the answers to all of the following questions are, "Yes", a redundant vendor may not be required to ensure continuity of operations. However, if all of the answers are, "No", consider establishing redundancy in third-party vendors required to support essential activities. Having knowledge of this information prior to an unexpected disruption can avoid delays in the recovery of critical operations and minimize the impacts to service levels.

BCP Assessment		Yes	No
1.	Do the recovery timelines meet specific department and essential services requirements?		
2.	Does the BCP address the (4) industry standard scenarios: ☑ Loss of Building or Geographic Region ☑ Loss of Technology ☑ Loss of Resources ☑ Loss of Critical Third-Party Vendor		
3.	Do the exercise results provide sufficient evidence to adequately support recovery capabilities?		

Section II. Plan Introduction

Purpose

The purpose of this Business Continuity Plan or Playbook (BCP) is to prepare Wake Forest Baptist Medical Health (WFBH) in responding to and recovering from an adverse condition that disrupts facilities, computer systems, personnel, and/or essential dependencies.

The BCP is considered secondary to the corporate Emergency Operations Plan (EOP) and is neither a strict set of rules nor a substitute for good judgment. Department Recovery Team Leaders (RTLs) may need to modify the plan and identify other strategies required to respond to and recover from a specific situation that is not highlighted in this document.

Objectives

The objective of the BCP is to coordinate response and recovery activities in response to an adverse condition that disrupts facilities, technology, staff, and third-party dependencies. These objectives include but are not limited to the following:

- Facilitate immediate, accurate and measured service continuity activities after emergency conditions are stabilized;
- Reduce the time it takes to make some critical decisions that personnel will need to make when a disaster occurs;
- Minimize the incident's effect on daily operations by ensuring a smooth transition from emergency response operations back to normal operations; and
- Expedite restoration of normal services.

Applicability and Scope

This BCP was developed using an all-hazards planning approach, which encompasses preparation and planning for any natural and man-made hazards and ranges from planned events to large-scale disasters. These include, but are not limited to the following:

Scenario Type: Loss of Building or Geographic Region
- Fire, Flood, Severe Weather, Power Failure

Scenario Type: Loss of Technology, Equipment or Telecommunications
- Technological Disasters, Cyber Security, Data Breach

Scenario Type: Loss of Resources or Pandemic
- Malicious Acts, Severe Weather

Scenario Type: Loss of Third-Party Vendor
- Severe Weather, Technology Disruption, Power Failure

Hazard Vulnerability Assessment

WFBH determines readiness for responding to all types of hazards by conducting an annual Hazard Vulnerability Assessment (HVA) using the following factors: probability of occurrence, magnitude (human impact, property impact, business impact), and mitigation (preparedness, internal response,

external response). Based on that assessment, WFBH and the Emergency Management Committee then structures mitigation improvements intended to decrease the high-risk vulnerabilities while coordinating with local, county, and state emergency management as appropriate.

Plan Development and Methodology

This document was developed by a collaborative planning process coordinated by the Manager, Emergency Management and Business Continuity. Department leadership and subject matter experts from participating areas also provided oversight and essential information that resulted in the development and validation of this plan.

Plan Development Assumptions

The successful implementation of this BCP in achieving its stated objectives is dependent on the following planning considerations and assumptions:

- The Hospital Incident Command System (HICS) is in place and select members will make the decision to activate a BCP in the event that any critical department is reduced or eliminated for any reason.
- The Emergency Operations Center (EOC) is operational, and staff is available to support continuity efforts throughout the event.
    - Relocation and Reestablishment of Essential Functions
- Department Subject Matter Experts are available to implement and manage response and recovery activities for the duration of the event.
- Departments must be capable of immediate activation and implementation of BCPs, with and without warning, and regardless of the emergency, disaster or event.
- BCP is scalable, both in scope and duration, depending on the emergency, disaster or event and fully operational no later than 48 hours after its activation.
- BCP is able to sustain all department critical operations indefinitely within seven days of its activation.

Channels of Communication and Authority

EOC leadership is responsible for overseeing the dissemination of internal and external communications during and after an emergency related event. Information regarding an emergency incident or unplanned disruption that needs to be communicated to third parties (e.g., other healthcare organizations, law enforcement, regulatory agencies, etc.) will be managed by Patient Relations under guidance from the Office of Privacy and Compliance according to normal operations and processes unless otherwise directed by the Hospital Incident Commander.

Emergency Notification

When an emergency is declared, Emergency Communications Operators notify key staff via the MIR-3 mass notification system (which simultaneously alerts staff both on and off campus) and overhead paging announcement.

Wake Forest uses multiple means of communication to staff, regional hospitals, Public Health and community partners. A summary of tools and methods available to ensure emergency notification include but are not limited to the following components. Refer to the EOP for a complete listing of available tools.

Telephones	Radios	Emergency	Other

		Notification System	
• ASCOM • Land-Line • Mobile • Satellite	• Hand-Held • Local EMS Radio	• MIR-3	• Overhead Paging • Alpha-Numeric Paging • Email • Wi-Fi Internet

Department Critical Contact Information
Critical internal and external contact information (e.g., hospital directory, department and third-party listings) are maintained and available in various sources. This includes but is not limited to SharePoint, Network Drive, and a Department Roster. In addition, department leadership maintains direct report contact information on cell phones.

Authority and Responsibility
Activation of the EOP, and any subsequent escalating or deescalating of the plan status (including initiation of recovery, evacuation or re-establishment of normal operations) is only done on the Authority and Responsibility of:

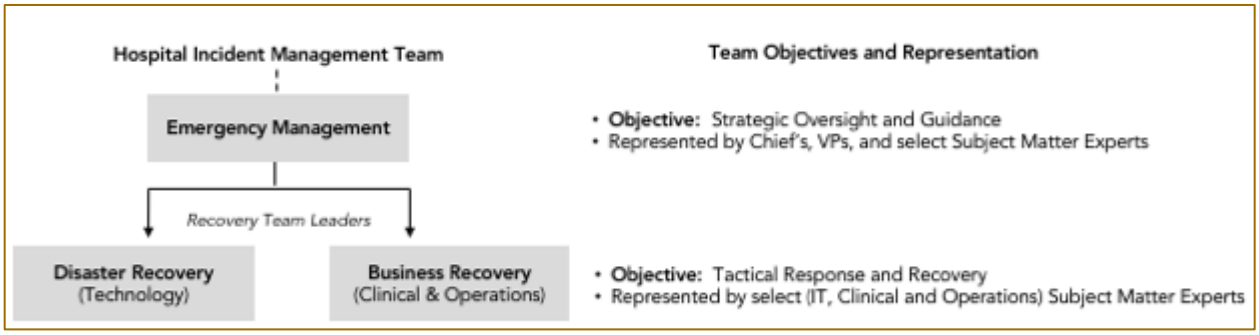
- Administrator On-Call (AOC)
- Associate Chief Medical Officer (ACMO)
- Emergency Department Attending Physician
- Nursing Operations Supervisor
- Chair of the Emergency Management Committee
- Manager for Emergency Management & Business Continuity

Devolution
If any WFBH facility is damaged beyond the ability to recover, the hospital will need to be shut down and patients transferred to other locations. Refer to the EOP for additional information.

Applicability to Other Plans
The associated internal documents and processes that can be referenced support and respond to an emergency related event or other unplanned disruption include but are not limited to:

- Hospital Incident Command System (HICS)
- Wake Forest Emergency Management Plan
- Downtime Procedures
- Building Evacuation Plans
- Information Technology Disaster Recovery Plans
- Department Specific Policies and Procedures
    - Blood Bank Policy – Unscheduled Interruptions Policy
    - Department of Pathology Laboratory Equipment Service Procedure
    - Laboratory Operations System Delay Notification Procedure
    - Emergency Operating Plan (Continuity of Business Plan) – Department of Pathology

Section III. Essential Staff Roles and Responsibilities



Hospital Incident Command System and Management Team

The HICS is an emergency management system that utilizes a logical management structure, defined responsibilities, clear channels of communication and authority, and a common language to help unify the hospital with other emergency agencies. HICS is the standard for disaster management and can be utilized to manage both small and large emergency and disaster situations within the hospital and for situations that occur externally requiring the involvement of the hospital. HICS is comprised of personnel with the knowledge and authority to provide support to the Emergency Response and Recovery activities.

Emergency Management

Emergency Management provides oversight, direction and actions when an unplanned disruption impacts the Wake Forest organization. The Director of Emergency Management works under the general direction of the Chief Operating Officer, Administration. The Director of Emergency Management in collaboration with other department heads, Safety Committee, and the Emergency Management Committee (EM) manages all aspects of the Emergency Management Program. The Director of Emergency Management advises the Safety Committee and the Emergency Management Committee regarding emergency management issues that may necessitate changes to policies, orientation, education, or purchase or procurement of supplies and equipment needed during a disaster.

Recovery Team Leader

The Primary and Alternate RTLs are appointed by department leadership and are primarily responsible for overseeing the response, recovery and reconstitution efforts in the event of a BCP activation. The RTL's are also responsible for BCP management and oversight that includes:

- Developing recovery strategies and ensuring succession planning for essential activities;
- Ensuring team members are trained and aware of their roles and responsibilities in the event of a BCP activation;
- Ensuring the BCP is continually updated to reflect the current operating environment; and
- Maintaining copies of the BCP and contact information on and off-site in hard copy or electronic format for use in an emergency or unplanned disruption.

Section IV. Time-Phased Implementation

This BCP considers the need for time-phased stages of implementation in recognition of the fact that department resources and responsibilities will shift depending on the type, scope and significance of the emergency or disaster; the day (weekday or weekend) and time (during or after hours) of the event; the extent to which department resources have been impacted; whether there was warning; and, the amount of time that has elapsed since the warning or occurrence of the emergency event or disaster.

A time-phased implementation of the BCP identified below, provides a way to prepare for all levels of an emergency and/or potential emergency. The recovery strategies and options identified within Sections I.I – I.IV provide guidance for a time-phased implementation.

Response (Phase I)
During this phase, notification to the appropriate employees and other organizations identified as "critical stakeholders" will be done. It is during this phase that essential staff will begin to assess resource limitations, specific needs, and availability to transition to alternate operations and/or modify activities to ensure continuity of essential activities.

Recovery (Phase II)
During this phase, the department is focused on the continued reallocation of its resources to support and restore its functions and operations as needed and appropriate, establishing manual work-around procedures required to support essential functions, and developing plans to sustain operations over long periods of time and to increase functionality. In the event of a building closure or partial disruption, this may also include the execution of essential operations at alternate operating facilities. In general, first priority for recovery will be to patient care and essential support services.

Reconstitution (Phase III)
Once it is confirmed that essential infrastructure and supplies are available, services may be resumed at primary workspace. The four key phases of reconstitution for any type of operating space include:

- Re-Enter the physical space
- Re-Open the physical space (replenish supplies, equipment, and staff)
- Repatriation of patients, if a patient care area
- Resumption of normal service delivery

Appendix A. Department Overview

Plan Information

Stakeholder Contact Information

The Department of Pathology maintains a phone tree of Pathology and Clinical staff for emergency response. It is the responsibility of the Laboratory Administration to implement department level notification of staffing using this directory. In addition, each leader is responsible for notifying internal and external stakeholders within their area of responsibility of emergency incidents or other unplanned events. For confidentiality purposes, all contact information has been intentionally omitted from this document.

Essential Services

Essential services and functions are considered critical, important, and/or essential to the mission of the organization (e.g., <72 Hours). The functions that fall under these categories cannot be deferred during an emergency, must be performed continuously or prioritized by the Recovery Time Objective that was identified during the Business Impact Analysis. An RTO of a business process or application is the determination of how quickly it must be recovered following an emergency incident.

Hours of Operation	24/7/365 Main Hospital, 7:00 AM – 5:00 PM Outpatient

Essential Function & RTO	Clinical Lab and Pathology Tests and Interpretation (<4 Hours) • All lab/pathology tests, pathologist reads and interpretations
Staff Count	One hundred and eighty
Cross Trained Staff Identified	Yes **Single Points of Failure?** No
Contractual Obligations	Not Applicable
Service Level Expectations	Stat: 60 minutes, Routine: 2 hours

Essential Function & RTO	Equipment Maintenance and Repair (<4 Hours) • Maintenance, repair and/or replacement of lab equipment
Staff Count	Fourteen
Cross Trained Staff Identified	Yes **Single Points of Failure?** No
Contractual Obligations	Not Applicable
Service Level Expectations	Based on Need

Essential Services (continued)

Essential Function & RTO	Supply Orders (<24 Hours) • Ordering standard and specialty items
Staff Count	Sixteen
Cross Trained Staff Identified	Yes **Single Points of Failure?** No
Contractual Obligations	Not Applicable
Service Level Expectations	Based on Need

Essential Function & RTO	Staff Scheduling (<72 Hours) • Scheduling staff 1-4 weeks out, adjustment made as needed
Staff Count	Five
Cross Trained Staff Identified	Yes **Single Points of Failure?** No
Contractual Obligations	Not Applicable
Service Level Expectations	Based on Need

Essential Function & RTO	Department Administration (<7 Days) • Non-clinical department tasks: Budget, HR, Finance, Compliance
Staff Count	Eleven
Cross Trained Staff Identified	Yes **Single Points of Failure?** No
Contractual Obligations	Not Applicable
Service Level Expectations	Based on Need

Essential Function & RTO	Lab Training (<7 Days) • Competency training for new staff, hands-on training w/mentor
Staff Count	Five
Cross Trained Staff Identified	Yes **Single Points of Failure?** No
Contractual Obligations	Not Applicable
Service Level Expectations	Based on Schedule

Regulatory Requirements

As with all health organizations, WFBH must adhere to the applicable state and federal codes of practice and directives as set forth by the following regulatory agencies:

- College of American Pathologists
- Clinical Laboratory Improvement Amendments (CLIA)
- Food & Drug Administration (FDA)
- Occupational Safety and Health Administration (OSHA)

Technology

The following is a list of standard and common systems and applications used by the majority of the organization in addition to department specific requirements. These components are listed by RTO and associated Recovery Point Objective (RPO). The RPO is defined as how much permanent data loss a process can tolerate in its dependent applications before it is critically impacted.

Legend RTO 1 (4 Hours), RTO 2 (12 Hours), RTO 3 (24 Hours), RTO 4 (72 Hours), RTO 5 (<7 Days), RTO 6 (>7 Days)
RPO 0 (No Data Loss), RPO 1 (4 Hours), RPO 2 (12 Hours), RPO 3 (24 Hours), RPO 4 (> 24 Hours)

Enterprise-Wide Technology Requirements

System/Application Name	Lowest RTO	Lowest RPO
Core Connect	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Internet	RTO 1 (4 Hours)	Not Applicable
Intranet	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Network Drive (Secure and Share Drives)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
O365 Suite (Email, MS Office, Teams)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
SharePoint Online	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Video Conference/Web Conference Tools	RTO 1 (4 Hours)	Not Applicable
VPN and/or VDI Access	RTO 1 (4 Hours)	Not Applicable

Department Specific Technology Requirements

Clinical Lab and Pathology Tests and Interpretation

CareEvolve	RTO 1 (4 Hours)	Not Applicable
Data Innovators	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
EPIC (Beaker)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
EPIC (WakeOne)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
RapidComm	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Remisol	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
SCC (Blood Bank LIS)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Siemens UniPOC	RTO 1 (4 Hours)	RPO 0 (No Data Loss)

Technology (continued)

Department Specific Technology Requirements
Clinical Lab and Pathology Tests and Interpretation

System/Application Name	Lowest RTO	Lowest RPO
SPOT	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Telcor	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Title 21 Repository	RTO 1 (4 Hours)	RPO 0 (No Data Loss)

Equipment Maintenance and Repair

TRIMEDX Clinical Work Order System	RTO 1 (4 Hours)	RPO 0 (No Data Loss)

Supply Orders

Stratajazz	RTO 1 (4 Hours)	RPO 0 (No Data Loss)

Staff Scheduling

Schedule Anywhere	RTO 4 (72 Hours)	RPO 0 (No Data Loss)

Department Administration

Employee Health Portal	RTO 5 (<7 Days)	RPO 0 (No Data Loss)
HealthStream	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Kronos	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
RL6 Occurrence Reporting	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Stratajazz	RTO 1 (4 Hours)	RPO 0 (No Data Loss)

Lab Training

CareEvolve	RTO 1 (4 Hours)	Not Applicable
Data Innovators	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
EPIC (Beaker)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
EPIC (WakeOne)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
HealthStream	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Medical Training Solutions	RTO 5 (<7 Days)	RPO 0 (No Data Loss)
Remisol	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
SCC (Blood Bank LIS)	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Siemens UniPOC	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Telcor	RTO 1 (4 Hours)	RPO 0 (No Data Loss)
Title 21 Repository	RTO 1 (4 Hours)	RPO 0 (No Data Loss)

Equipment and Supplies

The following includes a summary of equipment and supplies required to support essential department activities. The IT Service Desk and/or specialty vendors can be contacted for the repair and/or replacement of items required to support continuity of operations.

Standard/Assumed Requirements

- Laptops/Tablet w/Remote Connectivity
- Desktops
- Network Printers
- Phone System/Cell Phones

Summary of Clinical Pathology Supply Requirements

- Beaker
- Biological Safety Cabinets
- Blood Bank Analyzers
- Blood Gas Analyzers
- Centrifuges
- Chemistry Analyzers
- Differential Counters
- DNA Analyzers
- Freezers
- Glasswares (beakers, flasks)
- Haemocytometer
- Hematology Analyzer
- Immunoassay Analyzer
- Incubators
- Irradiator
- LN2 Freezers
- Magnetic Stirrers
- Medical Autoclave
- Micropipettes
- Microplate
- Readers/Washers
- Microscopes
- Point of Care Analyzers
- Racks
- Refrigerators
- Test Tubes
- Urinalysis Analyzers
- Water Bath

- Packing Supplies: Styrofoam shippers, gel packs, absorbent material
- Phlebotomy Supplies: Needles, vacutainers, butterflies, gauze, alcohol pads, band aids, blood collection tubes, tourniquet

Summary of Anatomic Pathology Supply Requirements

- Microtomes
- DNA Sequencers/Analyzers
- Embedding Workstations
- Flow Cytometers
- Glass Slides
- Cutting blades for specimen grossing
- Water Baths
- Clinical microscopes
- Electron microscope
- Ultramicrotome
- Immunohistochemistry Stainers
- Liquid-based preparation processors
- Refrigerators/Freezers (-30C/-80C)
- Routine slide stainers
- Tissue processors
- Tissue section floating baths

  Shipping supplies: gel packs, bubble mailers, tape
- Centrifuges
- FNA supplies: needles, gauze, alcohol prep pads, bandaids, conical tubes, syringes
- Cryostats
- Grossing workstations/benches
- Chemical hoods
- Class II Biosafety Cabinets
- Pathology band saw
- Thermocyclers

In a relocation and/or emergency incident, a complete listing of essential equipment can be obtained from Financial Services – Asset Management. Also, depending on the event, essential equipment/supplies may need to be purchased to support recovery strategies.

Interdependencies

To perform mission critical services, the department depends on the internal and external resources identified in this section. For most external dependencies, the department will rely on internal methods for procuring staffing and resources via the Emergency Operations Center.

Clinical Lab and Pathology Tests and Interpretation

Internal	Essential Service/Information	Reliance
BioMed	Equipment maintenance, repair, replacement	High
Medical Records	Scan test results into WakeOne	High

External	Essential Service/Information	Reliance
LabCorp	Secondary Reference Vendor (testing)	High
Mayo	Primary Reference Vendor (testing)	High
Specialty Equipment Vendors	Equipment maintenance, repair, replacement	High

Equipment Maintenance and Repair

Internal	Essential Service/Information	Reliance
BioMed	Clinical equipment repair, maintenance	High
Engineering	Facilities Maintenance	High
Service Response	Engineering Call Center and Dispatch	High

External	Essential Service/Information	Reliance
Specialty Equipment Vendors	Clinical equipment repair, replacement	High

Supply Orders

Internal	Essential Service/Information	Reliance
Finance	Approval on items >$5k	High
Supply Chain	Purchase orders and processing	High

External	Essential Service/Information	Reliance
Fisher Scientific	Punch-Out Vendor	High
MedLine Industries	Supplies	High
Office Depot	Supplies	High

Interdependencies (continued)

Staff Scheduling

Internal	Essential Service/Information	Reliance
Phlebotomy	Assistance with in-patient activities	High

External	Essential Service/Information	Reliance
Aureus	Temporary (traveling) Lab staff	High

Department Administration

Internal	Essential Service/Information	Reliance
Employee Health	Staff oversight, tracking, reporting	High
Finance	Cost and budget oversight	High
Human Resources	Staff compliance and oversight	High
Legal	Contract approval and oversight	High
Patient Financial Services	Pre-authorization specific services, tests	High

External	Essential Service/Information	Reliance
Not Applicable		-

Lab Training

Internal	Essential Service/Information	Reliance
IT	Epic (Wake One, Beaker) training	High
Select Lab Staff	Lab training, compliance, and oversight	

External	Essential Service/Information	Reliance
Not Applicable		-

Vital Records

Identify records that if lost would result in significant impacts to the functions identified in this document.

Clinical Lab and Pathology Tests and Interpretation

Record	Source/Location	Reliance
Test Results	Primary: Epic (Wake One) Alternate: Beaker	High

Equipment Maintenance and Repair

Work Order Reference	Primary: TRIMEDX Alternate: Not Applicable	High

Supply Orders

Tracking of Orders, Inventory	Primary: Core Connect (Fiinancials) Alternate: Not Applicable	High

Staff Scheduling

Staff Schedules	Primary: Paper Copies (on site) Alternate: Schedule Anywhere, Email	High

Department Administration

Staff Records	Primary: Core Connect (HR) Alternate: Not Applicable	High

Lab Training

Training Records (for Joint Commissions)	Primary: HealthStream Alternate: Medical Training Solutions	High

Forms

List (existing) forms required to support workaround activities for essential functions.

Form Name	Source/Location
Not Applicable	Primary: Alternate:

Offsite Storage

List essential records that are sent to an offsite storage facility that could be recalled to support continuity of operations.

Record Name	Storage Facility/Location
Not Applicable	The information sent offsite consists of Quality Check and Quality Assurance records and not required for business continuity purposes.

Essential Data

List data or unique applications that are stored on a laptop and/or standalone machine and not backed up on the corporate network.

Location of Machine	Description of Data
• Decision Tree Algorithms • Infectious Disease Reports	Various components of these items may not be backed-up on the corporate network, however, some vendors have the information.

Negotiable Items

List negotiable items (petty cash, check stock) available in this department.

Item Description	Security Protocol
Not Applicable	

Appendix B. Distribution, Exercise and Maintenance

Distribution

The RTL will maintain a formal distribution list of individuals and organizations that have copies of the plan. Those on the distribution list will automatically be provided updates and revisions. Plan holders are expected to post and record these changes. Revised copies will be dated to show where changes have been made.

BCP Recipient (Name, Title, or Organization)	**Distribution Date**	**Plan Version** (See Cover Page)	**Delivery Method** (Paper, Electronic)
Lauren Elmore Primary RTL	9/2/2021	8/31/2021	Electronic
Dr. Eric Hsi Primary RTL (II)	9/2/2021	8/31/2021	Electronic
Dr. Gregory Pomper Primary RTL (III)	9/2/2021	8/31/2021	Electronic
Andrew Adams Emergency Management & Business Continuity	9/2/2021	8/31/2021	Electronic
Alvin Battle ITS Business Continuity Manager	9/2/2021	8/31/2021	Electronic

Training and Exercises

In accordance with industry best practices, WFBH must implement measures to ensure that BCPs are capable of supporting the continued execution of essential functions in the event of an unplanned disruption. It is suggested that the BCP be exercised annually to ensure that it remains accurate, comprehensive and current. Exercises can be announced or unannounced and are performed for the purpose of training and conditioning team members. The RTL is responsible for tracking BCP training and exercise activities within the following table.

Exercise Attendees (Name, BCP Role)	**Date**	**BCP Focus Area** (Exercise Type/Training)

Plan Maintenance

The BCP and support reference (e.g., contact listings, etc.) should reviewed on a regular basis to ensure the data remain accurate and current. The suggested frequency noted below is not a strict set of rules

or a substitute for good judgment and should be modified at the discretion of the RTL.

Item	Summary of Task(s)	Frequency
BCP	• Review, update, re-distribute to applicable stakeholders	Annual
Contact Lists	• Review, update, re-distribute (internal and external listings)	Quarterly
Loss of Building	• Maintain relocation site readiness (remote access capability)	Bi-Annual
Loss of Technology	• Validate manual workarounds for essential technology	Bi-Annual
Loss of Resources	• Maintain Succession Planning, Orders of Succession	Bi-Annual
Loss of Vendors	• Assess recovery capability for essential Vendors	Bi-Annual

Record of Changes

The BCP Template was developed by G. Sargent, MHA Consulting, and approved by the WFBH Business Continuity Steering Committee and Project Leaders (2/1/2021).

This BCP will undergo revisions and require RTL approval at a minimum every two years and/or in the event of a significant change within the department that impacts recovery strategies. Minor modifications that would not interfere with BRP activation (i.e., formatting) must be reviewed by the RTL but does not require formal approval.

The RTLs are responsible for tracking all BCP modifications within this section.

Date of Change	Section	Revised By (Name of Person)	Summary of Changes

Appendix C. Event Reporting and Tracking

Overview: Department staff are responsible for tracking and reporting recovery-related activities, expenses, and other notable incidents during an unplanned disruption.

Event Reporting Form

Event Title:		**Date:**	
Notified By (Name):		**Time:**	
Recovery Team Leader:			
Number of Stakeholders Impacted:			

Summary of Event:
Summary of Opportunities:
Summary of Action Items & Notable Incidents:

Office Relocation Tracking Form

The following matrix can be utilized during an event to track and report on the number of team members (and hardware) relocating to an alternate worksite (e.g., home, other).

#	Team Member	Processes Supported	Relocation Site	Company Property Taken Offsite	Date Items Returned
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					

Asset Management Tracking

Track and report on equipment and supplies that are purchased to support recovery strategies during an emergency incident or business continuity event.

#	Item & Serial Number	Recipient Name	Other Information
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Appendix D. BCP Approval

Succession of Execution

The successful execution of this BCP is dependent on the following factors:

- Departments have the ability and tools required to work from an applicable relocation site in the event the permanent work site is inaccessible. Examples of relocation sites that allow for continuity of essential activities include but are not limited to the following:
    - WFBH Network of Hospitals, Third-Party Colocation Site, Home Office

Enterprise and Department Specific BCP Opportunities

MHA recommends that the organization address the following opportunities prior to an unplanned disruption or emergency incident. Business continuity best practices demonstrate that having the following measures in place prior to an unexpected disruption will avoid delays in the response, recovery, and reconstitution of essential operations and minimize the impacts to service levels.

- **Enterprise Relocation Plan**. An Enterprise Relocation Plan needs to be developed to include alternate locations (or options) available for use by essential departments in the event of a short and long term building disruption. An approved strategy and plan in advance of a Loss of Building or Geographic Region scenario will avoid delays in the restoration and recovery of essential operations.

  Representation from the Department of Pathology and Laboratory Services, Information Technologies, BioMed, Environmental Services, and other applicable areas should be involved in the selection of relocation space/sites in addition to determining the applicable recovery strategies and timeline associated with relocating, configuring, and bringing essential items online in advance of a Loss of Building or Geographic Region scenario.

- **Third Party Business Continuity Plans.** The department RTLs need to coordinate efforts with the Manager, Emergency Management and Business Continuity, to implement a process to obtain BCPs and exercise results from essential and single-source third-party dependencies for regular review and validation. An assessment of these documents will determine if the third-party recovery strategies meet (or exceed) WFBH requirements.

BCP Concurrence

Your approval attests that this BCP was prepared with your knowledge and understanding. By approving this document, you affirm that you understand and accept responsibility for assignments and recovery strategies, and that you concur with the recovery time objectives associated with the essential activities identified within this document.

Recovery Team Leader Primary or Alternate	Dr. Gregory Pomper, Primary RTL (III) Email Approval | Notification: August 31, 2021