Wake Forest Baptist Medical Center	Department of Pathology Laboratory Equipment Maintenance Policy	Dept:	Pathology
		Effective Date:	
		Revised Date:	New
		Contact:	Laboratory Compliance, QA, POC, and Safety
Name & Title: Greg Pomper, MD		Date:	1/2/19
Signature: G Pom			

1) **General Procedure Statement:**

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.

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. **Responsible Department/Scope:**
   i. Procedure owner/Implementer: Department of Pathology
   ii. Procedure prepared by: Department of Laboratory Compliance, Quality and Safety
   iii. Supervision: Department of Pathology Laboratories Managers and staff.
   iv. Implementation: Department of Pathology Medical Director, Department of Pathology Manager and the CLIA Lab Director.

2) **Procedure:**

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 tags".

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 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 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.

c. **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.

3) **Review/Revision/Implementation:**
All procedures must be reviewed at least every 2 years.
   - All new procedures and procedures that have major revisions must be signed by the Department Chairman.
   - All reviewed procedures and procedures with minor revisions can be signed by the designated section medical director.

4) **Related Procedures:** See individual lab section manuals.

5) **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.

6) **Attachments:**

7) Revised/Reviewed Dates and Signatures:

Review Date	Revision Date	Signature