Equipment Calibration and Maintenance

1 Guiding Principles and Scope

1.1 Equipment maintenance, calibration, and performance checks are essential for establishing confidence in the results that are generated during routine testing of forensic DNA samples. The Department of Forensic Biology uses equipment, and associated software, which is suitable for the tests conducted and will not use equipment or software that is outside of its permanent control.

1.1.1 Software utilized by the laboratory, including software that controls scientific instruments, must be thoroughly validated according to federal laws and FBI standards. The version of software used by the laboratory is written for compatibility to specific operating systems. Operating systems get updated at a faster pace than laboratory software. Therefore, the Department must use the currently validated laboratory software until the Department can purchase, validate and implement newer versions of software that are compatible for the most up-to-date computer operating systems. See the Validation and Control of Data procedures in the Quality Assurance Procedures Manuals.

1.2 Equipment and its associated software are operated solely by trained and authorized laboratory personnel. Vendor equipment manuals are maintained and are available to all laboratory personnel on the Forensic Biology network.

1.3 All laboratory equipment is given a unique identifier by the laboratory. This unique identifier, as well as the manufacturers unique identification, and the instrument's current location, is maintained within the LIMS. Maintenance, calibration, and performance check information specific to each instrument is maintained within the LIMS. Software records are maintained in Qualtrax (see the Control of Data Procedure). Equipment maintenance schedules are maintained by the Quality Assurance Team.

2 Critical Equipment

2.1 "Critical equipment" is that which requires calibration or a performance check prior to its use in casework and periodically thereafter. Such equipment must have records of calibration and/or preventative maintenance. Specific calibration, performance check, and/or preventative maintenance programs and procedures for critical equipment are found in the Quality Assurance/Quality Control Procedures Manual.

2.2 Critical equipment must have maintenance usage logs.

2.3 The following is "critical equipment" used within the Department of Forensic Biology for DNA testing:

- Heat blocks/Incubators used in analytical procedures
- Thermal cyclers
- Real-time PCR systems
- Robotic systems
- Mechanical pipettes
- Thermal cycler temperature-verification systems
- Electrophoresis detection systems, including Genetic analyzers
- Rapid DNA Instruments
- Thermometer traceable to national or international standard(s) used for performance checking of critical equipment.
- Any additional instruments or equipment that produce DNA typing results

2.4 Thermomixer, Thermostats and other equipment that function as heat blocks in analytical procedures are also considered critical.

3 Non-Critical Equipment

3.1 All other equipment that is not covered under the definition of a "critical equipment," as per the FBI Quality Assurance Standards for Forensic DNA Testing (July 2020) is considered "non-critical." Examples of such equipment include pH meters, vortexers, and centrifuges.

3.2 The Department shall strive to conduct preventative maintenance on all non-critical equipment whenever feasible; however, it is not required to do so.

4 General Preventative Maintenance

4.1 Maintaining cleanliness of any scientific equipment is the key to preventive maintenance. Spills must be taken care of IMMEDIATELY. Some spills may be corrosive to neighboring equipment and cause more damage than necessary. While some spills can be cleaned at the desk, some will require special treatment and/or additional follow-up. It is always best to contact the Forensic Biology Safety Coordinator or the OCME Health and Safety Unit for further information where needed.

5 Equipment Decontamination

5.1 Various Quality Control Procedures have been developed to help maintain a DNA-free environment at the points of sample contact with the equipment used in DNA analysis. A 10% bleach solution is extremely effective in degrading DNA and is thus used for general cleanup procedures of equipment and the laboratory environment (e.g. laboratory desks and benches). Because of its corrosive nature, the use of 10% bleach should be followed by the use of 70% ethanol and/or deionized water, unless specific instructions from the vendor state otherwise. Do no use Ethanol on acrylic surfaces, or bleach on instruments that are used with specific chemicals

as stated in manuals. Decontamination of equipment should be done before movement of equipment from one lab space to another or removal from the laboratory permanently.

6 Instrument Irregularities

6.1 Anyone observing any irregularities with any equipment may suspend the equipment from casework use to prevent the potential loss of sample. If this occurs, the Quality Assurance Unit and/or the appropriate Technical Leader must be notified shortly thereafter for follow-up. If the irregularity cannot be repaired and must be taken offline, the equipment must properly be marked to prevent further use.

6.2 Prior casework performed on an instrument exhibiting irregularities may be evaluated to determine if the equipment irregularities affected casework results. This will occur on an as-needed basis. If casework results have been affected, the CONTROL OF NON-CONFORMING WORK procedure shall be followed.

6.3 Should repair and/or re-calibration occur, only designated Quality Assurance Unit members or the appropriate Technical Leader may re-certify that the equipment is available for casework. Instruments taken offline are taken out of service in LIMS so they cannot be selected for casework use. Any equipment taken offline for an extended period of time must either be removed from the bench, or a sign must be placed on the equipment to ensure that it is not used until appropriate repairs are made.

6.4 Re-certification requires that a designated Quality Assurance Unit member and/or the appropriate Technical Leader ensure that any required performance checks have been successfully completed, documentation that the instrument is available for casework has been entered in the appropriate maintenance log (hard copy or LIMS), and any signage to indicate otherwise is removed.