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The quality assurance plan as presented in the Quality Manual should assure that constant and consistent test conditions are met and verified and should be tailored to the laboratory's activities. Quality control checks on equipment should be documented. The laboratory could use a bound notebook, three-ring binder, spreadsheet, database, or an equivalent, permanent record. At a minimum, the following items and associated records (as applicable) are to be included. Laboratories are required to follow the most stringent policies when methodologies and regulations differ.

#### **EQUIPMENT**

#### 1. Analytical balance

- <u>Annually</u>, analytical balances must be serviced by a qualified service organization and calibrated using acceptable methods, such as ASTM method E898, over the entire range of use.
  - Record: (1) list of balances including date of service and certificate of weight traceability, (2) service organization sticker with date of service fixed to each balance, and (3) calibration data.
- Daily, or with each use analytical balances must be checked in the working range daily or with each use with NIST-traceable weights (e.g., NBS Class S or ASTM Class 1). The range selected is to reflect the routine use of the balance and the actual weights used should test the optical scale at mid-point. For example, a sewage treatment plant laboratory that uses an analytical balance having an optical scale principally for gooch crucibles and evaporating dishes would select weights having target values of 20.0500 g and 50.0500 g. To do this, three weights are required: 20 g, 50 g and 50 mg.
  - Record: In a notebook, spreadsheet, or database set up in a tabular format, the (1) date, (2) target and actual readings and (3) analyst's initials.
- NIST traceable weights also need to be verified by an accredited calibration laboratory / firm with traceability back to NIST (SI) standards.
   At a minimum, the weights must be verified every five years.\*
  - \***NOTE:** The frequency may be increased dependent upon the usage and condition of the weights.
    - **Record:** Keep calibration certificate issued by manufacturer.

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### 2. Top-Load or Pan Balances

Top-load or pan balances is to be capable of detecting at least 100 mg for a load of 150 g and 1 mg for a load of 10 g or less when used for bacteriological media preparation and solid sample preparation (EPA 815-R-05-004).

- **Annually**, top-load or pan balances are to be cleaned and serviced by a qualified service organization and calibrated using acceptable methods, such as ASTM E898-88 (2005), over the entire range of use.
  - Record: (1) List of balances including date of service and Certificate of Weight Traceability, (2) Service organization sticker with date of service fixed to each balance, and (3) Calibration data.
- **Daily or with each use**, top-loading or pan balances must be checked **daily or with each use** using NIST-traceable weights (e.g., NBS Class S or ASTM Class 1) over the range representative of routine use.
  - **Record**: In a notebook, spreadsheet or database set up in a tabular format, the (1) date, (2) target and actual readings and (3) analyst's initials.

#### 3. pH Meter

The pH meter must be calibrated according to manufacturer's instructions. pH meters are to be calibrated using standard buffers *daily or with each use*, whichever is less frequent.

- For pH meters that display the slope after each calibration, record this value on each *day-of-use*.
  - Record: In a tabular format in a notebook, spreadsheet or database the (1) date and time of analysis, (2) pH buffer target values, (3) actual reading(s), (4) slope readings, if applicable to pH meter in use, (5) temperature at which pH was read, (6) lot numbers of standards/buffers, and (7) analyst's initials.

## 4. Conductivity meter and cell

• The conductivity meter and cell must be calibrated according to manufacturer's instructions *daily or with each use*, whichever is less frequent.

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Record: In a tabular format in a logbook, spreadsheet or database (1) date, (2) target value, (3) actual reading, (4) temperature, and (5) analyst's initials.

#### 5. Dissolved Oxygen Meter

- The dissolved oxygen (DO) meter and probe must be calibrated *daily or with each use*, whichever is less frequent. The meter may be calibrated according to the manufacturer's instructions or by the Winkler method which utilizes titration.
  - In the Winkler method, three biological oxygen demand (BOD) bottles are filled with aerated distilled water using a syphon. The dissolved oxygen concentration is determined in two of the three BOD bottles. The third BOD bottle is used to calibrate the meter at the average DO concentration found. Calibration against air saturated with water vapor is acceptable.
  - Record: In a tabular format in a logbook, spreadsheet or database
    (1) date, (2) titrants, (3) actual DO values, (4) average DO value, and (5) analyst's initials.

#### 6. Spectrophotometers

- NIST traceable color standards, or their equivalent, must be available to verify the wavelength settings on spectrophotometers. The settings must be checked *annually*.
  - Record: In a tabular format in a logbook, spreadsheet or database (1) date, (2) target value, (3) actual reading, and (4) analyst's initials.

## 7. Turbidimeters

- Turbidimeters should be checked *daily or with each use*, whichever is less frequent with formazin or an equivalent standard in the range(s) of interest.
  - Record: In a tabular format in a notebook, spreadsheet or database (1) date, (2) target value, (3) observed value, and (4) analyst's initials.

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#### 8. Thermometers

Laboratories **<u>must</u>** have a documented procedure for verifying thermometers.

#### 8.1 – Reference Thermometers

- Each laboratory shall must have access to a manufacturer-certified, NISTtraceable, thermometer, or use of a calibration service provider for the purpose of verifying their working thermometers. Certification shall must cover be at points of interest (temperatures of use) to the laboratory. Correction factors from the reference thermometer certificate must be applied. After the first year of service and **annually** thereafter, the certified thermometer must be verified calibrated. A single-point verification at ice-point must be used. If the ice-point temperature determination does not match the certificate value, adjust all subsequent temperature readings by the same amount. The NIST-traceable reference thermometer must be re-certified, at a minimum, every 5 years unless the manufacturer/calibration service requires recertification earlier.
  - Record: In a tabular format in a notebook, spreadsheet or database (1) date, (2) ice-point reading, (3) ice point adjustment to be made to the correction factors, (4) new correction factors, and (5) analyst's initials.

\*The corrected value of a reference thermometer is the observed temperature plus the correction factor.

#### 8.2 – Working Thermometers

- Temperature measuring devices shall must be calibrated or verified at least every 12 months, except for the IR gun and dial (Table 1) annually. Calibration or Verification is conducted using a certified traceable reference, such as the manufacturer-certified NIST-traceable reference thermometer. This can be done internally or by an outside calibration service provider. recognized National Metrology Institute traceable reference, such as NIST, when available.
  - If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable.
  - (ii) If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use.

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 Record: In a tabular format in a notebook, spreadsheet or database, (1) date, (2) reference thermometer reading (3) reference thermometer corrected value\* (4) working reading (5) new correction factors, and (6) analyst's initials.

\*The corrected value of a reference thermometer is the observed temperature plus the correction factor.

This requirement may be fulfilled using a digital thermometer, thermocouple, or other similar electronic temperature measuring device, but it must be calibrated at a frequency specified by the manufacturer and/or calibration service provider for calibration at all points of interest instead of performing an ice-point in-house. For liquid in glass NIST reference certified thermometer used in association with physical, chemical, and microbiological analysis, verify its accuracy as specified on the certificate of calibration or at least every 5 years.

- Working liquid in glass or digital thermometers may not be used for over a year without verification, even if they are supplied with a certificate verifying for >1 year.
- Every laboratory must have a sufficient number of working thermometers so that each may have a dedicated use. Each working thermometer shall must be uniquely identified by number and calibrated at the temperature(s) of interest prior to being placed into service and at the frequency specified below thereafter:

Table 1	
Measuring Device	Frequency
Liquid (spirit) in glass	Annually
Mercury in glass	Annually
Digital, thermocouple or	Annually
other similar device	
Dial	Quarterly
Infrared (IR) gun	Quarterly <sup>A</sup>

<sup>A</sup> – In addition, it is recommended that an IR gun be checked daily (on day of use) at a single point.

Mercury in glass thermometers that have separated columns are to be removed from service. If the thermometer differs by more than 1°C from the reference thermometer, it is to be discarded.

**Record**: In a tabular format in a notebook, (1) date, (2) thermometer ID, (3) calibration temperatures, (4) correction factors, and (5) analyst's initials.

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- Additionally, for equipment requiring temperature monitoring, including refrigerators, BOD incubators, bacteriological incubators, ovens and autoclaves, a digital thermometer may be used. Digital thermometers, thermocouples, or other similar electronic temperature measuring devices are exempted from the requirement that it be immersed in sand or water if the temperature measurement can be taken without altering the environment being measured (i.e., the door doesn't need to be opened to read the thermometer). If the environment being measured requires alteration to read temperature, the thermometer must be immersed in sand or water.
- For temperature measuring devices associated with asbestos analysis, please refer to the approved NYS DOH method (198.1, 198.4, 198.6, and 198.8) for additional information.

## 9. Refrigerators

- Laboratory refrigerators must maintain a temperature of 0° to 6°C. Refrigerator temperatures are to be checked *each day of use*. Temperature readings are to be taken using a dedicated and calibrated thermometer, having its bulb immersed in a liquid and kept in the refrigerator. The thermometer is to have graduations of no greater than 1°C.
  - Record: In a tabular format in a notebook, spreadsheet or database (1) date, (2) times, (3) temperature readings and (4) analyst's initials.

#### 10. Freezers

- Freezers must maintain a temperature of -5 to -15°C. Temperatures are to be checked **each day of use**. A recording thermometer and alarm system are highly desirable. Freezers should be defrosted and cleaned **annually (semiannually if needed)**.
  - Record: In a tabular format in a notebook, spreadsheet or database (1) date, (2) times, (3) temperature readings and defrosting/cleaning and (4) analyst's initials.

## 11. Biochemical Oxygen Demand (BOD) Incubators

• BOD incubators must maintain a temperature of 20° <u>+</u> 1°C. Temperature readings are to be taken using a calibrated and dedicated thermometer having its bulb immersed in liquid and kept in the incubator. The thermometer should have graduations no greater than 0.2°C.

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Temperature readings should be taken at least *daily* (on day of use), while samples are under test.

 Record: In a tabular format in a notebook, spreadsheet, or database (1) date, (2) times, (3) temperature readings and (4) analyst's initials.

#### **12. Bacteriological Incubators**

- Air bath bacteriological incubators used for the determination of total coliform and standard plate counts must maintain a temperature of 35° ± 0.5°C. The incubator temperature should be monitored at the top and bottom shelves of the incubator interior. Thus, each shelf should have a calibrated and dedicated thermometer with graduations no greater than 0.5°C (preferably, 0.1 °C increments) and the bulb immersed in liquid. Temperature readings must be taken at least *twice daily* (on day of use) with readings separated by at least four (4) hours.
  - **Record**: (1) Date, (2) times, (3) temperature readings, and (4) analyst's initials in a tabular format in a notebook, spreadsheet, or database.
- Circulating, water bath bacteriological incubators used for the determination of fecal coliforms must maintain a temperature of 44.5° + 0.2°C and be equipped with a gable cover. A calibrated and dedicated thermometer having graduations no greater than 0.2°C are to have the bulb immersed in the water bath. Temperatures must be read at least *twice daily* (on day of use) with readings separated by at least four (4) hours.
  - **Record**: (1) Date, (2) times, (3) temperature readings, and (4) analyst's initials in a tabular format in a notebook, spreadsheet, or database.

## 13. Bacteriological Ovens

 Ovens used for drying and/or sterilization must be maintained at the target temperature of interest during use. Oven temperatures are to be checked at the beginning and at the end of each cycle. Temperatures are measured using a calibrated, dedicated thermometer. The thermometer are to have graduations no greater than 1°C. If the oven door must be opened to read the thermometer, the thermometer's bulb is to be immersed in a sand bath.

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- Record: (1) Date, (2) target temperature, (3) time and temperature at the start and at the end of the cycle, (4) oven use or contents (e.g., "dried total suspended solids for sample number ..." or "sterilized 5 pipets" or "20 120-mL sample bottles") and (5) analyst's initials in a tabular format in a notebook, spreadsheet, or database.
- Spore strips must be used *monthly* to confirm sterilization of contents used for bacteriological analyses. Ampules are not recommended for hot air ovens because they may explode.
- Heat-indicating tape must be used with each load associated with bacteriological analyses.

# 14. Ultraviolet Light Sterilizers / Germicidal Units

- An ultraviolet (UV) sterilization or germicidal unit (254-nm) must be disconnected monthly and the lamp cleaned by wiping with a soft cloth moistened with ethanol. A longwave unit (365-366 nm), used for fluorometric tests, is to also be kept clean.
- New or re-lamped UV sterilizers are to be checked initially and *quarterly* thereafter. Quarterly checks may be done using either the agar spread plate irradiation test or a UV light intensity meter. If the UV light intensity meter is to be used for quarterly checks, an initial reading is to be taken when the unit is first placed into service or has been re-lamped. If the initial spread plate test is satisfactory, the initial UV light intensity can be used as a reference point for ensuing checks. The lamp should be replaced if it emits less than 70% of its initial output or if an agar spread plate containing 200 to 250 microorganisms, exposed to the UV light for two minutes, does not show a count reduction of 99%.

## • Record:

(1) For new or re-lamped units:

(1) Date, (2) control plate count, (3) irradiated plate counts, (4) kill efficiency for each irradiated plate, (5) UV light intensity (optional), and (6) analyst's initials in a logbook, spreadsheet, or notebook.

- (2) For quarterly checks:
  - a.) Irradiated spread plate test (1) Date, (2) control plate count, (3) irradiated plate counts, (4) kill efficiency for each irradiated plate, (5) UV light intensity (optional), and (6) analyst's initials in a logbook.

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b.) UV light intensity meter - (1) Date, (2) light intensity of new or re-lamped unit, (3) current light intensity, (4) the ratio of the current intensity to the new intensity expressed as a percentage, and (5) analyst's initials in a logbook, spreadsheet, or database.

#### 15. Autoclaves

- Autoclaves must maintain sterilization temperatures during the sterilization cycle and complete the entire cycle within 45 minutes when a 10-12 minute sterilization period is used. Autoclaves are to be equipped with a separate calibrated thermometer and a separate pressure gauge. Stripchart recording of temperatures is acceptable providing the chart is annotated as indicated below.
- Autoclave (or heat-indicating) tape must be used with each load to indicate that the load has been properly processed. Sterilization shall must be confirmed using appropriate biological indicators, such as spore strips or spore ampules, on a *monthly* basis. If temperature recording is not available, the demonstration of sterilization with biological indicators shall must be performed on a *weekly* basis.
  - Record: (1) Date, (2) description of contents, (3) time material was placed in autoclave, (4) sterilization temperature, (5) time material was removed from the autoclave, and (6) analyst's initials in a logbook, spreadsheet, or database.
- Both automatic and mechanical timing devices should be checked *quarterly* with a stopwatch or other timepiece.
  - **Record:** (1) Start time, (2) end time, (3) date, and (4) analyst's initials in a logbook, spreadsheet, or database.

#### **16. Volumetric Dispensing Devices**

- Repipets<sup>®</sup>, Eppendorfs<sup>®</sup>, and other pipets and automatic dilution/dispensing devices shall must be maintained in proper working order.
- Mechanical volumetric dispensing devices shall must be calibrated quarterly. An acceptable method of calibrating dispensing devices involves the use of high purity water and a calibrated analytical balance. Utilizing the principle that 1.0 ml of water = 1.0 g, pipet an appropriate

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volume of high purity water into a tared vessel on an analytical balance. Calculate the % accuracy and % error. For further details on calibrating on mechanical volumetric devices, refer to ASTM method E542.

Example: A fixed delivery pipet of 100  $\mu$ l (or 0.1 ml) yields a result of 0.097 g when weighed on an analytical balance. The expected value should be 0.1 g. Therefore, the accuracy is 97%. (0.097  $\div$  0.1) x 100 = 97%, or 3 % error

Record: In a logbook, spreadsheet, or database (1) weights, (2) volumes, (3) calculations, (4) % error, (5) date, and (6) analyst's initials.