

**APPENDIX N
GENERAL
REQUIREMENTS
(REV. 10/13)**

ITEM 1: WORK AREA

- ▣ Ample working space and utilities
- ▣ Clean and well ventilated, test kits used in temperature range specified by manufacturer
- ▣ Adequate lighting-meaning at least 50 foot candles at working surface, but preferably 100 foot candles
- ▣ Eating and drinking not permitted in immediate testing area





ITEM 2: STORAGE SPACE

- ▣ Cabinets, drawers, shelves adequate
- ▣ Areas neat, clean, and orderly

ITEM 3: THERMOMETERS

- ▣ Thermometers traceable to NIST certified thermometer. Certified thermometer must have current valid certificate available.
- ▣ NIST thermometer checked at ice point, annually, preferably just before checking test thermometers
- ▣ Range of thermometers appropriate for designated use
- ▣ Graduation not greater than 1.0°C for Screening Only facilities; Milk Industry and CIS facilities 0.5°C



Mercury in glass NIST certified thermometer

Digital NIST certified thermometer





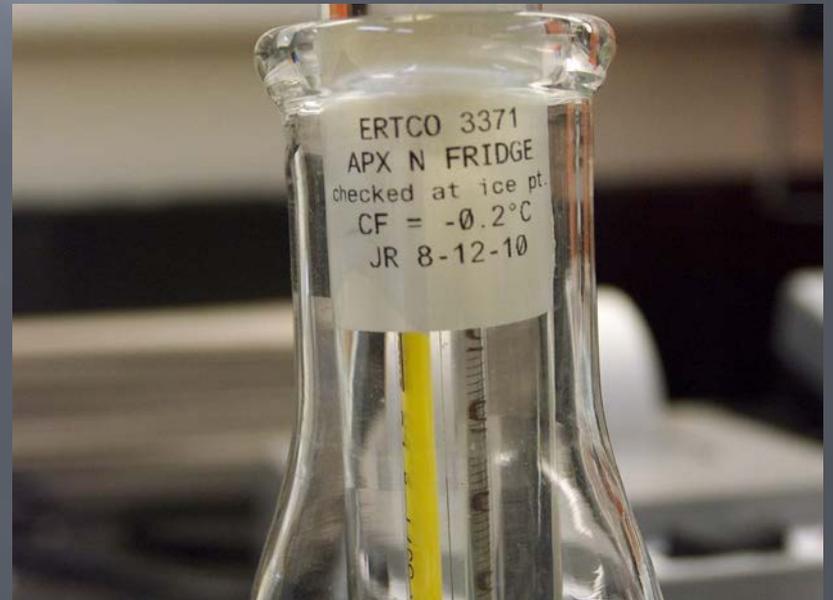
NIST thermometer tagged with results of ice point check

ITEM 3: THERMOMETERS

- ▣ Accuracy of test thermometers checked against certified NIST thermometer before initial use and annually, with a correction factor not to exceed $\pm 1^{\circ}\text{C}$
- ▣ Results recorded on BFSLS 515 (Rev 1/14) Thermometer Accuracy Check Log
- ▣ If certified NIST thermometer has a correction factor at ice point, use form BFSLS 515a and record raw and corrected NIST thermometer temperatures

ITEM 3: THERMOMETERS

- ▣ Thermometer tagged with date, identification/location, temperature checked, analyst's initials and any applicable correction factor (0.0°C, if none)
- ▣ Dial thermometers are not permitted in the testing area / laboratory!
- ▣ Automatic temperature recording instruments, if used, are to be compared weekly against an accurate thermometer with results recorded



ITEM 4: REFRIGERATION

- ▣ Size adequate for workload
- ▣ Must maintain samples at 0-4.5°C; if not, take corrective action and document!
- ▣ Documentation must include a recheck temperature taken 1-2 hours after correction
- ▣ Reagents must be stored according to manufacturer's instructions
- ▣ Not to be used to store food or drink for consumption



ITEM 4: REFRIGERATION

- ▣ Record temperatures twice daily (AM and PM) using two thermometers with bulbs submerged in liquid, placed on upper and lower shelves of the refrigerator
- ▣ Temperatures are to be read and recorded to the nearest 0.1°C.

ITEM 5: FREEZER

- ▣ Size adequate for workload
- ▣ Maintain temperature -15°C or below; if not, take corrective action and document!
- ▣ Documentation must include a recheck temperature taken 1-2 hours after correction.
- ▣ Reagents must be stored according to manufacturer's instructions
- ▣ Not to be used to store food or drink for consumption

ITEM 5: FREEZER

- ▣ Record temperatures twice daily (AM and PM) using thermometer(s) with bulbs submerged anti-freeze liquid
- ▣ Temperatures are to be read and recorded to the nearest 0.1°C.

ITEM 6: BALANCE

- ▣ Weight capability appropriate for intended use
- ▣ Appropriate sensitivity for accuracy check of pipetting devices within a tolerance of $\pm 5\%$
- ▣ Balance checked monthly with Class S or S1, or equivalent ASTM 1, 2, 3 weights with results recorded on BFSLS 497(Rev. 1/14)
- ▣ Weights have a valid certificate or other verification of authenticity
- ▣ Balance checked annually by a qualified service representative with records maintained



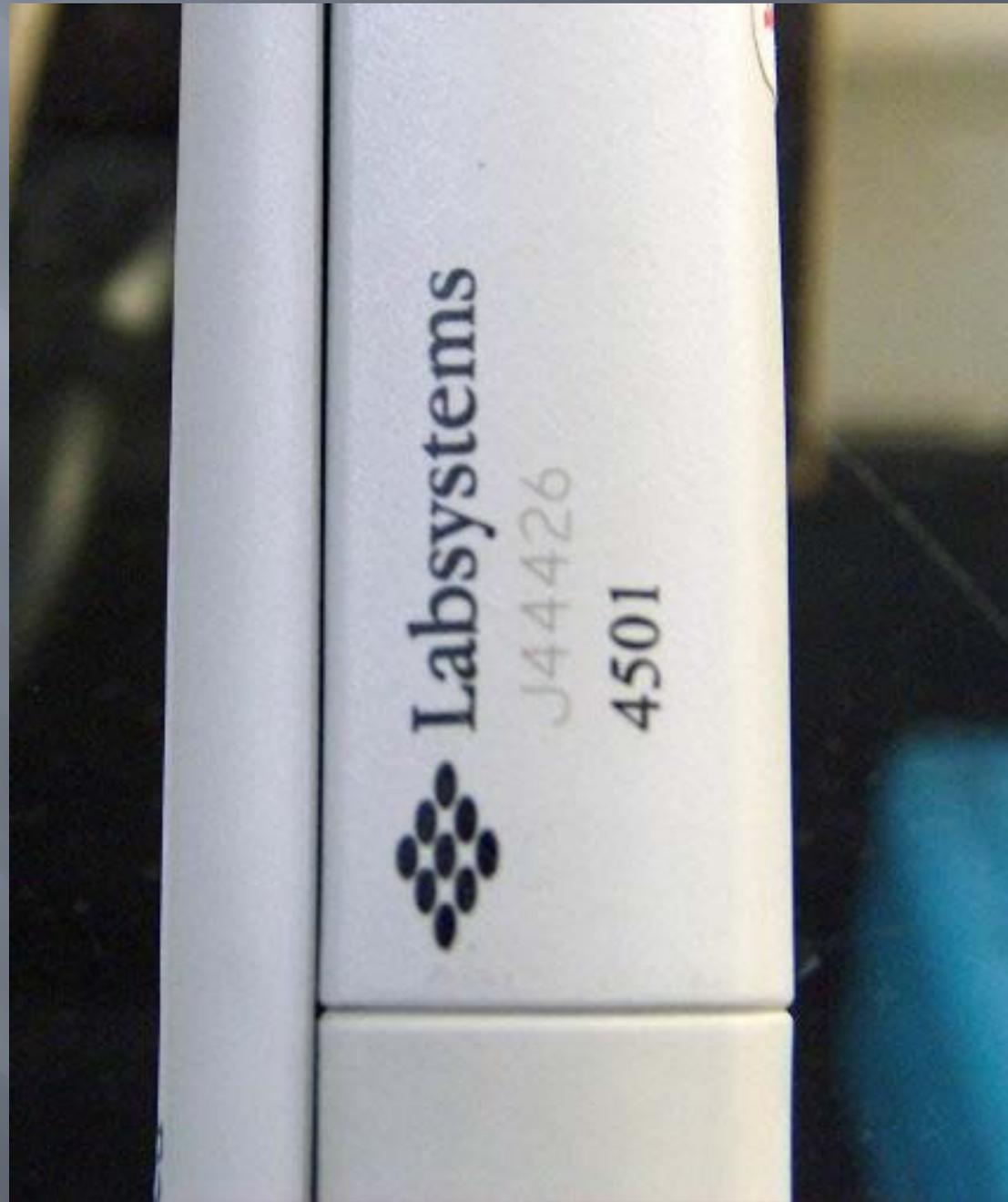
ITEM 7: PIPETTERS

- ▣ Checked for accuracy every 6 months with ten (10) consecutive measurements by weight or, by volume for pipettors of >1.0 ml using a Class A graduate
- ▣ Average of all ten measurements must be $\pm 5\%$ of the specified delivery volume

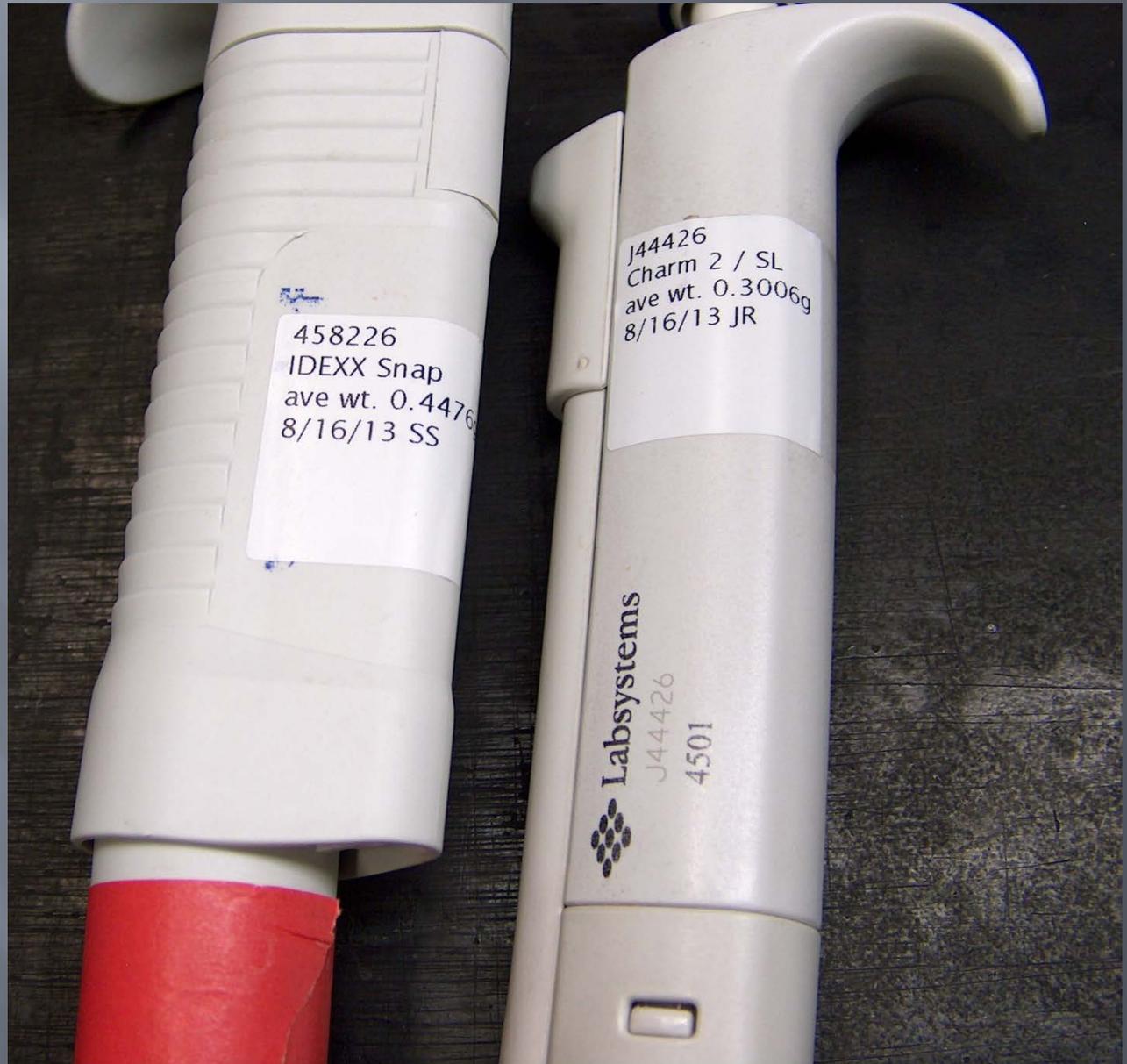
ITEM 7: PIPETTERS

- ▣ Pipettors must be etched with identification
Imprinted serial numbers are acceptable
- ▣ Pipettors are tagged with the date and analyst
of accuracy check
- ▣ Accuracy check records must be current and
acceptable whether checked onsite or at
another location
- ▣ Records maintained (BFSL 503, rev. 1/14)

Pipettor with
imprinted serial
number



Pipettors tagged
with date & results
of accuracy check
and analyst



ITEM 9: SAMPLE REQUIREMENTS

- ▣ Prevent contamination with disinfectants from hands or other sources
- ▣ Pipet tips or disposable pipets, test kits must be decontaminated before discarding, i.e. sanitizing solution used in plant is fine (200ppm chlorine or 25ppm iodine)



Container with 200ppm bleach solution and appropriate test kit



Waste bag for use in autoclave

ITEM 9: SAMPLE REQUIREMENTS

- ▣ Ascertain temperature of bulk milk tanker
- ▣ A TC (temperature control) sample must be taken, transported, and maintained with the tanker sample until it is tested
- ▣ Secure a representative sample for drug residue testing and transport promptly to testing location on ice to maintain temperature

ITEM 9: SAMPLE REQUIREMENTS

- ▣ Tanker samples tested promptly upon arriving at the testing location, measure TC provided
- ▣ If test kit indicates a positive result, confirmation must be completed within 72 hours of initial collection(time of truck sampling)

ITEM 9: SAMPLE REQUIREMENTS

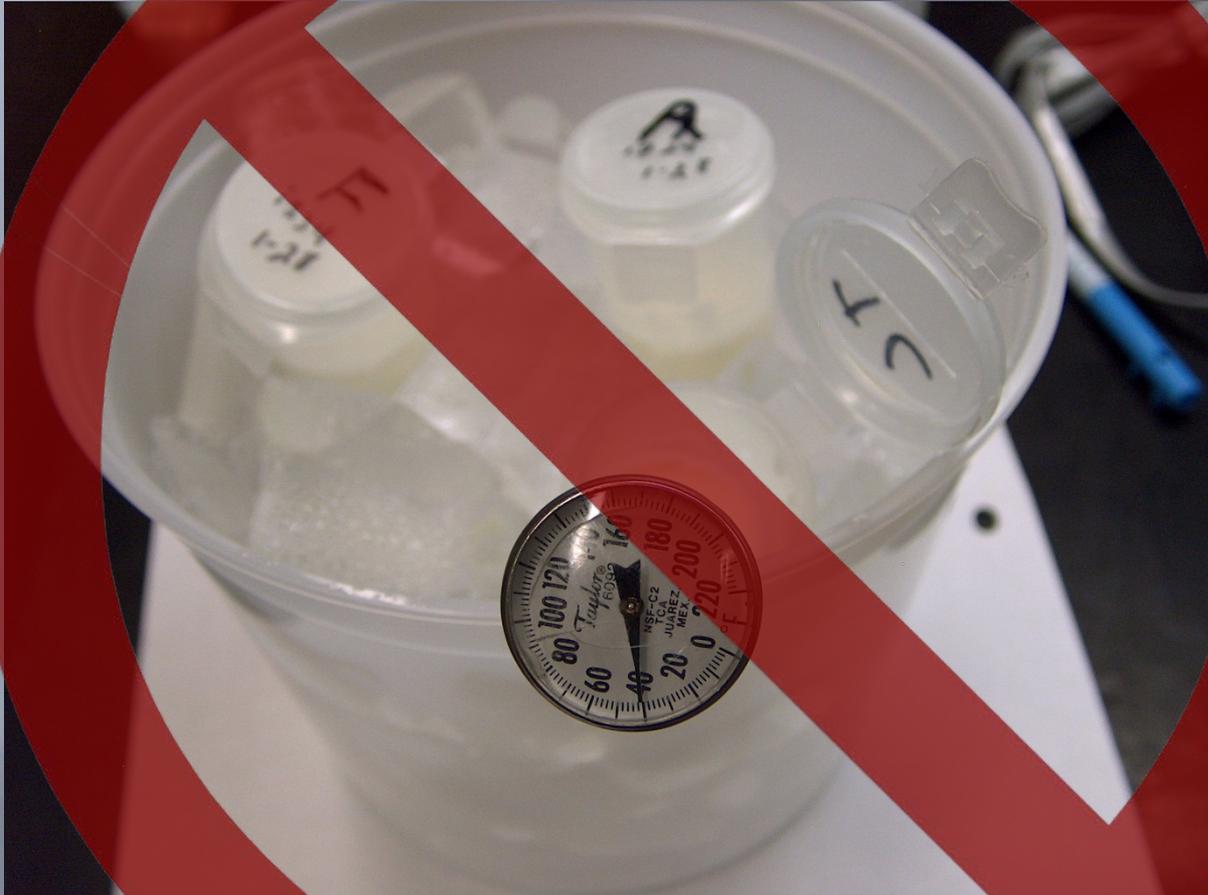
- ▣ Record date, time, and temperature of samples as received and tested
- ▣ Determine sample temperature by inserting a digital thermometer or pre-cooled glass into TC (temperature control)
- ▣ If no TC, aliquot samples for testing and measure temperature using one of the producer samples



Ice water bath for samples with Temperature Control (TC) sample

TC temperature determined using digital thermometer





DO NOT USE DIAL THERMOMETERS!



Digital probe TC thermometers

Glass TC thermometer kept in alcohol solution. Kept in the fridge when not in use (pre-cooled).



ITEM 9: SAMPLE REQUIREMENTS

- ▣ Samples that are not over-filled (more than $\frac{3}{4}$ full)
- ▣ Sample(s) are not leaking
- ▣ Tops of samples are protected from direct contact with ice (use of 'floater' racks)
- ▣ Unprotected samples are not submerged in water and/or ice or slush

ITEM 9: SAMPLE REQUIREMENTS

- ▣ If raw milk samples exceed 4.5°C on receipt, DO NOT TEST.
- ▣ However, samples may be received $>4.5^{\circ}\text{C}$ but $< 7^{\circ}\text{C}$ if time of receipt is ≤ 3 hours from collection and arrival temperature is equal to or less than the temperature of collection.

ITEM 10: PERFORMANCE TESTING

- ▣ Run a positive and negative control on each new lot of kits before use. Controls must give appropriate results, with records maintained (BFSL 513 Rev. 1/14).
- ▣ Control tested each time prepared and give appropriate results with records maintained. (BFSL 513a Rev 7/11, BFSL 513b Rev 7/11).
- ▣ Run a negative and positive control DAILY (on days of testing). Controls must give appropriate results before samples tested.

ITEM 10: PERFORMANCE TESTING

- ▣ If controls do not give appropriate results, re-run controls (may be necessary to make new controls).
- ▣ If problem persists, discontinue testing, contact one of the Laboratory Evaluation Officers and seek technical assistance from the manufacturer.

ITEM 10: PERFORMANCE TESTING

- ▣ Check instrument calibration with check devices DAILY (on days of testing), with records maintained (BFSLS 534 SNAP Rev 7/09 & BFSLS 535 Rosa Reader Rev 7/09).
- ▣ Devices must give appropriate results. If not, discontinue testing and seek technical assistance from the manufacturer.

IDEXX check devices



Charm Reader check devices



ITEM 10: PERFORMANCE TESTING

- ▣ If more than one analyst performs analysis, have a different analyst run performance checks on rotational basis.

ITEMS: 11-13 INITIAL, PRESUMPTIVE,
CONFIRMATION, & PRODUCER TRACEBACK OF
SAMPLES

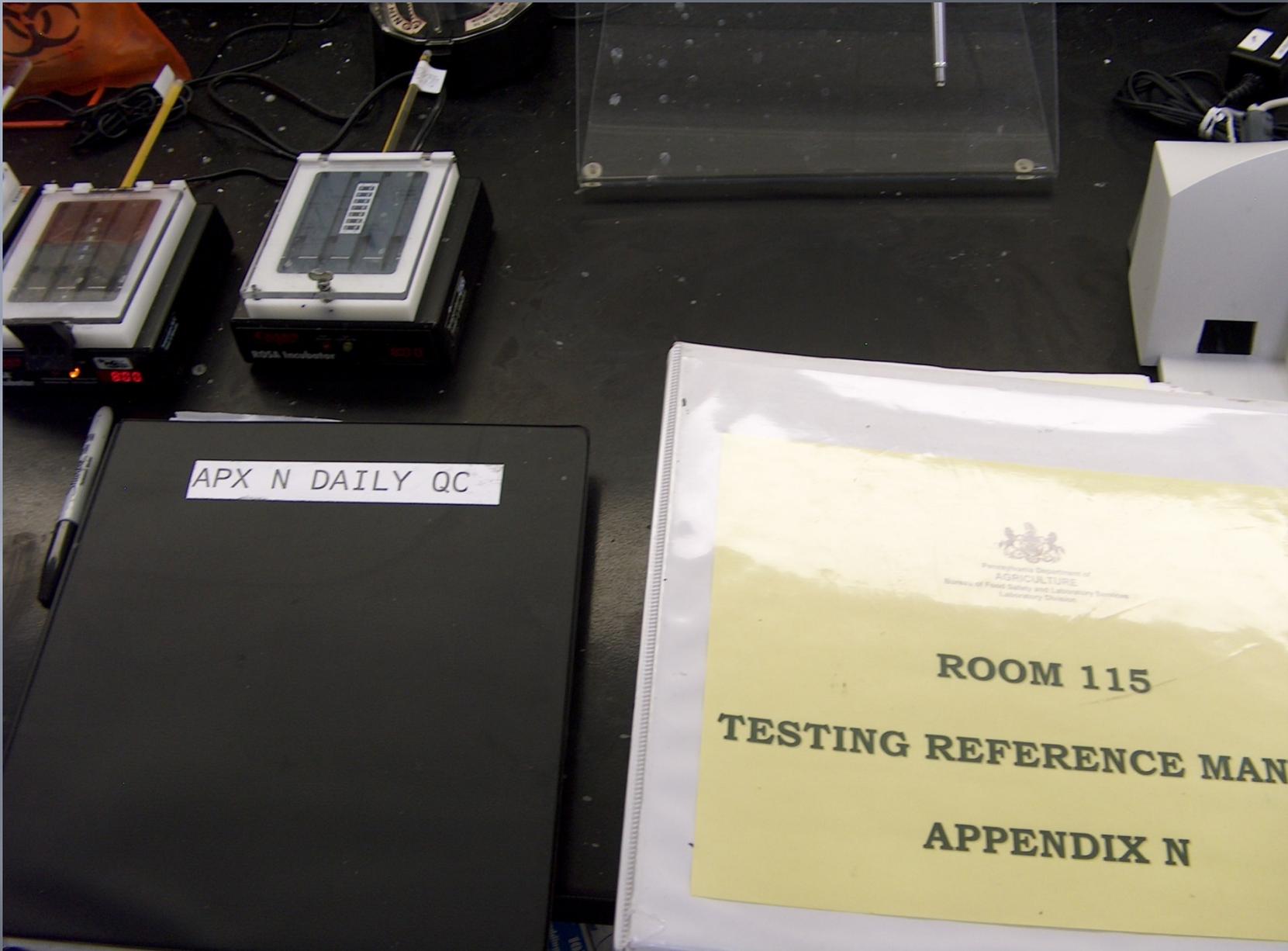
- ▣ This will be addressed in the upcoming Appendix N Flow Chart Presentation

ITEM 14: REPORTING & RECORDS

- ▣ Report Positive results as Positive (+) for Beta-Lactam
- ▣ Report Negative results as Not Found (NF)
- ▣ Report tests performed, interpretation of unknowns (samples) and controls (BFSLS 500 rev. 1/14 or BFSLS 500a rev. 1/14)

ITEM 14: REPORTING & RECORDS

- ▣ Records, including all printouts, must be maintained for 2 years and be available for the LEO to review during the biennial evaluation



APX N DAILY QC



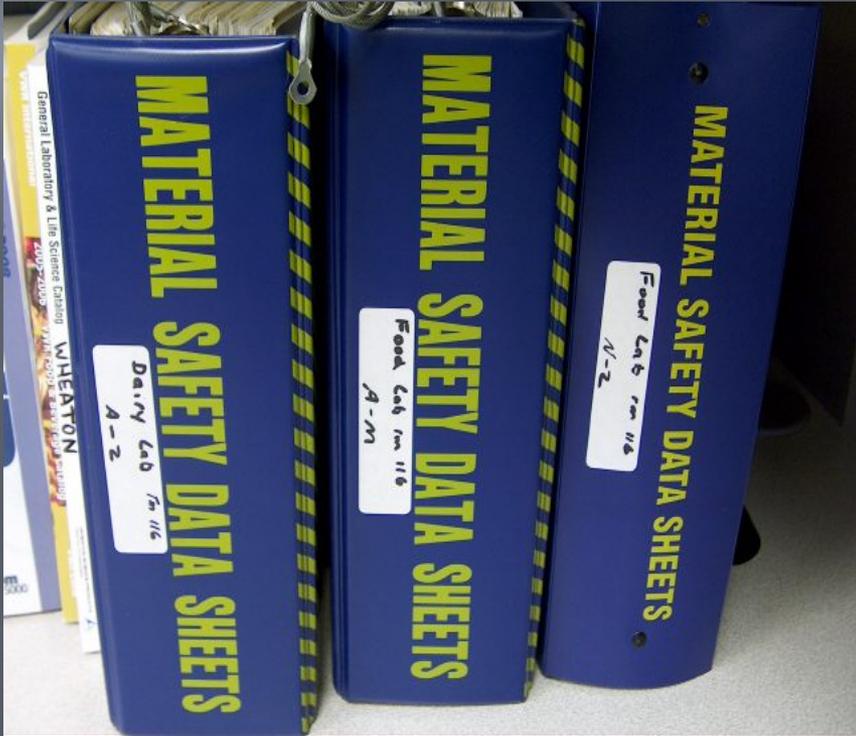
ROOM 115

TESTING REFERENCE MAN

APPENDIX N

ITEM 15: MISCELLANEOUS

- ▣ Safety Data Sheets (SDS) accessible to analysts
- ▣ Current, applicable survey forms (2400 forms) available in the laboratory
- ▣ Positive Report Forms available with instructions



ITEM 15: MISCELLANEOUS

- ▣ Personnel adequately trained
- ▣ If an analyst does not have a PA analyst number (PA#) assigned then no training documentation has been approved by PDA
- ▣ If no training documentation has been approved by PDA, the analyst in question cannot conduct testing
- ▣ All IA's (Industry Analysts) are to receive re-training annually. (BFSL 528 rev 1/14)

ITEM 15: MISCELLANEOUS

- ▣ Required split sample participation annually if receiving more than 200,000 pounds of milk a week (March Splits)
- ▣ Facilities receiving less than 200,000 pounds of milk a week will be required to test check samples brought by the LEO to each on-site evaluation

Please email
QUESTIONS OR
COMMENTS to
mhydock@pa.gov