

Computing Division Section Measuring & Test Equipment (M&TE) Independent Assessment

August 11 - 18, 2011



Closing Meeting Thursday, August 18, 2011

➤ **Assessment Interviewees:**

- Bob Tschirhart
- Adam Walters
- Alan Prosser
- Mark Bowden
- Rick Kwarciany
- Chuck Andrews
- Bob Forster
- John Chramowicz
- Gustavo Cancelo
- Tim Kasza
- Vince Pavlicek
- Joy Miletic

IQA Requirements:

- Section 5.4.2 Maintenance (as related to M&TE)

Divisions/sections/centers are responsible for ensuring maintenance is performed on facilities and equipment under their care. FESS is the primary maintenance service provider for facilities and the laboratory's infrastructure and these services are agreed upon between FESS and the divisions/ sections/ centers. Maintenance plans are documented by divisions/sections/centers. The organization coordinating or performing the maintenance is responsible for ensuring that records of maintenance are kept.
- Section 5.4.4 Calibration of process equipment

It is the responsibility of each division/section/center to identify, monitor and maintain key process equipment that requires calibration or verification. Results are maintained. (See also: Chapter 8 Inspection and Acceptance Testing.)

IQA Requirements (Continued):

- Section 8.5 Control of Measuring and Test Equipment

The measuring and test equipment (M&TE) used for inspection and acceptance tests are identified, calibrated, maintained, and controlled commensurate with their intended use. Procedures are established by divisions/sections/centers for testing, retesting, adjusting, and recalibrating M&TE.

Equipment is checked to ensure it is the proper type, range, accuracy, and precision and is uniquely identified and traceable to its calibration records.

The process of calibration compares an unknown, a test item, or an instrument with reference standards according to a specific procedure. Calibration standards are traceable to the National Institute of Standards and Technology or equivalent. Where no recognized standard exists, the basis for calibration is defined and documented.

When M&TE or standards are found to be out of tolerance, appropriate evaluations are performed to assess any adverse impact on previous inspection, testing, data collected or calibration using that equipment and to determine the acceptability of items previously inspected or tested and appropriate notifications made. The evaluation, including conclusions, is documented.

All M&TE equipment not operating to specifications is identified and pulled from service or locked out and are not returned to service until passing calibration requirements.

Consideration is given to computer programs that are part of the calibration of the equipment when calibrating and/or checking the equipment for use.

➤ General Observations:

- Calibration policy is not approved or implemented
- Test equipment is not being identified, calibrated, maintained and controlled commensurate with their intended use
- Procedures do not exist for the assessment and possible recall of previously calibrated equipment where out-of-calibration conditions are identified
- Numerous instruments were identified with passed due calibration dates
- Indications of out-of-calibration equipment being used to calibrate other instruments with certification of NIST traceability

➤ Concerns

- Lack of definition of instruments requiring or not requirement calibration (data application).

➤ Remaining Assessment Schedule

- ✓ Closing Meeting: Thursday, August 18
- ✓ Draft Report for Review: Friday, September 2
- ✓ Final Report: Friday, September 9

Questions or Comments?