

## Preparing a Biological Electron Microscopy Laboratory for ISO 17025 Accreditation

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There are many reasons to standardize procedures in an electron microscopy laboratory, including increasing reliability, consistency, and overall quality of output. The International Organization for Standardization (ISO) and ASTM International have developed guidelines for laboratory and procedure accreditation. ISO 9001 is a set of standards and guidelines for good quality management practices. Our biological electron microscopy laboratory supports the ISO 17025 accredited National Bioforensic Analysis Center (NBFAC) at the National Biodefense Analysis and Countermeasure Center (NBACC). ISO 17025 is a set of management and technical standards used by testing and calibration labs to show competence in producing consistent products or results [1].

Electron microscopy laboratories have many different and varied procedures. Many types of samples are typically processed for analysis. This paper documents the process for establishing an electron microscopy laboratory for ISO 17025 accreditation of TEM and SEM processing and analysis of biological specimens to support bioforensic analyses. There are many components necessary to support ISO 17025 assessment, including quality measures for document control, equipment calibration, as well as personnel competency and proficiency in the procedures (Fig. 1).

Our lab will receive bioforensic samples for analysis. We have written work instruction documents (stepwise procedures) for all of our sample preparation procedures which are approved through the document control system. We have performed competency and proficiency testing of the lab, its personnel and our procedures. NBFAC is seeking ISO 17025 accreditation for sample processing procedures in the Electron Microscopy Lab to support bioforensic analysis with consistent and reliable images from our lab processes.

There are specific mechanisms that can be applied to the art of microscopy so that all samples are processed the same and the resulting images can be compared. Figure 2 C, D show images of bacteria processed using approved procedures. Much equipment is required for sample preparation before imaging in the electron microscope. This requires tracking of service calls, and documentation of maintenance and calibration (Fig. 2A, B). Performance checks done daily or before each use, ensure that data is produced on functioning equipment. For the electron microscopes, we use magnification standards to document overall instrument functionality, correct magnification, and to ensure that images collected can be referenced to standards that meet ISO 17025 criteria.

### References

- [1] ANSI/ISO/IEC 17025: 2005 “General Requirements for the Competence of Testing and Calibration Laboratories.
- [2] This research was performed at NBACC (National Biodefense Analysis and Countermeasure Center) by BNBI employees for DHS.

## FIG. 1. Steps to ISO 17025 Accreditation

- 1) Develop work instructions (SOPs) with blank, standards.
- 2) Equipment qualification (IQ, OQ, PQ, and calibration)
- 3) Competency testing of staff members
- 4) Authorization memos to do work
- 5) Method validation plan & report
- 6) Proficiency testing of staff
- 7) Submit ISO expansion form to QA
- 8) Internal audit
- 9) Submit validation package to A2LA
- 10) On-site inspection
- 11) ISO 17025 accredited for TEM & SEM analysis of non-spore forming organisms

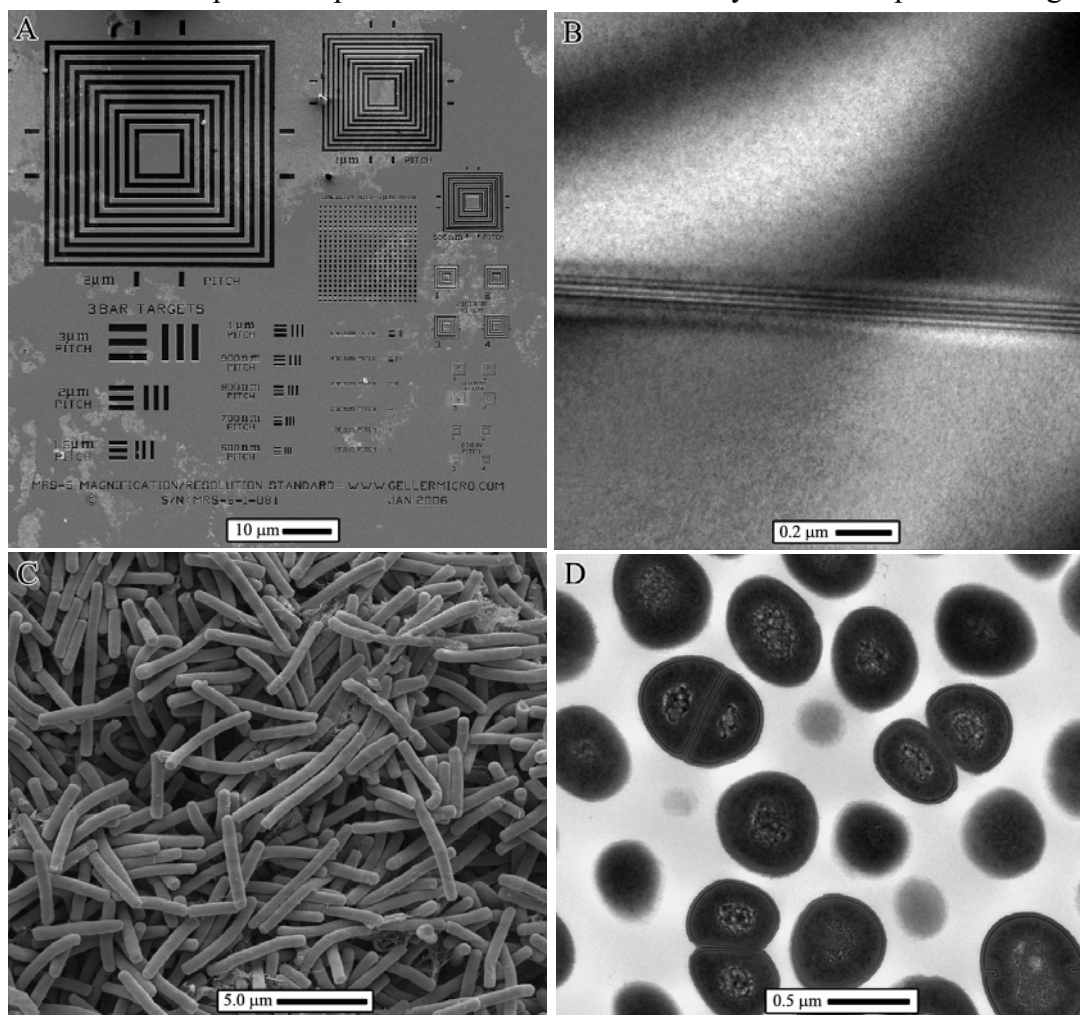


FIG. 2. A) SEM standard: Geller MSR5. B) TEM standard: MAG\*I\*CAL. C) *Bacillus cereus* and D) *Staphylococcus aureus*. These micrographs were produced using approved procedures.

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