

Achieving an ISO 20387 Accreditation for the ATCC Gaithersburg Repository

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BACKGROUND

ATCC is the world's premier biological resource center and standards organization that provides scientists with the biomaterials and resources they need to conduct critical life science research. ATCC has developed a quality commitment, which has allowed the company to evolve from a traditional culture collection founded in 1925 to a world-renowned biological resource center.

ATCC uses the International Organization for Standardization (ISO) 9001 standards to define its Quality Management System (QMS) and currently holds a wide variety of ISO accreditations (see Table 1). Most recently, ATCC obtained the ISO 20387:2018 accreditation, providing guidelines specifically for biobanks. This crucial standard ensures the quality, consistency, and traceability of materials stored at biobanks, promoting confidence in ATCC's operations.

METHODS

REQUIREMENTS REVIEW FINDINGS:

Identification of Requirements. A thorough review of the ISO standards for ISO 20387:2018 indicated that the requirements fell into four main categories: General/Resource, Structural, Procedural, and QMS Requirements.

Creation of A Roadmap. Identified our resources, gap analysis, document creation, and outlined our milestones of project completion

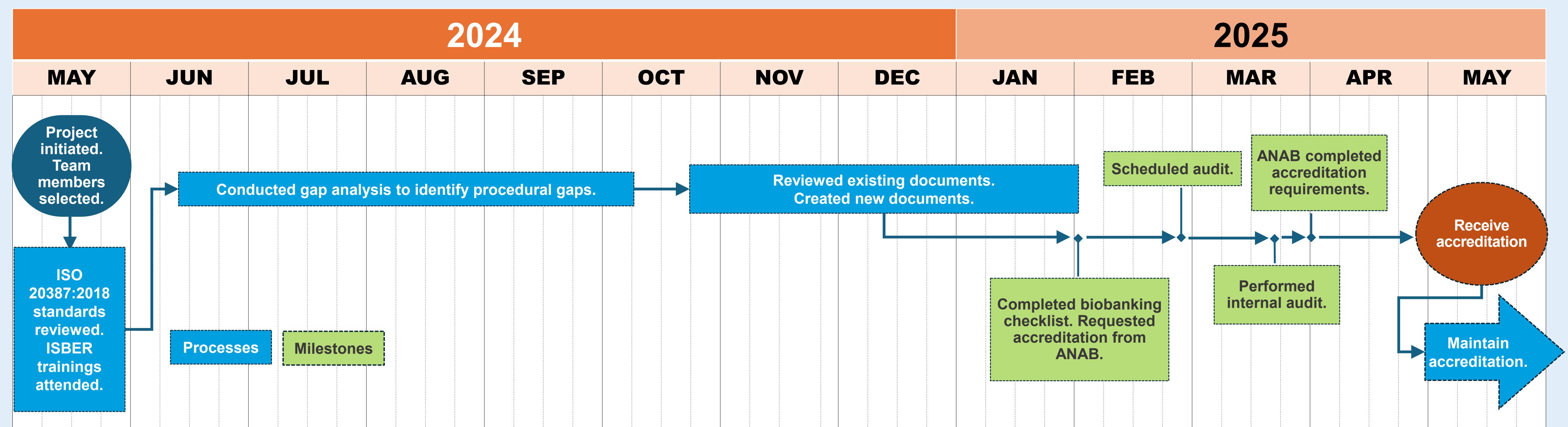
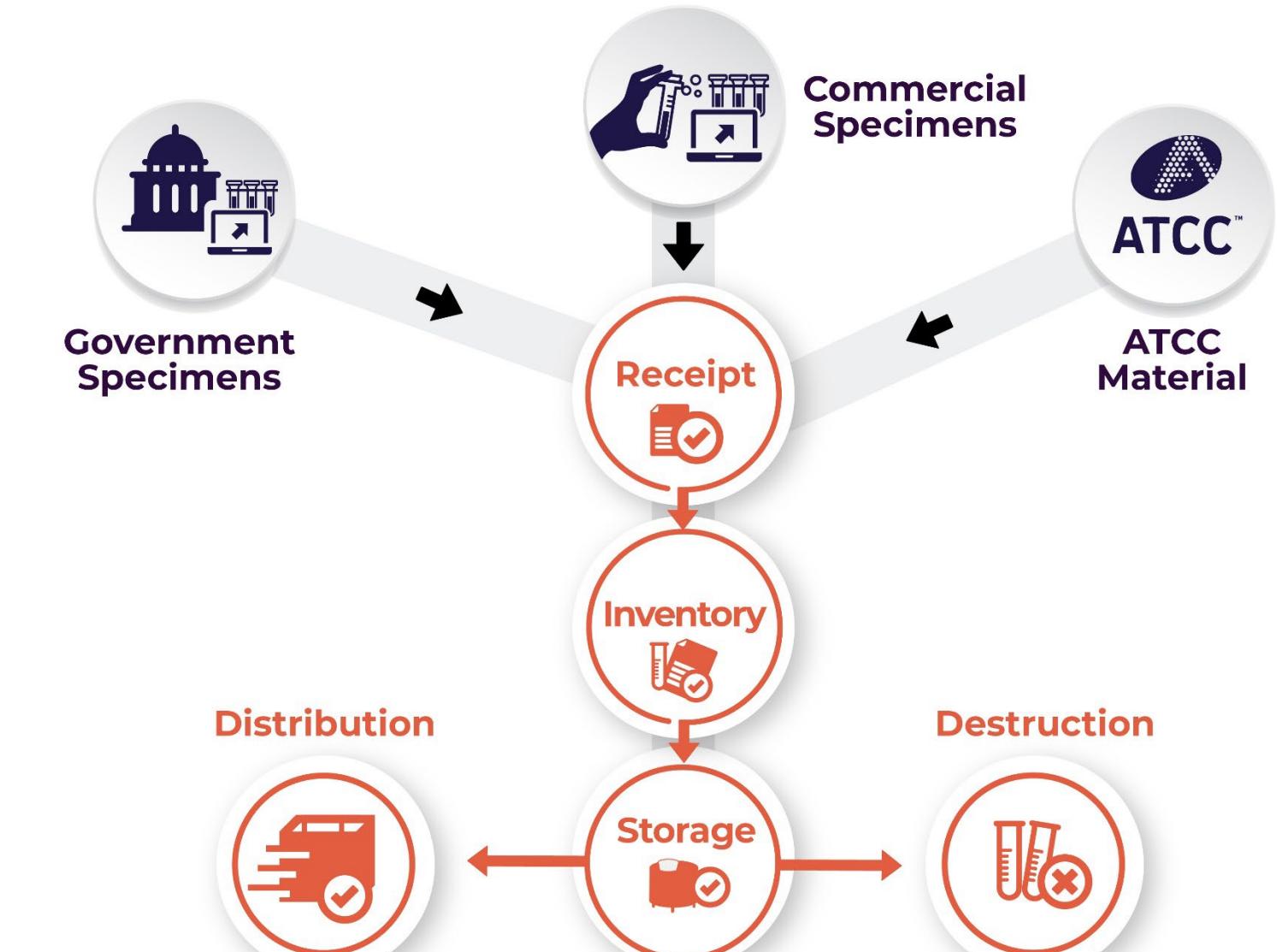


Figure 1. Approach to achieving ISO 20387 accreditation by the ANSI National Accreditation Board (ANAB):
Overview of steps and their completion dates in preparation for the ISO 20387 audit (April 2025)

SCOPE. The scope for ATCC's pursuit of ISO 20387:2018 accreditation encompassed the functional and operational processes applicable to biobanking, including the receipt, inventory, and storage of specimens and biological material through their subsequent distribution or destruction. These processes, which comprise the full product lifecycle, are illustrated in Figure 2.

Figure 2. Overview of biobanking activities at the ATCC Gaithersburg Biorepository. Functions within the scope of ISO 20387:2018 accreditation are shown in orange.



RESULTS

Overall, we identified that our current procedures adhered to the standard, and with the addition of 9 new documents, we would be compliant with the General/Resource, Procedural, and QMS requirements. The additional processes are captured in Table 2.

Table 2: Documentation Updates

Accreditation Scope	Pre-existing documents	Total number of created documents
General/Resource Requirements	12	7
Structural Requirements	2	1
Process Requirements	40	1
QMS Requirements	13	0
Total	67	9

An overarching quality manual was created to define our scope and adherence to the new ISO 20387 standard. Another document created was a data transfer procedure to ensure the appropriate governance of specimens by our clients. A procedure demonstrating our ability to comply with the standard's competency, confidentiality, and impartiality requirements was created with a corresponding form to be used when testing the competency of technicians performing scoped functions. Finally, two risk assessments, each with a supplemental summary, and a business continuity and disaster recovery (BCDR) plan were created to address any biosafety and biosecurity concerns.

The ANAB audit occurred on April 1st and 2nd, 2025. There were no major findings, and the auditor recommended ATCC for an ISO 20387 accreditation.

SUMMARY

ATCC's 100 years of experience in biomaterials management, with continuous improvement as our cornerstone, has actively worked to define industry best practices, which influenced the creation of ISO 20387 requirements. Therefore, ATCC processes were tailored to match the roadmap for accreditation. Acquiring the ISO 20387 accreditation verifies ATCC's compliance with regulatory agencies and continues to support our mission to provide credible, high-quality products and services to the scientific community. It enhances the desirability and reliability that federal clients require for contracts under the management of ATCC Federal Solutions (AFS). Furthermore, this accreditation ensures that ATCC is well-positioned to foster important collaborations within the scientific community to continue to advance biomedical research.