

Choose QC products your laboratory can rely on: How ISO 17034 accreditation equates to high quality, consistent reference materials

Robust and compliant microbiological quality control (QC) processes rest on a foundation of quality materials – a foundation assured by International Organization for Standardization ISO 17034 accreditation.

Following a three-year program of continual improvement, Thermo Fisher Scientific Microbiology has become an official accredited reference material (RM) producer, supplying our customers with trusted certified reference material (CRM).

In this SmartNote, we will look at what ISO 17034 is and why it matters, outline the intensive accreditation process, and explain how our QC products give our customers the added level of regulatory confidence they need.

The gold standard

Laboratories use reference materials in all stages of their work, from method validation, calibration, and QC to interlaboratory comparisons and assessing laboratory proficiency. Ensuring their quality, then, is tantamount to ensuring the quality, reliability, and reproducibility of results.

ISO 17034, developed by an international team of experts, gives reference material producers a set of gold standard quality management requirements – requirements organizations must

meet to become accredited RM producers.¹ The goal is to reduce the risk of product failure, and give laboratories confidence that the reference materials they use are of high quality, consistent, and fit for purpose.

“All laboratories that conduct any types of measurement activities need accredited reference materials to ensure the validity, precision, and accuracy of their measurements,” said Kelly Black, President of Neptune and Company, Incorporated, which worked closely with Thermo Fisher Scientific on the lengthy ISO accreditation process.

“The more frequently materials from an accredited reference material producer are used, the less risk laboratories have of false measurements,” added Black, who is also Chair of the ISO Technical Committee (TC) 69 (Applications of Statistical Methods) and the A2LA Reference Material Producer Technical Advisory Committee, as well as a member of ISO TC 334 (Reference Materials).

RM vs CRM: What's the difference?

All reference materials from a certified RM producer are accredited. Certified reference materials (CRM) are a subset of reference materials (RM) that include statements of uncertainty and traceability. Thermo Scientific™ Culti-Loops™ QC organisms, for example, are CRM products manufactured by an accredited RM producer.

Across clinical, water, food, and pharmaceutical settings, regulations call for RMs and CRMs. Clinical laboratories, for example, must adhere to ISO 15189, which requires the use of CRM for QC² and pharmaceutical and industrial manufacturer work to ISO 17025, which references compliance with ISO 17034.³

In addition, the World Health Organization (WHO),⁴ the US Food and Drug Administration (FDA)⁵ and Association of Official Agricultural Chemists International (AOAC International)⁶ all cite the need to use CRMs. Choosing ARM producers with ISO 17034 accreditation assures confidence in results, boosts productivity by reducing the need for avoidable retests and complies to regulations.

“Companies not using CRMs, if available, or not providing good justification for not using CRMs, will be cited for this non-conformance,”⁶



The road to accreditation

To become an accredited RM producer, Thermo Fisher Scientific Microbiology had to meet the exacting standards outlined in ISO 17034, which has 37 clauses and a great many more specific requirements.

Following an extensive and meticulous process to ensure the company either met or exceeded each stipulation, the American Association for Laboratory Accreditation (A2LA) carried out an independent audit.

A2LA's accreditation program for reference material producers is recognized by the Inter-American Accreditation Cooperation (IAAC), the Asia Pacific Accreditation Cooperation (APAC), and the International Laboratory Accreditation Cooperation (ILAC) under their mutual recognition arrangements.

It assigned certificate number 6559.01 to the Thermo Fisher Microbiology facility.

Black explained that ISO 17034 Section 7.2 requires that all aspects of production that could “possibly impact on the quality of reference materials be planned and documented”. “The team really took that to heart and gave serious consideration to the steps necessary to ensure their reference materials could meet the requirements of ISO 17034,” she added.

CRM products must also adhere to ISO Guide 31, which establishes Certificates of Analysis (COA) requirements.

To meet ISO 17034 producers must demonstrate compliance with ISO 17025 in terms of:

- *Use of a controlled testing environment*
- *Measurement procedures*
- *Calibration*
- *Measuring equipment*
- *Data control and integrity*
- *Metrological traceability of certified values*

As part of Thermo Fisher Scientific's commitment to continual improvement, documentation, manufacturing and QC testing, processes were updated to meet the highest standards of ISO compliance.

All aspects of the production life cycle - from materials and processes to labelling, distribution, and aftercare - were closely scrutinized and any necessary amendments were made.

These included changes such as replacing drying containers with humidity-controlled chambers for improved traceability and enhanced measurements of uncertainty and updating customer support programs to ensure access to recourse if a product does not perform as expected.

Black said: “The conclusion of all that work, from inception through the product lifecycle, is reference materials that will meet ISO 17034 requirements. The facilities that make use of these high-quality materials will be at a reduced risk of laboratory or production errors.”

The products

The ISO certification applies to the QC organisms portfolio, including more than 500 Thermo Scientific™ Culti-Loops™ and 25 Thermo Scientific™ Quanti-Cult Plus™ products.

- Culti-Loops qualitative QC organisms provide standardized cultures for QC testing that can be prepared quickly, easily and safely. These ready to use, disposable bacteriological loops contain stabilized viable microorganisms and offer complete traceability to ATCC® Licenced Derivative and NCTC cultures.
- Quanti-Cult Plus quantitative QC organisms are supplied as a film of preserved microorganisms inside the cap of a plastic vial. This matrix, which offers complete traceability to ATCC® Licenced Derivative and NCTC cultures, is ready for rehydration and use in QC procedures.

The bottom line

QC is essential to maintaining high levels of accuracy and proficiency regardless of variabilities such as changing methods or increasing sample sizes – but laboratories are only as good as the products they use.

Choosing products from an ISO 17034 accredited manufacturer assures superior quality of QC products, and, by extension, QC processes.



References:

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3. ISO, I. IEC 17025—Testing and Calibration Laboratories.
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