General Accreditation Criteria

Maintenance of Microbiological Reference Culture Collections (MRCC)

January 2019

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Maintenance of Microbiological Reference Culture Collections (MRCC)

Purpose

This document provides additional interpretative criteria and recommendations for both applicant and accredited facilities conducting testing that includes the use of microbiological reference cultures, including wild strains. Such reference cultures are most commonly used to undertake performance checks on prepared media, method verification and validation studies and internal quality control of routine testing.

Microbiological Reference Culture Collections (MRCC) consist of biologically active cultures that may change their original characteristics as a result of genetic changes during manipulation over time (e.g. when passaged).

These criteria are applicable to all microbiological collections held, including bacteria, viruses, fungi, protozoa etc.

Note: In terms of this document, a passage is defined as the transfer of microorganisms to a new growth medium, or host, and subsequent growth to create a fresh viable culture (which may represent several generations of organism). The following examples represent one passage: *Escherichia coli* subcultured into a Nutrient Broth and incubated overnight; or cells infected with Polio virus transferred to a flask of uninfected cells in a suitable growth medium and incubated.

The purpose of MRCCs is to ensure that cultures remain suitable for their intended use.

Facilities must also comply with other relevant General Accreditation Criteria and the relevant Specific Accreditation Criteria, including ISO/IEC 17025 Application Documents (ADs) and their associated Appendices and Annexes covering the specific activities for which accreditation is held or being sought. The *NATA Procedures for Accreditation* identifies the documents covering the criteria for accreditation.

The clause numbers in this document follow those of ISO/IEC 17025, however, as not all clauses require interpretation the numbering may not be consecutive.

6.4 Equipment

6.4.10 Facilities must:

- define and document the characteristics of the reference cultures maintained as fit for purpose for their intended use (e.g. propagation requirements, morphology and biochemical reactions);

  Note: Characterisation may be performed by an external provider. A competent external provider is for example, but not limited to, an accredited NATA facility or a facility accredited by a signatory to a Mutual Recognition Arrangement.

- establish a program of performance checks to confirm the key characteristics of each culture are expressed as expected, and that the cultures continue to remain suitable for their intended purpose.

Wild strains may be used when no reference strain is specified for a method or to supplement the reference strains specified. These should be confirmed by a recognised reference laboratory, where possible, or alternative methodologies (e.g. 16S gene sequencing). Where an organism is required for a particular characteristic only (e.g. hydrocarbon utilisation), the key characteristics only need be confirmed.

Note: It is recognised that in some cases (e.g. fungi), full characterisation by a reference laboratory is not possible or feasible.

Facilities should ensure that the total number of passages is minimised, where possible, in line with current published literature (not limited to the references included below) and supplier's recommendations.

6.5 Metrological traceability

6.5.3 Facilities must hold MRCCs of organisms necessary to perform, but not limited to, validation and verification of test methods, performance checks on test kits, reagents and prepared media and for use as method performance indicators as part of routine testing.

7.5 Technical Records

7.5.1 The following records must be maintained:

- identity, source and history of the culture;
- date of acquisition;
- conditions of resuscitation, preservation and storage;
- results of purity and performance checks against defined characteristics;
- dates of subculturing and passage number;
- conditions used to maintain working cultures.

Note: The records for identity should include, where relevant, the organism name (e.g. E coli), a unique identification (e.g. laboratory number) and the catalogue number (e.g. ATCC/NCTC/WDCM).

Further Reading

S.M.Bell, J.N. Pham, I.W.Carter. *Antibiotic Susceptibility Testing by the CDS Method. A Manual for Medical and Veterinary Laboratories 2009*

Australian Society for Microbiology. *Guidelines for Assuring Quality of Medical Microbiological Culture Media*

Australian Society for Microbiology. *Guidelines for Assuring Quality of Food and Water Microbiological Culture Media*

U.S. Pharmacopeial Convention. *General Notices and Requirements Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia 2011*

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Standards

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

Amendment Table

The table below provides a summary of changes made to the document with this issue.

Section or clause	**Amendment**
Whole document	Clauses have been aligned with ISO/IEC 17025:2017 No new interpretive criteria or recommendations have been included. Minor editorial amendments throughout the document.