Specific Accreditation Criteria
Reference Material Producers ISO 17034
Annex

Reference Culture Producers

January 2018

Reference Culture Producers

This document provides interpretative criteria and recommendations for the application of ISO 17034 for Reference Material Producers (RMP) for both applicant and accredited facilities.

Applicant and accredited facilities must also comply with ISO 17034 and the NATA ISO 17034 Standard Application Document (SAD).

The clause numbers in this document follow those of ISO 17034 *General requirements for the competence of reference material producers* but since not all clauses require interpretation the numbering may not be consecutive.

This annex details specific requirements for accreditation of reference culture producers under the following categories and subcategories of reference materials.

CATEGORY B BIOLOGICAL AND CLINICAL PROPERTIES

B7 Parasitology

B8 Bacteriology and mycology

B9 Virology

Producers of reference cultures are advised that a number of guidelines relating to procurement, preservation, maintenance and distribution of reference cultures are available from the World Federation for Culture Collections (www.wfcc.info) and the Common Access to Biological Resources and Information (www.cabri.org).

The clause numbers in this section follow those of ISO 17034 but since not all clauses require interpretation the numbering may not be consecutive.

6.3 Provision of equipment, services and supplies

6.3.2 Documented acceptance/rejection criteria must be available for new strains considered for the collection.

The facility must obtain all available information regarding the strain and origin of material being acquired from external organisations. The date of arrival, the depositor, the scientific name and the strain designation must be recorded. Further information to be considered should include the country of origin, name of isolator, date/time/geographic location of isolation, taxonomic identification (if known), phenotypic/genotypic strain properties, bibliographic references and known distribution restrictions.

6.3.3 The identity, viability, passages and purity of strains used in production must be confirmed. Refer to NATA's *Maintenance of Microbiological Reference Culture Collections (MRCC)* available on the NATA website.

7.12 Characterization

Including after preservation, the viability, purity and identity of the preserved strain must be confirmed.

7.14 RM documents and labels

Users of reference cultures must be provided with the conditions of resuscitation, preservation and storage e.g. media, time, temperature.

Instructions on opening ampoules, dehydration of (freeze-) dried cultures or other appropriate advice regarding management of the material must also be provided to users.

Strains that are potentially pathogenic to humans, animals or plants, or that produce toxic or hallucinogenic compounds, should be clearly labelled and secured in accordance with regulatory requirements.

Care must be taken to ensure that organisations requesting hazardous strains of microorganisms hold the necessary permits.

7.16 Control of quality and technical records

7.16.2 In addition to the records of identity, confirmation and maintenance on each strain held by the facility, the records must also include:

- the preservation procedures used;
- the optimal growth media and temperatures;
- any data on biochemical or other characteristics;
- regulatory conditions applying to the strain e.g. in relation to quarantine, containment levels, security and patent status.

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.

AMENDMENT TABLE	
Section or Title	**Amendment**
New document	This document represents a direct adoption of the former Reference Material Producers ISO 17034 Standard Application Document Appendix A. The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.