General Accreditation Criteria

Media Preparation and Quality Control

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Purpose

This document provides additional interpretative criteria and recommendations for both applicant and accredited facilities for the establishment of an effective media preparation and quality control (QC) program.

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.

Note: Even though the clause numbers of ISO/IEC 17025 are followed, this document is equally applicable to facilities accredited against other standards used in NATA's accreditation programs.

6.4 Equipment

6.4.3

Media preparation (solid, semi-solid, liquid)

Details of the procedures for preparation and QC of media and diluents must be documented consistent with the relevant current versions of the Australian Society for Microbiology (ASM) Guidelines and ISO 11133.

Prepared media purchased from accredited manufacturers

Accredited media manufacturers are those that hold ISO/IEC 17025 accreditation for QC testing of the media they produce. Facilities must assure themselves that such accreditation is held by checking the current scope of the manufacturer's accreditation. The scope of accreditation will specify the types of prepared media for which the manufacturer can issue endorsed reports or certificates.

All prepared media must be initially assessed for suitability to the particular requirements of the facility prior to purchase. This assessment should take into account the nature of the media and the type of test for which it is used, etc. It must be assured that QC organisms used and testing conditions (time and incubation temperature) are relevant to the testing for which the media is to be used. Where this is not the case the purchaser is responsible for undertaking additional QC if this cannot be undertaken by the manufacturer.

When the manufacturer releases a product, it must be labelled with the product name, batch number, date manufactured and expiry date. The customer must also have access to details of:

- testing and sterility protocols including test methods, and
- results of QC (e.g. organisms, pH, recovery etc.) for each batch produced and expected results.

Prepared media purchased from non-accredited manufacturers

Facilities purchasing prepared media from non-accredited manufacturers are required to perform complete QC testing on all media. This includes performance, sterility, and physical testing parameters on every batch received.

Prepared media produced in-house for distribution to satellite laboratories

In general, all facilities, including satellite sites receiving prepared media from a parent site not holding accreditation for media QC will be required to carry out full QC (physical, sterility, performance) on each batch of each medium made. Alternatively, facilities preparing media for distribution to satellite sites are encouraged to seek NATA accreditation for media QC.

It is recognised that under defined circumstances facilities may be required to produce media in-house (e.g. specialised media used by reference laboratories) which will not be available for purchase from commercial accredited manufacturers. In this situation, satellite sites receiving specialised media from a non-accredited parent site will not be required to perform full QC provided the following criteria are met:

- the parent site carries out QC evaluation on each batch of each medium made. A copy of the media preparation details and QC results for each batch of medium produced must be made available to the satellite site;
- the receiving satellite site must demonstrate that the media has not been adversely affected by transit, storage and change in environmental conditions;
- the sites must be part of the one organisation; and
- the media must not be sold or provided to other facilities outside the organisation.

If any of the above is not met, the requirement for full QC at the satellite site will apply.

Prepared media from suppliers holding ISO 9001 certification only

Certification of the operations of a manufacturer to ISO 9001 does not demonstrate technical competence. Accordingly, facilities purchasing media from suppliers certified to ISO 9001 only will be required to perform complete QC testing on all media. This includes performance, sterility, and physical testing parameters on every batch received.

Media batches with five or less units

The requirements of the *ASM Guidelines* for the number of samples to be selected for QC testing do not need to be followed when the unit number of the batch is five or less. In such cases, one unit can be selected for testing. This acknowledges the reduced likelihood of within batch variation when batch size is small.

Shelf life

Shelf life of all prepared media must be determined in accordance with the provisions in the *ASM Guidelines*. Prepared media shall be labelled with expiry dates as determined by this process.

Virology media

In addition to the above, virology culture medium must be tested to ensure:

- it supports the growth of the cell lines expected to grow;
- it supports the production of normal densities (e.g. monolayer);
- it supports growth in an appropriate time frame;
- it supports the production of normal cell morphology; and
- 'cells and medium' support the growth of viruses or other intracellular pathogens of interest.

Uninoculated and inoculated controls are to be used. Different controls may be used for different viruses. The appropriate use of controls must be able to be demonstrated.

Facilities must monitor the growth of viral cell lines by the following:

- recording of split ratios/seeding rates for both primary and continuous cell lines;
- testing for *Mycoplasma* yearly;
- setting up uninoculated cell cultures (cell culture only) with all viral assays. Inoculated cell cultures (cell culture with known virus) should be periodically set up with all viral assays; and
- using virus neutralisation tests (VNT) or periodic titration of a virus of known titre to monitor sensitivity.

Prepared media must be stored and used in accordance with manufacturers' instructions with appropriate inventory control.

6.6 Externally provided products and services

6.6.1 QC undertaken as a third party activity

A manufacturer of prepared media may utilise the services of another facility to perform QC testing. Where this occurs, the manufacturer must use a facility that is accredited to ISO/IEC 17025 for media QC. The testing facility must undertake all QC tests as required for media preparation and reports must include the results of all QC testing performed.

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*

NATA Publications

General NATA Documents *NATA Procedures for Accreditation*

Other Publications

ISO 9001 Quality Management System

Further reading

ASM Guidelines for Assuring Quality of Food and Water Microbiological Culture Media ASM Guidelines for Assuring Quality of Medical Microbiological Media

ASM Guidelines for Assuring Quality of Medical Mycological Culture Media

ASM Guidelines for Assuring Quality of solid media used in Australia for cultivation of medically important Mycobacteria

ISO 11133: Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media

Amendment table

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

Section or clause	**Amendment**
Whole document	No new interpretive criteria or recommendations have been included. Minor editorial amendments and rearrangement of text throughout the document. Deletion of previous wording of criteria already specified in the NATA Standard Application Document (SAD) and/or the Life Sciences Appendix and/or ISO/IEC 17025 (e.g. clauses 6.44, 6.4.13, 7.8.1.2).
6.4.10	Criteria removed as the review of the reliability of purchased prepared media is supported by its use in the quality control measures implemented by the laboratory.