Specific Accreditation Criteria

ISO/IEC 17025 Application Document

Life Sciences - Annex

Facilities using nucleic acid detection techniques (including for genetically modified materials)

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Facilities using nucleic acid detection techniques

Purpose

In addition to the *ISO/IEC 17025 Standard Application Document* (SAD) and the accompanying *Life Sciences* - Appendix, this document provides interpretative criteria and recommendations for nucleic acid detection techniques for both applicant and accredited facilities.

Facilities must comply with all relevant documents in the *NATA Accreditation Criteria* (NAC) package applicable to the activities covered, or proposed to be covered, by their scope of accreditation (refer to *NATA Procedures 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.

Scope of nucleic acid detection techniques

Accreditation for testing of nucleic acid material covers qualitative and quantitative analysis through use of nucleic acid extraction (if required), polymerase chain reaction (PCR) methods and sequencing methods.

While the contents of this document are generally applicable to all nucleic acid detection techniques, more specific criteria for applications such as Massively Parallel Sequencing (MPS) are available (e.g. National Pathology Accreditation Advisory Council (NPAAC), *Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies*).

Testing for genetically modified (GM) sequences in foodstuffs or whole grain and related plant materials relies on the ability to test for the specific DNA sequences associated with modifications and/or the promoter and terminator sequences associated with the inserted sequences.

A facility's competence to develop and implement tests for GM events and constructs will be ascertained at the initial assessment, or first assessment that such testing is requested for addition to the scope of accreditation. When the facility has developed the capacity to detect an additional GM event or construct, this will be added to the scope of accreditation, following a written request to NATA, without the need for submission of supporting documentation where the analysis is undertaken using the same technique covered by the existing scope of accreditation. At the first subsequent reassessment, a sample of GM events or constructs added since the last assessment will be reviewed. Where a new technique is implemented that has not been assessed, a variation visit will be required.

6 Resource requirements

6.3 Facilities and environmental conditions

6.3.1 Facilities undertaking nucleic acid testing must provide at least three contained areas in order to minimise the risk of cross-contamination and carry-over contamination of specimens and reagents. The normal airflow pattern between each of the areas and the layout of the laboratory must be designed to minimise the potential for aerosol cross-contamination. The three contained areas required are for:

- the preparation of reagents
- the extraction of nucleic acids from specimen and for the addition of specimen DNA to tubes containing master mix before PCR amplification
- amplification and product detection.

Where sample preparation procedures have the potential to produce fine ground particles (e.g. grinding or homogenisation) these processes must be carried out in an area separate to that used for DNA extraction to reduce the potential for cross contamination.

Where material is subjected to a further amplification such as in a nested PCR, these materials must be handled in a fourth separate area. These manipulations of specimens or of materials liable to contain amplified or other nucleic acids can be carried out in a Class I Biological Safety Cabinet (BSC), a Class II BSC with a High-Efficiency Particulate Absorbing (HEPA) filter on the exhaust, or within an instrument.

For further information on laboratory layout and workflow, the NPAAC document, *Requirements for Medical Testing of Microbial Nucleic Acids*, may be used as a reference.

6.4 Equipment

6.4.10 Specialised equipment (i.e. thermocycler, nucleic acid analyser, spectrophotometer) is required for detection of labelled and unlabeled nucleic acids. Many instruments have internal diagnostic checks built into them and as a minimum, the manufacturer's recommendations should be followed.

6.5 Metrological traceability

6.5.1 Reference materials used as controls in the validation of new assays and as routine controls in existing assays must comply with the criteria in the NATA *General Accreditation Criteria: Metrological Traceability Policy*.

7 Process Requirements

7.2 Selection, verification and validation of method

7.2.1.1 The following reference documents covering nucleic acid testing and sequencing should be consulted:

- Subcommittee of Animal Health Laboratory Standards (SCAHLS) *Veterinary Laboratory Guidelines for Nucleic Acid Detection Techniques*
- NPAAC, *Requirements for Medical Testing of Human Nucleic Acids*
- NPAAC, *Requirements for Medical Testing of Microbial Nucleic Acids*
- NPAAC, *Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies*

7.2.2.1 Where possible consideration should be given to grouping like matrices to reduce the volume of work required to undertake validation.

Note: Refer to the FSANZ website at www.foodstandards.gov.au for information on the currently approved/pending GM events.

7.4 Handling of test or calibration items

7.4.1 Due to the high sensitivity of methods, close attention must be given to measures to minimise the possibility of cross-contamination during transport, storage, preparation and analysis of samples. (Refer to clause 6.3.1).

7.7 Assuring the validity of results

7.7.1 Controls incorporated within test systems must address inhibition, sensitivity and contamination.

7.7.2 In MPS applications, the integrity of the indexes must be assured. Contamination of indexes can have the same downstream effects on results as sample contamination.

7.8 Reporting of results

7.8.1 General

7.8.1.2 Reporting of results must be sufficiently descriptive to provide end users a clear understanding of what tests have been conducted, what nucleic acid sequence(s) have been targeted for detection and the limit of detection.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the general requirements of ISO/IEC 17025, a test report must also include information on the limitations of the specific detection method used for the respective sample or sample type.

For GM material testing, the content of test reports is influenced by the nature of the matrix tested. For unprocessed materials such as soya beans, canola seeds or lupin seeds, it is important to indicate the amount of sample or number of seeds ground prior to DNA extraction.

Where highly processed matrices are tested for GM material, it is possible the amount of DNA extracted may be insufficient to allow the presence of GM material to be detected. In such cases a null result can be reported. The test report must include sufficient information to explain what is meant by the terminology used (e.g. null versus not detected). Facilities should discuss the possibility of a null result with clients prior to testing if the matrix submitted is highly processed.

For MPS, a coverage report specifying the regions sequenced/not sequenced or the number of reads generated should be considered.

7.8.7 Reporting opinions and interpretations

7.8.7.2 No affirmation shall be made stating that there is no GM material present in the sample analysed as determined from test samples.

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

NATA Accreditation Criteria (NAC) package applicable to the activities covered, or proposed to be covered, by the facility's scope of accreditation

General Accreditation Criteria: Metrological Traceability Policy

Other Publications

NPAAC *Requirements for Medical Testing of Human Nucleic Acids*

NPAAC *Requirements for Medical Testing of Microbial Nucleic Acids*

NPAAC *Requirements for Human Medical Genome Testing Utilising Massively Parallel Sequencing Technologies*

Subcommittee of Animal Health Laboratory Standards (SCAHLS) *Veterinary Laboratory Guidelines for Nucleic Acid Detection Techniques*

Amendment Table

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

Section or Clause	Amendment
Whole document	Scope of document revised to include PCR analysis other than for testing for GMO.
6.3.1	Minimum number of contained areas reduced to three in line with NPAAC requirements.
7.7.2	Inclusion of requirements for MPS analysis.