

NATA Research and Development Accreditation Program

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Facts on NATA

- What NATA does
 - assesses the technical competence of its customers
 - who produce reliable technical results that make the world a safer and more certain place
- National authority
 - is the national authority for the accreditation of
 - testing and calibration laboratories
 - producers of certified reference materials
 - a peak authority for inspection bodies
- Public database
 - NATA maintains a database of its accredited facilities, including their scopes of accreditation available on its website

What is accreditation?

“Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks”

Scope of R&D Program

- Accreditation of R&D facilities which produce technical data
 - stand alone research facilities
 - public or privately funded facilities
 - facilities that perform a blend of routine and research or non-routine testing
- Program is continually evolving and establishing its boundaries

Understanding R&D “Accreditation”

- Recognition is against international standards & guidelines which consider
 - “technical” competence and
 - research “management”
- Looks at all of a laboratory’s resources to determine competence within the framework of a management system

NB: Not just the paperwork but also the processes in place!

Benefits of R&D Accreditation

- R&D accreditation provides 3rd party assessment
 - independent secretariat provides reassurance that the review process is unbiased
- Provides opportunity for accredited R&D facilities to access (tender for) work when verification (accreditation) is specified
- Potential to reduce 2nd party audits (by clients) of R&D facilities
- Accreditation provides a point of differentiation between research facilities working in the same field
 - marketing advantage

Benefits of R&D Accreditation (cont)

Further benefits include that:

- research work is managed in accordance good practices and protects stakeholder interests
- R&D is conducted by competent staff
- processes are validated and records exist to support the data generated
- reports reflect the stated R&D objectives (project plans)
- reports supplied to clients are supported by documentation and records (including raw data)

Where does the R&D Program fit in?

Traditional Laboratory Accreditation

R&D Accreditation

Well characterised testing

Less well characterised testing



Standard test methods

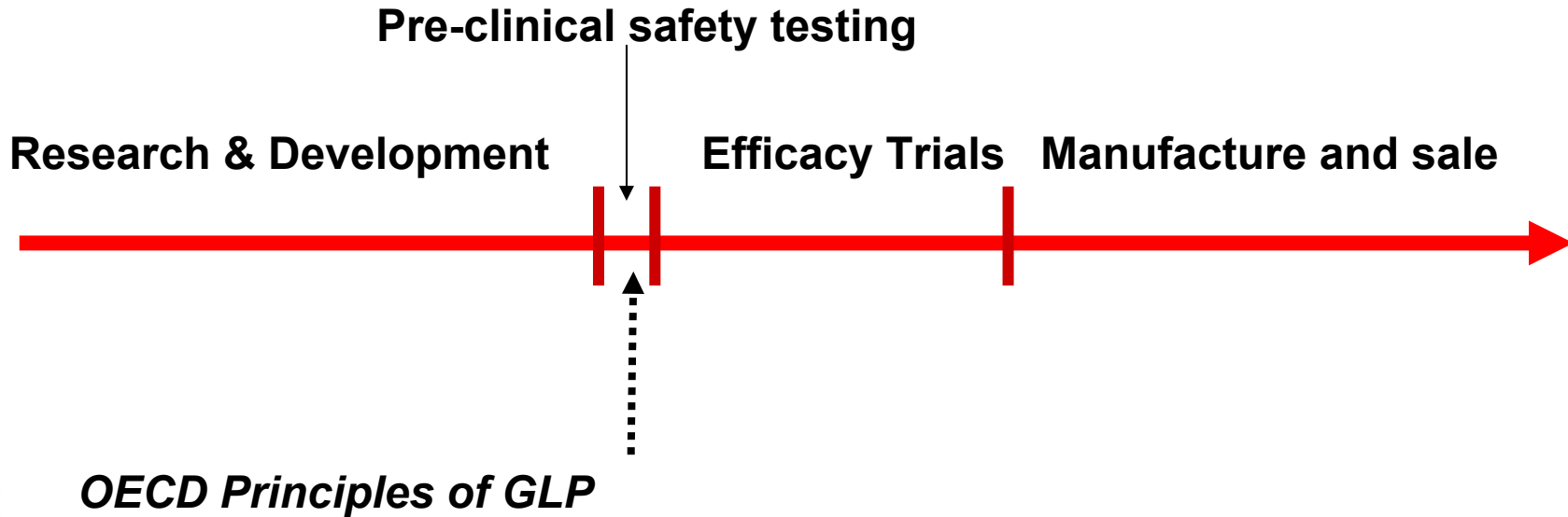
Laboratory developed test methods (in-house methods)

Non routine or non-standard methods

Research methods (novel or novel applications of existing methods)

ISO/IEC17025

← **Testing and Calibration (ISO/IEC 17025)** →



Which NATA Program?

Depending on your area of work, it might span a number of programs including:

- R&D
e.g. early stage research
- Chemical Testing
e.g. physicochemical analysis
- Veterinary Testing
e.g. toxicology of rodent/large animal samples
- Medical Testing
e.g. chemical pathology/haematology tests for patients in clinical trials

Which NATA Program? (cont)

- GLP Recognition
 - e.g. for data to be accepted for review by regulators and to access the benefits of MAD (Mutual Acceptance of Data), work needs to be performed by a facility that has been inspected by the national GLP compliance monitoring authority (NATA) for its compliance with the OECD *Principles of Good Laboratory Practice*

R&D Accreditation Criteria

R&D program accreditation criteria

- ISO/IEC 17025 (2005)
General requirements for the competence of testing and calibration laboratories
(available from NATA or Standards Australia)
- CITAC/EURACHEM Guide CG2 (1998) – Quality Assurance for R&D and Non-routine analysis
(available from www.eurachem.org/guides/rdguide)
- Supplementary Requirements for Accreditation for a given field of testing where these align with the research testing
(available from NATA)

Research Management Accreditation Criteria

Covered by Section 4 of ISO/IEC 17025 with interpretation for the research environment

- establishment and maintenance of a research management system
- review of contracts including responsibility for ongoing service to clients
 - client's requirements are clearly understood and agreed upon
 - client kept informed of changes to project plan, etc
- monitoring of purchased services and supplies
 - only supplies satisfying quality requirements are used
 - checked when received, etc

Research Management Accreditation Criteria (cont)

- control of documentation
 - identification, authorisation, change control
- control of records
 - record generation, integrity of data, storage, archiving and disposal
- arrangements for subcontracting
- internal auditing
 - ensure that staff comply with the facility's own documented procedures and the requirements for accreditation
 - also allows for early identification, resolution and prevention of problems
- periodic overview of work progress and highlighting of opportunities for continuous improvement

Technical Accreditation Criteria

Covered by Section 5 of ISO/IEC 17025 with interpretation for the research environment

- staffing
 - appropriate training
 - ongoing development
 - responsibilities defined
 - authorisations, etc
- accommodation and facilities
 - housekeeping
 - environmental conditions do not adversely affect testing performed
 - monitoring of environmental conditions, etc

Technical Accreditation Criteria (cont)

- sample handling and integrity
 - appropriate labelling
 - traceability of results back to sample
 - safekeeping and protection of sample
 - ensuring samples satisfy testing requirements, etc
- validation and control of methodology including statistical analysis and uncertainty of measurement
 - methods are documented
 - verification of std test methods
 - in-house developed or modified std methods are validated
 - methods are reviewed throughout study to ensure that they continue to satisfy objectives
 - appropriate level of QC is performed, etc

Technical Accreditation Criteria (cont)

- measurement traceability
 - results are traceable to SI units or other accepted reference parameters
- maintenance and calibration of equipment
 - calibrated to the extent necessary (where testing may be effected)
 - routinely checked and serviced
 - availability of operating manuals, etc
- trackability of data from receipt through testing phase to reporting

The Assessment Process

R&D program utilises NATA's existing assessment process

Advisory Visit

(NATA scientific officer)



Initial Assessment

(NATA SO + technical assessors* covering research and technical management)



Resolution of any Conditions for Accreditation

(NATA SO with input from technical assessors)



* NATA technical assessors are volunteers and experts working in the field

The Assessment Process (cont)



Accreditation granted

(certificate issued together with agreed scope of accreditation)



Surveillance Visit

(18 months from initial assessment a NATA staff officer reviews key accreditation matters with a focus on facility management issues)



Reassessment

(36 months from initial assessment a review is conducted by a NATA staff officer + technical assessors with a focus on technical issues)

R&D Program Status

- Program is operational since pilot assessment conducted in May 2004
- First R&D accreditation granted in 2005 to TetraQ - ADME
 - QLD based facility providing preclinical research and testing services to pharmaceutical companies in the areas of drug absorption, distribution, metabolism and elimination
 - also now holds GLP recognition

R&D Program Status (cont)

- 2nd R&D accreditation granted in Aug 2007
- Proteome Systems Limited
 - NSW based facility that performs disease specific biomarker research in various biological matrices to develop diagnostic tests and to identify therapeutic drug targets
- A number of advisory (early stage) visits to research facilities interested in R&D accreditation have been conducted

Defining Scopes of Accreditation

- “Scope of Accreditation”
 - is the manner by which NATA defines the range of activities covered by accreditation
 - format
 - identifies standard the facility was accessed against
 - includes description of the research activities
 - includes listing of the methods used

R&D scope of accreditation for TetraQ - ADME

This laboratory complies with the requirements of ISO/IEC 17025 (2005) interpreted for research using CITAC Guide CG2 *Quality Assurance for Research and Development and Non-Routine Analysis* (1998).

Management and conduct of research into pharmaceutical/biotechnology agents using appropriately validated human and mammalian animal models applicable to adsorption/distribution/metabolism/elimination studies and involving the determination of analytes in biological matrices.

Analysis of in-vivo and ex-vivo studies of biological tissues and fluids and non-biological matrices for drug and drug metabolite analytes using the following separation techniques and detection methods appropriately validated for the study being conducted:

HPLC with fluorescence, UV, electrochemical

GC with ECD, FID, NPD detection and GC-MS

LC & MS/MS

Radioisotope determination

ELISA using existing or transferred assays including development of assays utilising existing reagents

Accreditation No: 15153

Want to know more?

NATA welcomes the opportunity to talk with anyone interested in its programs

Specific contacts:

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QUESTIONS?

THANK YOU