

OPERATIONS & TECHNICAL UPDATE

MEMBERS' AND ASSESSORS' MEETING 2013

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- Assessment effort process
- Field Application Documents
- Format of scopes of accreditation
- Accreditation of new branch sites
- Technical assessors
- Sector updates

Assessment effort process

- January 2012 process was introduced
 - experience gained to-date has refined procedure (which will continue)
- The assessment of activities covered by the scope of accreditation is based on a sampling approach (core competencies)
 - move away from vertical audits for each 'method' covered by a core competency under the scope of accreditation
 - minimise duplication of assessment effort where additional confidence in competence is not provided

- Competencies are defined (based on field or program) as
 - disciplines, principles, techniques, modalities, materials/products, matrices, sample types etc (or a combination of these)
- Sampling plan developed by NATA is confirmed with assessment team to ensure adequate coverage of all activities under the scope of accreditation
- Dec 2012 NATA publicised the process and how competencies are defined in each field and program

Field Application Documents (FADs)

- Restructure of FADs was commenced in late 2011
 - extensive project which is now complete
 - new documents to be issued shortly on the NATA website
 - revamp of home page
 - communication to go out to members and assessors
- Purpose of the restructure
 - ensure
 - consistent accreditation application process across fields / programs
 - consistent expression of relevant NATA criteria applicable to all fields / programs
 - consistent guidance for equipment check and calibration intervals
 - In the past this information was repeated in all FADs which diverged over time
 - facilitate future reviews

- Hierarchy of restructured documents
 1. *NATA Accreditation Procedures Document*
 - relevant to all NATA applicant and accredited facilities
 - covers information on the application and accreditation process
 2. *Standard Application Document (SAD)*
 - 17025; 17020; 17043; Guide 34; R&D; OECD Principals for GLP
 - cover general NATA accreditation criteria + program specific interpretative information (other than for 17025 document)
 3. *ISO/IEC 17025 SAD* is supplemented with
 - Field specific interpretative information and criteria

- Separate guidance documents for equipment check and calibration intervals
 - reference equipment
 - general equipment

- Separate documents for classes and subclasses of tests

Format of scopes of accreditation

- Project commenced late 2011 to review the format (presentation) of scopes of accreditations
- Aims
 - to introduce a “*uniform format across all fields and programs*”
 - to improve search function on the NATA website
 - to ultimately allow in the future one scope to be issued per facility which may be accredited in more than one field and/or program
- Information to be presented in tabular format
 - fixed columns (mandatory information)
 - optional columns (dependent on specific industry, regulatory or member needs)
- Feedback from members and stakeholders to shortly be sourced on the information needing to be covered by the scopes

Accreditation of new branch sites

- Policy published In February 2013
 - allows a facility to claim accreditation for a new branch site established under its control prior to the new site gaining accreditation in its own right
 - for all or part of the base site's scope of accreditation
 - all relevant requirements for accreditation shall apply at the branch site
 - records to be submitted by the facility to demonstrate that branch site complies with requirements
 - once reviewed by NATA (chargeable activity) the application form is completed and the base site can then claim accreditation for the branch site with the expectation the branch site attain accreditation within 12 months

- Policy shall not apply where regulatory requirements preclude its application and to
 - CMT annex laboratories
 - Medical Imaging
 - Medical Testing (where Medicare benefits are claimed)
 - Sleep Disorders Services
 - calibration facilities

Technical Assessors

- *NATA Technical Assessors News*
 - Periodical publication dedicated to issues relevant to assessors was launched in April 2012

Life Science Sector update

Chemical Testing

- Review of NATA approval process for asbestos counters and identifiers
 - unless specified by regulatory requirements, individual approvals shall be discontinued following a review of the existing criteria

Forensic Science

- New policy issued Nov 2012 covering the accreditation of crime scene services
 - locations where crime scene officers are stationed and from where they attend a scene of crime no longer need to be separately accredited if the locations are under the control of a NATA accredited testing (examination) site
- Forensic Operations Module (FOM) FAD has been reissued as a Policy Circular and now only includes 4 criteria covering
 - control of case file records (including file reviews)
 - security and access of premises
 - evidence / sample control system (including integrity and storage)
 - monitoring of staff court testimony

Medical Testing

- Revision of ISO 15189
 - new version published in Nov 2012
 - Stds Aust has indicated it will publish the Australian version as AS ISO 15189
 - NATA is currently developing a transition policy which will include
 - appropriate lead-in time (tentative date of July 2013)
 - communication with members and assessor
 - gap analysis worksheet
 - revision of ISO 15189 Application Document
- Surveillance model
 - to be covered in Medical Testing forum

Good Laboratory Practice

- NATA is Australia's authoritative body for conducting audits against the OECD Principles on GLP
 - for non clinical health studies required by regulation for the registration of chemicals e.g. pharmaceuticals
- An evaluation of NATA by the OECD Working Group was conducted in September 2012
 - interim report identified only one minor non-conformity

Infrastructure Sector update

Construction Materials Testing

- Supervision arrangements
 - transition arrangements currently in place until July 2013
 - from July 2013
 - supervisory staff to be qualified based on their “level” (dependent on range and volume of services provided by the CMT facility)
 - removal of the NATA signatory approval process
 - any staff determined competent to approve results by the facility can do so irrespective of qualifications

Mechanical Testing

- Signatory approval process was ceased in March 2012

Inspection Sector update

- New version of ISO/IEC 17020 was published March 2012
- Stds Aust has received a proposal to adopt the standard without change
 - expected publication (if approved) is early 2013
- NATA is currently developing a transition policy which will include
 - appropriate lead-in time (tentative date of July 2013)
 - communication with members and assessor
 - gap analysis worksheet
 - revision of ISO/IEC 17020 Application Document

Clinical Services Sector update

Sleep Services Accreditation

- Joint accreditation program with the Australasian Sleep Association (ASA) launched in July 2012
- *ASA Standards for Sleep Disorders Services* have been developed which include the principles of ISO 15189
- 4 year assessment cycle with a surveillance visit scheduled mid cycle
- Two accreditations to-date