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UNIDO PROJECT FOR TRAINING OF STAFF OF BUREAU OF ACCREDITATION VIETNAM IN MEDICAL LABORATORY ACCREDITATION (ISO 15189:2007)

NATA REPORT TO BUREAU OF ACCREDITATION (BoA)

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Overview

The review was conducted in two parts; review of the BoA procedures, documentation and scope of accreditation; and full technical assessment of the Phu Phong Hospital in Binh Dinh province on behalf of the BoA, with Ms Jenny Lee, NATA as the Lead Assessor. Ms Lee was accompanied on the assessment by Ms Tran Thu Ha and Ms Nguyen Hong Nhung from the BoA. The technical assessor for the assessment was Dr Nguyen Gia Binh, Head of Medical Biochemistry, No. 108 Army Hospital, Hanoi.

As part of the UNIDO project, a training course was also provided for staff of the BoA together with staff from medical laboratories in Vietnam. The content of this course focused on the requirements of ISO 15189, validation of methods, measurement uncertainty and assessment techniques. The course was presented by Ms Edita Rokov, Learning and Development Consultant, NATA, from 6 to 9 June 2010, assisted by Ms Lee.

Background of current program

The BoA Medical Testing Accreditation program has been in operation since 2008, and currently has four accredited laboratories. Technical input is provided by the Medical Testing Technical Committee, which includes representatives from universities, technical institutes and accredited laboratories. There are approximately 20 invited members on the Technical Committee.

The Medical Testing program is generally in line with the other Laboratory Accreditation programs at the BoA, where reassessment is performed three years after the initial assessment of the laboratory, and surveillance visits are performed annually. However, due to the lack of medical testing experience of the Quality Assessors at the BoA, the surveillance visit also includes a technical assessor; surveillance visits in other programs do not use a technical assessor. It is intended that this training will assist them towards performing surveillance visits in line with the rest of the BoA programs.

Summary of review undertaken

A review of the procedures for accreditation by the BoA was undertaken to gain an understanding of the laboratory accreditation program, specifically for Medical Testing. This review included the review of the Supplementary Requirements for accreditation developed by the BoA, the scope of accreditation offered and the calibration requirements for equipment.

The on-site technical assessment of the Phu Phong Hospital in Binh Dinh province included a detailed review of the Quality Management System, specimen collection facilities and procedures and a review of the technical management of the laboratory as would normally be done at a surveillance visit.

Recommendations for changes to documentation

AGM01 Supplementary Requirements for Accreditation in the field of Medical Testing

It is recommended that those sections in this document which are duplications of wording from the ISO 15189 Standard be deleted. This information has been summarised in attachment 1. Further recommendations are detailed as follows:

2.1.2 It is understood that the disciplines listed in the Note will be combined and reduced to a maximum of 6 disciplines.
2.1.3 The services which must be performed by a pathologist should be more specifically stated e.g. tissue cut-up, reporting.
3.1.1 Requirements for information included on the request form could be tailored to include additional information required for Vietnamese laboratories, in line with Ministry of Health requirements. It is understood that there is limited control over the request forms which are government issued.
3.2.6 Requirements for acceptance of samples received with inadequate labelling information could be expanded to require that the action to be taken where these samples are rejected, or accepted for testing, is documented.
4.1 This paragraph should be moved to the Pre-examination procedures section.
4.6 The organisation may wish to consider specifying the minimum review period for methods documentation.
4.16 The organisation may wish to consider increasing the retention period for outdated procedures to three years, in line with the technical reassessment period of the BoA, and as a requirement rather than a recommendation. The current period is specified as two years, and is written as a recommendation only.
6.3 Consideration should be given as to whether the inclusion of gas is required in this requirement. Gas is rarely required in different grades of purity in medical laboratories.
7.1.4 This paragraph could be reworded to state “Records of calibration must be kept, which must also include the details of the reference material used”. A list of required details could also be included.
9.4 The following wording could be considered: “Tolerance limits shall be established from the results of the validation studies of the test”.
9.5, 9.6 and 9.7 These paragraphs should be moved to the Examination procedures section.
9.9 This paragraph should be deleted as it is a duplicate of 4.5.
11.2 Please refer to Attachment 2 for information requested regarding this section.
12 A copy of the document *Requirements for the Retention of Laboratory Records and Diagnostic Material* NPAAC (2009) has been provided to the organisation for guidance in developing retention periods for various sample and document types. It is recommended that the BoA develop retention periods relevant to Vietnamese laboratories and include this in the document.

Please note that no comments have been made on sections: 10. Laboratory Safety; 11. Biological Hazards and Control Safety; and 13. Radioactive Safety as NATA does not regulate safety requirements in Australian laboratories. The exception to this is 11.2 as above, for which input was specifically requested by the BoA. This request was referred to one of NATA’s Australian technical assessors and the feedback is provided in Attachment 2. The organisation should consider this information when formulating their requirements.

Additional information that the BoA may wish to consider including in the document:

- A requirement that the person making changes to data and the date on which the changes are made, is identified in the laboratory records. Consideration could also be given to requiring the identification of the operator performing critical steps of each testing process in the laboratory records;
- Retention of original data and calculations for all results;
- Where staff are employed to work outside regular hours (e.g. overnight or weekend shifts), there should be a requirement for them to have regular contact with supervisory staff;
- Stricter requirements should be included for monitoring of blood bank refrigerators, due to the high patient risks involved e.g. requirement for a dedicated refrigerator with continuous monitoring and thermostat alarm function, periodic checking of alarm function, specific temperatures for the high and low alarm points to be set. The organisation is encouraged to refer to AS 3864 – 1997 *Medical refrigeration equipment – For the storage of blood and blood products* Standards Australia for guidance;
- Minimum requirements for sample labelling on receipt into the laboratory and action to take in the event of receipt of an inadequately labelled or mislabelled sample;
- Criteria for mandatory review by a specialist doctor (e.g. Haematologist) for morphology blood films;
- Minimum requirements for information to be included in the validation or verification of methods, e.g. minimum number of samples, statistical analysis etc.;
- Additional requirements for QC performance and review, e.g.:
    - Acceptable ranges (tolerance limits) to be reviewed and set by the laboratory, and the criteria for setting these limits to be defined;
    - Consideration of graphical representation of QC results; and
    - Review of QC results on a long-term basis for trends and drift.
- More frequent monitoring of haematology analysers for "drift", (relevant for older, less stable analysers)
- Performance of QC testing on antibiotic discs using reference organisms
- Minimum requirements for estimating measurement uncertainty , which should be reviewed and increased on a periodic basis by the BoA e.g. Procedure for calculation, policy for reporting and completed estimates for at least one analyte; the minimum number of calculations could be increased annually or with each surveillance cycle; and
- QAP considerations:
    - Preference of enrolment in Vietnamese QAP programs to reduce variations due to patient populations;
    - All QAP samples should be treated as a normal patient sample, as far as possible;
    - Review of corrective action required to be taken to unacceptable QAP results must take into account the effect on patient results; and
    - All staff must participate in testing of QAP samples.

The above recommendations have been taken from the NATA Supplementary Requirements and could be considered as being relevant to Vietnamese laboratories also.

Additional useful publications may also be obtained from the National Pathology Accreditation Advisory Council (NPAAC) website: www.health.gov.au/npaac

AGM01 Supplementary Requirements for Accreditation in the field of Medical Testing Annex 1

Additional translation into English is required to complete the document. This has been identified and discussed with BoA staff.

3. It is recommended that this requirement be changed to state “Calibration in line with manufacturer’s recommendations”, as daily use of QC material is usually sufficient to monitor ongoing performance between calibrations.
9. Requirements for maintenance of gas chromatographs should be in line with manufacturer’s recommendations.
14. The name of the item of equipment should be titled: “PCR Machine”, and use of control samples should be required on each use, rather than periodically.
19. Manual testing for haematocrit is performed using a centrifuge, for which the checking requirements are already specified. This requirement should be removed.
21 and 37. The term “thermometer sink” should be amended to “water bath”.
23. The requirement for an annual check of the temperature using a calibrated thermometer is previously specified as a requirement for daily checks. This should be reviewed.
25. The English description of the checking requirements should be expanded to match the Vietnamese version.
28. Checking of pH meters should specify that the accuracy check should be performed using reagent buffers with known pH concentration.
29. Checking of a volumetric flask on a 6 month basis should be reviewed, as there is usually very little variation in glassware in its lifetime.
33. Checking of timers should be allowed to be performed internally, rather than external calibration. Consideration should also be given to the use of the timer, being critical or non-critical.
35. It is understood that this item is to be deleted.
37. The term “overheat” should be amended to “oven”. Further, the term “Divisional temperature” should be amended to “Spatial temperature”.

It is recommended that the BoA review the calibration requirements contained in the current NATA Supplementary Requirements document (July 2009), as these have changed significantly since first adopted by the BoA.

An offer to conduct a second review of the completed document for English grammatical changes has been made if required by the BoA.

AGY09 Guideline for the selection of medical disciplines for accreditation

3. The statement: “A standard examination procedure may be required by national or international standard organisation” should be removed, as there are no standard procedures used in medical testing laboratories. Consideration should also be given to combining the disciplines of Nuclear Medicine and Imaging Testing, as Nuclear Medicine is incorporated in Imaging Testing.

General discussion was conducted during the review regarding the inclusion of Medical Imaging in the Medical Testing accreditation program. The BoA were advised that the disciplines have been separated into two separate fields within NATA, as the Medical Imaging facilities follow a different set of standards written by the Royal Australian and New Zealand College of Radiologists (RANZCR). These standards can be obtained by application to the College via the website www.ranzcr.edu.au

Suggestions for the classification of items in the scope of accreditation:
2. Haematology and Blood Transfusion
- 2.1.3 Immunohaematology should be deleted as it is incorporated into section 2.2.
- 2.2.2 Blood bank investigation should be expanded to be titled “Blood bank investigation of transfusion reactions” to provide more clarification.

3. Clinical Microbiology and Infection
- 3.1.2 Examination of structure by electro-microscopy should be defined as “electronic microscope” to clearly differentiate from electron microscopes. This applies to all sections of the Microbiology scope.
- 3.1.3 and 3.1.7 Consideration should be given to combining these items unless the difference between “Molecular Biology” and “Genetic” can be defined. This applies to all sections of the Microbiology scope.
- 3.2.5, 3.3.5, 3.4.5, 3.5.5 and 3.6.5 should be reviewed for relevance, as the organism relevant to this section may not be affected by antibiotics. e.g. 3.5.5 may be more appropriately called Anti-fungal sensitivity tests.

4. Cytopathology
This section may be better defined as Anatomical Pathology, which incorporates both Cytology and Histology.

4.1.3 and 4.1.5 Consideration should be given to combining these items unless the difference between “Molecular Biology” and “Genetic” can be defined. This applies to all sections of the Anatomical Pathology scope.

Consideration could also be given to reorganising the scope to represent the following:

4. Anatomical Pathology
4.1 Histology
4.1.1 Anatomical
4.1.2 Surgical
4.1.3 Experimental
4.1.4 Clinical
4.1.5 Immunohistochemistry

4.2 Cytology
4.2.1 Fine Needle Aspiration
4.2.2 Exfoliative
(4.2.3 Gynaecological Cytology) [not currently included in document]

Copies of other useful documentation have also been provided to the BoA. These include but are not limited to:

- NATA Medical Testing proforma documents (report proforma, response review, Supplementary Requirements, Technical Guide for interpretation of Medical Testing scope of accreditation etc)
- NATA Rules and Technical and Policy Circulars
- Royal College of Pathologists of Australasia (RCPA) position statements
- Additional NPAAC documents

Recommendations for assessment procedures

On-site assessment of the Phu Phong hospital concentrated on the quality management system (QMS), specimen collection and technical management of the laboratory which are reviewed during surveillance visits. It was noted that no time was spent with the technical assessor during this review. Standard NATA practice during technical assessments is to spend a significant proportion of the assessment day assisting the technical assessor(s) and reviewing the technical aspects also. This allows consistency between assessments from a technical perspective, and ensures that the Lead Assessor is aware of the areas/testing which have been reviewed and the issues arising from this review. It is recommended that the Lead Assessor spend more time with the technical assessor during technical assessments, not only to ensure all areas are adequately reviewed, but to increase the knowledge of the Lead Assessor in medical laboratory practices. Focus on the QMS can be done during the annual surveillance visits.

It is also recommended that a checklist be provided to the technical assessor to ensure that all areas of the laboratory are reviewed. An example of the checklist used by NATA's technical assessors has been provided, however the BoA may wish to devise a shorter checklist for their own purposes.

It was observed during the assessment process that limited discussion on QC and QAP review was held by the technical assessor. Although the assessment performance of only one assessor cannot determine the techniques of other assessors, it also highlights the fact that the Lead Assessor was not able to ensure all areas of the laboratory were adequately reviewed. It is recommended that training in QC and QAP procedures and review be included in the technical assessor training programs conducted by the BoA. This training could include the following:

- Setting tolerance limits
- Long term review
- Action to take to failed QC and QAP results

Although the processes of hospital pathology in Vietnam differ greatly from those in Australia, an important part of review within medical testing laboratories is the input provided from clinical staff. The Medical Testing accreditation program within NATA is a joint program with the Royal College of Pathologists of Australasia (RCPA), and therefore requires a pathologist (speciality doctor) to be present on each assessment team. This ensures that the assessment of the laboratory not only covers the technical aspects of the laboratory testing but the clinical reporting also. It is strongly recommended that the BoA adopt a similar process in the medical testing field to ensure that clinical interpretation is covered by the assessment process.

Other recommendations for consideration

In addition to the training recommended for technical assessors in QC and QAP procedures and review, it may be beneficial for Lead Assessors to also be trained in these processes. This will assist the staff in not only understanding the issues that may be raised at the assessments, but should also allow a more effective surveillance visit to be conducted between technical reassessments.

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Att: 1. Comparison of duplicated sections of Supplementary Requirements and ISO 15189
2. Information from NATA technical assessor regarding handling of microbiology samples in a Biological Safety Cabinet

ATTACHMENT 1

Comparison of duplicated sections of Supplementary Requirements and ISO 15189

Supplementary requirements reference	ISO 15189 reference	Other comments
2.1.4	4.1.5h)	Not identical, but very similar and should be compared by the organisation for similarities
2.2.1	5.1.4	Identical for all clauses a) through to o)
2.2.2	5.1.4	Last paragraph of 5.1.4
3.1.1	5.4.1	Identical, refer also to comment in body of report
3.2.1	5.4.2	Identical
3.2.2	5.4.3a)	Identical for all clauses a) through to d)
3.2.3	5.4.3b)	Identical for all clauses a) through to c)
3.2.4	5.4.3c) & d)	Identical for all clauses a) through to m)
3.2.5	5.4.4	Identical
3.2.6	5.4.5	Identical, refer also to comment in body of report
3.2.7	5.4.6	Identical
3.2.8	5.4.7	Identical
3.2.9	5.4.8	Identical
3.2.10	5.4.9	Identical
3.2.11	5.4.10	Identical
3.2.12	5.4.11	Identical
3.2.13	5.4.12	Identical
3.2.14	5.4.13	Identical
3.2.15	5.4.14	Identical
4.2	5.5.1	Identical
4.4 first paragraph	5.5.2	Identical for first paragraph only, second paragraph OK
4.6	5.5.2 second paragraph	Identical, refer also to comment in body of report
4.7 – 4.9	5.5.3	Identical
4.10 second sentence	5.5.2 second paragraph	Similar, but not identical
4.12	5.5.4	Identical
4.13	5.5.5	Identical
4.14	5.5.6	Identical
4.15	5.5.7	Identical
5.1	5.2.1	Identical
5.2	5.2	Similar to a number of the clauses throughout 5.2
5.3	5.2.2	Identical
5.4	5.2.3	Identical
5.5	5.2.4	Identical
5.6	5.2.4 second paragraph	Identical
5.7 first sentence	5.2.5 first sentence	Identical

Supplementary requirements reference	ISO 15189 reference	Other comments
5.8	5.2.6	Similar, but not identical
5.10	5.2.7	Identical
5.11	5.2.8	Identical
5.12	5.2.9	Identical
5.13 and 5.14	5.2.10	Identical
7.2.3	4.6.2	This clause is incorporated in the requirements of clause 4.6.2, however the organisation may wish to retain this clause specific to reference materials
8.1	5.3.1	Identical
8.2 and 8.3	5.3.2	Identical
8.9	5.3.9	Identical
8.10	5.3.13	Identical
8.12	5.3.3	Identical
8.13	5.3.4	Identical
8.14	5.3.5	Identical
8.15	5.3.6	Identical
8.16	5.3.7	Identical
8.17	5.3.8	Identical
8.18	5.3.10	Identical
8.19	5.3.12	Identical
8.20	5.3.11	Identical
8.21	5.3.14	Identical
9.1	5.6.1	Identical
9.10 second sentence	5.6.5	This sentence could be referred to in the Standard as a reference to the additional information provided in the document
9.13	4.2.5	Identical

ATTACHMENT 2

Information from NATA technical assessor regarding handling of microbiology samples in a Biological Safety Cabinet

For handling of mycobacteria, fungi and viruses – Supplementary Requirements document reference 11.2.

Mycobacteria - Handling of any confirmed or presumptive mycobacteria samples should be performed within a BSC.

Viruses - all viral culture work in cell cultures should be done in a BSC. The only time this may differ is for Rotavirus and Adenovirus investigations in faecal samples. These may be done in a fume cupboard to reduce the smell rather than for safety reasons. They are antigen tests though, so don't strictly fit into the "virus culture" definition. However, there is a case for using a BSC where the sample may be mixed in a diluent thereby creating aerosols which could potentially cause infection in a staff member.

Fungi - all fungi mould cultures that have grown should be handled in a BSC, as the most innocuous looking white fungus could eventually be identified as a Histoplasma. However, for other fungi e.g. yeasts such as Candida, these may be handled on a bench, with the exception of Cryptococcus. Any mucoid yeast growing on the plate should be handled in a BSC for manipulation. However, these are only likely to be found in CSF samples.

Other samples that are taken as a direct fungal culture from a specimen may have various handling requirements. All genital swabs that are cultured for fungi (Candida) may be handled on the bench, as well as all Ear/Nose/Throat cultures. Skin Scrapings and Nail Clippings looking for tinea may be processed on a bench or in a BSC. Tissues, sterile fluids, and respiratory samples could potentially contain Mycobacteria or infectious fungus that should be prevented from inhalation by laboratory staff by handling in a BSC. However, the fungus is most dangerous when cultured, therefore cultures are usually required to be handled in a BSC.