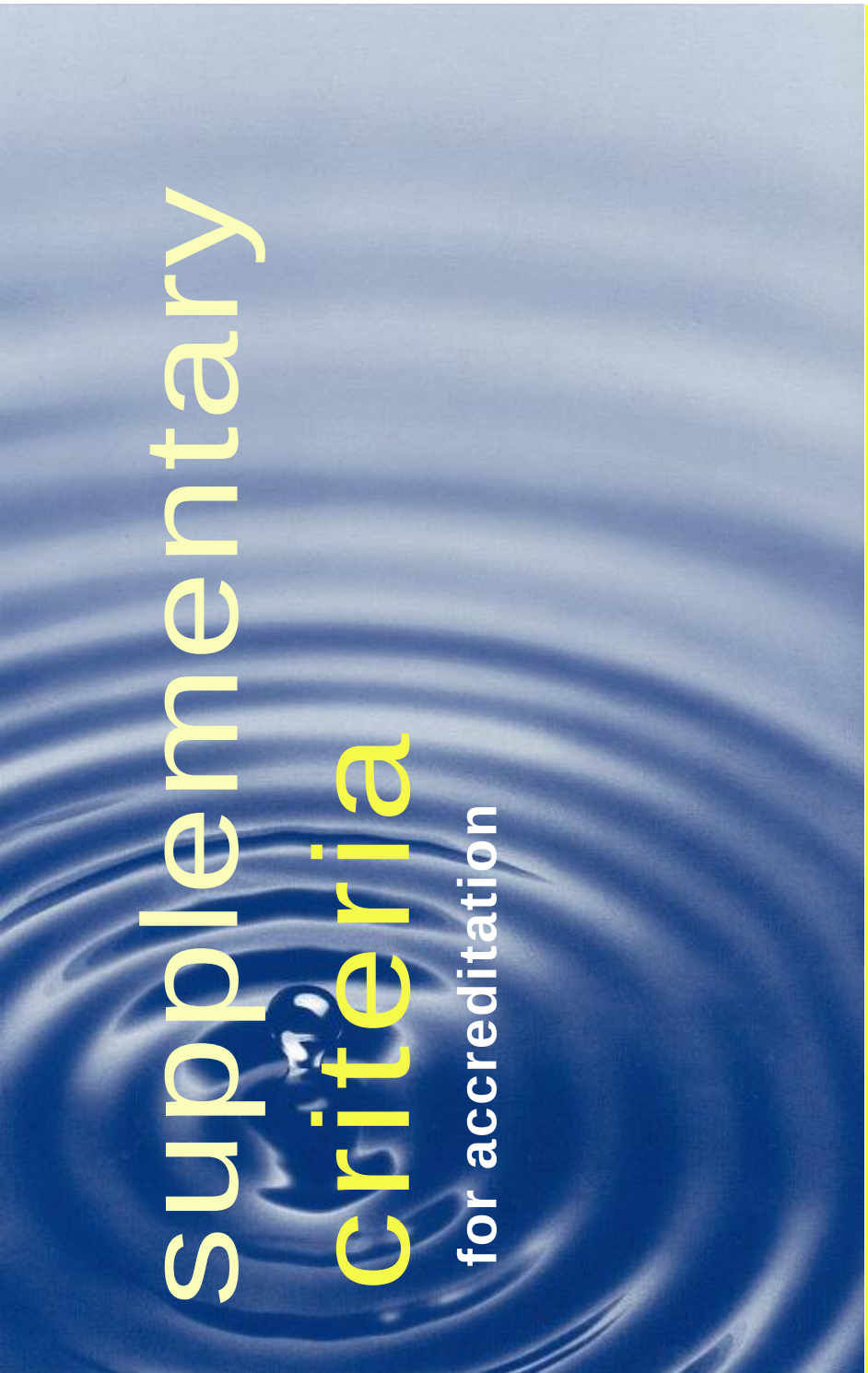
IANZ




**Medical Testing Laboratory Accreditation Programme**

# Requirements for Minimising Errors in Medical Histology Laboratories

# supplementary criteria for accreditation

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## AS LAB C7.2

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# 1 Introduction

**1.1** International Accreditation New Zealand's (IANZ) Supplementary Criteria provide supplementary information to the General Criteria and Specific Criteria for Accreditation for specific types of testing activities. They provide detail or add extra information to the generally stated requirements of IANZ General Criteria for Accreditation and IANZ Specific Criteria for the particular field.

**1.2** This supplementary criteria details the specific requirements covering the accreditation of medical testing laboratories carrying out histology examinations within their scope of accreditation.

**1.3** This is a supplementary document to IANZ Specific Criteria 7 (AS LAB C7) which includes general requirements for medical testing laboratories. This document must be read in conjunction with the current issues of the following standards and IANZ publications:

*(a)* ISO 15189 *Medical laboratories — Requirements for quality and competence*

*(b)* *Specific Criteria for Accreditation: Medical Testing* (AS LAB C7)

*(c)* *Procedures and Conditions of Accreditation* (AS1)

# 2 Requirements for Minimising Errors in Medical Histology Laboratories

## 2.1 Key

| |
|---|
| **Minimum Requirements**<br>Specific Criteria with which laboratories will need to demonstrate compliance. |
| **Best Practice**<br>These are not conditions for accreditation but may result in recommendations. |
| **Suggestions/Options**<br>It should be noted that the items in green are suggestions/options from literature that laboratories worldwide have adopted to minimise errors and as such are only considerations for laboratories in New Zealand to appraise. |

It is important to note that some of these checking systems will be incorporated if a tracking system has been implemented in the laboratory as some of these steps are inherent in such systems. Similarly, points regarding tracking systems are not applicable to laboratories with only manual systems in place.

It should be emphasised that tracking systems and barcoding are all optimal solutions, however these cannot be made compulsory so all aspects must be considered for laboratories whether using manual or tracking systems.

It is worth noting that before tracking systems are introduced a robust manual system must first be in place.

## 2.2 Overarching Requirements

Minimum requirements are the same regardless of whether a manual or an automated tracking system is in place. The processes utilised to achieve these requirements may differ between a manual and an automated tracking system.

| **The following are minimum requirements:** |
|---|
| **Staffing, training and competency:**<br>• The laboratory has appropriate FTE and skill mix to safely manage workload.<br>• Staff must be trained and competent for the tasks they perform.<br>• Detailed and robust training/supervision for all new staff members with comprehensive training and on-going competency records.<br>• Comprehensive training and on-going competency records are available for pathologists and laboratory staff performing cut-up with attestation of competency by a suitable/relevant person |
| **Processing tasks:**<br>• Single piece work flow.<br>• Identification of the staff member handling each specimen at each step in processing is recorded. |
| **Non-conformances and incident investigation:**<br>• Non-conformances are documented and addressed as they are noted.<br>• Any relevant discrepancies noted during the procedures, including pre-laboratory issues and inadequate labelling, are incorporated as cautionary/explanatory notes in the final authorised report.<br>• All incidents are identified, recorded and managed, including near misses, in line with organisational policies and procedures to detect trends and as a preventative measure and inclusion of root cause analysis where required.<br>• All records such as logs/schedules/audit trails are referenced and included as part of the investigation into incidents.<br>• There is a mechanism for feedback and follow-up of discrepant histology findings.<br>• Notification to the appropriate relevant authority of all critical events for review. |
| **Histology facilities:**<br>• Ventilation and extraction systems must be fit for purpose to ensure safe working conditions and air quality checks are performed periodically.<br>• Segregation of cut-up from other tasks to minimise distractions.<br>• Controlled working environment with minimisation of distractions and interruptions during all processing steps. |

## 2.3 Requirements by Histology Processing Tasks

| Task | Minimum Requirement | Best Practice | Options/Suggestions |
|---|---|---|---|
| **ACCESSIONING** | • Two independent checks to ensure that specimen and request form details match, including reconciliation between the registration and accession number where applicable. **(CRITICAL CONTROL POINT)**<br>• Single piece flow accessioning where one case is removed from the specimen bag, checked, labelled and completed, before the next case is started.<br>• Minimum labelling requirements of specimens are adhered to prior to processing of the specimen/s.<br>• At least two identifiers attributable to the patient that match between specimen/s and request form.<br>• Specimens with similar or same surnames are separated. | • Introduction of a LIS barcode tracking system or third party workflow system from registration through to reporting.<br>• Specimens of the same tissue type are separated so they are not sequential or if this is not possible, implement a process that separates the cases.<br>• Capture any additional annotation/notes/reports/images with the request form/documentation post registration. Scan and save all related documents including the request form again if it was used to add notes at cutup. | • Using one specimen number for the entire process rather than a registration and a histology accession number. |
| **GROSSING / CUT-UP** | • A segregated room/area with ventilation for formalin fume extraction for cut-up/grossing.<br>• Effective physical separation between specimens.<br>• Patient request form image or hard copy must be accessible for checking. | • The use of phones restricted to work-related calls/consultations ONLY. Automated verification of cassettes at cut-up.<br>• Single piece workflow Cassette/s labelled as being cut-up/grossed rather than pre-labelled. | • Labelling of consecutive specimens with alternating colours using approved diluted marking ink and the colour recorded on the request form.<br>• Inking core biopsies inked at cut-up/grossing station with differing colours by adding ink to the formalin solution and the colour recorded on the request form. |

| Task | Minimum Requirement | Best Practice | Options/Suggestions |
|---|---|---|---|
| | • Specimen barcode scanned into the LIS rather than manually entered.<br>• Confirmation that the specimen and request details match.<br>• Repeat dictation of registration and/or accession number, the patient name and block designation from the cassette in addition to the initial dictation from the specimen.<br>• One specimen/pot grossed/opened at a time.<br>• Before cup-up, three-way check that all details match on specimen pot, cassette and request form and against the tracking system if one is used. **(CRITICAL CONTROL POINT)**<br>• Minimum labelling requirements for cassettes are adhered to prior to processing of specimen/s.<br>• At least two **unique** identifiers that match between cassette/s, specimen/s and request form.<br>NOTE: If the surname is used as one of the unique identifiers it must include as many characters as possible.<br>• Designated area for cut-up/grossing. | • If the laboratory is utilising an automated system the barcode labels generated need to include at least a two 'human readable' unique identifiers. | • Additional specimen identification on the cassette/s such as specimen type or type of procedure. |

| Task | Minimum Requirement | Best Practice | Options/Suggestions |
|---|---|---|---|
| | • If the area is shared with other activities, ensure that entry by other staff members is restricted during cut-up/grossing. | | |
| **EMBEDDING** | • One cassette opened at a time for transfer of tissue. **(CRITICAL CONTROL POINT)**<br>• A system for recording embedding discrepancies is in place. | | |
| **MICROTOMY / CUTTING / SECTIONING** | • Effective physical separation between cases that require isolation / interruption to workflow, such as decal or cooling from other cases and those that are work in progress. **(CRITICAL CONTROL POINT)**<br>• Labels that are pre-printed must not be affixed to slides until the case is being cut.<br>• Slides should only be labelled once with labels that will survive subsequent staining processes rather than labelled with a new/different label at the booking-up/issuing/case assembly step.<br>• Tissue sections are cleared from the water bath between each block cut.<br>• Minimum labelling requirements for slides are adhered to. At least two | • Complete cases to be cut by one person.<br>• Slides are labelled as cut for each case rather than pre-labelled slides.<br>• Scanning of the block barcode for LIS initiated microtomy/cutting/sectioning instructions for each case with the ability to specify the number of slides required.<br>• If the laboratory is utilising an automated system the barcode labels generated need to include at least two ‘human readable ‘unique identifiers. | • Clear process to manage incomplete sectioning of a case – perhaps due to block warming etc. |

| Task | Minimum Requirement | Best Practice | Options/Suggestions |
|---|---|---|---|
| | **unique** identifiers that match between slide, block and request form.<br>NOTE: If the surname is used as one of the unique identifiers it must include as many characters as possible.<br>• Alterations to original labelling must be traceable.<br>• No answering of cell phones or taking telephone calls while performing microtomy / cutting / sectioning. | | |
| **BOOKING UP / ISSUING / CASE ASSEMBLY** | • Correlation of request form details to the slide/s and the macro appearance of the block to the corresponding slide and check against the LIS/Tracking system if one is in use. **(CRITICAL CONTROL POINT)**<br>• Specimens with similar or same surnames are separated. | • Like specimens of the same tissue type are physically separated. | |
| **MICROSCOPY** | • Policy/Procedure in place for confirmation of patient's specimen and request form prior to examination of slides. **(CRITICAL CONTROL POINT)** | • Implementation of barcode initiated reporting for pathologists. Must include a 3 way check with the request form, slide and LIS. | |

# 3 Histology Incidents – Identification, Management, Reporting & Monitoring

*Ratified by NZ Medical Laboratory Quality Managers' Group, 20 June 2014*

## 3.1 Incident Category

| Error Type: | Error occurred at: | | | | | | |
|---|---|---|---|---|---|---|---|
| | Pre-accession | Accessioning | Cut-up / Grossing | Embedding | Microtomy | Case issue | Microscopy / Reporting |
| **1 Labelling Error** | **1a** | **1b** | **1c** | **1d** | **1e** | **1f** | **1g** |
| **2 Specimen Transposition/ Mismatch** | **2a** | **2b** | **2c** | **2d** | **2e** | **2f** | **2g** |
| **3 Specimen Loss** | **3a** | **3b** | **3c** | **3d** | **3e** | **3f** | **3g** |
| **4 Reporting Error** | **4** | | | | | | |

## 3.2 Severity / Action Matrix

| Consequence | Action |
|---|---|
| **Pre-reporting - Specimen recoverable and/or clinical management NOT impacted** | **Near Miss/ Minor:**<br>Manage through team level review and improvement processes |
| **Pre-reporting - Specimen unrecoverable and/or clinical management impacted** | **Moderate / MAJOR:**<br>Escalate to senior management. Detailed investigation/ Root Cause Analysis required |
| **Post-reporting - Clinical management NOT impacted** | **Moderate:**<br>Escalate to senior management. Detailed investigation required |
| **Post-reporting - Clinical management impacted** | **MAJOR:**<br>Escalate to senior management. Detailed investigation/ Root Cause Analysis required |