

STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE:	Revision Date: Issue Date:
Creation, Review, and Approval of Documents	30 September 15 30 September 13
Document Number: QUA70000	Status: Approved
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Approved by:	Signed by:
C. Case, Manager of Diagnostic Services	Signed by: Cheryl Case

PURPOSE:

This policy provides guidance for the processes and procedures to be used in controlling Stanton Territorial Hospital Laboratory's documents and records.

POLICY:

Management of Stanton Territorial Hospital Laboratory ensures that documents and records are managed from creation or receipt to archive or destruction according to established processes that reflect the organization's commitment to quality as well as meet legal requirements.

RESPONSIBILITY:

The Manager of Diagnostic Services and the Laboratory Supervisor are responsible for establishing and maintaining the document control system for Laboratory documents. This includes the following:

- Following approved processes for receiving incoming documents and records
- Creating and gaining approval for all necessary documents and forms
- Ensuring that staff have immediate access to current copies of the documents they need to perform their work
- Overseeing the accurate and complete creation of records
- Prompt removal of obsolete documents from the workplace
- Ensuring destruction when appropriate
- Storage and access of all required documents and records.

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DOCUMENT CREATION:

Standardized formats are used for creating all types of documents to ensure consistent and effective representation of all requirements.

REVIEW and APPROVAL:

- Staff who are familiar with the subject matter of a given document are assigned to review new documents before they are implemented.
- Staff who are familiar with the original document review and approve changes to a document.
- Approval from the Laboratory Manager is obtained before implementation

DOCUMENT AVAILABILITY and STORAGE:

Controlled copies of documents are:

- Available to staff as required
- Maintained, stored and retrievable
- Retained for periods specified in the approved retention schedule outlined in Hospital Wide Policy R-1960 Retention of Hospital Records.

DOCUMENT MASTER LIST and NUMBERING SYSTEM:

- The Manager of Diagnostic Services and the Laboratory Supervisor maintain a
 master list of current versions and effective dates of documents in this quality
 management system, to ensure all staff accesses only the most recent document.
- Each document is uniquely identified to ensure traceability throughout the document life cycle.

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REVIEW and ISSUE:

Controlled documents are reviewed on a scheduled basis and reissued after significant changes are made.

RECORDS: REVIEWS, RETENTION, STORAGE, and RETRIEVAL:

- Managers, Supervisors and Tech IIs review records according to established schedules.
- Records are retained for periods mandated by government regulations, accreditation requirements, and the organization's policies.
- Records are stored in a manner that maintains integrity, prevents damage or destruction, and facilitates retrieval.

RELATED DOCUMENTS:

- QUA70200 Creating, Reviewing, and Approving Laboratory Documents
- QUA70100 Document Creation Review and Approval Flow Chart
- P-1760 Policy and Procedure Routing
- QUA70210 Document Creation/Change Request Form
- QUA70220 Laboratory Policy/Procedure Template
- QUA70230 Laboratory Document Template Portrait
- QUA70240 Laboratory Document Template Landscape
- QUA70250 Training of Laboratory Staff for New or Changed Procedures.
- QUA70300 Laboratory Document Review Procedure
- QUA70310 Laboratory Document Review Form
- QUA70410 Laboratory Master Document List
- QUA70400 Laboratory Master Document List Maintenance Procedure.
- QUA70500 Record Retention, Storage, Retrieval and Destruction
- QUA70510 Laboratory Archive Log Sheet

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QUA70520 Laminated Placeholder Job Aid

REFERENCES:

Clinical and Laboratory Standards Institute. (2006). *The Key to Quality:The fundamentals for implementing a quality management system in the clinical laboratory.* Wayne,Pennsylvania: Clinical and Laboratory Standards Institute.

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	30Sep13	Initial Release	C. Russell