STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: Laboratory Document Review	**Revision Date:** 30-September-15	**Issue Date:** 30-September-13
Document Number: QUA70300	**Status: Approved**	
Distribution: Laboratory Quality Manual	**Page:** 1 of 3	
Approved by: C. Case, Manager of Diagnostic Services	**Signed by:** Cheryl Case	

PURPOSE:

Periodic review of unchanged documents may be useful to detect errors, oversights, or work practices that have diverged from the formal procedures. Accreditation Canada states that every two years a review of documents is required.

Document review is also essential for new or edited procedures to ensure that Laboratory personnel have access to the information they require to perform their duties in a safe and effective manner.

POLICY:

See **QUA70000 Creation, Review, and Approval of Documents**

PROCEDURE INSTRUCTIONS:

Step	Action
Performing a Laboratory Document Review	
1	The Manager of Diagnostic Services and the Laboratory Supervisor may deem that a Laboratory document needs review at any time. This process may be the result of an incident or occurrence, as a refresher for a specific individual that has deviated from the formal procedure in their day to day work practices. The laboratory will also make an effort to review all controlled documents annually in order to apply with Accreditation Standards. The Manager of Diagnostic Services or the Laboratory Supervisor will initiate document reviews based on the review dates on each document as they appear in **QUA70410 Laboratory Master Document List**. 

2	The individual initiating the review will complete Section A of **QUA70310 Laboratory Document Review Form** and email it to the selected reviewer(s).
3	The reviewer(s) will print a hard copy of the document from the electronic manuals located in the laboratory shared drive. The reviewer(s) shall carefully review the document and mark any changes or corrections on the document in **red ink**. The reviewer(s) will then log the rest of their comments on Section B of **QUA70310 Laboratory Document Review Form** and email it to the person initiating the review. The hard copy can then be placed in the mail box on the door of the Laboratory Supervisor's office.
4	The Laboratory Supervisor will make any required changes to the document then forward the document to the Manager of Diagnostic Services for final approval. If no changes are required to the document the Laboratory Supervisor will log the review in the Revision History section of the document (if applicable) and change the Revision Date on the electronic version. The Manager of Diagnostic Services will not be required to re-sign unchanged controlled documents. Email notifications will also not be sent out to end users for documents not requiring change. 
5	Once the document receives final approval, the Laboratory Supervisor will place the new version of the document (hard copy) in the appropriate location and notify the applicable staff that the new document is available for use. An electronic copy will also be placed in PDF format in the Lab shared drive. 
6	If staff training is required, a copy of the document will be added to the MTS website along with a quiz to verify that the document has been read and understood by the applicable individuals. Should hands on competency training be required, training sessions will be performed by Tech IIs in the appropriate areas and documented. See **QUA70250 Training of Laboratory Staff for New or Changed Procedures.** 

7	The Laboratory Supervisor will then record the changes on **QUA70410 Laboratory Master Document List**. See **QUA70400 Laboratory Master Document List Maintenance Procedure**. Electronic copies of **QUA70310 Laboratory Document Review Form** will be saved in the Laboratory Supervisor shared drive.

RELATED DOCUMENTS:

- QUA70000 Creation, Review, and Approval of Documents
- QUA70410 Laboratory Master Document List
- QUA70310 Laboratory Document Review Form
- QUA70250 Training of Laboratory Staff for New or Changed Procedures
- QUA70400 Laboratory Master Document List Maintenance Procedure

REFERENCES:

- Clinical and Laboratory Standards Institute. (2006). *Laboratory Documents: Development and Control; Approved Guideline - Fifth Edition.* Wayne, Pennsylvania: Clinical and Laboratory Standards Institute.
- 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