

STANTON TERRITORIAL HEALTH AUTHORITY

Yellowknife, Northwest Territories

TITLE: Creating, Reviewing and Approving Laboratory Documents	Revision Date: 30 September 15	Issue Date: 30 September 13
Document Number: QUA70200	Status: Approved	
Distribution: Laboratory Quality Manual	Page: 1 of 4	
Approved by: C. Case, Manager of Diagnostic Services	Signed by: <i>Cheryl Case</i>	


PURPOSE:

The need to create a new document or change an existing document may arise at any time. Whether due to methodology changes, process changes, in response to an incident, or as an improvement based on quality indicator data, changes to laboratory documents occur on a regular basis. Regardless of the reason, this procedure outlines the steps to take.

POLICY:

- See QUA70000 Creation, Review, and Approval of Documents for Laboratory specific procedures
- See P-1760 Policy and Procedure Routing in the Hospital Wide Manual for documents that affect more than one department or discipline.

PROCEDURE INSTRUCTIONS:



Step	Action
Creating or Changing a Laboratory Document	
1	<p>Any laboratory personnel may request a change to an existing document or the creation of a new document. To request a new document, complete a copy of QUA70210 Document Creation/Change Request Form.</p> <p>To request a change to an existing document, complete the same form and attach a copy of the existing document with the edits being requested marked on it in red ink.</p> 

NOTE: This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against electronic version prior to use.

FILENAME:
QUA70200CreatingReviewingandApprovingLaboratoryDocumentsPRO.doc


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2	Submit the request to the Laboratory Supervisor. The Laboratory Supervisor may opt to create or change the document, delegate the creation or change of the document to another individual, or not create or change the document. Minor edits that do not affect the way that the document is interpreted may be left until the next scheduled review of the document. All changes made to in use documents must be approved by the Manager of Diagnostic Services or the Laboratory Supervisor.
3	The individual creating or changing the document will determine the correct document type to be created or edited and select the appropriate template. <ul style="list-style-type: none"> • QUA70220 Laboratory Policy/Procedure Template • QUA70230 Laboratory Document Template Portrait • QUA70240 Laboratory Document Template Landscape
4	Perform any necessary research to ensure that all current relevant information is included in the document.
5	Edit or draft the document in the appropriate template. Include individuals, departments, or pathologists in the development phase of the draft document to assist in reviewing or verifying that the document is effective. <div style="text-align: right;"></div>
6	Make any required adjustments to the document and review it again.
7	Submit the document to the Laboratory Supervisor. The Supervisor will then make final edits and formatting changes. This document will then be sent to the Manager of Diagnostic Services for final review and approval.
8	Once the document receives final approval, the Laboratory Supervisor will place the new version in 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. <div style="text-align: right;"></div>

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9	<p>If staff training is required, a copy of the document will be added to the MTS website (www.medtraining.org) along with a quiz to document 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.</p>	
10	<p>The Laboratory Supervisor will then record the changes on QUA70410 Laboratory Master Document List. See QUA70400 Laboratory Master Document List Maintenance Procedure.</p>	

RELATED DOCUMENTS:

- QUA70000 Creation, Review, and Approval of Documents
- 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.
- QUA70410 Laboratory Master Document List
- 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.

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- Institute, C. a. (2006). *The Key to Quality*. Wayne, Pennsylvania: Clinical and Laboratory Standards Institute.

REVISION HISTORY:

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

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