	Department of Microbiology	Policy # QDRMI01002	Page 1 of 9
Quality Manual		Version: 1.4 CURRENT	
Section: Documents and Records		Subject Title: **Manual Creation Revision Procedure**	
Prepared by QA Committee			
Issued by: Laboratory Manager		**Revision Date:4/6/2021**	
Approved by Laboratory Director: Microbiologist-in-Chief		**Next Review Date:4/6/2023**	

<p style="text-align:center;color:red">Uncontrolled When Printed</p>

Purpose:

To provide instructions for creation, revising and archiving laboratory manual documents for the department.

Responsibility:

Quality Assurance Technologist

Procedure:

Creating, revising and archiving of documents are done through two system, T:drive hospital network and Paradigm document control system

   A. Confidential microbiology laboratory manuals and study manual are located in the network directory "Microbio$ on 'Mshfile1' T:\Microbiology

Active files are located in "T:\Microbiology\Microbiology Internal Manual
Draft files are located in "T:\Microbiology\New Manual\Draft Manual"
Archived files are located in "T:\Microbiology\New Manual\Archive Manual"

   B. All other Microbiology laboratory manuals including the Quality Manual and Standard operating procedures are located in the Paradigm Document Control System within the Documents module for UHN_Mount Sinai Hospital Microbiology section.

Follow the appropriate system procedure below when a need for creating, revising or archiving documents is required. Refer to Paradigm Manual or Paradigm User Guide for further reference if needed.
Note: Contact Pathology and Laboratory medicine LIS or QA staff for any other Paradigm issue.

Change of Laboratory Director:

Following a change in laboratory directorship, the new laboratory director must approve the laboratory policies and procedures over a time period of three months.

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A. T:drive network Procedure

To update an existing file:

1. Make a copy of the existing file into the Draft Manual folder.
2. Work on the copy in the Draft Manual folder
3. Submit the revised document by email for approval to at minimum the Microbiologist-in-chief, Charge and senior technologists for department area and QA technologist.
    a. Remember to update the header dates.
    b. Versions increase by increments of 1.0 for each change including biannual reviews.
    c. For procedure changes, complete manual review sign-off form.
4. When the revision is completed, approved by the Microbiologist-in-Chief and ready for implementation, move the active file to the Archive Manual folder and rename the file in the Archive folder as the same name + date of archival.
5. Move the draft copy to the Microbiology Internal Manual.
6. Print the hard copy.
7. Stamp the hard copy with red "Master Copy" stamp.
8. Send the stamped copy for the Microbiologist-in-Chief to sign.
9. Insert sign and stamped copy into the appropriate Laboratory Manual Binder.

To create a new document:

1. Create a new file by exporting of the following templates below from paradigm to the Draft Manual folder within the Tdrive:
    Quality Manual Policy Template QDRMI01002a
    Quality Manual Process Template QDRMI1002b
    Quality Manual Procedure Template QDRMI01002c
    Standard Operating Procedure Template QDRMI01002d
2. Submit the document by email for approval to at minimum: the Microbiologist-in-chief, Charge and senior technologists for the department area.
    a. Remember to update the header dates.
    b. Versions increase by increments of 1.0 for each change.
    c. For procedure changes, complete manual review sign-off form.
3. When it is ready for implementation, move the draft copy to the Live Manual folder.
4. Print the hard copy.
5. Stamp the hard copy with red "Master Copy" stamp.
6. Send the stamped copy for the Microbiologist-in-Chief to sign.
7. Insert sign and stamped copy into the appropriate Laboratory Manual Binder.

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Periodic revision of documents:

1. Documents require periodic review, set to trigger based on the last Converted Date for the document
2. All documents must be reviewed with the minimum frequency outlined below:

Document Type	Frequency of Review
Policies, Processes, Procedures	Every 2 years
Laboratory General Safety Manual (Policy# MI_SAFETY)	Annually
Forms	Every 3 years

3. Identify sections or document to be reviewed.
4. Identify responsible senior technologist to review document or designate review to a technologist based on interest and ability.
5. Coordinate communication with the technologists and microbiologist(s) to discuss proposed changes.
6. Identify changes to be made including review of the entire document.
7. Follow steps for "To update an existing file:" listed above.
8. The most recent changes only(minor and major) made to documents are to be detailed in the revision chart located at the end of all SOPs

B. Paradigm system Procedure

To update an existing file:

Steps within Paradigm may only be done by designated Paradigm editors.

1. Click on the document you wish to update
2. Using the "top tool bar or right clicking the document select "status" and "create draft"
3. That document will now have a draft attached to it that is able to edit.
   Note: draft version is only viewable when "editing", when viewing the document, the current version will always appear.

A. Editing within Paradigm – **Paradigm Editors only**
   i. Select "Edit" from the top toolbar to edit the document within paradigm.
   ii. An editable version of the document will open within paradigm.

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    iii. The document may be saved and exited for further editing later by selecting the red and white Exit icon on the top tool bar.

    iv. Once editing is complete, the document may be checked out of Paradigm to email for review by Senior, Charge, Microbiologist or other personnel if needed.
Follow steps in section "B Editing outside of Paradigm" to check out document and email for review/approval. If not required proceed to next step.

    v. With the applicable document selected, right click or from the top tool bar select "Status" "Convert to Ready". This will create an automatic action item sent to the microbiologist in chief/document approver to approve or reject the draft document.

    vi. If rejected, restart the document revision process.

    vii. If approved, editors and print recipients will be sent an automatic action item to convert document to current and print a master hard copy.
        a. Headers will update automatically.
        b. Upon converting to current,
- Select "major change" if the document includes procedure changes which require manual review sign-off completion by staff. Version will increase by increments of 1.0 for major changes.
- Select "medium change" for all other revisions. Version will increase by increments of 0.1 for medium changes. If necessary a Bench update Staff update notificationmay be distributed.
- If a draft was made in error; convert item directly to current status. Document in the Paradigm history notes section no changes were made. Do not update the version.

    viii. For major procedure changes,completemanual review sign-off form.

B. Editing outside Paradigm – **Any personnel**
    i. A Paradigm editor must select the draft document, click "Manage" on the top toolbar and select "Check out"
    ii. The Paradigm editor will export the document to **their respective folder** in the following location: T:\microbiology\Paradigm Document Drafts for any personnel to edit and review.
- It is very important the editor exports the document into their folder and the file does NOT move from here. Only the editor who exported will be permitted to check the document back in.
- Once exported, DO NOT change the file name. The document properties must remain the same to be loaded back to Paradigm successfully.
- Once exported, editing within Paradigm is NOT permitted.

    iii. Once editing is complete, submit the revised document by email for review to the necessary personnel (Microbiologists, QA technologist, Laboratory Manager, Charge and/or Senior technologist)

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iv.   When the revision is completed, and ready for implementation, the Paradigm editor who checked-out the document must "Check in" the document back to Paradigm.
v.   Select the applicable document within Paradigm, select "Manage" and "Check in".
vi.   Select the file to be checked-in.
vii.   With the applicable document selected, right click or from the top tool bar select "Status" "Convert to Ready". This will create an automatic action item sent to the microbiologist in chief/document approver to approve or reject the draft document.
viii.   If rejected, restart the document revision process.
ix.   If approved, editors and print recipients will be sent an automatic action item to convert document to current and print a master hard copy.

To create a new document:

8.   Create a new file and save it in the Draft Manual folder using the following templates:
    Quality Manual Policy Template QDRMI01002a
    Quality Manual Process Template QDRMI01002b
    Quality Manual Procedure Template QDRMI01002c
    Standard Operating Procedure Template QDRMI01002d
9.   Submit the document by email for approval to at minimum: the Microbiologist-in-chief, Charge and senior technologists for the department area.
10.   When it is ready for implementation notify a paradigm editor to add the new document to the appropriate manual section.
11.   The paradigm editor will add the document using the "Add" button on the top tool bar and selecting "import item"
12.   The paradigm editor will
    • Apply the proper header/footer: right click document, apply header/footer choosing the appropriate template (SOP or Form, Portrait or Landscape)
    • Review publishing properties of the document: right click, properties, publishing tab
13.   The paradigm editor will convert the document to current: right click or select "Status" on top tool bar; "Convert to Current"
14.   The Paradigm Print recipient will receive an automatic email to print the hard copy for the Laboratory Manual Binder.

Bi-Annual revision of documents:

1.   Bi-Annual review alerts are automated and pre-programmed within Paradigm.
2.   Two months before a document's review is due an alert is sent to Paradigm Editors.
3.   Paradigm Editors will follow instructions in section "To update an existing file" to prepare a draft version and review document.

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Related Documents:

Paradigm User Guide	
Paradigm Manual	QDRMI01005
Bench Update notification form	QDRMI02004a
Manual Review Staff Sign off Form	QDRMI02004b
Documents and Records - Table of Contents	QDRMITOC
Microbiology Procedure Manual Format	QDRMI01001
Quality Manual Policy Template	QDRMI01002a
Quality Manual Process Template	QDRMI01002b
Quality Manual Procedure Template	QDRMI01002c
Standard Operation Procedure Template	QDRMI01002d
Orientation Training Checklist Template	QPEMI03001a
Format for documents and records	QDRMI01003
Document Distribution Process	QDRMI02000

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Record of Edited Revisions

Manual Section Name: Documents and Records

Page Number / Item	Date of Revision	Signature of Approval
Annual Review	April 20, 2005	Dr. T. Mazzulli
Annual Review	April 12, 2006	Dr. T. Mazzulli
Annual Review	April 12, 2007	Dr. T. Mazzulli
Annual Review	June 16, 2008	Dr. T. Mazzulli
Annual Review	June 16, 2009	Dr. T. Mazzulli
Annual Review	June 16, 2010	Dr. T. Mazzulli
Annual Review	May 31, 2011	Dr. T. Mazzulli
Annual Review	May 31, 2012	Dr. T. Mazzulli
Annual Review	May 31, 2013	Dr. T. Mazzulli
Annual Review	June 2, 2014	Dr. T. Mazzulli
Annual Review Updated UHN/MSH logo in header	June 1, 2015	Dr. T. Mazzulli
Annual Review Updated MSH logo in header For Annual Review procedure: Change of Laboratory Director requirement added. Revised document procedures to include email for approval.	June 3, 2016	Dr. T. Mazzulli
Conversion to Paradigm document control system. Annual Review Addition of Paradigm procedure.	November 1, 2017	Dr. T. Mazzulli
Annual Review	February 2, 2018	Dr. T. Mazzulli
Add paralink to Paradigm user manual.	June 21, 2018	Dr. T. Mazzulli
Update paradigm procedure to included status change to "Ready" Replace Dr. Mazzulli with Microbiologist-in-Chief. Addition of bench update and Manual review forms.	September 9, 2018	Dr. T. Mazzulli
Addition of instructions for Paradigm if draft made in error.	September 17, 2018	Dr. T. Mazzulli
Annual Review	June 05, 2019	Dr. T. Mazzulli
Annual Review	May 21, 2020	Dr. T. Mazzulli
T-Drive network procedure : changed draft copy to Microbiology Internal Manual	October 10, 2020	Dr. T. Mazzulli

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Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by:
Updated Biannual to Periodic revision of documents. Addition of frequency based on the last Converted Date	January 29, 2021	Dorna Zareianjahromi
Minor format change	March 30, 2021	Jessica Bourke

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