SUNY Downstate Medical Center -University Hospital of Brooklyn Network
Department of Pathology Policy and Procedure

Subject: Document Control System

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Supporting Documents:

Approval Workgroup: QMS Workgroup

Revision: 1

SUBJECT: QUALITY MANAGEMENT SYSTEMS [QMS S1 (t)/Retention S1]

TITLE: DOCUMENT CONTROL SYSTEM

PURPOSE

This policy establishes a uniform laboratory document control system that ensures that:

1. All policies, procedures and forms in use in the department have been authorized by the Director of the Laboratory; and are reviewed annually by the Director or designee.
2. Personnel have read the policies and procedures relevant to their job activities.
3. All departmental discontinued policies, procedures and forms are kept on file after discontinuation for the appropriate time-period in accordance with regulatory guidelines.

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POLICY

The Department of Pathology implements a document control system that is designed to direct all activities concerning the administrative and technical policies, procedures and forms which are used in the Department of Pathology.

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DEFINITIONS

1. Document: A piece of written, printed or electronic matter of a factual or informative nature that serves as an official record. Laboratory documents include policies, procedures, charts, and forms.
2. Record: information created, received, and maintained as evidence and information by an organization in the transaction of business.
3. Form: A paper or electronic document on which the results from the performance of a procedure or other information is captured.
4. Policy: A written statement of overall intentions and directions defined in the organization and endorsed by management.
5. Procedure: A specific way to perform an activity, or a set of introductions that describes the stepwise actions to be taken to complete activities identified in a process.
6. Process: A set of interrelated or interacting activities that transforms inputs into outputs including flowcharts, charts, bench excerpts and/or labels which are used to describe the path of operational workflow in the laboratory.

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PROCEDURE

I. Document Management System

A. Document Management System – Publication and Distribution

1. Institutional Policies are available on the SUNY Downstate Intranet at www.uhb.org/pnp/lab.
   a. Signed hardcopy originals are maintained by the Department of Regulatory Affairs.
2. Departmental Policies and Procedures for the Clinical and Anatomical Laboratory Divisions are available on the SUNY Downstate Intranet at www.uhb.org/pnp/lab/p&p.asp.
   a. Signed hardcopy originals are maintained by the Department of Pathology Administrative Office.
   b. Hardcopies of documents printed from the Department's website will have a watermark stating 'The most current version of this document is maintained online and in the Administrative Office of the Department of Pathology with a footnote indicating the date of printing which serve to direct the user to the intranet website for the most current version.
3. Laboratory section policies and procedures are reviewed annually by the laboratory director or designee and are maintained as signed hard copies in the respective laboratory section.
4. The laboratory utilizes SoftTech Health Lab QMS™ which is a comprehensive solution to assist in maintaining the laboratory's document management needs including:
   - Keeping policies and procedures in a central available repository so that authorized staff members with network access can have immediate access to the most current version of each policy, procedure, form.
   - Allowing easy, fast and comprehensive searching of manuals.
   - Providing of a complete document revision history and automated archiving and creation of an audit trail of all past versions of documents complete with date, time and approver information.
5. Personal copies of documents on thumb drives/flash drives are not allowed.

B. Document Management System- Content and Availability

The laboratory controls all documents and information that form its quality documentation to ensure that all version sensitive documents are approved and made available to users. The Document Management System assists with the following activities:

1. Document identification- document identification relates a process or task to a specific method or procedure used in the laboratory.
2. Initial approval of documents- All documents are reviewed and approved by the director prior to use.
3. Review and approval of unmodified documents: each year, each policy, procedure, form and process is reviewed and signed by the Director or the designee.
4. Review and approval of modified documents: Modifications to documents require that:
   a. The change is reviewed and approved by the Laboratory Director;
   b. The change is recorded;
   c. The staff is notified of the change;
   d. Copies of the revised document are provided to all appropriate staff and locations;
   e. Personnel are required to read the policies and procedures relevant to their job activities;
   f. Revision date or version number is indicated on document to ensure that current forms are in use.
5. Retirement of Documents: Obsolete and/or retired policies and procedures are quarantined in a separate file and clearly indicate the time period in which they were in use and their discontinuation date so as to determine its applicability to test performance and results.
6. Retention of Documents- Documents and records are retained and stored for the time periods as provided in the Department's Records Retention Policy and Procedure and archived in a fashion that allows for their ready retrieval when there is a need or a request to recreate the test protocols and processes employed for test results that were generated within the retention period.

II. Specimens Processing and Process Verification System

A. The laboratory believes that good records are an indication of good quality. As part of the Document Control System all records which are received, used, generated, created, or distributed during the phases of the laboratory's activities of specimen testing and result reporting are maintained to allow the recreation of the entire test process through document review so as to substantiate reported test findings, establish that the laboratory performed testing in accordance with quality standards and in accordance with its policies and procedures and with a high degree of care and skill. The documents employed in the recreation process are important to:
   1. Demonstrate that the tests were performed correctly;
   2. Demonstrate the tests were performed on the correct patient;

3. Demonstrate that the performing technical staff were qualified;
4. Demonstrate that the reagents and equipment used to perform the tests were operating correctly;
5. Demonstrate that the clinicians were provided with correct information which would allow them to correctly interpret the test results.

B. The laboratory records which allow the recreation of the complete test process include:
   1. Those records generated in the Pre-analytical procedure phase to demonstrate that reasonable care in identifying the patient, labeling the specimen and steps taken to carry the positive identification through all of the testing and reporting processes. Records relating to these processes include:

      a. Standard operating procedures to establish test ordering processes, specimen collection, handling and transport processes,

      b. Test requisitions,
      c. Accession records.

   2. Those records generated in the Analytical procedure phase include the identification of resources used for analysis including equipment, reagent lot numbers, and quality control lot numbers as well as testing performance and identification of personnel who performed pertinent tasks in the testing process. Records relating to these processes include:
      a. Equipment maintenance records.
         1. Equipment and reagent operations,
         2. Maintenance records,
         3. Functional checks, temperatures.

      b. Reagent and quality control validation records demonstrate proper functioning and acceptability of reagent lots test operation.
         1. Daily and cumulative QC records,
         2. Corrective actions taken when the QC limits were exceeded,
         3. PT testing results to show the performance of the laboratory as compared to a group of peers and corrective actions taken when PT testing results are unacceptable.

      c. Records to identify personnel who performed pertinent tasks in the testing process to establish personnel were qualified to perform tests, personnel were competent to perform the tests and the performing staff were appropriately trained and experienced to perform the tests.
         1. Documentation of education, previous work experience, copy of licensure or certification where appropriate,
         2. Continuing education to demonstrate analysts' skills and knowledge

remained current,

3. Current competency established through quality control data, PT records, and annual performance evaluations,
4. Job description to establish laboratory's requirements for hiring a technologist.

d. Worksheets

1. Test logs including instrument printouts and observations of reactions which can demonstrate that clerical errors in transcription of results did not occur as well as identification of the performing technologist and supervisor's review of test results.
2. If records are downloaded, entered via a direct interface in total or directly entered into the laboratory information system instrument printouts do not need to be kept. If the record is produced first in printed form or hard copy and then manually entered into the computer the original hard copy must be retained in order to prove transcription errors have not occurred.

C. Those records generated in the Post- analytical procedure phase which includes activities between the reporting of test results and the archiving of results and specimens. These procedures concern themselves with the:

1. The prioritization of results;
2. The entry of results into the information system;
    a. Reference ranges to demonstrate those in use at time of testing to allow clinician to determine normality.
3. The notification guidelines for the reporting of critical values;
4. Test reports;
    a. Hard copy, electronic or photographic medium.
    b. Stored indefinitely in the Anatomic and Clinical Laboratory Information Systems.
5. Specimen retention;
6. Record retention.

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REFERENCES

1. Medical Laboratory Management Forms, Checklists and Guidelines, Aspen Pub., Nov. 2003
2. New York State Department of Health Clinical Laboratory Standards of Practice