|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Document Change Control** | | | | | | | | |
| **Purpose** | This process describes how to ensure that laboratory staff use only the latest version of approved documents, establish a process to write new documents, revise current documents, and distribute and archive documents. | | | | | | | |
| **Policy Statements** | * Staff who identify needed document changes are required to complete the Document Change Request Form to assure proper approval. * A document is defined as a Policy, Process, procedure, form or job aid in written or electronic form. * See QP 6.10 Creating, Reviewing, * Revising Documents for document identification number, and version identification system. * Policies/Procedures and changes in policies/procedures must be approved, signed and dated by the current Laboratory Director or designee, such as a Section Medical Director, before use, or within 12 months of a change in directorship. | | | | | | | |
| **Process** |  | | | | | | | |
|  | **Step** | **Activity** | | | | | **Related Document** | |
|  | 1 | **Supervisor, Technical specialist, laboratory staff**   1. Determine need for new or revised procedure. 2. Determine need to archive a document 3. Complete Document Change Request 4. Review reference materials. | | | | | [QP 6.20 Document Change Request Form](http://khan.childrensmn.org/Manuals/Lab/SOP/Qual/Doc/199401.pdf) | |
|  | 2 | **Document authors**   1. If new document: obtain appropriate policy, process or procedure template and training guide templates. If revising document check out current document from Sharepoint. 2. Write new document and training guides **or** revise current versions 3. Develop or revise associated forms (see QP 6.30 Record Management) 4. Determine if other documents are affected by the new/revised document and revise if necessary 5. Follow QP 5.20 Change Control Process | | | | | [QP 6.10 Creating New Documents](http://khan.childrensmn.org/Manuals/Lab/SOP/Qual/Doc/199396.pdf)  Copy of current document  Copies of affected documents  [Sharepoint Training Guide](http://intranet.childrensmn.org/departments/pdf/sharepoint-training-guide.pdf) | |
|  | 3 | **Authorized SHAREPOINT user access**   1. Check-in the new or revised document into the SHAREPOINT system | | | | | See Section Document Masterlist on G-drive | |
|  | 4 | **Laboratory Management**  Perform document review:   1. Review policy statements and responsibility assignments, process workflow, and procedural information and adherence to format 2. Verify adherence to document format, title and revision structure and effective date 3. Approve or reject new/revised document. | | | | | [QP 6.13 Approval of Documents](http://khan.childrensmn.org/Manuals/Lab/SOP/Qual/Doc/199366.pdf) | |
|  | 5 | **Technical specialist, or Dept Lead**   1. Verify appropriate Process Change Control steps have occurred and are documented. 2. Archive obsolete documents in the SHAREPOINT system 3. Remove working copies of forms or job aids of revised or archived documents 4. Send notification through MedTraining to staff on new and/or revised policy or procedure to review. 5. Distribute new working copies of forms, job aids and training guides if new or revised 6. Delete Native document from G-drive or desktop 7. Scan the change control request to G:\Lab\Change Control | | | | | [QP 6.14 Document Review, Document Archive and Other Updates](http://khan.childrensmn.org/Manuals/Lab/SOP/Qual/Doc/199367.pdf) | |
|  | 6 | **Laboratory Staff**   1. Review new and/or revised policy or procedure in MedTraing before effective date. 2. Record review in MedTraining. 3. Staff with incomplete review may be subject to disciplinary action if review is not completed by the effective date of procedure or policy. | | | | |  | |
| **References** | *CLSI.The Key to Quality™.CLSI product K2Q.* Wayne PA: Clinical and Laboratory Standards Institute, 2013.  Berte L., et al, A Model Quality System for the Transfusion Service. Bethesda, MD: American Association of Blood Banks, 1997  Nevalainen D, Berte L., Quality Systems for the Laboratory. Chicago, IL.: American Society of Clinical Pathologists, 2000  Sarewitz S.. Et al, Application of Quality System Model for Laboratory; Approved Guideline-2nd Edition, NCCLS document GP26-A2, Wayne, PA.: National Committee for Clinical Laboratory Standards, 2002  Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Jan 24): 7164 [42CFR493.1251(d)] | | | | | | | |
|  |  | | |  | | | |  |
| **Historical Record** | **Version** | | **Written/Revised by:** | | **Effective Date:** | **Summary of Revisions** | | |
| 1 | | J. Wenzel | | 07/31/03 | Replaces elements previously addressed in section-specific quality documents | | |
|  | 2 | | L. Lichty | | 11/29/05 | Added change in medical directorship | | |
|  | 3 | | L. Lichty | | 06/29/09 | New control number. Elements of QP 5.10 “Development and Use of Standard Operating Procedures” incorporated. | | |
|  | 4 | | L. Lichty | | 06/30/2011 | Removed attachments | | |
|  | 5 | | J Wenzel | | 7/22/11 | Moved Notes to Policy Statements  Added steps and procedures related to the SHAREPOINT Document Management system | | |
|  | 6 | | R. Gulke | | 11/27/12 | Add scan change control request | | |
|  | 7 | | R. Gulke  Laboratory Quality and Patient Safety Council | | 06/29/2017 | CMS to Sharepoint | | |
|  | 8 | | S. Cassidy  Laboratory Quality and Patient Safety Council | | 11/30/2017 | Added how employees are notified or new and/or revised policy and procedures. | | |