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| **Change Control Process** | | | | | | | | |
| **Purpose** | | This process describes how to develop, implement, and control change in Children’s Minnesota Laboratory. | | | | | | |
| **Process** | |  | | | | | | |
|  | | **Step** | **Activity** | | | | **Related Document** | |
|  | |  | **Laboratory staff**   1. Identify process to be implemented or revised 2. Obtain approval from Laboratory Leadership. | | | |  | |
|  | |  | **Laboratory Leadership or designated laboratory staff**   1. Make recommendations to lab director for budgeting and resource need approval 2. Identify customers affected by change and request input 3. Develop communication plan for internal and external customers | | | |  | |
|  | |  | **Laboratory Leadership or designated laboratory staff**   1. Research and develop process    * Determine space/design and renovation needs    * Purchase new equipment, supplies, and reagents    * Investigate installation expenses    * Install information technology and telecommunications systems    * Notify Biomed and/or Facilities of new equipment    * Determine waste stream impact and update Safety Data Sheet (SDS)    * Plan for inventory management, and storage and handling of new reagents and supplies    * Determine hazardous chemical disposal    * Develop Quality Control Plan    * Determine preventive and vendor maintenance schedule 2. Validate the process. Refer to *Process Validation* | | | | [QP 5.20.f1 Process Change Control Checklist](https://starnet.childrenshc.org/References/labsop/qual/proc/qp-5.20.f1-process-change-checklist.pdf) | |
|  | |  | **Laboratory Leadership or Laboratory Information Systems (LIS) personnel:**   1. Determine changes to laboratory computer maintenance tables, order codes 2. Develop or submit LIS change requests 3. Validate integrity of data transmissions 4. Define patient charges 5. Update laboratory client/patient billing systems 6. Update/revise related computer systems, i.e. HIS 7. Determine confidentiality of patient information 8. Execute or revise contracts or agreements 9. Submit change request to Lab handbook | | | |  | |
|  | |  | **Laboratory Leadership or designated laboratory staff**   1. Flowchart the new or revised process (optional) 2. Write draft documents and forms for: (refer *to Document Change Control)*    * Calibration and maintenance    * Quality control    * Standard Operating procedure and policies    * Training and competency assessment 3. Assign or develop process monitors/system checks 4. Finalize documents and training guides 5. Document action on QP 5.20.f1 Process Change Control Checklist | | | | Flowchart  Draft document and forms  Completed/approved validation protocol  LIS Change Request forms | |
|  | |  | **Laboratory Leadership or designated laboratory staff**   1. Notify CAP of any change in laboratory test menu    1. Notification must occur prior to starting new patient testing    2. Make changes on cap.org > e-lab solutions suite > section activities 2. Update and/or order proficiency material 3. Review/revise quality monitors | | | | <https://www.cap.org> | |
|  | |  | **Laboratory Leadership**   1. Approve documents and training guides 2. Approve new or revised method/process for use at Children’s Hospitals and Clinics of Minnesota. | | | | Approved documents  Approved training guides  Approved Validation Protocol | |
|  | |  | **Trainer**   1. Train staff 2. Document training | | | | Training documentation | |
|  | |  | **Employees**   1. Complete required training 2. Review policy or procedure | | | |  | |
|  | |  | **Laboratory Leadership**   1. Review/approve personnel training 2. Notify hospital staff of method or analytical changes 3. Verify all change control steps have been completed 4. Implement process | | | | [QP 5.20.f1 Process Change Control Checklist](https://starnet.childrenshc.org/References/labsop/qual/proc/qp-5.20.f1-process-change-checklist.pdf) | |
|  | |  | **Laboratory staff** collect process monitor data | | | | Data collection forms | |
|  | |  | **Laboratory Leadership**   1. Evaluate monitor data 2. Determine if process is in control 3. Take action if not in control | | | |  | |
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| **References** | | CLSI. The Key to QualityTM. CLSI product K2Q. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.  Laessig RH, et al, The New Poor Man’s (Person’s) Guide to the Regulations (CLIA ’88, JCAHO, CAP & COLA), R & S Consultants, July 2002.  Nevalainen D, Berte L., Quality Systems for the Laboratory. Chicago, IL: American Society for Clinical Pathology, 2000.  CLSI. A Quality Management System Model for Laboratory Services. 5th ed. CLSI guideline QMS01. Wayne, PA: Clinical and Laboratory Standards Institute; 2019. | | | | | | |
| **Historical Record** | | **Version** | | | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** | |
|  | | | L. Rachford | 07/29/03 | Replaces elements previously in section-specific quality documents | |
|  | | | L. Rachford | 10/30/03 | Added hospital-related information (SMART protocol) | |
|  | | | L. Lichty | 10/26/05 | Added Change Notification | |
|  | | | J. Wenzel | 06/01/06 | Removed SMART protocol | |
|  | | | J. Heimkes, B. Kochevar | 08/01/07 | Added CAP notification information | |
|  | | | L. Lichty | 06/29/09 | Revised and reformatted | |
| PMRC/Linda Lichty | 7/22/2011 | Deleted Appendices. Document referenced under Related Documents.  CMS format | |
|  | | | PMRC/L. Lichty | 10/24/2012 | Revised steps 3 and 6 | |
|  | | | PMRC/L. Lichty | 7/8/2013 | Added Groupwise email notification | |
|  | | | PMRC/L Lichty | 9/25/2013 | Add Biomed/Facilities estimate of installation expense, fix typos | |
|  | | | L. Lichty/PMRC | 5/21/2015 | Updated CLSI reference | |
|  | | | L. Lichty | 9/1/2016 | Omit Change Notification form | |
|  | | | Erin Bartos | 7/7/2020 | Updated titles and fixed links. Removed historical section since it is archived in SharePoint. | |
|  | | | Matt Johnson | 9/26/2022 | Reviewed. Added Historical Record section. Updated steps to modify/update CAP activity menu. | |
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