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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.
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|  |  | **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
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|  |  | **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
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|  |  | **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
 | FlowchartDraft document and formsCompleted/approved validation protocolLIS 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 documentsApproved training guidesApproved Validation Protocol |
|  |  | **Trainer**1. Train staff
2. Document training
 | Training documentation |
|  |  | **Employees**1. Complete required training
2. Review policy or procedure
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|  |  | **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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