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| **Title: QUALITY MANAGEMENT PLAN** | | |
| **Scope:**  The Quality Management Plan encompasses all disciplines that are inclusive to LABORATORIES Northwest.   |  |  |  | | --- | --- | --- | | Transfusion Services | Chemistry | Molecular | | Hematology/Urinalysis | Microbiology | Flow Cytometry | | Immunology | Coagulation | Pathology |   These disciplines are supported by the following support services within the laboratory.   |  |  | | --- | --- | | Specimen Procurement | Laboratory Information Services | | Specimen Receiving and Processing | Client Services | | Couriers | Reference Laboratories | | Patient Service Centers | Point of Care Testing | | Business Development | Laboratory Billing | | | |
| **Policy Statement:**  Laboratories Northwest’s Quality and Performance Improvement Plan is to provide for a formalized, systematic process of developing and setting targets for monitoring, evaluating and improving the quality and appropriateness of laboratory products and services by utilizing occurrence management and process control. Our commitment is to a Quality Management program that is designed to benefit the health of the people we serve by utilizing state of the art diagnostic tools and integrated information in an environment that emphasizes customer service and fiscal responsibility. | | |
| **SERVICE OBJECTIVES:** As identified within the strategic framework of MultiCares’ Journey to Excellence, this laboratory subscribes to its philosophy is committed to support the following:   1. Culture and People: Understanding who our customers are and what they consider to be excellent customer service. 2. Clinical Quality: Set expectations among all staff that their top priority, in addition to quality of care and patient safety, is to exceed all expectations of service to our customers. 3. Service: Implement the best practice through process improvement and occurrence management activities and nonconformance follow up. 4. Financial Sustainability: Providing safe laboratory facilities that encourage an environment for adequate inventory management and appropriate instrumentation. 5. Information Integration: Allow for the utilization of laboratory generated information that supports the interest of the patient and providers within the guidelines of accreditation agencies. 6. Growth: Support the growth of the organization within the community it supports.   The Laboratory’s key Quality System Essentials are tied to the Multicare Strategic Framework pillars.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | *How can I support culture and people?* | *How can I support Clinical Quality?* | *How can I support service?* | *How can I support Financial Sustainability* | *How can I support Information Integration?* | *How can I support growth?* | | Customer Service | Process Control | Occurrence Management | Laboratory Facility and Employee Safety | Control of information, documents and records | Organization | | Patient Satisfaction | Assessments | Nonconformance and follow up | Purchasing and Inventory | Pre-analytic, analytic and post analytic processes and procedures | Community Integration | | Employee Satisfaction | Analytic Processes | Process Improvement | Equipment | Test Order Processes | Marketing | | Personnel | Specimen Handling |  | Billing |  | Test Menu |   An annual Balanced Scorecard is created to focus on the Quality System Essentials being monitored for that year. | | |
| **SERVICE QUALITY:** The Laboratory Quality Plan actively supports the Quality Patient Care initiatives of MultiCare Health Systems. The Laboratory focus is on satisfaction of staff, physicians, patients and the community. This is achieved by adhering to the following:   1. Work as a team within the hospital in order to understand the integration of all departments and how information, patients and results flow through the system. 2. Communicate problems and improvement with staff. 3. Define quality indicators that are measurable. 4. Utilize data to identify barriers to performance and service quality. 5. Create an environment where mistakes are not considered failures but learning opportunities. 6. Provide the highest quality medical technology to all patients. 7. To accurately perform all tests necessary for diagnosis, treatment and prevention of disease. 8. To provide quality services to newborns, children, adolescents, adults and the geriatric population. | | |
| **RESPONSIBILITIES:**  Medical Director (CLIA designation laboratory director) is responsible for the technical and scientific oversight of the laboratory including the review and initial approval of policies and procedures and additional changes that are made. The Medical Director of LABORATORIES Northwest may delegate qualified personnel the responsibility of specific duties. It is the responsibility of the Medical Directors to ensure the delegated functions are properly completed.  The Administrative Director directs and manages all aspects of Laboratory Services operations and leadership team. Responsible for contributing to the enhancement of the organizational culture/environment, transmitting core values, developing and implementing standards and programs, as well as achieving the organizational operating and financial goals. This position partners with the health system’s executive leadership team at each of the system’s institutions, Pathologists and community physicians in order to provide administrative and clinical direction for a broad range of MultiCare Laboratory Services.  The Pathologists (CLIA Designation Clinical Consultant) perform anatomic and/or clinical pathology evaluations and are available to provide consultation regarding the appropriateness of testing ordered and the interpretation of the results.  Managers and Supervisors (CLIA designation of General Supervisor) are qualified testing personnel responsible for the day to day supervision or oversight of laboratory operation including budgetary responsibility, staff competency and technical performance within their section.  Testing personnel for moderate and high complexity testing have a minimum of an associate degree in a laboratory science or medical technology program and have maintained their certification of MT (ASCP), MLS CM (ASCP), MT (AMT), MLT (ASCP),  MLT CM (ASCP), M(ASCP/RCM), HT (ASCP) or CT (ASCP).  Support staff includes processors, phlebotomists, Client Service Representatives, couriers, registration, coding staff, transcriptionists, receptionists, laboratory Information staff and others who are primarily responsible for the pre-analytic and post analytical and non-laboratory functions.  POCT (moderately complex and waived) are accredited through the Washington State Department of Health and related policies are located in the Ancillary testing department. | | |
| **QUALITY SYSTEM ESSENTIAL PROCESS INDICATORS:** Process indicators identified by laboratory management and staff monitor daily operations that are critical for maintaining quality daily operations. A balanced scorecard is used to measure basic performance indicators. Variations from standard internal operating procedures are monitored using the on line Midas Electronic Quality Improvement Manager (MeQim) and the events are classified as “Laboratory Internal Events” or QERN. (electronic Quality Event Report Notification) The reporting format categorizes processes into pre-analytical, analytical and post-analytic systems.  Additional internal reports and worksheets are generated daily and monitored for operational integrity. These include, but are not limited to pending reports, critical value notification and corrected reports.  External incidents are reported through the on line program Midas Electronic Quality Improvement Manager (MeQIM).  MeQIM events are reviewed individually and collectively. Specific issues may be assigned to the appropriate supervisory or management staff for process improvement, staff counseling, or work flow change. Key event types are aggregated and reflected on the BSC for monthly review.  The monthly reports will be reviewed by laboratory leadership and any trends or potential process issues are identified. The Laboratory Management and impacted departments within MultiCare Health System will determine the appropriate action plans and the effectiveness of the action plan will be evaluated. The Plan-Do-Study-Act worksheet is a tool that has been adopted and may be used to document any test of change and provides a means to report the development of a plan for improvement, the execution, evaluation and the resulting process change.  These reports are reviewed by the Medical Directors.   |  |  | | --- | --- | | Introduction and process review | Data analysis | | Flowcharting | Data confirmation | | Customer Identification | Root Cause Analysis | | Customer Interviews | Brain Storming | | Interview Analysis | Reporting | | Data Collection | Implementation of recommendation |   Communication and frequent updates with management are critical throughout this process. | | |
| **QUALITY CONTROL:** The frequency and content of the quality control run for the procedures in the laboratory is determined by a combination of instrument manufactures’ guidelines and regulatory agency requirements (CAP, CLIA, JCAHO, CLSI and the State of Washington). Standard Operating Procedures delineate specific details, such as which control materials to run and the frequency required. These procedures are department specific and are located in the department procedure manuals.  All quality control results that deviate from acceptable limits and the actions taken following those deviations are documented and reviewed by the manager of that department.  Corrective actions and preventative maintenance activities for all instrumentation are documented on daily logs located near each instrument. | | |
| **RECOGNIZED STANDARDS AND PRACTICE GUIDELINES:** LABORATORIES Northwest subscribes to the College of American Pathologists proficiency testing program and is surveyed on-site by the College of American Pathologists. | | |
| **ACCOUNTABILITY:** Laboratory Management is responsible for the coordination of a systematic laboratory quality plan to achieve desired levels of quality and customer service within all its locations and as it pertains to MultiCares’ strategic framework and objectives.  The Medical Directors and the Administrative Director of the Laboratory have the overall responsibility for LABORATORIES Northwest operations and quality management.  Each person in the laboratory is responsible for quality. Each testing technologist/technician is responsible to ensure that all testing methodologies include the required quality controls and that all quality controls fall within the established parameters prior to testing patient samples. | | |
| **Related Policies:** LABORATORIES Northwest Scope of Services | | |
| **Summary of Edits:**  Replaces retired procedure “Quality and Performance Improvement”  1/18/2012 Revised formatting and updated CAP references.  3/13/2012 Expanded Medical Director Review.  3/2014 Enhanced description of Laboratory Internal Events, updated references and expanded Medical Director review. | | |
| **References:**  Clinical Laboratory Standards Institute QMS01 (GP26-A4) 2011  Clinical Laboratory Standards Institute QMS02-A6 (GP02-A5) 2013  Clinical Laboratory Standards Institute QMS06-A3 (GP22-A3) 2011  CLIA ’88; 493.1449b and 493.1449q  College of American Pathologists GEN.13806  College of American Pathologists GEN.20208  College of American Pathologists GEN.20316  College of American Pathologists GEN.20325  College of American Pathologists GEN.40505 | | |
| **Point of Contact:** Laboratory Regulatory Compliance Consultant | | |
| ***Approval By:***  LABORATORIES Northwest Medical Directors  David Austin, M.D.  Eric Arntson, M.D.  George Hodges M.D.  Larry O’Bryant M.D. | ***Date of Approval:***  *3/15/2012*  *1/28/2013*  *1/28/2013*  *3/14/2014* | |
| Original Date:  Revision Dates:  Reviewed with no Changes Dates: | *1994*  *12/2007; 3/13/12/1/28/13;3/2014*  *12/2008;12/2009;12/16/2010* | |