QUALITY POLICY: PROCESS CONTROL

5.0 PURPOSE

This quality essential describes the key elements used by the Franciscan Health System Laboratory to ensure control of our processes and to maintain quality.

5.1 DEVELOPMENT AND USE OF PROCESS DESCRIPTIONS AND WORK INSTRUCTIONS

Process

FHS Laboratory defines a process by use of these three basic steps:
- Description of what the process includes.
- Identification of the starting and ending events of the process.
- A statement as to who has responsibility for and authority over the process output.

FHS Laboratory plans each process to ensure control of the process, and evaluate the following key aspects of process flow:
- External interfaces
- Process requirements
- Process measurements
- Process controls (feedback)

FHS Laboratory describes each process by use of table or flow chart.
- Each process references the Work Instructions for tasks in that process.
- Each process receives Document Approval.
- Each process description is available to staff.
- Each process follows standard format.

Work Instructions

Each Work Instruction within the FHS Laboratories is written in concise steps and:

- Provides directions for one person to perform a task.
- Is comprehensive, and appropriate for the tasks described.
- Follows standard format.
- Identifies specifications.
- Addresses each critical control point and key element associated with the task.
- Receives Document Approval.
- Is validated following standard validation protocol to verify that specifications have been met.
- Is readily available to staff.

- Training and competency of staff is completed before the Work Instruction is put into use.
- Variances are documented so functionality can be monitored.
- New work instructions are reviewed by staff and their review is documented on Staff Review Form R-F-AD0211.
- Work Instructions are readily available to staff where procedure is performed.
- Documentation/justification exists for any deviation in written procedure.

5.2 CHANGES TO PROCESSES AND WORK INSTRUCTIONS

Changes to Processes require the following steps:

Validating a process ensures that the output is what it is intended to be and provides objective evidence that variables were considered and control systems evaluated before the process is used in the live environment.

All validations are performed by staff trained and knowledgeable in the process or change being validated.

- Validation:
  Prospective validation for the introduction of new processes or products
  Installation qualification
  Operational qualification
  Product performance guide
  Retrospective validation used when a process or product has been used before validation was done.
  Examination of accumulated test data
  Qualification of test methodology
  Records for variable operating parameters

- Training and competency of staff is completed before the change is instituted.
- Staff review of work instruction revisions are documented on the Staff Review Form R-F-AD0211.
- **Note**: Non-substantive changes to processes and work instructions, such as formatting changes or correction of grammatical errors do not require staff review.

Changes to Work Instructions require the following steps:

- Re-evaluation of critical control points and key elements
- Re-validation by the personnel who will follow it using standard validation protocol
- Laboratory Management Document Committee (FLOAT) approval of the revised document.
- Training and competency of staff is completed before the change is implemented.
- Staff review of work instruction revisions are documented on the Staff Review Form R-F-AD0211.

5.3 QUALITY CONTROL PROGRAM

Each laboratory section has a defined, specific Quality Control procedure that meets the following standards:

- Fixed schedule for performance of testing
- Defined parameters of acceptance or rejection of results
- Specific procedure for dealing with results that fall outside defined parameters
- Documentation of corrective action
- Accurately maintained records
- Fixed schedule for monitoring of temperature dependent storage devices and testing equipment, at least once every 24 hours while storage device or equipment is in use
- Timely supervisor review
- Review for effectiveness

Each laboratory section has a defined procedure for calibration or control system failures to include:

- Supervisor or Tech-in-Charge notified
- Clinical Engineering notified, if problem is due to mechanical or instrument malfunction
- Process for determining alternate testing sites or testing delays

5.4 PROFICIENCY TESTING PROGRAM

Catholic Health initiatives (CHI) Guidance on Proficiency Testing

- The laboratory must not send proficiency testing samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.
- Any laboratory that CMS determines inappropriately referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year.
- Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

All FHS Laboratories participate in the College of American Pathologist (or other approved vendor) proficiency-testing program, subscribing to all proficiency surveys available for testing performed by the laboratory. FHS Laboratories recognizes that some special handling may be required due to the nature of proficiency testing materials, but as closely as is practical, FHS Lab will perform analysis in the same manner as patient samples. Inter-laboratory communication about proficiency testing samples or referral of testing to another lab is prohibited. All proficiency testing samples are treated in the same manner as patient samples,

and performed by the same personnel that perform patient testing. The laboratory has a work instruction that defines:

- How proficiency testing is performed
- Who performs proficiency testing
- Who assesses proficiency testing results
- Who reports proficiency testing results
- Who is responsible for corrective action, when necessary.

Tests for which there is no proficiency testing survey product available are assessed using biannual verification. Inter-lab communication about biannual verification testing samples is prohibited. Referring these samples to other laboratories is prohibited. The laboratory has a policy and work instruction that defines:

- What specific tests will be subject to biannual verification
- How biannual verification proficiency testing will be performed
- Who performs biannual verification testing
- Who assesses biannual verification testing results
- Who is responsible for corrective action if necessary