QUALITY FORM-HOW TO USE

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☒ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☒ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☒ Highline Medical Center Burien, WA	☒ PSC

PURPOSE

To provide instructions for the use of the Quality Form (QF) as a standardized format for reporting occurrences that deviate from established procedure, as well as non-conformances and complications. Error corrections are also documented using this Quality Form.

BACKGROUND

The employee who becomes aware of an occurrence which has the potential to adversely affect patients or services, or represents non-compliance with Laboratory Services policies and procedures and / or statutory requirements, is responsible for initiating and completing the QF. Note that any quality event involving a patient has the potential to cause different levels of harm depending upon the situation.

GUIDELINES

- Improvement in the CHI-FH Laboratory Services performance requires continuous evaluation of policies and procedures.
- The frequency and nature of occurrences that deviate from established procedure, regulatory and/or safety requirements are a significant indication of quality.
- The Quality Form is the tracking tool that provides a standardized format for capturing this information which is used to improve quality.
- The Quality Form is also used to document corrections to test results, notification, and requests for crediting.
- The Quality Form is not intended for documenting personnel performance issues. Lab ID numbers should be used on the forms.

RELATED DOCUMENTS

R-PR-AD0710 Occurrence Management Process
R-F-AD0902 Quality Form

STEPS FOR INITIATING THE QUALITY FORM

1. Complete the QF as follows, providing as much information as possible. Attach copies of all pertinent documentation, i.e. LIS print-outs or other copies.
   - An event which results in an adverse outcome for a patient OR an event which poses significant risk for an adverse outcome should also be IMMEDIATELY communicated to the appropriate supervisor or manager.

2. If the occurrence does not result in or pose risk for adverse outcome, route the QF to your manager within one working day.

QF SECTION (To Be Completed by Initiator)	INFORMATION REQUIRED
Reported by	Tech ID of employee initiating the QF
Date and Time of Incident	***Date*** and ***time*** of the occurrence.
Patient Name	Names of ***all*** patients involved in the occurrence
Medical Record Number/CSN	MRN and CSN of all patients involved in the occurrence
Specimen ID number	All Specimen ID numbers involved in the occurrence
Geographic Location	Location where the event occurred
Patient location/Nursing Unit	Patient's location, site, floor, unit, bed numbers
Error By (Use Tech ID)	Include Identity of all personnel involved with an occurrence, i.e. nursing, pharmacy, etc.
Lab Section	Lab department involved in event
EP Eval#	Enter the tracking number for the Lab Issue
IRIS#	Enter the IRIS number created for any patient safety issue
Was there a delay in reporting test results	Yes or No
Were incorrect results reported	Yes or No
Was the lab responsible for the error	Yes or No
What was the actual effect on the patient	Check the correct box
Credit Needed	Yes or No; indicate the test to be credited
Who has been notified of the event	Document the name, date , and time of any person notified of the issue with the sample
Credit Needed	Yes or No
Category of Occurrence **Choose section of the QF:** • **Patient Safety** • **Quality and Regulatory** • **Procedural** • **Safety/Environment of Care issues**	***Choose the correct event type within the category of Occurrence*** ***Pre-Analytical***—Occurred before testing—check applicable box. ***Analytical***—Occurred during testing—check applicable box. ***Post-Analytical***—Occurred after testing—check applicable box
Corrected Result Documentation	**Indicate if the original and correct result.** Attach pages if needed. Document Tech ID making correction.
Describe the Problem/Issue	Describe what happened—***be succinct***, and ***write legibly***, include all pertinent information not captured above.
What has been done to resolve the issue?	Describe immediate corrective action has been taken so far, and whether the issue is resolved.

QUALITY FORM HARM DEFINITIONS

Severity	Definition
Near Miss	**Caught during safety checks** -Circumstance, process, or event that did not reach the patient but has the potential to cause harm. (Examples: Provider ordering plasma instead of platelet, mislabeling aliquots, switching labels on pathology samples, etc.).
No Harm	An event that reached the patient and sufficient information available determined that no harm occurred. (Example: Tech error requires a look back resulting in an error correction with no clinical impact, delayed calling of critical value with no clinical impact, etc.).
No Detectable Harm	An event that reached the patient and unable to determine the existence or fact of harm, which might exist but might occur later in time (Examples: patient fainting, reported erroneous critically low platelet leading to transfusion, cancellation of ordered testing (lactic acids), timed study drawn at wrong time).
Minimal Harm	An event that reached the patient and caused minor harm requiring little or no intervention; may be temporary or permanent (Examples: hematoma, patient redraw due to false potassium or other redraws due to specimen handling, etc.).
Moderate Harm	An event that reached the patient resulting in significant harm resulting in increased patient monitoring or a change in treatment plan; does not impact activities of daily living. May be temporary or permanent. (Incorrect creatinine level leading to incorrect radiology contrast, nerve hit during phlebotomy, wrong dose of glucola leading to incorrect diagnosis, etc.).
Severe Harm	An event which reached the patient resulting in critical, potentially live threatening harm. (Examples: wrong site surgery, loss of specimen causing a repeat biopsy and/or inability to provide a diagnosis, reporting of an incorrect test value with a significant clinical impact due to misdiagnosis, etc.).

INSTRUCTIONS FOR MTC/ SUPERVISOR/MANAGER REVIEW AND FOLLOW-UP OF QUALITY FORM

Managers or supervisors will complete the following sections of the Quality Form in a timely manner.

QF SECTION (To be completed by Supervisor or Manager)	INFORMATION REQUIRED
Contributing Factor	Check any of the noted categories that may have contributed to the occurrence. NOTE: Those checked may require corrective or preventive action.
Investigation/Corrective Action Taken	Check the appropriate box(es) and / or describe actions taken including process changes. Describe and attach documentation for any process change made to prevent recurrence.
Investigated By	Record names of person(s) performing the investigation and date. Send the QF to manager for review.
Additional Review as Indicated	Enter the BPDR (FDA)# if needed, dates of presentation to Float, Risk Review, or Root Cause Analysis.
Credit (if needed)	Document date received in Client service area to credit. Document date of completion and CRM # if indicated.
Manager Review	Date and sign after completion of above steps. Set date to present the event to lab management for regional learning opportunities if needed.
Medical Director Review	Medical Director will review all significant events.