



**University of Pittsburgh Medical Center
Anatomic Pathology
Administrative Policies and Procedures**

**Subject: PROTOCOL FOR COMPLIANCE WITH PUH SHY
POLICY PI-01 and HS-RI1303**

Date: June 15, 2004

**Policy: INVESTIGATION AND REPORTING OF SERIOUS
EVENTS**

I. POLICY

It is the policy of the Department of Anatomic Pathology at PUH SHY to comply with system policy HS-RI1303 (Disclosures of Serious Events/Outcomes of Care) and PUH SHY Policy PI-01 (Events Related to Patient Safety: Review, Investigation & Reporting).

This policy defines protocol to be followed in the case of discovery of any Potential Event (an "Event" is any Incident, Infrastructure Failure, Sentinel Event or Serious Event defined by the policies listed above). It is recognized that events that do not result in potential harm to patients may still be serious and require immediate investigation.

II. DEFINITIONS

Types of events: See policy PI-01 for detailed definitions of "Incident, Infrastructure Failure, Sentinel Event and Serious Event". In Anatomic Pathology, examples of these types of potential events include, but are not limited to:

- specimen and/or slide mislabeling that could confuse the identity of the patient and affect diagnoses
- lost specimens
- incorrect diagnoses that could affect patient care

Immediate Response Team: AP QI Coordinator, AP Medical Director, AP Administrative Director, AP Medical Director of Quality Assurance, Lab Section Supervisor, and Case Pathologist. This team can include other AP personnel as appropriate that are involved in the potential event: Resident, Fellow, Department Employees, etc.

Potential Event Reporters: Staff members, physicians, employees, students or other persons who gain knowledge of a Potential Event.

III. PROTOCOL

When the discovery of a Potential Event occurs by anyone defined as a “Potential Event Reporter” the potential event must be immediately reported by verbal communication to the Supervisor (Medical or Technical) of that Section/Division and the AP QI Coordinator. This should not be done via email or voicemail. It is vital that the AP QI Coordinator, and subsequently the Immediate Response team if appropriate, be notified directly via face-to-face or telephone communication.

If the Section Supervisor or AP QI coordinator is unreachable, the following persons need to be notified in the following order until proper face-to-face or telephone communication is achieved: Section/Division Technical Supervisor, Section/Division Medical Chief, AP Administrative Director, AP Medical Director, AP Medical Director of QI.

The AP QI coordinator will initially evaluate the potential event and contact the Immediate Response Team if appropriate. This team will immediately convene and evaluate the potential event.

This initial investigation must be completed on the day of discovery and reporting of the event and all members of the department involved in the event must remain ON SITE until the AP Administrative Director or Medical Director approves the completion of the initial investigation. This approval will be finalized if the situation is appropriately understood as deemed so by the AP Administrative and/or Medical Directors.

The QA Division will utilize the QA Division Process Checklist for Reporting of Serious Events to ensure appropriate communication and follow-up. (See below)

Identity Testing

Investigation of serious events may reveal certain situations involving irreplaceable surgical specimens in which patient/specimen identity cannot be 100% assured. In these situations, identity (IDQA) testing may be used at the discretion of the case pathologist and Medical Director of the MAP lab. The QA Division will be responsible for providing the Medical Director of the MAP lab and case pathologist with the detailed information related to the event to allow the pathologists to make an informed decision regarding the necessity of IDQA testing. Based on the available material, the Medical Director of the MAP lab should make an assessment related to the technical aspects of performing the identity testing. The case pathologist can request a meeting with all involved parties to discuss the situation in further detail if appropriate. The QA Division may provide a recommendation, but it is the responsibility of the Medical Director of the MAP lab in consultation with the case pathologist to determine if IDQA testing is necessary and to place the order in CoPath as required. The Histology laboratory will be responsible for preparing the tissue sections for molecular analysis per protocol. The QA

Division will follow-up to ensure that the IDQA test was properly ordered in CoPath and that the Molecular Anatomic Pathology (MAP) Lab has received the material.

Risk Management

Once the initial immediate evaluation has taken place, the QI Coordinator will report the event to Risk Management per policy. If the Immediate Response Team determines that the clinician(s) involved in the care of the patient must be informed to insure the safety of the patient(s), this will be performed by the Case Pathologist or Medical Director as appropriate on that same day.

It is vital that in the course of the immediate investigation that email not be the choice of communication but that face-to-face or telephone communication be used to insure that no delay occurs in reporting and to avoid confusion. Failure to notify the Section / Department Supervisor or QI Coordinator (or their designees) immediately will result in disciplinary action. No alternative to this oral, face-to-face communication is acceptable.

Once the event is reported to Risk Management per policy, it is recognized that assistance from Risk Management, the PSPR Committee, the Patient Safety Committee and/or the Patient Safety Officer to determine root cause and define potential corrective action is required by policy and is appropriate. The Immediate Response Team will share all information gathered in the immediate investigation and any subsequent investigation with these entities to insure compliance with policy.

Corrective action will be taken per policy as appropriate.

QA Division Process Checklist Reporting of Serious Events

Accession #: _____ Patient Name: _____

Event Reported By: _____

Check each box as completed.

1. Notify following staff:

- | | |
|---|---|
| <input type="checkbox"/> Case pathologist | <input type="checkbox"/> AP Medical Director of QA |
| <input type="checkbox"/> AP Medical Director | <input type="checkbox"/> Lab Section Supervisor |
| <input type="checkbox"/> AP Administrative Director | <input type="checkbox"/> Medical Director of MAP Lab (if IDQA considered) |

2. Notify Risk Management:

- Contact name and #: _____
- Complete IIR
- Verify that Risk Management will notify Clinician

3. IDQA Testing (if required/requested):

- Verify order in CoPath
- Follow-up with MAP Lab regarding status of test and results
- Test performed internally Test performed at reference lab. Lab name: _____

4. Notify AP team of outcome:

- | | |
|---|--|
| <input type="checkbox"/> Case pathologist | <input type="checkbox"/> AP Medical Director of QA |
| <input type="checkbox"/> AP Medical Director | <input type="checkbox"/> Lab Section Supervisor |
| <input type="checkbox"/> AP Administrative Director | |

5. Issue Amended report:

- New accession #: _____

Approved by:

Approved by:

REVISED

06/01/2004(*to include UPMC Shadyside*)

06/04/2004

REVISED

04/07/2005(*to include UPMC Shadyside*)

04/08/2005

REVISED

03/10/2006(*to include UPMC Shadyside*)

03/10/2006

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