

**IFCC/AACC 2005 Annual Meeting**  
**Quality Issues in POCT:**  
**3<sup>rd</sup> Annual POC Coordinators Forum**  
**July 28, 2005**



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**Healthcare Organizations**

**Survey Process**  
**Patient Tracer Activity**  
**New and Revised Standards**  
**Unannounced Surveys**  
**Periodic Performance Review**



# Overview

- ◆ Accreditation process
  - ◆ Focuses on systems critical to safety and quality of care, treatment, and services
  - ◆ Focuses on continuous operational improvement
  - ◆ Encourages laboratories to continuously use the standards to achieve and maintain excellent operational systems



# New Survey Process

## A Systems Approach

- ◆ Priority Focus Areas identified by Priority Focus Process
- ◆ Traces patients through entire lab experience
- ◆ Patient record is selected in several departments
- ◆ Supporting activities reviewed: pre-analytical, analytical and post-analytical processes
- ◆ QC, PT, instrument calibration and maintenance, competency of staff, environment of care
- ◆ Multiple patients followed
- ◆ Issues may be identified in one or more steps of a process or in interfaces between processes



# Standards

- Elements of Performance (EP) are the same in the manual and in the surveyor's laptop
- Standards compliance is based on an aggregation of compliance with all EPs



# Priority Focus Process

- ◆ Uses pre-survey data to focus survey
- ◆ Provides consistent focus on relevant issues
- ◆ Specific to each health care organization
- ◆ Enables customized survey process
- ◆ Research and focus groups identified data associated with priority issues
  - ◆ Priority focus areas
- ◆ Includes top 4-5 priority focus areas
- ◆ Includes clinical service groups specific to organization being surveyed



# Priority Focus Process

For laboratories, data may be derived from

- Proficiency testing
- Electronic application
- Office of Quality Monitoring (OQM)
- Previous recommendations



# Priority Focus Areas for Lab

- ◆ Analytical Procedures
- ◆ Communication
- ◆ Credentialed Practitioners
- ◆ Equipment Use
- ◆ Infection Control
- ◆ Information Management
- ◆ Organizational Structure
- ◆ Orientation and Training
- ◆ Patient Safety
- ◆ Physical Environment
- ◆ Quality Improvement Expertise and Activity
- ◆ Staffing



# Clinical/Service Groups (CSG)

- ◆ Categories of patients/residents/clients or services of a health care organization for which data are collected
- ◆ CLIA specialties, subspecialties, and other



# Patient Tracers

- Review charts/reports for information management requirements
- Observation of clinical practices, e.g. blood transfusion, specimen collection, testing
- Patient preparation
- Pre- and Post-analytical processes, e.g. order entry, transportation, specimen collection; specimen preservation



# Tracer Activity

- ◆ Surveyor will trace the analytical procedures provided to selected patients
  - ◆ Specimen collection, transport, receipt and processing
  - ◆ Testing process and interpretation of results
  - ◆ Reporting of results (Turn-around-time; Critical values)



# **Tracer Activity for Pre-analytic process may Include:**

- **Ordering and order entry**
- **Patient/specimen identification**
- **National Patient Safety Goals**
- **Specimen collection, preservation, transportation and processing**
- **Handling unacceptable specimen**
- **Orientation and competence of those who collect and process specimens**
- **PI data collected**



# Tracer Activity for Analytic Process

**Procedure written, approved, implemented**

**Systems for assuring quality results including quality control and remedial action**

**Specimen Analysis**

**Method validation**

**Equipment performance testing**

**Assuring competence of staff**

**Temperature monitoring**

**Safety, hazmat measures implemented during testing**



# **Tracer Activity for Post-Analytic Process will include:**

**Review of results prior to reporting**

**Reporting results including clinical  
and emergency results**

**Assuring appropriate communication  
processes for reporting results**

**Assuring an acceptable process for  
correcting erroneous results**

**Surveillance**

**Data storage and retrieval**



# Evidence of Standards Compliance (ESC)

## > Clarifying ESC:

- » If organization believes it was in compliance

with standards at time of survey

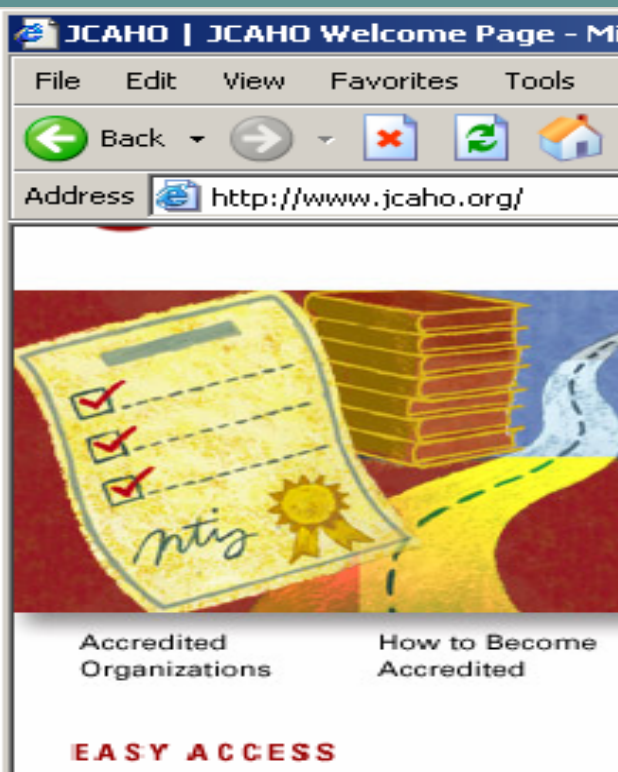
- » Evidence to submit will be specified

- » No “measures of success”

Submitted in ESC, not a separate process



# Accessing ESC and MOS on www.jcaho.org

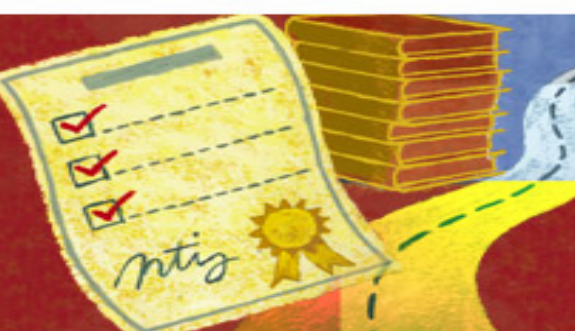


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Password:

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# Accessing ESC and MOS (cont'd)

## Step 4

Standards

Shared Visions-New Pathways

Survey Process

Sentinel Events

[Data Mart](#) | [Quality Check](#)

### What's New

- [Quality Reports Now Available](#)
- [Dear Colleague Letter: Dennis S. O'Leary, M.D., President, Joint Commission](#)
- [2005 Pre-publication Office-Based Surgery Standards](#)
- [Changes to the "Jayco" Home Page](#)
- [Health Care Staffing Services Field Review](#)
- [Potential 2005 NPSGs](#)

### Standards

- [National Patient Safety Goals](#)
- [Universal Protocol](#)
- [Standards Crosswalks](#)
- [Field Reviews](#)

### Application for Accreditation

- [Application for Accreditation - General](#)
- [Application for Accreditation - Laboratory](#)
- [HIPAA Business Associate Agreement](#)
- [Organization Contacts](#)

### Pre-Survey

- [Priority Focus Process](#)
- [Survey Agenda](#)
- [Survey Activity Guides](#)
- [Sample Forms and Tools](#)

### Post-Survey

- Evidence of Standards Compliance
- Measure of Success

**2005**  
**New and Revised**  
**Standards**

## EC.8.10

# Laboratory Environment

- ◆ Laboratory establishes and maintains an appropriate environment
- ◆ EP #35 (revised) — Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow that includes separate areas for:
  - ◆ Specimen preparation
  - ◆ Amplification and product detection
  - ◆ Reagent preparation, as applicable



## IM.3.10

# Managing Information

- ◆ Laboratory has processes in place to effectively manage information
- ◆ EP #17 (new) Provisions to ensure all records, slides, blocks, and tissues, as applicable are maintained and available for the time frames specified in Appendix E, in the event that the laboratory has ceased to operate.
  - ◆ Effective for scoring April 2005



# IM.6.190

## Laboratory-Specific Information

- ◆ Requests for lab tests made in writing or electronically
- ◆ Information clearly identified
  - ◆ EP #3 The patient's age or date of birth
    - ◆ Added bullet
    - ◆ April 2005 effective date



## IM.6.260

# Laboratory-Specific Information

- ◆ Lab has current descriptions of and instructions for all analytical methods and procedures
  - EP #1 “Procedures and changes in procedures are signed and dated by the director or designee before they are put into use”
    - Added bullet
    - April 2005 effective date



# WT.1.10

## Waived Testing

Changes underlined - effective January 1, 2005

- ◆ The organization establishes policies and procedures that define the context in which waived test results are used in patient care, treatment and services



# WT.1.10

## Waived Testing

### ◆ Revised EPs

- ◆ EP #1—Quantitative test result reports in the clinical record are accompanied by reference intervals specific to the test method used and appropriate to the population served
- ◆ EP #2 – Criteria for confirmatory testing for each test, qualitative or quantitative, are specified in the written procedure as dictated by clinical usage and methodology limitations



# WT.1.30

## Staff Training

- ◆ Staff performing tests have adequate, specific training and orientation to perform the tests and demonstrate satisfactory levels of competence.
- ◆ Revised EPs
  - ◆ EP #4 – Testing that requires use of an instrument is performed by staff with adequate and specific training on the use and care of that instrument



# WT.1.30

## Staff Training

- ◆ Revised EPs
  - ◆ EP #5 – Competence is assessed according to organization policy at defined intervals, but at least at time of orientation and once every year
  - ◆ EP #7 NEW (bullet 4) – Written testing specific to method assessed
    - ◆ Note: Staff that performs instrument based testing must participate in training and competence demonstrations



# WT.1.50\*

## Quality Control Checks

- ◆ Quality control checks, as defined by the organization, are conducted on each procedure.
- ◆ Revised EPs
  - ◆ EP #2 – Quality control procedures are performed at least as frequently as recommended by the manufacturer, according to the organization's policies

\*Top compliance issue for 2004



# WT.1.50\*

## Quality Control Checks

- ◆ Revised EPs
  - ◆ EP #3 – For instrument-based waived testing, quality control requirements include two levels of control, if commercially available
  - ◆ EP #4 – Quality control procedures are performed at least once each day on each instrument used for patient testing

\*Top compliance issue for 2004



# WT.1.60

## Quality Control

- ◆ Appropriate quality control and test records are maintained.
- ◆ Revised EP
  - ◆ EP #4 – A formal log is not required, but a functional audit trail is maintained that allows retrieval of results and associated quality control values for a minimum of two years



# QC.1.120

## Standard Revisions

- ◆ Quality control specimens are tested in the same manner as patient samples.
- ◆ EP #2 revised
  - ◆ Quality control specimens challenge each step in the testing process
- ◆ EP #4 revised
  - ◆ Scheduled quality control testing is routinely rotated among the personnel who perform the test



# New Standard QC.1.180

Effective January, 2005

- ◆ The laboratory determines the number, type, and frequency of testing control materials for each method performed using electronic quality control
  - ◆ Laboratory determines, through evaluation of validation and performance improvement data, the potential sources of error and frequency of quality control testing that is necessary to prevent medically significant errors in test results



# New Standard – QC.1.180

- ◆ Appropriate evaluations are performed and criteria met for test systems that utilize electronic quality control procedures
- ◆ Laboratory validates method for accuracy, precision, and reportable range by using external controls along with electronic check for statistically valid sample to verify confidence in the method
  - ◆ The number of data points required for validation is based on the laboratory's rationale; a minimum of 20 data points is suggested in order to produce meaningful data



# New Standard – QC.1.180

- ◆ After successful validation and evaluation the laboratory performs a less frequent use of external controls, such as once a week, but at least with each new lot number, shipment, or package of reagents and at an interval that meets manufacturer's recommendations and procedures defined by laboratory



# New Standard – QC.1.180

- ◆ There are at least two levels of electronic quality control performed and documented at the same level and frequency as required in the specialty and subspecialty sections, or more frequently if recommended by the manufacturer or defined by laboratory procedure



# Tissue Storage and Issuance

- ◆ QC.5.300\* Lab uses standardized procedures to acquire, receive, store, and issue tissue (effective July 1, 2005)
- ◆ QC.5.310\* Lab's record keeping permits traceability of all tissues from the donor or source facility to all recipients or other final disposition (effective July 1, 2005)
- ◆ QC.5.320 Lab has defined system to investigate adverse reactions to tissue or donor infections

\* Refer to February 2005 Perspectives



# Transplant and Implant Tissue Storage and Issuance Standards (AHC, OBS,CAH, HAP: PC.17.10 – PC.17.30) (LAB: QC.5.300-QC.5.320)

Why is this issue important?

- ◆ The potential for tissue-borne infections and other adverse outcomes in recipients of donor tissues is a significant quality and safety concern.
- ◆ The Food and Drug Administration (FDA) regulates tissue storage and issuance in healthcare organizations.
- ◆ Prior to July 2005, the Joint Commission only surveyed these standards in organizations where **laboratory services were JCAHO accredited.**



## Transplant and Implant Tissue Storage and Issuance Standards (AHC, OBS,CAH, HAP: PC.17.10 – PC.17.30) (LAB: QC.5.300-QC.5.320)

- ◆ Including these standards in hospital, critical access hospital, and ambulatory care manuals enables JCAHO to assess tissue storage and issuance policies and practices in all organizations accredited under these programs.
- ◆ These standards do not apply to solid organs used for transplants, such as kidneys, liver, heart, and spleen.



## QC.7.10

# Hematology and Coagulation

- ◆ The lab verifies each hematology procedure and test parameter against known standards or controls within range of clinically significant values on each day of use

For each automated test system:

- ◆ EPs #3 Tests at least two levels of commercial control every 24 hours of patient testing
- ◆ EP #4 Tests at least one level of control for each eight hours of patient testing



## QC.7.10

# Hematology and Coagulation

Each individual performing manual tests performs tests on controls as follows:

- ◆ EP #6 Cell counts require one level of control for every eight hours of testing
- ◆ EP #9 For manual tests, the laboratory defines and adheres to criteria for acceptable precision of duplicate samples



# QC.8.10

## Bacteriology, Mycobacteriology, and Mycology

- ◆ Chemical and biological solutions, reagents, and antisera are tested to provide proper reactivity and inspected for deterioration
  - ◆ EP #5 Biochemical panels are tested at intervals that meet manufacturer's directions, but at least once before putting into use for a new batch, lot or shipment



# QC.8.10

## Bacteriology, Mycobacteriology, and Mycology

- ◆ Revision of EP #6 – quality control frequencies:
  - ◆ Day of use: DNA probes, Beta-lactamase methods other than Cefinase, and camp test;
  - ◆ Each time a new batch, shipment, and lot number are prepared or opened: bacitracin, optochin, Cefinase, spot indole, ONPG, X, V, and XV factor discs or strips, germ tube, yeast morphology media, catalase, coagulase, and oxidase;
  - ◆ Typing sera: when prepared or opened and every six months thereafter;



# New Accreditation Participation Requirement: Continuous Public Involvement

- ◆ Encourages public to notify Joint Commission
  - ◆ Concern about quality of care and/or patient safety that organization has not addressed
- ◆ Effective January 1, 2006
  - ◆ Effective immediately for organizations voluntarily undergoing unannounced surveys



# 2006 Unannounced Surveys

- ◆ Not applicable to organizations seeking accreditation for the first time (initial survey)
- ◆ Short notice ( 5 day advance notice - not confirmed)
  - ◆ Bureau of Prisons
  - ◆ Department of Defense
  - ◆ In-Vitro Fertilization Laboratories (free standing)
- ◆ Applicable to all others



# Reasons for Implementing Unannounced Surveys

- ◆ Next evolutionary step
- ◆ Total revamping of accreditation process
- ◆ Focus shifts from survey prep and scores to systems improvement and direct patient care
- ◆ Focus on actual performance vs. potential



# Reasons for Implementing Unannounced Surveys

- ◆ Focus on execution vs. design
- ◆ New process directs greater attention to improving health care safety and quality
- ◆ New process is continuous vs. episodic
- ◆ Standards embedded in operations vs. expensive ramp-up costs
- ◆ Process viewed as more credible among public stakeholders



# Periodic Performance Review

- ◆ Effective October, 2005 for survey year 2006
  - ◆ Annual self-evaluation
    - ◆ Lab has opportunity for conference call to discuss PPR tool with Standards Interpretation Group(SIG)
    - ◆ Plan of Action reviewed and approved by SIG
  - ◆ Not used to direct survey activity
    - ◆ Surveyors are not given PPR or POA



# *Questions?*

*NPSG FAQs*

*<http://www.jcaho.org/accredited+organizations./patient+safety/npsg.htm>*

*Standards FAQs and Submit Questions on-line*

*<http://www.jcaho.org/accredited+organizations/standards+faqs.htm>*

*Call Standards Interpretation Group*

*630-792-5917*