Detecting Errors Before the Inspector: Auditing

Suzanne H. Butch, MA, MLS(ASCP)^{CM}
Michigan Medicine
University of Michigan Hospitals and Health Centers
Department of Pathology
Ann Arbor, Michigan

butchs@umich.edu

Objectives

- Define an audit
- Describe the role of auditing in quality management
- Define the elements of an audit
- Select audit topics
- Design an audit

What is An Audit?

Definition *from Quality Dictionary, Quality Council of Indiana*

A planned, independent and documented assessment to determine whether agreed upon requirements are met

Definition *from AABB Standards for Blood Banks and Transfusion Services 27th ed.*

Assessment: A systematic, independent examination that is performed at defined intervals and at sufficient frequency to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives.

Audit ≠ Assessment ≠ Inspection

- Assessment is less formal than an audit
- Assessment provides an estimate / determination of the significance, importance or value of something.
- Inspection: a tool to detect errors/defects before a product is approved for release or distribution

Audit

- a methodical examination and review
  - https://www.merriam-webster.com/dictionary/audit accessed 7/6/17

Methodical

- Planned
- Based on a requirement
  - Regulatory agency
  - Accrediting agency
  - Internal
- Designed
  - Procedures for performing the audit
  - Format

Audit Criteria

- Universal term that describes the reference used by an auditor against which the evidence collected during the audit can be compared

Examination

- Defined data elements evaluated
- Time frame or section of information
- Look for compliance
- Record non-compliance

Review

- Management reviews results
- Takes actions as necessary
- Determine if re-assessment is necessary

Audit Participants

- Client
- Auditor / Lead auditor
- Auditee
- Audit Program Manager

Why Do An Audit?

- Find and correct it before the inspector finds it
- Confirm compliance with requirements
  - New
  - At risk
- Confirm corrective and preventative action plans have been implemented and are effective

Quality Management Systems

- ISO
  - 15189 requirements for competence and quality of medical laboratories
  - Internal audits
- AABB
  - 8. Assessments – Internal and External
- CLSI Quality System Essential 11
  - Assessments

CAP

- COM.04000 Written QM Program
  - The laboratory has a written quality management program.
- Evidence of Compliance:
  - Records reflecting conformance with the program as designed AND
  - Results of quality surveillance

CAP

- *NOTE: The program must ensure quality throughout the pre-analytic, analytic, and post-analytic (reporting) phases of testing, including patient identification and preparation; specimen collection, identification, preservation, transportation, and processing; and accurate, timely result reporting. The program must be capable of detecting problems in the laboratory's systems, and identifying opportunities for system improvement. The laboratory must be able to develop plans of corrective action based on data from its QM system.*
- *All QM requirements in the Laboratory General Checklist pertain to the laboratory.*

The Joint Commission

- Audits needed to monitor effectiveness of corrective actions for citations

Classification of audits

- Internal audits

  First-party: audit your own organization
- External audits

  Second-party: Customer audits your organization

  Third party: Independent audit organization

Audit phases

- Preparation: planning ahead
- Performance: conducting the audit
- Report: what audit found
- Follow-up and Closure

Format


Facility Identification
QUALITY PROGRAM ASSESSMENT

NEW EQUIPMENT AUDIT

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Control points, quality elements:
Calibration, maintenance and monitoring of critical equipment conform to specified requirements.

Time Frame: New equipment placed into use before May 2017.

Materials:
Equipment Evaluation Checklist and/or IQ, OQ, PQ documentation and training plan
Equipment List
QC and maintenance records
Manufacturer's / Operator's Instructions
Equipment SOPs

Applicable regulations and SOPs:
- Process and Change Control
- AABB Standards for BBTS, 30th Edition: 3.0 Equipment

Methods/Procedure:
1. Identify all equipment placed into use before May 2017.
2. List the unique identifier for each piece of equipment.
3. Review the IQ, OQ, and PQ documentation and training education plan
4. Review the QC and maintenance requirements listed in the manufacturer's instructions / operator's manual
5. Review the QC and maintenance performed

Expectations (any predetermined threshold of performance):
1. Each piece of new equipment has an evaluation plan and unique identifier
2. Training, if required, was completed
3. Quality control and maintenance procedures are described in the SOPs as defined in the manufacturer's instructions / operator's manual and are performed on schedule
(+/- 1 month for annual and quarterly tasks)

AUDIT PLAN APPROVED BY: _____ DATE: _____

- Create a form
  - Header
    - Who is doing it
    - What expectations
    - When
    - Where
    - Why- regulation
  - Body
    - How to do it - methods
  - Approval to do the audit as designed

Summary of Findings


NEW EQUIPMENT AUDIT

- What was found
  - Of X number of records reviewed YY were compliant
    - ✓ (List of non-compliant records)
- Incidental Finding
  - Not part of the audit criteria but important to report

Who Should Do the Audit

- Can't audit your own work!
- Laboratory quality management section
  - If you have one
- Another lab section
- Trained Lab staff member
- Hospital quality management

Auditor must be

- Must be familiar with auditing techniques & the criteria they are auditing against
- Must be able to judge whether the intent is being met or addressed
- Must be OBJECTIVE: able to evaluate in a thorough but unbiased fashion

Focus of the audit

- Varies with the needs
- Product / service audit
- Process audit
- System audit
- Special-needs audits: environmental, safety, IT, etc.

Plan Audits for the Year

- Compliance with new/revised requirements
- "At risk" topics
- Known problems - confirm corrective action taken was effective
- Topic within each Quality System Essential (QSE)

At Risk

- Completion of paper records
  - Complete
    - No blanks
  - Legible
    - No Scribbles
    - No Overwrites
    - No White-out or other masking
  - Transfusion Record Forms
  - Logs

At Risk

- Specimen Acceptability
  - Standards followed
    - Transport/storage conditions
    - Phlebotomist identification
    - Specimen type
- Critical Values
  - Reported to caregiver in a timely manner
- Corrected reports
  - Caregiver notification
  - Report corrected in the computer with footnotes

Quality System Essentials

- CLSI
  - Organization
  - Customer Focus
  - Facilities and Safety
  - Personnel
  - Purchasing and Inventory
  - Equipment
  - Process Management
  - Documents and Records
  - Information Management
  - Nonconforming Events Management
  - Assessments
  - Continual Improvement

QSE Audit Suggestions

- Organization
  - Organizational charts up to date
  - Management review of quality is documented
- Customer Focus
  - Customer Surveys – management review and action plans
  - Complaints – response documented
- Facilities and Safety

Facilities and Safety

- Training Records
- Environmental monitors
- PPE Use
- Floor storage
- Waste is correct container
- Hazardous waste labeling
- Containers not too full
- Eyewash tested
- Safety equipment/electrical cabinets/exits blocked
- Ceiling tiles

QSE Audit Suggestions

- Personnel
  - Qualifications
  - Color blindness testing
  - Training records
  - Competency assessments
  - New procedure training
- Purchasing and Inventory
  - Disposal of outdated or unsatisfactory reagents and supplies
  - Lot number tracking
  - Track equipment specifications and purchases

QSE Audit Suggestions

- Equipment
  - Track from receipt to 2 years post removal from use
  - Maintenance performed as required by manufacturer's instructions
  - Validation records complete
- Process Management
  - Reagent manufacturer's instructions followed
  - Access audits

QSE Audit Suggestions

- Documents and Records
  - Incomplete paper records
  - SOP's are current and reviewed
- Information Management
  - Critical value notifications
  - Manual order entry
  - Manual result entry
  - Access audits
  - Documents can be recovered for time periods required

QSE Audit Suggestions

- Nonconforming Events Management
  - Investigations documented
  - Trend reports completed
- Assessments
  - Audits completed as scheduled
  - Response to external inspections implemented
- Continual Improvement
  - Projects documented
  - Monitors in place

How to Know About Changes

- Institutional member of a professional organization
- Become an individual member of your professional organization
  - Get newsletters and optional notifications
  - Scan the titles
- Get a sign on to the agency(ies) that accredit(s) your facility
- Sign-on to the agency web-site

Proposed Standards/Regulations

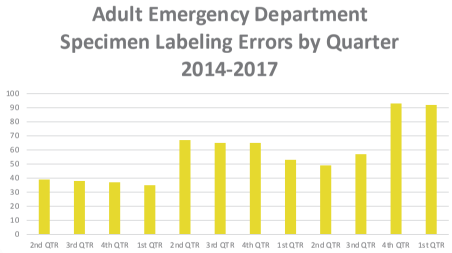
- All agencies now publish proposed changes for comment
- Read
- Respond if it is a problem
- Audit when final rules published

When New Standards Published

- Crosswalk – AABB current and previous edition
- CAP marks items if new or revised and listed deletions
- Joint Commission – publishes changes

A Monitor Is Not An Audit

- If are graphing the data, it is a monitor



Audit vs. monitor

- Completed audit report contains results of the investigation
- Corrective / Preventive action processes are implemented
- Monitor is established to systematically collect data to demonstrate effectiveness or corrective / preventive action.

Monitors

- Equipment or computer system down time
- Turn-Around-Time
- Percent errors
- Blood waste
- And many more

Summary

- Audit to confirm compliance
- Audits are
  - Planned
  - Documented
  - Reviewed by management
- A process is needed to keep up to date with requirements
- Monitors assess the success of corrective actions

Questions?