Audit Techniques and Assessment Tools

Holly Rapp, MT(ASCP)SBB, CQA(ASQ), CMQ/OE
Director, Accreditation and Quality
AABB

www.aabb.org
Agenda

- Definition of Auditing
- Auditing Techniques
- Assessment Tools
- Assessor Attributes
Auditing

- Determine state of completeness
- Performance of an activity to rules
Types of Audits

- **First-Party Audits**
  - Also known as an internal audit
  - Performed within your own company or facility

- **Second-Party Audits**
  - Performed by a customer on a supplier

- **Third Party Audits**
  - Performed by regulators, accrediting organizations
Third Party Audits

- System compliance audits
  - Look at products (both goods and services)
  - Look at processes
Fundamental Rules for Auditing

- Audits provide information for decisions
- Auditors are qualified to perform their tasks
- Defined requirements are used
- Conclusions are based on facts
Phases of an audit

- Preparation
  - Decision to perform the audit
  - Gather preliminary information
- Performance
  - Begins with an opening meeting
  - Includes the gathering of information
  - Analysis of information
- Reporting
  - Covers the translation of audit team conclusions to cited observations
  - Includes the audit report
- Closure
  - Development of corrective action by facility
Preparation

- Define the purpose of the audit
- Define the scope of the audit
- Identify the requirements/standards for the audit
- Prepare an audit schedule
Performance

- Data gathering
- Understanding facility processes
- Verifying system controls work
- Communicating among team members
- Communicating with the facility representatives
Definitions

- **Assessment** – an evaluation of system conformity to industry standards
- **Tool** – something used to do a job
Assessment Tools

- An aid to perform assessments/audits
- Include the requirements
- Include suggested questions for assessors to ask or to prompt discussion
- Do not contain yes/no questions
Assessor Attributes

- Knowledge of requirements
- Ability to communicate with team members and facility representatives
- Ability to ask open-ended questions
- Ability to synthesize information into systems
- Ability to manage facility information in a confidential manner
- Ability to relate observations to specific requirements
Opening Meeting

- All audits must have some sort of opening meeting
  - Introduce team members
  - Discuss audit schedule
  - State purpose and scope of audit
  - Identify facility escorts
  - Answer any preliminary questions
Gathering the Facts

- Observe
- Interview
  - Put the person at ease
  - Explain your purpose
  - Ask open-ended questions
- Corroborate information
- Trace a process
Perceptions

- Stick to the facts – not your feelings
- Pay attention to significant things
Team Meetings

- Share facts, concerns and problems seen
- Adjust data-gathering activities
- Start developing the report
Daily Briefings

- Enhance quality of the audit
- There should be no surprises
- Discuss what has been looked at
- Discuss what is to be looked at the next day
- Discuss any areas of concern
Reporting

- The audit report is the product
- Reports should have accuracy, conciseness and clarity and be factual
- Reports should be verifiable
  - Include enough information for facility to understand the issues
- Should not describe how to fix the issues
Exit Meeting

- Formal opportunity to present audit report
- Audit team speaks with one voice
- Compliment facility for good practices observed
- Summarize findings
- Answer questions/clarify issues
- Discuss corrective action process for responding to issues
Questions