Quality Management in the Transfusion Service

Suzanne H. Butch, MA, MLS(ASCP)^{CM}, DLM^{CM}
University of Michigan Hospitals & Health Centers
butchs@umich.edu

Objectives

- Describe a quality plan
- Set an indicator
- Design an audit

Quality Plan

- Describes the activities performed to ensure that the laboratory produces accurate results that meet the customer needs
- Based on the model chosen

Quality Plan Models

- ISO 9001
- ISO 15189
- AABB Standards
- FACT
- CLSI Keys to Quality
- Joint Commission

Need a Model Plan

- AABB Standards index
- AABB Web site Commendable Practices (members only)
- CLSI – Keys to Quality

ISO-15189 Medical laboratories -- Requirements for quality and competence

- **Quality Manual Contents**
  1. Introduction
  2. Description of medical laboratory
  3. Quality policy
  4. Staff education and training
  5. Quality assurance
  6. Document control
  7. Records, maintenance and archiving
  8. Accommodation and environment
  9. Instruments, reagents and consumables management
  10. Validation of examination
  11. Safety

ISO - Continued

12. Environmental aspects
13. Research and development
14. List of examination procedures
15. Request protocols, primary sample, collection and handling of laboratory samples
16. Validation of results
17. Quality control, including ILC
18. Laboratory information system
19. Reporting of results
20. Remedial actions and handling of complaints
21. Communication and other interactions with patients, health professionals, referral laboratories and suppliers.
22. Internal Audits
23. Ethics

Comparison CLSI vs AABB

CLSI Keys to Quality

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

AABB Standards

- **Organization**
- **Resources**
- **Equipment**
- **Supplier and Customer Issues**
- **Process Control**
- **Documents and Records**
- **Deviations, Nonconformances and Adverse Events**
- **Assessments: Internal and External**
- **Process Improvement Through Corrective and Preventative Action**
- **Facilities and Safety**

FACT

- **General**
- **Processing Facility**
- **Personnel**
- **Quality Management**
- **Policies and Procedures**
- **Process Control**
- **Coding and Labeling Cellular Therapy**
- **Distribution**
- **Storage**
- **Transportation, Shipping and Receipt**
- **Disposal**
- **Records**

Which One to Use?

- The one your accrediting agency uses
- They all cover the same requirements – just organized differently

What does a Quality Plan look like?

- Narrative
- Describes what will be done to ensure quality
- Example: Organization
  - The Blood Bank provides transfusion, apheresis and stem cell services to the _____ Health Centers. The organizational charts for the transfusion service are found at the end of this document. The most current institutional charts may be found on the _____ web page.

Structure of the Quality Function

- The Quality Assurance Program is the quality monitoring program of the ___Hospital. An overview of this program is described in the ___. The Blood Bank & Transfusion Service has separate quality plans for the Transfusion Service, Apheresis (APU) and the Cellular Therapy Laboratory (CTL).

- The Transfusion Service program is a part of the departmental and institutional quality system and encompasses several aspects of monitoring performance as outlined below

Executive Management

Blood Bank & Transfusion Service Executive Management	Consists of: • Medical Director • Associate Medical Director • Assistant Medical Director • Administrative Manager
Representatives to the Path. Quality Committee	• Administrative Manager • Quality Manager

Role of Executive Management

- Defines and documents the department's quality policy and objectives. The department's commitment to quality is defined in the Quality Policy (located on the X in the QA_DATA folder.
- Defines and documents the department's intent for implementing and supporting a quality system.
- Ensures that quality policy and objectives support the organizational goals and that they address the needs of the customer.
- Ensures that the quality policy and objectives are communicated, understood, implemented and maintained by quality systems training and availability of the Quality Policy.
- Assures operations are in compliance with laws, regulations and accrediting agency requirements.

Reporting and Review

- The Quality Manager and the Quality Assurance Technologist report directly to the Administrative Manager.
- The Corporate Quality Manager shall provide guidance and a review function.
- To further provide a separation of the review function from performance of a task, as much as possible a person who performs a task shall not be responsible for reviewing the activities.

Delegation

- The medical director of the Blood Bank & Transfusion Service has the ultimate responsibility for quality activities and the authority to approve changes required in support of the system. The medical director has delegated the responsibility and authority for administration of the Quality Program to the administrative manager. The administrative manager is responsible for and has the authority to
  - initiate corrective actions to ensure that products and services meet specified requirements
  - identify and address problems with product services or the quality system,
  - verify implementation and effectiveness of corrective action, and
  - implement control measures until problems have been resolved.

Emergency Preparedness

- The Blood Bank & Transfusion Service has an emergency preparedness plan that describes operations in the blood bank and is integrated with the institutional emergency preparedness plan and Continuity of Operations Plan. The institutional plans are described at http://www.med.umich.edu/i/safety/environment-emergency.htm .
- Site specific information.

Once You Have a Plan…

- How do you ensure you meet the objectives of the plan?
  - Answer: Monitoring
    - Indicators
    - Audits

Indicator

- Something you can put on a chart or graph
  - Number of Deviation Reports
  - Percentage: Number of X events per Y
  - Turn-around-times
  - Number of mislabeled specimens
  - Percent of mislabeled specimens
  - Percent or number of wasted units
  - Cancelled orders
  - Incomplete blood shipments

CAP Suggested Indicators

- ***Patient/Specimen Identification: Percent***
  - ***of patient wristbands with errors***
  - ***Percent of ordered tests with patient identification errors***
  - ***Percent of results with identification errors***
- ***Specimen Acceptability: Percent of specimens accepted for testing***

CAP Suggested Indicators

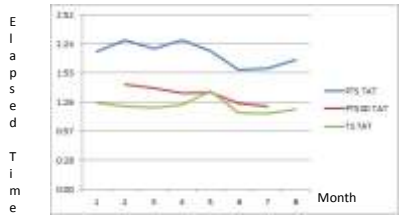
- ***Stat Test Turnaround Time***
- ***Critical Value Reporting***
- ***Customer Satisfaction***
- ***Corrected Reports***
- ***Blood Component Wastage***

AABB Required Monitoring

- Ordering practices
- Patient identification
- Sample collection and labeling
- Infectious and noninfectious adverse events
- Near-miss events
- Usage and discard
- Appropriateness of use
- Blood administration policies
- The ability of services to meet patient needs
- Compliance with peer-reviewed recommendations
- Clinically relevant laboratory results

Turn-Around-Time

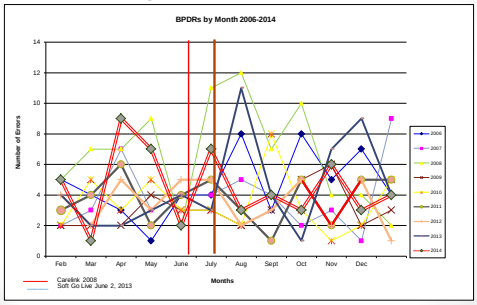
Type and Screens vs Preadmission Type and Screens



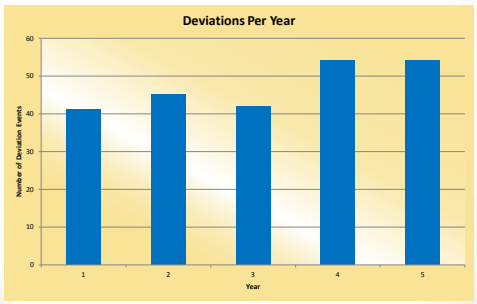
Data - Deviation Reports

	2010	2011	2012	2013	2014
Wrong Product/Patient Issued	7	6	7	6	14
2nd Blood type	1	3	0	0	0
Product requirements not Met	4	2	4	2	7
Labeling	15	9	11	17	12
Testing/Crossmatch selection	2	3	2	1	4
Unit not dispensed	6	14	13	13	13
Manufacturing problem - lab	1	0	0	0	0
QC failure	4	1	1	3	2
Product problem	1	1	1	1	0
Quarantine/Release Error	0	0	1	0	1
HPC Production	0	1	1	3	0
SOP Not Followed	0	5	1	8	1
	41	45	42	54	54

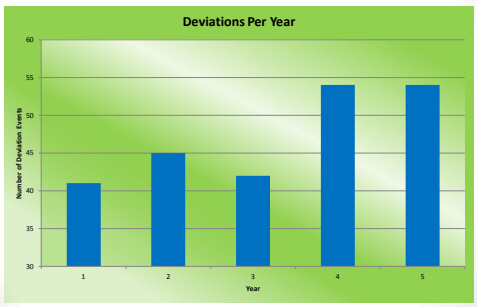
Deviations – Comparison
A bit busy!



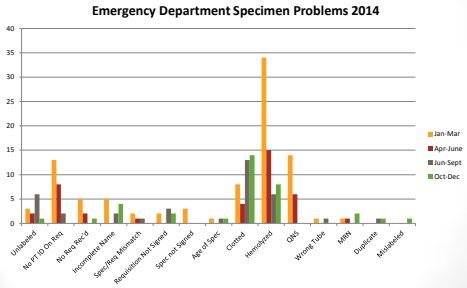
A Simple Graph



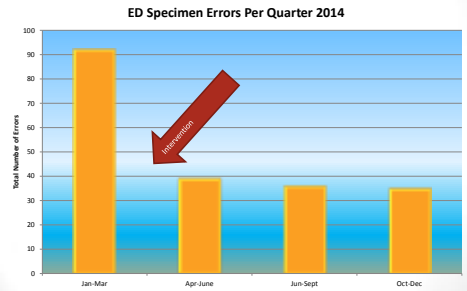
Modify Axis for Emphasis



Use Color

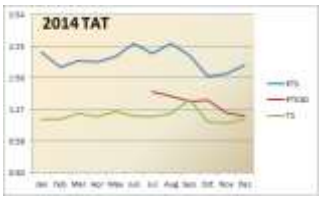


Use Arrows for Emphasis

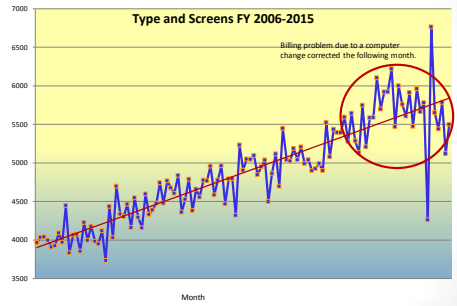


Turn-Around Time

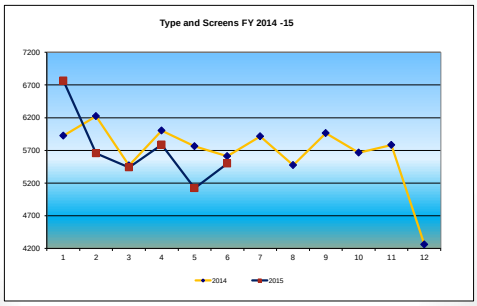
- **PTS = Preadmission Type and Screen**



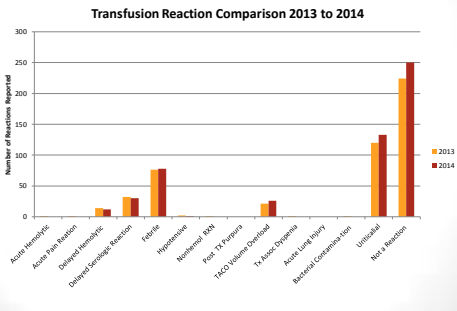
Type and Screen Activity



More graphs T & S



Transfusion Reactions



Track Errors

- Document
- Action taken to ameliorate and prevent recurrence
- Trend analysis

Audits

- Review of documentation to determine that a standard has been met
- Internal or external standard
- Benchmarking with published standards or other facilities
- Look for objective evidence that a standard is met

Audit Frequency

- Daily – computer exception report
- Weekly – daily quality control
- Monthly – QC performed
- Quarterly/Semi-annually – Transfusion Reactions Reported
- Annually – Completion of Transfusion Documentation
- One-time only – New standard

Schedule

- Doable
- 1-2 per month
- Cover each of the quality system essentials over time

Who Should Audit

- Institutional Auditors
- Department Auditing Staff
- Someone from another lab section
- Someone from the transfusion service who did not do the work

Audit Topics

- Specimen collection
- Component processing
- Computer functions
- Review and labeling
- Storage
- Patient testing – including reference laboratory procedures
- Component selection and compatibility testing
- Issue and administration of blood
- Investigation of adverse reactions

- Various statistical techniques are used to report process improvement and quality control data. Data is generally provided using reports or standard statistical tools and charts such as run, pie, Pareto and bar graphs

Audit Template

- audit name/number,
- description including audit purpose and scope, and time frame covered
- criteria/expectations,
- listing of regulatory requirement/ accreditation agency standard/internal facility requirement,
- materials/documents
- procedure or specific details audit performance
- audit approval,
- audit results section,
- recommendations,
- corrective and preventative actions, and
- final review of audit by management

Tracer Audit

- Pick a unit received or a unit transfused
- Follow the unit received through the laboratory
- Follow the transfused unit backwards

Review the records

- Equipment, reagents, staff for every step in the process
- QC done
- Equipment maintenance performed according to manufacturer's instructions
- Testing performed in accordance with manufacturer's instructions
- The staff member's competency assessed for the testing
- Etc.

Data Collection Tools

- Sampling Plan
- Log sheets
- Checklist

Data Collection Sheet

Date _____ by _____

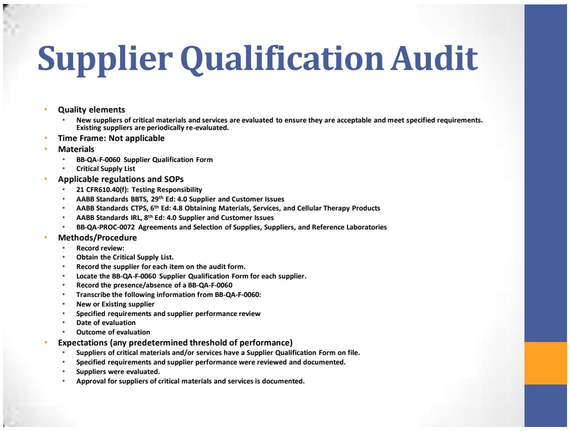
Data Element	Present	Criteria 1	Criteria 2
A			
B			
C			
D			
etc			

Non-Conformance

- Does the potential nonconformance pose a threat to staff or patients?
- Is there a failure to meet local, regional, state or federal regulations?
- Is it a requirement of an accrediting agency?
- Is it an internal requirement?

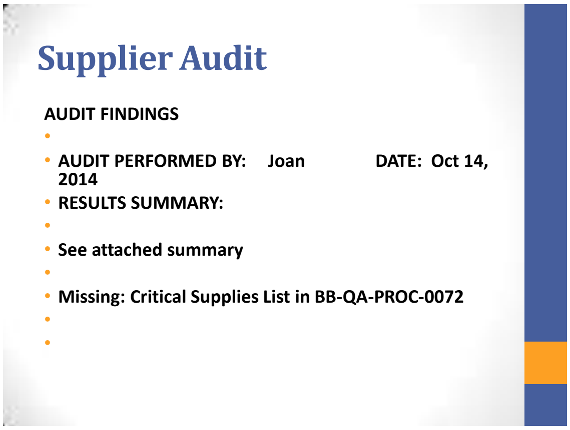
How to Write a Non-conformance

- Of the 25 records reviewed 15 lack ____
- Of the 12 staff interviewed 8 were unable to describe/answer the question _____
- The procedure _____ lacked ___.



Supplier Qualification Audit

- Quality elements
  - New suppliers of critical materials and services are evaluated to ensure they are acceptable and meet specified requirements. Existing suppliers are periodically re-evaluated.
- Time Frame: Not applicable
- Materials
  - BB-QA-F-0060 Supplier Qualification Form
  - Critical Supply List
- Applicable regulations and SOPs
  - 21 CFR610.40(f): Testing Responsibility
  - AABB Standards BBTS, 29th Ed: 4.0 Supplier and Customer Issues
  - AABB Standards CTPS, 6th Ed: 4.8 Obtaining Materials, Services, and Cellular Therapy Products
  - AABB Standards IRL, 8th Ed: 4.0 Supplier and Customer Issues
  - BB-QA-PROC-0072 Agreements and Selection of Supplies, Suppliers, and Reference Laboratories
- Methods/Procedure
  - Record review:
  - Obtain the Critical Supply List.
  - Record the supplier for each item on the audit form.
  - Locate the BB-QA-F-0060 Supplier Qualification Form for each supplier.
  - Record the presence/absence of a BB-QA-F-0060
  - Transcribe the following information from BB-QA-F-0060:
  - New or Existing supplier
  - Specified requirements and supplier performance review
  - Date of evaluation
  - Outcome of evaluation
- Expectations (any predetermined threshold of performance)
  - Suppliers of critical materials and/or services have a Supplier Qualification Form on file.
  - Specified requirements and supplier performance were reviewed and documented.
  - Suppliers were evaluated.
  - Approval for suppliers of critical materials and services is documented.



Supplier Audit

AUDIT FINDINGS

-
- AUDIT PERFORMED BY: Joan DATE: Oct 14, 2014
- RESULTS SUMMARY:
-
- See attached summary
-
- Missing: Critical Supplies List in BB-QA-PROC-0072
-
-

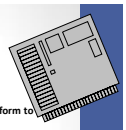
Corrective Actions

- CORRECTIVE ACTIONS
  - Revise BB-QA-PROC-0072, Agreements and Selections of Supplies, Suppliers and Reference Laboratories and add a revised Critical Supplies List.
  - Add 4 new/existing suppliers for ML/RL. BB-QA-F-0060 Supplier Qualification Forms are needed for:
- Marion Medical
- Ashland Specialty Ingredients All forms returned on 10/15/14 – Sherry
- Streck Labs
- Helmer, Inc.
-
- Add 4 new/existing suppliers for CTL. BB-QA-F-0060 Supplier Qualification Forms are needed for:
- Protide
- Hospira
- Cryogenic Gases All forms returned on 10/14/14 – Sandy
- Origen Cryostore
-
- Add 1 existing supplier for APU. BB-QA-F-0060 Supplier Qualification Form is needed for:
- Computype Form returned on 10/15/14 – Sherry
- The Charter Medical supplier is part of Med-Alliance Group
-
- Retire suppliers:
- Gibco Invitrogen
- International Specialty Products
- ARC National Testing Lab (Detroit, MI)
- Cardinal Health

Management Review

- **********
- FINAL REVIEW
- MEDICAL DIRECTOR REVIEW: _____DATE: _____
- ADMINISTRATIVE MANAGER REVIEW: _____ DATE: _____
- SUPERVISOR REVIEW: _____DATE: _____
- CLIA LABORATORY DIRECTORREVIEW: _____ DATE: _____
- QA REVIEW: _____DATE: _____

New Equipment Audit



- Quality elements: Calibration, maintenance and monitoring of critical equipment conform to specified requirements
- Time Frame: New equipment placed into use since last audit completed in April 2013.
- Materials:
  - QA154 Equipment Evaluation Form and/or IQ, OQ, PQ documentation and training plan
  - QC and maintenance records
  - Manufacturer's / Operator's Instructions
  - Equipment SOP's
- Applicable regulations and SOPs:
  - BB-QA-PROC-0071 (B794) Process and Change Control
  - AABB Standards for Blood Banks and Transfusion Services, 29th Edition: 3.0 Equipment
- Methods/Procedure:
  - 1. Identify all equipment placed into use after April 2013
  - 2. Review the IQ, OQ, and PQ documentation and training education plan
  - 3. Review the QC and maintenance requirements listed in the manufacturer's instructions / operator's manual
  - 4. Review the QC and maintenance performed
- Expectations (any predetermined threshold of performance):
  - Each piece of new equipment has an evaluation plan and unique identifier
  - Training, if required, was completed
  - Quality control and maintenance procedures are described in the SOP's 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: _____

Manufacturer's Instructions

- **Quality elements - Process control: All materials (containers and solutions used for collection, processing, preservation and storage of blood and blood components, all reagents used for tests) are stored and used in accordance with the manufacturer's written instructions. Written standard operating procedures are kept current with the revised manufacturer directions/product inserts. Quality control before placement into service is recorded. Staff can describe the steps for performing a test that are in accordance with manufacturer directions.**
- **Time Frame: One day**

Manufacturer's Instructions

- Audit Topic: _____ Date: _____
- Materials
  - Manufacturer Product Insert
  - Standard Operating Procedures
  - Quality Control records before placing into service
  - Day of use reagent quality control records
  - Testing personnel: direct observation or interview
- Applicable regulations and SOPs
  - 21 CFR 606.65(e) Supplies and Reagents
  - FACT CTL 5th Edition, D6.9.5, The use of supplies and reagents in a manner consistent with instructions provided by the manufacturer.
  - AABB Standards 29th Edition, 5.1.4, Use of Materials
  - AABB Technical Manual 2014, 18th Edition, p.xx, Process Management
  - CAP TRM.31227, Package Inserts
  - COMP-POL-0023, Manufacturer's Communications

Manufacturer's Instructions

- Methods/Procedure
  - Review the manufacturer's directions and compare to standard operating procedure(s).
  - Review quality control records before placement into service.
  - Review quality for day of use.
  - Observe/interview technologist. SOP/manufacturer directions are available for use.
  - Make copies of records that do not meet criteria.
- Expectations (any predetermined threshold of performance)
  1. The standard operating procedure reflects the use of the current manufacturer's directions.
  2. Before placement into use, quality control was done and recorded, the results were found
     acceptable and results were reviewed and signed by the medical director or designee.
  3. The quality control was acceptable for the day of use.
  4. All records are legible, dated, and initialed by the person performing the work.

Follow-up

- Documentation of any action taken
- Management - Final review and decision on re-audit

Annual Review

- Narrative report
  - Was plan effective
  - What needs to be improved
  - What modifications are being made to make the plan more effective

Summary

- A quality plan describes how we ensure quality
- An indicator monitors key activities
- An audit looks for evidence of compliance based on a requirement