Transfusion Medicine: Checklists and Challenges

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• Today’s presentation will review:
  o Most common checklist deficiencies
    • Lab General
    • All Common
    • Transfusion Medicine
  o Checklist Challenges
    • Interpretation of requirements
    • New requirements
Most Common Deficiencies – 2013

LAB GENERAL CHECKLIST

• GEN.55500 Competency Assessment
  o Each non-waived test system – to include all 6 required elements
  o Waived test systems – elements can be selected
  o Semiannually during first year of duties for new employees
  o Annually thereafter
  o Performed by Technical Supervisor or qualified designee (in writing)
• GEN.20375 Document Control System
  o Policies and procedures are current
  o Personnel are knowledgeable – including defined process for introduction of new or revised documents (sign-off sheets, electronic, meeting minutes)
  o Signed by Laboratory Director before implementation
  o Procedures reviewed per laboratory policy by director or designee (at least biennially)
  o Discontinued policies/procedures removed
• **GEN.75400 Annual Fire Drill**
  - All staff must participate annually
  - Exit fire drill required
  - Documented and available – eg, sign-off list or roster; facility fire drill report or assessment is NOT required

• **CHANGING in 2014 – annual in-service for all, exit fire drill recommended, not required**
Lab General (cont.)

• **GEN.77400 Eyewash**
  - Accessible – time/distance
  - Accessible – NOT blocked
  - Eyewash check documented weekly
  - Tepid temperature
Most Common Deficiencies – All Common Checklist

- **COM.01400 PT Attestation Page**
  - Written signature of Lab Director or designee (even if submitted electronically)
  - Designee must be in writing

- **COM.01700 PT Evaluation**
  - Prompt evaluation
  - **All** unacceptable results
  - Includes follow-up/corrective action
• COM.10000 Procedure Manual
  o Complete and current (outdated retired)
• COM.10100 Procedure Manual Review
  o Per laboratory policy (at least biennially)
  o At individual procedure level OR multiple signatures on a list of procedures
  o Electronic OR written signature acceptable
  o Laboratory Director or designee (in writing)
All Common Checklist (cont.)

- **COM.30300 Reagent Labeling** – revised expiration date must be recorded on container or log

- **COM.30350 Reagent Storage**
  - per manufacturer requirements
  - Temperatures recorded daily

- **COM.30400 Reagent Expiration Date** – used within expiration date

- **COM.30450 New Lot/Shipments** – confirmation of acceptability
Most Common Deficiencies – Transfusion Medicine Checklist

• TRM.31450 Comparability of Instrument/Method
  • Non-waived instruments/methods; eg, Gel vs. tube method, multiple instruments, etc.
  • Twice/year
  • Acceptability criteria defined
  • Documented review

Moving to All Common checklist in 2014
Most Common Deficiencies – Transfusion Medicine Checklist

- **TRM.41025/41650 Transfusionist Training and Transfusion Reaction Recognition** – annual education required for ALL transfusionists

- **TRM.31227 Package Inserts**
  - Current
  - Process defined to ensure current and no changes
Transfusion Medicine Checklist (cont.)

- **TRM.30000 Ongoing Record Evaluation**
  - QC records
  - Instrument maintenance/ function checks
  - Temperature records – 7 days/wk; 52 wks/yr
  - Comparability studies
  - Alarm checks

- **TRM.32000 Routine Maintenance Schedule**
  - All instruments/ equipment
  - As specified by manufacturer (at a minimum)
  - Reviewed monthly

*Moving to All Common checklist in 2014*
Transfusion Medicine Checklist (cont.)

• TRM.42850 Alarm Sensors To Trigger Action Needed
  o Set to alarm prior to falling out of range
  o Corrective action documented
  o Review documented

• TRM.42470 Acceptance Back Into Inventory
  o Process documented
  o Criteria defined

• TRM.30866 Service Agreement – approved, written agreement defining transfusion support services to all clinical areas served
Checklist “Challenges”

- Interpretation of requirements - sources
  - Participants - calls/accred@cap.org questions
  - Inspectors
  - Deficiency challenges

- Checklist changes
Interpretation “challenges”

- **GEN.54400/54750 Personnel Records**
  - Personnel license alone acceptable only if required by your state
  - Copy of diploma or transcript required if state licensure not applicable
    - Must include course of study, eg, Bachelor of Science in Medical Technology, Biology, etc.
  - Non-US degrees require foreign equivalency evaluation; eg, NACES, AICE and others
  - Certification – copy needed only if required by state or employer; eg, ASCP
Interpretation “challenges” (cont.)

• COM.30450 New Reagent Lot Verification
  o Applicable to all reagents/antisera/kits
  o Requires documentation and review

• COM.10600 Manufacturer Instructions
  o Any change to instructions requires verification
  o Change in waived test instructions makes test high complexity (and changes personnel requirements)
Interpretation “challenges” (cont.)

- **TRM.30575 Misidentification Risk** – documented action or plan to reduce misidentification risk
- **TRM.31900 Serologic Centrifuge Checks** – RPM and mechanical timer checks required each 6 months
- **TRM.42110 TRALI** - documented program or agreement with blood supplier for measures to reduce the risk of TRALI
Interpretation “challenges” (cont.)

- **TRM.41525/ 41550/ 41600 Perioperative/Intraoperative Blood Programs**
  - Defined responsibility of Laboratory Director and laboratory in perioperative and intraoperative programs
  - Documented Laboratory Director involvement in policies and procedures

- **TRM.30950 CBER Notification**
  - FDA biological product deviation reporting requirements (website: [www.fda.gov/cber](http://www.fda.gov/cber))
  - Includes testing, component prep, labeling, storage, and distribution of units
Checklist requirement update

New/Revised requirements – 2013

• TRM.45165 Blood Vessel Storage – requires procedures and records in accordance with US Organ Procurement and Transplantation Network (OPTN)

• TRM.42750/42800 Storage Unit Alarms
  o Combined into one requirement
  o Requires quarterly checks

• Separate Donor Apheresis and Therapeutic Apheresis sections; however, no “new” requirements
Checklist requirement update

New/Revised requirements – 2014

- Most instrument/equipment requirements moved to All Common Checklist; TRM-specific requirements only remain in TRM

- TRM.31250 Reagent Expiration Dates
  - Written policy required
  - Documented attempts to procure reagents

- TRM.42500 Blood/Component Storage Monitoring
  - Specific addition of applicability to storage outside of Transfusion Service, eg, surgery, nursing, dialysis
Checklist requirement update

DONOR APHERESIS

• TRM.42214  Donor Eligibility
  • Policy defining donor eligibility criteria
  • Documented evaluation of criteria

• TRM.42222  Donor Informed Consent – signed consent must be maintained

• TRM.42224  Adverse Reaction – documented procedure for the recognition, treatment, tracking, and trending of adverse reactions
Resources

• Phone: 1-800-323-4040 (CAP Customer Contact Center)

• E-mail: accred@cap.org

• cap.org/e-LAB Solutions

Connect tools:
• Personnel
• Proficiency Testing
• Change forms
• Master and Custom Checklists (eg, references, Word documents, and Excel spreadsheets)