SEABB Annual Meeting 2014

Transfusion Medicine: Checklists and Challenges

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Transfusion Medicine: Checklists and Challenges

- Today's presentation will review:
  - Most common checklist deficiencies
    - Lab General
    - All Common
    - Transfusion Medicine
  - Checklist Challenges
    - Interpretation of requirements
    - New requirements

Most Common Deficiencies – 2013

LAB GENERAL CHECKLIST

- GEN.55500 Competency Assessment
  - Each non-waived test system – to include all 6 required elements
  - Waived test systems – elements can be selected
  - Semiannually during first year of duties for new employees
  - Annually thereafter
  - Performed by Technical Supervisor or qualified designee (in writing)

Lab General (cont.)

- GEN.20375 Document Control System
  - Policies and procedures are current
  - Personnel are knowledgeable – including defined process for introduction of new or revised documents (sign-off sheets, electronic, meeting minutes)
  - Signed by Laboratory Director before implementation
  - Procedures reviewed per laboratory policy by director or designee (at least biennially)
  - Discontinued policies/procedures removed

Lab General (cont.)

- **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

All Common Checklist (cont.)

- COM.10000 Procedure Manual
  - Complete and current (outdated retired)
- COM.10100 Procedure Manual Review
  - Per laboratory policy (at least biennially)
  - At individual procedure level OR multiple signatures on a list of procedures
  - Electronic OR written signature acceptable
  - 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/Shipment – 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
  - Set to alarm prior to falling out of range
  - Corrective action documented
  - Review documented
- TRM.42470 Acceptance Back Into Inventory
  - Process documented
  - 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
  - Applicable to all reagents/antisera/kits
  - Requires documentation and review

- COM.10600 Manufacturer Instructions
  - Any change to instructions requires verification
  - 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)**
  - **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
  - Combined into one requirement
  - 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

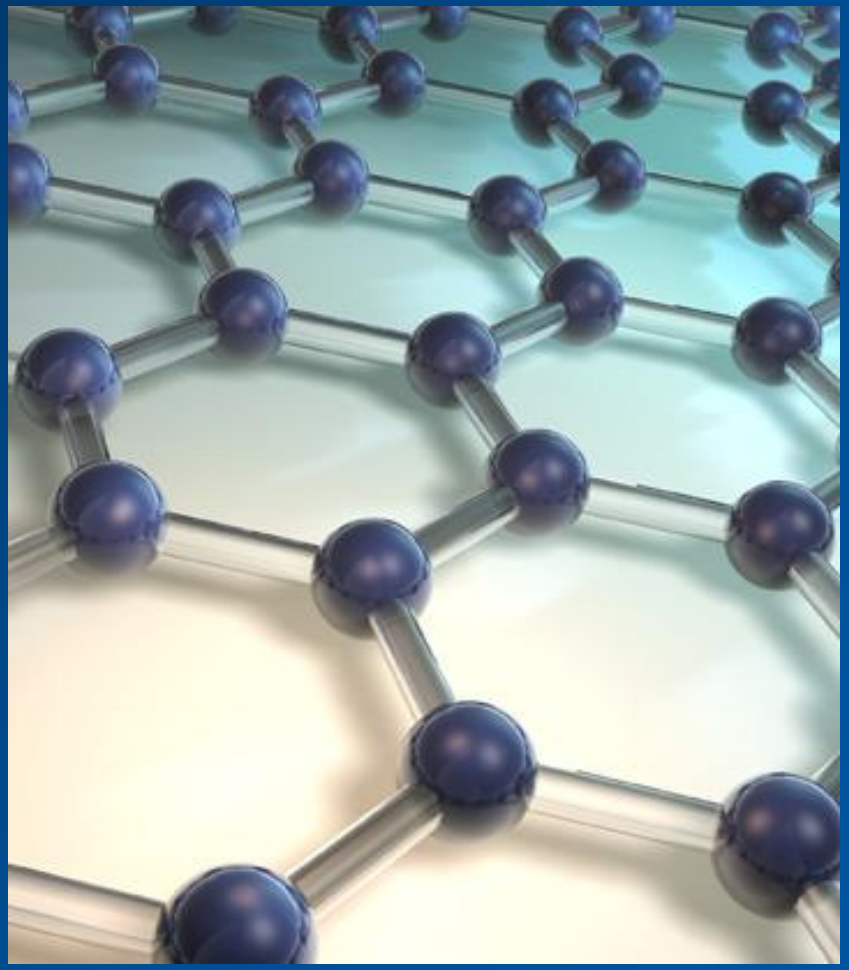
Checklist requirement update

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)

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