(99) Assessor Continuing Education Program

October 11, 2013 ♦ 8:30 AM - 5:30 PM
Event Outline

Event Title: (99) Assessor Continuing Education Program
Event Date: Friday, October 11, 2013
Event Time: 8:30 AM to 5:00 PM

Presenters: Anne Chenoweth, MBA, MT(ASCP)CM, CQA(ASQ); Denise Driscoll, MS, MT(ASCP)SBB; Nancy Friedman; Kathleen Houston, MLS(ASCP)SBB, CQA(ASQ); Holly Rapp, MT(ASCP)SBB, CQA(ASQ)CMQ/OE

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<td>8:30 AM - 9:00 AM</td>
<td>Kathleen Houston</td>
<td>Accreditation Report Card 2013</td>
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<td>9:00 AM - 10:30 AM</td>
<td>Nancy Friedman</td>
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<td>11:00 AM - 12:00 PM</td>
<td>Nancy Friedman</td>
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<td>1:00 PM - 3:00 PM</td>
<td>Holly Rapp</td>
<td>Group 1 &gt; 5 years</td>
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<td>Anne Chenoweth</td>
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<td>Denise Driscoll</td>
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<td>Holly Rapp</td>
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Event Faculty List

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Director/Moderator
Holly Rapp, MT(ASCP)SBB, CQA(ASQ)CMQ/OE
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Disclosures: NO

Speaker
Nancy Friedman
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Disclosures: No

Speaker
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Speaker
Kathleen Houston, MLS(ASCP)SBB, CQA(ASQ)
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Disclosures: NO

Speaker
Denise Driscoll, MS, MT(ASCP)SBB
Director, Laboratory Accreditation and Regulatory Affairs
College of American Pathologists
ddrisco@cap.org
Disclosures: NO
Welcome!

- Where assessors are from and where we assess
- New Personnel
- Reassessments
- Delayed assessments
- Program Ratings

Thank you! -- To

- Assessors for jobs well done
- for years of volunteer hours (> 24,000 hours in fiscal 2013)
- AABB National Office staff
  - For expertise, stability and customer service
- AABB
  - For the privilege of chairing this important activity
Assessors Around the World  
(2013)  
13 Countries  
- Canada  
- Singapore  
- Saudi Arabia  
- Kuwait  
- Honduras  
- Brazil  
- UAE  
- Argentina  
- Hong Kong  
- India  
- Greece  
- Netherlands  
- Qatar

AABB Accredited Facilities  
Around the World 2013  
(29 countries)  
- Canada  
- United Kingdom  
- Italy  
- Greece  
- Poland  
- Japan  
- Taiwan  
- Singapore  
- Hong Kong  
- India  
- Saudi Arabia  
- Kuwait  
- Mexico  
- Dominican Republic  
- Honduras  
- Colombia  
- Brazil  
- Portugal  
- Argentina  
- Hungary  
- China  
- Thailand  
- Mexico  
- United Arab Emirates  
- South Africa  
- Panama  
- Netherlands  
- Belgium  
- Israel

New Accreditation Staff  
2013  
- Nancy Shotas – Staff Lead Assessor  
- Brynna Gray – Technical Specialist
Reassessments 2013
- Following routine assessment – 0
- Complaint investigations - 2

Delayed Assessments 2013
- One due to assessor travel limitations
- One due to a landslide and closed road

New Standards -- Effective Dates
- Perioperative – 5th edition: November 1, 2012
- CT – 6th edition: July 1, 2013
- IRL – 8th edition: October 1, 2013
- MT – 2nd edition: October 1, 2013
- RT – 11th edition: January 1, 2014
- BBTS – 29th edition: April 1, 2014
PAQ scores

Need to Improve
PAQ Comments

- Some assessor judgments did not take our response into consideration
- Time seemed very rushed in the afternoon
- Time spent was not adequate to perform thorough assessment
- Logistics for system assessment did not work well

Need to Improve
PAQ Comments

- Assessor could have listened better
- More time should be spent observing actual testing, not just reviewing SOPs
- Trainee acted as an approved assessor
- Felt some nonconformances based on personal interpretation of standards
- Assessor consumed time talking about herself
Positive PAQ Comments

- Excellent assessment team – organized, professional and thorough
- AABB assessments are always a great experience
- Assessment was very thorough and fair
- Assessors knowledgeable and courteous
- From opening remarks to summation the assessor was pleasant, knowledgeable, and helpful

Projects

- ISQua accreditation (4 more years)
  - Accreditation Program
  - Assessor Training Program
- More electronic documents (less paper)
- Renew CLIA deemed status with CMS

Summary

There is considerable evidence to show that accreditation programs improve clinical outcomes of a wide spectrum of clinical conditions. 

Annals of Saudi Medicine
Assessor Breakout >5 years

Emcee
Holly Rapp

www.aabb.org

Program

- Vignettes
- Cast of Characters
  - Nancy Shotas
  - Marsha Garcia
  - Sheri Goertzen
  - Frances Ivester
  - Kim Charity
  - Judy Sullivan
- Interactive Questions

Assessing 101

- Accreditation Information Manual (AIM)
- Program Policies
- Program Process
- Assessor Handbook
- Facility Guide

www.aabb.org
Dress Code

- AIM
- Policy 5.7

Nancy Shotas and Marsha Garcia

Questions

- Are jeans of any type allowed?
- What kind of shoes must be worn?
- Is any type of head covering permitted?
Audit Behavior

- AIM
- Assessor Handbook

Questions

- If a facility business practice seems complicated what can you say about it?
- When staff is less than cooperative do you make a comment?
- Is it ok to be short and very negative about what you are seeing during the assessment?
- Is it okay to talk about the assessment or facility when you return to work?
Open-ended Questions

- AIM
- Assessor Handbook
  - Questioning Techniques

Questions

- How do you manage yes and no answers to questions?
- What is the best way to get additional information about a process?
Opening Session or Meeting

AIM
- Assessor Handbook

Kim Charity and Nancy Shotas

Questions
- What is the purpose of the opening meeting?
- Who should be invited?
- What is discussed?
- What if the medical director is not available?
Managing Trainees

- Pre-assessment
- During the assessment
- Completion of training checklist
- Completion of On-site Trainee Evaluation

Sheri Goertzen and Marsha Garcia

Questions

- When do you contact the trainee on your team?
- What is the trainee allowed to do during an assessment?
- Who sends in the training checklist and evaluation?
Summary Session
- Accreditation Information Manual
  - Assessor Handbook
    - Summary Session

Questions
- Who is invited to the summary session (closing meeting)?
- How long should be planned for the summary session?
- What happens to all the facility materials?
- Who signs the summary report?
Assessor Breakout
<5years

Emcee
Anne Chenoweth

Afternoon entertainment

- Vignettes
- Cast of Characters
  - Linda Sigg  Pat Ooley
  - Liz Smith   Mary Lieb
  - Jill Hoag   Maureen Beaton
- Interactive questions

Conflict of Interest

- Assessors may decline an assignment due to a conflict
- Facility may decline assessor due to a conflict
Questions

Are these statements a conflict?

- If my facility sends testing to that laboratory is that a conflict?
- If you work for a blood center that periodically offers services to another blood center and you are assigned that assessment, is it a conflict?
- My husband works there

Dress Code

- Accreditation Information Manual
- Policy 5.7
Questions

- I am leaving right after the assessment can I dress in comfortable dress jeans?
- I have really cute peek toe heels can I wear them?!
- Is it ok to wear a hat or head covering?

Audit Behavior

- Accreditation Information Manual
- Assessor Handbook
Questions

- What would you say if the process for temperature checks at a facility is really complex and time consuming?
- You see a form you would really like to use in your facility can you ask for a copy?

Open-ended Questions

- Accreditation Information Manual
- Assessor Handbook
  - Questioning Techniques
Questions
- Which question is open-ended
  - You do run a positive control with that test, don’t you?
  - Show me your process for QC for that test?

Writing Nonconformances
- Objective evidence
- Relate to Standards
Questions

- Why do we group objective evidence?
- Can you cite the Technical Manual as a requirement?

Summary Session

- Accreditation Information Manual
  - Assessor Handbook
    - Summary Session
Mary Lieb and Pat Ooley

Questions

- Who is invited to the summary session (closing meeting)?
- How long should be planned for the summary session?
- What happens to all the facility materials?
- Who signs the summary report?

General Questions
Transfusion Medicine: Checklists and Challenges

Denise Driscoll, MS, MT (ASCP)
Director, Accreditation and Regulatory Affairs
College of American Pathologists
AAIB 2013 - Denver

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 - 2012

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 lab 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 - e.g. sign-off list or roster; facility fire drill report or assessment is NOT required

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.01100 Ungraded PT Challenges - all ungraded results
**All Common Checklist (cont.)**

- COM.30300 Reagent Labeling – revised expiration date must be recorded on container or log
- COM.10100 Procedure Manual Review
  - Per lab policy (at least biennially)
  - At individual procedure level OR multiple signatures on a list of procedures
  - Electronic OR written signature acceptable
  - Lab Director or designee (in writing)

**Most Common Deficiencies - Transfusion Medicine Checklist**

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

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

**Transfusion Medicine Checklist (cont.)**

- TRM.30000 Ongoing Record Evaluation
  - QC records
  - Instrument maintenance/ function checks
  - Temperature records
  - Comparability studies
  - Alarm checks

- TRM.32000 Routine Maintenance Schedule
  - All instruments/ equipment
  - As specified by manufacturer (at a minimum)
  - Reviewed monthly
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.org questions
  - Inspectors
  - Deficiency challenges

- 2013 Checklist changes

Interpretation “challenges”

- GBN.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, e.g. Bachelor of Science in Medical Technology, Biology, etc.
  - Non-US degrees require foreign equivalency evaluation; e.g. NACES, AICE and others
  - Certification - copy needed only if required by state or employer; e.g. 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)

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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**

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Interpretation “challenges” (cont.)

- **TRM.41525/ 41550/ 41600 Perioperative/Intraoperative Blood Programs**
  - Defined responsibility of Laboratory Director and lab in perioperative and intraoperative programs
  - Documented Lab 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
2013 Checklist requirement “challenges”

2013 Checklist edition release scheduled for late July/early August

NEW requirements

- **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

Resources

- Customer Contact Center: 1-800-323-4040
- E-mail: accred@cap.org
- CAP website tools: e-LAB Solutions
  - Personnel
  - Proficiency Testing
  - Change forms
  - Master and Custom Checklists (including references, Word documents and Excel spreadsheets)
Assessor Update 2013
Holly Rapp, Director
Accreditation & Quality
Assessor Day 2013
Denver

Agenda
- ISQua
- Annual Report
- Membership dues
- Assessor Responsibilities
- Desk Assessments
- Assessor Report Cards
- Assessor Thank you letters
- Reminders
- News
- Questions

Sheila is in Denver....
- If you have not said hello to her today, please visit her at the Information Booth during the meeting!
ISQua

Accreditation Program and Assessor Training granted new 4 year accreditation in 2013

Accreditation Annual Report

- 2012 Annual Report
  - Summary of activities
  - Posted on AABB web site
  - www.aabb.org>Standards & Accreditation>Member Tools>

AABB Membership

- Renew your membership for 2014 here in Denver (active individual membership is required to be an assessor)
  - Membership Booth in the Registration area
Assessor Responsibilities

- Accreditation Information Manual (AIM)
  - Know where it is
  - Know what it says
- Continuing Education
  - Know policy
  - Be familiar with the form
  - Submit on time!

Assessor Continuing Education

- Redesigned program for 2013-2014
  - Same 65 hour requirement
  - Same categories for CE
  - New date for submission
    - All approved and hold assessors submit completed form by December 31, 2014

Assessor Report Cards

- Sent by email
- Average score from PAQs (facility evaluation)
- A score below 2 will be investigated
  (you will get a phone call or email from me!)
Team Member scores

- Represents the AABB with integrity
- You are representing AABB when doing an assessment
- Manages facility information in a confidential manner
- Do not discuss facility at work, home, in elevators, in cafeteria, etc.
- Let your team members know what you are seeing
- Keep the facility folks aware of issues and your schedule
- Demonstrates knowledge of AABB Standards
- Be familiar with the standards you are assessing to
- Relates observations to specific standards
- Do not use phrases like "the facility needs to" or "the facility should" in objective evidence – objective evidence should be what was observed
- Synthesizes information by asking open-ended questions
- Use words like "explain to me", "how do you", and "do you have" or I know you do this.
- Applies systems analysis to the assessment process
- Look at the systems in place, not each individual item when evaluating conformance

Team Leader

- Represents the AABB with integrity
- Manages facility information in a confidential manner
- Communicates effectively with team and facility
- Demonstrates knowledge of AABB Standards
- Skews separately and interrupts disconnection during the visit
- Organizes and directs the assessment team
- Be aware of your team’s progress and findings
- Be available to help and answer questions
- Be aware of what was reviewed before the team enters the facility
- Shows sensitivity and minimizes disruption during the visit
- Follows the planned schedule that you presented at the opening meeting – a schedule must be agreed with the facility at the opening meeting.
- Be aware of your team’s schedule – make sure there is enough time to complete the assessment without rushing at the end
- Synthesizes information by asking open-ended questions
- Applies systems analysis to the assessment process

Assessor Competency

- Areas of concern (low scores)
  - Observations not related to a standard
  - Questions are not open-ended
  - Assessor does not know/understand the Standards
  - Communication is not effective
    - Do not use acronyms when asking questions
    - Make sure your questions are understood
Pet Peeves

- Do not use something I said as a requirement (use the standards)
- Do not use your facility policy as a requirement (use the standards)
- Do not question business practices (AABB standards do not address business practice)
- Wait until an assessment is completed to share your facility documents or request documents to take home

Other Concerns

- PAQ comments
  - Not enough time to discuss findings and ask questions
  - Surprises at the summary session
  - Assessors are looking for how they do things in their own facility
  - Assessors seem to have an agenda to find things wrong
- Allow adequate time to perform the assessment, write the summary report and conduct the closing without rushing
- Be open to other ways to meet requirements (Do not focus on how you do things at home)

Thank you letters

- Provide assessors documentation for purposes of CE
Reminders

- Assessment dates
  - Notify Accreditation Department of assessment date within 10 days of receiving pre-assessment packet
  - Remember that we notify the facility on Friday of upcoming assessment so we need plenty of notice if the date has to be changed (unless it is an emergency situation)
  - AABB assessors do not call the facility 1 hour before arriving

Reminder

- Schedule your assigned assessment in the correct quarter and before the CAP anniversary date (if CAP coordinated)
- Do not wait until the end of the quarter!

Reminder

- Focus assessment on timeframe since previous assessment (don’t request documents older than 2 years)
- Ensure corrective action from last assessment has been implemented
Reminder

- **Assessor CE Update**
  - Published quarterly
  - Posted on the AABB web site
    - Standards and Accreditation>Member Tools>Assessors>Assessor CE update
  - **Required reading! There is important information for you.**

Reminder

- **International Assessment Assignment**
  - Before you accept the assignment make sure you have a valid US passport
    - There must be enough time before expiration to cover the assessment dates (at least 6 months)
    - If you do not have a US passport (and you live in the US do not accept the assignment unless you are sure you can return to the US)
  - Find out if you need a visa to enter the country (www.travisa.com)
  - Make sure you get required vaccinations before you go!

AIM, 8th edition

- **Reminder**
  - Available on-line
  - Accreditation Information Manual (AIM)
  - Updated as needed (so review periodically)
  - **You are responsible for knowing accreditation policies and procedures!**
Reminder

- Physician CME
  - AABB offers CME for performance of AABB assessments
  - Complete form and submit with expense report

www.aabb.org

Direct Deposit for Reimbursement

- Please complete the form
  (We have forms in Denver or it is on the web!)
- Attach a voided check
- Send to AABB Accreditation Department

www.aabb.org

Please remember...

- Thank the facility at the end of the assessment for being AABB accredited and for supporting AABB
- Compliment the good things they do!

www.aabb.org
Thank You!

- For your support of the accreditation program
- For the time you donate
- For your constructive comments about the program

Questions