



(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

<u>Time</u>	<u>Speaker</u>	<u>Presentation</u>
8:30 AM - 9:00 AM	Kathleen Houston	Accreditation Report Card 2013
9:00 AM - 10:30 AM	Nancy Friedman	Soft Skills
11:00 AM - 12:00 PM	Nancy Friedman	Golden Nuggets
1:00 PM - 3:00 PM	Holly Rapp	Group 1 > 5 years
1:00 PM - 3:00 PM	Anne Chenoweth	Group 2 <5 years
3:30 PM - 4:15 PM	Denise Driscoll	CAP Update
4:15 PM - 5:00 PM	Holly Rapp	Assessor Update 2013

Event Faculty List

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Event Date: Friday, October 11, 2013

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Director/Moderator

Holly Rapp, MT(ASCP)SBB,
CQA(ASQ)CMQ/OE
Director, Accreditation and Quality
AABB
holly@aabb.org
Disclosures: NO

Speaker

Nancy Friedman
President
Telephone Doctor
nancy@telephonedoctor.com
Disclosures: No

Speaker

Anne Chenoweth, MBA, MT(ASCP)CM,
CQA(ASQ)
Accreditation Manager
AABB
achenoweth@aabb.org
Disclosures: NO

Speaker

Kathleen Houston, MLS(ASCP)SBB, CQA(ASQ)
Chair, Accreditation Program Committee
Children's Hospital Association
kathleen.houston@childrenscolorado.org
Disclosures: NO

Speaker

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

Accreditation Report Card 2013

Kathleen Houston,
MT(ASCP)SBB, CQA(ASQ)
Chair, Accreditation
Program Committee
AABB Assessor Training Day
October 11, 2013



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Welcome!

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



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Thank you! -- To

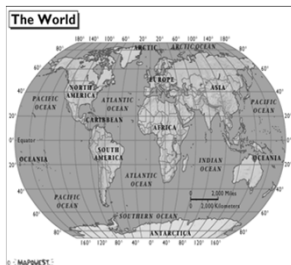
- Assessors
 - for jobs well done
 - for years of volunteer hours (> 24,000 hours in fiscal 2013)
- AABB National Office staff
 - For expertise, stability and customer service
- AABB
 - For the privilege of chairing this important activity



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Assessors Around the World (2013) 13 Countries

- Canada
- Singapore
- Saudi Arabia
- Kuwait
- Honduras
- Brazil
- UAE
- Argentina
- Hong Kong
- India
- Greece
- Netherlands
- Qatar

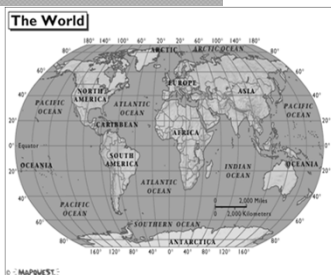


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AABB Accredited Facilities Around the World 2013 (29 countries)

- Canada
- United Kingdom
- Italy
- Greece
- Poland
- Japan
- Taiwan
- Singapore
- Hong Kong
- India
- Saudi Arabia
- Kuwait
- Mexico
- Dominican Republic
- Honduras
- Colombia
- Brazil
- Portugal
- Argentina
- Hungary
- Thailand
- Cyprus
- United Arab Emirates
- South Africa
- Panama
- Netherlands
- Belgium
- Israel



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New Accreditation Staff 2013

- Nancy Shotas –
Staff Lead
Assessor
- Brynna Gray –
Technical
Specialist



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Reassessments 2013

- Following routine assessment – 0
- Complaint investigations - 2



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Delayed Assessments 2013

- One due to assessor travel limitations



- One due to a landslide and closed road



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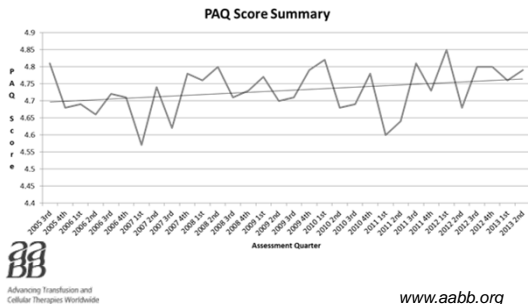
New Standards -- Effective Dates

- | | |
|---|--------------------|
| ■ Perioperative – 5 th edition | ■ November 1, 2012 |
| ■ CT – 6 th edition | ■ July 1, 2013 |
| ■ IRL – 8 th edition | ■ October 1, 2013 |
| ■ MT – 2 nd edition | ■ October 1, 2013 |
| ■ RT – 11 th edition | ■ January 1, 2014 |
| ■ BBTS – 29 th edition | ■ April 1, 2014 |



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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



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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



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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



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Projects

ISQua accreditation (4 more years)

- ❖ Accreditation Program
- ❖ Assessor Training Program

More electronic documents (less paper)

Renew CLIA deemed status with CMS



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Summary



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

Annals of Saudi Medicine





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Assessor Breakout >5 years

Emcee
Holly Rapp





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Program

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




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Assessing 101

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



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Dress Code

■AIM

■Policy 5.7



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Nancy Shotas and Marsha Garcia



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Questions

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



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Audit Behavior

■ AIM

■ Assessor Handbook



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Kim Charity and Frances Ivester



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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?



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Open-ended Questions

■ AIM

■ Assessor Handbook

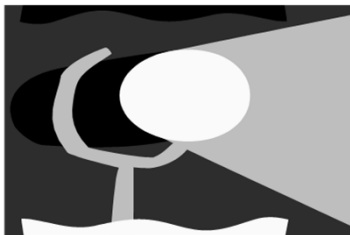
• Questioning Techniques



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Judy Sullivan and Sheri Goertzen



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Questions

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



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Opening Session or Meeting

■ AIM

■ Assessor Handbook



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Kim Charity and Nancy Shotas



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Questions

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



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Managing Trainees

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



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Sheri Goertzen and Marsha Garcia



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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?



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Summary Session

- Accreditation Information Manual
 - Assessor Handbook
 - Summary Session



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Frances Ivester and Judy Sullivan



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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?



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General Questions





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Assessor Breakout <5years

Emcee
Anne Chenoweth






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Afternoon entertainment


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



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Conflict of Interest

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



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Jill Hoag and Linda Sigg



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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



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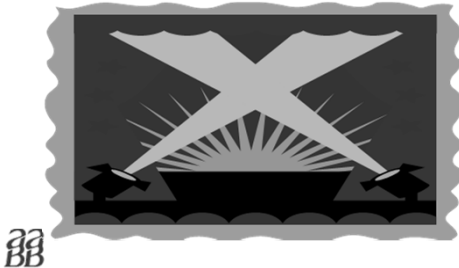
Dress Code

- Accreditation Information Manual
- Policy 5.7



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Mary Lieb and Maureen Beaton



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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?

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Audit Behavior

- Accreditation Information Manual
- Assessor Handbook

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Liz Smith and Pat Ooley



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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?



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Open-ended Questions

- Accreditation Information Manual
 - Assessor Handbook
 - Questioning Techniques



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Mary Lieb and Linda Sigg



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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?



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Writing Nonconformances

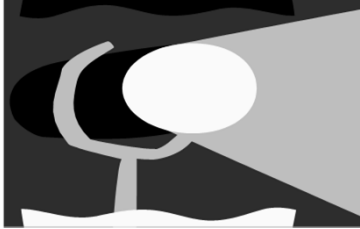
- Objective evidence
- Relate to Standards



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Jill Hoag and Maureen
Beaton



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Questions

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



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Summary Session

- Accreditation Information Manual
 - Assessor Handbook
 - Summary Session



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Mary Lieb and Pat Ooley



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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?




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General Questions




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Place sub-brand here



Transfusion Medicine: Checklists and Challenges

Denise Driscoll, MS, MT(ASCP)SBB
Director, Accreditation and
Regulatory Affairs
College of American Pathologists

AABB 2013 - Denver

cap.org v. #

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

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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)

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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”

- 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, 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)

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 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

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2013 Checklist requirement "challenges"

NEW requirements

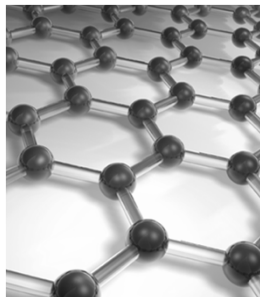
- TRM.45165 Blood Vessel Storage – requires procedures and records in accordance with US Organ Procurement and Transplantation Network (OPTN)
- TRM.42750/42800 Storage Unit Alarms
 - Combined into one requirement
 - Requires quarterly checks
- Separate Donor Apheresis and Therapeutic Apheresis sections; however, no "new" requirements

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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)



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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



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Sheila is in Denver....

- If you have not said hello to her today, please visit her at the Information Booth during the meeting!



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ISQua

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



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Accreditation Annual Report

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



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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



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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!



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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**



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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!)



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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.
- Communicates effectively with team and facility
 - 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
 - "Show me", "explain to me", "How do you...", **not** "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



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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
- Shows sensitivity and minimizes disruption during the visit
 - If staff is busy with a stat do not distract them with questions – review documents instead
- 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 issues and discussions that could cause confusion
- Conducts the assessment within the agreed timetable
 - **Follow the planned schedule that you presented at the opening meeting – a schedule must be shared with the facility at the opening meeting**
 - When planning your schedule allow 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



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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



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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



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Other Concerns



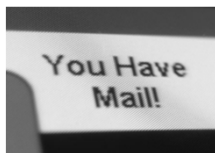
- PAQ comments
 - Not enough time to discuss findings and ask questions
 - Surprises at the summary session
 - Assessors are looking for how they do things in their own facility
 - Assessors seem to have an agenda to find things wrong
- Allow adequate time to perform the assessment, write the summary 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**)



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Thank you letters

- Provide assessors documentation for purposes of CE



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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



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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!**



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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



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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.



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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!



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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!



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Reminder

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



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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



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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!



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Thank You!

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



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Questions



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