



# ***LABORATORY ACCREDITATION ASSESSOR TRAINING***

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HPS Midyear Meeting

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# *Outline*

- **Qualification and training of assessment team**
  - **Assessment team leader**
  - **Assessor**
  - **Observer**
- **Phases of the assessment**
  - **Planning**
  - **Performing**
  - **Reporting**
  - **Follow-up**
  - **Closeout**

# Assessment Organization Responsibilities

- **Appoint an assessment team, including**
  - **A lead assessor**
  - **Sufficient number of assessors in relation to the scope of assessment**
    - **Assessment team members shall not have provided consultancy to the candidate lab (CAB)**
    - **Observers (for training, if CAB agrees)**
- **Notify the CAB of the assessment team members, provide assessors' resumes to CAB – the CAB has the right of objection**

# Qualification Records for Assessors

- **Name and address**
- **Position held**
- **Educational qualifications; professional status**
- **Work experience**
- **Training in management systems and assessment**
- **Competence for specific tasks**
- **Experience in assessment**

# *Objective of Training*

- **To ensure a common understanding of the recommended principles and practices of the assessment process**

***ASSESSMENT  
TEAM  
LEADER***

# *Selection of Assessment Team Leader*

- **Communication Skills (written and oral)**
- **Assessment process training**
- **Assessment experience (recommendation: at least 3 assessments prior to assignment as the ATL)**
- **In-depth knowledge of ANSI/IEC/ISO 17025 and HPS Laboratory Accreditation Manual**
- **Knowledge and understanding of the applicable codes, standards, and regulations**
  - **CFRs, ANSI standards, ISO/IEC17011**

# *Maintaining Qualification: Assessment Team Leaders*

- **Regular and active participation in the assessment process, or**
- **Participation in assessment training (as attendee or instructor), or**
- **Review and study of the codes, standards and other documents associated with the HPSLAP and assessments.**



# *Tasks for Lead Assessor*

- **Ensure that assessment procedure meets requirements**
- **Define authority and responsibilities for assessor**
- **Specify the approach to the assessment**
- **Follow the procedure for selection and ensuring assessors are trained**
- **Follow steps involved in preparing for and conducting assessment (obtaining information and evidence) and reporting deficiencies**

# *Tasks for Lead Assessor*

- **Ensure the team is provided with relevant criteria, documents, records**
- **Specify forms and checklists used**
- **Use the expected assessment reports and record system**
- **Define implementation of and follow-up for corrective actions**

# *Selection of Assessors*

- **Understanding of assessment body philosophy and procedures**
- **Knowledge of the laboratory's quality system**
- **Technically competent on test methods**
- **Excellent communication skills (written and oral)**
- **Ability to probe and analyze – not obnoxious**
- **Good logic, judgment and integrity**
- **Poise, tact, persistence and maturity**
- **Easy going and positive attitude**

# *Assessor Qualification*

- **Participation in assessment training**
- **Review and study of the codes, standards and other documents associated with the HPSLAP and assessments**
- **Evaluation of assessors' qualifications by LAPC and LAAC chairs and the HPS LAP Technical Director**

# *Keep a Good Assessment Attitude*

- **Goal is to improve quality of work in the lab**
- **Assessments are tools to improve quality**
- **Show no enthusiasm on finding a non-compliance**
- **Do not take over-advantage of internal assessment findings**

# *Communicate Effectively*

- **Keep it simple: clear, brief, direct, focused**
- **Three ways of receiving information:**
  - **Seeing, hearing, experiencing**
  - **Spend most of your time listening**
- **Stay in an equal mode**
- **Express yourself in a positive way**
- **It's what we say and how we say it**
- **Address the person by name**

# *Listening Skills*

- **You will capture**
  - **Important statements**
  - **Significance of what was said**
  - **Interactions and body language**
- **Slow down! We think faster than we talk**
- **Don't**
  - **Get bored and we're ready to say something ourselves**
  - **Think about a reply while they're talking**
  - **Jump to conclusions or making assumptions**

# *Qualities of a Good Listener*

- **A good listener**
  - **Keeps the focus on the speaker**
  - **Is open to other perspectives**
  - **Doesn't finish someone else's sentence**
  - **Stays cool and calm, not defensive**



# *Qualities of a Good Listener*

- **Attending skills**
  - **Shows we are prepared to listen**
  - **Is being sensitive to the speaker's feelings**
  - **Is asking relevant questions and using minimal encouragers**
  - **Is mirroring the mode and pace of the other person's speech**

# *Body Language and Eye Contact*

- **Be relaxed and alert**
- **Smile**
- **Use good and open posture**
- **Lean forward slightly**
- **Keep eye contact ~25% of the time**
  - **5-10-20 rule (5 sec → interest, 10 sec → intimidating, 20 sec → intimate)**
  - **Expresses interest, establishes trust**
  - **Focus softly and shift gaze**

# *Reducing the Tension*

- **Effects of tension**
  - **Defensiveness, reluctance, aggression**
  - **Poor performance and mistakes by interviewee**
- **Reduce by:**
  - **Being human**
  - **Putting people at ease**
  - **Projecting the right image – quiet confidence**
  - **Challenging the issue, not the person**
  - **Avoiding absolutes and attacking statements**

# *Understanding What an Assessment is*

**A fearful thing?**

**An opportunity?**

*Some people feel that an assessor is someone who comes in when the battle is raging and attacks the wounded!*

# *Types of Assessments*

- **First Party**
  - **Internal**
  - **The laboratory's own assessment**
- **Second Party**
  - **External**
  - **Usually by a client to their own specific requirements**
  - **Should be objective, but not always...**

# *Types of Assessments*

- **Third Party**
  - **External**
  - **By independent organization, full quality system evaluation**
  - **Objective – done by trained and qualified assessors**

# *Definition of Terms*

- **Shall = mandatory**
- **Should = recommended practice**
- **Policy = house rules. Should have procedures**
- **Procedure = detail how policies are carried out**
- **Documents = procedure**
- **Quality System = procedures, policy, documents, and commitment from management**
- **Record = technical record**

# *Primary Rule of Assessing*

**If you can't express the non-conformance in the words of the quality system standard, the appropriate technical specification or test method, or the laboratory's own policies and procedures...**

***THEN YOU DO NOT HAVE A  
NON-CONFORMANCE***



# *Thoughts On Best Practices for a Laboratory*

- **Does the laboratory “say” what they do?**
  - **Do they have written documents (policies and procedures) that meet the requirements of ISO 17025?**
- **Does the laboratory “do” what they say?**
  - **Are they in compliance with their own quality system and ISO 17025?**

# *Thoughts On Best Practices for a Laboratory*

- **Can they “prove” it with their records?**
  - **Training records, standards preparation, work books, client reports, assessment reports, and everything else?**
- **Conformance does not always require best practices**

# *Conformance Usually Means:*

*Doing what you say you are doing  
and being able to prove it;*

*And nonconformance suggests  
fines, legal/regulatory action,  
accreditation status review.*

# *Non-conformance*

- **Definition - Technical or programmatic issue in which the practice at the laboratory does not conform to the requirements**
- **For HPSLAP, all non-conformances must be corrected prior to accreditation**

# *Observation*

- **Definition - Issue of minor nature which does not affect the quality of the laboratory process, but, if implemented, would enhance the overall program**
- **Additionally, an exemplary practice which could be of use to other processors and could be noted as a “Best Management Practice”**
- **No written response is required**

# *Interview Techniques*

# *Actions to Help Ease Your Stress*

- **Arrive on time**
- **Be mentally and physically prepared**
- **Be enthusiastic**
- **Be unbiased**
  - **Challenge issues, not individuals**
  - **Avoid absolutes and attacking statements**

# *Interview Techniques*

- **Ask open-ended questions**
- **Follow-up and clarify with yes/no questions**
- **Listen actively**
- **Take notes - explain need for time to prepare accurate notes**
- **As findings are identified, verify its accuracy and relevance**



# *Asking Questions*

- **Key Questions**
  - **What is happening?**
  - **Why is it happening?**
  - **Where is it happening? Why is it happening there?**
  - **When was it done? Why was it done then?**
  - **Who did it? Why was it done by that person?**
  - **How was it done? Why was it done that way?**

# *Direct Questions*

- **Require definite answers**
- **Establishes something factual**
- **Useful for clarifying detail**
- **Brings discussion back on track**
- **Often results in a “yes” or “no”, like “Do you calibrate these instruments daily?”**
- **Not effective in having the assessee explain**

# *Hypothetical Questions*

- **Poses the unusual**
- **“What do you do when you find that the instrument is out of calibration?”**
- **What does the response indicate?**
- **Has a contingency been planned for?**
- **Encourages the assessee to explain further**

# *Clarifying Questions*

- Prevents misunderstanding
- “Do I understand that you will perform daily instrument calibrations only when the daily intermediate checks are unacceptable?”
- Enables the person to explain even further
- Repetitive question to further clarify
- **AVOID** leading questions

# *Other Questions*

- **Answer your own questions**
  - **Avoids questioning the obvious**
  - **Reassures the person while you examine more**
- **Get confirmation**
  - **Same question, different perspective**
  - **Same question, different person**
- **Even silence can be useful**
  - **Gives person time to think**
  - **Places person under pressure to respond**
  - **But generates tension (so use with care)**

# *Limitations of Questions*

- **Don't always take answers at face value**
- **Answers may not be truth**
- **May be intentionally misleading**
- **Coached responses**
- **Remember. Slow down! We think faster than we talk.**

*Assessors are in the evidence business*

# *Writing Deficiencies*

- **Clear**
- **Concise**
- **Non-confrontational**
- **Non-blaming**
- **Non-personal**

# *Writing Deficiencies*

- **Traceable to the assessment**
- **Sufficient detail to assure understanding of the deficiency**
- **Include the requirements associated with the deficiency**



# *Writing Deficiencies*

## *Examples*

- **The laboratory does not have a documented system for uniquely identifying test items as required by section 5.8.2 of ISO 17025.**
- **Test samples were observed on the work bench with no identification as required by Lab Procedures 16.4.**

Crosswalk between Sections of Laboratory's Quality Assurance Documents and ANSI/ISO/IEC 17025

Laboratory:

Document(s) Reviewed:

ISO 17025 Req't	✓/X/NA	Laboratory's Conforming QA Document and Section	Further Investigation
<b>Organization</b>			
4.1.1			
4.1.2			
4.1.3			
4.1.4			
4.1.5a			
4.1.5b			
4.1.5c			

# *THE ASSESSMENT*

# *The Four Phases of the Assessment Process Are:*

- **Planning**
  - In advance, off-site
- **Performing/Implementing**
  - Are you doing what your procedures say you are doing?
- **Reporting/Effectiveness**
  - Is there validity in the operating system?
- **Evaluating response, follow-up, and close-out**

**All Phases are Important to the  
Success of the Assessment Process**

# *PLANNING PHASE*

*Take a 10 minute break !!*

# *The Assessment Process - Planned and Scheduled to:*

- **Support the overall verification and assessment process**
- **Maximize the effectiveness of the assessment itself**
- **Assure that there are NO SURPRISES to the organization being assessed**

# *Assessment Preparation*

- **Preparation helps to make the best use of time available during the assessment**
- **Critical to the success of the assessment process**
- **Assessing is an ongoing process, not an event**

# *Ordered Approach*

- **A well-prepared assessment demonstrates that the assessment team has done its homework and that the assessment is a manner of good business**
- **A good mechanism for making sure that the planning process is consistently applied is to use an *assessment preparation checklist***



# *Assessment Team Orientation*

- **Discuss procedures for performing and reporting the assessment**
- **Discuss assessment scope and individual assignments**
- **Assign checklist preparation responsibilities**

# *Checklist*

- **A key tool in performing assessments and its development is critical to the success of the assessment**
- **Used as a guide and should not rigidly dictate how to perform the assessment**
- **Provide additional blank pages to allow changes in direction**
- **Remember: NO SURPRISES**

# *Preparation of Checklists*

- **Use open-ended questions which require investigation to answer**
- **Use yes/no questions to confirm facts**
- **Use the “Vertical Slice” concept to assist in the formulation of checklist questions**

# *Completed Checklists Provide:*

- **Objective evidence that an assessment was performed in an orderly and complete manner**
- **Historical information on activities assessed**
- **Basis for the post-assessment meeting and written report**

# *Timing*

- **Goal - Maximum results with minimal disruption**
- **Plan field work to occur within normal working day**
- **Debriefing meetings at the start of each day**

# *Assessment Plan*

- **Provide concise summary of assessment scope and duration**
- **Identify assessment team and individual roles**
- **Help management prepare for the assessment**
- **Use as basis for assessment report format**

# *Notification*

- **Verbal at least 30 days before planned arrival at the site**
- **Written (with Assessment Plan included) within 2 weeks before arrival at the site**
- **Include request for any special support needed**

# *Final Team Preparation & Orientation - Obtain and Study:*

- **Scope of Accreditation**
- **Assessment plan and checklist(s)**
- **Copies of applicable manuals and procedures**
- **Pre-assessment and Post-assessment meeting attendance forms**
- **Other relevant background information**



***PERFORMING /  
IMPLEMENTING PHASE***

# *Performance Phase*

- **Pre-assessment Meeting**
- **Tour**
- **Field investigation**
- **Daily caucus and debriefing meetings**

# *Pre-Assessment Meeting*

- **Introduction of participants**
- **Sign attendance roster**
- **Discuss assessment scope, plan & schedule**
- **Establish contacts**
- **Identify additional support needed**
- **Confirm post-assessment meeting date, time and location**

# *Daily Team Caucus Meetings*

- **Held prior to the daily debriefing meetings**
- **Conducted for the benefit of assessment team**
- **Used to develop assessment results**

# *Daily Debriefing Meetings*

- **Meet with assessed organization daily**
- **Conducted for the benefit of the assessed organization**
- **Discuss findings uncovered the previous day**
- **Reinforces the “NO SURPRISES” philosophy**

# *Checklist Completion*

- **Address checklist questions or extend an explanation for those that were not used**
- **Indicate on checklist all action taken related to unsatisfactory or deficient conditions identified on the checklist**
- **Record on the checklist, by number or title, documents reviewed and the revision**

# *Tour of the Facility*

- **Tour to “get the feel” of how the organization approaches Quality**
  - **Housekeeping**
  - **Environmental monitoring**
  - **Tracking and trending**
  - **Morale**

# *Inspect Facility & Equipment*

- **Evaluate design layout of laboratory**
- **Proper environmental conditions and monitoring?**
- **Sufficient lighting? Temperature?**
- **Effective separation between areas?**
- **Appropriate security?**
- **Good housekeeping?**
- **Suitable equipment, range, precision?**
- **Status of equipment, maintenance, calibration?**



# *Field Investigation*

- **Document reviews**
- **Data traceability**
- **Direct observation**
- **Interviews**

# *Observation of Activities*

- **Witness demonstrations of procedures**
- **Confirms what we heard from our questions**
- **Confirms that analysts are following procedures**
- **Determines status of equipment and setup**
- **Enables us to judge technical skills**
- **Establishes the level and depth of training**
- **Gains information on supervision**

# *Data Traceability*

- **Start with the final result and work backwards**
- **Start with the step that establishes the design and work forward**

# *Examining Documents*

- **Documents available for use? Implemented?**
- **Is there proper document control for**
  - **Internal documents?**
  - **External documents?**
- **Document changes properly made?**
- **Draft procedures in use?**
- **Obsolete documents removed?**
- **Verify that testing follows written procedures**

# *Examining Records*

- **Quality and technical records in place?**
- **Records allow traceability and repetition?**
- **Procedures being followed for archiving?**
- **Records include identity of all personnel?**
- **Contemporaneous records? Complete?**
- **Error corrections properly made?**

# *Data Traceability, Look For:*

- **Who performed the work?**
- **What equipment was used?**
- **What procedures were used?**
- **What calculations were performed?**

# *Direct Observation Requires Detailed Planning*

- **Activities to be observed**
- **Work location(s)**
- **Time of day**
- **Access requirements**
- **Relevant procedures, drawings, instructions, etc.**

# *REPORTING PHASE*



# *Reporting Phase*

- **Final Team Caucus Meeting**
- **Post-Assessment Meeting**
- **Written Report**

# *Final Caucus Session*

- **Identify the results to be reported**
  - **Define terms**
  - **Compliance/conformance**
  - **Non-conformance/Deficiency**
  - **Observation/Noteworthy Practice**
- **Plan the post-assessment meeting**

# *Evaluation of Assessment Results*

- **Team analyses relevant information from document review and the on-site assessment**
- **Determine the extent of conformity**
  - Check items against the “so what?” reaction
  - Try to group multiple related findings and report as a single deficiency
- **Closing meeting to provide report of findings**
  - Written and/or oral reports
- **Written report shall be promptly issued to CAB**
- **Report must contain comments on competence, conformity and non-conformity (if any)**

# *Written Report*

- **Executive Summary**
- **Body of the Report**
- **Deficiency Forms**

# *Executive Summary*

- **Purpose is to provide senior management with a condensed overview of the assessment results**
- **Executive Summary**
  - **Brief summary of the scope**
  - **Identify good points**
  - **Brief summary of the results**

# *Written Report Content*

- **Description of the assessment scope**
- **Identification of the assessment team**
- **Lists of personnel contacted during the assessment (including the pre- and post-assessment meetings)**
- **Detailed summary of the results (including the background information supporting each deficiency)**

# *Written Report Content*

- **Guidance on desired format/content for the response**
- **When the response is required**
- **Departures from requirements that were discovered, acted upon, and corrected during the assessment are best mentioned in the body of the report, and should not formally be cited as deficiencies**

# *Written Report Content*

- **The following *should not* be in an assessment report**
  - **Items that were not discussed during the post-assessment meeting**
  - **Irrelevant information**
  - **Subjective opinions; deal only with verifiable information**
  - **Ambiguous statements**



# *Post Assessment Meeting: Team Leader Responsibilities*

- **Conduct and control the post-assessment meeting**
- **Ensure the team is fully prepared for the meeting**
- **Ensure that the group assessed fully understands each deficiency and concern**
- **Answer questions associated with corrective action: make it clear that options do exist on how to correct the deficiencies and concerns**

# *Post-Assessment Meeting*

- **Gather all participants if possible**
  - **Give compliments for help, attitude, etc. when appropriate**
- **Present an executive summary of the results**
  - **Describe conformances and exemplary practices**
  - **Present non-conformances, concerns and observations (be brief)**
- **Complete any records**
- **Thank everyone**

# *Post-Assessment Meeting*

- **Attempt to get a commitment from the assessed organization to take action on the findings as soon as possible**
- **Inform the group as to what is required in the corrective action response, and when it is required**
- **State any additional requirements**

# *Corrective Action Response Evaluation*

- **A non-conformance triggers a corrective action**
- **Determine if:**
  - **The response addresses all assessment issues**
  - **The proposed corrective action will preclude recurrence (a root cause analysis may be required for some deficiencies)**
  - **The appropriate people are assigned the responsibility for taking action**
  - **The schedule for each action is appropriate**

# *Follow-UP*

- **Follow-up is needed because solutions that look good on paper may not work in practice.**
- **Methods of follow-up include:**
  - **A complete re-assessment of the organization**
  - **Review of new or revised documents**
  - **Verification at next scheduled assessment**
  - **Surveillance of the specific issues**

# *Close-Out Notification*

- **It is good practice to provide the organization assessed with written notification when all corrective action has been completed to the satisfaction of the assessment team**
- **An assessment is formally closed out when**
  - **Each non-conformance is in a corrective action plan**
  - **Corrective action is implemented**
  - **Corrective action is verified effective**

# *Do's*

- **Dress professionally and appropriately for the type and location of the assessment**
- **Speak in a professional manner**
- **Be prepared and familiar with the scope of work**
- **Be composed at all times**
- **Be flexible and listen to “minority opinion”**

# *Don'ts*

- **Lose objectivity and independence**
- **Use foul, inappropriate, or condescending language**
- **Pass judgement or make requirements/commitments**
- **Use the words “I” or “My”**
- **Let them trap you into solving personal and/or internal problems**



# *Avoid*

- **Getting into “how to do it the right way” discussions**
- **Engaging in comparative discussions**
- **Becoming isolated**

# *Remember*

- **Establish and maintain rapport with the organization assessed**
- **Use the checklists**
- **Report on areas of excellence and departures from requirements**

# *Questions or Comments ?*

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