

UEMS SMB - Inspection Program

Team Member Inspection Planner

1. Pre-inspection phase

- **Arrange for Inspection**
- After receiving notification from UEMS SMB of your assignment as team member
- Make sure the inspection date and anticipated time for visitation does not interfere with other duties or appointments.

- **Review**
- Review inspection rule and requirements to determine skill necessary for your team members
- Make travel and/or hotel arrangements, if necessary. If air travel is required, arrangements are made by each team member. Hotel reservations must be made by the laboratory being visited. To save on airfares, make travel arrangements at least 14-21 days prior to the travel date.

- **Prepare for the Team**
- Ensure you have a complete inspection Training. Examine inspection requirements carefully prior to the inspection date to ensure that you are familiar with the standards and procedures recommended by UEMS SMB.

- **Other ways to prepare are:**
- Perform a mock inspection of your own laboratories educational procedures.
- If you have questions about interpretation of items, email a question to the the UEMS SMB Secretary.
- Be sure that you feel qualified to carry out the inspection assigned.
- Discuss any questions you have with the inspection Team Leader prior to the inspection.
- Discuss all deficiencies with the supervisor/laboratory representative as they are identified and summarize them at the exit interview at the end of the section inspection.
- During lunchtime, inform the Team Leader of your progress. If uncertain about the interpretation of a checklist question: discuss with the Team Leader

2. During inspection

- Arrive on time. Inspection typically begin before 9 a.m. and conclude between 4 p.m. and 6 p.m. Be sure to allow adequate time for a thorough visitation.

- **Pre-inspection meeting of team**
- Receive additional information from team leader.
- Discuss "visitation rules", e.g., who handles what.
- Remind to conclude each interview with an explicit discussion of any deficiencies identified and suggestions for corrective action.
- Inspectors should be thorough and fair-minded, never picky or dictatorial about how something is done in their own laboratories
- Inspectors need to avoid punitive, hypercritical, or sarcastic comments.
- Inspectors should share their experiences
- Review the schedule and timetable for the on-site visit
- Each inspector should wear the provided name tag.
- Note time for the summation conference

- **Pre-inspection meeting of team and laboratory personnel**
- Note arrangements for lunch, summation conference, interviews for the Team Leader and working area for the team, etc.

3. Inspecting the laboratory

- Use active dialog among Biopathologists, trainees and inspectors
- Mark the deficiencies found and review them with the team leader.
- **Interviews**
- **General:**
- According to visitation rules and requirements
- Consult organizational plan
- Consult personal policies
- Check quality improvement plan and records
- Check continuing education records
- **Sections:**
- Consult procedure manual
- Check QC and proficiency testing results
- Consult safety manuals
- Control examples of report forms.
- There must be up to date facilities for Clinical Haematology, Blood Banking, Clinical Chemistry, Clinical Immunology, Clinical Microbiology, Medical Genetics and Laboratory services
- There must be a regular discussion of indications for laboratory tests, a weekly programme of teaching, regular discussions of morbidity and mortality, ready access to an adequate library with international journals and recent books and facilities for clinical and experimental research.
- The programme of training must give graded and progressive responsibility to the trainee under the supervision of responsible Medical Biopathologists and must be recorded in a detailed log book as approved by the EBMB.

4. Pre-summation conference

- Meet with the team leader prior to the summation conference to discuss all deficiencies.
- Complete list of deficiency and recommendations.
- Complete lists prior to summation conference and write legibly
- For each citation, enter the specific reason the laboratory is deficient.

5. Summation Conference

- **When presenting your findings at the Summation conference:**
- Thank the supervisor that you worked with by name.
- "Findings" include both positive and negative observations. Compliments for good work set a favourable tone.
- Discuss all deficiencies and recommendations.
- Present deficiencies in a straightforward manner. Do not mix with recommendations.
- Give laboratory personnel time to ask questions.

- If the lab personnel disagree with a citation, listen carefully to their explanation, but do not get into an argument. If you continue to believe your finding is a deficiency, the lab can provide documentation to UEMS why it believes it is non-compliance. UEMS SMB Board will decide which interpretation is correct.
- Return list of Deficiency and Recommendations to the Team Leader for collation and copying.
- Don't be in a rush to leave immediately after Summation. If you have performed your job with fairness and respect, there are usually good feelings to be shared at the end of the day.
- Each inspector fills out and sign an Inspector Summation Report for each area he or she has inspected and hands it out to the Team Leader.

6. After the Inspection

- Fill out reimbursement form
- Discard all personal notes and any other information regarding the visitation.

Revision History

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