

UEMS SMB - Inspection Program

Team Leader Inspection Planner

1. Pre-inspection phase

Arrange the inspection

- After receiving notification from UEMS SMB of your assignment as team leader
- Contact the Laboratory Director and set an inspection date.
- Begin to select your team, including the number and types of inspectors needed.
- Arrange reimbursement and CME credits.
- Notify UEMS-SMB-Secretary of your scheduled visitation date.
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Letter to the director

- send a letter or e-mail to the laboratory director confirming the visitation date
- include the inspection date, time of arrival and anticipated time for visitation
- include disciplines and items to be inspected
- include names and disciplines of your team members
- request the names of the inspector's counterparts
- ask the director to set up brief appointments for visits with a member of the institution's administration and medical staff

Review

- Review inspection rule and requirements to determine skill necessary for your team members
- Confirm commitment of all team members
- Send a confirmation letter.
- The team leader should request brief appointments of 15 minutes each with the hospital administrator and a representative of the medical staff.
- 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 the Team

- Decide how many inspectors you need and put your team together.
- Choose team members as specialized inspectors and check if there are additional laboratory disciplines that require additional team members
- Ensure Team Members have completed visitation Training.
- Contact members of the inspection team at least two weeks prior to the inspection to discuss travel arrangements, visitation conduct, timing, etc.
- By E-mail distribute information material on visitation, activity menu and other appropriate information.

2. During inspection

- Arrive on time. inspection typically begins before 9 a.m. and concludes between 4 p.m. and 6 p.m. Be sure to allow adequate time for a thorough visitation.

Pre-inspection meeting of team

- Distribute additional information to team members
- Review the philosophy of the visitation program
- Discuss "visitation rules", e.g., who handles what.
- Remind team 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.
- Target time for the summation conference

Pre-inspection meeting of team and laboratory personnel

- Team leader and laboratory director should have a brief, private conference early in the on-site visit
- Introduce the team to the laboratory personnel with whom each will be working.
- Identify areas or section units of particular concern
- Discuss arrangements for lunch, summation conference, interviews for the Team Leader and working area for the team, etc.
- Inform everyone of the approximate time and location of the summation conference.
- Maintain contact with the team during the day (e.g., brief mid-day meeting, working lunch, etc.) to verify progress and answer questions.

Inspecting the laboratory

- Encourage active dialog among Biopathologists, trainees and inspectors
- Each inspector should mark the deficiencies found and review them with the team leader.

3. 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 one or more of the following fields: 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.

Pre-summation conference

- Meet with the team prior to the summation conference to discuss all deficiencies, answer team members' questions, and establish consistency.
- team leader should be available to review completed information and to confirm deficiencies found.
- Remind team to 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.
- Team leader completes summation report

Summation Conference

- Conduct the summation conference. Be sure to state and discuss each deficiency.
- Restate objectives of visitation and standards required.
- State that Visitation is a voluntary, educational and peer review process.
- Ask inspectors to present their findings.
- Discuss all deficiencies and recommendations grading the deficiencies in: minor – major
- Give laboratory personnel time to ask questions.
- Have each individual inspector fill out and sign an Inspector Summation Report for each area he or she has inspected.
- Collect completed reports from each team member
- Team leader and Lab director sign the report
- Make copies of summation report for each section of the laboratory and leave copies of all with the Laboratory Director.
- Retain copies for UEMS SMB Secretariat
- Thank Laboratory Director for choosing UEMS SMB Visitation Program

4. After the Inspection

- Send complete Summation Report and the list of inspectors to UEMS SMB Secretariat.
- Fill out reimbursement form
- Discard all personal notes and any other information regarding the visitation.

Revision History

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Revised: by Damiano Castelli may 2012

Revised by the working group "Inspection documents" (D.Castelli; A. Robalonunes; L.Marcelis) June 2012.

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