

ST101 Inspection Team Leader Workshop

Pre-Event Course Materials

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Team Leader Essentials

- Activity # 4 – Pre-Inspection Scenarios



Education by the Experts

Purpose

Apply best Team Leader practices to pre-inspection situations.

Directions

- Read each scenario and determine your approach as Team Leader.
- Be prepared to discuss your response.

Activity #4 – Scenario 1



Avoid an overnight stay if they take an early morning flight...begin the inspection at 10:00 am, and a late afternoon flight home that leaves at 5:30 pm. Good Idea?

- A. No, you should drive
- B. Yes, lab can complete its morning run
- C. No, fly in the night before



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1. After reviewing the information in the Inspector's Inspection Packet, you determine that your most efficient trip for the inspection would be by air. After reviewing the airline schedules, you see that your team can avoid an overnight stay if they take an early morning flight that would allow them (assuming no delays) to begin the inspection at 10:00 am. The late afternoon flight home leaves at 5:30 pm. The facility has a full-service lab, but you could bring 3 extra inspectors and finish in half a day.

Is this a reasonable plan? What is your rationale?

- A) No, you should drive to have more flexibility.
- B) Yes, it allows the lab to complete its morning run.
- C) No, you should fly in the night before.

ANSWER

Activity #4 – Scenario 2



A week before the inspection, the inspector assigned to Histocompatibility has major surgery. What would you do?

- A. Reschedule inspection
- B. Inspect Histo later
- C. Find another inspector



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2. You have accepted the assignment to be the Team Leader for the team inspecting a large university hospital laboratory very similar to your own facility. The lab's anniversary date is August 31. After selecting several possible inspection dates, a date of August 9 is finalized with all team members and travel arrangements are made. One week before the inspection date, the inspector assigned to Histocompatibility is involved in a car accident requiring major surgery, but he feels he can do the inspection if it is postponed a few weeks. No one else in your laboratory has the expertise.



What would you do and what is your rationale?

- A) Wait until he can join the team and reschedule the inspection
- B) Inspect the lab as scheduled, but have him inspect Histocompatibility when he is able.
- C) Contact CAP for assistance in finding another inspector.

ANSWER

Team Leader Essentials

- Activity # 5 – Time Management



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Purpose

Demonstrate time management skills. (Manages time for team members and self; keeps track of team progress.)

Directions

- Read each scenario and determine your approach as Team Leader.
- Be prepared to discuss your response.

Activity #5 – Scenario 1



Inspection is proceeding very slowly...finding pertinent document has been time-consuming. What should team members do?

- A. Confirm all documentation
- B. Accept verbal confirmation
- C. Cite deficiencies and remove them when documentation is found



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1. By lunch time, your evaluation is that the laboratory is providing excellent patient care services, but the inspection is proceeding very slowly. Due to a recent reorganization and physical relocation of several lab sections, finding pertinent documentation has been time-consuming. Another “glitch” is that two staff members are out with the flu and the Emergency Room is especially busy.

What would you do?


- A) Ask team members to be patient with the lab staff as they search for items. So as not to confuse staff, confirm that all documentation is complete and appropriate for each question before going on to the next.
- B) Ask team members to continue to ask for documentation. If lab techs state that they do have it, but it is not readily available, get a verbal confirmation from the supervisor and continue with the next item.
- C) Ask team members to cite appropriate deficiencies for documentation that is not available. If the appropriate documentation is found prior to the end of the Summation Conference, draw a line through the deficiency, date, initial, and indicate “Documentation found.”

ANSWER

Activity #5 – Scenario 2 

Does not have appropriate virology checklist questions, still has Immunology to inspect

- A. Download checklist from the Web
- B. Call CAP for additional checklist
- C. Notify CAP after inspection

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2. It is now 2:00 pm and the microbiology inspector informs you that the lab has recently added a virology section. She is familiar with the testing, but does not have the appropriate checklist questions, and still has immunology testing to look at.

What would you do?

- A) Download the checklist section from the CAP Web site and ask the microbiology inspector to complete both virology and immunology.
- B) Confirm that another inspector has the time and experience to inspect immunology, and then call the CAP to get the additional checklist questions faxed to you.
- C) Notify the CAP after the inspection so that a non-routine inspection may be scheduled to inspect virology.

ANSWER

Activity #5 – Scenario 3



4:00 PM and five of the seven inspectors need another two hours; you have not talked with the lab director.

- A. Hold Summation based on the information you have.
- B. Continue to inspect; hold Summation when you have completed the inspection.
- C. Make arrangements to continue the inspection the following day.



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3. It is now 4:00 pm and you have assembled the team for a quick status update. Five of the seven inspectors estimate they will need another two hours. Each have cited a few deficiencies and agree that the lab is doing a fine job overall. The remaining two inspectors are just completing their work. You have talked with the CEO and CMO and completed the Anatomic Pathology Checklist. Due to the time required to address the virology issue, you have not had an opportunity to talk with the lab director.

What would you do?

- A) Stop and hold the Pre-summation and Summation Conferences based on the information you have.
- B) Continue to inspect through dinner and hold the Pre-summation and Summation Conferences when you have completed the inspection.
- C) Continue to inspect for another hour and make arrangements to continue the inspection the following day.

ANSWER

Team Leader Essentials

- Activity #6 – Team Leader Checklist



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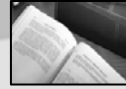
Purpose

Apply inspection techniques to the Team Leader Checklist. (Uses appropriate inspection approach.)

Directions

- Read each scenario and determine your approach as Team Leader.
- Be prepared to discuss your response.

Activity #6 – Scenario



You ask how the lab director is involved with the QM system. He calls the lab manager who produces a copy of the QM plan.

- A. Cite a deficiency
- B. Write a recommendation
- C. Thank him for showing you the documentation



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Scenario:

It is mid-afternoon and your next appointment is with the lab director. At lunch, a few team members commented on PT problems they observed and the Lab General inspector asked if you would verify the lab director's involvement with the CAP Patient Safety Goals. You made a note to ask yourself to talk to him about these issues. After a few minutes discussing his general involvement in the laboratory's activities, you ask how he is involved with the quality management system. In response, he calls the lab manager who produces a copy of the QM plan and gives the data collection report (see report on following page) for last year. The first item that you notice is the "Continue to monitor" comment for each indicator, regardless of its performance. You see several indicators regarding PT and patient safety goals that do not show improvement. Recalling the comments that your team members made during lunch, you ask how he is involved.

His response is that in the last year, he has been increasingly busy with administrative functions outside of the lab and has delegated quality management to the lab manager. He realizes that she is also very busy, but he is sure she is doing a fine job.

The checklist question you are considering is:

TLC.10900 Phase II
Is the laboratory director actively involved in the design, implementation and oversight of the quality management system?

NOTE: The director is responsible for the laboratory's overall quality management program, including the monitoring of key indicators; investigation of problems, with corrective/preventive action as appropriate; maintenance of patient safety; analytic quality control; and ensuring the quality of tests referred to outside laboratories.

What would you do?

- A. Cite a deficiency.
- B. Write a recommendation.
- C. Thank him for showing you the documentation and move on to the next topic.

ANSWER

If you answered A) Cite a deficiency or B) Write a recommendation, how would you document this on the ISR?

ANSWER

Team Leader Essentials

- Activity #7 – Pre-Summation Conference



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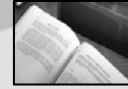
Purpose

Ensures consistency of interpretation. (Compares findings to uncover systemic problems.)

Directions

- Read each scenario and determine your approach as Team Leader.
- Be prepared to discuss your response.

Activity #7 – Scenario 1



Some inspectors cited space deficiencies, some gave recommendations, others did nothing.

- A. Too late to change the ISR
- B. Remove all the deficiencies and recommendations
- C. Review for consistency and notify supervisors of changes




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1. The hematology inspector comments that she barely had room to sit down and write. She didn't know how the technologists managed. The chemistry inspector said that he had the same problem, but wrote a recommendation to increase the clerical work area space. In microbiology, the inspector cited deficiencies for inadequate space for media preparation, equipment, and bench space. Of the remaining team members, two more had noticed a space problem, but were embarrassed to say anything. One cited one deficiency; three had given recommendations.

What would you do?


- A. Nothing. It is too late in the day to investigate the discrepancies in the findings between lab sections.
- B. Since there is no consensus, remove all the deficiencies and recommendations. You will write up the space issue in the confidential comments section of Part A in the ISR.
- C. Review the problem in each section and ensure that the same degree of space deficiency is cited consistently in each. Remind each inspector to notify any supervisor of any change before the Summation Conference.

ANSWER

Activity #7 – Scenario 2 

No documentation of deficiencies found during self-inspection; only faxed statement

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing

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2. The Lab General inspector would like to get an opinion. She states that a year ago the lab had performed the interim self-inspection. The required signed statement was faxed to the CAP Central Office. The report has no further information regarding the deficiencies that were found or the corrective actions taken. The Lab General inspector is not sure what she should do.

What would you tell her?

- A) Cite the deficiency because there is no documentation of the actual deficiencies or the corrective actions taken.
- B) Write a recommendation including methods to improve the documentation of investigations and corrective actions.
- C) Tell her the signed statement is sufficient.

ANSWER

Activity #7 – Scenario 3



Reporting of troubleshooting and corrective actions on worksheets and reagent logs makes it difficult to find info.

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



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3. The Chemistry inspector needs your advice. She explains that the Chemistry laboratory has been recording troubleshooting and corrective actions on the testing worksheets and occasionally on the reagent logs. A few of the bench techs find it difficult to locate the information and use it to spot trends and recurrent problems. The inspector explains that she did investigate and found all the problems documented in various locations.

What you you tell her to do?

- A) Cite the deficiency because the documentation is not organized and is not being used by everyone.
- B) Write a recommendation to centralize the documentation, perhaps into a separate troubleshooting log.
- C) Tell her that since there is some form of documentation, it is acceptable as is.

ANSWER

Activity #7 – Scenario 4



Molecular Pathology refrigerator missing occasional temperatures in 2 years; QC records show no problems; corrective actions complete.

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



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4. The Molecular Pathology inspector notices that in the two-year period since the last inspection, one refrigerator in the Molecular Pathology lab had no temperature record for one day in January, March, and again in May of last year. QC records for the dates in question did not indicate any reagent problems. Sporadically, the refrigerator temperature was out of range, but corrective actions have been documented. Records for the other two refrigerators are complete.

There is a policy requiring a record of temperature each day and documentation of corrective actions. She isn't sure what she should do.

What would you tell her?

- A) Cite the deficiency. The temperature could have been out of range on one of the days that was not recorded.
- B) Write a recommendation so the laboratory will be more diligent in recording the temperatures.
- C) Explain that because it was an isolated case, it isn't worth mentioning. It does not appear to be a reoccurring problem for the lab.

ANSWER

Activity #7 – Scenario 5



3 refrigerators in Transfusion Medicine; only one with complete temp records. Policy only covers blood storage refrigerator. Had written a deficiency; should she change it?

- A. Do not change it
- B. Change it to a recommendation
- C. Remove the deficiency



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5. In Transfusion Medicine, the inspector noticed a similar circumstance as Situation 4. There were three refrigerators and only one had complete temperature records. The policy covered only the blood storage refrigerator and had specific actions to be taken in case of power outage or severe temperature fluctuations. She had written a deficiency, but wants to know if she should change it to a recommendation.

What would you tell her?

- A) Do not change it to a recommendation. The situations are not the same.
- B) Change the deficiency to a recommendation so that findings are consistent throughout the lab.
- C) Remove the deficiency since refrigerator temperatures were being covered in Molecular Pathology.

ANSWER

Activity #7 – Scenario 6

Lab monitors all four CAP Patient Safety Goals in QM Plan; no evaluation/actions taken; no improvement.

- A. Cite a deficiency
- B. Write a recommendation
- C. Do nothing



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6. Just before the team is ready to leave for the Summation Conference, the Lab General inspector asked the team what she should do regarding the Patient Safety Goal question:

GEN.20365 Phase II

Does the laboratory address the current CAP Laboratory Patient Safety Goals?

NOTE: The current CAP Laboratory Patient Safety Goals are:

- 1) Improve patient and sample identification at specimen collection, analysis and resulting;
- 2) Improve verification and communication of life-threatening or life-altering information regarding malignancies, HIV (and other serious infectious diseases), cytogenetic abnormalities, and critical results;
- 3) Improve identification, communication and correction of errors in a timely manner;
- 4) Improve the coordination of the laboratory's patient safety role within healthcare organizations.

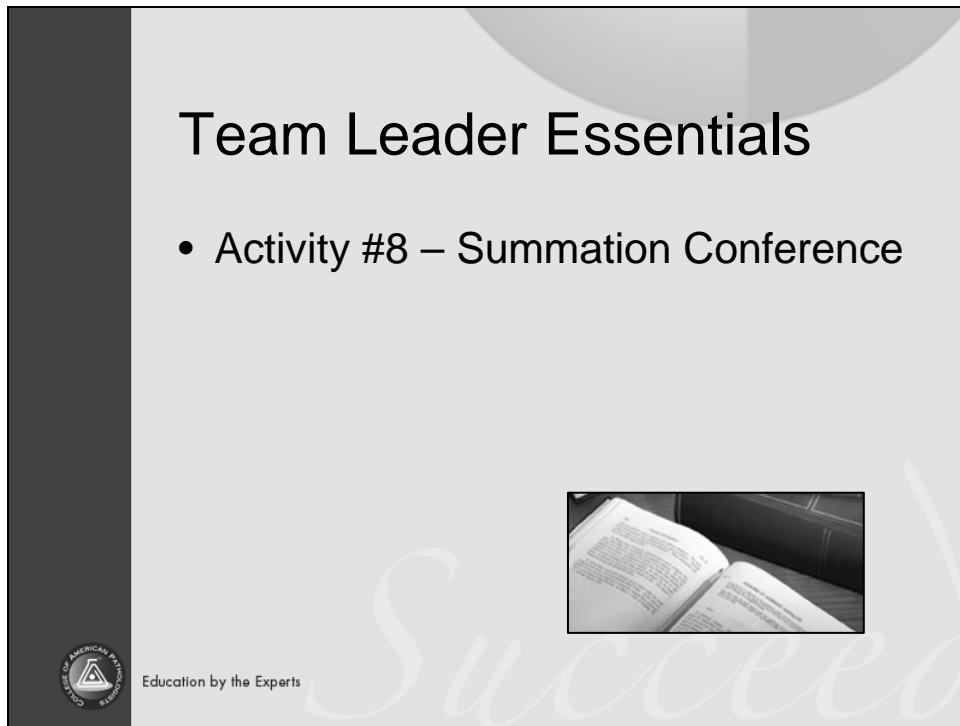
The laboratory must document that these goals have been addressed by evaluation and/or monitoring of the processes involved. Laboratory processes related to the Patient Safety Goals must be evaluated on an annual basis.

The QM data collection report showed that all four goals were being monitored, but there was no evidence of improvements and in some cases, especially patient identification, errors were actually increasing. You remembered the report you were shown by the lab manager with "Continue to monitor" as the only action item.

What would you tell her to do?


- A) Cite a deficiency for inadequate evaluation and improvement.
- B) Write a recommendation to document specific actions taken to improve performance.
- C) Do nothing. The lab is in compliance by monitoring all four goals.

ANSWER




Team Leader Essentials

- Activity #8 – Summation Conference

 Education by the Experts

Succeed



Purpose

Determines what constitutes compliance for requirements common to all checklists, applies “corrected-on-site”, removing deficiencies appropriately.

Directions

- Read each scenario and determine your approach as Team Leader.
- Be prepared to discuss your response.

Activity #8 – Scenario 1



Several unacceptable PT results not evaluated. At Summation, chief tech gives you copy of results indicating review done day of inspection.

- A. Keep it unchanged
- B. Mark it corrected-onsite
- C. Remove the deficiency



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1. The laboratory has a written policy to evaluate unacceptable PT results within one month of receiving the results, but the designated supervisor has been on a leave of absence and no one had completed the review in her place. At the Summation Conference, the section chief tech hands you a copy of the PT results with her initials and today's date. She explains that all the errors had been clerical in nature and since no patient results are reported manually, there was no need to investigate the problem any further.

What would you do?

- A) Keep it unchanged.
- B) Mark it corrected onsite.
- C) Remove the deficiency.

ANSWER

Activity #8 – Scenario 2



QC is performed as described in technical procedure. Corrective actions complete; reviews performed; no policy describing QC program. At Summation, director gives you policy that was misfiled.

- A. Keep it unchanged
- B. Mark it corrected-onsite
- C. Remove the deficiency



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2. The lab performs QC as described for each technical procedure. Corrective actions are logged and the section manager reviews all QC records within the first week of each month. There is no policy to describe the QC program, responsibility for review, etc. During the Summation Conference, the director shows you the policy that had been misfiled, describing the process you observed.

What would you do?


- A) Keep it unchanged.
- B) Mark it corrected onsite.
- C) Remove the deficiency.


ANSWER

Activity #8 – Scenario 3

QC is performed as described in technical procedure. Corrective actions complete; reviews performed monthly; no policy describing QC program. At Summation, director gives you policy that was misfiled, but policy changed from weekly review to monthly review with today's date.

- A. Keep it unchanged
- B. Mark it corrected-onsite
- C. Remove the deficiency





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3. As in the last scenario, the lab performs QC as described for each technical procedure. Corrective actions are logged and the section manager reviews all QC records within the first week of each month. There is no policy to describe the QC program, responsibility for review, etc.

However, this time at the Summation Conference, the director gives you a policy that was found, but also revised to reflect current practices. It had stated that the lab manager would review all QC records weekly. It now states the section supervisor will review all QC records monthly.

What would you do?

- A) Keep it unchanged.
- B) Mark it corrected onsite.
- C) Remove the deficiency.

ANSWER

Activity #8 – Scenario 4



Several deficiencies cited because records could not be located. Just prior to the Summation, you receive a binder with method validations for two new instruments, reviewed and approved prior to the beginning of testing.

- A. Keep them unchanged
- B. Mark them corrected-onsite
- C. Remove the deficiencies



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4. During the Pre-summation Conference, several inspectors noted citing deficiencies because records could not be located. The chemistry inspector cited four deficiencies regarding lack of documentation for accuracy and precision, sensitivity, analytic interferences, and reportable range validation studies. Two new instruments had been installed in the last six months and the binder with the test method validations was missing.

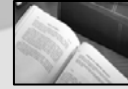
At about 4:00 pm, just as the team was preparing to leave for the Summation Conference, the lab manager appears and gives you the binder. The chemistry inspector reviews the data quickly and determines that all the studies have been performed.

If all the studies had been reviewed and approved prior to the beginning of the testing, what would you do?

- A) Keep them unchanged.
- B) Mark all four as corrected-onsite.
- C) Remove all four deficiencies.

ANSWER

Activity #8 – Scenario 5



Final procedures reviewed prior to Summation; had been previous deficiency; 23-month interval for annual review.

- A. Keep them unchanged
- B. Mark them corrected-onsite
- C. Remove the deficiencies



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5. While reviewing the previous deficiencies in preparation for the inspection, you had noted that several sections of the laboratory had been cited for inadequate review of procedure manuals. During the team meeting, you mentioned this and asked each inspector to be sure to verify that this and all other previous deficiencies had been corrected.

During the Pre-summation Conference, you asked about previous deficiencies and, again, review of procedure manuals was a problem in several sections of the lab. Just as the team is leaving for the Summation Conference, the lab director approaches with several binders and explains that he has completed the procedure manual reviews. You tell the team to go on and that you will join them in a minute. You verify that all the procedures do indeed appear to have documentation of review (signature and date) but even the ones that had been reviewed prior to today had been reviewed in January 2005 and then again November 2006. When you question the lab director about this, he explains that he “annually” reviews the manuals.

Since all the procedures now have been reviewed, what would you do?

- A) Keep them unchanged.
- B) Mark all as corrected-onsite.
- C) Remove all the deficiencies regarding procedure manual review.

ANSWER
