

# CAP Internal Auditing Course – Sample Content

## Background

This section provides background information about internal auditing.

### Definition

An internal audit, sometimes called a first-party audit, is a careful, independent look at a work process, or set of work processes, to see:

- Whether they are operating as planned and defined by the Quality Management System (QMS)
- Whether they meet a chosen standard or regulation
- Whether they are effective
- How they can be improved



An internal audit is conducted by someone within the organization but outside the discipline being audited.

An effective internal auditing program is a requirement in ISO quality management standards such as 9001 and 15189.

Internal audits tell you about problems that you need to correct. Hopefully, the problems are small when you find them. You can resolve them before they get big.

The output of the internal audit is a report. Review the report form below to see the issues internal audit reports address.

### [Audit Report Format](#)

## CAP Internal Auditing Course – Sample Content

### Internal Auditing and Similar Processes

The table below compares ISO internal audits with similar processes.

	ISO Internal Audit	ISO External Audit	CAP Laboratory Accreditation Program Self-Inspection
<b>Purpose</b>	<ul style="list-style-type: none"> <li>• Improve processes</li> <li>• Verify adherence to ISO standard</li> <li>• Identify issues before they become serious</li> <li>• Assess effectiveness of QMS</li> </ul>	<ul style="list-style-type: none"> <li>• Determine if QMS meets ISO standard</li> <li>• Assess effectiveness of QMS</li> </ul>	Determine if laboratory meets CAP checklist requirements
<b>Who Does It?</b>	Laboratory personnel	Trained, professional auditors from outside organization	Laboratory personnel
<b>When Does It Happen?</b>	<ul style="list-style-type: none"> <li>• Timing is driven by organization's needs</li> <li>• Proactive</li> </ul>	Timing based on accreditation cycle	Before CAP inspections

### Significance of Internal Audits for External Audits

External ISO auditors look carefully at internal audit results. Auditors can tell a lot about the health of a QMS simply by looking at the internal audit reports. Auditors ask themselves the following kinds of questions:

- How comprehensive is the internal audit program? Does it address technical processes only, or management/support systems as well? Does it only address analytical processes, or pre- and post-analytical processes as well?
- Is the audit thorough, or is it simply a set of yes/no checklist questions?
- What kinds of issues did the team identify? Did they follow up?

# CAP Internal Auditing Course – Sample Content

## Process Overview

There are two types of internal audits:

1. Organizational-level audits – These are routine, scheduled audits of all processes in the organization.
  - These are sometimes called “horizontal audits” because they span many different areas, and span different phases of the process from beginning to end.
2. Focused audits – These are audits of a specific process or a specific part of a process because that process is high risk, has shown weakness in prior audits, or because of a corrective action/customer complaint.
  - These are sometimes called “vertical audits” because they focus on one process in considerable depth.



## High-level Description

Here is a high-level description of the auditing process. The rest of this course will provide descriptions and examples of each of these steps.

1. *Create the conditions* – Provide a structure for the internal audits, train auditors, and show management support.
2. *Select auditors* – Choose individuals who know enough about the process to conduct the audit but can be objective in their conclusions.
3. *Create initial plan* – Develop an understanding of the process so you can identify and focus on important issues.
4. *Create final plan* – Become familiar with any known problems so you can ask about improvements. Determine what documents you need to study so you can better understand the process, and then review those documents.
5. *Conduct the audit* – Interview individuals doing the work. Observe the process. Identify issues and document them.
6. *Report findings* – Create an audit report that summarizes positive aspects, opportunities for improvement, nonconformities, and other QMS issues. Conduct a closing meeting in which you present your findings and conclusions to the auditee.
7. *Follow up on audit(s)* – Compare the result of individual process audits with the results of other relevant processes. Look for trends and systemic issues. Decide what needs to be revisited or re-audited. Analyze non-conformities and find root causes.

Click the link below for a more detailed summary that includes inputs, process, and outputs for each step.

## Internal Auditing Methodology

### Pitfalls

Here are some general pitfalls in internal auditing:

- Organizations only audit laboratory test activities and fail to evaluate all aspects of the QMS outside of direct test performance.
- Auditors lack training or proper training.

## CAP Internal Auditing Course – Sample Content

- Auditors rely on checklists with “yes/no” questions. This enables them to “perform” the audit without really understanding the processes they are auditing. New applicants to CAP 15189 often say, “Where’s the checklist?”

## CAP Internal Auditing Course – Sample Content

### Step 1 - Create the Conditions

#### Explanation

The table below provides a summary of the process for Step 1 – Create the Conditions.

Input	Process	Output
Process(es) to be audited	<ol style="list-style-type: none"> <li>1. Document the organization’s processes and their interactions.</li> <li>2. Create an audit program.</li> <li>3. Provide training in internal audit.</li> <li>4. Provide messages of support from management.</li> <li>5. Encourage auditees to be forthcoming.</li> </ol>	<p>Documented processes</p> <p>Qualified auditors</p>

As Ann Phillips states in her book *ISO 9001:2008 Internal Audits Made Easy*, conducting an effective audit assumes that management has created the right conditions for the auditing program. This includes the right infrastructure, and the right attitude toward audits.

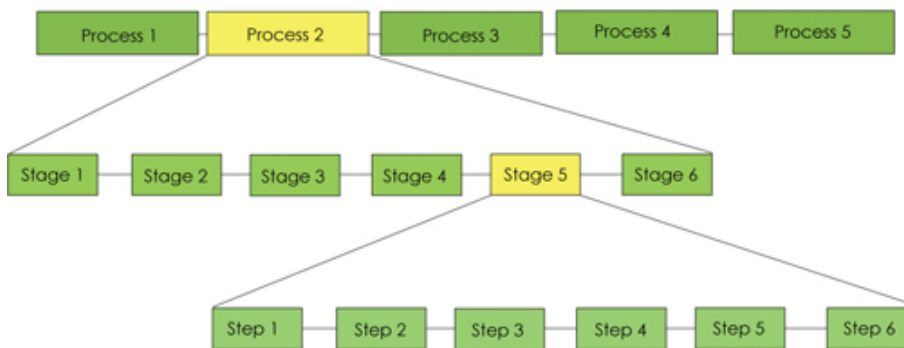
Management should do the following:

1. Document the organization’s processes and their interactions.

The cornerstone of a QMS that meets ISO standards is an understanding of the organization’s processes and their interactions. Document them in an easily readable form.

A best practice is to have processes mapped in a “layered” fashion. Create a high-level map of the organization’s processes. Then, for each of these processes, create a map of the sub-processes. Continue until you get to the level of procedures, work instructions, and forms.

### “Layered” Set of Processes



## CAP Internal Auditing Course – Sample Content

### 2. Create an audit program

Create an audit program that provides structure. The program should include all activities necessary for planning and organizing the audits, and for providing resources to conduct them efficiently. Top management should assign responsibility for managing the program to one or more individuals who have a general understanding of audit principles as well as management skills.

Responsibilities would include:

Role	Responsibilities
Audit management representative/Audit coordinator	Establish, implement, monitor, review, and improve audit program  Establish objectives and extent of audits  Establish audit procedure and provide training  Select audit teams, define scope, schedule audits, receive and review audit report, track corrective action
Auditee management (management of process being audited)	Approve audit, brief employees/auditees, provide resources, determine corrective action
Auditors	Prep for audit, conduct opening meeting, gather data, report non-conformities, answer questions, issue reports, hold closing meeting

Note: Roles differ by laboratory. The audit coordinator does not always follow up on corrective action.

### 3. Provide training in internal audit.

A reliable audit process depends on the competence of the auditor. By making sure auditors go through a program such as this one, you will ensure a baseline understanding of the process, preempt mistakes, and gain efficiencies by enabling auditors to make use of examples and tools like those found in the Wolfe-Christopher Hospital case study/demonstration.

### 4. Provide messages of support about the audit program.

In emails, town hall meetings, and other public forums, management should make it clear that it supports the program and expects cooperation. These messages need to define what an internal audit is and its purpose

## CAP Internal Auditing Course – Sample Content

5. Encourage employees to be forthcoming in their responses.

Emphasize that the outcome is improvement. Many problems that employees may think are their fault are in reality just the natural evolution of a process. Sometimes the only way to find issues is to implement a process and see what issues arise.

Make sure employees understand they will not be punished if issues are uncovered unless there are special circumstances (e.g., flagrant dishonesty). Management assumes everyone wants to do a good job. Mistakes are typically the result of bad processes, not bad individuals.



You may want to play the “Red Bead” game with top management and then with your employees to drive this point home. Click the link below to see a video simulation of the game in action.

[Dr. Deming’s Red Bead Experiment](#)

### Recommended Resources

International Organization for Standardization. ISO 19011:2018: Guidelines for Auditing Management Systems

See specifically section 7 on attributes of an auditor.

# CAP Internal Auditing Course – Sample Content

## Demonstration

This section provides a demonstration of Step 1 – Create the Conditions.

### Background

Wolfe-Christopher Hospital provides inpatient, outpatient, diagnostic, surgical, rehabilitative, behavioral, kidney dialysis, emergency, and outreach services.

The hospital has a yearly audit schedule. This is their completed audit schedule from 2010:

#### [Audit Schedule 2010](#)

Georgene Miller (GM) is the quality manager for Wolfe-Christopher.



### 1. Document the organization's processes and their interactions

Here is a document containing the processes for Wolfe-Christopher:

#### [Core Processes QMS](#)

### 2. Create an audit program

This chart depicts the organizational structure.

Position	Responsibilities
Quality manager	<ul style="list-style-type: none"><li>• Establish, implement, monitor, and review internal audit program</li><li>• Establish objectives and extent of the internal audit program</li><li>• Establish responsibilities and procedures</li><li>• Ensure resources are provided</li><li>• Ensure audit records are maintained</li></ul>
Top management	<ul style="list-style-type: none"><li>• Provide resources for all activities necessary for planning and organizing the Internal Audit Program (IAP)</li><li>• Conduct management review of audits</li></ul>



## CAP Internal Auditing Course – Sample Content

Auditors	<ul style="list-style-type: none"><li>• Prepare for audit</li><li>• Conduct opening meeting</li><li>• Conduct audit</li><li>• Hold closing meeting<ul style="list-style-type: none"><li>○ Report non-conformities</li><li>○ Answer questions</li><li>○ Issue reports</li></ul></li></ul>
----------	--

Here is the internal audit program document:

[Internal Audit Program](#)

### 3. Provide training in internal audit

GM initially evaluated each auditor at Wolfe-Christopher Laboratory to ensure they met personnel qualifications. Here is the evaluation form:

[Auditor Evaluation](#)

Here is an example of a completed auditor evaluation form:

[Auditor Evaluation CD](#)

As described in the “Internal Audit Program” document, each auditor reads the Internal Audit Program document and the Wolfe-Christopher Quality Manual. Each takes a written test that covers the key concepts of both texts. Those that do not attain 90% correct answers get a one-on-one review with the quality manager. All of the auditors also participate in the required CAP quality management course “Internal Auditing.”

### 4. Provide messages of support from management

Here is a Microsoft® PowerPoint® presentation that the hospital CEO delivered at the last town hall meeting.

[Internal Audit Presentation Slides](#)

### 5. Encourage auditees to be forthcoming

Here is an email that the quality manager asked division managers to cascade to their staff.

[Audit Notification](#)

## CAP Internal Auditing Course – Sample Content

### Workplace Learning

1. Evaluate the conditions of your internal audit program. Are your organization's processes documented to provide understanding of their interactions? Do you have a structure for your program? Are responsibilities for the program defined? Do you have a process for training your auditors?
2. Meet with your quality manager to discuss what you have found.

## CAP Internal Auditing Course – Sample Content

### Step 5 – Conduct Audit

#### Explanation

The table below provides a summary of the process for Step 5 – Conduct Audit.

Input	Process	Output
Audit plan  Individuals doing the work/auditees  Functioning processes	<ol style="list-style-type: none"> <li>1. Conduct an opening meeting.</li> <li>2. Interview individuals doing the work                             <ol style="list-style-type: none"> <li>a. Create environment for discussion.</li> <li>b. Ask questions.</li> <li>c. Deal with difficult issues that come up.</li> </ol> </li> <li>3. Observe the process.</li> <li>4. Review documents.</li> <li>5. Identify problems and potential areas of risk.</li> <li>6. Follow up on any audit trails.</li> <li>7. Review findings with auditee.</li> <li>8. Document findings.</li> </ol>	Audit notes and ideas

#### 1. Conduct an opening meeting.

In small organizations, the opening meeting may be informal, but it should at least announce the start of the audit, the nature of the audit, and allow time for any questions. In larger organizations, a more formal opening meeting may be desired. Participants should introduce themselves, and the auditor should provide information about the scope, methods, and criteria of the audit. Allow time for any questions that come up.

#### 1. Interview individuals doing the work.

First, create a comfortable environment for discussion. Explain the purpose of the audit and reiterate that it is the process that is under inspection, not the performance of any individual. Get to know the person a bit. The auditor should partner with the auditee to evaluate the process and look for opportunities for continual improvement.

In asking questions, it's important to use a "top down approach." Start with verifying the basic inputs, processes, and outputs. Then go to more detailed issues and procedures.

The person you are interviewing may be evasive, defensive, or even angry. It's important to deal with these situations in a tactful way. Keep in mind that some behavior may be due to things that are outside of the audit.

Take notes on what you hear.

#### 2. Observe the process.

It's important to be a keen observer of all aspects of the environment. Take notes on what you observe. Listen to what people say.

## CAP Internal Auditing Course – Sample Content

### 3. Review documents.

If you are auditing core processes, this may mean reviewing temperature, maintenance, and QC log sheets.

If you are auditing management requirements, documents may include evaluations of reference laboratories, meetings between laboratory professional staff and clinical staff regarding laboratory services, examples of root cause analysis, and continual improvement activities.

### 4. Identify problems and potential areas of risk. This includes ways the actual process varies from the planned process.

### 5. Follow up on any audit trails or questions that come up as a result of a certain discussion or observation.

The person you interview and/or observe may not have the answers to many of your questions. He or she may say, "Ask Joe about that question" or refer you to a particular document.

While reviewing temperature charts, you may notice that a refrigerator was replaced last month and decide to look at how this process was handled. Use your "audit plan" as a guide during the audit, but don't let it hinder you from following any audit trails.

### 6. Review findings with auditee.

Make sure that there is a clear understanding of any nonconformities. There should be no surprises at the closing meeting. Communicate any significant concerns to the audit manager. If it turns out that you have not interpreted audit evidence correctly, acknowledge your mistake.

### 7. Document findings.

Record document numbers and revisions of procedures, departments, and instrument identifiers. Your notes should be a reflection of what happened.

#### **Pitfalls**

- Auditors try to audit compliance to individual procedures rather than process and interactions; it should be the reverse – they should focus on process and interactions, then drill down into procedures. An effective audit requires both.
- Auditors use closed-end questions (yes/no) rather than open-ended questions (show me/tell me).
- Auditors do not review records to verify verbal answers.
- Auditors do not use visual observations to verify activities.

## CAP Internal Auditing Course – Sample Content

### Demonstration

This section provides a demonstration of Step 5 – Conduct Audit.

#### 1. Conduct opening meeting

Here is a summary of the opening meeting:

In attendance:

- Clair Dennis (CD), Dialysis Director
- Georgene Miller (GM), Quality Manager
- Joanne Nadal (JN), Support Services Manager

CD begins: My name is CD, and I am the director of the dialysis department. I have experience in the pre-analytic process and have participated in other audit programs. I've also been trained according to the Wolfe-Christopher Internal Audits Program.

This week, I will look at your pre-analytical process: test ordering, specimen collection, specimen transport, and specimen receipt. I will be interviewing staff, observing work activities, and reviewing documents and records.

Please understand that this is a snapshot in time and a small representation of the entire pre-analytical process, so there is an element of uncertainty to any findings or lack of findings.

The purpose of the internal audits is to determine that requirements of the Quality Management System and ISO 15189 are fulfilled and that processes are effective.

I must add that if there appear to be any areas of immediate and significant risk during the audit, I'll need to report it to GM immediately. Also, since I am directly involved with nurse-collected specimens, GM will do that part of the audit at a later time.

JN: I'll be available most of the week if there is anything you need, and please communicate any of your audit findings to me.

GM: Thank you, CD, for helping us audit our pre-analytic process. Would you like to start with a tour?

CD: Yes, but before we begin, are there any questions?

JN: In what order would you like to look at each sub-process?

CD: I would like to observe actual work in action. Maybe you could help me with that.

JN takes CD on a brief tour of the pre-analytical process. This gives CD a better understanding of the workflow and layout. They visit the courier base station, the outpatient drawing area, and the accessioning area. JN explains some of the work that is going on.

CD tells JN that she would like to start with an interview with one of the accessioners. Based on the information collected and the audit plan, CD meets with Ronald Childs (RC) in accessioning.

## CAP Internal Auditing Course – Sample Content

### 2. Interview individuals doing the work

Here is a transcript of the interview with the accessioner:

#### Interview with Accessioner

Here is the set of interview notes the auditor completed, based on the interview:

#### Audit Notes

Note how the auditor did the following:

1. Started with the overall process and the interactions between the sub-processes
2. After this, drilled into the details
3. Asked open-ended questions during the interview
4. Asked for clarification for understanding and accuracy
5. Documented findings with audit evidence

### 3. Observe the process

Here is a summary of CD's observations:

A courier delivered a batch of specimens from a local physician's office. This gives CD an opportunity to observe a work activity first hand. She tells Raymond Findlay (RF), another accessioner, that she would like to observe how he processes these specimens.

She reinforces that the purpose of the audit is to improve the laboratory's processes, not to determine if he's doing his job correctly.

CD tells him that she understands that he might be nervous, but to carry out his job as he normally would, and she adds, "Pretend that I'm a new employee, and I'm watching you so I can begin to learn my job. I might ask some questions for clarification, too."

As RF is processing specimens, CD watches while he opens a biohazard bag with eight specimens from one patient. She notices that two of the specimens are labeled with a hand-written first and last name, while the others have computer labels containing the patient name and at least one other unique identifier.

CD asks if he has to do anything special with the two specimens without computer labels (she remembers from the procedure review that there is a log sheet and a specific procedure to follow when there are not two unique identifiers on specimens.)

He tells her that the person who performs the recheck will take care of this. During the tour, JN explained to CD that the recheck verifies that information entered into the computer matches information on the requisition. The specimens are not involved in this check. She makes a note of this and allows the accessioner to carry on with his work.

## CAP Internal Auditing Course – Sample Content

As RF loads tubes of blood into the centrifuge, she asks, "Tell me how you can be sure that this centrifuge is spinning patient specimens at the correct speed?"

He goes on to explain, "There is a sticker on the side that tells the last time the RPMs were checked. Someone comes in every six months. Each sticker has the expected RPM range and the actual reading, and the next time it is due. See, the RPM they recorded is within the expected range." CD thanks him for letting her observe his work.

CD notes that all of the specimens processed by RF are delivered to the analytical areas for testing.

She continues the audit by walking around the area and taking in the environment, quietly observing others as they work.

### **4. Review documents**

CD reviews some of the requisitions that are waiting to be rechecked. They appear to be filled out completely. She notices that some specimens are put into a large walk-in refrigerator. There is no log sheet for recording temperatures so she asks JN how the temperature is monitored.

JN explains that a computer program monitors all of the refrigerators and freezers in the laboratory. She goes on to say that the Support/LIS audit monitors this process separately.

### **5. Follow up on any audit trails**

See "Audit Notes Final" below.

### **6. Review findings with auditee for accuracy**

CD asks JN to sit down with her so that she can go over her findings based on her time spent in the accession area. JN seems upset about the non-conformities but she agrees that CD's findings are accurate.

### **7. Document findings**

CD completes her audit of the pre-analytic process by going through the same process with the courier and phlebotomy sub-processes as well as some parts of the client service processes. She audited the outpatient drawing facility at the change of shift so that she could observe specimen collections by two phlebotomists on different shifts.

[Audit Notes Final](#)

## CAP Internal Auditing Course – Sample Content

### Workplace Learning

1. Go out into the areas for which you have an audit plan and try out what you've learned. This can be an actual audit of the process.
2. Document your findings, review them with the person who is responsible for the process, and get ready to create a report.



## CAP Internal Auditing Course – Sample Content

### Appendix – Summary of Process Audit Methodology

Step	Input	Process	Output
1. Create the conditions	Process(es) to be audited	<ol style="list-style-type: none"> <li>1. Document the organization’s processes and their interactions.</li> <li>2. Create an audit program.</li> <li>3. Provide training in internal audit.</li> <li>4. Provide messages of support from management.</li> <li>5. Encourage auditees to be forthcoming.</li> </ol>	<p>Documented processes</p> <p>Qualified auditors</p>
2. Select auditors	<p>Process(es) to audit</p> <p>Qualified auditors</p>	<ol style="list-style-type: none"> <li>1. Choose qualified individuals.</li> <li>2. Create an audit schedule.</li> </ol>	<p>Audit team</p> <p>Audit schedule</p>
3. Create initial plan	<p>Audit schedule</p> <p>Documented processes</p> <p>Quality objectives</p> <p>Relevant standard</p>	<ol style="list-style-type: none"> <li>1. Gain an understanding of the process in terms of inputs, outputs, factors and influences.</li> <li>2. Study your organization’s model of the process (create it if none exists).</li> <li>3. Study the relevant standard.</li> <li>4. Begin audit plan.               <ol style="list-style-type: none"> <li>a. What should you look for?</li> <li>b. What is the intent of the requirement?</li> </ol> </li> </ol>	<p>Models of processes</p> <p>Initial audit plan</p> <p>Individuals with knowledge of the process</p>
4. Create final plan	<p>Models of processes</p> <p>Initial audit plan</p> <p>Organization’s document log</p> <p>Customer complaints</p> <p>Past audit results (internal and external)</p> <p>Specific departmental procedures</p>	<ol style="list-style-type: none"> <li>1. Become familiar with any known issues for that process.</li> <li>2. Determine what documents are needed to better understand the process/sub-process.</li> <li>3. Request and review documents.</li> <li>4. Complete Audit Plan to help you determine whether:               <ol style="list-style-type: none"> <li>a. The process is operating as planned</li> <li>b. The process is effective</li> <li>c. The process meets a standard</li> <li>d. The process can be improved</li> </ol> </li> <li>5. Evaluate if additional documents are needed.</li> </ol>	<p>Final audit plan</p>

## CAP Internal Auditing Course – Sample Content

Step	Input	Process	Output
5. Conduct audit	Final audit plan  Individuals doing the work / auditees  Functioning processes	<ol style="list-style-type: none"> <li>1. Conduct opening meeting.</li> <li>2. Interview individuals doing the work.                             <ol style="list-style-type: none"> <li>a. Create environment for discussion.</li> <li>b. Ask questions.</li> <li>c. Deal with difficult issues that come up.</li> </ol> </li> <li>3. Observe the process.</li> <li>4. Review documents.</li> <li>5. Identify problems and possible areas of risk.</li> <li>6. Follow up on any audit trails.</li> <li>7. Review findings with auditee.</li> <li>8. Document findings.</li> </ol>	Audit notes and ideas
6. Report findings	Audit notes and ideas	<ol style="list-style-type: none"> <li>1. Prepare audit report.                             <ol style="list-style-type: none"> <li>a. Summarize the following:                                     <ol style="list-style-type: none"> <li>i. Positive aspects</li> <li>ii. Ways to improve</li> <li>iii. Ways the actual process does not meet the planned process</li> <li>iv. Ways the process does not meet the chosen quality standard or regulation</li> <li>v. Areas where the process is not effective</li> </ol> </li> <li>b. Itemize non-conformities.</li> </ol> </li> <li>2. Conduct closing meeting.                             <ol style="list-style-type: none"> <li>a. Present the findings and conclusions to the auditee.</li> <li>b. Invite discussion to ensure understanding and acknowledgement by auditee.</li> <li>c. If appropriate, agree on time-frame for a corrective and preventive action plan.</li> </ol> </li> </ol>	Audit report  Action items
7. Follow up on audit(s)	Audit report  Action items	<ol style="list-style-type: none"> <li>1. Follow up on individual findings.</li> <li>2. Look for trends among findings.</li> <li>3. Put audit findings into management review.</li> </ol>	Improved processes