A Quintessential Introduction to Compliance Monitoring: Principles and Practice

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What is Involved in the Compliance Audit?

When we talk about compliance audits, we essentially mean comparing an organization's practices against a predefined standard. Any deviation from this standard is identified as a "GAP," which translates to a finding. This finding indicates a need for corrective action, aiming to understand the root cause of the deviation and implement appropriate remedial measures.

So, How Do We Conduct the Audit?

Conducting an audit is a step-by-step process. The very first thing we need to consider is: why are we auditing? This fundamental question might seem obvious at first, but often, people have the wrong idea about the purpose of an audit. It's crucial to clarify this right from the start.

The Purpose and Role of an EASA Compliant Audit

An EASA (European Union Aviation Safety Agency) compliant audit is different from other types of audits. It focuses specifically on ensuring adherence to aviation safety regulations rather than general best practices or performance metrics.

What the Audit Is

The Joint Airworthiness Authority (JAA) originally implemented, and EASA has continued, the role of Quality Assurance. A unique aspect of this role is the need to demonstrate independence from the function or activity being audited.

Types of Compliance Audits

There are several types of compliance audits, each serving a specific purpose:

1. **Product Audit:** This type examines a finished product, process, or procedure against the expected standard.

2. **Process Audit:** Here, we look at the processes to verify that inputs, actions, and outputs align with defined requirements.

3. **System Audits:** These evaluate multiple processes within a system to provide an organizational solution to the objective.

4. **Surveillance Audits:** These are unplanned audits that can reveal non-conformities not typically found in pre-planned audits.

Conducting a Product Audit

Product audits focus on the completeness of the finished process, activity, or services. They don't require extensive training for the auditors, making them straightforward but effective.

Conducting a Process Audit

Process audits, on the other hand, are short but intense. They focus on verifying that the inputs, actions, and outputs of an activity are in accordance with defined requirements.

What Will We Look For During Process Audits?

1. **Manpower:**

   o Does the process have sufficient manpower?

   o Has the manpower received appropriate training?

   o Is the competence of the manpower managed to a controlled and documented standard?

2. **Documented Procedures:**

   o Who manages the procedures, and do they have the authority to modify them?

   o What triggers a modification of the procedures?

   o How are changes in regulations reflected in the procedures?

3. **Facilities, Tooling, and Equipment:**

   o Are the specified facilities, tooling, and equipment available and managed correctly?

Asking Questions

A key part of a successful audit is the ability to interview the auditee and ask questions that provide confidence in how the process or system is working. This involves not just asking questions but also processing the information received and making comparisons against the expected standard.

Things to Consider

Several factors need to be considered during an audit:

- **Validity of the Source Information:** Ensure the information is accurate and correctly interpreted.

- **Visibility (Evidence):** Check that the activity is carried out correctly according to requirements.

- **Oversight and Management:** Confirm that the process is managed correctly and that any related training is conducted as needed.

- **Competence:** Verify that all personnel involved are competent for their tasks.

- **Facilities, Tooling, and Equipment:** Ensure these are appropriate for the tasks and correctly managed.

Typical Findings

Common issues found during audits include:

- Problems with procedures not reflecting the standard correctly.

- Issues with manpower, competence, and training.

- Ineffectiveness of the management process.

Root Cause and Corrective Action

It's crucial that the root cause of a finding is determined by the auditee, not the auditor. The auditor's role is to validate that the identified root cause is correct and that the corrective action will likely resolve the issue.

Carrying Out the Audit

When performing an audit, it's important to focus on the process and procedures rather than the people. This means looking at the organization's ability to deliver in three main areas: suitable facilities, documented processes, and trained and competent staff.

Primary Audit Criteria

1. **People:** This includes competencies, training & records, and manpower resources.

2. **Paper:** This covers documentation, procedures, and forms.

3. **Prerequisites:** These are facilities, equipment, and material.

Process Auditing: Diving Deeper

People

- Is there a training/testing requirement for this process?

- Has this person been trained?

- How is competency managed?

Paper

- Are the requirements reflected in procedures?
- Are the right versions of documents available where needed?

Prerequisites

- Is the equipment serviceable?
- Who is responsible for the control of materials?
- Are there any environmental aspects to consider?

Organizational Compliance

Organizational compliance involves adhering to all external regulatory requirements and internal obligations driven by company documentation, manuals, and procedures.

Quality Control and Quality Assurance

Quality control is the responsibility of individual post holders and business area owners. It's delivered through regulatory-compliant processes and procedures followed by trained staff. All QC processes should be audited by the QA process.

The Role of the Compliance Manager (CM)

The CM leads the independent process for performing a gap analysis of the organization's documentation systems and processes. The CM's role is also to protect the Accountable Manager by ensuring all significant organizational non-conformities are addressed.

Further Considerations

Regulatory audits might miss some aspects due to constraints, but agencies like the National Transportation Safety Board (NTSB) or Aircraft Accident Investigation Board (AAIB) will not overlook these. An effective aviation quality and compliance system should generate few non-conformities during regulatory audits.

What the EASA Audit Is Not

It doesn't consider best practices, performance, or customer satisfaction. EASA compliance audits are narrow in scope, focusing strictly on regulatory adherence.

Types and Relationships of Audits

Compliance audits may be classified by scope as product, process, and system audits.

Role of Surveillance Audits

Surveillance audits are unplanned and provide additional oversight and confidence in the compliance system. They prevent audit preparation and show the subject as it actually is.

How to Perform an Effective Audit

Effective auditing involves several techniques:

- **Interviews/Discussions:** Engage with personnel to understand their roles and the processes they follow.

- **Document Review:** Examine published documents to ensure they are up-to-date and accurately reflect procedures.

- **Record Examination:** Look at a sample of records to verify compliance.

- **Observation:** Witness activities to ensure they are performed correctly and record observations.

Audit Preparation and Planning

Preparation is key to a successful audit. This involves:

- **Reviewing Previous Audits:** Understand past issues but avoid dwelling on them.

- **Researching the Department/Organization:** Know the product or service being audited.

- **Reviewing Applicable Regulatory Requirements:** Ensure you understand the standards that apply.

Time Allocation for an Audit

- **Planning and Preparation:** 40% of total time.

- **Conducting the Audit:** 40% of total time.

- **Analysis and Reporting:** 10% of total time.

- **Corrective Actions and Follow-Up:** 10% of total time.

Asking Questions During the Audit

Effective questioning is crucial. This involves asking questions that provide confidence in the process or system and comparing the responses to the expected standard.

Challenges in Auditing

- **Validity of Information:** Ensure the information source is valid and interpreted correctly.

- **Visibility of Evidence:** Verify that activities are carried out correctly.

- **Oversight and Management:** Ensure processes are managed correctly and training is provided where needed.

- **Competence of Personnel:** Verify that all personnel are competent for their tasks.

- **Facilities, Tooling, and Equipment:** Ensure these are appropriate for the tasks and managed correctly.

Typical Findings and Their Root Causes

Common issues include problems with procedures, manpower, competence, and training, and ineffective management processes. The root cause should be determined by the auditee, with the auditor validating that it is correct and that the corrective action will likely resolve the issue.

In summary, conducting an effective compliance audit involves careful planning, thorough questioning, and a focus on processes and procedures. By ensuring adherence to standards and addressing any gaps found, an organization can maintain high levels of safety and quality in its operations.

Next Steps

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