Amera-Veritas, Inc.™

Experts in Quality, Risk & Safety Management Systems

ADVANCED INTERNAL AUDIT WORKSHOP

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TOPICS

- Internal Audit Process

- Auditing For Effectivity vs. Conformity

- Auditing Top Management

- Auditing Continual Improvement

- Auditing Processes

- Questions To Ask People In Your Organization

Workshop Opening

To assure customer satisfaction, aviation, space, and defense organizations must produce and continually improve safe reliable products that meet or exceed customer and applicable statutory/regulatory requirements.

The globalization of the industry and the resulting diversity of regional and national requirements and expectations have complicated the supply chain.

Organizations have the challenge of purchasing products from suppliers, at all levels of the supply chain, throughout the world. Conversely, suppliers have the challenge of delivering products to multiple customers having varying quality requirements and expectations.

INTERNAL AUDIT PROCESS

Workshop Opening

Internal audits form an integral part of managements assurance that their organization is fulfilling the needs and expectation of customers and their requirements.

An effective internal audit is essential to the solid QMS.

Although "paperwork" is important, management must also understand "does it work."

- *In this presentation, the word "**Shall**" indicates a requirement and the word "**Should**" a recommendation to meet the intent of the training.*
- *Words "typical", "example", or "e.g." indicate suggestions given for guidance.*
- *Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.*

Purpose of Auditing

Auditing is a basic tool to assess effective implementation of and conformity to QMS requirements. In addition to the determination of conformity, an auditor must also focus on the evaluation of effectiveness of the QMS and its processes to achieve the organizations objectives.

Conformity <u>without</u> effectiveness is bad. Effectiveness <u>without</u> conformity is bad. Being in conformity and effective is the real goal!

Auditing Approach

An auditor must engage the auditee and evaluate the QMS approach. The basic question that should be asked of every process includes:

- Is the process identified and appropriately defined?
- Are responsibilities assigned?
- Are the processes adequately implemented and maintained?
- Is the process effective in achieving the desired results?

The collective answers to these and other associated questions should contribute to the evaluation results.

Audit Planning

The audit plan **Shall** be based on the processes defined by the organization and documented in the QMS Process Matrix Report (see Form 2).

The audit team leader **Shall** use the organization's customer feedback requests, including those received through the OASIS database (see 9104/1 clause 14.2), to assist with audit planning for surveillance and recertification audits. The audit activities **Shall** be prioritized based upon performance data for business risks that could impact the customer (i.e., customer concerns, customer special statuses) and on processes that are not achieving planned results.

Audit Planning

Audit planning **Shall** take into account:

- The sequence and interactions of the organization's processes;
- The criticality of products and processes, including special processes;
- The risks associated with product or process maturity (e.g., new product introduction, new process equipment or facilities);
- Product related safety issues (e.g., airworthiness issues, reporting to customer and/or authorities);
- Results of internal audits;
- Previous audit findings (e.g., CBs, customers, regulatory authorities);

Audit Planning

Audit planning **Shall** take into account:

- Performance measures and trends for quality and OTD (e.g., KPIs, scorecards, dashboards);
- Previous management review results;
- Customer requirements;
- Statutory/regulatory requirements;
- Customer satisfaction/performance data;
- Certification structure [i.e., single site, multiple site, campus, several sites, complex organization];
- The proportion of aviation, space, and defense business each customer represents.

NOTE: The audit team leader **Should** ensure that the amount of audit time planned on auditing any one customer's specific QMS requirements is consistent (approximately) with the proportion of aviation, space, and defense business each customer represents (e.g., if customer X has 20% of the business, the audit team **Should** not spend 80% of their time verifying customer X's specific QMS requirements).

Audit Planning

The audit team leader **Shall** require the organization to provide the information and documentation for review including:

- Quality manual and supporting procedures;
- Description of processes showing their sequence and interactions, including the identification of any outsourced processes;
- Product conformity and OTD performance measures and trends;
- Interactions with support functions on-site or at remote locations/sites;
- Results of internal audits and to what criteria (e.g., processes, procedures, external requirements, etc.);
- Management review results;
- List of the top five customers including evidence of customer satisfaction and complaint summaries (e.g., customer reports, scorecards, and special status or equivalent).

Audit Planning

NOTE 1: The processes can be documented in various ways, including but not limited to process maps, turtle diagrams, SIPOC method (breakdown of Supplier, Inputs, Process steps/tasks, Outputs, and Customer), and octopus.

NOTE 2: The data **Should** be sufficient to allow the audit team leader to make a judgment on performance and trends.

NOTE 3: Examples of customer specific QMS requirements are: product process verification, including First Article Inspection (FAI) requirements; quality records to be created and maintained by the organization; coordination of document changes; defined special requirements/critical items/key characteristics; approval of design changes by the customer; flow down of requirements to sub-tiers; customer notification of production process changes; traceability; handling of nonconformities; and applicability of other IAQG AQMS standards in contracts.

Conducting On-site Audits - General

Each on-site audit **Shall** include the following, as applicable:

- A review of the changes to the QMS, since the last audit;
- A review of requirements from new aviation, space, and defense customers, since the last audit;
- A review of customer satisfaction information and requested corrective actions;
- An interview with top management;
- An audit of the organization's processes, including their performance and as identified in the audit plan;
- An audit of continual improvement;
- An audit of follow-up actions from previous audits; and
- An audit of the purchasing process.

NOTE: If there is more than one surveillance audit during a year (e.g., every six months), some activities (e.g., interview with top management) may be spread over these audits.

AUDITING
CONFORMITY vs. EFFECTIVITY

Auditing For Effectivity vs. Conformity

ISO 9000:2005 Vocabulary

Historically….

3.6.1 Conformity
Fulfilment of a requirement.

NOTE: The term "conformance" is synonymous but deprecated.

Today…..

3.2.14 Effectiveness
Extent to which planned activities are realized and planned results achieved

Auditing For Effectivity vs. Conformity

The Organization May Not Be Effective If:

- Planned activities are not realized and desired results are not achieved,   *(Is there a CAR?)*

- Planned activities are not realized but desired results are achieved,   *(Is there a CAR?)*

- Planned activities are realized but the desired results not achieved,   *(Is there a CAR?)*

The Organization May Be Effective If:

- Planned activities are realized and desired results are achieved.

Auditing For Effectivity vs. Conformity

The Organization must be able to…

- Demonstrate conformity of the QMS Organization to the standard.
- Show process definition (identified, sequence and interaction).
- Explain how process measures are identified:
  - Who reviews the data?
  - Targets defined?
  - Targets are met?
  - Are the measures actionable?
  - How is the data used?
- Show actions taken when product quality and on-time delivery performance targets are not met.
- Show customer satisfaction data.

Overall QMS Performance and Effectiveness

The audit of QMS performance and effectiveness **Shall** include a review of the following:

- The processing of customer complaints, customer feedback data (e.g., periodic performance reports received from customers), and other relevant customer data (e.g., results of customer surveys);
- Results and actions from internal and external audits of the QMS, including their associated records;
- Stakeholder feedback (e.g., feedback from regulatory authorities or other interested parties);
- The processing of process/product nonconformities, including review of associated corrective actions and evaluation on the effectiveness of actions taken;
- The processing of preventive actions, including evaluation on the effectiveness of actions taken;

Overall QMS Performance and Effectiveness

The audit of QMS performance and effectiveness **Shall** include a review of the following:

- Management review conduct, including associated records (e.g., process inputs/outputs, actions taken);
- Internal performance monitoring, measurement, reporting, and reviews against stakeholder and internal performance objectives and targets, including continual improvement activities and associated records;
- The organization's current performance against targets, including customer specific targets and associated records of applicable actions taken where targets are not being met; and
- The status and effectiveness of the organization's process performance improvement activities and their outcomes related to product quality.

Process Effectiveness (Continued)
The audit team **Shall** evaluate the effectiveness of each audited product realization process considering:
- Process realization - the extent to which planned activities are realized; and
- Process results - the extent to which planned results are achieved.

The audit team **Shall** evaluate the audit evidence arising from the audit and determine the effectiveness of the process being audited.

The process effectiveness derived from the evaluation **Shall** be recorded and documented in the audit report.

Process Results
The audit team **Shall** record measures, targets, and values of KPIs related to each audited product realization process in their internal audit reports.

See
Process Evaluation Matrix.

PROCESS EVALUATION MATRIX

Process Realization (a)		Process Results (b)		
		Planned results not achieved and appropriate action is not taken	Planned results not achieved, but appropriate action is being taken	Planned results are achieved
Planned activities fully realized		a) The process is defined, implemented, and planned activities fully realized; however, b) The process is not delivering the planned results and appropriate action is not being taken. **2**	a) The process is defined, implemented, and planned activities fully realized; however, b) The process is not delivering the planned results, but appropriate action is being taken. **3**	a) The process is defined, implemented, and planned activities fully realized; and b) The process is delivering the planned results. **4**
Planned activities not fully realized		a) The process is defined and implemented, but planned activities not fully realized; and b) The process is not delivering the planned results and appropriate action is not being taken. **2**	a) The process is defined and implemented, but planned activities not fully realized; and b) The process is not delivering the planned results, but appropriate action is being taken. **2**	a) The process is defined and implemented, but planned activities not fully realized; however, b) The process is delivering the planned results. **3**
Planned activities not realized		a) The process is not defined, implemented, and planned activities not realized; and b) The process is not delivering the planned results and appropriate action is not being taken. **1**	a) The process is not defined, implemented, and planned activities not realized; and b) The process is not delivering the planned results, but appropriate action is being taken. **2**	a) The process is not defined, implemented, and planned activities not realized; however b) The process is delivering the planned results. **2**

AUDITING
TOP MANAGEMENT

WHAT TO LOOK FOR?

Is The Organization Customer Focused?
The audit team **Shall** inquire with top management to determine if customer satisfaction is being evaluated and appropriate actions are being taken by the organization based on performance information:

- Nonconformity data,
- Corrective action requests,
- Results of surveys, scorecards, report cards, etc.
- Complaints regarding product quality,
- On time delivery (OTD),
- Service provision, and
- Responsiveness to customer and internal requests.

Organizational Leadership

There **Shall** be an interview(s) with top management to evaluate the:

a) Establishment and continued relevance of the organization's quality policy and objectives;

b) Establishment of performance measures aligned to quality objectives;

c) QMS development, implementation, and continual improvement;

d) Top management commitment;

e) QMS performance and effectiveness;

f) Performance to customer expectations (e.g., supplier rating, scorecard, audit results); and

g) Actions taken to address issues that are not meeting customer performance expectations

Management Review – What to ask

Top management should be interviewed to ask:

a. How often the review takes place?
b. Is it possible to look at the last two minutes (records) of your reviews?
c. Are the topics in line with that expected in 5.6.2 a) thru h)?
d. Do the minutes reflect a robust discussion of the topics?
e. Was all of top management participating?
f. Are their appropriate actions and decisions by top management given the information provided?
g. Are there improvements as a result of the review?
h. Were previous action items closed out?
i. How does top management feel about the reviews?

AUDITING
CONTINUAL IMPROVEMENT

WHAT TO LOOK FOR?

Continual Improvement

The audit team **Shall** evaluate the organization's interrelated processes and activities for continual improvement of the QMS, its processes, their conformity, and effectiveness in order to:

Ensure focus on issues that are important to the organization, their customers, and regulatory authorities; and

Determine the effectiveness of an organization's approach to continually improving process performance.

NOTE: The organization **Should** be able to demonstrate that they have a structured approach to achieve continual improvement of the QMS and its processes.

Customer Satisfaction

1. What techniques are being used to understand customer satisfaction (e.g., surveys, studies, scorecards, etc.)?
2. How robust is the system gathering this information (e.g., lots of inputs, no inputs)?
3. Does the data received indicate that the customer is satisfied or unsatisfied with the service/product being provided?
4. Does the organization react to negative comments received by initiating corrections or corrective actions?
5. Are decisions on improvements being made as the result of information received?

Corrective Action Process
1. How many corrective actions have been issued in the past 12 months?
2. Is the volume indicative of a static or dynamic organization?
3. Are the quality of the issues raised of value?
4. Is the organization reacting to the issues raised in timely manner?
5. Do reactions to the issues being raised include correction and corrective actions?
6. Sample CAR's to understand if there's a good:
   - Problem statements?
   - Root cause?
   - Effective actions to resolve issues?

Analysis of Data
1. How often is the organization analyzing data?
2. Is this analysis occuring at the local (department, cell, etc.) level by process owners?
3. Is the data relevant to the organization conducting the review?
4. Does the data review include that data that's required in the Standard?
5. Is the organization making changes based on the information being analyzed?
6. Are the changes or decisions being made, impacting the organization and making improvements?
7. Are personnel involved in the data collection aware of their role and how their duties impact quality?

AUDITING PROCESSES

WHAT TO LOOK FOR?

Process Management
The audit team **Shall** conduct QMS audits using a method that focuses on process performance and effectiveness.

Priority must be given to the following:
- Reviewing the organization's processes, their sequence and interactions, the identification of functions and assignment of responsibilities, and performance against requirements and defined measures, with focus on processes that directly impact the customer;
- Reviewing the process for validation and approval of processes and process changes;

Process Management (Continued)
Priority must be given to the following:
- Reviewing the organization's processes, their sequence and interactions, the identification of functions and assignment of responsibilities, and performance against requirements and defined measures, with focus on processes that directly impact the customer;
- Reviewing the process for validation and approval of processes and process changes;
- Reviewing the availability of resources and information required to operate and support associated activities, including appropriate training and competency of personnel;

Process Management (Continued)

Priority must be given to the following:

- Reviewing the process-based management techniques, including the examination of process measures (e.g., quality, TAKT time, cycle time, output effectiveness, control limits, process capability determination);

- Reviewing plans in place to ensure performance objectives/targets are monitored, measured, and analyzed in order to realize the planned activities and achieve the planned results (e.g., verify performance information availability, percentage of nonconforming parts/products, percentage OTD);

Process Management (Continued)

Priority must be given to the following:

- Reviewing applicable action taken when objectives/targets are not met to promote continual improvement; and
- Pursuing audit trails addressing customer concerns or requests for corrective actions, performance against objectives, and relevant process controls.
- The audit team **Shall** audit processes to sufficient depth and detail to evaluate if the organization's processes are capable of meeting planned results and performance levels, including applicable customer specific targets.

Process Management (Continued)

NOTE 1: KPIs are used to identify an organization's progress towards achieving its performance goals.

NOTE 2:   KPIs relating to financial information are not in the scope of the 9101 standard.

NOTE 3: The audit team **Should** pursue process-based audit trails by following actual products, customer orders, and related documents (e.g., customer contracts, drawings, shop orders, inspection records) through the organization's product realization and associated processes. Verifying the interfaces between processes and the linked documentation requirements (see 9100-series standards clause 4.2); resource management (see 9100-series standards clause 6); and measurement, analysis, and improvement (see 9100-series standards clause 8).

Special Processes (e.g., Welding, Soldering, Heat Treating, etc.)
When special processes (see 9100/9110 clause 7.5.2) are included in the audit plan, the audit team **Shall** evaluate process validation, as well as, the monitoring, measuring, and control of these processes, including the following:

The process records **Shall** be reviewed for each audited special process, including the established arrangements and a comparison between actual and planned results.

The audit team **Shall** identify and select a sample of special processes, including those defined by the customer. For the selected special processes, the audit team **Shall** audit the monitoring and measuring equipment used (e.g., calibration, accuracy) and the method for recording the results. If required, the traceability between the process (e.g., batch or load charge identification) and the resulting products **Shall** be verified.

Special Processes (e.g., Welding, Soldering, Heat Treating, etc.)
In the case of outsourced special processes, the audit team **Shall** verify that the organization's supplier control process addresses these items accordingly. In addition, the audit team **Shall** review the use of customer-designated sources, as required.

NOTE 1: Special processes are managed by using personnel qualified, as required by organization and/or customer requirements, and by controlling physical or chemical process characteristics [e.g., temperature, time (process duration), pressure, chemical composition of product or process treatment material (surface treatment solution)].

NOTE 2: If an audit(s) has been performed by a customer or by a specialized independent 3rd party, the audit team can take the audit by these organizations into account. This can include audit results, sampling of the findings, and verification of any reported nonconformities to determine adequate resolution (i.e., no recurrence).

QUESTION TO ASK
PEOPLE IN YOUR ORGANIZATION

# Audit Interviewing – What To Ask Whom?

Process Managers & Supervisors

1. What are the key process indicator measures (KPI's, etc.)?
2. Does the desired level of performance reflect specified customer targets/performance requirements?
3. What is the process's current level of performance?
4. Is the process performance regularly reviewed?
5. Where process performance is not being achieved, are improvement plans in place?
6. Are corrective actions initiated if process targets are not achieved?
7. Has the process been audited in the past and what where the results?
8. Are there any customer complaints connected to this process?

Audit Interviewing – What To Ask Whom?

Process Owners

1. What is the process?
2. What is the process trying to achieve?
3. Who is the "customer" of the process?
4. What are process deliverables and end product?
5. Is the process defined (inputs, outputs, resources, and controls) anywhere?
6. Does the process include any applicable customer specific requirements?
7. Are the responsibilities of the process owner and process performers defined?
8. Who is responsible to monitor the process effectiveness?
9. Are the competencies for personnel performing tasks within the process identified?
10. What is the desired level of performance?
11. Are there improvement actions in place to achieve the desired level of performance?

THANK YOU!

QUESTIONS?
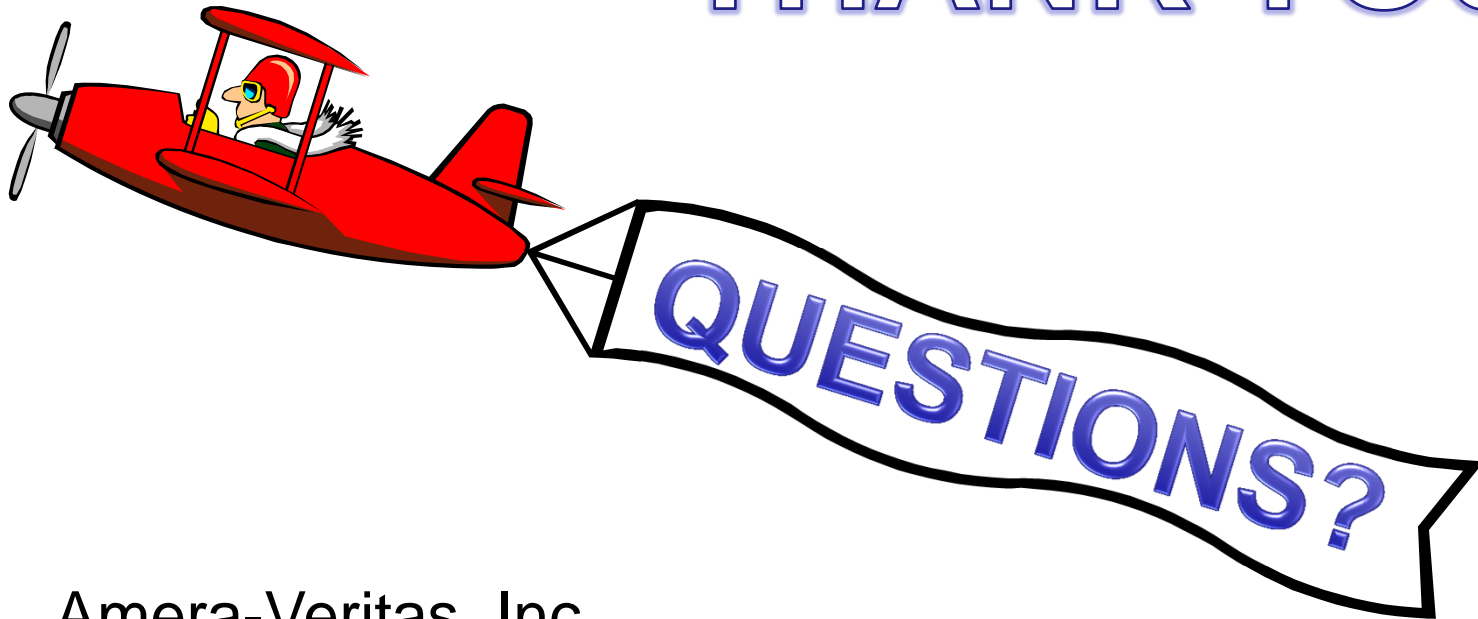
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