Practical Audit Tools

Session 1:
Process Flow Chart & Audit Checklist

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Quality @ Saint Gobain NorPro

- Saint-Gobain – very large French conglomerate, founded in 1665 (over 350 years old!)
- NorPro – a very small subsidiary of SG
- Catalytic Products – a business element of NorPro
  - Located in Bryan, TX
  - Producing ceramic carriers for the chemical industry
  - When you drink out of a PET water bottle or wear polyester clothing odds are that the Ethylene Oxide that made the MEG that made the PET was made in a reactor using a catalyst made from our carriers.

The tools we’ll look at today are generalized versions of the ones used at NorPro.
Today's Topics

- Process Approach (a Powerpoint picture)
- Audit Conduct (a Word Checklist)
- Audit Planning
- Auditor Competency (an Excel workbook)
- Audit Reporting

3 preformatted tools to help you document your audit process performance effectively and efficiently

- **Process Flowchart and Checklist covered in 1st half of this extended session**
- Auditor Competency, Planning, and Reporting covered in 2nd half.
Process Approach

ISO 9001:2015

0.3 Process approach

0.3.1 General

• This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. *Specific requirements considered essential to the adoption of a process approach are included in 4.4.*
ISO 9001: 2015

4.4 Quality Management System and its Processes

- **4.4.1** The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.

- The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:
  - a) determine the **inputs** required and the outputs expected from these processes;
  - b) determine the **sequence** and **interaction** of these processes;
  - c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to **ensure the effective operation and control** of these processes;
  - d) determine the **resources** needed for these processes and ensure their availability;
  - e) assign the **responsibilities and authorities** for these processes;
  - f) address the **risks and opportunities** as determined in accordance with the requirements of 6.1;
  - g) **evaluate** these processes and implement any changes needed to ensure that these processes achieve their intended results;
  - h) **improve** the processes and the quality management system.

- **4.4.2** To the extent necessary, the organization shall:
  - a) **maintain documented information** to support the operation of its processes;
  - b) **retain documented information** to have confidence that the processes are being carried out as planned.
Simple Form of a Process
SIPOC Form of a Process

Supplier → Input → Process → Output → Customer

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26th Annual ASQ Audit Division Conference: The Intercontinental Addison
ISO Form of a Process

ISO 9001:2015
0.3 Process approach
0.3.1 General
My Example Manufacturing Process

Sequence, Interaction, inputs, outputs, etc. Drill down to details . . .
Quality Management System

The QMS Process document provides either the details needed to describe the various activities of the process or points to where to find more detailed information. This is the starting point for the process owner for all audits.
The QA Lab Process document provides either the details needed to describe the various activities of the process or points to where to find more detailed information. This is the starting point for the process owner for all audits.
No requirement to reformat your system to match the current ISO structure . . . I choose to organize my folders by process step instead of by ISO numbers to make life easier in the future.
## Process / ISO Cross Reference Matrix

<table>
<thead>
<tr>
<th>Bryan-IMS Sub-Folder</th>
<th>Topics Covered</th>
<th>Owner</th>
<th>ISO 9001/2015</th>
<th>ISO 14001 2015</th>
<th>OHSAS 18001</th>
<th>ICRF</th>
<th>20 Step Requirement</th>
<th>ISO 17025</th>
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<tbody>
<tr>
<td>Commercial</td>
<td>Determining Requirements for Products (Quality Plans / Specifications)</td>
<td>McCormick</td>
<td>8.2</td>
<td>4.1</td>
<td>4.22</td>
<td>4.5.3</td>
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<td></td>
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<td></td>
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<td>9.1.0</td>
<td>6.1.2</td>
<td>4.3.1</td>
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<tr>
<td>EHS.20 Step</td>
<td>Documents providing reference from the 20 step requirements to the existing ISO documentation</td>
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<td>1 - 20</td>
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<tr>
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<td>Evaluation of Compliance</td>
<td>Goodwin</td>
<td>8.2</td>
<td>4.4.7</td>
<td>11.20 11.21 11.22 11.23</td>
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<td>EHS.Emergency_Prep</td>
<td>Emergency Preparedness and Response</td>
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<td>HRLiveWell</td>
<td>LiveWell (Wellness) information to support healthy lifestyles for employees</td>
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<td>Competence, Awareness and Training</td>
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<td>4.4.2</td>
<td>2.4</td>
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Obviously only a snippet of the full matrix . . . Our “Rosetta Stone”
Summary of Process Approach

- Level 1 = our plant management system process overview
- Level 2 = each process within the plant, what tasks/topics apply and where will we find details?
- Level 3 = detailed work instructions for each task

Bryan Integrated Management System
Penetrometer and Mercury Cleaning

1. Purpose/Summary
   a. The mercury cleaning procedure defines the method of triple filter cleaning mercury for the purpose of minimizing environmental impact and cost of analysis.

2. Applicability/Responsibility
   a. Analytical technician or designate.

3. Safety
   a. All cleaning involving Hg must be under the Hg Fume hood to avoid the uncontrolled release of mercury vapor. The fume hood must remain closed when not in use.
   b. Refer to the MSDS for safety precautions for mercury.
   c. Samples that have been exposed to mercury are hazardous. Apply the precautions given by the following:
      i. Mercury is a hazardous substance that can cause illness and death. Mercury can be absorbed through the skin, avoid direct contact. Handling should be done below 25°C to minimize vapor formation.
      ii. Always store mercury in closed containers to control its evaporation.

Bryan IMS – BQA Lab Process

7. Documented Information (Procedures, Methods & Records)
   a. Documented lab operations procedures are used to ensure work processes in the Bryan QA lab are standardized, communicated, and implemented within the laboratory. See the NIMS:BryanQA:Lab:Procedures folder.
   b. Documented lab EHS procedures are used to ensure that work in the lab is carried out in accordance with all regulatory and legal requirements and that these processes are standardized, communicated, and effectively implemented within the laboratory. See the NIMS:BryanQA:Lab:EHS folder.
   c. Documented test methods are used to conduct all analytical tests in the Bryan QA lab. See the NIMS:BryanQA:Lab:Methods folder.
   d. Documented calculators are used to ensure that the calculations required by the various test methods in the Bryan QA lab are standardized, communicated, and implemented within the laboratory. See the NIMS:BryanQA:Lab:Calculators folder.
   e. Documented records of tests performed are maintained to demonstrate compliance to testing requirements.
      i. The master results file is by definition the data stored in Exact.
      ii. Records of the raw testing measurements (where applicable) and the calculations that convert the raw measurements to final analyses are maintained as well. See the NIMS:BryanQA:Lab:Testing folder.
   f. Product Specifications (Quality Plans) are managed via an Excel database in the NIMS:BryanQA:Lab:SpecTool folder. This database is available for display on the QP Monitors for the lab personnel. Electronic printouts of the Quality Plans are stored in PDF format in the NIMS:BryanCommercialQualityPlans folder for read access by R&D, Commercial, Manufacturing, etc.
Because Saint-Gobain has a corporate wide risk protocol in place, we use it to meet the ISO risk based thinking requirements.

- a couple hundred corporate risks identified in 18 categories (HR, Production, EHS, Finance, etc.)
- Over 500 controls specified to mitigate and/or control these risks (some “key” controls are mandated, others are strongly recommended – at Bryan, we’ve chosen to implement them all since more than 2/3 of them overlap with our integrated management system anyway!)

If we didn’t have ICRF, my approach would be to identify risks in the business at each of the processes on our flow chart. The process documentation provides an excellent place to capture that piece of the ISO puzzle.

Risk based thinking is not part of this presentation, but a quick pointer to where to put it seemed appropriate . . .
ISO 9001:2015 9.2 Internal Audit

- **9.2.1** The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
  - a) conforms to:
    - 1) the organization’s own requirements for its quality management system;
    - 2) the requirements of this International Standard;
  - b) is effectively implemented and maintained.

- **9.2.2** The organization shall:
  - a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
  - b) define the audit criteria and scope for each audit;
  - c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
  - d) ensure that the results of the audits are reported to relevant management;
  - e) take appropriate correction and corrective actions without undue delay;
  - f) retain documented information as evidence of the implementation of the audit programme and the audit results.
Is an Audit Checklist an ISO 9001 Requirement?

• Nope. Nothing about audit checklists in ISO 9001

• ISO 9001:2015 clause 9.2 tells us we must conduct internal audits and provides some requirements around the audit program but it doesn’t tell us *how* to conduct an audit.

• But there is a NOTE See ISO 19011 for guidance at the end of the clause. . .

• ISO 19011:2011 helps us with the *how* in regards to managing an audit program and conducting an audit.
6.3.4 Preparing work documents

The audit team members should collect and review the information relevant to their audit assignments and prepare work documents, as necessary, for reference and for recording audit evidence. Such work documents may include the following:

— checklists;
— audit sampling plans;
— forms for recording information, such as supporting evidence, audit findings and records of meetings.

The use of checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit.

NOTE Guidance on preparing work documents is given in Clause B.4.
Our Audit Checklist

• …provides the checklist questions, a recommended sample plan and a form for recording your information as outlined in ISO 19011:2011

• Process aligned
• Use Process Overview documentation to define the ISO topics that apply
• Develop audit checklist to ensure each process is fully compliant as well as effective in accomplishing its goals
  – Questions based on the standard to see if the standard is being met
  – Questions based on process knowledge to ensure a deep dive into the organization’s effectiveness
• Provides much needed structure and guidance to internal auditors who may not perform this function routinely.
Example: Our QA Lab Process

Our process documentation provides information about which ISO topics are relevant.

- Monitoring & Measuring Resources (7.1.5)
- Competence (7.2)
- Awareness (7.3)
- Documented Info (7.5)
- Release of Product (8.6)
- Control of Nonconforming Outputs (8.7)
Checklist Cover

Customize for your organization
Document control stuff

Demographic info for this audit

Instructions to the auditors

Define the possible responses

Who ya gonna call?
QA Lab Checklist Components

- Who did you talk to?
- What topic did you cover?
- What questions were asked?
- What responses were provided?
- What evidence did you examine?
- What was your sample size?
- Plenty of room for notes

Auditor guidance

Results - auditor summary of this topic
ISO 9001:2015 Process Audit Checklist  

### Clause 7.2. Competence (Dept)

**Where does this department document their process for competency of their workers?**

(Folder/document – rev level & date)

**What is the mechanism for documenting the various job positions in this department?**

Select 3-5 job positions from this list. Capture the names of 1-2 employees currently listed as qualified in this position. Validate the dates that these employees were qualified to fill the position. Record your observations here:

<table>
<thead>
<tr>
<th>Position</th>
<th>Employee</th>
<th>Date Qualified</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
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</table>

If a discrepancy is noted, be sure to capture sufficient details to drive correction action by the site.

To satisfy this requirement the host should point to their departmental system for managing employee competence. It should include at least a1) identification of necessary competence, b) assurance of competence via training, education or experience, c) actions to acquire the necessary competence and d) records to provide evidence of competence.

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ISO 9001:2015 Process Audit Checklist  

### Clause 7.3. Awareness

**Select a random listing of 3-5 workers in this department or just walk through the department and talk to those who are present. Ask each worker the following questions, noting their ability to demonstrate that they are aware of each topic.**

1. **What is the quality policy?**
2. **What are the quality objectives for the site?**
3. **How do you personally contribute to the success of these quality objectives?**
4. **What would happen if you failed to follow your management system requirements?**

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To satisfy this requirement the auditor will interview the workers in the department and validate that they are aware of the various requirements listed above.
More topics

ISO 9001:2015 Process Audit Checklist

Process: QA Lab

Clause 7.5 Documented Information

Review the site documented information process briefly. Select 4-7 work instructions (procedures, test methods, etc.) from the department. For each of these, validate the following, recording your observations in the table provided:

<table>
<thead>
<tr>
<th>Document</th>
<th>Title</th>
<th>Date</th>
<th>Documented</th>
<th>Issued to</th>
<th>Approved by</th>
<th>Reissued</th>
<th>Replaced</th>
<th>Notes</th>
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As you find references to required records in these documents, capture 5-7 of them for review. For each one, validate that the records are being stored in the specified location for the specified time frame and are being disposed of as specified.

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</table>

If there are any discrepancies or nonconformances, the details provided here will become the basis for developing corrective actions.

To satisfy this requirement the auditor will examine the documentation (work instructions and records) to determine if the documentation is being managed as specified.

Circle Result: N/A OK OFI NC NW Page 32 of 55

ISO 9001:2015 Process Audit Checklist

Process: QA Lab

Clause 8.6 Release of Products

Where does this department document their process for release of products? (folder/document - rev level & date)

Does the process define who has the authority to release product? Yes No

Who is the release authority? ___________________________

Are records kept to demonstrate who releases product for shipment? Yes No

- Where are they kept? _________________________
- For how long are they kept? _____________

Examine records for the last 4-6 shipments. Document the release authority for each shipment and verify that the product either passed all specifications or had a release waiver. Record your observations here:

<table>
<thead>
<tr>
<th>Product</th>
<th>Ship Date</th>
<th>Who released?</th>
<th>Passed Spec?</th>
<th>Waiver obtained?</th>
</tr>
</thead>
<tbody>
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If there are any discrepancies or nonconformances, the details provided here will become the basis for developing corrective actions.

To satisfy this requirement the host should point to their departmental system for declaring product to be in-spec and released for shipment. Records are required.

Circle Result: N/A OK OFI NC NW Page 33 of 55

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For each process in your management system and for each applicable topic within that process, create a custom checklist to ensure the clause is effectively implemented and controlled.
Sometimes what you observe while looking at one topic triggers a question about another topic and you need a place to capture those notes and observations.

As stated in ISO 19011:2011 “…checklists and forms should not restrict the extent of audit activities, which can change as a result of information collected during the audit.”

If this page is needed to expand my notes from the Release of Products topic on page 33 I would number this page 33A so that I could keep my notes organized.
More Checklist Guidance

ISO 19011:2011 Appendix B

• **B.4 Preparing work documents**

  When preparing work documents, the audit team should consider the questions below for each document.

  a) Which audit record will be created by using this work document?
  b) Which audit activity is linked to this particular work document?
  c) Who will be the user of this work document?
  d) What information is needed to prepare this work document?

• For combined audits, work documents should be developed to avoid duplication of audit activities by:

  • — clustering of similar requirements from different criteria;
  • — coordinating the content of related checklists and questionnaires.

• The work documents should be adequate to address all those elements of the management system within the

• audit scope and may be provided in any media.
B.4 Preparing Working Documents

• The cover page of our checklist defines the audit record created by the checklist as well as the date of the audit, etc.

• Our audits are combined audits by definition, integrating the requirements of ISO 9001, ISO 14001, OHSAS 18001, 20 Step, ICRF etc. so our checklist has been “developed to avoid duplication of audit activities.”

• The example checklist being provided to you covers only ISO 9001. It will get you started. Your next step is to integrate your specific business requirements and think through how to best define your audit checklist using the guidance from ISO 19011.
Final Comments on the Checklist

• Aligning the checklist to the work process flow chart is a key point
• For each process (e.g. QA Lab) defining what topics/clauses apply must be done
• This example checklist is organized and aligned to the example process diagram. It covers all of the clauses of ISO 9001:2015 where they were determined to be applicable.
• Once your process flow is defined, you will probably need to move certain pages of the checklist around and add additional pages to certain process steps to make the checklist fit your business needs. While the content is all there, you really need to make it fit your organization.
End of Session 1

Some thumb drives will be available with the tools presented today at the end of the second session.

Coming up in Session 2: Auditor Competence, Audit Planning, & Audit Reporting tool