Verification Auditing

Inputs

VERIFIED

Processes

Outputs

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Verification Audits

“little q”
- Process audit
- Product audit
- Service audit

“Big Q”
- System audit
- Integrated audit

Tactical

Strategic
System Audit

Process Audit

Product Audit
Verification Audit

Process Audit

Product Audit
Verification Methods

- Audit?

Other methods?
Verification Audit

- The act or process of verifying product and service characteristics by means of observation and examination
- Means to confirm and authenticate actions
- Isolated activities or part of project execution
- Yes-No outcomes
Why Verify?

- Standards require it
- Lower risk of failure
  - product/service
  - process
- Prudent due to qualitative nature
  - amount transacted, not reversible, nature of product or service (i.e. medical, nuclear).
- Business/relationship environment

Or increase?
Outsourcing

- Reliance on critical products and services
- Organizations with different goals, skills, values, cultures, management styles
- Tomorrow

*More options but advantages must be verified*
Field Failure

- Broken spring to 9 month old saltwater- ready trolling motor. Spring engages locking mechanism during operation and storage. Used less than 12 times.
Project Design/ Construction

• Outsource elements of design
• Verify materials and services used in implementation/construction of project design/plan
In-house verification/validation

- Verify process inputs, outputs and performance
  - complexity
  - not able to verify by inspection or test
  - critical due to negative consequences

FMEA
Verification Audit Preparation

- Criteria
  - procedures, methods, standards
  - product/service specifications
  - product/service performance
- Approved Equipment? How approved?
- Qualifications of personnel/operators
  - method?
- Ongoing process verification
Internal Audit Objectives

- Verify process
  - special test or procedure
- Verify product characteristics/ performance
- Verify project implementation
  - new product
  - construction
- Verify defects/ nonconformities addressed
- Verify training, equipment capabilities, process setting(s)
2nd Party Audit Objectives

- Verify supplier processes
  - calibration process
  - heat treatment
  - maintenance

- Verify supplier product/service characteristics or performance measures

- Verify conformance to contract requirements

- Verify nonconformities have been addressed

- Verify material sources and traceability

Others?
3rd-Party Audit Objectives

- Approve/Disapprove *process* for license or certification
- Approve/Disapprove *product* or service for license or certification
Scope

- Product, service, process
- Internal or supplier
- One time, many times, depends
Auditing Strategies

Project and Department Activities

- Construction Project
- Implementation of a new method
- Oper.
- Treating
- Checking
- Sawing
- Finishing
- Packing
- Shipping
Verification Audit Preparation

- Auditor
  - product (equipment) knowledge
  - process/service knowledge (good practices)
- How many auditors?
  - how many processes?
Verification Audit Preparation

- Contact the auditee
  - request documents related to product/service or process
- Verify
  - coordinate time of visit
- Surprise?
Understand the process

- Prior experience
- Use tools to evaluate
Tools

Fishbone Diagram/Cause and Effect Diagram

Turtle Diagram

Spider Diagram
Turtle Diagram for Realization

People (who):
- competence
  (skills, knowledge and training)

Inputs:
- product
- material
- information
  (drawings, specifications)

Methods (how):
- step-by-step
- procedures
- standards

Outputs:
- completed service
- finished product

Materials/Equipment/Service (what):
- defined and approved
- maintained
  (in-sourced and outsourced)

Measures (results):
- rate or units completed
- rate or units defined
- rate or units monitored

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CE Diagram

Exhibit C: Cause-and-Effect Diagram

IMPROPER PACKAGE LABEL (Code & Series)

MATERIALS
- Uneven Surface
- Poor Package Design

METHODS
- Equipment Bypassed
- Select Wrong Label
- Label Not Changed
- No Standards

IMPROPER LABEL

EQUIPMENT
- Too Much Ink
- No Ink
- Worn Roller
- Frequent Breakdowns

MEASUREMENT
- Warehouse Inspection
- Loader Inspection
- Cause Enumeration Type

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Tree Diagrams - for Processes

Grouping

Work Process

People
- Staffing
- Training
- Qualification

Methods
- Standards
- Procedures
- Updated

Materials
- Defined
- Procured
- Certified/Approved

Measures
- Defined
- Product
- Process
- Monitored

Equipment
- Approved
- Maintained
- Calibrated
Check-Diagram for Production

Mfg. Run Control

People
- Staffing, 6.1
- Training 6.2.2
- Qualification 6.2.2

Methods
- Standards
  - ISO 9001
- Procedures
  - MFG7511
- Updated
  - 4.2.3
- Sufficient, 4.2.1
- Process Changes
  - 7.3.3, 7.3.7
- Identification & Traceability
  - 7.5.3
- Storage, 7.5.5
- Nonconforming, 8.3
- Corrective Action, 8.5.2

Materials
- Defined, 7.1
- Procured, 7.4
- Certified/Approved
  - 7.4.1, 7.4.3
- Customer
  - 7.5.4

Measures
- Defined
  - MFG-SP05
- Product
  - 7.5.1
- Process, Run
  - Monitored
    - 8.2.3, 8.2.4
    - Record, 4.2.4

Equipment
- Approved
- Maintained
  - 9.3, 7.5.2
- Calibrated
  - 7.5.1, 7.6

Environment
- Safety, 6.4
- Ergonomics, 6.4
- Health Facilities
- Appropriate
Spider Diagram

- **Products**
  - Records
  - Revalidation
  - Process Approved
  - Change Controlled

- **Materials**
  - Setup/Startup
  - Pans
  - Standards
  - Operating Methods

- **Methods**
  - Staffing
  - Competency

- **People**
  - Staffing
  - Experience
  - Skills
  - Education
  - Training
  - Re-certification/Certification

- **Equipment**
  - Approved
  - Maintained
  - Preventive and Predictive Maintenance Program

- **Operations**
  - Calibration, accurate
  - Documentation, operating instructions
  - FMEA, Error Proof
  - Change control, documents, process, product

- **Environment**
  - Safety
  - Environmental Aspects and Impacts
  - Management Support

- **Measures**
  - Defined and understood
  - Product/Process
  - Output rates
  - Capacity
  - Criteria and actions

- **Process 1**
  - Validated
  - Verified, Approved
  - Records
  - Revalidation
  - Process Approved
  - Change Controlled
  - Nonconforming product actions
  - Staffing
  - Experience
  - Skills
  - Education
  - Training
  - Re-certification/Certification
  - Setup/Startup
  - Pans
  - Standards
  - Operating Methods
  - Validated
  - Verified, Approved

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Checklist

- Checklist
- Diagrams
- Flowchart
Receive/ View Schedule

Set-up Machine per work order and procedure. Shift Mechanic

Verify mold, conditions and materials, approve on WO. Line Sup. and operator [MFG7511:2.2]

Set up area for run. Check WO for totes, markers, materials, instruments, reject box, etc.. Operator [MFG7511:2.3]

Start up machine and sample for first article. Adjust controls as necessary. Operator MFG7511:2.4

Operate per schedule. Follow WO. Take samples and test as directed. Sort rejects. Operator [MFG7511:2.6]

Inspect sample and report results to Operator. MFG7511:2.5

Identify and prepare scrap Salvage Operator. MFG7511:2.7
Documentation

- Plans
- Methods
- Output criteria
  - specification, list
  - drawing, picture, diagram
  - desired result or avoidance of undesired result
- Non conforming product/service controls

Other criteria?
History

- History
  - defects and corrections made
  - internal and field failures
  - process and product changes
  - operator/technician changes
  - corrective actions
  - safety
  - environmental aspects
  - customer complaints
Performing

- Meet with area supervisor/ manager
- Observe process
- Sample product, records and people
- Interview (if process)
- Collect evidence
- Verify characteristics
- Verify outputs

Validate?
Make Observations
Performing plus

- Mistake proofing
- Lean/ performance indicators
- Opportunities for improvement
- Good practices
Process Performance Indicators

- **Start**
- **Finish**
- **Waiting**
- **By-pass**
- **Redoing**
- **Rejecting**

**Movement**

parts and people

**Tracing?**

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Report

- Keep it short and to the point
- Address objectives/purpose
# Process Audit Report and Corrective Action Record

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<th>Status</th>
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What should you audit?

- Based on Risk
  - direct dollars (cost)
  - indirect dollars (customer goodwill)
- Areas of weakness
- Legal, regulatory requirements
- Consistent with organization’s risk policy
- Consider alternate less expensive verification methods
Risk

Event—likelihood—consequences (in **dollars**)
Prevention—acceptable--consequences

Use **collaborative approach** involving a wide cross-section of interested parties and participants

*Rebar not installed correctly, mix-up of organ donor records, spring not heat-treated, contamination, metal fatigue, discoloration..*
Results come from checking, not expecting.

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