PRODUCT ESCAPES

HOW AUDITORS CAN HELP TO MINIMIZE

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WHAT IS A PRODUCT ESCAPE?

Any product released by an internal or external supplier that is subsequently determined to be nonconforming to contract and/or product specification requirements. – IAQG International Dictionary

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WHY THE FOCUS ON PRODUCT ESCAPES?

Industries increased dependence on supply chain. Industry continues to see escapes.

Impacts of product escapes in the supply chain:
- Cause damage to reputation/customer satisfaction
- Cause delays in deliveries
- Cause increase cost
This International Standard specifies requirements for a quality management system when an organization:

a. needs to **demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements**, and

b. aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
CONTROL OF NONCONFORMING PRODUCT (8.7)

The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

... timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties.
HOW CAN AUDITORS SUPPORT THE INDUSTRY?

Focus on areas with known association with escapes
Evaluate customer complaints as part of audit planning
Be observant during the audit
AWARENESS DURING THE DURATION OF THE AUDIT

• Site tour
• Auditing production process
• Walking through an area to get to another area
• Audit trails following changes to product
• Flow down of customer specific requirements
FOD

Does the organization have a method to ensure that all components are consumed?

Containment trays

Release of exact quantities (kitting)
FOD

Does the organization have a method to ensure no tools are ‘left behind’?

Shadow box or shadow board

Tool crib

Tool identification
FOD

Does the organization have a way to ensure FOD does not enter orifices?

Caps
Taping
ESTABLISHMENT OF CRITERIA FOR WORKMANSHIP

Does the organization’s manufacturing documents adequately define the workmanship?

Use pictures

Sample boards
Does the organization ensure that the employees that are performing the work were not only trained but competent?

Demonstrate during training the ability to implement what was taught

Observation of performing the task
FAI – PRODUCTION PROCESS VERIFICATION

Does the organization verify the product realization process meets the design engineering requirements?

FAI done to engineering drawing not manufacturing drawing or plan

First piece inspection is not the same as Production Process Verification.
FAI – PRODUCTION PROCESS VERIFICATION

Are FAIs done when changes are made to the product?

Audit trails to follow to FAI include:

Changes in revision levels
Change in supplier
Change in tooling
Change in material
Change in NC program
Change in inspection method
Change in location of manufacturing
CUSTOMER REQUIREMENTS

Does the organization have an effective method to identify, and implement customer requirements?

Follow the audit trail from contract review to internal implementation:

- Record retention requirements
- Certification of conformance
- Country of origin
- Packaging
- Manufacturing processes
- Customer designated supplier
CUSTOMER REQUIREMENTS

Does the organization have an effective method to identify and flow-down customer requirements?

Follow the audit trail from contract review to external flow down:

Notice of escape
Record retention
Right of access
Certification of conformance
Country of origin
Product characteristics
Customer designated suppliers
CUSTOMER APPROVED PLANNING

Does the organization have a method to ensure customer approved planning is controlled?

Is it identified

Are there approvals for the latest changes

Flowed down to suppliers
SPECIAL PROCESSORS

Does the organization have adequate product verification activities for these suppliers?

Organization is responsible for these activities even if they are a customer’s approved source.

Was this evaluated as part of the risk when selecting the supplier?

More detailed purchase orders and provide access to specifications.
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SPECIAL PROCESSORS

Door Hinge
The cadmium plating specification called out on the drawing requires that heat treated parts must be stress relieved before plating if straightening or grinding have been performed. Stress relief must also be completed prior to shot peen. A supporting specification referenced in the specification also requires that MPI is performed after plating.
SPECIAL PROCESSORS

Stress relief was not performed.

Since the requirement was in the end plate specification – the plater assumed the customer had accomplished the stress relief and the customer assumed it would be done by the plater as it was in the plating spec.
WORK TRANSFERS

Does the organization have a process to plan, manage, and report when there is a change in the manufacturing location?

Have operators and engineers observe on site at current location before moving.

Hire key individuals from original manufacturing location.

Monthly meetings to monitor progress and address any needed clarifications.

Risk mitigation plan.

Maintain dual sources during transition period.
WORK TRANSFERS

Does the organization flow down requirements for notification of changes?

8.4.3.k  the need to notify the organization of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain the organization’s approval
MISTAKE PROOFING

Does the organization use standard work and mistake proofing practices?

Design process

Corrective Action

Manufacturing processes
TOOL CONTROL AND PREVENTATIVE MAINTENANCE

Does the organization have a process to validate tools prior to release to production and to maintain them?

Look at condition of tools

Look for regularly scheduled maintenance

Look for tools to be protected from damage while in use and storage

Do operators check for damage before using
OPERATOR SELF VERIFICATION

Does the organization ensure the controls over an operator self verification program?

Established criteria
Risk assessment
How were the processes chosen
How were the operators trained and verified as competent
What oversight has been established
CHANGE MANAGEMENT

Does the organization have a proactive and stable change management process?
Understanding of the nature of the change
Deployment of proactive tools and measurements
Robust verification process
Configuration management
Risk based oversight of process
**Boeing Supplier Quality**

**Top 13 Things You Can Do To Eliminate Escapes**

1. **Strong internal process for requirement consumption**
2. **Risk-based approach to change management**
3. **Mistake proof operations and products**
4. **Tool Control and Preventative Maintenance**
5. **“FOD protection” and “Clean as you go”**
6. **Conduct FAs against defined engineering**

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**Customer Expectations/Communications**

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**Top 13 Things You Can Do To Eliminate Escapes**

1. Ensure a strong internal process for requirements consumption
2. Ensure a proactive, risk-based approach to change management
3. Conduct thorough contract reviews with your suppliers to ensure they understand requirements that are flowed to them
4. Verify processes are in place to ensure work coming from special processors is to the correct specification and that the processors are in good standing
5. Ensure that any products with customer directed planning are clearly identified so that changes are not made without customer approval
6. Ensure FAs are conducted against the defined engineering – not planning!
7. Ensure your process for identifying delta FAs for any change affecting form, fit or function is effective
8. Require your suppliers and their sub-tier to formally notify you of Work Transfers
9. Employ a robust, proactive process for tool control and preventative maintenance
10. Relentlessly pursue standard work – “mistake proof” your operations and products
11. Incorporate both “FOD protection” and a “clean as you go” approach to FOD
12. Ensure strong quality controls over any Operator Verification program
13. Ensure new employees, or employees doing new work, receive the training needed to perform work flawlessly – the first time
Conclusion

Auditors can help support the industry to maintain cost, delivery, and reputation.

Many requirements of the standard support the control on nonconforming product other than just 8.7.

Keep a sense of awareness during audit planning and the entire audit duration.
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