Guidance

Scoring Criteria

The following audit scoring criteria have been used to identify the level of compliance with each requirement that is set out in the standard. In the 'Opportunities for Improvement' field, note down any situation or condition of the management system that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for the organization to improve its current status. In the 'Audit Evidence' field, fill in the evidence that you saw and your thoughts about the implementation and documentation. If any of the requirements are not applicable, please type 'N/A' to denote that the particular requirement is not applicable to the organization.

Compliant:	Yes, requirement fully documented and implemented. Adherence with the requirements of the standard or specification. No major or minor non-conformances found.
Opportunity for Improvement (OFI):	Minor gap, mostly documented and implemented The management system that may be weak, cumbersome, redundant, overly complex, or in some other manner, may, in the opinion of the auditor, offer an opportunity for an organization to improve its current status.
Minor Non-conformance:	Requirement partially implemented but no documentation or partially documented but not implemented. A non-conformity that, based on the judgment and experience of the auditor, is not likely to result in the failure of the management system or reduce its ability to assure controlled processes or products. It may be either a failure in some part of the supplier's management system relative to a specified requirement or a single observed lapse in following one item of a company's management system.
Major Non-conformance:	No provision, requirement not documented or implemented. The absence (omission, not addressed) or total breakdown (commission, failure, not implemented) of a system to meet a specified requirement. A number of minor non-conformities against one requirement can represent a total breakdown of the system and thus be considered a major non-conformity. Any non-compliance that would result in the probable shipment of a non-conforming product. Conditions that may result in the failure of or materially reduce the usability of the products or services for their intended purpose. A non-compliance that, in the judgment and experience of the auditor, is likely to either to result in the failure of the management system or to materially reduce its ability to assure controlled processes and products.

Requirements

An audit of customer related processes should be conducted at planned intervals in order to determine whether the process conforms to planned arrangements in order to determine whether the process is properly implemented and maintained and to provide process performance information to top management. Effective auditing requires the

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auditor to identify and record audit trails that will make a difference to the organization. The audit should begin with the process owner in order to understand how the process interacts with the other process inputs, outputs, suppliers and/or customers. The auditor should be able to determine whether the outputs are complete and that process measurements demonstrate whether all of the outputs are consistently fit for purpose and are efficiently managed. Do the customers agree with the outputs and the measures?

An audit of customer related processes is conducted at planned intervals to:

- Determine whether the process conforms to planned arrangements
- Determine whether the process is properly implemented and maintained
- Provide information on process performance to Top Management

Consider these points during the audit:

- Is there continuity between the various support processes?
- Is the task done consistently on a person-to-person or day-to-day basis?
- Do the interfaces between the departments operate smoothly?
- Does product information flow freely?
- Is the procedure right?
- Does it meet the requirements of the standard or specification?
- Is it helping the organization effectively?

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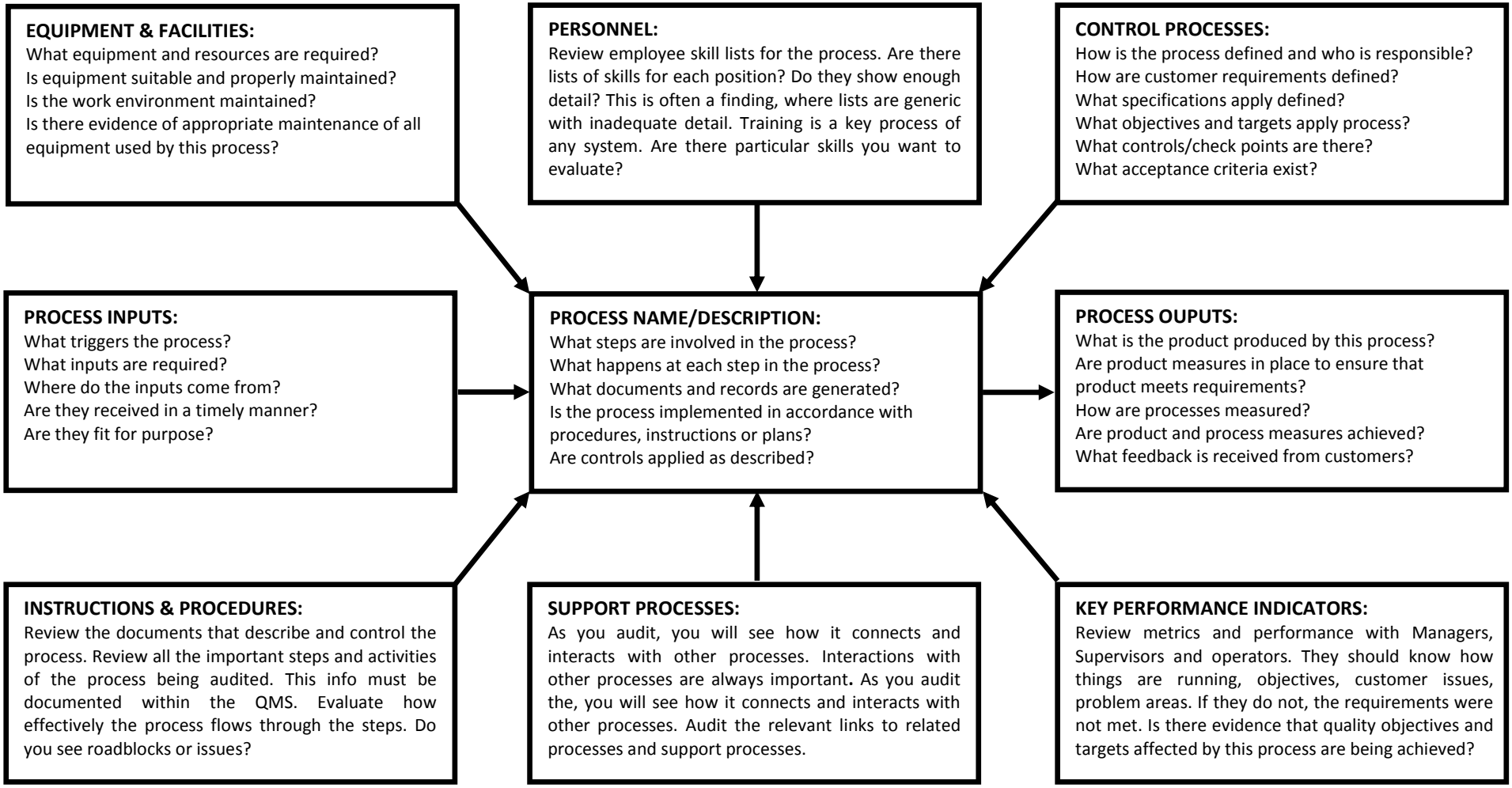
Process Audit Turtle Diagram



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Supplier Audit Questions

Quality Management

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
1	Is the quality system documented, controlled and maintained to clearly describe current practice?					Quality manual and all procedures show revision control (sign-offs & dates), history of changes
2	Do quality reports, trend charts and data analysis identify areas of opportunity and are used by management on a routine basis?					Product quality yield data, problems and corresponding improvement actions, status of preventive/ corrective/audit results
3	Are quality-performance targets clearly defined, included in the business plan and monitored for improvements?					Strategic and tactical objectives, goals, action plans, etc.
4	Does executive management participate in periodic quality system reviews that address quality related feedback from customers and internal quality metrics?					Analysis of field failures, inspection yields, resource needs, internal audit results, corrective action status, etc.

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Continuous Improvement

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
5	Are preventive actions taken based on the analysis of significant business trends, design reviews, customer satisfaction surveys or other meaningful inputs?					Management review meetings, goal setting, performance measurement, internal audits, action plans, customer surveys
6	Is there a formal approach used to actively pursue cost containment and other continual improvement activities throughout the organization?					Employee involvement/recognition program, Lean, Six Sigma, kaizen, SPC, 5-S, cost reduction programme
7	Is a corrective action system in place that provides root cause analysis and takes timely and effective action to prevent recurrence?					Corrective actions, trend charts, meeting minutes, non-conformance frequency & cost analysis
8	Does the corrective action system cover customer, internal and supplier issues?					Management review meetings and corrective actions

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Education & Training

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
9	Is the skill and education level required for each job documented and appropriate training provided?					Look for use of training aids and work instructions at work stations
10	Is employee qualification/certification maintained where the quality outcome of the process cannot be verified and is strongly dependent upon operator skill?					Qualification records, certification history
11	Are suitable methods used to verify training effectiveness?					Records of testing, production quality records, audit records, interview workers to validate training records
12	Are suitable records of maintained?					Job descriptions, job skills assessment, training records, training manuals

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Occupational Health & Safety

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
13	Does the health and safety management system address the safety of personnel without comprising the achievement of product quality requirements?					Procedure for training and communication and participation
14	Does the health and safety management system address the requirement for emergency planning?					Emergency preparedness and response plan, monitoring and performance measurements
15	Does the health and safety policy state the organization's health and safety objectives and management's commitment to continual improvement of H&S metrics?					Policies and procedures, health and safety trend charts, accident rate improvement history
16	Are procedures used for the on-going identification of hazards, the assessment of risks, and the implementation of necessary control measures?					Safety committee or group meeting minutes, accident investigation reports, safety audit reports

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Supplier Audit Checklist

Design & Development Support

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
16	Are customer needs and requirements incorporated into product designs and/or manufacturing processes?					Market studies, customer/end-user surveys, technical design reviews
17	Are Critical-to-Quality (CTQ) characteristics are identified, understood and records retained?					Process capability studies, process plan, manufacturing verification tests
18	Are product specifications and drawings generated, controlled and maintained for new or changed product designs?					Product characteristics, application requirements and other information for safe and proper use and disposal
19	Is design validation is an integral part of the design process and occurs prior to production release?					Design results, manufacturability, productivity and cost studies, confirmation that product fulfils its specified requirements or intended use or applications
20	Are human and technical resources are adequate to meet the requirements for design collaboration, tooling design and electronic drawing and data exchange?					Qualification of technical staff. Equipment/software capabilities, CAD

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Quality Planning

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
21	Are production samples inspected and provided to customers upon request?					Completed PPAP or similar forms, inspection reports, availability of qualified resources
22	Are customer production requirements and quality specifications are reviewed to ensure they can be met on a consistent basis?					Procedures, design/process review, capacity plans, resource plans, product test, storage, packaging and shipment requirements
23	Are reliability test plans developed and routinely followed?					Reliability test plans, test reports
24	Is testing is used to verify the design specifications, drive design improvements and provide an on-going check of materials and workmanship?					Improvement/corrective actions taken, design changes implemented
25	Is product reliability test data is available upon request and historical test performance data shows a highly stable process and product design?					Reliability test summary reports/charts

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Customer Documentation

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
26	Are new and revised customer specifications reviewed and implemented in a timely manner?					Technical review of methods to be used, capability studies on similar parts, documented review procedure
27	Are current process control documents in place and used for production start-up and continuing production?					Specifications, engineering drawings, change notices, work instructions and specifications as applicable
28	Does customer notification/approval occur for changes to control plans, manufacturing site, product transfers, raw material or product obsolescence?					Customer notification procedure on major changes
29	Is there a record control system is in place for the identification, storage, protection, retrieval, retention time, and disposition of quality records?					Document control procedure
29	Are quality records maintained?					List of records to be kept with retention periods specified

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Procurement

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
30	Is there a formal process used for the selection, qualification and re-qualification of suppliers?					Supplier quality audits and corrective actions, engineering testing, approval records, production trials
31	Are purchases from unapproved suppliers prevented by a properly controlled and available approved supplier list?					Approved supplier list, procedures, production material receipt records
32	Are preventive actions taken to continuously improve performance of the supplier base?					Supplier quality performance analysis, performance trends, supplier audit reports
33	Does the supplier assurance system ensure that all purchased product or material conforms to defined specifications and applicable regulatory or customer requirements?					Receiving inspection, supplier audits, source inspection, qualification testing, Certificate of Compliance, component marking, labelling, etc.
34	Does a system exist for the identification, verification and protection of customer supplied product that includes notifying the customer if product is damaged or lost?					Procedures, segregation during storage, limited and controlled access to stored inventories

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Incoming Material

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
35	Is receiving inspection performed per documented procedures and detailed work instructions?					Procedures, inspection instructions resources (manpower and equipment) allocated for incoming inspection
36	Is inspected material adequately identified as to acceptance or rejection and traceable to receiving inspection report?					Quality control label, marking or use of designated hold area as indicated in the procedure
37	Do supplier corrective action requests requiring root cause investigation show responses are analyzed?					Availability of written procedure, standardized corrective action form, analysis of corrective action cycle time and closure measurements

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Manufacturing Quality

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
38	Is there is a formal method used to qualify new or rebuilt production equipment prior to production use?					Qualification plan that includes established goals for process yields. Records of process capability, review and approval
39	Are control plans used to plan and deploy inspection and test functions throughout the production process?					Process flow chart, statistical tools, key inspection points, inspection frequency, inspection/test method, gaging used, acceptable yield rates
40	Are appropriate work instructions are available where needed that accurately describe all work methods including inspections and tests to be done during production?					Sample size, frequency, method, document control dates/revision level
41	Are appropriate inspections, tests and process adjustments made per applicable work instructions to verify conformance at key points throughout the process and prior to shipment?					Records of inspections performed at incoming, first piece, in-process and/or final inspection or test
42	Is the inspection and process status of the product identified and maintained throughout the production process?					Batch records, travellers, tags, labels, product markings or use of designated and identified areas
43	Are customers notified of low yield production lots or issues that affect product reliability?					Corrective actions, records of customer notifications, reliability test data

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Process Control

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
44	Are key part characteristics and process parameters are reviewed and statistically based controls and/or problem solving tools are used to control variation?					Histograms, run charts, SPC charts, pareto analysis, cause and effect diagrams, mistake proofing, reaction plan & process corrections.
45	Are written improvement plans are implemented to reduce sources of variation?					Documented reaction plan and process corrections. SPC trend charts showing current status vs. goals, improvement plans
46	Is process capability is measured and actions are taken to maintain established minimum Cpk/Ppk targets?					Documented process capability studies and results (actual vs target Cpk/Ppk)
47	Are out of control conditions are noted on charts and documented corrective action is taken to bring the process back into control?					Control charts

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Nonconforming Material

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
48	Are nonconforming materials, parts and assemblies are segregated (where practical) and identified to prevent unapproved use?					Tags, marking, controlled staging areas
49	Is reworked material, parts and assemblies are re-inspected or re-tested to confirm compliance to requirements?					Inspection record, tag and stamp
50	Is the use of nonconforming material is documented under a formal waiver or concession system?					Written procedure, waiver or concession records
51	Is product traceability maintained to facilitate problem evaluation and corrective action?					Serial number records, lot number, date of manufacture, labelling and marking of containers or product
52	Is there a positive recall system to notify customers of nonconforming product that has already been shipped?					Documented procedure and review of system

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Supplier Audit Checklist

Monitoring & Measurement

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
53	Are gauge repeatability and reproducibility studies conducted to verify suitability of measuring devices for their use in checking product quality or control of processes?					GR&R studies, reports
54	Are measuring devices and gauges and test equipment are routinely calibrated and controlled per documented procedures?					Calibration stickers and records, positive identification or segregation of out-of-calibration devices, and inventory, location & status records.
55	Are gauges and test equipment calibrated against standards traceable to a recognized regulatory body or agency?					Calibration procedures, and calibration stickers and other records
56	Are assessments made to check the validity of previous measurements done on products where out-of-calibration measuring devices were used?					Assessment records and corrective actions
57	Are appropriate controls are in place to verify the suitability and accuracy of computer software prior to initial use in checking product quality or control of processes?					Verification methods and records, revision levels, distribution/use control

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Maintenance

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
58	Are tools stored in an appropriate, clearly defined area, with systematic tracking that provides traceability, particularly of customer-owned tools and equipment?					Review of storage area, labelling, tooling records
59	Does a formal preventive maintenance system (PM) exist for production equipment, tools and fixtures?					Review of system, PM plans, PM schedule and compliance results
60	Is the preventive maintenance schedule is followed since product cannot be made with tools that are outside of maintenance period?					No equipment, tools, or fixtures are in use that are outside TPM schedule, or have unclear status

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Environment

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
60	Does a documented environmental policy exist that includes a commitment to comply with relevant environmental legislation and regulations and to continual improvement and pollution prevention?					Environmental policy statement document
61	Is there is an environmental management system that ensures compliance to all applicable government regulations and there are no outstanding, unresolved violations of these regulations?					Records of agency/government inspection, procedures for measuring and monitoring environmentally sensitive activities.
62	Is there a system is in place to minimize the use, disposal and emissions of hazardous chemicals are not used in the manufacturing process?					Record of purchases, waste stream and consumption; inventory control procedures.
63	Is there an on-going emphasis is placed on using materials that are; compliant with applicable regulations like WEEE, biodegradable, recyclable, re-usable, reduces pollutant emissions at the point of use?					Records/use of; non-hazardous (RoHS/WEEE compliant) materials in production, biodegradable materials, returnable containers or packaging, recycling program, packaging materials made of recycled materials.

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Supplier Audit Checklist

Storage & Packing

QUESTION No.	Audit Question	Finding (Tick)			Audit Evidence	What to Look For
		COMPLIANT	MINOR N/C	MAJOR N/C	Provide reference to documentation or records that justify the finding	
64	Are areas around the facility clean and orderly and are tools and equipment properly stored and readily available for use and is lighting and air quality are adequate?					Observe production, office & product storage areas. (Sort, Set-in-order, Shine, Standardize, Sustain + Safety)
65	Is proper equipment and methods used to prevent product damage or loss in all phases of the material handling process?					Observe handling and transit of raw material, work-in-process, and finished goods.
66	Are documented procedures followed to ensure proper control and preservation of handling, storage (FIFO), packaging, and delivery of product?					FIFO practices are defined, packaging specifications, test results, handling and storage procedures.
67	Is the suitability of product packaging reviewed and concerns communicated to the customer prior to initial production shipment?					Technical review, packaging/shipping tests, packaging work instructions, carton strength tests
68	Is stored product/material periodically inspected, and where applicable, actions are taken to prevent deterioration per documented procedures?					Lists of shelf-life sensitive materials. Look for poor storage conditions and damage. Handling procedures
69	Have contingency plans been developed that describe actions to be taken in the event of a major interruption of the manufacturing process?					Process covering utility interruptions, labour shortages, key equipment failures, major production issues

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Findings Summary

Non-conformance

No.	ISO/Specification Ref.	Summary	Root Cause	NCR No.	Rectification Date

Corrective Action

No.	ISO/Specification Ref.	Summary	Root Cause	CAR No.	Rectification Date

Preventive Action & OFI

No.	ISO/Specification Ref.	Summary	Root Cause	PAR No.	Implementation Date

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Observations, Comments & Notes

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