

INTERNAL PROCESS VERIFICATION

- A. Management System
- B. Management Responsibility
- C. Resource Management
- D. Product Realisation
- E. Design & Development
- F. Product Provision
- G. Process Monitoring

#	Question	Answer	O.K.?
A MANAGEMENT SYSTEM			
1	Is the management system applications a series of process controls, and that they are in place throughout the organisation. Are processes identified and are charts produced to this effect. Are copies of these charts in place in strategic locations for use by personnel.	New system breaking down processes into sections being introduced. Y	
2	Check the documented system for its policies and objectives, and its control of the above processes and procedures. Is the Process Manual up-to-date and does it indicate the company's objectives. Are procedures in place Are they available, to all personnel Are other company documents i.e. Technical Drawings, Standards; Operators Manuals etc. also available and controlled	BSI Non conformance on objective not clear, being added to the new process Break Down. Manual being upgraded. Intra Stats	YES
3	Are documents controlled by version & date status; Is the latest revision is the one that is available Is the Managing Director or designate still giving final approval) for document changes. Are all documents in the library controlled numerically and by barcode Is a tracer file still used to control withdrawals and re-entry. — NO Is disaster planning still. — YES Doc 9546 / SYSTEM Backup Process	intraStats	YES
4	Are any records produced controlled for identity and easily retrieved	Y	Yes
B MANAGEMENT RESPONSIBILITY			
1	Is Top management showing full commitment to the overall system, and that communication lines are in place.	Y Issues	YES
2	Are all customer requirements defined and met.	Order checking Active List Reviews	YES
3	Is all planning of the processes and objectives undertaken at all levels within the organisation, and is it measurable.	Being Re-worked.	YES
4	Does the person responsible for the management systems have the authority to implement actions, and reports directly to top management with the need for these actions	Y	YES
5	Are reviews of the management system undertaken regularly and the results, and actions, relayed throughout the organisation.	Live Reviews now continuous	YES
6	Are all required actions are undertaken timely and closed out where appropriate.	Y Issues	YES
4	Are all output requirements in such a format, that verification against inputs is applicable and appropriate, and that Fitness-for-Purpose is validated.	Y QA Reports	YES
5	Are actions recorded against verifications completed in a timely and responsible manner.	Issues / Auto Management weekly	YES
6	Are validation processes in place, and that they are determined in accordance with the relevant requirements.	TASK and Audit Rolling issues	YES
7	Are design changes recorded and all the relevant information filed in the appropriate places.	intraStats	YES
C RESOURCE MANAGEMENT			
1	Has top management established a mechanism for identifying and providing required resources, training etc.	IntraStats training system	YES
2	Does this includes existing and new personnel.	New Process Overview Y	YES

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3	Has top management identified the competency levels and attributes required for existing and new personnel.	Y Processes / QA Procedures	YES
4	Is the competency of personnel monitored and verified, and the appropriate records are maintained	Y QA Reviews	YES
5	Is the need for equipment, plant, services etc. identified and acted upon where necessary.	Y Issues / maintenance Headers	YES
6	Has the basic working infrastructure has been planned with conformity to requirements in mind.	Y	YES
5	Check validations of unknown process control criteria.	N/A	N/A
6	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	Y Barcode Product Tracking	YES
7	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Returns System.	
8	Is the process for monitoring and measurement of product is in place at all stages throughout the production process.	Y END LEVEL QA shelf locations	YES
9	Is the process for control of measuring equipment adequate for the monitoring of product verifications.	Calibration index	Yes
10	Are validity processes are in place to safeguard product integrity.	Y	YES
D PRODUCT REALISATION			
1	Is the planning process for the realisation of product undertaken at the relevant stages.	Y Production Reviews	YES
2	Does planning identify documentation, testing and other such activities as required, and that all appropriate records are maintained.	Y	YES
3	Are all customer requirements being addressed, including statutory and regulatory, and that the capabilities are identified to meet those requirements.	Y	YES
4	Establish that mechanisms are in place to review all customer requirements prior to any commitments by the organisation.	order checking.	YES
5	Check that there are adequate arrangements for customer communications and feedback.	Y	YES
4	Is collation and analysis of all relevant data determined and effective, and corrective actions identified.	Review Feedback Customer Complaints	YES
5	Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.	Issues Reviews	YES
6	Does the organisation have preventive measures in place to control potential non-conformities.	Y Order Checkings QA Reports Reviews	YES
7	Are all the above actions are reviewed adequately?	Y	YES
E DESIGN & DEVELOPMENT			
1	Are procedures in place to ensure adequate planning of product design, and that all relevant stages are identified.	Y	YES
2	Are the interfaces and assignments of responsibilities identified.	Y New	YES
3	Are all input requirements determined, and documentation identified.	Y	YES
4	Are all output requirements in such a format, that verification against inputs is applicable and appropriate, and that Fitness-for-Purpose is validated.	Y Design	YES
5	Are actions recorded against verifications completed in a timely and responsible manner.	Y	YES
6	Are validation processes in place, and that they are determined in accordance with the relevant requirements.	Y	YES
7	Are design changes recorded and all the relevant information filed in the appropriate places.	Instructions	YES
F PRODUCT PROVISION			
1	Are supplier profiles adequate and appropriate for the organisation, and are they monitored, for their ability to provide the requirements, and is this monitoring controlled.	Supplier Review New Log of History + changes + PMS Reports	YES
2	Is all the required information necessary forwarded to suppliers in the correct format, and that is this authorised prior to order placement.	OPERA P.O.	YES
3	Are goods and services received correct to the requirements stipulated.	goods in / QA Procedures	YES
4	Are the provisions available suitable for control of production and service, including procedures and equipment etc.	Yes	YES
5	Check validations of unknown process control criteria.	N/A	N/A

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6	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	intrastats tracking	YES
7	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Returns tracking.	
8	Is the process for monitoring and measurement of product is in place at all stages throughout the production process.	final QA	YES
9	Is the process for control of measuring equipment adequate for the monitoring of product verifications.	Calibration index	Yes
10	Are validity processes are in place to safeguard product integrity.	Y	YES
G PROCESS MONITORING			
1	Are mechanisms are in place to monitor all relevant processes, including customer satisfaction, and to verify these against known criteria.	new process system being added.	YES
2	Are controls in place for non-conforming product and processes, are adequate to prevent unintended uses.	Quarantine areas are in place	YES
3	Where non-conforming product / process has been detected is appropriate action taken.	Y	YES
4	Is collation and analysis of all relevant data determined and effective, and corrective actions identified.	Y Non Conformance Reviews	YES
5	Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.	Y Issue Reviews	YES
6	Does the organisation have preventive measures in place to control potential non-conformities.	Y PO Log / order checking QA Reviews	YES
7	Are all the above actions are reviewed adequately.	Y	YES