

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	<p>Is the management system applications a series of process controls, and that they are in place throughout the organisation.</p> <p>Are processes identified and are charts produced to this effect.</p> <p>Are copies of these charts in place in strategic locations for use by personnel.</p>	Yes	
2	<p>Check the documented system for its policies and objectives, and its control of the above processes and procedures.</p> <p>Is the Process Manual up-to-date and does it indicate the company's objectives.</p> <p>Are procedures in place</p> <p>Are they available to all personnel</p> <p>Are other company documents i.e. Technical Drawings, Standards; Operators Manuals etc. also available and controlled</p>	Intra Scales	YES
3	<p>Are documents controlled by version & date status;</p> <p>Is the latest revision is the one that is available</p> <p>Is the Managing Director or designate still giving final approval for document changes.</p> <p>Are all documents in the library controlled numerically and by barcode</p> <p>Is a tracer file still used to control withdrawals and re-entry.</p> <p>Is disaster planning still.</p>	Intra Scales	YES
4	Are any records produced controlled for identity and easily retrieved	Intra Scales	Yes
B MANAGEMENT RESPONSIBILITY			
1	Is Top management showing full commitment to the overall system, and that communication lines are in place.	Y	YES
2	Are all customer requirements defined and met.	order checking	YES
3	Is all planning of the processes and objectives undertaken at all levels within the organisation, and is it measurable.	Y measurable?	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.	Y	YES
6	Are all required actions are undertaken timely and closed out where appropriate.	Y	YES
7	Are all output requirements in such a format, that verification against inputs is applicable and appropriate, and that Fitness-for-Purpose is validated.	issues	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.	Intra Scales	YES
C RESOURCE MANAGEMENT			
1	Has top management established a mechanism for identifying and providing required resources, training etc.	Y	YES
2	Does this include existing and new personnel.	Y	YES

INTERNAL PROCESS VERIFICATION

3	Has top management identified the competency levels and attributes required for existing and new personnel.	Y	YES
4	Is the competency of personnel monitored and verified, and the appropriate records are maintained	Y	YES
5	Is the need for equipment, plant, services etc. identified and acted upon where necessary.	Y	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 Tracking	YES
7	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Returns Barcodes	
8	Is the process for monitoring and measurement of product is in place at all stages throughout the production process.	QA Records	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.	QA	YES
D PRODUCT REALISATION			
1	Is the planning process for the realisation of product undertaken at the relevant stages.	Y	YES
2	Does planning identify documentation, testing and other such activities as required, and that all appropriate records are maintained.	initial stages	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.	Feedback Reviews	YES
4	Is collation and analysis of all relevant data determined and effective, and corrective actions identified.	Y issues	YES
5	Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.	Y issue monitoring in meetings	YES
6	Does the organisation have preventive measures in place to control potential non-conformities.	Y QA.	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	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	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.	initial stages	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 PMS Reviews	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 ORDERS	YES
3	Are goods and services received correct to the requirements stipulated.	OPERA GOODS IN	YES
4	Are the provisions available suitable for control of production and service, including procedures and equipment etc.	Y	YES
5	Check validations of unknown process control criteria.	N/A	N/A

INTERNAL PROCESS VERIFICATION

6	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages.	Yes	YES
7	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Y	
8	Is the process for monitoring and measurement of product is in place at all stages throughout the production process.	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.	Y	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 Quarantined/Retained	YES
4	Is collation and analysis of all relevant data determined and effective, and corrective actions identified.	Task 114	YES
5	Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.	Yes	YES
6	Does the organisation have preventive measures in place to control potential non-conformities.	Yes	YES
7	Are all the above actions are reviewed adequately.	Yes	YES