Sections to be Audited	How is Audit carried out	Frequency
Purchasing Controls Supplier/Sub-contractor Performance	Weekly meetings	
Goods Inward	STOCK MEETING	MONTHLY
Storage and Stock Control	Stock check annually	
Contract Review, Picking, Packing and Despatch	STOCK MEETING	
Sales invoicing	ORDER REVIEW	
Customer Complaints	Weekly meetings/complait file	
Calibration	Annual/or bi-annual checks	
Training	Employee self assessment	ANNUAL
Documentation and Records systems	/	ANNUAL
Classification of products	CE Technical Files	ANN.
Health & Safety	HSE audit and Risk assessment	ANN
Non conformances & Corrective Actions	Complaints file/Intrastats	MONTHLY
Design	Requirement charts in Intrastats	ANNUAL
CE & Technical files	Requirement charts in Intrastats	ANN
Review of Responsibilities	Employee assessment	YEARLY
Resources required	Weekly meetings	
New products	Weekly meetings	
New services	Weekly meetings	
Space	Weekly meetings	
Test Equipment	Weekly meetings	
Space	Weekly meetings	
Quality Planing	Weekly meetings	
Achievement of Quality Policy	Management review	
Advisory notices & recalls	Complaints file	
Vigilance System	Weekly meetings	
Complaints	Weekly meetings	
Repairs (levels & throughput times) Servicing	Weekly meetings	
Surveillance reply cards	Weekly meetings	
Changes to the Quality Management System	Weekly meetings	
Changes to CE marked products	AS REQUIRED	
Management Review	Directors meeting	

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	Are the management system applications a series of process controls, and are they in place throughout the organisation. Are processes identified and are charts produced to this effect. Are copies of theses charts in place in strategic locations for use by personnel?	Company has processes for every area and action Yes Yes	
2	Has the document system changed since last Audit If yes has its policies and objectives changed Has control of the above processes and procedures changed? Is the Process Manual up-to-date and does it indicates the company's objectives. Are procedures are in place and being used Are they available, to all personnel Are other company documents i.e. Technical Drawings, Standards; Operators Manuals etc. also available and controlled	Changing to Electronic No Quality statement valid Increased with centralisation M.D. Being updated Yes Yes electronically Yes electronically Yes electronically and paper	
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 Is a tracer file still used to control withdrawals and re-entry. Is disaster planning still current	Yes Intrastats Yes Intrastats Yes Yes Yes Yes	
4	Are all records produced, controlled for identity and easily retrieved	Yes	
B	MANAGEMENT RESPONSIBILITY		
1	Is Top management showing full commitment to the overall system, Are communication lines in place?	Top management write it Yes total access up & down	
2	Are all customer requirements defined and met.	Goldmine/Intrastats/Opera	
3	Is all planning of the processes and objectives undertaken at all levels within the organisation, and is it measurable.	Weekly management meetings Yes Intrastats	
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	Person is Top management	
5	Are reviews of the management system undertaken regularly and the results, and actions, relayed throughout the organisation.	Regularly Management meetings / Company meeting	
6	Are all required actions undertaken timely and closed out where appropriate.	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.	?	
5	Are actions recorded against verifications completed in a timely and responsible manner?	?	
6	Are validation processes in place, and are they determined in accordance with the relevant requirements.	?	
7	Are design changes recorded and all the relevant information filed in the appropriate places.	Yes CE Tech Files	
C	**RESOURCE MANAGEMENT**		
1	Has top management established a mechanism for identifying and providing required resources, training etc.	Weekly meetings	
2	Does this includes existing and new personnel.	Yes Induction	
3	Has top management identified the competency levels and attributes required for existing and new personnel?	Training records / Assessment	
4	Is the competency of personnel monitored and verified, and the appropriate records maintained	Yes Intrastats	

5	Is the need for equipment, plant, services etc. identified and acted upon where necessary.	Weekly meetings & Issues	
6	Has the basic working infrastructure has been planned with conformity to requirements in mind.	Yes HES ISO	
5	Check validations of unknown process control criteria.	No unknown	
6	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages?	Yes Bar codes of product and location	
7	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Bar codes/location/duckets	
8	Is the process for monitoring and measurement of product in place at all stages throughout the production process?	Yes Bar codes of product and location	
9	Is the process for control of measuring equipment adequate for the monitoring of product verifications?	Yes Bar codes of product and location / Calibration	
10	Are validity processes in place to safeguard product integrity? ?		
D PRODUCT REALISATION			
1	Is the planning process for the realisation of product undertaken at the relevant stages?	Design process/ Exhibitions etc.	
2	Does planning identify documentation, testing and other such activities as required, and are all appropriate records are maintained.	Yes Intrastats	
3	Are all customer requirements being addressed, including statutory and regulatory, and that the capabilities are identified to meet those requirements.	Opera/Goldmine	
4	Are mechanisms in place to review all customer requirements prior to any commitments by the organisation.	Contract review Opera/Goldmine	
5	Check that there are adequate arrangements for customer communications and feedback.	Opera/Goldmine	
4	Is collation and analysis of all relevant data determined and effective, and corrective actions identified.	Non conformance/ Complaints file	
5	Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.	Non conformance/ Complaints file	
6	Does the organisation have preventive measures in place to control potential non-conformities?	Management meetings	
7	Are all the above actions are reviewed adequately?	Management meetings	
E DESIGN & DEVELOPMENT			
1	Are procedures in place to ensure adequate planning of product design, and that all relevant stages are identified?	Design procedures	
2	Are the interfaces and assignments of responsibilities identified?	Identified at start of design	
3	Are all input requirements determined, and documentation identified?	Identified at start of design	
4	Are all output requirements in such a format, that verification against inputs is applicable and appropriate, and that Fitness-for-Purpose is validated.		
5	Are actions recorded against verifications completed in a timely and responsible manner?	?	
6	Are validation processes in place, and that they are determined in accordance with the relevant requirements.	Validation in Technical file	
7	Are design changes recorded and all the relevant information filed in the appropriate places.	Technical file	
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.	Intrastats suppliers efficacy recorded at management meetings	
2	Is all the required information necessary forwarded to suppliers in the correct format, and that is this authorised prior to order placement.	Countersigned by a director	
3	Are goods and services received, correct to the requirements stipulated.	Goods in	
4	Are the provisions available, suitable for control of production and service, including procedures and equipment etc.	Reviewed at weekly meetings	
5	Check validations of unknown process control criteria.	N/A	

6	Are there adequate mechanisms in place for the identification, handling etc. of product through all stages?	Bar codes/ duckets	
7	Are the controls in place to safeguard customer property adequate for full protection against loss damage etc.	Bar codes/ duckets	
8	Is the process for monitoring and measurement of product in place at all stages throughout the production process.	Bar codes/ duckets/worksheets	
9	Is the process for control of measuring equipment adequate for the monitoring of product verifications?	Calibration	
10	Are validity processes in place to safeguard product integrity?	Bar codes/ duckets/worksheets	
G	PROCESS MONITORING		
1	Are mechanisms in place to monitor all relevant processes, including customer satisfaction, and to verify these against known criteria?	Audits	
2	Are controls in place for non-conforming product and processes, are adequate to prevent unintended uses.	Quarantine areas	
3	Where non-conforming product / process has been detected is appropriate action taken.	Non conforming file	
4	Is collation and analysis of all relevant data determined and effective, and corrective actions identified.	Weekly meetings	
5	Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.	Weekly meetings	
6	Does the organisation have preventive measures in place to control potential non-conformities?	INTRASTATS	
7	Are all the above actions are reviewed adequately?	Weekly meetings	