

# 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.? |
|------------------------------------|--|--------------------------------------|-------|
| <b>A MANAGEMENT SYSTEM</b>         |  |                                      |       |
| 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>   | Yes<br>intraStaTs                    | YES   |
| 3                                  | <p>Are documents controlled by version &amp; 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 <sup>No need</sup>.</p> <p>Is a tracer file still used to control withdrawals and re-entry. <sup>No need</sup>.</p> <p>Is disaster planning still. <sup>DOC 9546</sup> <sup>DOC 9441</sup></p> | intraStaTs<br>controlled.<br>Yes     | YES   |
| 4                                  | Are any records produced controlled for identity and easily retrieved  | Yes                                  | Yes   |
| <b>B MANAGEMENT RESPONSIBILITY</b> |  |                                      |       |
| 1                                  | Is Top management showing full commitment to the overall system, and that communication lines are in place.  | Yes issues                           | YES   |
| 2                                  | Are all customer requirements defined and met.   | OPERA / ORDER checking               | YES   |
| 3                                  | Is all planning of the processes and objectives undertaken at all levels within the organisation, and is it measurable.  | Yes                                  | 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   | Yes                                  | YES   |
| 5                                  | Are reviews of the management system undertaken regularly and the results, and actions, relayed throughout the organisation.   | intraStaTs meetings & Rolling issues | 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.   | QA Forms intraStaTs                  | YES   |
| 5                                  | Are actions recorded against verifications completed in a timely and responsible manner.   | QA                                   | YES   |
| 6                                  | Are validation processes in place, and that they are determined in accordance with the relevant requirements.  | QA                                   | YES   |
| 7                                  | Are design changes recorded and all the relevant information filed in the appropriate places.  | intraStaTs                           | YES   |
| <b>C RESOURCE MANAGEMENT</b>       |  |                                      |       |
| 1                                  | Has top management established a mechanism for identifying and providing required resources, training etc.   | Y                                    | YES   |
| 2                                  | Does this includes existing and new personnel.   | Y                                    | YES   |

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| 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 maintenance reviews              | YES |
| 6                                 | Has the basic working infrastructure 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.  | Barcode 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 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<br>TATTS ON GAT  | Yes |
| 10                                | Are validity processes in place to safeguard product integrity.  | Y                                  | YES |
| <b>D PRODUCT REALISATION</b>      |  |                                    |     |
| 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.  | Intrastats documents<br>QA Records | 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<br>intradata        | YES |
| 5                                 | Check that there are adequate arrangements for customer communications and feedback.   | Feedback/customer<br>Reviews       | YES |
| 4                                 | Is collation and analysis of all relevant data determined and effective, and corrective actions identified.  | Intradata Reports<br>Issues        | YES |
| 5                                 | Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.   | Y meeting<br>Reviews               | YES |
| 6                                 | Does the organisation have preventive measures in place to control potential non-conformities.   | QA Order picking                   | YES |
| 7                                 | Are all the above actions are reviewed adequately?   |                                    | YES |
| <b>E DESIGN &amp; DEVELOPMENT</b> |  |                                    |     |
| 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.  | QA                                 | YES |
| 7                                 | Are design changes recorded and all the relevant information filed in the appropriate places.  | Intrastats                         | YES |
| <b>F PRODUCT PROVISION</b>        |  |                                    |     |
| 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<br>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 ORDER Processing             | YES |
| 3                                 | Are goods and services received correct to the requirements stipulated.  | goods in/OPERA/QA.                 | YES |
| 4                                 | Are the provisions available suitable for control of production and service, including procedures and equipment etc.   | Y intrastats                       | 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.                                 | Barcodes                         | 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.                       | Q.A.                             | 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 |
| <b>G PROCESS MONITORING</b> |   |                                  |     |
| 1                           | Are mechanisms are in place to monitor all relevant processes, including customer satisfaction, and to verify these against known criteria. | meetings / issues reviews        | 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.   | issues                           | YES |
| 4                           | Is collation and analysis of all relevant data determined and effective, and corrective actions identified.                                 | Y                                | YES |
| 5                           | Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements.                          | Y <i>see is immediately long</i> | YES |
| 6                           | Does the organisation have preventive measures in place to control potential non-conformities.  | Y <i>Barcode tracking</i>        | YES |
| 7                           | Are all the above actions are reviewed adequately.  | Y                                | YES |