

Internal Audit Check list

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INTERNAL PROCESS VERIFICATION

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|------------|--------------|-------------------------------------|-------------------|
| Created: | 17/May 1995 | Audit No 20 | VM3/COP VOP 13 |
| Revised: | 11 July 2011 | Last printed 02/05/2007 11:48:00 AM | Page 1 of 4 |
| Audit Date | | Auditor <i>DLAMB</i> | ISO 5.6 |

SEE VIAMED AUDIT!

INTERNAL PROCESS VERIFICATION

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

The following are questions that should be asked and answered either through Internal audits or at this meeting

| | | |
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| A MANAGEMENT SYSTEM | | ISO |
| Is 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 these charts in place in strategic locations for use by personnel. | Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 | 4.2 |
| 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 indicates the company's objectives. Are procedures are in place Are they available, to all personnel Are other company documents i.e. Technical Drawings, Standards; Operators Manuals etc. also available and controlled | Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 | 4.2 |
| Are documents are 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. | Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 Documentation & Records Audit 10 | |
| Is disaster planning still Valid | | |
| Are any records produced controlled for identity and easily retrieved | Documentation & Records Audit 10 | |
| B MANAGEMENT RESPONSIBILITY | | 5.1-5.6 |
| Is Top management showing full commitment to the overall system, and are communication lines in place. | Director control of QA system | |
| Are all customer requirements defined and met. | Contract Review Audit 2 | |
| Is all planning of the processes and objectives undertaken at all levels within the organisation, and is it measurable. | | |
| 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 Director | |

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| Are reviews of the management system undertaken regularly and the results, and actions, relayed throughout the organisation? | Yes, Issues, Message of Day, company meetings, management meetings. Management reviews | 4.2 5.6 8.2 8.4 8.5 ✓ |
| Are all required actions are undertaken timely and closed out where appropriate. | Required actions are now "Issues" (measured) | ✓ |
| Are all output requirements in such a format, that verification against inputs is applicable and appropriate, and that Fitness-for-Purpose is validated. | | ✓ |
| Are actions recorded against verifications completed in a timely and responsible manner. | Intrastat Issues | ✓ |
| Are validation processes in place, and that they are determined in accordance with the relevant requirements. | | |
| Are design changes recorded and all the relevant information filed in the appropriate places. | Design control Audit 3 | 7.3 ✓ |
| C RESOURCE MANAGEMENT | | 6.1-6.4 |
| Has top management established a mechanism for identifying and providing required resources, training etc. ✓ | Training Audit 8 | 6.2 |
| Does this include existing and new personnel? ✓ | Training Audit 8 | 6.2 ✓ |
| Has top management identified the competency levels and attributes required for existing and new personnel. | Training Audit 8 | |
| Is the competency of personnel monitored and verified, and the appropriate records are maintained | Training Audit 8 | ✓ |
| Are personnel responsibilities defined? | ?? In process of re-write 96.11 | |
| Do individuals know their responsibilities, reporting and communicating lines | Intrastat communication | ✓ |
| Verify that all procedures detail who is responsible for that function / scope. | | ✓ |
| Check that these responsibilities also cover personnel Health & Safety functions. | | ✓ |
| Is the need for equipment, plant, services etc. identified and acted upon where necessary. | Production meetings, management meetings | ✓ |
| Has the basic working infrastructure has been planned with conformity to requirements in mind. | Health & safety Audit 19 | 6.3 6.4 7.2 ✓ |
| Check validations of unknown process control criteria. | No unknown processes | ✓ |
| Are there adequate mechanisms in place for the identification, handling etc. of product through all stages. | COP/07 | ✓ |
| Are the controls in place to safeguard customer property adequate for full protection against loss damage etc. | COP/09 | ✓ |
| Is the process for monitoring and measurement of product is in place at all stages throughout the production process. | Production COPs | ✓ |
| Is the process for control of measuring equipment adequate for the monitoring of product verifications? | | ✓ |
| Are validity processes are in place to safeguard product integrity. | Bar coding traceability | ✓ |
| D PRODUCT REALISATION | | 7.1 7.5 |
| Is the planning process for the realisation of product undertaken at the relevant stages. | | ✓ |

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| Does planning identify documentation, testing and other such activities as required, and that all appropriate records are maintained. | <i>work- path way</i> | ✓ |
| Are all customer requirements being addressed, including statutory and regulatory, and that the capabilities are identified to meet those requirements. | Contract Review Audit 02 | 7.2 ✓ |
| Establish that mechanisms are in place to review all customer requirements prior to any commitments by the organisation. | Contract Review Audit 02 | 7.2 ✓ |
| Check that there are adequate arrangements for customer communications and feedback. | Contract Review Audit 02 | 7.2 ✓ |
| Is collation and analysis of all relevant data determined and effective, and corrective actions identified. | | 8.4 ✓ |
| Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements. | | ✓ |
| Does the organisation have preventive measures in place to control potential non-conformities? | | ✓ |
| Are all the above actions are reviewed adequately? | | |
| E DESIGN & DEVELOPMENT | | 7.3 |
| Are procedures in place to ensure adequate planning of product design, and that all relevant stages are identified? | Design control Audit 3 | 7.3 ✓ |
| Are the interfaces and assignments of responsibilities identified? | Design control Audit 3 | 7.3 ✓ |
| Are all input requirements determined, and documentation identified? | Design control Audit 3 | 7.3 ✓ |
| Are all output requirements in such a format, that verification against inputs is applicable and appropriate, and that Fitness-for-Purpose is validated. | Design control Audit 3 | 7.3 ✓ |
| Are actions recorded against verifications completed in a timely and responsible manner. | Design control Audit 3 | 7.3 ✓ |
| Are validation processes in place, and that they are determined in accordance with the relevant requirements. | Design control Audit 3 | 7.3 ✓ |
| Are design changes recorded and all the relevant information filed in the appropriate places. | Design control Audit 3 | 7.3 ✓ |
| F PRODUCT PROVISION | | |
| 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. | Purchasing Controls (Supplier Performance) Audit 5 | 7.4 ✓ |
| Is all the required information necessary forwarded to suppliers in the correct format, and that is this authorised prior to order placement. | Purchasing Controls (Supplier Performance) Audit 5 | 7.4 ✓ |
| Are goods and services received correct to the requirements stipulated. | Goods Inward Audit 9 | 7.4 7.5 8.2 ✓ |
| Are the provisions available suitable for control of production and service, including procedures and equipment etc. | Production Audit 15 | ✓ |
| Check validations of unknown process control criteria. | | ✓ |
| Are there adequate mechanisms in place for the identification, handling etc. of product through all stages? | Production Audit 15 | ✓ |
| Are the controls in place to safeguard customer property adequate for full protection against loss damage etc. | Production Audit 15 | ✓ |

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| Is the process for monitoring and measurement of product is in place at all stages throughout the production process. | Production Audit 15 | ✓ |
| Is the process for control of measuring equipment adequate for the monitoring of product verifications? | Calibration Audit 6 | ✓ |
| Are validity processes are in place to safeguard product integrity. | | ✓ |
| G PROCESS MONITORING | | 8.1-8.5 |
| Are mechanisms are in place to monitor all relevant processes, including customer satisfaction, and to verify these against known criteria. | | ✓ |
| Are controls in place for non-conforming product and processes, are adequate to prevent unintended uses. | Goods Inward Audit 9 | ✓ |
| Where non-conforming product / process has been detected is appropriate action taken. | Goods Inward Audit 9 | ✓ |
| Is collation and analysis of all relevant data determined and effective, and corrective actions identified. | | ✓ |
| Are these actions completed in a timely and adequate manner, and are these actions part of continual improvements. | | ✓ |
| Does the organisation have preventive measures in place to control potential non-conformities? | Goods Inward Audit 9 | ✓ |
| Are all the above actions are reviewed adequately? | | ✓ |
| Are regular analyses undertaken to identify any outstanding requirements | | ✓ |
| Are necessary changes implemented where and when required | | ✓ |
| Is any outsourcing done | | ✓ |
| Check the documented system for its policies and objectives, and its control of the above processes and procedures. | | ✓ |
| Are records of inspections filed | | ✓ |