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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | 4 Quality Management System |  |  |  |
|  |  |  |  |  |
|  | **4.1 General Requirements** |  |  |  |
|  |  |  |  |  |
| 1 | Has the organization established, documented, implemented and maintained a quality management system in accordance with requirements of ISO 9001? |  | Y |  |
|  |  |  | Y |  |
| 2 | Is the effectiveness of the quality management system continually improved? |  |  |  |
|  |  |  |  |  |
| 3 | Has the organization :   1. ***determine*** the processes needed for the quality management system including their applications throughout the organization? 2. Determined the sequence and interaction of these processes? 3. Determined the criteria and methods needed to ensure that both the operation and control of these processes are effective? 4. Ensured the availability of resources and information necessary to support the operation and monitoring of these processes? 5. Monitored, measured ***where applicable,*** and analyzed these processes? 6. Implemented actions needed to achieve planned results and continual improvement of these processes? |  | Y  Y  Y  Y  Y  Y |  |
|  |  |  |  |  |
| 4 | Does the organization manage these processes in accordance with the requirements of ISO 9001? |  | Y |  |
|  |  |  |  |  |
| 5 | Where processes that affect product conformity ***to*** requirements are outsourced, are the ***type and extent of control to be applied to these*** outsourced processes ***defined*** within the quality management system? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **4.2 Documentation Requirements** |  |  |  |
|  |  |  |  |  |
|  | **4.3 4.2.1 General** |  |  |  |
|  |  |  |  |  |
| 6 | Does the quality management system documentation include :  a) Documented statement of a quality policy and quality objectives?  b) Quality Manual?  c) Documented procedures ***and records*** required by ISO 9001?  d) Documents, ***including records,******determined*** by the organization ***to be necessary*** to ensure the effective planning, operation and control of its processes? |  | Y  Y  Y  Y |  |
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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **4.2.2 Quality Manual** |  |  |  |
|  |  |  |  |  |
| 7 | Has a quality manual been established and maintained that includes :  a) The scope of the quality management system, including details of, and justification for any exclusions?  b) Documented procedures established for the quality management system, or reference to them?  c) Description of the interaction between the processes of the quality management system? |  | Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **4.2.3 Control of Documents** |  |  |  |
|  |  |  |  |  |
| 8 | Are documents required for the quality management system controlled? |  | Y |  |
|  |  |  |  |  |
| 9 | Has a documented procedure been established identifying the following controls needed?  a) Approval of documents for adequacy prior to issue?  b) Review, update as necessary and re-approval of documents?  c) Ensure that changes and the current revision status of documents are identified?  d) Ensure that relevant versions of applicable documents are available at point of use?  e) Ensure that documents remain legible and readily identifiable?  f) Ensure that documents of external origin ***determined by the organization to be necessary for the planning and operation of the quality management system*** are identified and their distribution controlled?  g) Preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained? |  | Y  Y  Y  Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **4.2.4 Control of Records** |  |  |  |
|  |  |  |  |  |
| 10 | Have records been established ***and controlled*** to provide evidence of conformity to requirements and of the effective operation of the quality management system? |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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| 11 | Has a documented procedure been established to define the following controls needed  a) Identification?  b) Storage?  c) Protection?  d) Retrieval?  e) Retention?  f) Disposition? |  | Y  Y  Y  Y  Y  Y |  |
| 12 | Are records legible, readily identifiable and retrievable? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | 5 Management Responsibility |  |  |  |
|  |  |  |  |  |
|  | **5.1 Management Commitment** |  |  |  |
|  |  |  |  |  |
| 1 | Has top management provided evidence of its commitment to the development and implementation of the quality management system and for the continual improvement of its effectiveness by :  a) Communicating to the organization the importance of meeting customer as well as regulatory and legal requirements?  b) Establishing the quality policy?  c) Ensuring that quality objectives are established?  d) Conducting management reviews?  e) Ensuring the availability of resources? |  | Y  Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.2 Customer Focus** |  |  |  |
|  |  |  |  |  |
| 2 | Has top management ensured that customer requirements are determined and met with the aim of enhancing customer satisfaction? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.3 Quality Policy** |  |  |  |
|  |  |  |  |  |
| 3 | Has top management ensured that the quality policy :  a) Is appropriate to the purpose of the organization?  b) Includes a commitment to comply with requirements and to continually improve the effectiveness of the quality management system?  c) Provides a framework for establishing and reviewing quality objectives?  d) Is communicated and understood within the organization?  e) Is reviewed for continuing suitability? |  | Y  Y  Y  Y  Y |  |
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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **5.4 Planning** |  |  |  |
|  |  |  |  |  |
|  | **5.4.1 Quality Objectives** |  |  |  |
|  |  |  |  |  |
| 4 | Has top management ensured that quality objectives are established at relevant functions and levels within the organization? |  | Y |  |
|  |  |  | Y |  |
| 5 | Have quality objectives needed to meet the requirements of the product been established? |  |  |  |
|  |  |  |  |  |
| 6 | Are quality objectives measurable and consistent with the quality policy? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.4.2 Quality Management System Planning** |  |  |  |
|  |  |  |  |  |
| 7 | Has top management ensured that the resources needed to achieve the quality objectives are identified and planned? |  | Y |  |
|  |  |  |  |  |
| 8 | Is the output of the planning documented? (e.g., quality manual, procedures, work instructions, quality plans, etc.) |  | Y |  |
|  |  |  |  |  |
| 9 | Does top management ensure that the integrity of the quality management system is maintained when changes are planned and implemented? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.5 Responsibility, Authority and Communication** |  |  |  |
|  |  |  |  |  |
|  | **5.5.1 Responsibility and Authority** |  |  |  |
|  |  |  | Y |  |
| 10 | Has top management ensured that responsibilities, authorities are defined and communicated within the organization? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.5.2 Management Representative** |  |  |  |
|  |  |  |  |  |
| 11 | Has top management appointed member(s) of ***the organization's*** management who have responsibility and authority for :  a) Ensuring that processes are established, implemented and maintained?  b) Reporting to top management on the performance of the quality management system, including needs for improvement?  c) Promoting awareness of customer requirements throughout the organization? |  | Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.5.3 Internal Communication** |  |  |  |
|  |  |  |  |  |
| 12 | Has top management ensured that appropriate communication processes have been established within the organization? |  | Y |  |
|  |  |  |  |  |
| 13 | Does communication take place regarding the effectiveness of the quality management system? |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **5.6 Management Review** |  |  |  |
|  |  |  |  |  |
|  | **5.6.1 General** |  |  |  |
|  |  |  |  |  |
| 14 | Does top management review the quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness? |  | Y |  |
|  |  |  |  |  |
| 15 | Are opportunities for improvement and the need for changes to the quality management system, including quality policy and objectives, reviewed during the review? |  | Y |  |
|  |  |  | Y |  |
| 16 | Are records of management reviews maintained as quality records? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.6.2 Review Input** |  |  |  |
|  |  |  |  |  |
| 17 | Do the inputs to management review include information on :  a) Results of audit?  b) Customer feedback?  c) Process performance and product conformity?   1. Status of preventive and corrective actions? 2. Follow-up actions from previous management review? 3. Planned changes that could affect the quality management system? 4. Recommendations for improvement? |  | Y  Y  Y  Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **5.6.3 Review Output** |  |  |  |
|  |  |  |  |  |
| 18 | Do the outputs from the management review include the decisions and actions related to :  a) Improvement of the effectiveness of the quality management system and its processes?  b) Improvement of the product related to customer requirements?  c) Resources needed? |  | Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | 6 Resource Management |  |  |  |
|  |  |  |  |  |
|  | **6 Resource Management** |  |  |  |
|  |  |  |  |  |
|  | **6.1 Provision of Resources** |  |  |  |
|  |  |  |  |  |
| 1 | Have the resources been determined and provided for :  a) Implementing and maintaining quality management system and continually improving its effectiveness?  b) Enhancing customer satisfaction by meeting customer requirements? |  | Y  Y |  |
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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **6.2 Human Resources** |  |  |  |
|  |  |  |  |  |
|  | **6.2.1 General** |  |  |  |
|  |  |  |  |  |
| 2 | Is competency for personnel who perform work affecting ***conformity to*** product ***requirements*** based on appropriate education, training, skills, and experience? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **6.2.2 Competency, training and awareness** |  |  |  |
|  |  |  |  |  |
| 3 | Has the organization :  a) Determined the necessary competency for personnel performing work affecting ***conformity to*** product ***requirements***?  b) Provided training, ***where applicable*,** or take other actions to ***achieve the necessary competence***?  c) Evaluated the effectiveness of the actions taken?  d) Ensured that employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?  e) Maintained appropriate records of education, training, skills and experience? |  | Y  Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **6.3 Infrastructure** |  |  |  |
|  |  |  |  |  |
| 4 | To achieve conformity of product, does the organization identify, provide, and maintain the facilities including :  a) Buildings, Workspace and associated utilities?  b) Process Equipment, hardware and software?   1. Supporting services (such as transport, communication, ***or information******systems***)? |  | Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **6.4 Work Environment** |  |  |  |
|  |  |  | Y |  |
| 5 | Has the environment needed to achieve conformity to product requirements been determined and managed? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | 7 Product Realization |  |  |  |
|  |  |  |  |  |
|  | **7 Product Realization** |  |  |  |
|  |  |  |  |  |
|  | **7.1 Planning of Realization Process** |  |  |  |
|  |  |  |  |  |
| 1 | Is planning of the organization’s product realization consistent with requirements of the other processes of the quality management system? |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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| 2 | Are the following being determined when planning the product realization :  a) Quality objectives and requirements for the product?  b) The need to establish processes ***and*** documents, and ***to*** provide resources specific to the product?   1. Required verification, validation, monitoring, ***measurement*,** inspection and test activities specific to the product and criteria for product acceptance? 2. Records needed to provide evidence that the realization processes and resulting product fulfill requirements? |  | Y  Y  Y  Y |  |
|  |  |  | Y |  |
| 3 | Is the planning output in a form that is suitable for the organization’s method of operation? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.2 Customer-Related Processes** |  |  |  |
|  |  |  |  |  |
|  | **7.2.1 Determination of Requirements Related to the Product** |  |  |  |
|  |  |  |  |  |
| 4 | Has the organization determined :  a) Requirements specified by customer, including the requirements for delivery and post-delivery activities?  b) Requirements not stated by the customer but necessary specified or intended use, where known?   1. Statutory and regulatory requirements ***applicable*** to the product? 2. Any additional requirements ***considered necessary*** by the organization? |  | Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.2.2 Review of Requirements Related to the Product** |  |  |  |
|  |  |  |  |  |
| 5 | Prior to the commitment to the customer, (e.g., submission of tenders, acceptance of contracts or orders or acceptance of change orders) are requirements reviewed to ensure that :  a) Product requirements are defined?  b) Contract or order requirements differing from those previously expressed are resolved?  c) The organization has the ability to meet defined requirements? |  | Y  Y  Y |  |
|  |  |  | Y |  |
| 6 | Are results of reviews and actions arising from these reviews recorded and maintained as records? |  |  |  |
|  |  |  |  |  |
| 7 | Where the customer has not provided a documented statement of requirements, are customer requirements confirmed by the organization before acceptance? |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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| 8 | Where product requirements are changed, does the organization ensure that relevant documentation is amended and relevant personnel are made aware of the changed requirements? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.2.3 Customer Communication** |  |  |  |
|  |  |  |  |  |
| 9 | Has the organization determined and implemented effective arrangements for communicating with customers relating to :  a) Product information?  b) Inquiries, contracts, amendments or order handling?  c) Customer feedback, including customer complaints? |  | Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.3 Design and Development** |  |  |  |
|  |  |  |  |  |
|  | **7.3.1 Design and Development Planning** |  |  |  |
|  |  |  |  |  |
| 10 | Are product design and development activities planned and controlled? |  |  |  |
|  |  |  |  |  |
| 11 | During design and development planning has the organization determined :  a) Stages of design and development?  b) Review, verification and validation that are appropriate to each design and development stage?  c) Responsibilities and authorities for design and development? |  |  |  |
|  |  |  |  |  |
| 12 | Are interfaces between different groups involved in design and development managed to ensure effective communication and clear assignment of responsibilities? |  |  |  |
|  |  |  |  |  |
| 13 | Is planning output updated as the design and development progresses? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.3.2 Design and Development Inputs** |  |  |  |
|  |  |  |  |  |
| 14 | Are inputs relating to product requirements defined, documented and maintained as records? |  |  |  |
|  |  |  |  |  |
| 15 | Does design and development input include :  a) Functional and performance requirements?  b) Applicable statutory and regulatory requirements?  c) Applicable information derived from previous similar designs?  d) Other requirements essential for designs and development? |  |  |  |
|  |  |  |  |  |
| 16 | Are design and development inputs reviewed for adequacy? |  |  |  |
|  |  |  |  |  |
| 17 | Are incomplete, unambiguous or conflicting requirements resolved? |  |  |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **7.3.3 Design and Development Outputs** |  |  |  |
|  |  |  |  |  |
| 18 | Are outputs of the design and development in a form ***suitable for*** verification against the design and development inputs? |  |  |  |
|  |  |  |  |  |
| 19 | Are design outputs approved prior to release? |  |  |  |
|  |  |  |  |  |
| 20 | Does the design and development output :  a) Meet the design and development input requirements?  b) Provide appropriate information for purchasing, production and service provision?  c) Contain or reference product acceptance criteria?  d) Specify the product characteristics that are essential to its safe and proper use? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.3.4 Design and Development Review** |  |  |  |
|  |  |  |  |  |
| 21 | Are systematic reviews performed in accordance with planned arrangements at suitable stages of the design and development? |  |  |  |
|  |  |  |  |  |
| 22 | Do design and development reviews :  a) Evaluate the ability of the results of design and development to meet requirements?  b) Identify problems and propose necessary actions? |  |  |  |
|  |  |  |  |  |
| 23 | Do review participants include representative of functions concerned with the design and development stage(s) being reviewed? |  |  |  |
|  |  |  |  |  |
| 24 | Are results of reviews and any actions necessary maintained as records? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.3.5 Design and Development Verification** |  |  |  |
|  |  |  |  |  |
| 25 | Is design and development verification performed in accordance with planned arrangements to ensure that the design outputs have met the design and development input requirements? |  |  |  |
|  |  |  |  |  |
| 26 | Are results of the verification and actions maintained as records? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.3.6 Design and Development Validation** |  |  |  |
|  |  |  |  |  |
| 27 | Are design and development validation performed in accordance with planned arrangements? |  |  |  |
|  |  |  |  |  |
| 28 | Are design and development validation performed to confirm that the product is capable of meeting the requirements for the specified application or intended use, where known? |  |  |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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| 29 | Is validation completed prior to delivery or implementation of the product whenever applicable? |  |  |  |
|  |  |  |  |  |
| 30 | Are results of the validation and actions maintained as records? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.3.7 Control of Design and Development Changes** |  |  |  |
|  |  |  |  |  |
| 31 | Are design and / or development changes identified and recorded? |  |  |  |
|  |  |  |  |  |
| 32 | Do reviews of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered? |  |  |  |
|  |  |  |  |  |
| 33 | Are design and development changes reviewed, verified, validated as appropriate and approved before implementation? |  |  |  |
|  |  |  |  |  |
| 34 | Are results of the review of changes and necessary actions maintained as records? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.4 Purchasing** |  |  |  |
|  |  |  |  |  |
|  | **7.4.1 Purchasing Control** |  |  |  |
|  |  |  |  |  |
| 35 | Are the purchasing processes controlled to ensure purchased product (or service) conforms to requirements? |  | Y |  |
|  |  |  |  |  |
| 36 | Is the type and extent of control applied to the supplier and purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product? |  | Y |  |
|  |  |  |  |  |
| 37 | Are suppliers selected and evaluated based on their ability to supply product in accordance with the organization’s requirements? |  | Y |  |
|  |  |  |  |  |
| 38 | Has the organization established criteria for selection, evaluation & re-evaluation of suppliers? |  | Y |  |
|  |  |  |  |  |
| 39 | Are results of the evaluations and any necessary actions maintained as records? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.4.2 Purchasing Information** |  |  |  |
|  |  |  |  |  |
| 40 | Does purchasing information describe the product to be purchased :  Including where appropriate :   1. Requirements for approval of product, procedures, processes and equipment? 2. Requirements for qualification of personnel? 3. Quality management system requirements? |  | Y  Y  Y |  |
|  |  |  |  |  |
| 41 | Is the adequacy of specified purchased requirements ensured prior to their communication to the supplier? |  |  |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **7.4.3 Verification of Purchased Product** |  |  |  |
|  |  |  |  |  |
| 42 | Have the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements been established and implemented? |  | Y |  |
|  |  |  |  |  |
| 43 | Are verification arrangements and method of product release specified in the purchasing information where the organization or its customer intends to perform verification at the supplier’s premises? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.5 Production and Service Provision** |  |  |  |
|  |  |  |  |  |
|  | **7.5.1 Control of Production and Service Provision** |  |  |  |
|  |  |  |  |  |
| 44 | Are the production and service provision planned and carried out under controlled conditions including :  a) Availability of information that describes the product characteristics?   1. Availability of work instructions, as necessary? 2. Use of suitable equipment? 3. Availability and use of monitoring and measuring ***equipment***? 4. Implementation of monitoring and measurement? 5. Implementation of ***product*** release, delivery and post-delivery activities? |  | Y  Y  Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.5.2 Validation of Processes for Production and Service Provision** |  |  |  |
|  |  |  |  |  |
| 45 | Has the organization validated any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement ***and as a consequence,*** deficiencies become apparent only after the product is in use or the service has been delivered. |  | Y |  |
|  |  |  |  |  |
| 46 | Do the results of validation demonstrate the ability of processes to achieve planned results? |  | Y |  |
|  |  |  |  |  |
| 47 | Where applicable, have the arrangements been established for :  a) Defining criteria for review and approval of processes?   1. Approval of equipment and qualification of personnel? 2. Use of specific methods and procedures? 3. Requirements for records? 4. Re-validation? |  | Y  Y  Y  Y  Y  Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **7.5.3 Identification and Traceability** |  |  |  |
|  |  |  |  |  |
| 48 | Is the product identified by suitable means throughout product realization? |  | Y |  |
|  |  |  |  |  |
| 49 | Is the product status identified with respect to monitoring and measurement requirements ***throughout product realization***? |  | Y |  |
|  |  |  |  |  |
| 50 | Where traceability is a requirement, does the organization control the unique identification of the product ***and maintain records***? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.5.4 Customer Property** |  |  |  |
|  |  |  |  |  |
| 51 | Does the organization exercise care with customer property while it is under the organization’s control or being used by the organization? |  | Y |  |
|  |  |  |  |  |
| 52 | Is customer property ***(including intellectual property and personal data)*** identified, verified, protected and safeguarded? |  | Y |  |
|  |  |  |  |  |
| 53 | If any customer property is lost, damaged or otherwise found to be unsuitable for use, does ***the organization report this*** to the customer and ***maintain records*?** |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.5.5 Preservation of Product** |  |  |  |
|  |  |  |  |  |
| 54 | Is product preserved during internal processing and delivery to the intended destination ***in order to maintain conformity to requirements***? |  | Y |  |
|  |  |  |  |  |
| 55 | **As applicable,** does preservation activities include :   1. Identification? 2. Handling? 3. Packaging? 4. Storage? 5. Protection? |  | Y  Y  Y  Y  Y |  |
|  |  |  | Y |  |
| 56 | Are preservation activities applied to constituent parts of a product? |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **7.6 Control of Measuring and Monitoring *Equipment*** |  |  |  |
|  |  |  |  |  |
| 57 | Has the organization determined the monitoring and measurement to be undertaken and the monitoring and measurement ***equipment*** needed to provide evidence of conformity of product to determined requirements? |  | Y |  |
|  |  |  |  |  |
| 58 | Have processes been established to ensure that monitoring and measurement can be carried out in manner consistent with the monitoring and measurement requirements? |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
|  |  |  |  |  |
| 59 | Where necessary to ensure valid results, are measuring equipment :   1. Calibrated or verified, ***or both***, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, is the basis used for calibration or verification recorded? 2. Adjusted or re-adjusted as necessary? 3. Identified ***in order to determine its calibration status***? 4. Safeguarded from adjustments that would invalidate the measurement result? 5. Protected from damage and deterioration during handling, maintenance and storage? |  |  |  |
|  |  |  |  |  |
| 60 | Has the organization assessed and recorded and validity of the previous measuring results when the equipment is found not to conform to requirements, and taken the appropriate action on the equipment and any product affected? |  | Y |  |
|  |  |  |  |  |
| 61 | Are records of the calibration and verification results maintained? |  | Y |  |
|  |  |  |  |  |
| 62 | ***Has the organization confirmed the ability of computer software to satisfy the intended application?*** |  | Y |  |
|  |  |  | Y |  |
| 63 | ***Has the organization include its verification and configuration management to maintain its suitability for use?*** |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | 8 Measurement, Analysis and Improvement |  |  |  |
|  |  |  |  |  |
|  | **8 Measurement, analysis and improvement** |  |  |  |
|  |  |  |  |  |
|  | **8.1 General** |  |  |  |
|  |  |  |  |  |
| 1 | Have the monitoring, measurement, analysis and improvement processes been planned, and implemented to :  a) Demonstrate conformity ***to*** product ***requirements***?   1. Ensure conformity of the quality management system?   c) Continually improve the effectiveness of the quality management system? |  | Y  Y  Y |  |
|  |  |  |  |  |
| 2 | Have the applicable methods including statistical techniques and their extent of use been determined? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **8.2 Monitoring and Measurement** |  |  |  |
|  |  |  |  |  |
|  | **8.2.1 Customer Satisfaction** |  |  |  |
|  |  |  |  |  |
| 3 | Is information relating to customer perception monitored by the organization as to whether customer requirements have been met? |  | Y |  |
|  |  |  |  |  |
| 4 | Have the methodologies for obtaining and using information related to customer perception been determined? |  | Y |  |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **8.2.1 Internal Audit** |  |  |  |
|  |  |  |  |  |
| 5 | Are internal audits conducted at planned intervals to determine whether the quality management system :   1. Conforms to planned arrangements, requirements of ISO 9001 and the quality management system? 2. Is effectively implemented and maintained? |  | Y  Y |  |
|  |  |  |  |  |
| 6 | ***Is a documented procedure established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results?*** |  | Y |  |
|  |  |  |  |  |
| 7 | Are the audit programs planned taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits? |  | Y |  |
|  |  |  | Y |  |
| 8 | Is the audit criteria, scope, frequency and method defined? |  |  |  |
|  |  |  |  |  |
| 9 | Do the selection of auditor and conduct of audits ensure objectivity and impartiality of the audit process? |  | Y |  |
|  |  |  |  |  |
| 10 | Is it ensured that auditors do not audit their own work? |  | Y |  |
|  |  |  |  |  |
| 11 | Are records of the audits and their results maintained? |  | Y |  |
|  |  |  |  |  |
| 12 | Have management responsible for the area being audited ensured that ***any necessary corrections and corrective***actions have been taken without undue delay to eliminate detected nonconformities and their causes? |  | Y |  |
|  |  |  |  |  |
| 13 | Do follow-up activities include the verification of the actions taken, and the reporting of the verification results? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **8.2.3 Monitoring and Measurement of Processes** |  |  |  |
|  |  |  |  |  |
| 14 | Are suitable methods applied for monitoring and where applicable, measurement of the quality management system processes necessary to meet customer requirements? |  | Y |  |
|  |  |  |  |  |
| 15 | Do these methods demonstrate the ability of the processes to achieve planned results? |  | Y |  |
|  |  |  |  |  |
| 16 | Are correction and corrective actions taken when planned results are not achieved? |  | Y |  |
|  |  |  |  |  |
| 17 | ***Has the organization considered the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system?*** |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **8.2.4 Monitoring and Measurement of Product** |  |  |  |
|  |  |  |  |  |
| 18 | Are product characteristics monitored and measured to verify that product requirements are met? |  | Y |  |
|  |  |  |  |  |
| 19 | Is monitoring and measurement of product characteristics carried out at appropriate stages of the product realization process in accordance with the planned arrangements? |  | Y |  |
|  |  |  |  |  |
| 20 | Is evidence of conformity with the acceptance criteria documented and maintained? |  | Y |  |
|  |  |  |  |  |
| 21 | Are records maintained to indicate the person(s) authorizing release of product ***for delivery to the customer***? |  | Y |  |
|  |  |  |  |  |
| 22 | ***Has the organization ensured the release of product and delivery of service to the customer*** do not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **8.3 Control of Nonconforming Product** |  |  |  |
|  |  |  |  |  |
| 23 | Is nonconforming product identified and controlled to prevent unintended use or delivery? |  | Y |  |
|  |  |  |  |  |
| 24 | Has a documented procedure been established to define controls and related responsibilities and authorities for dealing with nonconforming product? |  | Y |  |
|  |  |  |  |  |
| 25 | ***Where practicable*,** are nonconforming product dealt with by one or more of the following ways:  a) by taking action to eliminate the detected nonconformity?  b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?  c) by taking action to preclude its original intended use or application?  ***d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started?*** |  | Y  Y  Y  Y |  |
|  |  |  |  |  |
| 26 | Are records maintained identifying the nature of nonconformities and any subsequent actions taken, including any concessions? |  | Y |  |
|  |  |  |  |  |
| 27 | When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements? |  | Y |  |
|  |  |  |  |  |
| 28 | When nonconforming product is detected after delivery, or use has started, is appropriate action taken by the organization to the effect or potential effect? |  | Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **8.4 Analysis of Data** |  |  |  |
|  |  |  |  |  |
| 28 | Is appropriate data determined, collected and analyzed to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made? |  | Y |  |
|  |  |  |  |  |
| 29 | Does this data include data generated from monitoring, measurement and other relevant sources? |  | Y |  |
|  |  |  |  |  |
| 30 | Does the analysis of this data provide information related to :   1. Customer satisfaction? 2. Conformance to product requirements? 3. Characteristics and trends of processes and products including, opportunities for preventive actions? 4. Suppliers? |  | Y  Y  Y  Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **8.5 Improvement** |  |  |  |
|  |  |  |  |  |
|  | **8.5.1 Continual Improvement** |  |  |  |
|  |  |  |  |  |
| 31 | Does the organization continually improve the effectiveness of the quality management system? |  | Y |  |
|  |  |  |  |  |
| 32 | Are results of audits, analysis of data, corrective and preventive actions, management reviews, quality policy and quality objectives used for continual improvement? |  | Y |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  | **8.5.2 Corrective Action** |  |  |  |
|  |  |  |  |  |
| 33 | Are corrective actions taken to eliminate the causes of nonconformities and to prevent recurrence? |  | Y |  |
|  |  |  |  |  |
| 34 | Are corrective actions appropriate to the effects of the nonconformities encountered? |  | Y |  |
|  |  |  |  |  |
| 35 | Has a documented procedure been established to define the requirements for :   1. Reviewing nonconformities, including customer complaints? 2. Determining the causes of nonconformity? 3. Evaluating the need for action to ensure that nonconformities do not recur? 4. Determining and implementing action needed? 5. Recording and maintaining the results of action taken? 6. Reviewing ***the effectiveness of the*** corrective action taken? |  | Y  Y  Y  Y  Y  Y |  |
|  |  |  |  |  |

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| **NO.** | QUESTION | **SAMPLE OBSERVED** | **YES / NO** | **(if NO) NCR #** |
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|  | **8.5.3 Preventive Action** |  |  |  |
|  |  |  |  |  |
| 36 | Has the organization determined actions to eliminate the causes of potential nonconformities in order to prevent occurrence? |  | Y |  |
|  |  |  | Y |  |
| 37 | Are preventive actions appropriate to the effects of the potential problems? |  |  |  |
|  |  |  |  |  |
| 38 | Has a documented procedure been established to define the requirements for :   1. Determining potential nonconformities and their causes? 2. Evaluating the need for action to prevent occurrence of nonconformities? 3. Determining and implementing actions needed? 4. Recording and maintaining the results of action taken? 5. Reviewing ***the effectiveness of the*** preventive action taken? |  | Y  Y  Y  Y  Y |  |
|  |  |  |  |  |