

VENDOR QUALITY SURVEY REPORT
(TO BE FILLED BY CAPACITY VERIFICATION TEAM)
PART-I QUALITY SYSTEM OF VENDOR

	MARKS ALLOTTED
1. <u>QUALITY MANAGEMENT SYSTEM</u>	3
1.1 General requirement	
1.1.1 Whether the organisation has established, documented, implemented, maintained and continually improves a quality management system in accordance with the requirements of ISO 9000-2000?	
1.1.2 Whether the organisation has identified the processes needed for the quality management system, determined the sequence and interaction of these processes, criteria and methods required to ensure the effective operation and control of these processes, ensure the availability of information necessary to support the operation and monitoring of these processes, measures, monitors and analyses these processes and implements action necessary to achieve planned results and continual improvement.	
2. <u>Management Responsibility</u>	
2.1 Management Commitment: Whether the top management is committed to the development of the quality management system.	3
2.2 Customer Focus: Whether the top management ensures that customer needs and expectations are determined considering obligations related to product including regulatory and legal requirements, converted into requirements and fulfilled with the aim of achieving customer satisfaction.	3
2.3 Quality Policy: Has the top management defined its Quality policy? Is it appropriate to the purpose of the organisation, committed to meeting requirements of customers and to continual improvement, provides a framework for establishing and reviewing quality objectives, communicated and understood at appropriate levels in the organisation, reviewed for continuing suitability and controlled?	3
2.4 Planning	
2.4.1 Quality Objectives: Whether the top management ensures quality objectives needed to meet requirements for product are established at relevant functions and levels within the organization	2

and are measurable and consistent with the quality policy including the commitment to continual improvement

2.4.2 Quality Planning: Whether the top management ensures resources needed to achieve the quality objectives are identified, planned and the output of the planning documented. **2**

2.5 Administration **5**

2.5.1 Responsibility and Authority: Whether the organization has defined the functions and their interrelations within the organization including responsibilities and authorities and communicated in order to facilitate effective quality management.

2.5.2 Management Representative: Whether the top management has appointed members of the management who have responsibility and authority to ensure establishment and maintenance of quality management system?

2.5.3 Internal Communication: Whether the organization ensures effective communication between its various levels and functions regarding the processes of the quality management system and their effectiveness

2.5.4 Quality Manual : Whether a well defined quality manual has been established maintained and controlled which includes scope , Documented Procedures and processes?

2.5.5 Control of Documents: Whether a well defined documented procedure available for the controlling of Quality Management system documents.

2.5.6 Control of Quality Records: Whether a documented procedure is established/available for the identification, storage, retrieval, protection, retention time and disposition of quality records

2.6 Management Review **4**

2.6.1 General: Whether the Top Management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness.

2.6.2 Review Input: Whether the inputs to the management review include Results of audits, Customer feedback, Process performance and product conformance, Status of preventive and corrective actions, follow up actions from earlier management reviews recorded?

2.6.3 Review Output: Are the outputs from the management review include actions related to Improvement of the quality management system and its processes, products related to customer requirements and resource needs. Are the results from the management reviews

recorded?

- 3.0 Resource Management** **5**
- 3.1 Provision of Resources:** Has the organisation determined and provided in a timely manner the resources needed to implement and improve the processes of the quality management system and to address customer satisfaction?
- 3.2 Human Resources** **4**
- 3.2.1 Assignment of Personnel:** Whether the Personnel assigned responsibilities defined in the quality management system are competent on the basis of applicable education, training, skills and experience.
- 3.2.2 Training, Awareness and Competency:** Whether the organisation has established a system for identifying competency needs of personnel and provide training, Evaluate the effectiveness of the training provided, and maintain appropriate records of education, experience, training and qualifications of its personnel?
- 3.2.3 Facilities:** Has the organisation identified, provided and maintained facilities such as Workspace, Equipment, hardware and software and supporting services it needed to achieve the conformity of product?
- 3.2.4. Work Environment:** Whether the organisation has a system for identification and management of human and physical factors of the work environment needed to achieve conformity of product.
- 4.0 Product Realisation** **5**
- 4.1 Planning of Realization Processes:** Whether the organisation has determined Quality objectives for the product, project or contract, processes and documentation, resources and facilities specific to the product verification and validation activities, the criteria for acceptability, and records that are necessary to provide confidence of conformity in the process planning for product realization.
- 4.2 Customer Related Process** **5**
- 4.2.1 Identification of Customer Requirements:** Whether the organisation has established a system for determining customer requirements with regard to quality, availability, delivery and support, intended unspecified requirements and to meet regulatory and legal requirements.
- 4.2.2 Review of Product Requirements:** Whether the organisation reviews the identified and additional customer requirements and ensures that Product requirements are defined, unstated customer requirements are confirmed before acceptance, discrepancies between contract and a tender are resolved, products/services meet

defined requirements and records available of the reviews and subsequent follow up actions.

4.2.3 Customer Communication: Whether the organization identifies and implements arrangements for communication with customers relating to:

4.2.3.1 Product information

4.2.3.2 Enquiries, contracts or order handling, including amendments

4.2.3.3 Customer feedback, including customer complaints

4.3 Design and / or Development

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4.3.1 Design and / or Development Planning

4.3.1.1 Whether the organization plans and controls design and/or development of the product by determining/verifying stages of design and /or development process, Validation activities appropriate to each design and/or development stage Responsibilities and authorities for design and/or development activities.

4.3.1.2 Are the Interfaces between different groups involved in design and /or developments are managed to ensure effective communication and clarity of responsibilities.

4.3.1.3 Is the Planning output updated as appropriate as the design and/or development progresses.

4.3.2 Design and / or Development Inputs

4.3.2.1 Whether the Inputs relating to product requirements have been defined and documented.

4.3.2.2 Are the inputs reviewed for adequacy and incomplete, ambiguous or conflicting requirements resolved.

4.3.3 Design and /or Development Outputs: Whether the outputs of the design and /or development process documented in a manner and enables verification against the design and /or development inputs. Are the Design and/or development output documents approved prior to release?

4.3.4 Design and / or Development Review

4.3.4.1 Whether, systematic reviews of design and / or development conducted at suitable stages.

4.3.4.2 Are the participants in such reviews including representatives of function concerned with the design and /or

development stage(s) being reviewed

4.3.4.3 Are the results of the reviews and subsequent follow-up actions recorded and records made available.

4.3.5 Design and/ or Development Verification:

4.3.5.1 Are Design and/or development verification performed to ensure the output meets the design and/ or development inputs?

4.3.5.2 Are the results of the verification and subsequent follow-up actions recorded?

4.3.6 Design and/ or Development Validation:

4.3.6.1 Whether Design and/ or development validation performed to confirm that resulting product is capable of meeting the requirement for intended use.

4.3.6.2 Whether validation completed prior to the delivery or implementation of the product where applicable.

4.3.6.3 Whether partial validation performed wherever it is impractical to perform full validation prior to delivery or implementation.

4.3.6.4 Are the results of the validation and subsequent follow-up actions recorded?

4.3.7 Control of Design and/ or development Changes

4.3.7.1 Whether design and/ or development changes identified, documented and controlled and include evaluation of the effect of the changes on constituent parts and delivered products.

4.3.7.2 Are the changes verified and validated as appropriate and approved before implementation and results of the review of changes and subsequent follow up actions documented.

4.4 Purchasing

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4.4.1 Purchasing Control

4.4.1.1 Existence of effective control on purchasing processes to ensure purchased product conforms to requirements.

4.4.1.2 Whether the organisation evaluates and selects suppliers based on their ability to supply products in accordance with the organisation's requirements, whether the criteria for selection and periodic evaluation are defined and the results of evaluations and follow-up actions recorded.

4.4.2 **Purchasing Information**

4.4.2.1 Whether the Purchasing documents contain information describing the product to be purchased.

4.4.2.2 Whether the organization identifies and implements the activities necessary for verification of purchased product.

4.4.3 **Verification of Purchased Product**

4.4.3.1 Whether the organization has specified the intended verification arrangements and methods of product release in the purchasing information whenever the organization or its customer proposes to perform verification activities at the supplier's premises

4.5 **Production and Service Operations**

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4.5.1 **Operation Control:** Whether the organization has arrangements for controlling production and service operations through specifying product characteristics, making available work instructions, use and maintenance of suitable equipment implementing monitoring activities.

4.5.2 **Identification and Trace-ability**

4.5.2.1 Whether the organization has a system for identifying, where appropriate, the product by suitable means throughout production and service operations, and the status of the product with respect to measurement and monitoring requirements.

4.5.2.2 Whether the organization has controlling and recording system for unique identification of the product, where Trace-ability is requirement.

4.5.3 **Customer Property:** Whether the organization exercises care with customer property while it is under the organization's control, identifies, verifies, protects and maintains customer property provided for use or incorporation into the product and records and reports to the customer any customer property that is lost/damaged.

4.5.4 **Preservation of Product :** Whether the organization preserves conformity of product with customer requirements during internal processing and delivery to the intended destination.

4.5.5 **Validation of Processes**

4.5.5.1 Whether the organization validates any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring.

4.5.5.2 Whether the Validation demonstrates the ability of the processes to achieve planned results.

4.5.5.3 Whether the organisation has defined arrangements for validation that includes Qualification of processes, equipment and personnel, methodologies and procedures records and re-validation.

4.6 Control of Measuring and Monitoring Devices

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4.6.1 Whether the organisation has identified the measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements.

4.6.2. Are measuring and monitoring devices used and controlled to ensure that measurement capability is consistent with the measurement requirements.

4.6.3 Are measurement and monitoring devices, where applicable, calibrated and adjusted periodically or prior to use against devices traceable to international or national standards, safeguarded from adjustment that would invalidate the calibration protected from damage and deterioration during handling, maintenance and storage results re-assessed if they are subsequently found to be out of calibration and corrective action taken.

5.0 Measurement, Analysis and Improvement

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5.1 **Planning:** Has the organisation defined, planned and implemented the measurement and monitoring activities needed to assure conformity and achieve improvement including the determination of the need for and use of applicable methodologies including statistical techniques.

5.2 Measurement and Monitoring

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5.2.1 Customer Satisfaction

5.2.1.1 Whether the organisation monitors information on customer satisfaction and/ or dissatisfaction as one of the measurements of performance of the quality management system.

5.2.1.2 Are the methodologies for obtaining and using this information determined?

5.2.2. Internal Audit

5.2.2.1 Whether the organisation conducts periodic internal audits to determine whether the quality management system conforms to the requirements of this standard, and it has been effectively implemented and maintained.

5.2.2.2 Whether the audit plans take into consideration the status and importance of the activities and areas to be audited

as well as the results of previous audits, defines the audit scope, frequency and methodologies conducted by personnel other than those who perform the activity being audited.

5.2.2.3 Whether a documented procedure for conducting audits available.

5.2.2.4 Whether the management takes timely corrective action on deficiencies found during the audit and follow-up action including the verification of the implementation of corrective action and the reporting of verifications results.

5.2.3 Measurement and Monitoring of Processes

5.2.3.1 Whether the organization applies suitable methods for measurement and monitoring of those realization processes necessary to meet customer requirements.

5.2.3.2 Are these methods confirming the continuing ability of each process to satisfy its intended purpose ?

5.2.3.3 Whether evidence of conformity with the acceptance criteria documented .

5.2.3.4 Whether the records indicate the authority responsible for release of product.

5.2.3.5 Whether Product releases and service delivery do not proceed until all the specified activities are satisfactorily completed unless otherwise approved by the customer.

5.3 Control of Non-conformity

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5.3.1 Whether the organization ensures identification of non-conforming products, which do not conform to requirements and controlled to prevent unintended use or delivery and these activities are defined in a documented procedure.

5.3.2 Whether the organization takes appropriate action regarding the consequences of the nonconformity when nonconforming product is detected after delivery or use has started.

5.3.3 Whether the organization reports for concession to the customer, the end user, regulatory body or other body .The proposed rectification of nonconforming product where required.

5.4 **Analysis of Data:** Whether the organization collects and analyses appropriate data to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made.

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5.5 **Corrective Action** : Whether the organization takes corrective action to eliminate the cause of non-conformities in order to prevent recurrence and documented the procedure for corrective action. 2

5.6 **Preventive Action**: Whether the organisation has identified preventive action to eliminate the cause of potential non-conformities to prevent occurrence and documented the procedure for preventive action 2

TOTAL MARKS

100

VENDOR QUALITY SURVEY REPORT (VQSR)
(TO BE FILLED BY CAPACITY VERIFICATION TEAM)
PART –II PRODUCT SPECIFIC TECHNICAL CAPABILITY OF VENDORS

1. <u>MANUFACTURING PLANT & MACHINCERY</u>	MARKS ALLOTTED
1.1 Whether essential Plant & Machinery are available for the product range under consideration to the required specification. (Enclose list with capacity verification report)	35
1.2 Whether desirable Plant & Machinery for the product are available. (Enclose list with capacity verification report)	10
1.3 Whether the Plant and Machinery is adequately sophisticated/state of the art technology as relevant to the product requirements. Give brief details to support assessment. (Enclose list with capacity verification report)	10
2. <u>MANUFACTURING PROCESS:</u>	
2.1 Availability of all manufacturing operations and process in – house. (These include all process/operations required to be performed on the raw materials, for conformity of end product to required applications including packing, marking, handling and storage/delivery).	10

2.2	Whether the available process capability is adequate and compatible with the product specific requirements.	5
3.	<u>TESTING</u>	
3.1	Whether essential test equipment for all quality control and measurements are available in – house. (Enclose list with capacity verification report)	10
3.2	Whether desirable test equipment are available as per laid down norms. (Enclose list with capacity verification report)	5
3.3	Whether Firm has NABL Accredited Lab	15
4.	<u>IN – HOUSE QUALITY CONTROL</u>	
4.1	Whether there is adequate quality plan to meet the technical specifications and check product related requirements at all stages during the manufacturing process as adopted to the product.	10
4.2	Whether in – process inspection and testing is systematically carried out as per the quality plan and data is recorded as adopted to the product.	10
4.3	Whether in – house controls as per quality plant adequate to ensure product conformance.	5

4.4 Whether performance of machines instruments, jigs, fixtures, gauges and operations is monitored during the manufacturing process. 5

5. **MANPOWER RESOURCES:**

5.1 Whether personnel assigned manufacturing responsibilities are adequate in number and have requisite qualifications/experience and expertise for product. 5
(Team must verify the VQSR point No. 35)

5.2 Whether personnel assigned quality control responsibility are adequate in number and have requisite expertise and authority for the product. 5

6. **ADEQUACY OF INFRASTRUCUTURE FACILITIES:**

6.1. Covered and open space for manufacturing facilities. 5

6.2 Bond Rooms commensurate to the stores and quantum of supplies and its security. 5

6.3 Maintenance set – up for the in – house plant/machinery and test equipment. 5

6.4 Inspection facilities 5

NOTE: Grading of Firms based on capacity assessment from:

TOTAL MARKS OBTAINED IN PART – I & II

Maximum Marks = 300

<i>If firm scores > 225 marks</i>	<i>Grade I</i>
<i>180 to 224</i>	<i>Grade II</i>
<i>150 to 179</i>	<i>Grade III</i>
<i><150</i>	<i>Firm not considered for Registration</i>

Date of visit to the firm

Signature of Members of Assessment Team

Rank and Name

Signature with date

- 1.
- 2.