Appendix- II
Part-I

VENDOR QUALITY SURVEY REPORT (VQSR)

(TO BE FILLED BY CAPACITY VERIFICATION TEAM)
(TEAM MUST VERIFY ALL THE CLAUSES OF VRRF)
QUALITY SYSTEM OF VENDOR

Sl. No.			
1.	**QUALITY MANAGEMENT SYSTEM**	**Mark**	**Documents to be referred**
1.1	**General requirement**	**3**	
	Whether the organization has established, documented, implemented, maintained and continually improves a quality management system in accordance with the requirements of ISO 9001-2008?	3	Process schedule, Quality manual & QAP
2.	**Management Responsibility**	**7**	
2.1	Management Commitment: Whether the top management is committed to the development of the quality management system.	2	Mission &Vision statement, Quality Policy Statement
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.	2	
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	Quality policy duly authorised by Top Management and properly communicated
2.4	**Planning**	**2**	
	Quality Objectives & Planning: Availability of Quality Objectives and planning to achieve these objectives	2	Relevant provision in Quality manual
2.5	**Administration**	**9**	
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	Organisation chart and allocation of duty
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	Appointment of MR
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.	1	Minutes of meetings, circulars, intersectional notes, etc.

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	Quality manual
2.5.5	**Control of Documents & Records:** Whether a well-defined documented procedure available for the controlling of Quality Management system , documents & quality records.	2	Documented procedure for control of documents
2.6	**Management Review**	**4**	
	General : Whether the Top Management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness & improvement	4	Records of Management Review by top management at planned intervals
3.0	**Resource Management**	**6**	
3.1	**Provision of Resources:** Has the organization 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?	2	
3.2	**Human Resources**		
3.2.1	**Assignment of Personnel:** Whether responsibility of Quality Management System has been assigned to competent personnel in terms of skill, knowledge & experience	1	Documents/Records of human resources planning and its implementation
3.2.2	**Training, Awareness and Competency:** Whether training need has been identified & training imparted accordingly	1	Relevant provisions in Documents/Records of human resources planning and its implementation
3.2.3	**Facilities & Work Environment:** Whether buildings, workspace, equipments, services, work environments, etc. are adequate to achieve the conformity of product	2	
4.0	**Product Realization**	**10**	
4.1	**Planning of Realization Processes**: Whether Organisation has developed the processes needed to achieve quality objectives for the product	5	Process schedule, QAP, Quality records
4.2	**Customer Related Process**		
4.2.1	**Identification of Customer Requirements:** Whether the organization 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 & its review.	3	Copy of contract specifying technical ,legal, delivery, service, etc. requirement

4.2.3	**Customer Communication:** Whether the organization identifies and implements arrangements for communication with customers relating to product information, enquiries, order handling, amendments, customer feedback including customer complaints	2	System of customer communication
4.3	**Design and / or Development**	**7**	
4.3.1	**Design and / or Development Planning**		
	Whether organization has well established R&D setup to design, verify, validate, review and control changes for required output	1	Organisational setup for R&D
4.3.2	**Design and / or Development Inputs**		
4.3.2.1	Whether the inputs and outputs of design and / or development relating to product requirements are determined ,verified , approved and records maintained	1	
4.3.3	**Design and / or Development Review**		
	Whether organization ,at suitable stages, carries out systematic review of design and development in accordance with the planned arrangements	1	Record of reviews at suitable stages.
4.3.4	**Design and/ or Development Verification:**		
	Whether organization has system of verification of product design and / or development to meet the output required	1	Results of design and or development verification meet
4.3.5	**Design and/ or Development Validation:**		
	Whether Design and /or development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirement and record maintained.	1	Proof of validation
4.3.6	**Control of Design and/ or development Changes**		
	Whether design and/ or development changes are identified, documented, controlled and implemented after evaluation and approval.	2	
4.4	**Purchasing**	**7**	
4.4.1	**Purchasing Control**		
4.4.1.1	Existence of effective control on purchasing processes to ensure purchased product conforms to requirements.	1	Documented procedure for Material Management
4.4.1.2	Whether the organization evaluates and selects suppliers based on their ability to supply products in accordance with the organization's requirements, whether the criteria for selection and periodic evaluation are defined and the results of evaluations and follow-up actions recorded.	1	Evaluation procedure , record of evaluation and necessary actions ,if any
4.4.2	**Purchasing Information**		
4.4.2.1	Whether the Purchasing documents contain information describing the product to be purchased.	3	Product detail in Purchase order
4.4.2.2	Whether the organization identifies and implements the activities necessary for verification of purchased product.	1	

4.4.3	**Verification of Purchased Product**		
	Whether the organization has specified the intended verification arrangements and methods of product release in the purchasing information to perform verification activities at the supplier's premises	1	
4.5	**Production and Service Operations**	**9**	
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.	3	Process schedule, inspection schedule, work instructions
4.5.2	**Identification and Trace-ability**		
	Whether organization has a system to identify the product and its status with respect to measurement and monitoring requirements & records maintained	2	Traceability of the product
4.5.3	Whether the organization identifies, verifies, protects and maintains customer property provided for use, while under organisation's control.	1	Procedures and record for receipt, store, maintain & issue of customer's property
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	1	
4.5.5	**Validation of Processes**		
	Whether the organization validates any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring.	2	Report of process audit
4.6	**Control of Measuring and Monitoring Devices**	**5**	
4.6.1	Whether the organization has identified the measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements.	2	List of measuring instruments
4.6.2	Are measuring and monitoring devices used to ensure that measurement is consistent with the measurement requirements.	1	
4.6.3	Are measuring and monitoring devices calibrated periodically.	2	Calibration record
5.0	**Measurement, Analysis and Improvement**	**5**	
5.1	**Planning:** Whether the organisation has a plan for monitoring, measurement, analysis and improvement processes needed to demonstrate conformity to product quality requirements and its implementation	5	QAP, its implementation and Quality review mechanism
5.2	**Measurement and Monitoring**	**15**	
5.2.1	**Customer Satisfaction**		
	Whether the organisation monitors customer feedback and follow up actions	2	Customer feedback

5.2.2	**Internal Audit**		
5.2.2.1	Whether the organization conducts internal audits at planned intervals to determine that the quality management system conforms to the planned arrangements and it has been effectively implemented and maintained.	2	Records of internal audit
5.2.2.2	Whether a documented procedure for conducting audits available.	1	Audit procedure
5.2.2.3	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.	2	Record of corrective actions
5.2.3	**Measurement and Monitoring of Processes**		
5.2.3.1	Whether the organization applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes	1	
5.2.3.2	Do these methods demonstrate the ability of the processes to achieve planned results.	1	
5.2.3.3	Whether evidence of conformity with the acceptance criteria documented.	2	Test/Inspection Reports
5.2.3.4	Whether the records indicate the authority responsible for release of product.	2	Authority of Inspection Note
5.2.3.5	Whether Product release and service delivery do not proceed until all the specified activities are satisfactorily completed unless otherwise approved by the customer.	2	
5.3	**Control of Non-conformity**	**5**	
5.3.1	Whether the organization ensures that non-conforming product is identified and controlled to prevent its unintended use or delivery	3	Documented procedure for control of non-conforming products
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.	1	Documented mechanism for action in case of delivery of non-conforming product
5.3.3	Whether organisation maintains records of the nature of nonconformities and any subsequent actions taken, including concessions obtained	1	Record of concession taken
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.	**2**	Review mechanism of Quality Management System
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**	Records of corrective actions maintained

5.6	**Preventive Action:** Whether the organization has identified preventive action to eliminate the cause of potential non-conformities to prevent occurrence and documented the procedure for preventive action	**2**	Documented procedure is available for preventive action.
		100	

Appendix- II
Part-II

VENDOR QUALITY SURVEY REPORT (VQSR)

(TO BE FILLED BY CAPACITY VERIFICATION TEAM)

PRODUCT SPECIFIC TECHNICAL CAPABILITY OF VENDORS

1.	**MANUFACTURING PLANT & MACHINCERY**	**Marks Allotted**
1.1	Whether essential Plant & Machinery are available for the product range under consideration to the required specification.(Verification to be done based on List prepared by MFT/included in TE, and list to be Enclosed with capacity verification report)	**40/0**
1.2	Whether desirable Plant & Machinery for the product are available. (Enclose list with capacity verification report)	**5**
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)	**5**
2.	**MANUFACTURING PROCESS:**	
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.	**TESTING**	
3.1	Whether essential test equipment for all quality control and measurements are available in – house. (Enclose list with capacity verification report)	**15/0**
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.	**IN – HOUSE QUALITY CONTROL**	
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**
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 INFRASTRCUTURE 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**
7.	**POWER SUPLY:**	
7.1	Availability of stand – by power arrangement and its adequacy.	**5**
7.2	Availability of adequate water arrangement.	**5**
8.	**GENERAL**	
8.1	Lighting and Ventilation.	**5**
8.2	Hygiene and Sanitation of the firm and surrounding area	**5**
8.3	Firefighting arrangements	**5**
8.4	First aid and Medical arrangements	**5**
8.5	Approach to firm	**5**
8.6	ECO – friendly waste disposal	**5**
9.0	All the clauses of VRRF (submitted by the Firm) Verified. (YES/NO)	

PART -II TOTAL MARKS **200**

MARKS OBTAINED

ASSESSMENT	**TOTAL MARKS**	**MARKS OBTAINED**
PART- I	**100**	
PART- II	**200**	
GRAND TOTAL	**300**	

NOTE- GRADING OF Firms Based on Capacity assessment from:
TOTAL MARKS OBTAINED IN PART - I & II

Maximum Marks= 300

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

N.B.: i) It is mandatory that vendor has to score minimum 50% marks in both Part-I and Part-II separately to get qualified and deemed fit for registration. Provided the vendor meet all other requirements as per the guidelines in this SOP.

Date of visit to the firm

Signature of Members of Assessment Team

Rank and Name **Signature with date**

1.

2.