The Standards Institution of Israel

SII Procedure 005

December 2020 – Edition B

REQUIREMENTS FOR QUALITY SYSTEMS OPERATED BY MANUFACTURERS PRODUCING PRODUCTS BEARING THE STANDARDS MARK

Signature of Dr. Gilad Golob
SII's CEO

1. General

1.1 This document specifies the quality system requirements for manufacturers who have been certified by the Standards Institution of Israel (hereinafter, "SII") to mark products with the Standards Mark, or for manufacturers who are interested in obtaining this certification.

1.2 The requirements specified in this document apply to manufacturers in addition to their other obligations to SII, as set forth in the Standards Law, 1953, the Standards Mark Regulations, the agreement between the manufacturer and SII, and SII's procedures.

1.3 Effective implementation of the requirements specified in this document should ensure stability of the manufacturing process thus obtaining long term conformity of the products to the requirements of the Standard, reduce the probability of producing non-conforming products and prevent the need for actions taken against manufacturers who are producing such products.

1.4 The requirements in this document are minimal requirements. Certain products may necessitate setting specific additional requirements to be determined by the relevant Professional Committee.

1.5 It is emphasized that the use of the Standards Mark is a declaration by the manufacturer that the product conforms to the relevant Standard. For this reason, the manufacturer himself must be capable of testing the product he is manufacturing, of detecting the incompatible products, of amending the defects (if there were defects) that were detected, of determining the reasons for nonconformity and of taking the necessary action to remove these reasons for nonconformity, so that the defect will not be repeated.

1.6 SII's representative shall verify that the requirements set forth in this document are implemented. Nonconformity with these requirements, regardless of whether the product is compatible or incompatible with the Standard, may cause the cancellation of the product's Standards Mark.

2. Definitions

2.1 Products – including materials, components, subsystems, services, etc. marked with a Standards Mark, or to be marked with a Standards Mark.

2.2 Manufacturer – for definition, refer to the Standards Mark Regulations.

2.3 Standards – Israel Standards and Specifications published by SII.

2.4 Subcontractor – manufacturer who manufactures or performs processing for a permit holder for specific parts of the finished product in accordance with the design of the permit holder (a new definition).

2.5 Supplier – the supplier of a product not only for the standard mark license holder, e.g. manufacturer, distributor, retailer or seller of a product or service .

3. Requirements

3.1 Management responsibility

3.1.1 The management shall demonstrate leadership and responsibility relative to the quality system, shall set limits, responsibility and applicability of the quality management system, shall apply and maintain a quality policy that is suitable for the purpose and context of the organization and supports its strategic objective and displays responsibility for constant improvement of the quality management system, to ensure meeting the requirements of the Standards relevant to the products and requirements in this document .

3.1.2 The manufacturer's management shall appoint an employee responsible for the quality system. It is desirable

that this employee be at the management level or reporting directly to the management on the performance of the quality system, including laboratory test results, quality tests and process inspections carried out by SII .

3.1.3 The manufacturer's management shall allow his representative freedom of operation and appropriate authority to perform his duties and implement the requirements of this document and to ensure that his responsibility and authority are communicated and understood within the organization.

3.1.4 The person responsible for the quality system or the delegate on his behalf shall be present during testing and the selection of products for testing. Also, The Standards Institution of Israel (SII) will send him the product test reports, process examinations and audits. The person responsible for the quality system shall notify The Standards Institution of Israel of the corrective action required due to the nonconformities found in the actions carried out by SII .

3.1.5 The manufacturer's management shall assign appropriate resources and capable manpower, as necessary to implement the requirement of this document.

3.2 Quality management system and processes (design)

3.2.1 The manufacturer shall establish and maintain an effective and documented quality system, ensuring that the products conform to the requirements of the Standard. This system shall incorporate procedures, work instructions, test instructions, etc. consistent with the requirements specified in this document and in the applicable Standards.

3.2.2 The manufacturer shall prepare a detailed quality plan for each product (hereinafter, quality plan for the product) to be approved by the SII's representative. The quality plan for the product shall include, but not limited to, the following details:

a. Detailed flow chart, specification, file, etc. of the production process, starting from the acceptance of raw materials and up to the final product, its packaging and storage.

b. Indication of the test points in the production process.

c. As relevant, details of the stop stations in the process (those test points from which products are not transferred to the next production phase until tests are run and positive results are obtained).

d. Details of properties tested at each test station and their required results, including tolerances, possible ranges.

e. Details of the test equipment and the test procedures used at each test station.

f. Description of the forms on which the test results are recorded, as required.

g. Sample size and test frequency at each test station.

h. Identifying the personnel responsible for carrying out the tests.

3.3 Product File

3.3.1 A product file shall be prepared for each product, specifying, unambiguously, its design. In general, the product file shall include, as necessary and relevant, the following items:

a. Product drawing, containing a general description of the product and its major dimensions.

b. General photographs of the product (from various angles).

c. Photographs of its major components.

d. Schematic diagrams of the major electrical circuits, where applicable, including wiring diagrams indicating wire color marking, terminal marking, etc.

e. List of major components that details the component type, manufacturer's name, model, name of institutions/laboratories that have approved the component (if any), and the essential technical characteristics of the components. (note: Major components are those that affect the product's safety, and properties that may affect the product's conformity to the Standard). Additional definitions may be required and this according to the product approved for the Standards Mark. Components supplied from suppliers and conforming to a specific purpose may be specified as replacements, provided that they have the same properties and approvals (e.g. electrical components such as a capacitor, resistor, etc.).

f. Specifications of the main materials from which the product is constructed, including the material name, name of the manufacturer, name of the supplier, model (e.g. degree of cleanliness, etc.) with special reference to flammable and toxic materials.

g. Catalogs, instruction sheets and any other technical material that may assist in the product specification.

3.3.2 The manufacturer shall maintain the product file. In cases where the product file is a digital file, SII's representative may request that the product file be retained at SII'scomputer systems. In certain cases, SII's representative may request that the product file itself (hard copy) also be retained at SII or request to receive it for evaluation and inspection.

3.3.3 The manufacturer shall inform SII regarding any essential modification to the product. This modification shall be denoted appropriately in the product file. Changes to the product file shall be approved by SII's representative.

3.4 Quality Procedures

3.4.1 The manufacturer shall prepare detailed documented quality procedures that describe the quality system maintained by the manufacturer according to the requirements of this document.

3.4.2 The quality procedures shall specify the responsibilities, authorities and mutual relations of all of the manufacturer's functionaries associated with the products.

3.4.3 The quality procedures shall be authorized and signed by the person responsible for quality in the company.

3.5 Customer Order Review

When the products are to be manufactured in accordance with a customer's specific order, the manufacturer shall review the customer's requirements to ensure, among other issues, that these requirements do not conflict with the product's applicable Standard. When any such conflict is found, the manufacturer shall reject the order unless he receives prior approval from the head of the Standard's Mark Operational Directorate.

3.6 Documented information

3.6.1 The manufacturer shall have in his possession all updated documentation necessary for the production of the products and testing thereof, including Standards applicable to the products, drawings, production instructions, test instructions, etc.

3.6.2 The manufacturer shall establish and maintain documented procedures for documentation control. This control shall include, among other things:

a. Assurance that the pertinent documents are accessible for the employees to conduct operations connected to product manufacturing and testing.

b. Monitoring such that the documentation is protected in a suitable manner (e,g. loss of confidentiality, improper use or loss of integrity).

c. Method for updating, distribution, access, recovery, protecting the documentation, as necessary.

d. Appropriate arrangements for prompt removal of obsolete documents, their destruction or unequivocal identification.

e. Securing documented information maintained as substantiation of compliance so that changes cannot be made.

f. Monitoring of documentation from an external source that the organization determined is necessary for the design and operation of the product quality system.

3.7 Monitoring of processes, products and services supplied from external sources

3.7.1 All purchase orders from suppliers and subcontractors shall be prepared in writing and contain precise specification of the ordered materials, components, subassemblies, processes, etc. (hereinafter, materials). The purchase order shall also specify the tests to be carried out by the supplier/subcontractor and the records accompanying the deliverables.

3.7.2 The manufacturer shall specify and implement criteria for evaluation, selection, monitoring performance, and re-evaluation of suppliers based on their ability to carry out processes or to supply products and services in accordance with the requirements and Standards applicable to this product. The manufacture shall disengage from subcontractors whose quality of work does not meet the requirements.

3.7.3 The manufacturer shall define the inspections to be enacted on the goods received from suppliers and subcontractors.

3.7.4 The manufacturer shall maintain documented information on these activities and on any other necessary activity resulting from the evaluations presented.

3.7.5 The manufacturer shall take all steps necessary to assure that purchased material shall not cause the final product to deviate from the Standard. When the Standard specifies requirements for materials, it is the manufacturer's responsibility to verify their compliance.

3.7.6 The manufacturer shall prepare a list of all the approved suppliers and subcontractors for the main components and materials.

3.8 Product Identification and Traceability

The manufacturer shall establish, set and operate a documented method for identifying the products during all stages of productions, delivery and installation. This identification shall include the following, to the extent applicable:

a. Identification of the production batch.

b. Identification of all production phases, the production phase date and the responsible employee.

c. Identification of the materials and components comprising the product.

d. Quantity of products in the production batch.

e. Identification number for each individual product, provided it is required by the Standard.

3.9 Inspection and Testing

3.9.1 General

3.9.1.1 The inspections shall be carried out according to Standards, drawings, specifications and test instructions, detailed and valid.

3.9.1.2 According to the work instructions, the inspection results shall be documented on forms approved for this purpose, and signed by the person who actually conducted the tests.

3.9.1.3 Sampling inspections shall be based on commonly accepted statistical sampling programs or experience in the process.

3.9.1.4 The manufacturer shall ensure that the manufacturing and environmental conditions at the test location are suitable for their purpose, taking into consideration the product, the test accuracy and the Standard's requirements.

3.9.2 Receiving Inspection

3.9.2.1 The manufacturer shall carry out receiving inspections for incoming material from suppliers and/or subcontractors. The inspections shall be carried out according to inspection specifications that shall specify, among other things, the size of the test sample, the properties to be inspected, the inspection methods, and the acceptance and rejection criteria.

3.9.2.2 The sample size and properties to be inspected shall be determined according to the nature of the material, the supplier's or the subcontractor's reliability, historical quality records of the material received from the same source, test reports accompanying the shipment, etc.

3.9.2.3 As a minimum requirement, the manufacturer shall carry out visual inspections to detect any external defect, verify the incoming quantity, and inspect the test reports of the supplier/sub-contractor, as required.

3.9.3 In-process tests

3.9.3.1 In-process testing shall include inspection and testing the product at the test stations specified in the product's quality plan.

3.9.3.2 At stop stations specified in the product's quality plan, a positive result of the test carried out at the station shall be required for forwarding the material to the next production phase.

3.9.4 Final inspection

3.9.4.1 The manufacturer shall carry out final inspection according to, but not limited to, the product quality plan, to confirm compliance of the product with the Standard. When the Standard requires certain tests of the finished product, the manufacturer shall carry out these tests as required.

3.9.4.2 The final inspection shall verify that all tests specified in the production process were carried out as required.

3.9.4.3 In the final inspection, compliance of the product with the marking requirements in the Standard and in the Special Conditions Appendix applicable to the product shall be checked.

3.10 Inspection, Measuring and Test Equipment (monitoring and measurement)

3.10.1 The manufacturer shall ensure the availability of all inspection, measuring and test equipment (hereinafter, test equipment) required for the specified tests, in the specified accuracy and in accordance with the product quality plan. Specifically, the manufacturer shall provide test equipment that allows the manufacturer to determine the product's conformity to the standard.

3.10.2 When expensive test equipment is not in the possession of the manufacturer, the manufacturer shall make appropriate arrangements acceptable to SII to carry out the required test, at the required frequency, by another laboratory acceptable to SII.

3.10.3 The test equipment shall be calibrated against certified equipment having a known valid relationship to national Standards. The calibration frequency shall be determined by an orderly procedure of the plant. Where the installations, fixtures, templates, etc. are used for determining compliance of the product with the requirements, they shall be considered as test equipment.

3.10.4 Calibration shall be performed by a laboratory, having approval by a national authority in accordance with Standard ISO 17025. It shall be confirmed that the laboratory has been approved for calibrating the subject equipment.

3.10.5 The test equipment shall be suitably identified to determine its calibration status.

3.10.6 The manufacturer shall verify that faulty or uncalibrated test equipment are neither used by nor accessible to the manufacturer's workers.

3.10.7 The manufacturer shall ensure that handling, preservation and storage of test equipment are such that their fitness for use and accuracy are maintained.

3.10.8 The manufacturer shall maintain an organized card file for test equipment giving the technical data of the test equipment, the calibration details (date of last calibration and date of next calibration or the calibration frequency) and the repairs and rework to which they were subjected.

3.10.9 Despite the aforementioned, it is permissible that test equipment only used for instruction and not for measurement purposes, not be periodically calibrated, provided that this test equipment item carries readily apparent marking indicating that this equipment is not to be used for measurement purposes.

3.10.10 The manufacturer is permitted to verify, by certified employees in the organization, to see that the test equipment is functioning properly in accordance with the internal procedures and the rules of the

profession.

3.11 Inspection and Test Status

3.11.1 The inspection and test status shall identify the status of the products according to two criteria:

a. That the products are prior to or after testing;

b. That the products have been approved (products conforming to the requirements) or rejected in the tests.

3.11.2 The marking shall be performed by means appropriate to the product and production process, such as, stamping the product itself, a tag attached to the product, a symbol on the accompanying card, etc.

3.11.3 In the event that, for technical reasons, the product itself cannot be marked, the status shall be exhibited by other appropriate means, such as, physical location, color of the storage facilities, etc.

3.11.4 Nonconforming products shall be conspicuously marked.

3.11.5 The inspection and test status records shall provide identification of the person who determined the status of the product.

3.11.6 The manufacturer's procedures shall identify which personnel are authorized to change the status of the nonconforming product.

3.12 Control of a Nonconforming Product

3.12.1 Products found to be nonconforming to the requirements at any phase of the production process, shall be physically segregated from other production process products and stored in a designated storage area and appropriately identified. When this requirement cannot be met for objective reasons, other extreme measures shall be taken to ensure that no use shall be made of these products unless approved by an authorized person.

3.12.2 The manufacturer shall establish procedures to handle nonconforming products, which shall explicitly determine who is authorized to decide their status.

3.12.3 The manufacturer shall establish and maintain orderly records of nonconforming products detected during the receiving inspection, the production process, the final inspection, or are found defective by the customers (either as a result of complaints or during the warranty period).

3.12.4 Repaired or reworked nonconforming products shall be reinspected after the completion of the repair/rework.

3.13 Handling, Storage, Packaging and Delivery (preservation)

3.13.1 The manufacturer shall provide suitable conveyed equipment in order to prevent damage to the conveying products, or to other products that are in the transport route. The customer's needs as well as the shelf life expectancy of the product will also be taken into account.

3.13.2 The manufacturer shall provide suitable storage facilities, taking into consideration conditions appropriate to the stored products, to prevent damage or deterioration. Raw materials shall be separated from final products.

3.13.3 Raw materials shall be properly marked in order to ensure their full and unambiguous identification. In general, materials that may deteriorate during storage shall be taken from storage using the "first-in first-out" principle.

3.13.4 The manufacturer shall ensure that only products that meet all the requirements are stored in the final products storage area. Products shall not be marked with a Standards Mark if they do not conform with the Standard.

3.13.5 The manufacturer shall inspect the stored materials and products, at appropriate intervals, for identification of possible deterioration..

3.13.6 The manufacturer shall establish and maintain special control procedures for materials with limited storage time, and shall dispose of these materials when their usability has expired.

3.13.7 The packaging of the final products shall provide appropriate protection against damage during conveying in the plant, during delivery to the customer, and shall also anticipate the customer's storage conditions. These requirements shall be met even when the Standard does not set forth packaging requirements. Packaging shall verify that all accompanying materials, such as operating instructions and installation accessories, are contained in the package.

3.14 Corrective Action

3.14.1 The manufacturer shall take corrective actions in the event of quality problems, associated with the nonconformance of the product to the Standard. These quality problems may be detected by the manufacturer (at various phases of the production process), following customer complaints, or following tests that were carried out by SII.

3.14.2 The corrective action shall include investigation to identify the causes for the quality problem, shall set forth the method to remove these defects, and shall take all necessary steps to prevent recurrence of the problem. The manufacturer shall review the effectiveness of the corrective action taken.

3.14.3 The manufacturer shall report to SII of each correction action needed to be taken on products bearing the Standards Mark, due to a nonconformity revealed by SII or due to a complaint by a customer.

3.14.4 Where necessary, the manufacturer shall make changes to the product quality plan in coordination with SII.

3.14.5 The manufacturer shall maintain full documentation of each corrective action taken.

3.15 Quality Records

3.15.1 Inspection and test activities, starting with raw material inspection and up to the final product inspection, shall be accompanied by appropriate records according to that defined in the product quality plan.

3.15.2 The manufacturer shall maintain the quality records (previously called, test reports) in such a way that they are readily retrievable according to various data elements, such as: date, number of production batch, type of product, etc. The records shall be stored in an appropriate location, taking care that damage, deterioration or loss is prevented.

3.15.3 The manufacturer shall maintain the customer complaints in an orderly manner (file or computerized form or other acceptable manner) indicating the type of action taken towards the customer and corrective actions taken, if required, consequent to these complaints.

3.15.4 The quality records shall be maintained for a period, customarily used by the organization for retaining documents, unless otherwise required by SII, the Standard, or the law.

3.15.5 The quality records shall be accessible for inspection and control by SII's representative.

3.15.6 The requirements of this clause are in addition to the special instructions regarding records that are included in other clauses of this document.

3.16 Personnel Training and their Certification

3.16.1 The manufacturer shall provide training for those personnel whose activities may affect the product's quality. The training shall cover, as relevant, the manufacturer's quality procedures, production methods, test methods, the Standard's requirements, the requirements of this document, etc.

316.2 The manufacturer shall provide certification of the personnel associated with activities for which the Standard, or the law, requires certification. The manufacturer shall insure that these personnel are qualified on the basis of education, training or experience.

316.3 The manufacturer shall specify the special activities that may strongly affect the product's quality, and shall provide certification of the personnel associated with these activities.

316.4 The manufacturer shall maintain appropriate records concerning the training and certification of his personnel.

316.5 When certain physical conditions of the personnel may adversely affect the quality of products for whose manufacture they are responsible, these personnel shall be subject to medical tests at appropriate intervals. The manufacturer shall take all precautions in order to prevent personnel having such medical disabilities from being employed in types of work that may result in the production of nonconforming products, e.g. colorblindness of a quality inspector examining the color finish.