SCHEME OF SUPERVISION AND CONTROL RELATING TO THE USE OF THE HONG KONG Q-MARK

PART 2. **QUALITY SYSTEM REQUIREMENTS. (Non Hygiene related)**

2.1. GENERAL

The aim of this part is to ensure a system is in place for the continuous production of products satisfying Part 3 of the Scheme of Supervision and Control. These requirements are in addition to the requirements set out in Part 1 of the Scheme of Supervision and Control.

2.2. APPLICABILITY OF PART 1 & PART 3 REQUIREMENTS

All the requirements of Part 1 & 3 shall apply.

2.3. MATERIALS AND COMPONENTS

The licensee shall ensure that all materials and components are supplied in a suitable forms and conditions, which shall be verified in compliance with appropriate requirements.

The licensee shall establish and maintain procedures for identification, storage, segregation and handling of materials and components to prevent them from contamination or deterioration.

In addition, the licensee shall assess condition of materials and components, which need shelf-life control, in regular basis in order to detect deterioration. They shall bear identification of expiry date, which shall be justified and specified by the licensee. They shall not be used after the expiry date, except for further evaluation with appropriate record maintained (see 2.10).

2.4. DOCUMENT CONTROL

The licensee shall control, but not limited to, following documents which are made available in production floor to provide instructions:-

a. Defining the manner, including sequence, step or method, of manufacturing processes of products for workers to comply with;

b. Defining process control method for workers to comply with (see 2.9);

c. Defining in-process and final inspection and testing activities for inspectors and/or workers to comply with (see 2.7.2).

Document control includes review and approval of issue and change, revision level, availability of updated revision in location of use and removal of outdated copy from point of use.

2.5. PRODUCTION PROCEDURE

2.5.1. Prior to release for production, materials and components shall be inspected as defined in company standards to assure the conformance to specified requirements.

2.5.2. Urgently needed materials or components can be released if positive identification is made to permit necessary recall when the test result is found to be unsatisfactory. However, prior to release of final products for delivery to customer, all planned inspection and testing activities shall have been completed with satisfactory result.

2.5.3. The production shall be proceeded in accordance to specified flow stipulated and documented in company standards.

2.5.4. The quality control procedures shall be proceeded in accordance to specified flow stipulated and documented in company standards.

2.5.5. Any change to manufacturing flow shall have approval from authorized staff, which shall keep the Council in writing.

2.5.6. The licensee shall prepare adequate work instructions (see 2.4a) to define the manner of production and operation of production machines/equipment and make them available on production line so that workers know how to perform their daily jobs.

2.5.7. Final products are to be manufactured to meet the standard as specified in Part 3 of the Scheme of Supervision and Control and in-house specification.

2.6. PRODUCT IDENTIFICATION

The licensee shall identify product for both its identify and production status throughout factory facility. If traceability is a specified requirement, individual product or batch/lot shall be uniquely identified, which means shall be recorded (see 2.10).

2.7. INSPECTION AND TESTING

2.7.1. TEST FACILITIES

The licensee shall identify, establish, operate, and maintain adequate test facilities in the production premises. In addition, tests done by external laboratory may be needed in order to ensure material, component, semi-finished, or final product can meet specified requirements.

2.7.2. INSPECTION AND ROUTINE TEST

Inspection and routine test shall be performed according to the corresponding measures and acceptance criteria specified and documented by the company standards.

Before delivery to customer, final product shall be inspected to give evidence that they comply with Part 3 of the Scheme of Supervision and Control, and any other specified requirements.

Inspection and test records (see 2.10) shall be maintained to demonstrate conformance to specified requirements. Inspection and test status, and nonconforming product status shall be properly identified throughout production line.

The licensee shall implement appropriate actions, which are justified by designated staff, to prevent recurrence of product nonconformances.

2.7.3. EQUIPMENT CALIBRATION

The licensee shall identify and justify equipment used for inspecting, measuring and testing final product nonconformance to be put under appropriate calibration control.

Particularly, measuring tape and weight balance used for measuring overall dimensions and weight respectively must be calibrated at defined intervals. Calibration status and records (see 2.10) shall be maintained which should contain following data:-

- Date of calibration or repair;
- Method of calibration with detailed procedure or reference to procedure;
- Acceptance criteria;
- Result of calibration with detailed data.

Calibration shall be conducted against certified equipment, which can be designated as in-house calibration master. This master must be calibrated by external body which can demonstrate calibration traceability to nationally or internationally recognized standard. Where no such standard exists, the basis for calibration shall be documented.

2.7.4 EQUIPMENT VERIFICATION

Where test software or comparative references such as test hardware are used as suitable form of inspection, they shall be checked to prove that they are capable of verifying the acceptability of final product, prior to release for use during production, and shall be rechecked at prescribed intervals. The licensee shall establish the extent and frequency of such checks and shall maintain records as evidence of control (see 2.10).

2.8. PRODUCTION EQUIPMENT

Equipment shall be designed, installed and located to suit the process capability and product quality requirements. It shall be properly maintained to ensure its continuous capability and present no hazard to the involved product.

Cleaning, checking, testing, calibration, maintenance, etc... of the equipment shall be regularly performed in a suitable interval according to the company standards. Record of any preventive and/or breakdown maintenance shall be maintained (see 2.10).

The accuracy and capability of equipment have to be maintained or upgraded if needs arise.

Specifically, equipment and instrumentation in any quality control laboratory shall be appropriate to the required test requirements (see 2.7.3 and 2.7.4).

2.9. PROCESS CONTROL

The licensee shall establish and maintain documented procedures which are known to be capable of producing final products that meet the specified requirements. Specifically, the control items, control method, quality characteristics, and testing method shall be established and documented for following appropriate control mechanism.

a. Initial process approval (pre-setting) before mass production;
b. Monitoring and control of identified critical process parameters and/or product characteristics;
c. Compliance with code of practices, regulatory or statutory requirements.

Records of implementation of either control mechanism "a" or "b" shall be maintained (see 2.10).

2.9.1. Production staff shall follow the defined, authorized and documented procedures for each stage of production process.

2.9.2. Any deviation from defined procedures must be reported, approved, and recorded (see 2.10). The approval shall be granted by authorized persons from production and/or quality control or top management.

2.9.3. Before the start of production, steps shall be taken to ensure that the work area and the environmental conditions are suitable. If environment control is a must, equipment used for monitoring controlled environment parameters shall be calibrated in accordance to 2.7.3

2.9.4. Defects and irregularities are recorded (see 2.10) and appropriate corrective and preventive actions shall be taken and recorded (see 2.10) to avoid their reoccurrence and occurrence.

2.10. QUALITY RECORDS

The licensee shall maintain up-to-date records to demonstrate the achievement of the required quality. The records should also be used to promote quality control method. Besides those quality records identified in above requirements, the licensee shall identify other quality records by their own.

All records shall be legible and identifiable to the product or process involved. They shall be readily retrievable and is available for inspection by the representative of Hong Kong Q-Mark Council. The licensee shall define and document retention time of quality records, which minimum period shall be six months.

2.11. MARKING

Each pack of product manufactured under the Licence shall be legibly and permanently marked either on the product or packaging with the following information :-

(a) The Hong Kong Q-Mark Logo with the designated Licence number shall be permanently marked;

(b) Name or trademark of the manufacturer or supplier;

(c) Product number, brand name and model number.

2.12. PACKAGING

All products manufactured under the Hong Kong Q-Mark Licence shall be packed in clean and new container in a appropriate manner suitable for the purpose. The overall package shall give adequate protection against shock and vibration expected during storage and delivery to customer. The licensee shall prepare documented instructions for defining the method of packing of final products in order to prevent them from damage.