THE STANDARDS INSTITUTION OF ISRAEL - SII

SII Proposed Procedure 007
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Rules for Operating the Standards Mark System

Director General

This procedure replaces SII Procedure 007 from May 2003

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0. Preface

0.1 The Standards Mark, marked on a product, is confirmation by the manufacturer that the product meets the requirements of the Israeli Standards that apply to it. The manufacturer is only allowed to mark the product with the Standards Mark if they received a license from the Standards Institute. The license is given after the Institute is convinced that the product meets the requirements of the standards and that the manufacturer has suitable means of production, review installations and appropriate control processes and a suitable organizational system, that will enable them to maintain consistently the quality of the product over time. The Institute, for its part will maintain ongoing overview of the manufacturer's quality system, and performs testing of the product, at suitable frequency, in order to ensure that it remains compliant to the standard.

0.2 The Standards Mark System serves consumers since 1954 by providing a simple and convenient means to distinguish between standard compliant products and other products. In a time when many of the sophisticated products offered to the consumer, who is unable to evaluate their quality and safety, this discerning ability is of great importance to maintain the interests of the consumer and their rights.

0.3 The Standards Mark System also serves the manufacturer. Being granted a license , by an independent factor, that the product meets the requirements of the standard and noting this fact on the product, serve as an important, often critical, marketing tool.

0.4 In many cases the need to mark the product with the Standards Mark derives from requirements of the customers - factories, government offices, purchasing organizations - and in some cases, required by government decrees.

0.5 The Israeli Standards Mark System, described in this document, operates under section 11 of the Standards Law, 1953 and the Standards Regulations (Standards Mark and Inspection Mark), 1982.

0.6 The Standards Mark System is operated by the Standards Institute of Israel, but is under public overview through the Standards Mark Directorate, various Professional Committees and License Committee. These bodies are authorized to make the various operative decisions relating to operating the system.

0.7 The Israeli Standards Mark System operates in accordance with the rules of the international standard for certifying products, ISO/IEC Guide 65: 1996, General requirements for bodies operating product certification systems.

1. General

1.1 Scope of Procedure

1.1.1 This procedure specifies the procedures for granting licenses to manufacturers, by the Standards Institute, to mark products with the Standards/Safety Mark that describe the basic rules of the ongoing supervision, after the license is granted, and refers to a number of other topics, that are related to operating the Standards Mark System.

1.1.2 This procedure is a general procedure. Based on the policy specified in it, detailed work procedures will be published.

1.2 Purposes of Procedure

1.2.1 To provide information, to those who want to receive a license to mark products with the Standards/Safety Mark, about the processed, procedures and rules that this involves.

1.2.2 To define the policy, which will serve as base for preparing detailed work procedures that are published by the Standards Institute of Israel.

1.2.3 To guide members of the License Committee and the professional Committees, the workers of the Standards Mark Operations Directorate, and other workers of the SII that are connected to the Standards Mark System, in their work.

2. Applicable Documents

2.1 Documents referred to in this procedure

Note: For documents without a date - the latest edition is applicable.

2.1.1 Standards Regulations (Standards- Mark and Inspection Mark), 1982 (hereafter - the Regulations)

2.1.2 Standards Order (Defining Standards Marks), 1992

2.1.3 Standards Order (Prohibition on manufacturing Produce), 1981 - Requirement for a Standards- Mark

2.1.4 Israeli Standard 9001 - Requirements for Quality Systems

2.1.5 SII Procedure 005 - Requirements from Quality Systems used by manufacturers that manufacture products marked with the Standards Mark

2.1.6 SII Procedure 006 - Policy of defining the arrangements, the essence and amount of the overview of the Institute over manufacturers making products that are carry the Standards Mark.

2.1.7 SII Procedure 008 - Procedure for Preventing Conflict of Interest and Maintaining

Confidentiality of Information in the Standards Mark System

2.1.8 SII Procedure 013 - Rules for Running the License Committees and the Professional Committee by the Standards Mark Directorate.

2.1.9 ISO/IEC Guide 65: 1996, General requirements for bodies operating product certification systems.

2.1.10 Israeli Standard 17025 - General Requirements for the competence of testing and calibration laboratories

2.2 Appendices to the procedure

2.2.1 Appendix A - Request form to grant a Standards Mark

2.2.2 Appendix B - Questionnaire for initial introduction of the manufacturer

2.2.3 Appendix C - Letter of consent for preliminary queries

2.2.4 Appendix D - Letter of consent for ongoing overview as part of the Standards Mark

2.2.5 Appendix E - Letter of consent for a three way agreement

2.2.6 Appendix F - License to mark a product with the Standards Mark

2.2.7 Appendix G - License to mark a product with the Safety Mark

2.2.8 Appendix H - The Standards Mark symbol - General

2.2.9 Appendix I - The Safety Mark

3. Definitions of Terms

The following terms are valid for this procedure:

3.1 The Institute -- Standards Institution of Israel (SII)

3.2 Standards Mark Directorate - Directorate founded per Regulation 2 of the Regulations.

3.3 Chief Executive Officer (CEO) - the General Manager of the SII, or anybody that they have appointed in writing to carry out one of their roles per this procedure.

3.4 The Department - The Institute's Quality and Certification Department.

3.5 Standards Mark Operations Directorate - an organizational unit that operates on behalf of the CEO and who role is to put into effect the policies of the Standards Mark Directorate.

3.6 Standard - As defined in the Standards Law, including institute specifications, and including official standards.

3.7 General Mark - A Standards Mark that relates to a product, whose applicable standard includes both quality requirements and safety requirements.

3.8 Safety Standards Mark - A Standards Mark that relates to a product, whose applicable standard includes only safety requirements.

3.9 Standards Mark - Whenever Standards Mark or Safety Mark appears, without the 'General' qualifier, the instructions apply to both.

3.10 License Committee - Committee founded per Regulation 3 of the Regulations.

3.11 Professional Committee - Committee founded per Regulation 4 of the Regulations.

3.12 Laboratory - A laboratory of the institute's laboratories that deal with testing the product made by the manufacturer.

3.13 External Laboratory - A laboratory that is not of the institute's laboratories.

3.14 Accredited Certification Body - An entity that was accredited by a certification body that is a member of the IAF.

3.15 Product Quality Plan - The Quality Plan through which the manufacturer guarantees that the product is compliant with all requirements of the standard.

3.16 Institute Specification - A technical Specification that is not an Israeli Standard which was prepared and published by the institute according to rules made by the executive committee of the institute.

3.17 Defects - Categorization:

3.17.1 Defect: Non-compliance with one or more of the following:

A. The Standard that applies to the product;
B. SII / ISO 9001 - Quality Control Systems - Requirements;
C. SII Procedure 005 - Requirements from Quality Systems used by manufacturers that manufacture products marked with the Standards Mark;
D. Product's Process Review Specification.

3.17.2 Critical Defect:

A. As a finding of a laboratory test: A result that indicates that the tested product is a safety or health hazard to the user or third party.
B. As a finding of a quality examination or Process inspection: A result that indicates that the manufacture produced or produces products that are a safety or health hazard to the user or third party.

3.17.3 Severe Defect:

A defect that is not critical and that might cause the unit to fail or to severely reduce its usability for the purpose it was meant to fill, also a deviation from the standard that would mislead the customer by misleading advertisement.

3.17.4 Minor Defect:

A defect that is neither a Critical Defect nor a Severe Defect.

Note: All defects found in the quality examinations will be categorized as minor defects. A defect in the Quality System is any non-compliance found in the factory inspection that was defined as “Requires significant improvement”.

3.17.5 Recurring Minor Defect:

A Minor Defect (the same defect) that was found in 2 out of 3 of the last factory inspections.

4. Instructions

4.1 General Instructions

4.1.1 A license to mark products with the Standards Mark will be granted to a manufacturer, only if the following basic conditions are fulfilled -

A. The product is compatible with the requirements of the Israeli Standards that apply to it.

B. The manufacturer operates a Quality System that meets the requirements of SII Procedure 005, or has valid certification from an accredited body, for SII ISO 9001.

C. The manufacturing processes of the product and the manufacturer's control system for the product and its manufacturing process were authorized by the institute in a process inspection.

D. The manufacturer operates a special Quality System that consistently ensures compliance with the standard over time.

E. The manufacturer has a Product File and a configuration control system that enables identifying any change in the materials and components, and their suppliers.

4.1.2 The scope of the ongoing factory inspection of the manufacturer by the institute will be determined in procedure 006.

4.1.3 Representative of SII will perform all activities related to granting a Standards Mark and inspection the manufacturer in an objective fashion and without bias.

4.1.4 All manufacturers will have access to the Standards Mark System, without discrimination.

4.1.5 All activities of the Standards Mark system will be performed according to the procedures, according to decisions of the Standards Mark Directorate and in accordance with SII procedures as published from time to time.

4.1.6 The organizational unit in the SII that is responsible to operate the Standards-Mark System is the Standards Mark Operations directorate that operates as part of the Quality and Certification Department

4.1.7 The activities of the Standards Mark system will be funded by those who request a license to mark their products with the Standards Mark and by those who have been granted such a license.

4.1.8 If the standards that apply to a product only include safety requirements, the manufacturer will be granted a Safety Mark. If the standards that apply to a product include both safety requirements and requirements for quality, reliability, operations etc., the manufacturer will be granted a general Standards Mark. That said if the safety requirements are specified in one specific standard while the requirements for quality, reliability, operations etc. are specified in a different standard, if the manufacturer requests, they can be granted, only a Safety -Mark, for compliance with the standard having only the safety requirements.

4.1.9 The decision that the standards that apply to the product are suitable for granting a General Standards Mark, or Safety Standards Mark, as described in section 4.1.8 above, will be made by the appropriate Professional Committee.

4.2 Stages in the Process to receive a Standards Marks

The following are the stages in granting a License:

A. Supplying information (see Section 4.3)

B. Submitting a request (see Section 4.4)

C. Preliminary inquiries (see Section 4.5)

D. Professional Committee Activities (see Section 4.6)

E. License Committee Activities (see Section 4.7)

F. Onsight inspection agreement and the Standard Mark License (see Section 4.8)

4.3 License Supplying Information

4.3.1 A manufacturer that is interested to receive information about the Standards Mark System will contact the Standards Mark Operation Directorate, in writing or verbally and will specify the product they wish to mark with the Standards Mark and the type of mark (Sections 3.7 and 3.8).

4.3.2 The Standards Mark Operations Directorate will check if there is a Standard or SII Specification that applies to the product. If no such standard exists, the Standards Mark Operations Directorate will notify the manufacturer.

4.3.3 If a suitable standard exists, the Standards Mark Operations Directorate will send the following information to the manufacturer:

A. Document describing the Standards Mark System.

B. SII Procedure 005 (If necessary) .

C. Form to request granting a Standards Mark

D. Questionnaire for initial introduction of the manufacturer

4.3.4 The Standards Mark Operations Directorate will acknowledge, in writing, to the manufacturer, that they received the request and will note its serial number, for identification purposes throughout handling the request.

4.4 Submitting a Request

4.4.1 A manufacturer that wants to receive a Standards Mark will submit the following documents to the Standards Mark Operations Directorate:

A. The Request Form and the Self-Evaluation Questionnaire.

B. Detailed description of the product. It would be preferable, if possible at this stage, to submit the Product File to the Standards Mark Operations directorate/ Direct to the relevant lab.

C. The General Quality Policy of the factory, including a file of procedures as per requirements of SII Procedure 005/ISO 9001.

D. Quality Plan for the product.

4.4.2 The Standards Mark Operations Directorate will check the documents that the manufacturer submitted. If necessary the manufacturer will be requested to clarify things, or to fill in missing information.

4.5 Preliminary Inquiries

4.5.1 Before beginning the formal preliminary inquiries, the SII can decide to conduct a preliminary factory inspection at the requester. The purposes of the preliminary inspection are to get to know the requester, the production lines at their factory, the products being manufactured and the senior workers and to review the possibility of working with them. The costs of conducting the preliminary inspection will fall on SII.

4.5.2 Based on the information that SII has, the Standards Mark Operations Directorate will send a letter to the manufacturer, specifying the activities that will be taken as part of the preliminary inquiries, as authorized by the Professional Committee as well as a written agreement for the preliminary inquiries with a quotation to cover the cost of these activities and an estimated schedule to conduct them. The manufacturer will be asked to return to the Standards Mark Operations directorate, the agreement signed by the manufacturer's authorized signatories. The preliminary inquiry plan will

primarily include a single full and comprehensive review as well as some/all of the following activities:

A. Review of the Product File and approving it.

B. Examining the manufacturer's Quality System Procedures.

C. Conduct a quality audit to demonstrate implementation of SII Procedure 005/ISO 9001.

D. Conduct a process review.

E. Examining the products.

F. Approval of the Product Quality Plan.

4.5.3 The manufacturer having signed the agreement that was sent to them, the Standards Mark Operations directorate will send the requester a bill to cover the costs of the preliminary inquiries that will be based upon the institute's defined pricelist. As a general rule, the preliminary inquiries will only be started after the manufacturer signed the preliminary inquiries agreement and after the requester submitted the Product File to the Standards Mark Operations Directorate.

[Note: Despite the above, the preliminary inquiries can be started even if a detailed Product File and compliance to the standard were not attached to the submitted request form and the self-evaluation questionnaire, although the manufacturer will be requested to submit this file before the end of the preliminary inquiries].

4.5.4 The Standards Mark Operations Directorate together with the relevant laboratory will review the Product File to ensure that it contains all of the information needed to unambiguously define the product. If necessary the manufacturer will be requested to fill in the missing information in the Product File.

Should it be found that the Product File meets the requirements, it will be approved by the appropriate laboratory. The approval will be done by the approver signature on the file, along with the date of approval. The signed file will be kept at the institute, or at the manufacturer's factory, according to the laboratory's decision.

After granting the Standards-Mark the Product File will be used for ongoing factory inspection to ensure that no changes were made to the product, unbeknownst to the SII that could make it non-compliant to the standard.

4.5.5 Representatives of the institute will audit the Quality System and conduct process inspections in the factory, in order to examine the production system, to determine if the Quality System at the factory is suitable for the requirements of SII Procedure 005 or ISO 9001, to examine whether the Quality Plan for the product is properly implemented and the arrangements at the factory to conduct ongoing product tests and ensuring maintaining the quality of the product. The quality examinations and process reviews will be done according to institute procedures. Following the examination or process inspections a detailed report will be sent to the manufacturer.

When significant parts of the product are manufactured by sub-contractors, the SII can also conduct examinations or process inspections at the sub-contractors. It is the manufacturer's responsibility to arrange the sub-contractors' agreement to cooperate with the SII in conduction the factory inspection, that the SII will decide to perform at

the sub-contractors.

If deficiencies are found in the manufacturer's production system, the manufacturer will be required to fix them. If the deficiencies are critical or severe, the SII will conduct a re- examination, to review implementation of the corrective actions that the manufacturer was asked to implement. The manufacturer will be billed separately for these additional inspections.

4.5.6 As part of the preliminary inquiries, a representative of the institute will take samples of the product of the production line for laboratory testing. In certain cases, and with permission from the laboratory, the manufacturer will be given the option to bring these samples to the SII after they were selected and marked by a representative for the SII. The tests will be performed at the SII laboratories, or at other laboratories authorized for this purpose by the SII, according to SII procedure 120505 - using subcontractor to perform laboratory tests.

In certain cases and especially when there are various models of the same product (optional add-ons), partial tests will also be done. The partial tests will be done regarding those attributes that vary between the models of the product.

The test report will be sent by the laboratory to the Standards Mark Operations Directorate and to the manufacturer. When defects were found in the product, the manufacturer is allowed to request to test it again, in order to ascertain that the defective factor has been removed, provided that they pay for these tests.

4.5.7 If the preliminary inquiries have not been completed within 6 months - in the case of elevators according to the Special Condition Appendix (S.C.A) 1-2481 parts 1&2 - from the date the request was submitted by the manufacturer, the Standards Mark Operations Directorate will report to the relevant Professional Committee that will recommend to the License Committee to take one of two following courses of action:

A. To reject the manufacturer's request to be granted a License Standard Mark License;

B. To set a new finish date for the preliminary inquiries, and in the case of elevators to extend by 6 additional months.

The License Committee will make its decision, giving reasons for their decision that will be included in the meeting protocol. Notification regarding the decision of the License Committee to reject the manufacturer's request will be sent to them via registered mail, with the reasons for their decision included. In cases where the License Committee decided to reject the manufacturer's request to be granted a license, a new request for a license, from the same manufacturer, for the same model of the product, will not be accepted before the end of six months from the date of the License Committee's decision.

4.6 Professional Committee Activities

(See also SII Procedure 013: Rules for Running the Professional Committees and the License

Committee by the Standards Mark Directorate)

4.6.1 The Professional Committee will define:

A. Whether the Standards to apply to the product, are suitable for the purpose and granting a Standards Mark license.

B. Whether the product will be granted a general Standards Mark or Safety Mark, as a recommendation to be approved by the License Committee.

C. The preliminary inquiry plan.

D. The special conditions for performing the ongoing inspections, after granting the license, as a recommendation to be approved by the License Committee (The special conditions will be defined according to the guidelines of SII Procedure 006).

E. How the product will be marked with the Standards Mark, as a recommendation to be approved by the License Committee.

4.6.2 The Standards Mark Operations Directorate will give the Professional Committee a detailed report about the actions taken by the SII, as part of the preliminary inquiries and their results, including the negative results received in testing for which the manufacturer later performed corrective actions. The Professional Committee will review the reports submitted to it and after considering the factors of the issue, will decide whether to recommend to the License Committee, to grant the license or not.

4.6.3 If the Professional Committee decided to not recommend granting the license, the Standards Mark Operations Directorate will notify the manufacturer of this, also providing the reasons that brought the committee to this decision. The manufacturer will be requested to notify the SII if they are interested that the SII bring this recommendation to the License Committee, or that they wish to delay the procedures until removal of the deficiencies that were found as part of the preliminary inquiries.

4.6.4 If the Professional Committee decided to recommend to the License Committee, to grant the Standards Mark to the manufacturer, the recommendation will be passed to the License Committee.

4.7 License Committee Activities

4.7.1 The License Committee will discuss the Professional Committee's recommendation and decide whether to grant the manufacturer the requested license.

4.7.2 If the License Committee decided to grant the license, they will define the special conditions for performing the ongoing inspection, of the manufacturer by the SII, and how to mark the product with the Standards Mark.

4.7.3 If the License Committee decided to not grant the license, the Standards Mark Operations will notify the manufacturer in writing, giving the committees reasons. The manufacturer can submit an appeal of this decision to the Directorate (Section 4.1.6).

4.8 Inspectoin Agreement and the License

4.8.1 The Standards Mark Operations Directorate will notify the manufacturer, in writing, about the decision of the License Committee whether to grant them the requested license to mark the product with a Standards Mark and will attach to the notice the wording of the Oversight Agreement and the bill for payment, that will be conducted according to the special conditions that were approved and according to the SII pricelist.

4.8.2 The manufacturer having returned the signed Inspection Agreement and arranged the required payments, according to the bill they were given, will be provide with the requested license by the Department (Appendix D or Appendix E, as relevant). The License will be valid until December 31st of the year in which the agreement was signed, but if the agreement was signed after June 30th, the license will be given until December 31st of the following year.

4.8.3 The Inspection Agreement is written as a multi-year agreement, in which the inspection will be performed continually according to the frequency defined in the Special Conditions Procedures **[S,C,A]** - starting from the day the agreement was signed until its cancellation according to the terms defined in the agreement.

4.8.4 Expanding the license to use the Standards Mark on additional models of the same product, shall be treated the same as granting a new license. The method of handling these cases will be determined on a case by case basis, as relevant.

4.9 Ongoing Inspection

4.9.1 The ongoing inspection will be done according to the special conditions authorized by the License Committee that were attached to the Inspection Agreement and are an inseparable part of it.

4.9.2 Throughout the year, quality examinations and process inspection, as well as full and partial testing of the product, will be conducted at the manufacturer, as specified in the special conditions.

The purposes of these operations are:

A. To ensure that the products are compliant to the requirements of the standard.

B. To ensure that no significant changes were made in the product design, without knowledge of the SII.

C. To ensure that the Quality Plan continues to be implemented as required.

D. To check if any changes occurred at the manufacturer that would necessitate changes to the Quality Plan and the Quality System.

E. To ensure that corrective actions, that were requested in the past, by the institute, were in fact implemented as promised.

F. To determine if changes were made in the production methods.

G. To verify how the tests are performed by the manufacturer.

4.9.3 The quality examinations and process inspection will be performed according to SII procedures. The tests will be performed according to standards that apply to the product.

4.9.4 Factory relocated to a new site

4.9.4.1 An inspection will be carried out at the factory on the new site. The purpose of the inspection will be to ensure that there has been no changes in the following issues: management, manpower, product quality plan (including production processes), which may affect product design.

4.9.4.2 If changes are found in the inspection, it will be necessary to check that these changes meet the standard requirements and/or do not affect the product's design

4.9.4.3 If the factory on the new site meets all the requirements, it will be submitted for approval to grant a license of standard mark to the factory at the new address and the license of the factory at the previous site will be canceled (if necessary).

4.9.5 The SII will provide the manufacturer with copies of the test reports for the product, reports on the quality examinations and process reviews conducted at their factory.

4.9.6 If while performing the product tests deficiencies were found or discrepancies in the quality examinations and process inspections, the SII will take the steps required, according to instructions of the Standards Regulations and SII procedures, or according to decisions of the Standards Mark Directorate.

4.9.7 When the product is manufactured during a specific season or time of year, the factory inspections activities will be concentrated in this season or time.

4.9.8 If production is stopped for more than 3 months, a special process review will be performed near the time production is resumed, to verify that the competence is maintained. In case were production is stopped for more than 12 months - the license will be cancelled.

4.10 Publications

4.10.1 On granting the license to the manufacturer, the SII will publish, at the manufacturer's expense, a notice regarding grating the license, in two daily newspapers, chosen by the manufacturer. The SII will publish every month in the records the list of licenses that the SII granted in the passing month.

4.10.2 The SII will publish, on its website (sii.org.il) a complete and current list of all the manufacturers that were granted licenses, and the products and models included in these licenses. Similarly the SII will publish a list of all of the licenses that are temporarily suspended due to cessation of production and a list of the licenses cancelled over the last 12 months.

4.11 Maintaining Confidentiality & Lack of Conflict of Interests

4.11.1 The SII employees and those performing supervision tasks as subcontractors, Professional Committee members and License Committee members and the Standards Mark Directorate shall maintain confidentiality of the information came to their notice as part of their duties, including information related to products, their manufacture process, the manufacturer’s quality system, etc. and shall not publish any material regarding them, unless approved in writing by the General Manager

(CEO). The committee members shall sign a commitment to maintain confidentiality as specified in Regulation 11 of the Regulations.

4.11.2 Notwithstanding the above, the SII may report to the Commissioner of Standardization on the noncompliance of a product with the requirements of an official Standard and to take any action within its authorities, if the product constitutes a safety/health danger to the public or that it may impair the environment. (Note: a distinction shall be made between detailed information and general information.)

4.11.3 Members of the Professional Committee and License Committee and the Standards Mark Directorate shall avoid any conflict of interest whatsoever between their activities in the Standards Mark system and their other occupations. They shall inform the chairman of the committee in which they serve and the SII General Director at once of any suspicion of conflict of interest and they shall avoid any participation in a meeting or deliberations or decisions in the matter of such suspicion of conflict of interest.

4.11.4 The SII General Director and the chairman of any committee in which he serves may prevent the committee member from participation in a meeting or deliberations or decisions in any case where he believes that the committee member is found in conflict of interest. Where the committee member believes that there is no conflict of interest, the General Director or the chairman, as the case may be, will allow him to state his case before him, however the final decision shall be of the General Director or the chairman, as the case may be.

4.12 When the License Owner is not the Actual Manufacturer

4.12.1 The Requester for the license can also be someone who presents themselves as the manufacturer, by use of their name or trademark (hereafter: "**seller**").

4.12.2 In this case granting the license will be contingent on conditions in addition to the ones specified in this procedure, including:

A. A triangle agreement will be made between the seller, the actual manufacturer and the institute. A separate agreement will be made with each actual manufacturer.

B. The seller will buy the products only from those manufacturers that were given a License to mark the products with the Standards Mark, which are already marked with the Standards Mark.

C. The seller will not sell products of the same type that received a license that do not carry a Standards Mark.

D. The seller will not mark products with the Standards Mark by himself.

E. The actual manufacturer of the products gave their agreement in writing to this arrangement.

F. Cancellation of the license of the actual manufacturer will result in the

cancellation of the seller's license.

4.12.3 In addition to the oversight according to the Special Conditions Procedures at the actual manufacturer of the products, the SII will also perform ongoing factory Inspection at the seller to ensure that the seller meets the conditions specified in Section 4.12.2.

4.12.4 When the manufacturer, the license requester, manufactures the products at the factory of another party, granting the license will be contingent on conditions in addition to the ones specified in this procedure, including:

A. The factory has a dedicated and separate production line for products that carry the Standards Mark.

B. The requester will take care to ensure that the SII will be able to conduct factory inspection and product tests, at the production line on which the products are manufactured, fully and unrestrictedly, as if it was the factory of the requester.

4.13 Laboratories that are not Institute Laboratories.

4.13.1 The manufacturer is allowed to request that the testing of the product, both during the preliminary inquiries and as part of the ongoing inspection, be performed at an external laboratory.

4.13.2 The decision whether to grant this request will be made by the CEO, depending on the circumstances. In any case, the CEO's agreement will be contingent on the laboratory having been certified by the SII, or by a factor known to the SII, in accordance with Israeli Standard SII 17025 and only after having signed a suitable agreement between the external laboratory and the SII. In all case,

the external laboratory will function as a sub-contractor of the SII and will report to it, the findings of its tests and other activities.

4.13.3 The department will notify the manufacturer, in writing, about the CEO's reasoned decision.

4.13.4 In certain cases, it will be possible to conduct the tests in the manufacturer's laboratory, under conditions that the SII will define.

4.14 Actions on Finding Defects [1]

Defects in the product and in the quality system are found while doing laboratory tests, in factory inspection or as part of examinations performed at the manufacturer factory. Accordingly, the following actions must be taken:

4.14.1 **Notification to the manufacturer and requiring corrective action -** The laboratory / inspector / auditor will give the manufacturer the test certificate / process review report / examination report that describes the defect together with a letter from the Head of the Standards Mark Operations Directorate (the contents of which

[1] Categorization of Defects - See Section 3.17 above

are in the following table), and requiring them to take corrective action accordingly, within a limited timeframe. Additionally the Head of the Standards Mark Operations Directorate will do the following:

Minor Defect	Severe Defect / Recurring Minor Defect	Critical Defect
Request in writing within 10 work-days from the date of the product test / factory inspection /audit, to take a corrective action.[3]	• Direct the manufacturer in writing, within 5 work-days from the date of the product test / factory inspection /audit, to require taking corrective actions that will remove the defects [1][4] • Collect from the manufacturer the Standards Mark decals (or other markings).[2] • Require taking corrective action. • Perform special factory inspection to monitor the product's compliance with Standard. • Debate in the Professional Committee and in the license Committee accordingly.	• Direct the manufacturer in writing, immediately after performing the product test / factory inspection /audit, to immediately stop marking. [1][4] • Collect from the manufacturer the Standards Mark decals (or other markings). [2] • Perform Recall. [1] • Report within 48 hours to the CEO of the SII, Head of Quality and Certification Department, Head of the Department the laboratory belongs to, and the Commissioner of Standardization. • The CEO of the institute can decide to publicize the defect and/or suspend the preliminary inquiry process until the License Committee is convened. • Immediately notify the Professional Committee and after that the License Committee with a recommendation of the Professional Committee to completely cancel the license or any other recommendation they define. • Require taking corrective action. [3] • Perform special factory inspection to monitor the product's compliance with the Standard.

Comments:

1) The Head of the Standards Mark Operations Directorate must confront the manufacturer with the findings before the Professional Committee is convened in cases were sub-standard products were distributed to the public. It must be clarified, even before the committee is convened, if the manufacturer is willing to cooperate with a Recall.
2) Head of the Standards Mark Operations Directorate will ensure that products that aren't standard compliant (severe or critical defect) will not be marked with the Standards Mark, by collecting the decals, by demanding the manufacturer stop the marking (when there's no other option), or in any fashion that will be agreed upon between the institute and the manufacturer.
3) The corrective action will require acting immediately to find the reason for the presence of the defect and to prepare a plan of corrective action that will be presented to the Professional Committee and the License Committee.
4) Do not delay taking measures until the tests are complete or the information is passed in writing to the manufacturer.

4.14.2 **<u>Notification to the following factors - when the defect is severe or critical (copy of</u> letter sent to a manufacturer):**

A. The Institute Engineer that is responsible for the manufacturer and conducts the quality audits.

B. The Commissioner of Standardization (when the Standard is official).

C. Coordinator of the Professional Committee.

4.14.3 **Decisions of the Professional Committee and the License Committee - when the defect is severe or critical:**

A. When according to the estimate of the manufacturer and the relevant laboratory, the correction will take up to 14 days - the defect and that it was fixed must be reported.

B. When according to the estimate of the manufacturer and the relevant laboratory, the correction will take more than 14 days and up to 6 months - the manufacturer will submit a corrective action + implementation schedule + Quality Plan that will ensure that the products leaving the factory are standard compliant. The institute will conduct examinations to check that the corrective action is being done. If necessary and according to circumstances, increased oversight will be required.

C. When according to the estimate of the manufacturer and the relevant laboratory, the correction will take more than 6 months - will recommend cancelling the license.

4.14.4 **Testing the product / quality system after corrective action by the manufacturer:**

Minor Defect	Severe Defect / Recurring Minor Defect	Critical Defect
Test the product / quality system at next factory inspection after the corrective action	Test the product / quality system after the corrective action, within 30 days	Test the product / quality system immediately after the corrective action

4.14.5 **Actions based on results of testing product/Quality System after corrective action:**

The Professional Committee will recommend:

4.14.6 **With increased supervision -**

A. Returning to normal supervision, if found that the defect was removed.

B. If found that the defect still exists, must enable the manufacturer to try again to remove the defects or to recommend complete cancelation of the license, all according to circumstances of the case.

C. The Professional Committee will define what the necessary mechanisms are, if any, for monitoring the complete removal of the defects from the product.

4.14.7 **With Permanent cancelation -**

A. To act according to the rules for preliminary inquiries.

B. The Professional Committee can decide that the retesting will be part of the testing required for the preliminary inquiries.

4.15 Cancelling Licenses

4.15.1 If the Head of the Standards Mark Operations Directorate receives information, that allegedly there are grounds to cancel the license of a specific manufacturer, they will prepare a detailed reasoned document that includes the reasons that justify canceling the license, and will note in the document that CEO's delegates recommend canceling the License, and request that the License be canceled by the License Committee.

The document will contain all data relevant to the case, and to which will be attached all of the test certificates and examination results, as relevant, that supposedly justify canceling the License, including all of the raw material - and not just the processed information prepared for the discussion about canceling the license. The document that will be prepared, together with its attachments, will be given to the members of the Professional Committee that is appropriate to the product for which the License was given, and a copy of which will be given to the manufacturer.

4.15.2 If the manufacturer declares they are halting production for a period of two to six months, the institute will issue a letter that temporarily cancels the license, and give it suitable publication. Renewing the License will be contingent on a factory inspection having the scope and content specified by the institute. If the manufacturer did not invite the institute to perform a factory inspection for renewing the License at the end of six months from the date of halting production, the Professional Committee will request to consider cancelling the license completely.

4.15.3 The above document will be given to the members of the Professional Committee and the manufacturer no later than 7 days before the date set for convening the Professional Committee on whose agenda appears the discussion to cancel the License, where together with the document, the manufacturer will receive an invitation to appear before the Professional Committee in order to make his case against canceling the license.

4.15.4 The absence of the manufacturer from the Professional Committee is not a reason to not discuss the issue, but if the manufacturer appeals to request a reasonable postponement in the date of the meeting for compelling reasons, and if it is not an argument to cancel the license because the defects in the products, manufactured according to this license are critical, the chairman of the committee is allowed, at their discretion, to postpone the date of the meeting of the Professional Committee.

4.15.5 The manufacturer representatives will only be present in the first part of the discussion regarding their issue in the Professional Committee, for as long as reasonably required in order to make their claims, answer the committee members questions and other SII representatives present, and will then leave the meeting, and the discussion will continue without them.

4.15.6 The Professional Committee will discuss the recommendation of the CEO's delegate to cancel the license, and they are authorized to make a decision which is a recommendation to the License Committee, to make one of the

following decisions:

A. Completely cancel the license;

B. Temporarily cancel the license for a period of time;

C. Reject the recommendation of the CEO's delegate to cancel the license.

4.15.7 The decision of the Professional Committee must be explained, and if claims are raised by the manufacturer against canceling the license, the committee must address those claims. The discussion will be recorded in the protocol and will be signed by the committee chairman.

4.15.8 On concluding the discussion, the Head of the Standards Mark Operations Directorate will make sure to send the manufacturer a written notice about the recommendation of the Professional Committee, specifying a summary of the committee's reasoning. It will be made clear, in the letter, that the decision of the Professional Committee is only a recommendation, and that this recommendation will be brought before the License Committee in order that they make a decision in that matter. The letter will be sent to the manufacturer as soon as possible, without waiting for the finalized protocol of the Meeting, via E-mail and/or registered mail and/or facsimile, The Head of the Standards Mark Operations Directorate will document the letter as well as all of the evidence of sending it to the manufacturer using these means:
Ticket for registered mail, fax send report and printing a screen-capture of the email. Nevertheless, it is enough that the manufacturer received the letter by one of these means to fulfill the requirements of this procedure.

4.15.9 The detailed letter in Section 4.15.8 above will be sent, at the same time, to the members of the License Committee at least 7 days before they convene to discuss the recommendation of the Professional Committee. To the copies of the letter sent to the License Committee will be attached all of the documents that were attached to the document sent to the Professional Committee, and any document presented by the manufacturer in the Professional Committee, with all of the material reaching the members of the License Committee, at least 7 days before they convene to discuss the issue. If possible, the members of the License Committee will also receive the protocol of the Meeting of the Professional Committee.

4.15.10 In cases in which the CEO's delegates request to cancel the license due to critical defects in the product, the CEO can decide by himself to temporarily suspend the license until a decision is reached by the License Committee, and the deadlines for submitting material to the Professional Committee, the License Committee, and to the manufacturer, can be shortened from 7 to 3 days, in order to enable the committees to convene more quickly.

4.15.11 It is not required to enable the manufacturer to appear before the License Committee, although the committee chairman can allow the manufacturer to appear. It is forbidden to invite any 3rd party that wishes to intervene in the decision or to influence it, and only committee members, the Head of Standards Mark Operations Directorate and the CEO's delegates will be present in the meeting.

4.15.12 The License Committee will study the material it receives as mentioned, including the recommendation of the Professional Committee, and will decide whether to completely cancel the license, to cancel it for a time period they specify, or to reject

the recommendation of the CEO's delegate to cancel the license. As soon as the committee makes a decision, it will be sent immediately to the manufacturer, in the ways described in Section 4.15.8 above. If the decision is to cancel the license, for a period or completely, the notification should mention to the manufacturer his right to appeal the decision before the Standards Mark Directorate within 30 days of the send date of the letter. The Head of Standards Mark Operations Directorate or anyone appointed by them will be available to the manufacturer as much as required in order to guide on the procedure of filing an appeal.

4.16 Discussing Appeals

4.16.1 Any manufacturer that feels deprived by a decision of the License Committee can submit an appeal, to the Standards Mark Directorate.

4.16.2 The discussion regarding the appeals at the Standards Mark Directorate will be held before the Directorate members, excluding those that are serving as members of the License Committee.

4.16.3 The Directorate will appoint a member who will serve as chairman of the Standards Mark Directorate while discussing appeals.

4.16.4 The Directorate is authorized to:

(A) Discuss and decide regarding appeals that manufacturers submit about decisions of the License Committee to not grant a license or to cancel a license that was granted.

(B) Discuss and decide regarding appeals that manufacturers submit about decisions of the License Committee about arrangements, the essence and amount of the supervision by the SII on the quality and manufacturing of the products.

4.16.5 Each appeal will be submitted to the SII in writing, within four weeks of the manufacturer being given the notification of the decision of the License Committee. The manufacturer will specify the reasons for appealing and will attach, as relevant or needed, documents and documentation to support their request.

4.16.6 The Directorate will discuss the appeal within two weeks of its submittal date.

4.16.7 The submitter of the appeal will be invited to the Directorate discussion to make their case. If they did not appear for the meeting they were invited to, for reasons that are not acceptable to the Directorate chairman, it will be considered as if he/she waived their wish to appeal.

4.16.8 The Directorate chairman is allowed to invite to its meetings anyone that can contribute to their discussions, although the discussion after hearing the manufacturer's claims; hearing the claims of the laboratory representative and making decisions by the Directorate will be done only in the presence of members of the Directorate and the Head of Standards Mark Operations Directorate.

4.16.9 Notification of the decision made will be sent to the manufacturer in writing by the Head of Standards Mark Operations Directorate, within seven work-days from making the decision, specifying the reasoning of the decision, the decision of the Directorate will be final.

4.16.10 After each convention of the Directorate protocol of the discussions and decisions will be made, that will be signed by the Directorate chairman.

4.16.11 Even if the appeal deals with the License Committee decision to cancel a license, the publishing in the newspapers will not be delayed unless the Directorate decides otherwise. In any case the SII will publish the cancelation of the license in its records within 30 days.

4.16.12 If an appeal was submitted and the Directorate convened before the end of the 30 days since the License Committee's decision to cancel the license, and if the Directorate decided to cancel the License Committee's decision, the SII will not publish the cancelation of the license in its records.