SASO Scopes Product Certification Scheme

1. Purpose & Scope

This procedure aims to describe the steps followed by RACS as Certification Body authorized by Saudi Standards, Metrology & Quality organization (SASO) to ensure that Conformity Assessment of products which are exported and distributed to Kingdom of Saudi Arabia comply with the relevant mandatory Technical Regulations and applicable standards.

Since SASO has launched the Saudi Product Safety Program (SALEEM) to achieve the kingdom objectives regarding raising the level of product safety and quality, SABER electronic platform became an important tool to ensure the conformity of imported goods.

Accordingly, a new conformity assessment program was designed based on a two-stage process with a separate certificate for each of them as follows:

Stage 1: Product Certification of Conformity (PCoC)
Stage 2: Shipment Certification of Conformity (SCoC)

2. Responsibilities:

It is the responsibility of RACS Quality Certificates Issuing Services as an Authorized Certification Body to issue Certificate of Conformity to export to Kingdom of Saudi Arabia and to assure all steps of compliance verification are applied in this regard. RACS is responsible for the correctness of all information specified in the Certificate of Conformity and to establish and maintain the appropriate system to satisfy both SASO and Applicant's requirements in accordance with the certification system mandated by SASO.

It is the responsibility of Importer, Exporter and/or Manufacturer, hereby referred to as "Applicant" provide all needed requirements to ensure product compliance to the applicable SASO Technical Regulations and standards.

3. Definitions:

- **Saudi Standards, Metrology and Quality Organization (SASO)** – a technical governing body in the Kingdom of Saudi Arabia to govern tasks related to standards, metrology, and quality.
- **Saudi Product Safety Programme (SALEEM)** – a conformity assessment programme developed by SASO to ensure the quality and safety of products imported into the Kingdom of Saudi Arabia.
- **SABER** – a mandatory online portal system facilitating online certification of imports into Saudi Arabia.
- **RACS**: RACS Quality Certificates Issuing Services
- **Authorized Certification Body**: a 3rd party Conformity Assessment Body (CAB) authorized and designated by the related authority to conduct conformity assessment process on products and processes on behalf of the authority in accordance with related schemes/standards/regulations mandated by this body
- **Product Certificate of Conformity (PCoC)** – an official certificate which demonstrates that product has been registered within SABER and are compliant with applicable Technical Regulations. The PCoC is valid for one year upon issuance.
- **Shipment Certificate of Conformity (SCoC)** – an official certificate issued electronically via SABER and is mandatory to be issued for each shipment of Regulated and Non-regulated products. The SCOC is valid for that specific shipment only.
- **CM**: Conformity Manager
- **QAM**: Quality Assurance Manager
- **RACS assigned Personnel:** Inspector, Auditor, or any other assigned person by RACS to perform the compliance verification procedure.

4. Scope of certified products and applicable schemes by RACS Certification Body including Requirements for Certification (below attached excel sheet):

List of Products -
Type of Certification

5. Stage 1: Procedure for the Issuance of Product Certification of Conformity (PCoC):

Procedure of issuance of PCoC consists of the following steps:

Application:

- The Applicant shall submit the full details of application online via SABER Portal or by submission of Registration for Certification (RFC). Please refer to SASO/REC/01-Registration for Certification (RFC) in below related form table.
- Applicant shall submit the following documents.

Please refer to below Process map in Clause 11 for required documents as per certification type

- **Legal Agreements:** RACS/Ag/10 General Conditions for Certification Services
- Fees as detailed in RACS Schedule of Fees (RACS/REC/46)

6. Preparatory Steps:

- Application Form shall be submitted by the Applicant in SASO SABER platform or by submission of RFC.
- Sales and Marketing Executive/Administrative assistant will review it to check documents availability on a primary basis.
- A quotation will be sent to the Applicant by Sales and Marketing; containing the scope of certification and fees related to each step of the certification process.
- Payment via SADAD shall be done by the Applicant.

7. Certification Procedures:

Depending on the product's Technical Regulation, two types of product certification schemes are applicable:

- Product Certification (Type 1a)
- Production Line Certification (type 3)

7.1 Application Review

- Upon acceptance of quotation by the Applicant, he is requested to sign the General Conditions for Certification Services (RACS/Ag/10), this agreement to be signed one time from the Applicant regardless of number of applications.

- Application along with related supportive documents will be received by RACS Senior Conformity Manager who shall assign one of RACS technical team members (Conformity Engineer- (Evaluator or Auditor)).

7.2 Application Evaluation

- Conformity Engineer (Evaluator or Auditor) shall perform conformity assessment (Evaluation) steps related to the certification scheme types and fill-in SASO/REC/09:

A. Product Certification (Type 1a):

- Detailed documents review checking of import eligibility, HS Code, assessment of risk, product description.

- Document review includes the checkup of Test Reports parameters and results, done by third party ISO 17025-accredited laboratory according to the specific test parameters required by the Technical Regulations and applicable standards. In case there is no 3rd party accredited laboratory for some requested test parameters, one of the qualified RACS Conformity Engineer/Technical Expert will be witnessing and approving the test parameters.
- If test report is missing or insufficient, then product testing will be requested as per the full requirements of the Technical Regulation and/or applicable standard/s.

  *Note: No. of samples to be selected for testing is defined by the specific technical requirements and as per the Technical Regulation owner and/or applicable standard/s.

Evaluation Outcome results:
- If evaluation is pending for missing or invalid documents or other needed information to complete evaluation, additional supporting documents will be requested from the Applicant.
- Evaluation includes Product Safety Verification through test reports provided on all safety test parameters requested by applicable Technical Regulation/standards, test reports shall be issued by third party ISO 17025 accredited laboratory according to the approved Standards and applicable technical requirements. In case there is no 3rd party accredited laboratory for some requested test parameters, one of the qualified RACS Conformity Engineer/Technical Expert will be witnessing and approving the test parameters.
- RACS to request further missing documentation especially insufficient Test Report. Testing details such as test parameters, shall be agreed upon with the Applicant, in this case, the Applicant will receive a notice from RACS regarding the missing documentations. The Applicant shall initiate the provision of a representative product sample, its preferred lab, tests to be performed. Such information shall be always coordinated with RACS.
- Reports/Study' on alternative solutions applied by the applicant is not sufficient evidence for compliance – RACS may require testing of the subject item as per relevant SASO standard, in this case, the Applicant will receive a notice from RACS regarding the need to have the product be tested as per SASO standard/s. The Applicant shall initiate the provision of a representative product sample, its preferred lab, tests to be performed. Such information shall be coordinated with RACS at all times.
- Evaluation will be repeated upon applicant re-submission of needed documents/information.

Decision of Certification:
- Upon submission of this information, and as per the result of documents review and completing product evaluation process.

Recommendation of approval of Product certification:
- If product evaluation shows full compliance with applicable Technical Regulation/Standard, then the application/request is approved in SABER Portal and the official Product Certificate of Conformity (PCoC) is generated in ESMA Portal.

Recommendation of rejection of Product certification:
- If product evaluation shows non-compliance with applicable Technical Regulation/standard, due to any reason preventing product from Certification: then the application/request is rejected in SABER Portal and RACS will inform the Applicant by an official rejection statement by e-mail stating the reason of rejection.

Post Certification:

1. **Manufacturer's Modification of original Product Design and/or Manufacturing Process:**
   - Certificate holder is obligated to notify RACS of any design or manufacturing modification during the Certificate's validity period. Note: Failure to do so is a violation of the SASO TR.
   - Upon receipt of notice, RACS shall perform an assessment to determine whether the stated modification/s merit a retest of the product. The nature of re-test depends on the

extent of the modifications declared by the Applicant.
- If the assessment merits a non-retest, RACS shall notify the Certificate holder the Certificate holder receives a notice of non-retest and continuation of the Certificate validity.
- If the assessment merits a re-test, RACS shall notify the Certificate holder on the following:
  - Need to re-test the product on the affected parameters as per SASO standard.
  - What product sample is needed (complete product, a component, instruction material,
- Certificate holder to acknowledge and agree on the notification requirements sent by RACS.
- RACS shall repeat the Procedures A above, but ONLY limiting the scope to the affected parameters.

2. **Withdrawal, suspension and cancellation of the Type Approval Certification:** Please refer to below **Clause 8** (Termination, reduction, suspension or withdrawal of certification)

B. PRODUCTION LINE CERTIFICATION (type 3)

Audit Preparation:
- Preparation of the audit is as follows.
  - Manager assigns the auditor(s), including Lead Auditor and rest of audit team.
- Criteria of Audit Team selection, as following: Audit team shall consist of at least two personnel covering below roles, Audit Team Members shall be selected to be competent and to cover the scope of category and consist of the following roles:
  a. Lead Auditor
  b. Auditor
  c. Technical Expert
- Additionally, other roles can be included in audit team if needed as following:
  a. Translator
  b. Observer
  c. Witnessing auditor
- Lead Auditor (audit team leader) shall perform conformity assessment steps (Evaluation) related to the certification scheme to decide on the audit:
  - Detailed documents review for all the documents to primarily verify compliance according to applicable Technical Regulations and Standards.
  - Document review includes the check up for Test Reports parameters and results
- Audit team leader to prepare audit duration plan based on applicable standards then finalize primary audit schedule.
- After which, Lead Auditor will be responsible for:
  - Identifying audit location and related suitable logistics tools that should be available.
  - No Conflict of Interest against any of the suggested audit team members.
  - Share by e-mail or any other accessible documented method the primary audit schedule RACS/REC/13 for the Applicant approval and signature, or for further advice about the dates audit to reach a mutually agreed schedule.
  - Send the Applicant the invoice for actual on-site audit Fees, containing Terms & Conditions of Invoice of payment as per RACS Policy:
- Upon the Applicant review, approval, and signature, Sales and Marketing Executive/Administrative assistant will request the Applicant to send back the audit schedule form to proceed with the actual on-site audit.

Conduct of audit
- Assessment of the factory quality management system and factory production control shall be according to the Technical Regulation and shall be carried out by the duly authorized auditor(s). In case of extraordinary events, the audit can be carried out remotely as per RACS-SOP74 - Online Assessment Procedure.
- If samples to be taken for testing purposes, No of Samples to be selected for testing is

defined by the specific technical requirements and as per Technical Regulation. Furthermore, sample request form (RACS/REC/15) should be filled in on three copies; one copy to accompany the sample and sent to the accredited laboratory selected by the Applicant, the other copy to be kept with The Applicant for his reference, the last copy will be kept with RACS file also for RACS future reference.

Application Evaluation Outcome:

Evaluation Reports along with all related assessment checklists will be documented. Any nonconformities found are identified as:

- Major Non-conformities:
  - A major nonconformity is the absence or total breakdown of a system to meet a clause or sub-clause of a standard.
  - A number of minor nonconformities against one clause or sub-clause can represent a total breakdown of the system and thus be considered a major nonconformity.
  - A situation that raises significant doubt about the ability of the applicant's management system to achieve its intended outputs is also a major nonconformity.
  - A major nonconformity may require a separate re-audit of the applicable clause or sub clause before the applicant can be certified.
- Minor nonconformities:
  - Minor nonconformity might be a procedure that is not comprehensive enough, a person who did not follow the procedure, or a lack of a required record.
  - A minor nonconformity will generally be addressed by the Applicant submitting a response to the Lead Auditor before he can be certified. Depending on the standard, the corrective action for a minor nonconformity may not necessarily be closed prior to certification.

A written audit report, containing any nonconformity, is issued after the audit, and assessment checklists related to each specific applicable standard to be filled with remarks whether the Applicant is complying with each clause or not.

Corrective Action (if needed): At the conclusion of the audit, any nonconformities found will be documented and communicated to the Applicant via RACS/REC/12 - Evaluation Report.

If nonconformities are found which cannot be corrected electronically and send back to RACS, an onsite complementary audit might be needed to be scheduled to verify the implementation of the action(s) to resolve the nonconformities. The scope of the audit is limited to the clause or sub clause where major nonconformities were found. Non-conformances will need to be resolved in a timely fashion as per RACS's Certification Regulations. Other than that, The Applicant replies (root cause analysis, corrective action plan) filled in evaluation report, and actual corrective actions for non-conformities including supportive documents can be received via any accessible means by RACS (email, hardcopies, E System, etc.)

Certification Review

- Once all corrective actions are fulfilled, the lead auditor will complete evaluation report summary in evaluation report (RACS/REC/12) and shall raise the final evaluation report with his recommendation to the conformity manager for certification review step of the products/facility intended for certification, recommendation is either:
- Either recommending approval of certification by Issuance of Certificate of Conformity; or
- Recommending rejection of certification by issuing Final Decision Letter.

- Conformity Manager or his delegates (Conformity Supervisor) will perform Certification Review.

- One of which will perform certification review to verify Audit Team Leader recommendation by checking if evaluation report content is found satisfactory along with complete review for the whole application and then grant the final recommendation or certification decision.

- Based on audit team leader recommendation and certification review result presented by Certification Reviewer, all outcome is endorsed to the Certification Decision by filling in the RACS-REC99-Certification Decision for Product Certification-Document Review & RACS-REC100-Certification Decision for On-site Audit as Certification Decision Record.

Certification Decision

Granting Certificate:
- If all documents provided are complete and are satisfactory, then the Senior Conformity Manager will approve the certification, and the PCoC will be issued electronically on SABER system.

Decision as Rejection of Certification:
- Failure to comply with the requirements of the Technical Regulation and applicable standard merits the rejection of the application in SABER.

Post Certification
- Periodic factory audit/Surveillance during PC validity period:
  - As part of the Certification Scheme type 3, RACS shall perform a regular factory visit, at least once a year, to ensure that the originally approved product safety management system is continuously implemented by the manufacturer concerned.
  - Audit team leader prepares a factory audit report and submit such to the RACS Conformity Department with recommendation such as: continuation of the Certificate validity, suspension, or cancellation of the certificate. Nature of recommendation depends on the auditor's findings during the audit/ surveillance visits.

Manufacturer's Modification of original Product Design and/or Manufacturing Process:
- Certificate holder is obligated to notify RACS any design or manufacturing modification during the Certificate's validity period. Note: Failure to do so is a violation of the SASO TR.
- Upon receipt of notice, RACS shall perform an assessment to determine whether the stated modification/s merit a retest of the product. The nature of re-test depends on the extent of the modifications declared by the Applicant.
- If the assessment merits a non-retest, RACS shall notify the Certificate holder the Certificate holder receives a notice of non-retest and continuation of the Certificate validity.
- If the assessment merits a re-test, RACS shall notify the Certificate holder on the following:
  - Need to re-test the product on the affected parameters as per SASO Standard.
  - What product sample is needed (complete product, a component, instruction material.
- Certificate holder to acknowledge and agree on the notification requirements sent by RACS.
- RACS shall repeat the Procedures A above, but ONLY limiting the scope to the affected parameters.

Withdrawal, suspension, and cancellation of the Type Approval Certification:
Please refer to below **Clause 8** (Termination, reduction, suspension or withdrawal of certification)

7.3 Certification Documentation

Product Certificate of conformity (PCoC) is issued electronically and can be downloaded by the Applicant via SABER Portal.

8 Termination, Reduction, Suspension or Withdrawal of Certification

RACS QUALITY reserves the right to suspend or withdraw the Certificate of Conformity/ Compliance at any time. The Certificate may be suspended should the Company:

- Failure to complete corrective actions within the agreed time.
- Misuse the Certification mark
- Failure to comply with the financial requirements of the Agreement entered with RACS QUALITY (Nonpayment of any of certification fees) or Bring RACS QUALITY into disrepute in any way.
- The Applicant's certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the quality management system"
- The certified Applicant does not allow surveillance or re-certification audits to be conducted at the required and agreed surveillance frequencies.
- The certified Applicant has voluntarily requested a suspension.

Any apparent contravention of Certification agreement which might lead to suspicion of certification will be brought to the attention of the Chief Executive Officer or his delegate who then investigates the report. Should the result of the investigation reveal non-compliance with Certification agreement, then RACS Sales and Marketing Manager will issue a letter which will be sent to the Applicant company outlining the non-compliance details and requesting their correction within an agreed and reasonable period of time (Usually RACS gives 90 days to make the correction needed, unless for a critical non-conformity timeline will be minimized), and explaining that their registration may be suspended until the corrective action is completed.

Should the necessary corrective action not be taken within the agreed period, then a further letter will be sent to the Applicant company, informing them that their registration is suspended and another very limited time (30 days) will be given to Applicant as a final chance to restore the certificate suspension by performing the corrective actions needed.

Whenever certification is suspended, RACS Sales and Marketing Manager will communicate the actions needed to end suspension and restore certification for the Applicant certified product in accordance with the RACS Rules of certification and the scheme of certification, these actions depend on the defect that is committed by Applicant and that lead to the suspension of the certificate.

RACS Sales and Marketing Manager will make sure Applicant understands the reason of suspension and the actions that need to be done to reverse the suspension decision.

In such cases the Applicant will be asked to stop claiming that their organization is certified by RACS, and withdraw from use any letterheads, business cards, etc. that indicate RACS certification validity.

Once Applicant takes measurements needed for restoring certification, Applicant shall bring to RACS Knowledge by informing RACS Sales and Marketing Manager with the actions and measurements taken by Applicant through any accessible means to RACS with providing the corrective actions taken in this regard.

Sales and Marketing Manager in return will transfer the request with supportive evidence to RACS Senior Conformity Manager to follow the same certification plan adopted by RACS (evaluation, review, decision) needed to resolve the suspension, similar to the core certification process, Senior Conformity Manager will make the final recommendation and transfer the request to the Chief Executive Officer or his delegate who will take the final decision to restore certification, keep suspension, or withdraw certification.

The conditions for certification reinstatement may include:

- Re-verification of management systems effectiveness through on-site audit.
- Re-testing of the Product
- Discontinuation of misleading stationery and other advertising material.
- Removal of other reasons responsible for suspension of the certificate.

If the Applicant does still not complete the corrective action the further agreed final time, then a further letter will be sent by RACS Sales and Marketing Manager detailing the fact that their registration with RACS is withdrawn. Such withdrawal of certification will be published on the web site of RACS to make note of the withdrawal. The status of the Applicant will update on the Applicant file and certified products registry (RACS/REC/14). A request that the Applicant to return the certificate and discontinue the use of the certification mark in any way, as Certificates and marks of compliance remain the property of RACS QUALITY.

If certification is reinstated after suspension, RACS shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified.

If a decision to reduce the scope of certification is made as a condition of reinstatement, RACS shall make all necessary modifications to formal certification documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of certification is clearly communicated to the Applicant and clearly specified in certification documentation and public information.

For this purpose, RACS/REC/44 Suspended Certificates Tracking form should be filled for each case.

9 Renewal:

- Validity of PCoC is one year
- COC should be renewed 2 months prior to expiry.

10 Stage 2: Procedure for the Issuance of Shipment Certificate of Conformity (SCoC)

10.1 SCoC registration and issuance process

10.1.1 Shipment Certificate of Conformity (SCoC) shall be issued for each shipment of both regulated and non-regulated products. For regulated products, only those products which have obtained Product Certificate of Conformity are available to be added for Shipment Certificate.

10.1.2 The Applicant, which is the Importer or Distributor, submits a new SCoC application request for each shipment through SABER platform. An application request should contain the following:
- correct product selection
- the required invoice/s
- the required product information/description
- the quantity and value of the product in the invoice
- the shipping country

10.1.3 For regulated items in the invoice, SABER will send the request to the certification body who issued the Product Certificate of Conformity (PCoC) to perform conformity assurance activities for regulated items in the invoice. Certification Body will check the shipment eligibility of the product based on the relevant PCoC and the Shipment Certificate of Conformity (SCoC) will be approved electronically through the SABER platform. SCoC will be issued after creating invoice and paying sadad by the Applicant accordingly.

10.1.4 This process must be conducted for each shipment the importer/distributor wishes to send to the Saudi market.

10 Process Map

10.1 SASO TR - Type 1a Conformity Assessment Process

SASO-SABER-SOP-01-Rev00_SASO TR - 1

10.2 SASO TR - Scheme Type 3 Conformity Assessment Process

SASO-SABER-SOP-0
2-Rev00_SASO TR - S

10.3 SASO TR - Scheme Type 5 Conformity Assessment Process

SASO-SABER-SOP-0
3-Rev00_SASO TR - S

10.4 SABER Portal and Racs Process Flow under Saleem Program

SASO-SABER-SOP-0
4-Rev00_SABER POR

11 Related Forms:

Listed Agreements, SOPs, Records related to the SOP as follows:

TITLE OF DOCUMENT	IDENTIFICATION
Quality Master List	RACS/REC/01
Quality Manual	RACS/QM/01
Registration for Certification (RFC)	SASO/REC/01
General Conditions for Certification Services	RACS/Ag/10
Products Review and Evaluation	SASO/REC/09
Factory Audit Checklist Type 3	SASO/REC/10
Type 1a Conformity Assessment Process	SASO/SABER/SOP/01
Type 3 Conformity Assessment Process	SASO/SABER/SOP/02
SASO Application Review	RACS/REC/111
Online Assessment Risk Analysis	RACS/REC109
Evaluation Report	RACS/REC/12
Audit Schedule Form	RACS/REC/13
Opening and Closing Meeting Form	RACS/REC/41
Certification Decision for Product Certification-Document Review	RACS/REC/99
Certification Decision for On-site Audit as Certification Decision Record	RACS/REC/100
Online Assessment Procedure	RACS/SOP/74

12 References:

- ISO/IEC 17065, Conformity Assessment - Requirements for bodies certifying Products, Processes and services.
- ISO/IEC 17021, Conformity Assessment — Requirements for bodies Providing audit and Certification of management systems.
- ISO/IEC 17000, Conformity Assessment — Vocabulary and general principles.
- ISO/IEC 17020, Conformity Assessment— Requirements for the operation of various types of bodies performing inspection.
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.
- ISO17067, in combination with ISO Guide 28 and ISO Guide 53
- ISO/IEC 17030, Conformity Assessment — General requirements for third-party marks of conformity.
- ISO Guide 23:1982 Methods of indicating conformity with Standards for third-Party certification Systems
- ISO Guide 27:1983 Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity
- RACS Quality Manual RACS/QM/01
- All controlled QMS records-Please refer to RACS/REC/01-Quality Master List.
- Ministerial Decree No. (6386) Dated 21/6/1425 AH
- Royal Decree No. M/10 dated 03/03/1392H (1972)

SASO Scopes Product Certification Scheme

Revision History:

Date	Revision #	Description of Changes
February 26, 2018	00	Initial
August 26, 2020	01	Scopes excel sheet updated – Packaging & Building materials 2 added
September 05, 2020	02	Added clause: C. FACILITY CERTIFICATION - SQM (type 5 Certification under clause 6. Certification Procedures
October 5, 2020	03	• Under Clause 6.3.1 A & Clause 6.3.2 the below added: In case there is no 3rd party accredited laboratory for some requested test parameters, one of the qualified RACS Conformity Engineer/Technical Expert will be witnessing and approving the test parameters
March 29, 2022	04	Revisions made based on the specific process flow on Saber System and the new launched **Saudi Product Safety Programme (SALEEM).**