Pre-Certification Procedures

(Handling Applications from Submission until Issuance of COC - Facilities & Products)

1. Purpose and Scope:

This procedure aims to describe the steps adopted by RACS for:

- Application for certification related to **HALAL Scope**
- Submission Procedures

This procedure is applicable for both Facilities and Products Certification.

2. Responsibilities:

It is the responsibility of the Certification Decision Committee, Management Representative (MR) and Conformity Manager (CM) to ensure the appropriate implementation of this procedure. All departments' managers also have immediate responsibility for the management of records relating to their activities.

3. Definitions:

QAM   - Quality Assurance Manager
QP   - Quality Procedures
MR   - Management Representative
QM   - Quality Manual
QMS   - Quality Management System
SOP   - Standard Operating Procedure
QML   - Quality Master List
QF   - Quality Form
CM   - Conformity Manager

4. Requirements for certification:

- The requirements against which the products of a client are evaluated shall be those contained in specified schemes, applicable standards and other normative documents/ISO DOC, explanations and clarifications.
- Furthermore, if RACS seeks collaboration with other organization to perform any related evaluation activity to certification, testing activities, it is done exclusively through accredited laboratories as per ISO 17025.
- Clients seeking to be certified for any of their (products or services or facilities) to UAE   Schemes and applicable standards through RACS are requested to implement relevant Quality System including documentation in a way to meet all requirements of this standard and all relevant specific standards depending on the nature of service (certified Product & Facility).
- Where applicable, in case of a client newly operating, and seeking to be certified, client is required to demonstrate more than **3 months compliance against the standard** immediately preceding the date of audit performed by RACS Conformity Audit Body. This will prove the efficacy and sustainability of the implemented system. After which RACS will be contacted to make arrangements for required audits and certification.

- Requirements varies depending on the scope of certified products; Details of the documents required for certification for each scope as per scheme owner requirements are detailed in the following procedure **SOP44: Product Certification Scheme-HALAL Products**
- Generally, the requirements for certification are detailed as following:

    A. **Application for Certification (Application Form)**: Application to be filled by the client will contain all the necessary information needed by RACS for conducting the certification Process, such important information is:
    - Type of product to be certified: Product, facility (Process) to identify the related scheme implemented by scheme owner.
    - Relevant standard or normative documents clients is seeking certification for.
    - General information: Applicant Business activities & related business facilities & relationship between their facilities, in relevance to the certification scheme applied for information about outsourced processes relevant to product conformity.
    - Any other information needed related to certification requirements.

By signing the application form, the applicant and the manufacturer agrees to comply with these General Rules and with the Specific Product Standard for the product covered by Registration / CB Certification.

It also includes checklist which aligns all requirements of the specific standard to which client wishes to be certified.
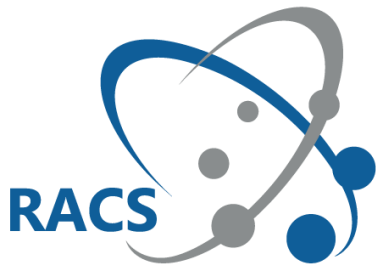
B. <u>Legal Agreements:</u>
- Certification Agreement

C. <u>Fees</u> as detailed in RACS Schedule of Fees (RACS-GER/REC46)

Please refer to <u>related form</u> below:
- Application Forms
- Legal & Quality Documents-List of certification activities and requirements per certification Schemes
- Product Certification Schemes

Client seeking extension or renewal of certification scope shall as well submit the application form specifying the extension or renewal of the certification scope.

Whenever applicable, additional certification requirements per certification schemes: Legal & Quality documents (such as Client Quality Manual) and supportive documents (records and checklists used by applicant), are to be attached to the application form.

5. Procedure for certification:

<u>Although two types of certification are applicable;</u>

- **HALAL Facility Certification**
- **HALAL Product Certification**

<u>However, for HALAL scope, both type of certification requires performing audit for the manufacturing facility, to be more specific as per scheme owner (ESMA) HALAL scope falls under Module H Certification Type (which is product certification requiring facility audit).</u>

5.1 Preparatory Steps:
- Client Inquiry shall be received by a Sales and Marketing Executive/Administrative Assistant, an application form shall be submitted by the applicant to RACS (submission can be done via RACS affordable communication methods (mail, emails, hard copy, website, E-System).
- Sales and Marketing Executive/Administrative assistant will review it to check documents availability on a primary basis.
- Sales and Marketing Executive/Administrative assistant will transfer application to the Conformity Manager
- Conformity Manager will evaluate the client request through reviewing the Application form, and the information included to ensure the following:
  - ✓ Approval of Sharia committee for new and critical product certification
  - ✓ Define standards applicable and scope of certification.
  - ✓ Define and confirm RACS capability of performing the requested scope of Certification with all needed tools (personnel and documents) this should be assured by RACS prior to conduct the Certification Process. RACS defines and check its capabilities and competence to perform the Certification scheme which RACS has no previous experience.
  - ✓ Gather all information related to client and ensure they are sufficient for the certification Process.
  - ✓ Obtain Client agreement on certification scope and standards assuring full understanding of the certification Process.
  - ✓ Request obtaining all other necessary information to complete the Certification Process according to relevant Certification scheme.
  - ✓ Provide a quotation to the client; containing the scope of work and fees related to each step of the certification process.

  Conformity Manager performs the explanatory roles whenever needed in the initial step upon providing the Application form.

5.2 Application Review
- Upon acceptance of quotation by client, he is requested to sign the General Conditions for Certification Services.
- Application along with related supportive documents will be received by RACS Conformity manager or his delegates (Conformity Supervisor) who shall perform the application review as per the requirements in the RACS-GER/REC48 Application review

- If found satisfactory, Conformity manager assigns one of RACS qualified technical team members (Conformity Officer/ (Evaluator or Auditor) to act as lead auditor (Audit team leader). If not, satisfactory application will be returned to client for completion till it is found accepted by conformity manager.
- In case of a positive declaration of previous rejection of certification by an accredited certification body: lead auditor will identify areas of potential non-conformities and set exact points that will depend on in further investigation of these areas (including whether any area of Certification should be more addressed, or the points changes per standards to be more investigated to proof applicant completely removed previous non-conformities preventing certification).
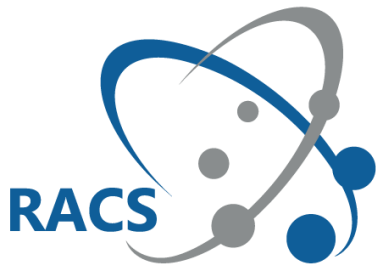
- In case of positive declaration of previous successful certification by an accredited certification body: RACS will consider this point included in changes affecting certification, please refer to RACS-GER/SOP19 Post certification procedures.

5.3 Application Evaluation

5.3.1 Pre-Audit (optional)

- Pre-Audit is an optional step chosen by applicant, its objective is to assist applicant to determine that Quality System adapted meets requirements of certification scheme and applicable standards, and it grants efficacy and sustainability for his operations related to the Product/service applicant wish to certify
- Pre-Audit is conducted once fees are paid by applicant and received by RACS.
- Steps applicable on pre-audit similar to an official audit are: Preparatory steps, application review, application evaluation except that it is not mandatory for client to reply the evaluation report and close his NCs, unless he would like to continue and close his non-conformities.
- Pre-Audit process is conducted at RACS offices or on actual site depending on the individual case in hand.
- Upon performing the Pre-Audit, audit team leader will issue the **REC12** Evaluation Report.
- The Pre-audit Report will give the result whether the applicant is eligible to move forward to the next step of evaluation (Actual on-site audit) or there are discrepancies and major non-conformities.
- The Pre-Audit Report will be sent from lead auditor (audit team leader) to Conformity Manager for his review and approval, and then sent to applicant. Here the evaluation ends and there is no proceeding to certification decision.
- Pre-Audit Evaluation Report to be sent by e-mail or any other suitable method, during which applicant to be informed of all the discrepancies and non-conformities that have been encountered and pointed out, to be addressed and rectified prior to the actual on-site audit.
- In case interested in continuing the Certification Process, Applicant will be requested to confirm proceeding with the Certification process (actual on-site audit).

5.3.2 Actual on-site audit
5.3.2.1 Audit Preparation: preparation of the audit starts to be done by RACS as following:
- If pre-audit exists, after applicant's assurance that he rectified all discrepancies available in the Pre-Audit Report, actual audit start.
- Conformity 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:
  - **Lead Auditor**
  - **Auditor**
 - **Technical Expert**
  - **Islamic Affairs personnel**

Additionally, and optionally and depending on each case, other roles can be included in audit team if needed as following:

- **Translator.**
- **Observer.**
- **Witnessing auditor**
- Lead Auditor (audit team leader) shall perform conformity assessment steps (Evaluation) related to the certification scheme to decide on the nature of Stage I and Stage II:
  - o Detailed documents review for all the documents to primarily verify compliance according to applicable schemes and standards.
  - o Document review includes the check up for Test Reports parameters and results
  - o The criteria of approving Certificates of raw materials composing the finished products is that to be issued by 3rd party accredited certification body recognized by scheme owner.

- Islamic Committee (Sharia Board) to appoint the Islamic experts to do the audits.
- Audit team leader to prepare audit duration plan based on applicable standards then finalize primary audit schedule.
- Where Stage I audit has not been performed on-site, the duration of Stage I audit may not exceed 20% of the total audit time. Where it covers an on-site work, duration of the Stage I audit may not exceed 30% of the total audit duration.
- Whenever Stage I and II will be performed on site, a separate audit schedule will be designated for Stage I and Stage II).
- The Lead Auditor should also be responsible for:
  - Identifying audit location and related suitable logistics tools that should be available.
  - Share by e-mail or any other accessible documented method the primary audit plan RACS-GER/REC13 for applicant approval and signature, by signing the applicant assures that there is No Conflict of Interest against any of the suggested audit team members or for further advice about the dates audit to reach a mutually agreed schedule.
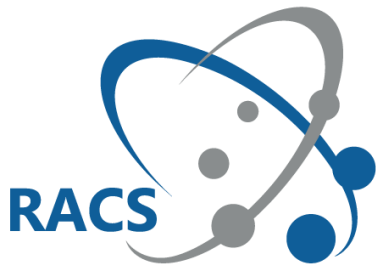
SOP18

- Sales and Marketing Executive/Administrative Assistant shall send applicant the invoice for actual on-site audit fees, containing terms and conditions of Invoice of payment as per RACS Policy.
- Upon Applicant review, approval, and signature, Lead Auditor will request applicant to send back the audit schedule form to proceed with the actual on-site audit.

Note: For one specific audit, the same personnel can perform the Pre-Audit, and perform actual on-site audit, as he is more aware about applicant specifications and previous discrepancies and this will lead to a continuous convenient performance of the certification process. However, to assure no risk of no conflict, for surveillance and renewal of certification, RACS assigns a new different personnel/Lead auditor not previously related to the Pre-Audit/and initial Audit step.

5.3.2.2   **Conduct of Audit**:

Audit procedures are applicable on all different types of Certification including New or Initial Certification, Surveillance, and Re-Certification.

Stages of Audits: Audit includes a 2-stage process:

a. **Stage I Audit**: The purpose of the Stage I audit is to evaluate applicant location and site-specific conditions and to determine preparedness for the Stage II audit.
    - During Stage I audit, audit team will check:
        - Applicant's documents submitted along with the application of certification such as company manual, system level procedures, product specifications, other certificates
        - Applicant's understanding and implementation of the standard and related statutory, regulatory, and compliance issues
        - Verification of scope and other relevant information needed for certification
        - Applicant management system and various mechanisms are functioning properly as per the applicable standards applied for certification.
    - The audit will identify any areas of concern that could become nonconformities. I communicates with any concern that prevents to proceed with
    - For HALAL scope, **in the case of categories A, B, F, J, H, G (Annex A) in GSO 2055-2, it is not necessary that stage 1 audit be on-site. However, it is up to the audit team to decide to carry out an onsite audit. In categories C, D, E, I, and K (Annex A) in GSO 2055-2 it is obligatory that stage 1 audit is done on-site.**

b. **Stage II Audit:**
    - At on-site Stage II audit, RACS audit team will conduct interviews, examine records and documents, and observe the company's activities.
    - The Stage II audit determines if the company has successfully documented and implemented all the requirements of the specified standard. This is accomplished via an in-depth review of manuals and procedures and the confirmation of their implementation. The audit also verifies conformance to the identified standard.
    - This audit also reviews and clarifies any areas of concern identified in Stage I, and Pre-Audit if applicable, Non-conformities

    - 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 scheme owner. Furthermore, sample request form (REC015) should be filled in on three copies; one copy to accompany the sample and sent to the accredited laboratory selected by client, the other copy to be kept with client for his reference, the last copy will be kept with RACS file also for RACS future reference.
    - Criteria for acceptance of halal evidence for raw material:
      a) Halal certificate required when the raw material sourced from animal or originated from animals,
      b) Halal Declaration accepted when the raw material is made of plants or originated from plant, c) Synthetic raw materials derived from animal should have Halal certificate and for the synthetic raw material derived from plants the Halal Declaration can be accepted d) Islamic expert recommendation to be followed as final when there is uncertainty in some materials.

c. **Application Evaluation Outcome:**
    - **Nonconformity Reports (NCRs) along with all related assessment checklists of the applicable standards** will be documented and identified as major or minor:
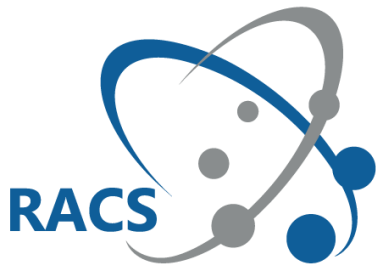
- Major Non-conformities:
  - ✓ A major nonconformity is the absence or total breakdown of a system to meet a clause or sub-clause of a standard.
  - ✓ A number of minor nonconformities against one clause or sub-clause can represent a total breakdown of the system and thus be considered a major nonconformity.
  - ✓ 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 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 applicant is complying with each clause or not.
- Although RACS is constrained from consulting, and therefore cannot advise the applicant on how to react to a nonconformity, RACS auditors are often able to offer a range of examples of actions that would meet the requirements of the standard, or examples of compliant (and nonproprietary) systems from experience
- RACS can provide resources to applicant to better understand appropriate responses to non-conformances and root cause analysis.
- Because only the applicant knows what is right for his business, RACS auditors cannot say what solutions will work best within his company. He must determine his own nonconformity resolutions. The applicant may call RACS for assistance if he encountered difficulties.
- Corrective Action (if needed): At the conclusion of the Stage II audit, nonconformities (NCRs) will be documented and identified as either major or minor then communicates to applicant via RACS-GER/REC12 Evaluation Report, discussing the same with him during the closing meeting to ensure applicant recognizes the non-conformities and undertake to make the necessary corrective actions within the agreed time frame.
- 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' Certification Regulations. Other than that, client 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.)

5.3.2.3   **Decision of Certification:** Please refer to SOP19 Post-certification procedures-HALAL Scope.

5.3.2.4   **First Certification Audit:**
- Certification Audit takes place at the Company's headquarters location and, based on the Audit Schedule, at a sampling of other non-headquarter locations beginning with the most significantly sized ones will be considered as well.
- Processes and activities carried out by the company, within the scope of certification schemes, and that most significantly affect the Quality of the company's product or service shall be included in the certification audit.
- Where Processes and activities relate to Projects, enough Projects, or sampled sections of Projects, shall be audited to enable a decision to be made relating to compliance or non-compliance to the audit criteria.
- Records reviewed in the audit should also cover both current and closed projects. Companies shall have approximately 3 months of Project records including completed Projects to undergo a Certification Audit. There shall be adequate documentation to demonstrate the sustainability of the company's Quality System.

5.3.2.5   **Surveillance Audits**: Please refer to SOP19 Post-certification procedures –HALAL Scope.
5.3.2.6   **Sudden Audits:** Please refer to SOP19 Post-certification procedures –HALAL Scope.
5.3.2.7   **Re-Certification Audits**: Please refer to SOP19 Post-certification procedures – HALAL Scope.
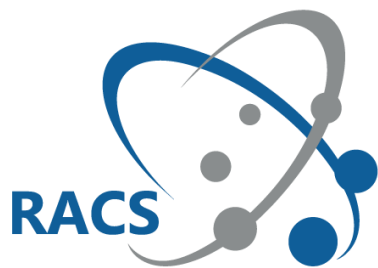
6. Justification of Certification Decision:

6.1 Review

In Certification, as it is crucial to differentiate the roles of evaluators and certifiers in order to be able to respect and meet the 4-eye principle. The final recommendation (certification Review) and approval of audit result (Certification Decision) will be done by personnel who was not involved in the audit Process and who will review the audit result then issue the recommendation for Certification.

Done by	Decision	Justification
Audit Team Leader (Lead Auditor)	**Application Evaluation**	1. Product Certification: Approved when: A) 100% of points highlighted in assessment checklist per relevant UAE scheme is complying. b) Lab test findings are satisfactory either during the corrective actions 2. Facility Certification: Approved when: a) 100% of major non-conformities highlighted in Evaluation report is rectified by corrective actions with supporting evidence of these actions before approval is granted and certificate is issued. Please refer to Notice Period for suspension and withdrawal and decline certification in procedure: RACS-GER/SOP19-Rev02-Post Certification Procedures (COC Issuance Surveillance and Recertification) b)100% of Minor non-conformities highlighted in evaluation report is rectified by corrective actions with supporting evidence of these actions (implemented either prior to approval is granted and certificate is issued, or after approval is granted by providing a detailed time lined action plan to eliminate the non-conformities) c) Lab test findings are satisfactory either during the certification or during the corrective actions.

7. Process Map

- RACS /WI/01Certification Process Flow Chart (RACS-Notified Body)
- RACS/WI/02 Certification Process Flow Chart (RACS-Certification Body)
- RACS/WI/03 (Flow chart) Procedure Certification Application-Conformity Officers

8. Related Forms:

8.1 Application Form:

R002 Application form and self-assessment for Halal food

8.2 Legal & Quality Documents-List

HALAL/REC/05 Legal & Quality Documents-List of certification requirements per UAE HALAL Scheme- HALAL Food, HALAL Cosmetics, HALAL Slaughtering Houses

8.3 Assessment Checklist:

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GSO 1694:2007 General Principles of Food Hygiene	R106
GSO 21:1984: Hygienic Regulations for Food Plants and Their Personnel	R107
GSO 713 :1997: Hygienic Regulations for Poultry Processing Abattoirs and Their Personnel	R108
HALAL Supervisor Attendance sheet	R109
HALAL Supervisor Shipments& Certificates log	R109
Assessment Checklist - GSO 2055-1 HALAL Food	R100
Assessment Checklist- GSO 2055 - 4 Cosmetics & Personal Care Products	R101
Assessment Checklist - GSO 993 Slaughtering House	R102
Assessment Checklist- GSO 2469 - 2015 Halal foods - Management system requirements for warehousing and related activities	R112
Assessment Checklist- GSO 2470 - 2015 Halal foods - Management system requirements for retailing	R113

8.4 Certificates Templates:

HALAL-Cosmetics- Facility Certificate Template (Previous RACS-GER/REC60)	R060
HALAL-Cosmetics-Products Certificate Template	R061
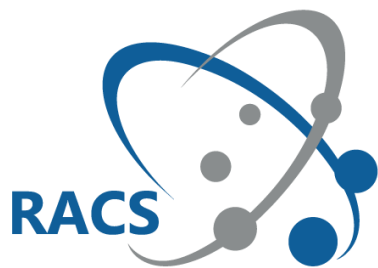
(Previous RACS-GER/REC61)	
HALAL-Food- Facility Certificate Template (Previous RACS-GER/REC62)	R062
HALAL-Food- Product Certificate Template (Previous RACS-GER/REC63)	R063
HALAL Slaughtering house Certificate Template (Previous RACS-GER/REC55)	R055
HALAL Certificate per shipment (Previous RACS-GER/REC64)	R064

8.5 General Forms:

Other Agreements, SOPs, Records related to this SOP as follows:

Quality Master List	R001
Evaluation Report	R012
Audit Schedule Form	R013
Post-certification Procedures (COC issuance, Surveillance and re-certification)-HALAL Scope	SOP19
RACS Certified Clients/Products Registry.	R014
Audit Planning Procedure (Preparation, stage I, Stage II, Audit Realization)	SOP04
Sample Request Form	R026
Invoice	R043
Schedule of Fees	R046
Opening/Closing Meeting	R041
Certification Agreement	R146

9. 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.
- GSO 2055-2 Halal products- Part two: General Requirements for Halal Certification Bodies.
- GAC Document: FAD- 4.0: Supplementary accreditation requirements for Product Certification Bodies.
- GAC document: FAD-12: Supplementary accreditation requirements for Halal Certification Bodies, in addition to applicable scheme and Standards
- R105: Requirements when making reference to A2LA Accredited Status
- R307: General Requirements Accreditation of ISO /IEC 17065 Product Certification Bodies
- R334: Specific Requirements: HALAL Certification Body Program.
- IAF Mandatory Document: Determination of Audit Time of Quality and Environmental Management System.
- 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.
- ISO 17067, 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 Manual QM01
- All controlled QMS records-Please refer to R001-Quality Master List.

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