Guide for Accreditation of Reference Material Producers
PB23 RMP

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1. INTRODUCTION

EGAC developing a Reference Material Producers accreditation program based on ISO 17034: 2016 General requirements for the competence of Reference Material Producers, relevant ILAC requirements, relevant EA requirements and EGAC requirements.

These documents require RMP to demonstrate their technical competence as well as their ability to run a supporting quality system.

Benefits of Accreditation

EGAC accreditation of RMP involves independent, unbiased assessment of the RMP facility to determine competence, impartiality, and consistent operation by independent technical experts with relevant experience, Buyers and specifiers look for accreditation mark on RMP certificates so that they can be sure that work has been done to agreed specification.

RMP accredited by EGAC are entitled to use the RMP's accreditation mark

Who can seek accreditation?

Any organization that produce Reference material may seek accreditation, whether these activities are carried out by it or subcontracted activities.

2. THE ACCREDITATION PROCESS

2.1. Preparing for application

To gain accreditation, RMP must be fully conversant, and comply, with the requirements of ISO 17034:2016 relevant EA guidance and EGAC regulations.

2.2. Preliminary application

Applicants will be supplied with an information pack containing the following:

- Application form.
- EGAC–Agreement form.
- Self-assessment report for RMP quality system implementation.
- Current fee structure.
- EGAC regulation.
- Description of the accreditation scheme (this document).
- EGAC Scope of accreditation.
- Some EGAC publications (as a guidance).

Processing of application shall be conducted exactly in accordance with EGAC publications PB1G_Handling of application.

Applicant RMP shall submit the following:

- Fully completed EGAC application form (soft and hard)
- Two copies of EGAC CAB agreement to be signed and submitted with the application form.
- Self-assessment report for RMP quality system implementation.
- RMP quality system documents.
- Application fee according to R3G
- RMP regulatory documents applicable to the applicant's scope;
- RMP documentation/articles of association, or equivalent, for review by EGAC.

A preliminary meeting at EGAC office is recommended for the purposes of clarifying initial questions. Afterwards, the application form is to be completed and signed by a duly authorized applicant representative, and submitted to EGAC together with:

If the applicant has not sent the completed application form accompanied with the RMP quality system, the application will be considered to be lapsed.
If the applicant wishes to be assessed at some later date, it shall have to re-apply to EGAC for accreditation, and pay a further application charges.

In all stages of the accreditation process, only applicant RMP staff members are allowed to attend, participate, and/or communicate with EGAC. By RMP staff members we mean: RMP employees who occupy positions in RMP organizational structure and its parent organizational structure. Those RMP staff employees will participate in the activities that match with their job description documented in their management system.

2.3. Requests for Assessment

The second stage of application is the submission of application form. This should be done when:

- The applicant is satisfied with his quality management system;
- The applicant has produced the quality management system and believed that it meets accreditation requirements;
- The applicant produced a draft scope of RMP activities for which he wishes to become accredited

The applicant shall complete the application form, and send it, together with a copy of the management system to EGAC.
The application will be handled by EGAC RMP accreditation manager, who will study the documentation. EGAC RMP accreditation manager will contact the applicant to discuss the arrangements for the assessment process.

3. THE ASSESSMENT PROCESS (IN BRIEF)

The main function of EGAC is to assess and accredit the competence of RMP to carry out specified/types of RM production, and subsequently to ensure by monitoring that the relevant requirements are maintained. Each applicant RMP basic information on its activities, equipment and staff in the application form, and its quality documentation, but it is essential to check the competence of the RMP by assessment in the RMP and other sites, where appropriate. The purpose of this assessment is to determine whether a RMP complies with the EGAC requirements for accreditation and the accreditation standard ISO 17034:2016. In some circumstances specialized publications issued by EGAC or other national, regional or international organizations, for example ILAC provide guidance of these criteria.
On receipt of a completed application form for accreditation, EGAC RMP accreditation manager with EGAC accreditation director will deal with the application. EGAC RMP accreditation manager shall check that all documents indicated on the application form have been received with the

application form. In addition, it shall be verified that all sections of the application form have been completed in full.

EGAC RMP accreditation manager shall examine the quality management system to check that it addresses all the key elements specified in the relevant standards. He also shall check if the application fee has accompanied the form and shall ensure that all necessary information is completed.

Should any additional information or documentation be required, this will be requested from the applicant. When EGAC RMP accreditation manager is satisfied that all the relevant information has been supplied the applicant shall be sent a notification of receipt of application.

RMPs should discuss the need for a pre-assessment visit with EGAC RMP accreditation manager. The discussion will also cover the scope of the accreditation it seeks. A pre-assessment visit can be designed to provide an overview of the RMP's readiness for full assessment. Before the pre-assessment EGAC will inform the assessed CAB to avoid the attendance of its consultant.

EGAC RMP accreditation manager shall administer the entire application process. The information received shall be used for the preparation of the on-site assessment and shall be treated with appropriate confidentiality.

EGAC RMP accreditation manager in consultancy with EGAC accreditation director shall identify an appropriate team leader, assessors and/or technical expert according to their area of expertise to allow for a full initial assessment of the applicant for the scope of accreditation. All assessors shall be totally independent of any connection what so ever with the applicant to be accredited.
All assessors appointed for a specific assessment shall comply with the requirements of EGAC.

EGAC shall notify the applicant in writing of the names and affiliations of the nominated assessors. The notification shall seek the approval of the applicant to the nominated team. Objection to any nominated team members shall be in writing, include a detailed justification from RMP to his objection, and shall be lodged with EGAC within ***seven*** working days of receipt of the nominations. Failure by the applicant to object to any of the nominated tea members shall be considered as acceptance of the team as a whole.

Objections from RMP to any of the nominated assessors will be investigated by EGAC RMP accreditation manager. If EGAC RMP accreditation manager satisfied with RMP's justification to his objection, he will change this nominated assessors, otherwise he shall inform RMP that his objection is not accepted and EGAC will keep the nominated assessors. RMP accreditation manager decision shall be final.

The applicant will be advised of the fees for full assessment and consecutive assessment visits before the visits take place, and it will be asked to confirm acceptance of these fees.

All team members shall be informed of the proposed assessment. EGAC RMP accreditation manager shall give both team leader and assessor a copy of RMP quality manual and relevant procedures for document review according to the relevant accreditation procedure.

The assessment team shall sign confidentiality and impartiality agreement before starting the assessment.

Experts are used as assessors to judge the competence of the RMP to produce RM or CRM for which accreditation is sought. Their responsibility is therefore to assess a RMP's compliance with ISO 17034:2016, relevant ILAC requirements, relevant EA requirements and EGAC requirements. Their assessment shall be confined to investigating and reporting the findings that result from observation

and discussion in the RMP and through examination of documentation.

All information obtained before, during or after assessment, including the fact that a particular RMP has applied for accreditation, or that an application for accreditation has been deferred or rejected, shall be treated as strictly confidential by EGAC staff, the external assessors and the EGAC council and committees.
EGAC normally uses assessors contracted from external sources to assess RMP on its behalf. EGAC staff member will normally visit RMP as part of the assessment team. EGAC RMP accreditation manager/team leader, being familiar with EGAC policies, procedures and regulations, will be able to respond during visits to inquiries from RMP management on such matters. EGAC RMP accreditation manager will communicate and assist his/her assessors and RMP management with the interpretation of EGAC requirements in appropriate circumstances.

Assessment team shall take into account the size and complexity of the organization when assessing the quality system of RMP. The quality system of RMP must provide assurance that whatever its size or complexity, or the location where work is carried out, meets EGAC requirements.

All costs associated with the initial assessment must be paid prior to the assessment date. Failure to receive payment shall stop the application process and the applicant shall be notified by telephone and in writing. The application process shall be re-started only after receipt of the full amount.

EGAC assessment team through the team leader can communicate with EGAC RMP accreditation manager for administrative and technical assistance at any point before and during the assessment process. The team shall also use all the resources of EGAC including documents, standards and guidance papers. EGAC RMP accreditation manager reviews all activities and reports of assessment team during the assessment process.
The nature of the initial assessment will be dependent upon the schedule of accreditation and the complexity of the supporting quality system that is being operated. However, the following elements will be covered:
a) Assessment of RMP headquarter/facilities;
b) Assessment of satellites, branches, temporary sites;
c) Assessment of site activities.

The accreditation process shall be according to the flowchart in item 6 below. Any nonconformity with accreditation requirements found will be notified to the applicant in writing at the end of the assessment visit, and it will be asked to state how it will clear them. An assessment report shall be sent to RMP after the assessment visit containing all findings and the assessment team's recommendation. All findings shall be cleared to the satisfaction of the assessment team before the accreditation process can continue. The applicant shall be granted accreditation according to the process in item 4 below.

EGAC assessment team will seek to establish through objective evidence and by using various techniques that:
a) The quality system supports competence against their schedule of accreditation, it is appropriate to the organization’s needs, organizational arrangements and methods of operations, including

away sites operations and number of staff members;
b) All of the requirements of the relevant standard have been appropriately addressed;
c) The organization has implemented all the requirements of the quality system
d) The operational, administrative and technical procedures used to support the quality manual are complete, technically valid and appropriate.

EGAC assessors/technical experts will be looking to see that as a minimum:
I. The RMP personnel member has proven competent at the time that the work was performed;
II. The RMP personnel member's competence is consistent with the records of authorization, educational and professional qualifications;
III. The RMP personnel member has been supplied with all necessary documented methods and procedures;
IV. The procedures are up-to-date;
V. The RMP personnel member implements the procedures in full and correctly, i.e. no short cuts, no personalized application where it is not permissible to do so;
VI. All records and raw data are signed/initialed, stamped and traceable as applicable;
VII. Facilities and equipment are fit and adequately maintained for accreditation purposes.
VIII. Accommodation adequate for the operation of the RM production;
IX. Environmental conditions are such that they did not compromise the RM production;
X. Records available for the monitoring of the environmental conditions.

The team will assess the technical competence of the RMP personnel in each field or type of operation covered by the schedule. This will be done through:
- The examination of the records outlined above;
- Discussions with staff, supervisors and managers;
- Assessment of the performance of the staff whilst performing work. The performance of staff is assessed in the RMP headquarter and at other sites where relevant operations may be performed;
- Witnessing the implementation of the procedures of preparation of RM/CRM, if applicable, or assessment of the procedures followed by the RMP to assess the technical competence of the RMP.
- Assessment of the nature of the RM/CRM and how sampling/tests/calibrations relevant to the schemes are performed;
- Monitoring the application of homogeneity and stability testing procedure;
- Tracing of the basic statistical data, including the number of samples (n), mean value, the certified values assigned to CRMs for each analyte/property, and summary data for each different method used for each analyte/property;
- Validation of any software used for data analysis
- Assessment of certificates issued by the RMP.

EGAC assessment team, if applicable, pays particular attention to subcontracting. It concerns the way in which the RMP assesses the supplier.
Periodically an assessment takes place of the applied statistics.
Sampling/Testing/Calibration activities relevant to the scheme is carried out in accordance with ISOLIEC 17025:2017/ISO 15189:2012, EGAC assessors must witness those activities according to the same principles.

Applicant's obligations for timings are according to regulation (R5G accreditation process timings and response actions).
This accreditation will be confirmed by consecutive assessment visits, with a full re-assessment on the fourth anniversary of accreditation.

Sampling of assessment for RMP

For Initial and Re-Assessment:
No sampling is applied. The RMP and all other locations (if any) will be assessed as part of the initial/re-assessment. All scopes applied for, will be subject to an office assessment and technical review.

For Consecutive Assessment [4 years]
Normally, during a single assessment visit, assessors will not be expected to check the whole of the RMP activities work for which a RMP is accredited. However, all the accreditation activities covering all areas of competence and a good representative sample of all RMP authorized personnel shall be assessed during the validity period of the accreditation certificate. Equally not all the quality system needs to be covered at each assessment visit. The assessment team will take into account the outcomes of the previous audits to be covered. The team leader will normally look at the management review(s), internal audit(s) and compliant records at each assessment visit.
A full re-assessment on the fourth anniversary of accreditation.
The RMP may apply for extension of the scope of accreditation at any time, but the cost will be minimized if extensions are assessed as part of the normal annual visits.

SUBCONTRACTORS
-The reference material producer (RMP) may use subcontractors for selected activities permitted by the standard. When using subcontractors, the RMP must be able to demonstrate to EGAC that each subcontractor complies with the relevant standard requirements.

- The information that shall be made available to EGAC includes:
  a. Name and address of the subcontractor(s).
  b. Key activities performed by the subcontractor(s), including but not limited to item preparation or
  c. the type of testing, calibration, and measurement activities done by the subcontractor(s).
  d. Information about how the RMP assesses the competence of each subcontractor.

-The accredited RMP shall notify EGAC within one calendar month if the key activities defined between the RMP and any of its subcontractors change.

-A task which is originally performed by a competent subcontractor at the time of initial accreditation/assessment of competence cannot be subsequently carried out by the RMP itself unless its competence in that task has been demonstrated to EGAC. For example, characterization of a RM by a single (primary) method may be carried out by a competent laboratory but may not be by the RMP itself if it does not have the expertise to enable it to ensure metrological traceability (see clause 7.12 of ISO 17034:2016). It may also be possible that the RMP may lack the

necessary equipment for the tasks (e.g. homogenizer for homogenizing the candidate material, measuring equipment for characterization, etc.). In other words, if the characterization of a RM by a single (primary) method was initial carried out by a laboratory as per the RMP's system for subcontracting and the same was assessed as competent during initial assessment then this arrangement may not be suddenly changed without information to EGAC. In all such cases a fresh assessment may be carried out by EGAC for assessing competence as per the revised sub-contracting arrangement of the RMP.

There are some processes that are not allowed to be subcontracted. Such processes are:
1) Production planning,
2) Selection of Subcontractors
3) Assignment of Property Values & their uncertainties,
4) Authorization of property values & their uncertainties.
5) Authorization of RM documents

- The RMP shall provide written details of provisions that are in place to ensure continued technical competency and ensure measures demonstrating that accreditation is being effectively maintained.
- A competent subcontractor is one which is accredited by an ILAC / IAF signatory accreditation body for the specific scope as per ISOLIEC 17025/ ISO 15189 for testing, calibration and measurement activities. RMP to ensure that subcontractor has participated in a PT program for same or closely similar materials
wherever available.
- For other activities like Material preparation, Material Handling and storage (including post certification testing) and Material Distribution & post distribution services, EGAC accepts ISO 9001 Certification issued by certification bodies which are accredited by an IAF signatory accreditation body and whose certification scopes cover activities sub-contracted.

RMP shall cover the sub-contractor's activities in its internal audit schedule, The Internal Audit of such subcontracted activities should preferably be carried out during actual execution of the job at the subcontractor site.

Subcontractor activities may also be assessed by EGAC during RMP assessment.

Activities that can be subcontracted cover a part of the procedure for production including the following:
1) Processing
2) Homogeneity and stability testing
3) Characterization
4) Handling
5) Storage
6) Distribution
Primarily it is the responsibility of the RMP to demonstrate that the sub-contractor is competent to perform the concerned part of the procedure and the work is carried out and the results produced are of required quality. RMP shall also ensure that the subcontractor complies with all the relevant requirements as specified in clauses 6.1(Personal), 7.2, 7.3 (Production planning and control), 6.4 (Facilities and environmental conditions), 7.4 (Material handling and storage), 7.5 (Material processing), 7.6 (Measurement procedures), 7.7 (Measuring equipment), 7.8 (Data integrity and evaluation), 7.9 (Metrological traceability), 7.10 (Assessment of homogeneity), 7.11 (Assessment of

stability), 7.12 (Characterization).
The appropriate evidences, records, etc. shall be maintained and available with the RMP to demonstrate the above as well as the records of evaluation and re-evaluation of the sub-contractor as per defined frequency.

EGAC shall invariably confirm the competence of sub-contractor through an assessment of the sub-contractor as relevant, however this does not absolve the RMP of its primary responsibility as stated above.

METROLOGICAL TRACEABILITY

- All equipment used for production and/or measurement when the results of use of such equipment have a significant influence on the results of the reference material property value shall be calibrated maintaining metrological traceability. The RMP shall ensure that all certified values are metrologically traceable whenever possible to the International System of Units (SI units).

- The hierarchy of acceptable sources of traceability is:
Metrological Traceability from a NMI (NIS): Applicant and accredited RMPs can submit appropriate physical standards and measurement and test equipment (M&TE) directly to a NMI (NIS). A NMI whose service is suitable for the intended use but not covered by the CIPM MRA shall be approved by EGAC.

- **Metrological Traceability from an ISO/IEC 17025 Accredited Calibration Laboratory**:

Applicant and accredited RMPs should use ISO/IEC 17025 accredited calibration laboratory services whenever available. Acceptable ISO/IEC 17025 accredited calibration laboratories are those accredited by EGAC or another accreditation body that is a signatory of the International Laboratory Accreditation Cooperation (ILAC) MRA with the appropriate calibration services listed in the scope of accreditation. A list of ISO/IEC 17025 laboratories accredited by EGAC is available on EGAC's website. When using accredited calibration laboratory services, the calibration certificates shall be accompanied by a recognized accreditation body symbol or otherwise refer to accredited status to be considered satisfactory for traceability purposes.

- **Metrological Traceability Using Intrinsic Standards**:

The RMP shall demonstrate traceability by measurement-assurance techniques, inter-laboratory comparison, or other suitable means that its intrinsic-measurement results are correlated with an NMI (e.g., Josephson Junction, Triple-Point
Devices,…….).

- When the RMP obtains measurement traceability by using certified reference materials it shall use:
a. Certified Reference Materials (CRMs) (of a smaller uncertainty to that being produced, when available) from an RMP accredited by EGAC or another accreditation body that is a signatory to the ILAC; or
b. Standard Reference Materials (SRMs) (called under trademark) from NIS; or
c. Materials from another National Metrology Institute (NMI). Use of NMI material other than NIS must be documented as the appropriate NMI relevant for the scope of accreditation and stated uncertainties.
d. The certified values assigned to CRMs that are covered by entries in the Joint Committee for

Traceability in Laboratory Medicine (JCTLM) database.

If traceability per above not possible, the RMP shall obtain measurement traceability from an available authoritative source.
a. The RMP shall determine that reference materials obtained from an authoritative source are fit for their intended use in accordance with established and validated procedures.

If traceability per both above options is not possible, or in cases when no reference methods or reference materials are available, the RMP shall develop reference methods or material from internal validation.
a. The RMP shall validate methods and determine fitness for use.

- The RMP shall define the specification and tolerance requirements for reference materials.
- If a CRM is used for establishing metrological traceability, the uncertainties of the certified values of the CRM used shall be suitable for establishing metrological traceability of the CRMs being produced.
When possible, the CRM used for establishing metrological traceability shall have comparatively small uncertainty to the CRM being produced and thus be higher in the metrological traceability hierarchy.
- The RMP shall determine the competence of the producer of any CRM it uses to support its own metrological traceability of the assigned value of its CRM. A competent producer of a CRM used to support metrological traceability is one that:
a. Is an NMI that is a signatory to the CIPM MRA, participates regularly in BIPM or Regional Key Comparisons, and has the relevant CMCs included in Appendix C of the BIPM Key Comparison Database (KCDB); or
b. Has values assigned to CRMs covered by entries in the Joint Committee for Traceability in Laboratory Medicine database; or
c. Is an RMP accredited by EGAC or another accreditation body that is a signatory to the ILAC with those CRMs listed on the scope of accreditation.

PROPERTY AND CERTIFIED VALUES AND THEIR UNCERTAINTIES

The assignment of reference material property values and, when relevant for certified values, their uncertainties must use either the processes identified in ISO Guide 35 or a technically sound alternative approach. In such cases, the RMP must provide sufficient valid technical justifications for using the method it selected.

Selection and Use of Proficiency Testing (PT) Schemes: -

-When the RMP or specified subcontractor(s) performs testing, calibration, or measurement that significantly affects the validity and uncertainty of the property value of a measurand of the reference material, the RMP or its subcontractor(s) shall have a PT program that meets the Proficiency Test requirements of EGAC.

- When the RMP uses a subcontractor to perform the testing, calibration, measurement, or examination activities, the RMP must be able to demonstrate to EGAC that the subcontractor participates in proficiency testing relevant to those activities.

4. THE PROCESS FOR GRANTING ACCREDITATION

a. Appointing the members of the Technical Committee (TC)

TC is formed for each applicant according to its specific discipline or scope. Each TC shall Consist of at least two members All these members shall be not involved in the assessment process in any way. EGAC has TC members covering the main disciplines and sectors within which it operates, who are drawn from experts in the field as appropriate.

b. Conducting the Technical Advisory Committee meeting.

After TC members are appointed, they shall sign confidentiality and impartiality agreement before their meeting. TC members with EGAC RMPs accreditation manager shall review RMP assessment file to verify its harmony with the relevant international standard and EGAC requirements. The assessment file shall include the proposed scope of accreditation assessed, the assessment report, and the resolution of all nonconformities and the recommendation of the assessment team. The decision of TC is taken by consensus. TC may decide that further actions or information are required. When satisfied, TC shall recommend the accreditation of RMP on specified scope. This shall be recorded on the TC report.

c. Conducting the Accreditation Committee (AC) meeting.

EGAC AC is headed by EGAC Executive Director. It has 7 members representing the Stakeholders. In case that the TC recommends the accreditation of the conformity assessment body, AC meeting shall be invited to meet by EGAC Executive Director. AC shall meet as needed typically every one month.

Meeting papers shall include assessment reports for the assessment activities and TC report. The AC may invite to the attendance of its meeting whoever it sees fit for help with experience in the field of accreditation activities without having a vote to be counted in the proceedings. When setting up a meeting, AC members shall be required to sign a confidentiality and impartiality Agreement. EGAC Accreditation Director shall attend the meeting to provide any required information about accreditation subjects and to be responsible for the administrative work of the meeting.

d. Decision making and granting accreditation

AC meeting shall be considered legal if more than50 % of its members attend. Resolutions shall be based on the majority of votes of the attending members, with the executive director vote as casting vote. Members involved with RMP being discussed, will neither participate nor attend the voting process. AC can decide granting the accreditation to RMP directly or require further actions to be taken or information to be provided. This shall be recorded on AC minutes of meeting. In case that AC decides granting the accreditation to RMP, EGAC shall inform RMP and ask for its representative to receive the accreditation certificate with the approved scope of accreditation.

4.4.1 Accreditation cycle

Following granting of accreditation, CABs shall be subject to periodic consecutive assessment visits according to an accreditation program prepared by EGAC relative accreditation manager on the form F21P9G_Accreditation Program which starts after accredited CAB decision of granting/renewal accreditation.

EGAC policy on the implementation of an accreditation cycle:

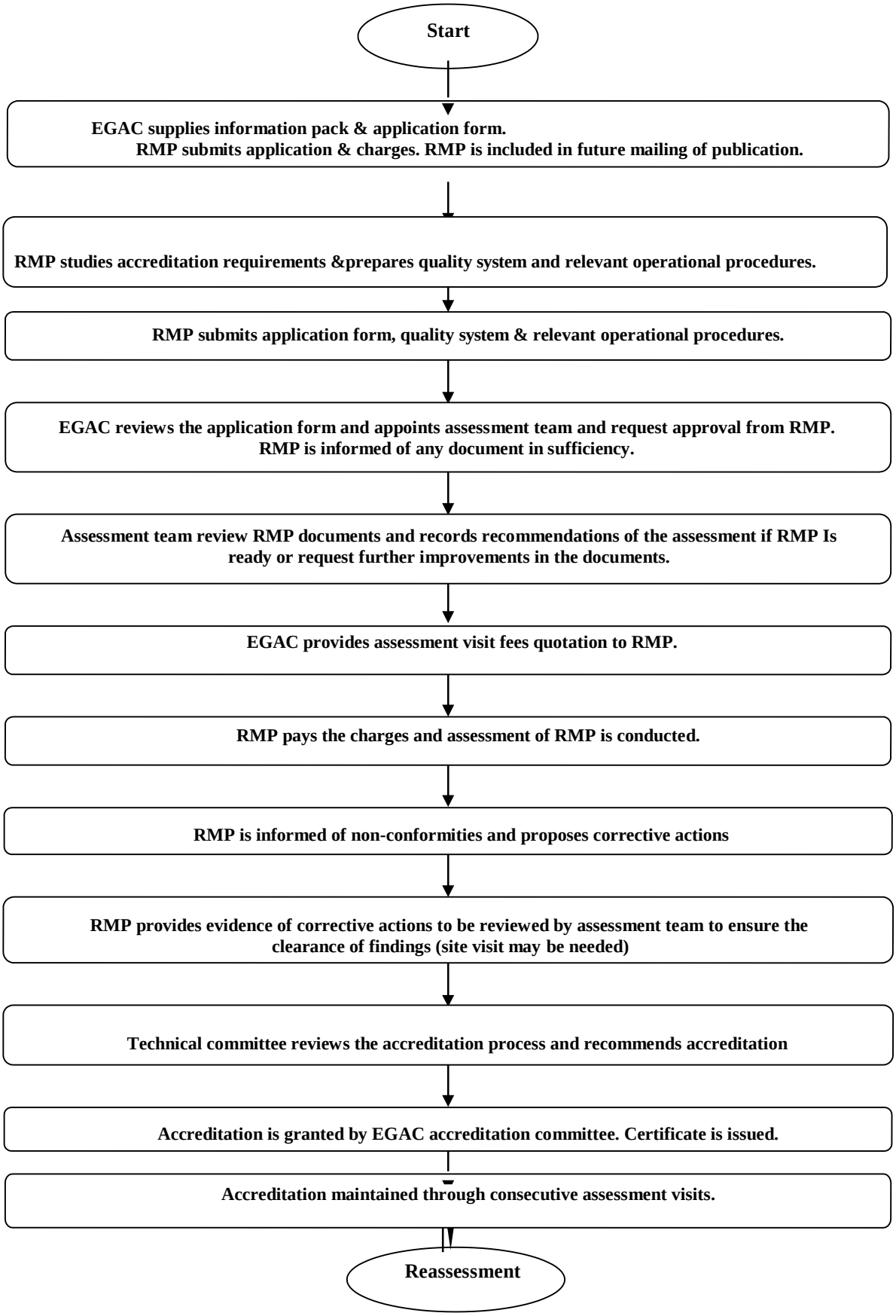
- EGAC select an accreditation cycle (4- years) for its accredited CAB.
- In the normal situations EGAC will plan for two consecutive assessments and reassessment visit within the CAB accreditation cycle.
- In all cases the duration between the sequential assessment visits shall not exceed 2 years.
- According to each accredited CAB case, EGAC may implement additional assessment visit during CAB accreditation cycle (with RAM justification) in case of:
  a. A complaint against performance of accredited CAB
  b. An accredited CAB seeking an extension for its scope.
  c. A recommendation by an assessment TL to verify performance of assessed CAB

The reassessment will be every 4 years, reassessment preparations will start by inform EGAC its CAB within11 months before the expiry date of the accreditation certificate

5. FEEDBACK, COMPLAINTS AND APPEALS

After receiving the accreditation certificate, the accredited body will be asked to fill a feedback Report about EGAC's performance during the accreditation process which shall be used for improvement of assessors' performance and/or accreditation process. If RMP has any complaint it can file this complaint at EGAC or by phone. Also, if AC did not grant the accreditation to RMP, RMP has the right to appeal. If RMP decides to appeal, it can file an appeal at EGAC complaints and appeals shall be handled by EGAC's quality department and according to EGAC's procedure (PB3G-Guidelines for dealing with complain and appeal) which is available on demand. A neutral appeal committee shall be appointed to resolve this appeal according to the mentioned procedure.

7.THE ROUTE TO ACCREDITATION



6. REFERENCIES

- ISO 17034:2016; General requirements for the competence of reference material producers;
- ISO Guide 30:2015, Reference materials – Selected terms and definitions
- ISO Guide 31:2015, Reference materials – Contents of certificates, labels and accompanying
- documentation
- ISO Guide 35:2017, Reference materials – Guidance for characterization and assessment of homogeneity and stability
- ISO 15189:2012 Medical laboratories – Requirements for quality and competence
- ISO/IEC 17025:2017; General requirements for the competence of testing and calibration laboratories
- APAC TEC1-008, APAC Guidance on Reference Material Use and Production

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