KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

SDE-PR-02-02

Development and Extension of Accreditation Schemes and Scopes Procedure

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1 Background Information

1.1 Purpose

This document describes the process of developing new accreditation schemes or extending existing schemes into new areas (scopes or sub-scopes)..

1.2 Scope

The document is applicable to all accreditation schemes, scopes, and sub-scopes being developed and extended within KENAS.

1.3 Role(s) and Responsibility

Role	Responsibility
All KENAS Staff	Process owner
SDEO	Reviewer
PSDO	Recommender
CEO	Approval
All KENAS Staff	Compliance

2 Terms and Definitions

For the purpose of this manual, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the KENAS 2019.

2.1 Acronyms and Abbreviations

AAC	Accreditation Advisory Committee
AB	Accreditation Body
CAB	Conformity Assessment Body
CEO	Chief Executive Officer
IEC	International Electro-technical Commission
ISO	International Organisation for Standardisation
KENAS	Kenya Accreditation Service
MDAs	Ministries, Departments & Agencies
MSTA	Manager Scheme Development, Training & Advocacy
QM	Quality Manual
SDO	Scheme Development Officer

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SWOT	Strength, Weakness, Opportunity and Threat

2.2 Definition of Terms

2.2.1 Accreditation Scheme

Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply. Accreditation scheme requirements include, but are not limited to, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065.

2.2.2 Scope of Accreditation

Specific conformity assessment activities for which accreditation is sought or has been granted.

2.2.3 Conformity Assessment Body

A body that performs conformity assessment activities and that can be the object of accreditation.

2.2.4 Conformity Assessment Activities:

Activity conducted by a conformity assessment body when assessing conformity. Activities covered by accreditation include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification.

2.2.5 Scheme owner

A scheme owner can be:

a) A CAB itself, a governmental authority, an industry association, another body; or
b) A person or organization responsible for developing and maintaining a specific accreditation or certification scheme.

2.2.6 Adopting an accreditation scheme:

This is whereby KENAS incorporates and operates an already existing accreditation scheme as established by a separate entity which could be an AB or a privately owned or from a governmental entity.

2.2.7 Adapting an accreditation scheme

This is whereby KENAS borrows some information from an existing accreditation scheme or scope that is operated by a foreign AB, or a private entity or a governmental organisation and incorporates it into a new or existing accreditation scheme with some adjustment taking into consideration the geographical, regulatory context in Kenya.

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3 Process Detail

3.1 Request for Development or Extension of an Accreditation Scheme

3.1.1 The development of a new accreditation scheme or extending the scope of an existing accreditation scheme may be initiated by KENAS or any of its interested parties, such as:

a) Scheme owners;
b) Regulators;
c) Government agencies (MDAs);
d) Trade associations;
e) Conformity Assessment Bodies;
f) Non-governmental organisations;
g) Professional Bodies.

3.1.2 Interested parties shall propose a request for development of a new accreditation scheme or extension of an existing accreditation scheme to include a new scope or sub-scope to KENAS by filling out the **SDE-FM-01**.

3.1.3 Upon receipt of the scheme development or extension of scope request form, the CEO shall assign the MSTA to review the request and establish whether there is a feasible need for the scheme or scope to be developed/extended/adopted/adapted by determining the following;

a) Determine the required accreditation scheme or scope extension.
b) Determine the availability of required documents such as National Standards, International Standards / Guidance and other requirements from regulators.
c) Determine the availability of technical experts for the development / extension and implementation of the accreditation scheme and determine the number of assessors (Team Leaders and Technical) required for servicing the industry.
d) Determine the need to conduct a benchmarking exercise in other economies where such an accreditation scheme has been implemented.
e) Determine financial requirements to set up the accreditation scheme. This includes the cost of the research, workshops, benchmarking exercises, meetings, trainings and other set-up costs. Over and above, an indication of the projected implementation costs to be provided by industry if they request for the scheme.
f) The financial requirements should be included in KENAS' budget for the subsequent financial year if not already covered in the current budget.

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g) The MSTA shall do an evaluation on the need for the scheme or extension of scope based on a feasibility study carried out by the PSDO/SDEO.

3.1.4 The MSTA shall consider the suitability of the proposed conformity assessment scheme or extension or adoption and the standards or requirements that apply to the accreditation scheme sought in order to set up a working group for the project.

3.2 Conducting a Feasibility Study

The PSDO/SDEO may carry out consultations with industry and interested parties or research to inform and/or get a view of the broader interested parties about the development or extension of an accreditation scheme for launching the new or extended accreditation scheme, addressing as a minimum the following aspects:

3.2.1 Problem Statement

This involves stating the reasons and the need for accreditation in the scheme or extended scope, and an investigation and identification of any economic or market benefit or failure that needs to be addressed by the new or extended scheme. Information shall be provided on the nature and magnitude of the problem.

3.2.2 Statement of the Desired Objectives

This shall specify what is to be achieved through setting up of the new or extended accreditation scheme.

3.2.3 Analysis of the Regulatory Environment

This shall identify the pre-existing policy and regulator (if any) for a possible regulatory initiative. Industry stakeholders including government departments and regulatory institutions involved in the industry shall be identified and involved.

3.2.4 Industry Analysis

This section should present all the industry known dynamics that could influence or affect the new or extended accreditation scheme. These could include the size of the industry, the structure, geographic spread, and availability of required skills.

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3.3 Approval of the feasibility Study

3.3.1 The MSTA shall consider the feasibility study for approval. The approval team may decide to approve or to reject the recommendations presented in the feasibility study.

3.3.2 The approval team shall constitute of the CEO, MSTA, and the relevant accreditation/certification manager.

3.3.3 If the feasibility study is approved, the team will consider the time-lines for the development of the scheme. A relevant working group shall then be set up.

3.3.4 A rejection of the recommendations must be supported with reasons and a recommendation on the way forward.

3.4 Signing of the Co-operation Framework

3.4.1 After the approval of the project, KENAS and the relevant industry Principal, Regulator, Government Department, as applicable, may enter into a legal framework of co-operation clearly outlining how the accreditation scheme would be developed and implemented as well as the roles and responsibilities of each party in the implementation.

3.4.2 A co-operation framework may not be necessary if the regulations are clear regarding the roles and responsibilities of all economic operators in the implementation of the requirements or where it is an extension of an accreditation scheme's scope, or where the accreditation scheme is initiated by industry.

Note: Co-operation frameworks are not necessary within the private sector, as accreditation schemes are mostly voluntary in nature.

3.5 Working Group

3.5.1 Appointment of a Working Group

3.5.1.1 The membership of the WG shall be proposed by the respective Manager in charge of a scheme to the MSTA.

3.5.1.2 The MSTA shall recommend the names to the CEO for formal appointment.

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3.5.2 Roles of a Working Group

3.5.2.1 A working group shall be established whose role shall be to provide input on technical issues relating to the accreditation scheme and or accreditation scope being developed, extended or adopted. Input provided shall including the following;

a) Structures, processes and outcome of accreditation and the technical influence of the same on the credibility of accreditation activities in the said areas of accreditation.
b) Technical issues emanating from the International Laboratory Accreditation Cooperation/International Accreditation Forum (ILAC/IAF); regional and national regulations and guidelines.
c) Assist in the development, harmonization and interpretation of technical guidance on documents.
d) The WG shall also be responsible for the development of any guidance, application or normative documents for the accreditation scheme under development or extension, as required. This can also include a benchmarking exercises, which could be done by determining whether any other accreditation body has developed or extended a similar accreditation scheme and examining their criteria in order to adapt where possible.
e) The WG shall ensure that any documents developed do not contradict or exclude any of the requirements included in relevant international standards and/or other normative documents.
f) Advise KENAS on technical and scientific matters relating to the operation of accreditation schemes;
g) Guide on interpretation of technical requirements of international standards and regulatory requirements of specific accreditation schemes;
h) Formulate or review the technical criteria or other sector specific application requirements related to accreditation schemes;
i) Develop or review technical criteria adopted by the Service for specific accreditation activities;
j) Advise on the competence criteria for accreditation assessors and technical experts including identifying relevant proficiency testing programmes applicable to specific accreditation schemes; and
k) Offer advisory support activities including accreditation assessment reviews, research and other matters as may be required by Service from time to time.

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3.5.2.2 Persons representing appropriate interested parties and who possess the required competencies, i.e. relevant technical expertise in the specific scope of activity shall be nominated into the WG. The membership of the Working Group formed may include representation from at least the following:

a) Conformity Assessment Body
b) Business and Industry
c) Consumer and public interest
d) Regulators and government
e) Research and Academia

3.5.2.3 If the development or extension of accreditation scheme is requested by a Government Department or Regulator, the scheme sponsor should nominate a representative to the WG and all other committees established for the accreditation scheme. This is to allow for effective information exchange between KENAS and the sponsor.

3.5.2.4 The purpose and deliverables of the WG shall be communicated to the members in the request for nomination. The WG shall be dissolved once the deliverables for the accreditation scheme have been completed.

3.6 Identification and Training of Assessors

3.6.1 As a means to ensure knowledge and understanding of the documents developed, assessors and the relevant KENAS staff shall be trained during the assessors training course or workshop, as relevant, for the new or extended accreditation schemes.

3.6.2 The MSTA shall determine the competence of the resource required for training on the developed/extended/adopted schemes. This shall include the personnel to carry out the training and the assessors to be trained.

3.6.3 The selection and number of assessors required for a new accreditation scheme or extension of scope of an accreditation scheme is influenced by the following factors:

a) Current number of scopes in the accreditation scheme;
b) The overlapping between the scopes;
c) Complexity within the scopes;
d) Skills pool in the particular sector; and
e) The size of the potential applicant(s)

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3.7 Roles of a Technical Reference Group

3.7.1 The MSTA shall submit the guidance and criteria document(s) as drafted by the working group to the reference group to review and approve for adequacy.

3.7.2 The technical reference working group shall be comprised of:

3.7.3 The head of an existing KENAS accreditation scheme relevant to the scope under review;

a) The existing KENAS scheme representative
b) Officer(s) from the Training and Capacity Building Departments; and
c) The client involved in the piloting of the developed schemes or scopes.

3.8 Implementation of the scheme or Extended Scope

3.8.1 KENAS through the marketing and advocacy division shall informing the industry about the accreditation scheme or extended scope and invite applications for accreditation through awareness campaigns, publicising on the KENAS website, or any other means as appropriate.

3.8.2 The Marketing Division will put out a call for interest in implementing the developed scheme or scope to interested Conformity Assessment Bodies to be considered for piloting as applicable.

3.8.3 The new accreditation scheme or extended scope shall be handed over to the Accreditation Manager once the following has been concluded:

a) Technical requirements;
b) Technical guidance documents, where applicable;
c) Updating the application form;
d) Assessment Checklist;
e) Trained Technical Assessors;
f) Roll-out workshops (Stakeholder Engagements)

3.8.4 After the first assessment is conducted, the MSTA and the relevant scheme owner shall evaluate post assessment reports including the feedback from the assessed facility to determine the adequacy of the new or extended accreditation scheme and recommend adjustments to the requirements / documents, if necessary.

3.9 Discontinuation of an accreditation scheme or scope

3.9.1 KENAS may discontinue in part or in full an accreditation scheme or scope where the scheme is deemed not to meet the market demands.

3.9.2 A scheme or scope may be discontinued when:

a) The requirements of the project changing fundamentally.
b) The requirements of the project result are unclear or are unrealistic.

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c) The intended outcome of the project is no longer needed so the project becomes obsolete.
d) The project cost becomes too high or the projected revenue is too low.
e) Required material, tools, or technical personnel are completely unavailable.
f) Lack of management support.
g) Lack of customer support.

3.9.3 An accreditation scheme or scope can be discontinued through the following ways:

3.9.3.1 Termination by extinction

a) A scheme discontinuation by extinction is when a project is stopped due to its unsuccessful conclusion.
b) Project termination by extinction could happen in the following cases:
    i) The project has been superseded by external developments like a market crisis, technological advancements.
    ii) The project has failed to achieve its goal.

3.9.3.2 Termination by integration

a) In the case of a scheme discontinuation by integration, the scheme or extended scope that is being discontinued either is integrated into other larger projects that are underway or becomes part of the ongoing operation of the organization.
b) Project resources in this case are redistributed and the project as a whole loses both its purpose and identity as an individual project.

3.9.3.3 Termination by Starvation

Termination by starvation is the act of depriving a project of necessary resources it needs to sustain its ongoing activities. This leads to the inevitable cease of function.

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3.9.4 KENAS shall communicate with stakeholders concerning the discontinuation.

3.9.5 KENAS shall withdraw any information related to the scheme or part of the scheme as soon as transition is complete.

3.9.6 Once all issues are resolved, KENAS shall communicate with all stakeholders concerning the discontinuation as well as post the communication on its website.

3.9.7 Review any contractual obligations it has and plan for transition of accredited CABs to other ABs offering the scheme or part of the scheme.

3.9.8 Withdraw any information related to the scheme or part of the scheme as soon as transition is complete.

4 Associated Documents

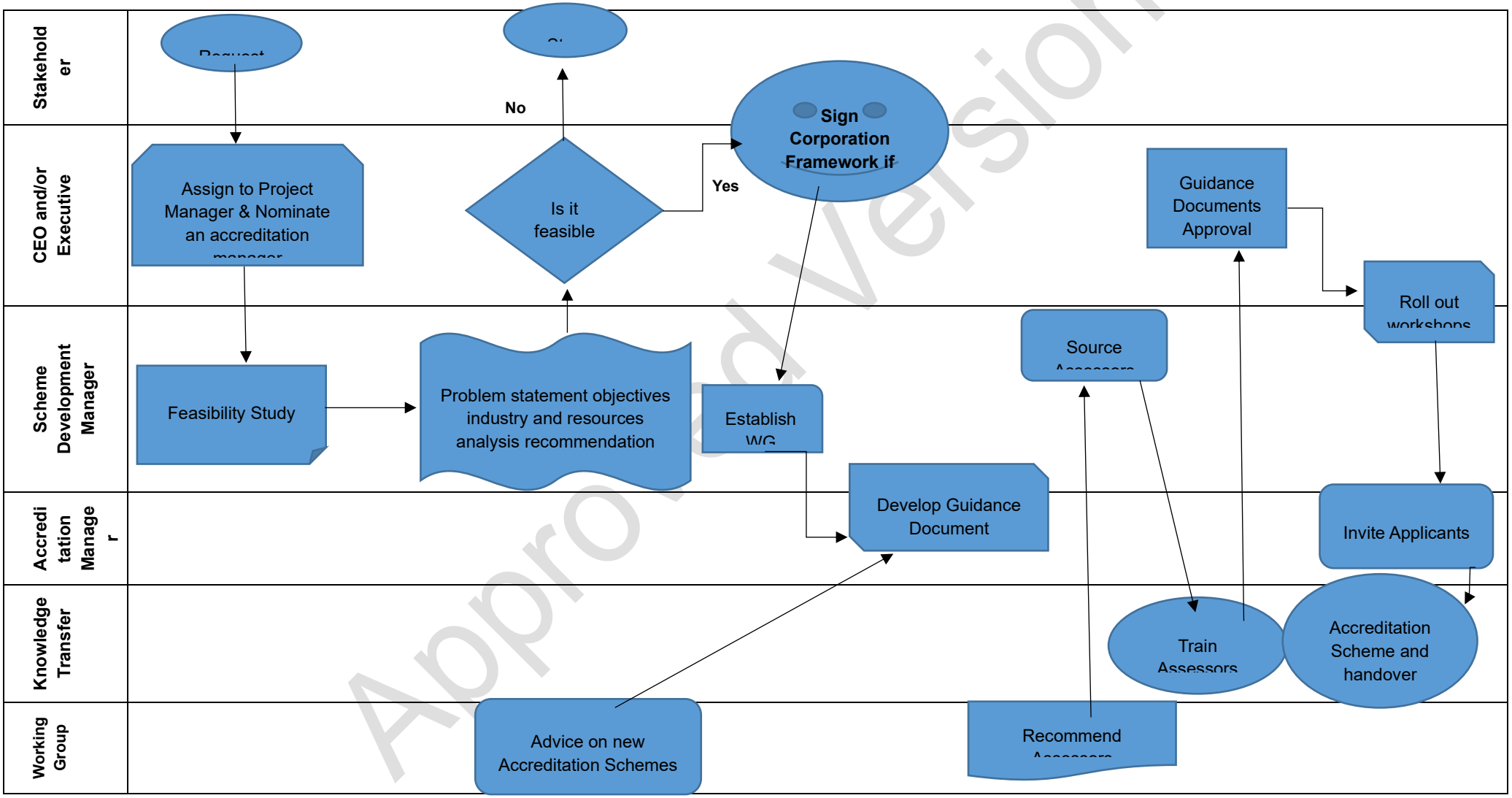
Ref	Document Identifier	Document Title
1.	ISO/IEC 17011	Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
2.	QMM-01	Quality Manual (QM)
3.	ACC-01	Assessment & Accreditation Manual
4.	ACC-CD-06	Criteria for Selection and Management of Assessment Personnel
5.	SDE-FM-01	Scheme Development or extension of scope request form.

5 Revision/ Amendment Records

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	STA	Newly developed/formatted document
09/12/2022	02	STA	Inclusion of appointment of the WGs Addition of roles of the WGs

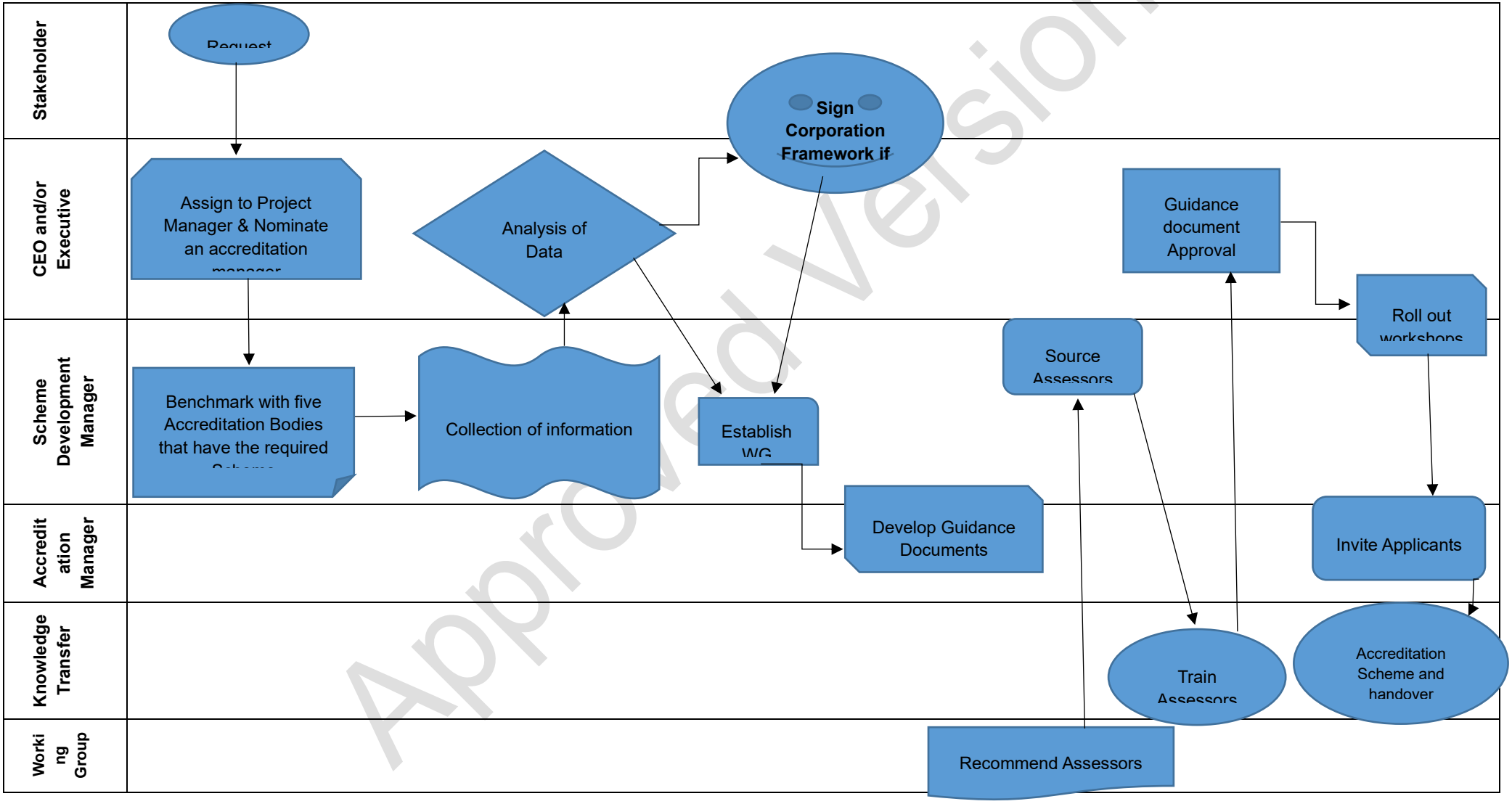
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Annex 1: Accreditation Scheme Development / Extension Process (Pathway 1)



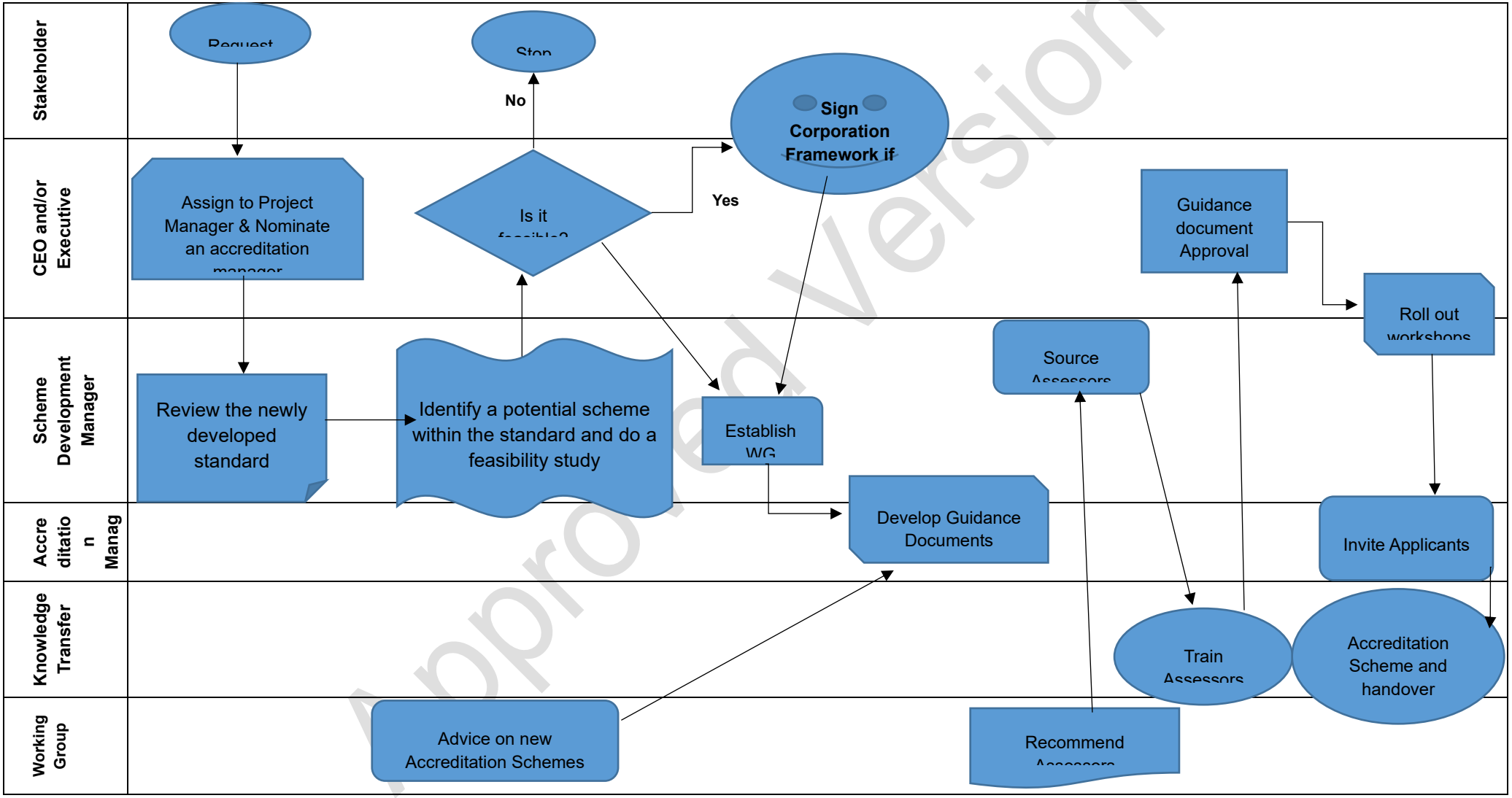
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Annex 2: Accreditation Scheme Development / Extension Process (Pathway 2)



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Annex 3: Accreditation Scheme Development Process (Pathway 3)



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