ISO 15189 Accreditation Scheme Lifecycle

Purpose:
This document describes how COLA develops, extends, maintains, and discontinues accreditation schemes, including the procedures, processes, and application of international standards. Development of accreditation schemes will follow COLA's *New Product Development Process*. Changes to the accreditation scheme international standards will follow COLA's *Implementing ISO New & Changed Requirements* procedure.

Scope:
COLA will consider developing and extending accreditation schemes that align with our corporate mission. The process begins with an idea for a new or extended accreditation. If a project is authorized to develop the accreditation scheme, then the development follows all stages of the *New Product Development Process* until the scheme is launched or the project is terminated. The accreditation scheme is operated and maintained until it's discontinued.

Responsibility and Authority:

- The COLA Board of Directors authorizes COLA's Executive Team to develop new products and services that align with our corporate mission and key strengths of the organization. The Board also approves any plans to discontinue existing products and services.
- During development or extension of the accreditation scheme, responsibilities and authorities will follow the *New Product Development Process* (if a project is created). The Team Leader selected should be the manager who will be responsible for the operation of the new or extended accreditation scheme.
- During operations and maintenance of the accreditation scheme, the responsibilities and authorities will follow the policies and procedures developed for the accreditation scheme and those described in the position descriptions of the staff who operate and maintain the scheme.
- The CEO will make the final determination when an accreditation scheme is ready for release into the marketplace. This role assigns the overall responsibility for conducting the work and will make a recommendation to the Board of Directors for discontinuing an accreditation scheme.

Terms and Definitions:

Accreditation scheme	Rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply

Development or Extension of an Accreditation Scheme:
After a project to develop or extend an accreditation scheme is approved, the Team leader and Project Manager are appointed. They, in turn, select the project team. The project team follows the *New Product Development Process* and uses the supplemental requirements below. Depending

on the nature of the extension, a project may not be necessary and the work may be completed as part of managing operations.

1. Concept Development stage
    a. The Team Leader or Project Manager will identify international standards that apply to the accreditation scheme and obtain current versions through the Director of Quality Systems.
    b. The Team reviews the project goals, environmental scan, VOC information, applicable international standards, relevant lessons learned, and considers:
        i. Feasibility of launching or extending the accreditation scheme;
        ii. Analysis of COLA's present competence and resources;
        iii. Accessing and employing expertise;
        iv. The need for application or guidance documents;
        v. Training of COLA staff;
        vi. Implementation or transition arrangements;
        vii. Views of interested parties.
    c. The Team includes its analysis and conclusions of the topics above in the Concept Development stage, Go/No-Go Review.
2. Business Analysis stage
    a. The Business Plan should incorporate the information from item 1.b (above).
3. Product Development stage
    a. If the Team utilizes any guidance, application, or normative documents to develop the accreditation scheme, it shall ensure that the documents were developed by committees or persons possessing the necessary competence and with participation of appropriate interested parties. Documents developed by ISO/IEC Technical Committees or ILAC-recognized organizations should meet these requirements. However, the Team shall ensure that these documents do not contradict or exclude any of the requirements included in the relevant international standards and/or other normative documents.
    b. The Team will utilize PowerDMS workflows to review and approve documents developed for the accreditation scheme to ensure their suitability for accreditation purposes.
    c. The Go/No-go Review should confirm the suitability of the developed scheme for accreditation purposes.
4. Commercialization stage
    a. Staff test standard work references and materials to verify their suitability for accreditation purposes.

5. Launch stage
    a. No additional requirements.

Operating an Accreditation Scheme

1. Staff will follow the policies and procedures developed for the scheme.
2. If the international standards associated with the scheme are revised, *Implementing ISO/IEC New & Changed Requirements* procedure is followed.

Discontinuing an Accreditation Scheme

COLA will consider the following topics before discontinuing an accreditation scheme in part or in full:

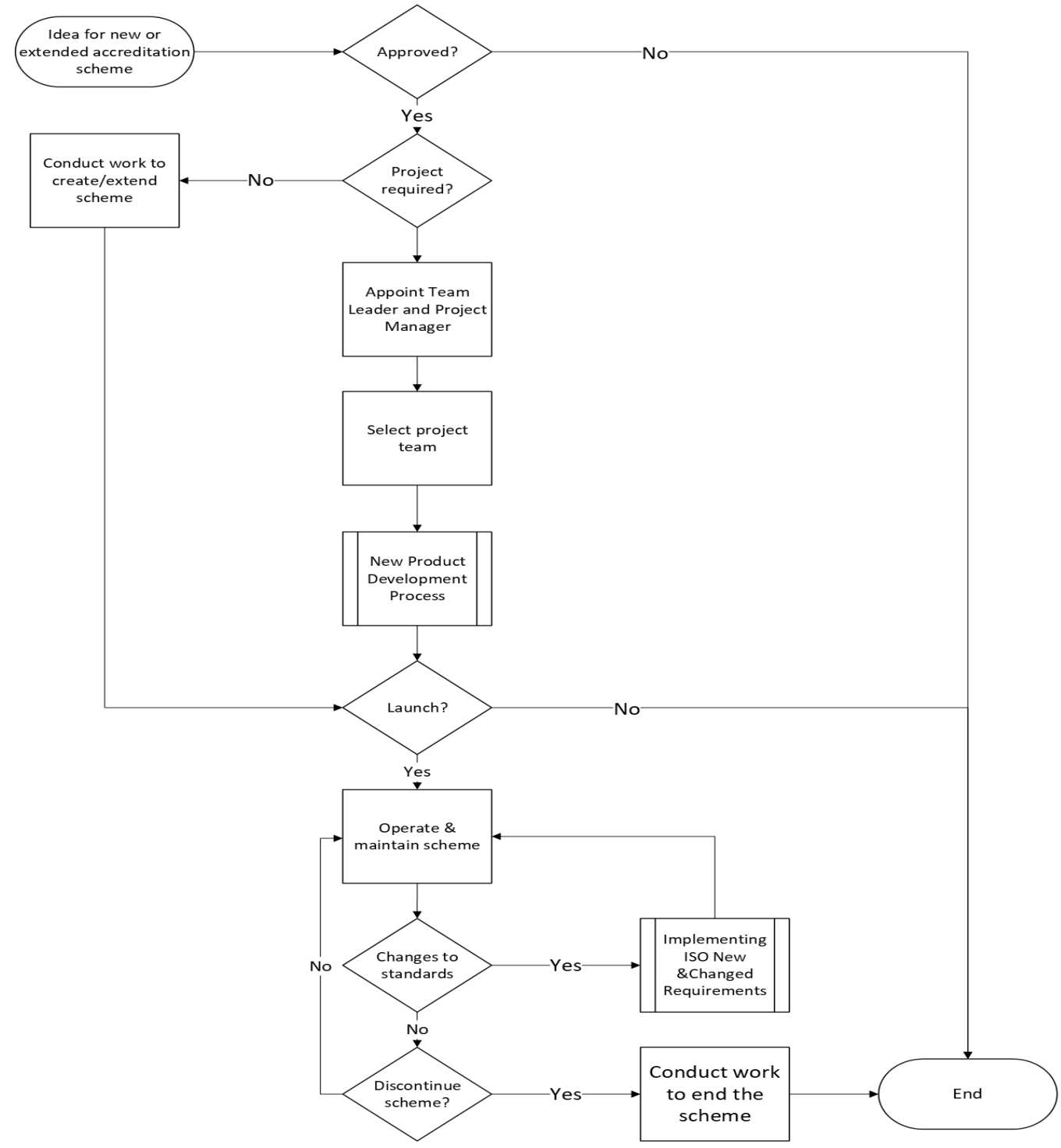
1. Views of interested parties
2. Contractual responsibilities
3. Transition arrangements
4. Internal and external communications regarding the discontinuation
5. Information published by COLA

The CEO makes the decision to discontinue an accreditation scheme, which requires approval by COLA's Board of Directors. The CEO will appoint a staff member with the overall responsibility to conduct the work. If a project team is formed for this work, then the team should follow the stages of the *New Product Development Process* to plan and implement the discontinuation of the accreditation scheme.

- Concept Development for Discontinuation – why, view of interested parties
- Business Plan – contractual responsibilities
- Product Development – Developing the necessary procedures and timelines for transitions and communications
- Commercialization – implementing the procedures and communications for discontinuation
- Launch – completion of the discontinuation plan

Staff will capture lessons learned from the operations, maintenance, and discontinuation activities for application to future accreditation schemes.

Flow Chart:


Idea for new or extended accreditation scheme
Approved?
No
Yes
Project required?
No
Conduct work to create/extend scheme
Appoint Team Leader and Project Manager
Select project team
New Product Development Process
Launch?
No
Yes
Operate & maintain scheme
Changes to standards
Yes
Implementing ISO New &Changed Requirements
No
No
Discontinue scheme?
Yes
Conduct work to end the scheme
End

Monitoring and Measurement:

Methods Used	Metrics
Quality and Time project metrics	To be determined for each accreditation scheme

Supporting Materials:
New Product Development Process
Implementing ISO/IEC New & Changed Requirements
ISO/IED 17011

Records:

Record ID	Custodian	Where Stored	Retention Period
Decision to discontinue accreditation scheme	Chief Executive Officer	Board Minutes	Permanent
Project Plans & Lessons Learned	Project Manager	S:\Quality Systems\Project Management\ Lessons Learned	Permanent

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