ISO Accreditation Impartiality Policy

I. Scope:

Pursuant to the requirements of ISO 17011:2017, COLA adopts this public-facing policy and procedure, which shall apply to all directors, officers, employees and contractors who carry out ISO accreditation activities on COLA's behalf.

II. Policy:

COLA Inc. is committed to high standards of business and personal ethics, honesty, and objectivity in the provision of accreditation services. COLA provides ISO accreditation services to international laboratories or biobank facilities, as well as laboratories or facilities within the U.S.

Any laboratory providing testing on human specimens for diagnostic or treatment purposes may apply to COLA for ISO accreditation. Any biobank that stores biologic materials may apply to COLA for accreditation. Accreditation services are available to all laboratories and biobank facilities, regardless of size, organizational structure, or number of locations.

COLA Inc. does not provide any testing or calibration services, certification of management systems, persons, products, or processes, provision of proficiency testing, production of reference materials, validation, verification, or consultancy.

COLA Inc. does offer educational materials related to its ISO accreditation processes and associated standards and requirements. These materials are limited to the provision of generic information that is readily accessible in the public domain. Employees and contractors involved in ISO accreditation processes or decisions may author or contribute to the development of educational materials and may serve as speakers. However, COLA Inc. has established a firewall that prevents employees and contractors involved in ISO accreditation processes and decisions from having access to COLA files and records that would reveal whether a given laboratory or facility, or its' staff members utilized any of COLA's educational materials and the results of any knowledge assessments conducted as part of an educational program, thereby preventing these factors from influencing ISO accreditation processes and decisions.

COLA Inc. has identified interested parties relative to its ISO accreditation programs. These interested parties are engaged in an annual review to provide input regarding potential risks to impartiality and actions to mitigate those risks to an acceptable level.

Directors, officers, employees and contractors who carry out ISO accreditation activities must act honestly and with integrity in fulfilling their responsibilities, comply with all applicable laws and regulations, and be free from undue commercial, financial, or other pressures that could compromise impartiality.

COLA employees and contractors shall not participate in ISO accreditation activities involving any laboratory or facility where the individual has been employed or engaged as a consultant in the last five years or is engaged by another laboratory or facility that could be viewed as a competitor.

COLA employees and contractors shall not participate in ISO accreditation activities involving any laboratory or facility where an immediate family member is employed or where the individual or family member has a financial interest.

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If there is a risk to impartiality that cannot be mitigated to bring the risk to an acceptable level, COLA Inc will decline to provide ISO accreditation services.

It is COLA policy that employees and contractors acting on COLA's behalf behave in an ethical manner that is free from conflicts of interest and avoid any actions or relationships that create an appearance of a conflict of interest.

COLA employees and contractors are expected to conduct business in a manner that:

- Maintains and promotes high standards of excellence
- Discloses any potential conflicts of interest, as soon as they arise, and recuses themselves from participating in any aspect of the accreditation process or decisions until the risk associated with the conflict can be satisfactorily mitigated
- Safeguards the privacy and confidentiality of the client's business and/or other confidential proprietary information
- Actively demonstrates commitment to quality, professionalism and ethical business practices
- Respects colleagues, co-workers, and clients

III. Procedures:

A. Risks to Impartiality:

The reputation and effective functioning of COLA's ISO accreditation programs depend on recognizing actual and potential risks and identifying them to COLA management. Employees and contractors must immediately inform the Chief Executive Officer (CEO) and the Director of Standards, Regulations and Policies of any commercial, financial or other pressures that could compromise the impartiality of COLA's ISO accreditation processes or decisions. Sources of impartiality could arise from ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and sales practices.

A risk may exist when the interests or concerns of COLA, its Board of Directors, an employee, or contracted expert or vendor may be seen as impeding the objectivity of ISO accreditation processes or decisions. There are a variety of situations that raise concerns regarding impartiality, including, but not limited to, the following:

1. Commercial Interests – A risk may exist where an individual or entity receives or is perceived to receive a competitive benefit as a result of an ISO accreditation process or decision made by COLA.
    - An individual seeks to make use of confidential information obtained as a result of conducting ISO accreditation activities on behalf of COLA for his own benefit, or for the benefit of a relative, business associate, or other organization

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- COLA accredits the laboratory or facility of a contractor used to provide training or education materials for COLA's use

2. Financial Interests - A risk may exist where an individual or entity directly or indirectly benefits or profits as a result of an ISO accreditation activity or decision made by COLA. Examples include situations where:

    - COLA contracts to purchase or lease goods, services, or materials from an individual associated with a laboratory or facility seeking or receiving accreditation from COLA

    - COLA provides a sales commission or other inducement for the referral of new clients

    - COLA provides ISO accreditation to a laboratory or facility owned by an employee or contractor, or by a relative or business associate of an employee or contractor

    - An employee or contractor, or a relative or business associate of an employee or contractor, is provided with a gift, gratuity or favor, of a substantial nature, from a person or laboratory seeking or receiving ISO accreditation from COLA

3. Other Pressures
   A risk may also exist where an individual or entity obtains a non-financial benefit or advantage that he would not have obtained absent his/her involvement in ISO accreditation processes, or where his/her duty or responsibility to be impartial conflicts with a duty or responsibility owed to some other organization. Examples include where:

    - An employee or contractor, or a relative or business associate of an employee or contractor, is gratuitously provided use of the facilities, property, or services of a laboratory or facility seeking or receiving ISO accreditation by COLA
    - An employee or contractor seeks to obtain preferential treatment within ISO accreditation processes for a laboratory or facility in which the employee/contractor, a relative, or a business associate is involved
    - An employee or contractor involved in the ISO accreditation process or decision-making has an ongoing or prior relationship with a member of the laboratory or facility seeking or receiving accreditation

B. <u>Role of Industry Experts in the Accreditation Process</u>:
COLA must at all times maintain an arm's length relationship with manufacturers of laboratory instruments and reagents, industry experts, and laboratory consultants. COLA must also at all times maintain nan arm's length relationship with manufacturers of biobanking instruments, industry experts and consultants. These individuals may be involved in:
    - Training of COLA Assessors and Accreditation staff members
    - Discussion of best practices in the industry

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- Development or delivery of educational materials for COLA staff members and/or laboratories

COLA does, however, utilize such individuals in a training capacity. Prior to attending an assessment, contractors will be required to identify any potential conflicts or risks to impartiality. In addition, the laboratory or facility will be notified of the contractor's participation and given the opportunity to raise any concerns.

In any consultation outside of an assessment of a laboratory or facility, the identity and location of the laboratory or facility will be blinded to mitigate any risk to impartiality.

C. Disclosure of Actual or Potential Risks to Impartiality

An employee or contractor is under a continuing obligation to disclose any actual or potential conflict of interest or risk to impartiality as soon as it is known or reasonably should be known.

All employees involved in ISO accreditation processes and decision-making, and contracted industry experts, shall complete a questionnaire to fully and completely disclose the material facts about any actual or potential conflicts of interest. The disclosure statement shall be completed upon his/her association with COLA and shall be updated annually thereafter.

Employees and contractors are prohibited from participating in an ISO accreditation activity of any laboratory or facility where the individual was employed or engaged as a consultant in the last five years, or where the individual or an immediate family member is employed or has a financial interest.

An additional disclosure statement shall be filed at such time as an actual or potential conflict arises. Until a determination is made regarding the risk of any new conflict, the individual shall refrain from any participation in ISO accreditation processes or decisions involving the identified laboratories or facilities.

Copies shall be provided to COLA's COO for review. Completed employee forms will be kept by the COO, while forms completed by contractors will be retained with the contract. In the case of the CEO's disclosure, that statement shall be provided to the Chairman of the Board and Corporate Secretary.

D. Review of Risks to Impartiality

On an annual basis and when a new risk is identified, the Director of Standards, Regulations and Policies, the Director of Quality Management, and the COO identify actual or potential risks to impartiality arising from COLA's activities, including its relationships or from the relationships of its personnel. This team conducts an initial risk assessment and proposes actions to mitigate or monitor risks to the CEO.

The CEO approves actions required to mitigate identified risks. Once actions are completed, the risk assessment is updated to determine the residual risk. The CEO makes the final determination whether the residual risk is acceptable.

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Should a situation exist where the risk cannot be mitigated to bring the residual risk to an acceptable level, accreditation will not be provided.
All analyses, decisions, actions to mitigate the risk, and determination of residual risk shall be documented.

IV. Violations of Conflict of Interest Policy
An employee's failure to adhere to this policy and procedure or failure to timely disclose an actual or potential conflict may result in disciplinary action, including but not limited to termination for cause.

A contractor's failure to adhere to this policy and procedure or failure to timely disclose an actual or potential conflict may result in termination of their contract.

V. Safeguarding Impartiality
On an annual basis, COLA will convene a group of interested parties to discuss potential risks to impartiality and advise on matters affecting impartiality, including openness and public perception. The results of this review are submitted to the Director of Quality Management for inclusion in COLA's Management Review process.

Responsibilities:

The CEO is responsible for the establishment and enforcement of COLA's policy on impartiality and the determination of an acceptable level of risk.

The COO is responsible for reviewing annual conflict of interest statements to identify and report potential risks. This individual collaborates with the Director of Standards, Regulations and Policies and the Director of Quality Management to analyze and evaluate the risk, propose actions to mitigate or monitor ongoing risk, and oversee the implementation of approved actions. ,

The Chief Human Resources Officer is responsible for obtaining completed and signed Annual Conflict of Interest forms and providing them to the COO.

The Director of Standards, Regulations and Policies is responsible for identifying interested parties with respect to ISO accreditation services and engaging these parties in discussions regarding potential risks and their elimination or mitigation.

The Director of Quality Management is responsible for organizing and reporting the results of an annual review to identify, analyze, evaluate, treat, monitor and document the risks to impartiality.

All employees who conduct ISO accreditation activities are responsible for reading, understanding, and adhering to COLA's policy concerning impartiality, and for immediately reporting any potential or actual action that might be perceived as creating a risk to impartiality, or any other violation of this policy.

Contracted experts providing services to COLA in support of industry-specific education or training are responsible for reading, understanding and adhering to COLA's ISO Impartiality Policy. These individuals are required to report any potential or actual action that might be perceived as creating a risk to impartiality, or any other violation of this policy.

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TERMS & DEFINITIONS:

Impartiality	The presence of objectivity and the prevention of any type or form of discrimination that could occur in accreditation activities and decisions. Risks are eliminated or mitigated so as not to adversely influence accreditation activities.
Interested Parties	Various groups that are affected by a laboratory's operation, including patients, clinicians or providers, laboratory personnel, vendors, accreditation bodies, regulators or governmental oversight

Supporting Materials:

Conflict of Interest forms
Risk Register
COLA Quality Manual
Management Review Process

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