Risks to Impartiality:
One of the Most Commonly Missed Accreditation Requirements!

By Dr. George Anastasopoulos

PJLA, Technical & Intl. Business Development Manager

About PJLA

Perry Johnson Laboratory Accreditation, Inc. (PJLA)

Established in 1999 by Mr. Perry L. Johnson

Headquartered in Troy, Michigan.

More than 2300 accreditations globally in 32 countries.



Perry L. Johnson

Perry Johnson Laboratory Accreditation NP, Inc. (PJLANP)
Michigan nonprofit organization established in 2016.

Member and signatory of APAC, ILAC MRAs

PJLA's Global Network



PJLA Accreditation Programs

ISO/IEC 17025

Testing/Calibration Labs

- FCC OET Equipment Authorization
- FDA ASCA
- ENERGY STAR
- Cannabis Testing
- Hemp Testing
- Horseracing Laboratories Program
- CPSC
- AS6171A Testing
- Food, Feeds, and Pharmaceutical: *AOAC, AAFCO, LAAF*
- Environmental Testing: *TNI-NEFAP, DoD ELAP, DOECAP-AP, EPA NLLAP*
  TNI-EL: *MNELAP, CA ELAP, LELAP*

ISO/IEC 17020 – Inspection Bodies

ISO/IEC 17065 – Product Certification Bodies

ISO/IEC 17043 – Proficiency Testing Providers

ISO 17034 – Reference Material Producers

ISO 15189 – Medical Laboratories

ISO/IEC 17024 – Personnel Certification Bodies

ASTM E2659– Training Providers

PJLA

APAC
ASIA PACIFIC ACCREDITATION COOPERATION

ilac-MRA

Today’s objectives

- Locate the core impartiality requirements in ISO/IEC 17000 series.
- Distinguish a policy or declaration from an effective impartiality-risk process.
- Recognize practical threats arising from activities, relationships, personnel and financial pressures.
- Evaluate significance and select proportionate controls.
- Build evidence that can withstand an accreditation assessment.

01
Standards requirements

02
What is an impartiality risk?

03
Where threats come from

04
How to assess and control

05
Examples & case studies

06
Assessment evidence

What do we mean by impartiality?

"Presence of objectivity."

ISO/IEC 17021-1:2015, ISO/IEC 17011:2017

It means that conflicts of interest must be absent or resolved so they do not negatively affect the body's activities. In practical terms, assessments and decisions must remain free from bias, conflicts of interest and inappropriate influence.

"Objectivity concerning the certification body's activities, certification process and outcome"

ISO/IEC 17024:2026

OBJECTIVITY

Decisions and technical judgments are made on evidence and applicable requirements - not on pressure, preference, relationships or personal interest.

PERCEPTION MATTERS

A threat can exist even when no improper decision has occurred. Credibility depends on both actual objectivity and reasonable confidence in objectivity.

Question to ask: Could this circumstance influence, or reasonably appear to influence, the outcome?

Laboratory activities must be impartial and safeguarded by structure and management.

Management is committed to impartiality; commercial, financial or other pressures cannot compromise it.

Risks must be identified on an ongoing basis from activities, relationships and personnel relationships.

When a risk is identified, the laboratory must demonstrate how it eliminates or minimizes that risk.

Clause 4.1 Impartiality requirements

Inspection activities must be undertaken impartially.

The inspection body is responsible for impartiality and must monitor activities and relationships, including personnel relationships, to identify threats on an ongoing basis.

Identified threats must be eliminated or minimized, and the body must demonstrate how.

Top management commitment, structure and impartial conduct of personnel are explicit requirements.

Clause 4.1 Impartiality requirements

The certification body must document how impartiality is managed, maintain top-management commitment, act fairly, and prevent commercial or financial pressure from compromising objectivity.

It must continuously monitor activities and relationships - including personnel and related bodies - and address actual or perceived threats.

Potential conflicts must be identified, analyzed, monitored, documented and controlled.

Clause 4.3 Impartiality requirements

Product/process/service certification activities must be impartial.

The certification body is responsible for impartiality and cannot allow commercial, financial or other pressures to compromise it.

Risks arising from activities, relationships and personnel relationships must be identified on an ongoing basis.

Identified risks must be eliminated or minimized and the controls demonstrated.

Clause 4.2 Impartiality requirements

ISO/IEC 17021:2015

- Management system certification activities must be impartial, with top management commitment.
- The certification body is responsible for impartiality and must prevent commercial, financial or other pressures from compromising it.
- Conflict-of-interest risks must be identified, analyzed, evaluated, treated, monitored and documented on an ongoing basis.
- Threats must be eliminated or minimized, with controls demonstrated and residual risks documented and reviewed by top management.
- Certification must not proceed where a relationship creates an unacceptable threat.
- Appropriate interested parties must be consulted, with no single interest predominating.

Clause 4.2 & 5.2 Impartiality requirements

The common thread across the standards

Standard	Core expectation	Ongoing?	Control evidence?
17025:2017	Identify risks to impartiality	Yes	Eliminate/minimize
17020:2026	Monitor threats from activities & relationships	Yes	Demonstrate controls
17024:2026	Monitor threats + analyze/document conflicts	Yes	Eliminate/minimize/manage
17065:2012	Identify risks from activities & relationships	Yes	Demonstrate controls
17021:2015	Identify risks to impartiality	Yes	Eliminate/minimize

The requirement is a PROCESS - not merely a statement of intent

A risk is not the same as a compromised result

- Identifying a relationship does not automatically mean impartiality is compromised.
- The CAB must determine whether the circumstance creates a meaningful threat.
- If it does, the CAB must eliminate or minimize the effect and retain evidence that the control works.



Risks do not automatically mean Crisis

Where can impartiality threats come from?

Activities

Consultancy, design, training, evaluation, research collaboration

Relationships

Ownership, governance, shared management/resources, contracts, branding

Personnel

Prior employment, family ties, financial interests, outside work

Commercial

Customer concentration, sales targets, retention pressure

Financial

Bonuses, commissions, funding, investments, debt or dependency

Other pressures

Regulatory, political, schedule, production or internal management pressure

Prognosis is crucial

The three-question test

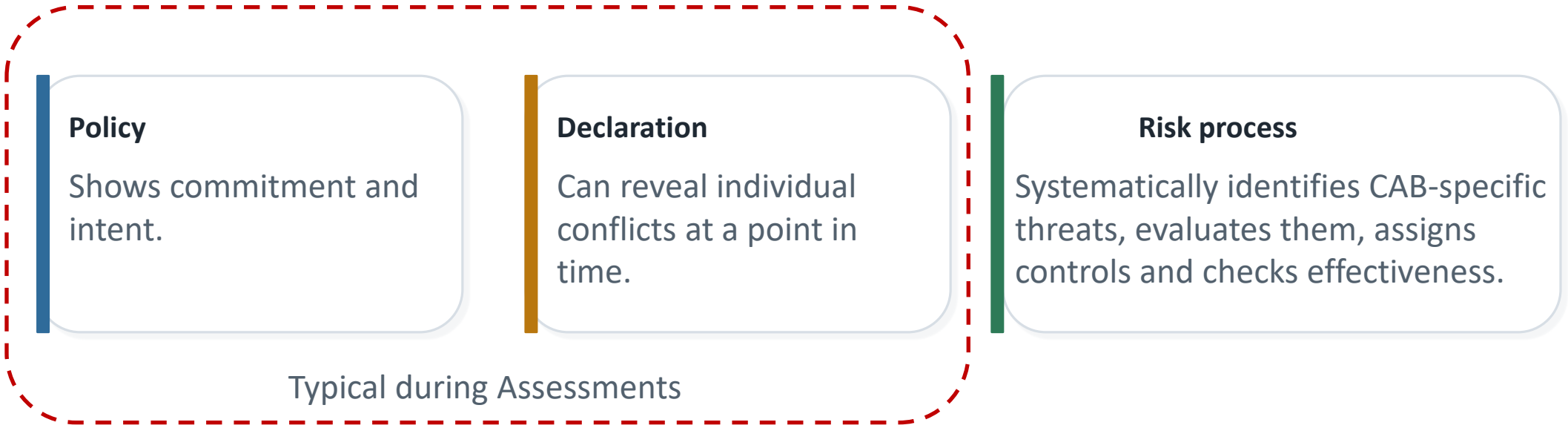
1 What could threaten our objectivity?

2 How significant is that risk?

3 What are we doing about it?

If the CAB cannot answer all three with evidence, the impartiality process is probably incomplete

Why a policy and signed declaration are not enough



Accreditation evidence must connect the actual threat → evaluation → control → follow-up

A practical impartiality-risk process

1	**Identify**	Activities, relationships, personnel, finances
2	**Describe**	What could influence or appear to influence judgment?
3	**Evaluate**	Likelihood / significance / potential impact
4	**Control**	Eliminate, separate, reassign, review, restrict
5	**Record**	Owner, action, evidence, residual risk
6	**Monitor**	Changes, new clients, new personnel, effectiveness

Keep it simple, but make it systematic

What should an impartiality-risk register contain?

Field	Example
Risk / threat	40% of annual revenue from one customer
Source	Commercial / Financial relationship
Potential effect	Pressure to avoid unfavorable results
Significance	High - based on dependency and decision influence
Control	Independent technical review; escalation; no sales role in technical decisions
Owner	Laboratory Manager
Evidence	Review records, org chart, meeting minutes
Residual risk / status	Acceptable; reviewed quarterly

Keep it simple, but make it systematic

Case 1 – Commercial pressure

Risk: A laboratory receives 40% of its annual revenue from one customer

THREAT

Personnel may feel pressure when results are unfavorable to the customer - even without an explicit instruction.

KEY FACTORS - QUESTIONS

- Who can influence technical decisions?
- Is revenue concentration tracked?
- Has pressure occurred?
- Who reviews disputed results?

POSSIBLE CONTROLS

Separate sales from technical decisions; independent review; escalation route; management monitoring; diversify dependency over time.

The risk is the dependency - not the mere existence of a major customer

Case 2 – Prior relationships

Risk: An inspector is assigned to a company where they previously worked or consulted

THREAT

familiarity, loyalty, confidential knowledge, or perceived lack of independence.

KEY FACTORS - QUESTIONS

- How recent was the relationship?
- What exact role did the inspector hold?
- What is being inspected, and could prior work be evaluated?

POSSIBLE CONTROLS

Disclosure, reassignment, defined cooling-off period, independent review, restricted scope.

A generic annual declaration may not catch a conflict created by today's assignment

Case 3 - Related organizations

Risk: Certification body and consultancy share ownership, management, marketing or resources

LOOK BEYOND THE ORG CHART

Common ownership is only one indicator. Consider common directors, staff, contracts, branding, websites, sales channels, offices and financial arrangements.

CONTROL THE INFLUENCE PATH

Separate responsibilities, prohibit referrals/claims that create advantage, protect decisions, restrict access to files, independent oversight and documented monitoring.

Check the standard for specific conflict cases (i.e., 17024 for training/certification vs 17021 for consulting/certification)

Case 4 - Personal relationships

Risk: A technical evaluator is assigned to an organization employing a close relative or business associate

- Threat may be actual or perceived.
- The evaluator should disclose the relationship before accepting the assignment.
- The CAB should define when reassignment is mandatory and when additional review is sufficient.
- Evidence should show the decision made and why the selected control was appropriate.

“I can still be objective” is not, by itself, a risk control

Case 5 - Performance incentives

Risk: Bonuses linked to customer retention, certificates issued, tests performed or favorable outcomes

WHY IT MATTERS

Compensation design can unintentionally reward speed, volume, retention or positive outcomes over technical judgment.

BETTER DESIGN

Use incentives that do not depend on conformity outcomes; separate commercial metrics from technical authority; review compensation arrangements as part of impartiality monitoring.

ISO/IEC 17020:2026 explicitly addresses remuneration that could influence inspection results

Case 6 - Research funding and other financial relationships

Risk: A laboratory collaborates with a major client on a research project far larger than the testing contract

THREAT

May come from the broader financial relationship, not from the testing fee itself.

KEY FACTORS - QUESTIONS

Ask whether unfavorable test/calibration results could jeopardize research funding, future collaboration, intellectual property or management relationships.

POSSIBLE CONTROLS

Separate project and laboratory decision authority, independent review, disclosure, contractual safeguards, alternate personnel.

Reminder: Standards don't explicitly require a documented risk assessment

What an assessor may look for

Risk register

CAB-specific threats; not a generic template

Org / ownership records

Related entities, reporting lines, shared resources

Personnel records

Declarations, outside activities, assignment checks

Contracts / incentives

Sales commissions, bonuses, funding, referral arrangements

Assignment records

Reassignments, recusals, independent reviews

Management review

Discussion about risks to impartiality, Trends, changes, unresolved or new threats

Internal audit

Whether controls are implemented and effective

Corrective action

Response when a threat was missed or a control failed

Evidence that the process is alive, specific and effective

Common nonconformity patterns

- Only a generic statement: “We are committed to impartiality.”
- Only annual declarations - no review of CAB activities or organizational relationships.
- Risk register exists, but threats are generic and unrelated to actual operations.
- Controls are listed but there is no evidence they were implemented or effective.
- No ongoing update after new clients, staff, ownership, incentives, services or partnerships.
- Commercial or financial relationships are excluded from the analysis.

“Ongoing” means keeping risk analysis current through regular reviews and reassessment whenever circumstances change, not completing it once or waiting for the next annual review while new risks go unaddressed

A quick self-assessment checklist

- Have we identified threats from our actual activities and services?
- Have we reviewed ownership, governance, related bodies, contracts and shared resources?
- Do personnel conflicts get checked at assignment - not just annually?
- Have we considered customer concentration, funding, commissions and incentives?
- Do we evaluate significance and residual risk?
- Are controls specific, assigned, implemented and evidenced?
- Do we revisit risks when circumstances change?
- Can we demonstrate effectiveness during an accreditation assessment?

Impartiality is demonstrated by understanding where threats can arise - and showing that they are effectively controlled

- Questions
- Discussion

ganast@pjlabs.com

PJLA

pjlabs.com