Risk Management for Conformity Assessment Bodies

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 2100 accreditations 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 Laboratories
Calibration Laboratories

ISO 15189
Medical Laboratories

PJLA, up to 2025, has accredited **2024** Laboratories to ISO/IEC 17025, out of which **1308** have been Testing Laboratories.

ISO/IEC 17020 – Inspection Bodies

ISO/IEC 17065 – Product Certification Bodies

ISO/IEC 17043 – Proficiency Testing Providers

ISO 17034 – Reference Material Producers

ISO/IEC 17024 – Personnel Certification

ASTM E2659 – Training Providers & Curriculum Development for Certificate Programs

PJLA Industry Specific Accreditation Programs

- Federal Communications Commission (FCC) and the Office of Engineering and Technology (OET) Equipment Authorization for type approval of Radio Frequency devices
- AS6171A - Suspect/Counterfeit, Electrical, Electronic, and Electromechanical Parts Testing.
- US Environmental Protection Agency (EPA) for the ENERGY STAR Testing Laboratory Accreditation Program.
- Consumer Product Safety Commission (CPSC) Requirements as outlined in the CPSC 16 C.F.R.
- The National Environmental Field Activities Program (NEFAP) TNI - General Requirements for Field Sampling and Measurement Organizations (FSMOs).
- The Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP)
- DOECAP-AP, The Department of Energy Consolidated Audit Program – Accreditation Program (DOECAP-AP)

PJLA Industry Specific Accreditation Programs

- The EPA National Lead Laboratory Accreditation Program (NLLAP), testing of lead in paint chips, dust, or soil.
- FDA ASCA (The Accreditation Scheme for Conformity Assessment)
- The NELAC Institute Environmental Laboratory (TNI-EL) Accreditation:
  - California Environmental Laboratory Accreditation Program (CA ELAP),
  - Louisiana Environmental Laboratory Accreditation Program (LELAP) and
  - Minnesota Department of Health Environmental Laboratory Accreditation Program (MNELAP).
- AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements, and Pharmaceuticals.
- Association of American Feed Control Officials (AAFCO) for Feed Laboratories.
- FDA Laboratory Accreditation for Analyses of Food (LAAF) program
- Horseracing Laboratories Program (ILAC G7:02/2016)
- IPC – International Personnel Certification Association MS Auditor Specification

PJLA International Memberships – MLAs/MRAs

ilac

APAC
ASIA PACIFIC
ACCREDITATION COOPERATION

ilac-MRA

PJLA
Testing
Accreditation No. 59423

NAAF
North American Accreditation Forum

Introduction

- **Risk assessment** and **risk-based thinking** are both key aspects in Conformity Assessment.
- **Accreditation Bodies**, and accredited **CABs (Conformity Assessment Bodies)**, must consider the **impact of risk** on all activities on **an ongoing basis**.
- Risk assessment is used to ensure a **consistent**, **data-based** approach for Conformity Assessment Bodies.

ISO/IEC 17011:2017 on Risk Evaluation

- *"… shall have a process to **identify, analyze, evaluate, treat, monitor and document** on an ongoing basis the risks to impartiality arising from its activities".*

- **Risk-based thinking** is not limited to impartiality considerations.

- **"risk"** is mentioned:
  in **ISO/IEC 17011** a total of **21 times!**
  in **ISO/IEC 17021** a total of **26 times!**
  in **ISO/IEC 17025** a total of **31 times!**

Scope

Implement a risk analysis to identify risks related to CAB activities

- Address applicable MS requirements
- Detect areas of risk
- Perform risk analysis
- Develop contingency plans
- Develop mitigation plans

Risk Evaluation Metrics

- Number of total staff (full-time/contractors) involved
- Rounds of staff involvement
- Number of total risks identified
- Groups to categorize risks
- Number of actions to be considered for contingency plan
- Number of actions to be considered mitigation plan
- Time period – **6** months
    - Analysis - Methodology: **1** month
    - Execution: **3** months
    - Data processing - Reporting: **2** months

Grouping of Risks

Consider **specific risks** grouped in broad **categories** related to the overall organization:

1. General, Financial and Administrative
2. Business, Markets, Context
3. IT Systems
4. CAB Main Process (i.e., Testing, Inspection, Certification)
5. MS Policies, Procedures and Processes
6. Conflicts of Interest/Impartiality
7. Miscellaneous

Methodology

Risk Analysis Model: Modified **Fink approach – 10 step method**

Steps:

1. Seek input from personnel to ascertain the top risks as perceived by the various staff members.

2. Risks are divided into broad categories referenced above.

3. Risks are combined to bring the overall list to a more manageable level.

Methodology

4. Staff and all individuals are asked to estimate:

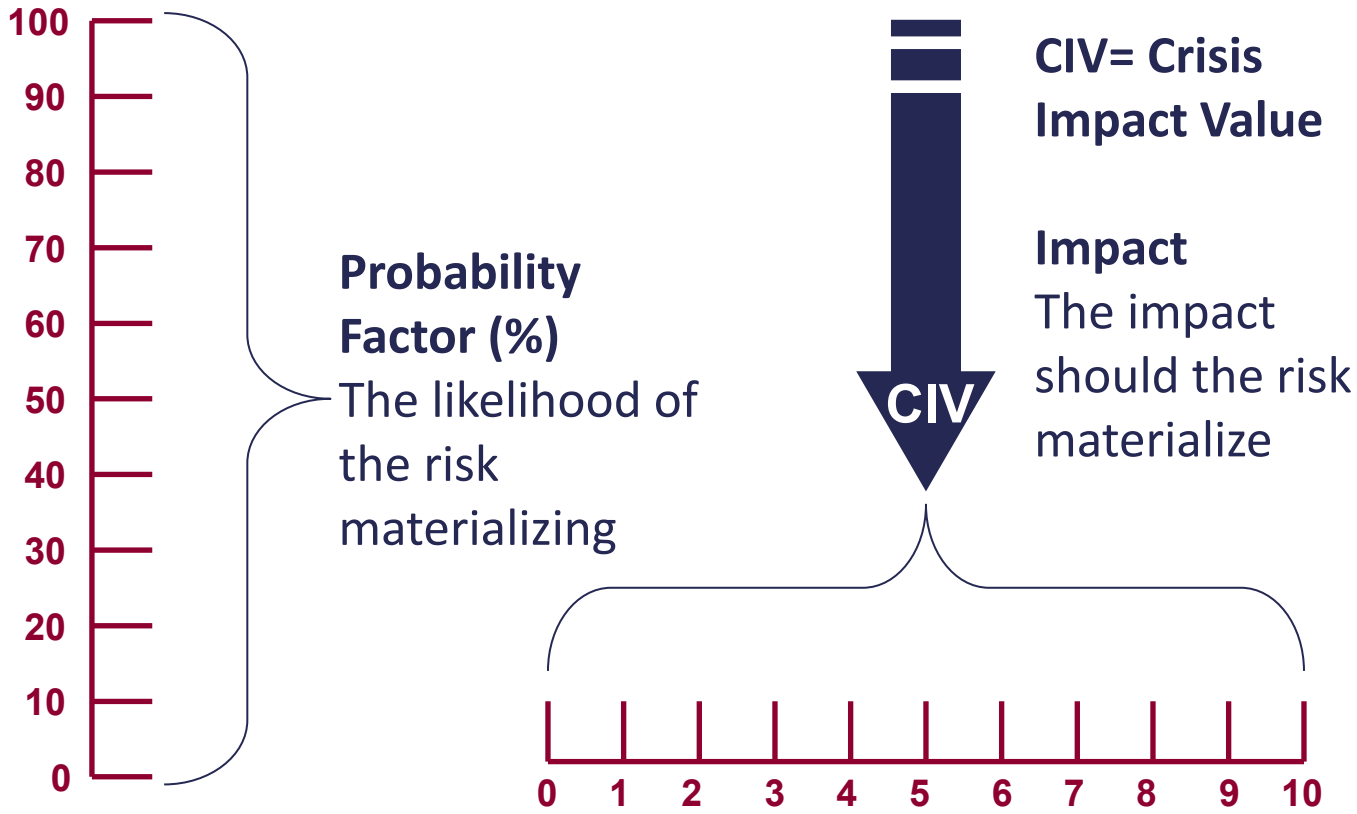
   The **likelihood** of the risk materializing
   (0 [Not Likely] – 100% [Extremely Likely])

   The **impact** should the risk materialize
   (0 [No Impact] – 10 [Significant Impact])

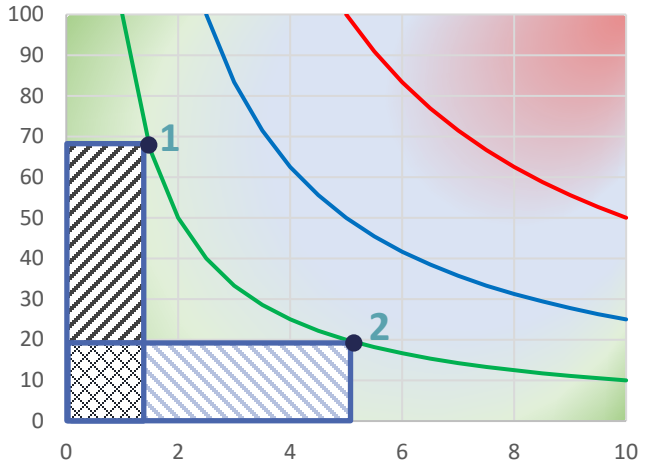
5. CIVs are calculated for each risk presented.

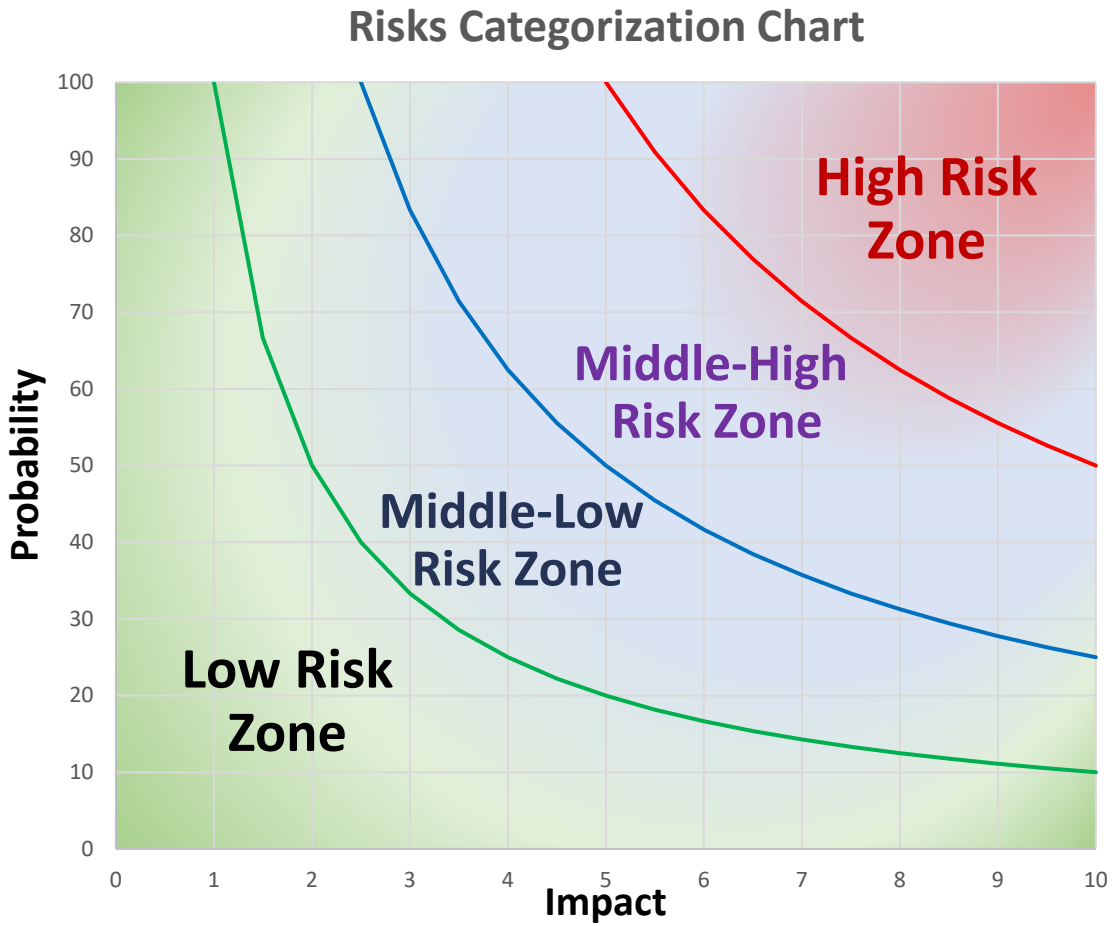
6. Risks are ordered according to CIV (largest to smallest)

Methodology – Step 4



Methodology – Steps 5-6





Methodology

7. Risks falling within the Medium to High risk levels (CIV>250) can be isolated.

8. Each risk value is plotted on a risk matrix to provide visual representation of where each risk falls on the graph, per category.

9. A Mitigation Plan is enacted to reduce the likelihood and/or impact of a specific risk; it is synonymous with a preventive action.

10. A Contingency Plan is enacted to respond to a crisis arising due to a specific risk; it is synonymous with a corrective action.

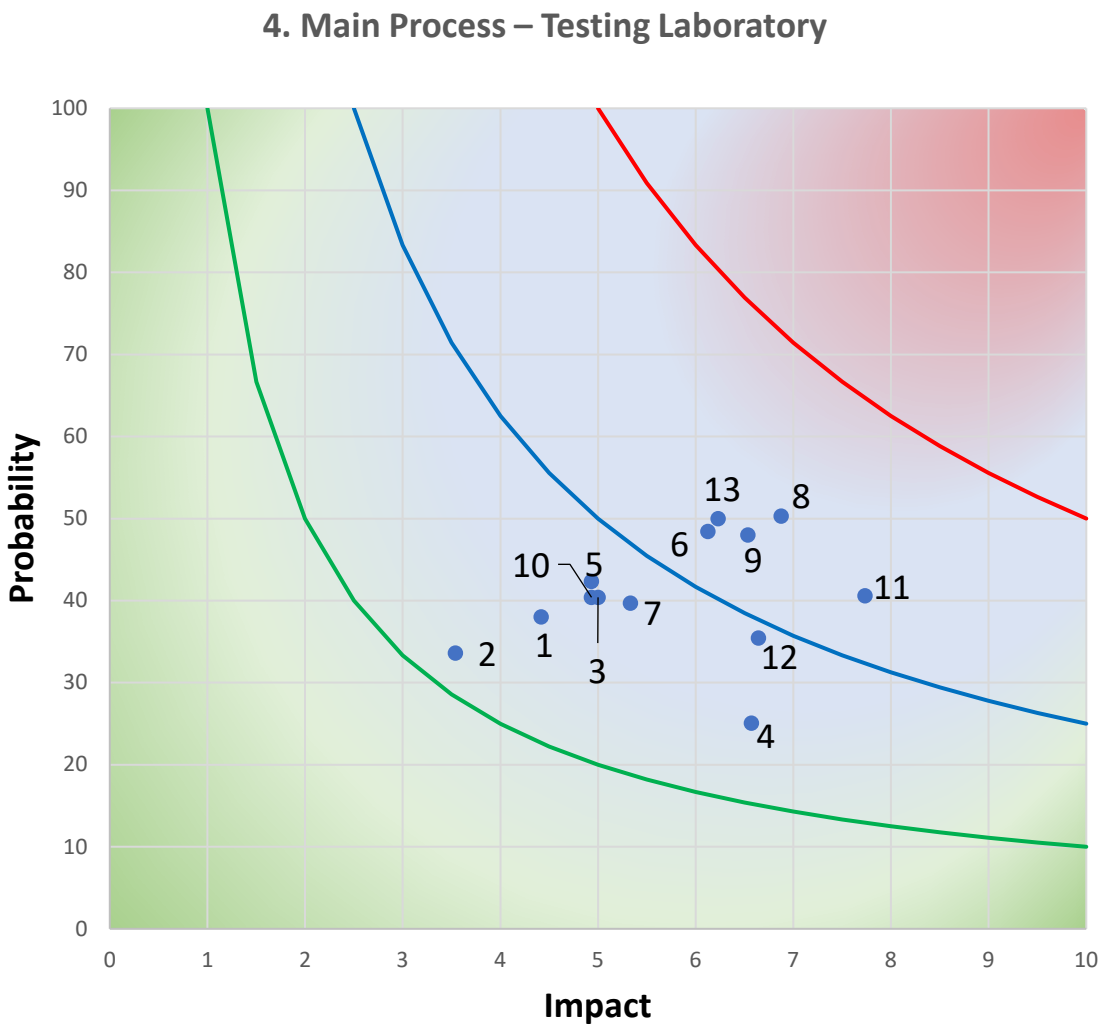
Results

Risks categorized per calculated **CIV** for all broad **groups** related to CABs organizational structure:

1. General, Financial and Administrative
2. Business, Markets, Context
3. IT Systems
4. Main Process (i.e., Testing, Inspection, Certification)
5. MS Policies, Procedures and Processes
6. Conflicts of Interest/Impartiality
7. Miscellaneous

Presenting Results

Risk	Risk Description	CIV
8	Limited personnel during peak season	346
9	Technicians not trained for “rare” tests	330
11	Non calibrated instrumentation	315
13	Limited availability of proficiency/interlaboratory test	314
6	Lack of consumables	312
12	Inconsistent results due to signal Interference	296
7	Misaligned testing machines	235
5	Discounted prices effecting perceived value of testing	212
3	Inconsistent billing process	208
10	Misplaced Specimens	202
1	Specimen not provided in time by customer	199
2	Errors in sampling	168



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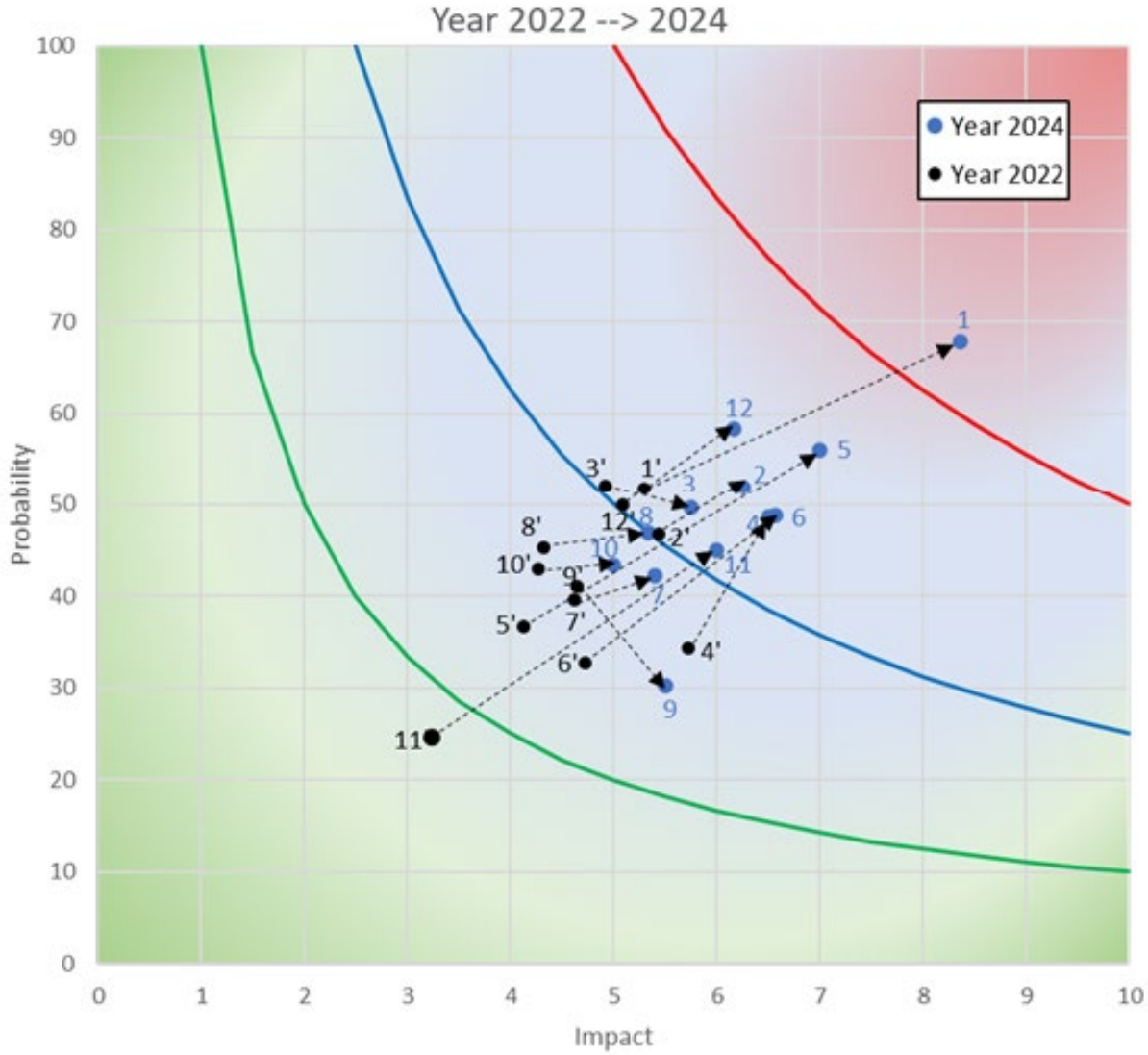

Examples of Mitigation & Contingency Plans

Risk Group with Risk	Mitigation Plan	Contingency Plan
Main Process – Testing Laboratory Limited personnel during peak season	Cross-training of staff	Subcontract tests
Main Process – Testing Laboratory Non calibrated instrumentation	Update and check regularly calibration schedule	Utilize back-up instruments
Main Process – Testing Laboratory Limited availability of proficiency/interlaboratory test	Prepare annual schedule by the end of each year.	Coordinate with subcontractors
Main Process – Testing Laboratory Lack of consumables	Introduce minimum quantities in warehouse list and check/update in a monthly base	Urgent supplies from approved suppliers list
Main Process – Testing Laboratory Misaligned testing machines	Update preventive maintenance program, perform internal control before each test	Utilize alternate testing machine

Thank You!

- Questions
- Discussion

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