



## **Guidelines for Risk based assessment**

### **PB17G**

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# **Egyptian Accreditation Council EGAC**

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## **Egyptian Accreditation Council EGAC**

### **1. PURPOSE**

The purpose of this guideline is to demonstrate knowledge of risk based assessment principles for EGAC assessment team and persons who dealt with assessment or accreditation process and document on the risks that may arising during implementation of CAB assessment activities.

#### **Note:**

EGAC evaluates its assessor by a monitoring may be conducted during their assessment by EGAC to verify their implementation for risk-based thinking assessment during their CAB assessments.

### **2. REFERENCES**

- ISO 17011:2017
- ISO 31000:2018

### **3. DEFINITION S**

#### **3.1 Risk**

A risk is an uncertain internally or externally event or factors that, if it occurs, it may have one or more impacts .that creates the possibility of negative or positive outcomes on one or more objectives of the accreditation Process such as impartiality, Personnel, assessment.....

#### **3.2 Identify risks**

This process identifies and documents risks that might occur for a given process.

#### **3.3 Control risks**

The steps track identified risks, identify new risks, executes risk response plans, and evaluates the effectiveness of executing responses throughout the lifecycle of the accreditation Process.

#### **3.4 likelihood**

The Probability (chance) that the risk (threat or opportunity) will occur.

#### **3.5 Impact (Consequences)**

The effect on the process if the risk (threat or opportunity) occurs.

### **3.6 Risk management framework**

A set of components that provide the foundations and organizational arrangements for designing, implementing, monitoring, reviewing and continually improving risk management throughout the organization.

### **3.7 Risk attitude**

Organization's approach to assess and eventually pursue, retain, take or turn away from risk.

### **3.8 Establishing the context**

Defining the external and internal parameters to be taken into account when managing risk, and setting the scope and risk criteria for the risk management policy.

### **3.9 Risk assessment**

Overall process of risk identification, risk analysis and risk evaluation.

### **3.10 Risk management policy**

It is the overall intentions and direction of an organization related to risk management.

### **3.11 Risk analysis**

A process to comprehend the nature of risk, and to determine the level of risk.

### **3.12 Risk monitoring**

Continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected.

### **3.13 Level of risk**

Magnitude of a risk or combination of risks, expressed in terms of the combination of consequences and their likelihood.

### **3.14 Risk treatment**

Process to modify / reduce risk.

### **3.15 residual risk**

Risk remaining after risk treatment.

### **3.16 consequence**

outcome of an event affecting objectives

### 3.17 Risk Management.

is a systematic approach to reducing the harm due to risks, making a process less vulnerable to challenge or failure (e.g., time overruns, scope decrease, quality reduction) and its resulting product/service more robust

## 4. Risk assessment Process

The Risk assessment implementation process involves the systematic application for the assessed CAB policies, procedures and practices to its accredited scope activities by communicating , determine , assessing, reviewing, recording and reporting risk during this CAB assessments.

### **Assessment team have to do a :**

#### **4.1.1 Risk assessment including review for :**

- risk identification to find, recognize and describe risks that affect objectives and have consequences;
- risk analysis of risk, including the level, sources, consequences, likelihood, controls, effectiveness;
- risk evaluation to support decisions by comparing the results with criteria to determine the significance.

#### **4.1.2. Communication and consultation including:**

- bringing different areas of expertise together for each step of the assessment process;
- ensuring different views are considered when defining risk criteria and evaluating risks;
- providing sufficient information to facilitate risk oversight for decision-making; and
- building a sense of inclusiveness and ownership among those affected by risk.

#### **4.1.3. Recording and reporting including:**

- communicating Risk assessment activities and outcomes across the organization;
- providing information for decision-making;
- improving Risk assessment for CAB activities; and
- providing risk information and interacting with CAB organization.

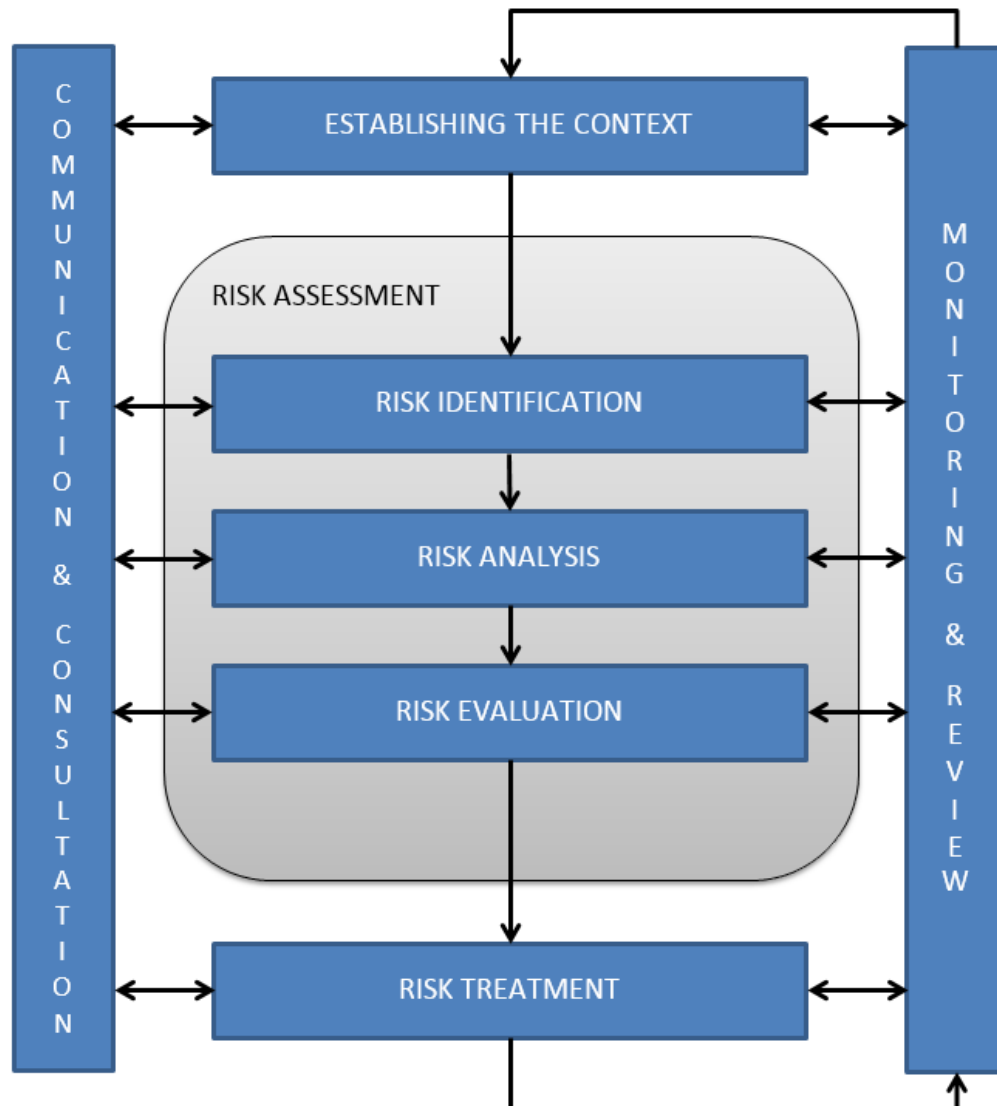
## 4.2 Risk assessment Principles

- It improves performance, encourages innovation and supports the achievement of objectives for the assessed CAB.
- Assessors have to get the principles of CAB risk that include the requirement for the risk management initiative to be:
  - (1) **customized;**
  - (2) **inclusive;**
  - (3) **structured and comprehensive;**
  - (4) **integrated; and**
  - (5) **dynamic.**

## 5. Steps of the Risk assessment Process

EGAC assessors have to ensure that the assessed CAB achieve the following steps for its risk

- **Step 1. Communicate and consult.**
- **Step 2. Establish the context.**
- **Step 3. Identify the risks.**
- **Step 4. Analyze the risks.**
- **Step 5. Evaluate (Leveling) the risks.**
- **Step 6. Treat the risks.**



## 6. Risk Leveling

### 6.1 A guide for Leveling of risk consequence (Severity)

Rating Level	Meaning
1	Very minor
2	Minor part effected
3	Moderate effect
4	High (loss or dissatisfaction )
5	Very high (Hazard)

### 6.2A guide for Leveling of risk likelihood (probability)

Rating Level	Meaning
1	Very minor to be happen (seldom)
2	Minor to be happen (rarely)
3	Moderate to be happen
4	High to be happen (for new action, application or change)
5	Very high to be happen, almost certain (for new action, application or change)

### 6.3A guide for Leveling of risk detection

Rating Level	Meaning
1	Strongly detected or highly correlated (fault will not pass)
2	Can be detected at source
3	Problem detecting post processing
4	Not easily detected
5	Can't be detected or analyzed (fault will pass )

### Risk Index values "criticality" = consequence x Probability

Note : If Risk Index values "criticality" is < 10 then risk doesn't to be treated.

If Risk Index values "criticality" is from 10 to 20 then risk has to be treated.

If Risk Index values "criticality" is > 20 then Process should be stopped.

Note :

### Risk Priority Number (RPN):

These numbers provide guidance for ranking potential failures in the order they should be addressed.

### Risk Priority Number (RPN) = consequence x Probability risk detection



## 6 . Risk-based assessment

ISO/IEC 17011 in its latest revision has introduced the concept of risk-based assessment. The standard requires risks to be considered by accreditation body in different stages of accreditation process. The risk-based assessment requires to focus more on the accreditation activities and CAB activities which have high risk compared to others with lower risk level. Risk-based assessment is inherited to a great extent in ISO/IEC 17011 standard as well in other accreditation standards, e.g. ISO/IEC 17020, ISO/IEC 17024, ISO/IEC 17025, ISO/IEC 17043, ISO 15189.

On practical sense, EGAC is considering the principles and concepts of risk-based assessment during structuring its rules and regulations. For example, EGAC requirements for labs implementing PT requires more frequent participations for high-risk labs, e.g. environmental, food.

In addition, EGAC considers risk-based assessment as part of its overall risk assessment and in different stages of accreditation process, i.e. planning, on-site assessment, and decision making.

The following table includes some of situation that s related to risk-based assessment and the actions to be initiated for each. It is known to the EGAC staff and assessment teams that this list is not comprehensive and there may be situations out of the list. In such case, EGAC staff and assessment team should take necessary measures to avoid negative impact on accreditation process.

No.	Situation	Counter action	Responsibility
1	Findings of assessment cast doubt in CAB capacity <ul style="list-style-type: none"> <li>• Number of nonconformity is relatively large</li> <li>• Some of the detected nonconformities are critical ones</li> </ul>	Recommendation for re-assessment	Assessment team
		Performance of next assessment earlier than regular scheduling	Accreditation Committee
2	CAB failure to address critical nonconformities in due time	Implementation of Rules and regulations of EGAC	EGAC accreditation manager & Accreditation committee
3	CAB activities are related to human health and safety	Longer on-site assessment duration	EGAC Accreditation manager
		Choice of experienced assessors / experts	EGAC accreditation manager
		Assignment of technical committee of experienced assessors / experts	EGAC accreditation managers

4	CAB has insufficient resources to manage its activities	Issuance of nonconformity or remark depending of level of shortage (assessment team should be careful in reaching to such conclusion – it has to consider the amount of work required)	Assessment team
5	CAB has a high turnover in staff	Increase witnessing activities in surveillance assessments	EGAC accreditation manager
6	Situation in lab comprise risk on safety and health of assessment team	Assessment should be stopped	Team leader

### 7. Options for risk treatment:

Assessed CAB has to identify the following options that may assist in the minimization of negative risk or an increase in the impact of positive risk.

- 1- Avoid the risk
- 2- Change the likelihood of the occurrence
- 3- Change the consequences
- 4- Share the risk
- 5- Retain the risk

### 8 . RELATED FORMS

Forms to be used in the implementation of procedure are:

- |     |   |             |
|-----|---|-------------|
| 8.1 | Risk Identification and Assigned treatment Personnel. | Form F1P17G |
| 8.2 | Risk treatment plan and decision.                     | Form F2P17G |
| 8.3 | Risk analysis.  | Form F3P17G |