

Analysis report on EGAC's Related Bodies

(Revised on November 2023)

1-GENERAL:

- *EGAC is an entity affiliated with the Ministry of Industry and Trade.*
- *The risk that might arise from the related bodies is analyzed and dealt with to guarantee impartiality, confidentiality, and improve performance of EGAC.*
- *The related bodies to EGAC are classified into 3 categories according to the following table:*

1 - CABs related to organization and affiliated to ministry of Trade and Industry. (For example, but not limited to)	2- CABs governmental and not affiliated to Ministry of Trade and Industry. (For example, but not limited to)	3- government organization others. (For example, but not limited to)
1) The Egyptian Organization for Standardization (EOS). 2) General Organization for Export and Import Control (GOEIC) 3) National Quality Institute (NQI)	1) Food Safety Authority. 2) Egyptian Drug Authority 3) Ministry of Health & Population Medical Labs 4) Ministry of Defense & Military Product 5) Administration of assay and weights (AAW) 6) The National Institute for Standards (NIS). 7) The Ministry of electrical and renewable Energy.	1) The National Institute for Standards (NIS). 2) Ministry of Higher Education & Scientific Research

2- RELATED BODIES RISK & RISK Control:

SN	Related Body	Risk	Actions for Risk control
1	1 - CABs related to organization and affiliated to ministry of Trade and Industry	<p><u>*Risk to impartiality arise from:-</u> 1-Relation between EGAC and other related governmental organizations as (GOEIC, EOS...) that may affect accreditation decision for their CAB's. 2-MTI Minister as a BOD chair pressure on accreditation process or its decision making. 3-Specific training may affect the impartiality</p>	<ul style="list-style-type: none"> • Accreditation decision is taken by independent accreditation committee. • Board of Directors is not involved in accreditation process including accreditation decision. • Its EGAC policy for each BOD and committee member has to sign a form (F1P10G) Confidentiality and impartiality agreement during each participation. • EGAC does not provide specific training to CABs • All training courses provided to CABs are generic training • Selection of trainers
2	2- CABs governmental and not affiliated to Ministry of Trade and Industry	<p><u>*Risk to impartiality arise from: -</u> 1-Relation between EGAC and other related governmental organizations as (FSA, EDA...) that may affect accreditation decision for their CAB's.</p>	<ul style="list-style-type: none"> • Accreditation decision is taken by independent accreditation committee. • Board of Directors is not involved in accreditation process including accreditation decision.
3	government organization others.	<p><u>*A Risk to impartiality arises from The National Institute for Standards (NIS).</u> 1- This Organization is the organization responsible for the traceability in Egypt. 2-Aaccrediting bodies that have EGAC member relations.AS (Use of assessors belong to EGAC related bodies) 3-It also has a proficiency testing provider unit that accredited by EGAC.</p>	<ul style="list-style-type: none"> • EGAC always revise the situation of NIS Laboratories traceability according to the ILAC procedure ILAC P10-07 and R2G - Policy on metrological traceability- • The presidential decree stated the independency of EGAC at all accreditation decisions So, Accreditation decision is taken by independent accreditation committee. • Board of Directors is not involved

SN	Related Body	Risk	Actions for Risk control
			<p>in accreditation process including accreditation decision.</p> <ul style="list-style-type: none"> • EGAC ensure that there is no conflict of interest between assessors and CABs • EGAC Assessors are not involved in assessment of their own organization • Assessors sign Confidentiality and impartiality agreement before assessment. • CABs accept the assessment team before the assessment visit.

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Nov. 25, 2023

Risk Analysis

Egyptian Accreditation Council
EGAC

Residual Risk values (RIV)

Risk ID, according to ISO/IEC17011:2017	Context	Source	Description of risk	Impact	Risk Owner	Severity	Likelihood	Risk Index values (RIV)	Treatment action	Implementation in management system	Severity	Likelihood	Risk Index values (RIV)	Need for additional action
1	Impartiality	Personnel	Use of assessors predominantly from one organization	Loss of accreditation credibility due to conflict of interest -Accredited CAB's dissatisfaction.	Technical department	3	2	6	1-Criteria for selection of assessment team 2-Impartiality statement signed by assessors in advance 3-Rotation of the assessment teams with the same CAB	1-P7G - Competence and contracting of personnel 2- FIP10G Confidentiality and impartiality agreement. 3-Records of assessment	3	1	3	No additional action is required
2	Impartiality	Related bodies	Relation between EGAC and other related governmental organizations as (GOIEC, EOS,...) that may affect accreditation decision for their CAB's.	Loss of accreditation credibility. -Accredited CAB's dissatisfaction.	Technical departments	4	3	12	Accreditation decision is taken by independent accreditation committee	P10G - Decision making and granting accreditation.	2	2	4	No additional action is required
3	Impartiality	Related bodies (MTI)	MTI Minister as a BOD chair pressure on accreditation process or its decision making.	MTI Minister pressures leading to violation of accreditation requirements & Loss of accreditation credibility	Technical departments & administration department.	3	2	6	Accreditation decision is taken by independent accreditation committee Board of Directors is not involved in accreditation process including accreditation decision	P10G - Decision making and granting accreditation. QM (clause 5.2.3)	2	2	4	No additional action is required
4	Impartiality	Related bodies (Governmental organizations)	Accrediting bodies that have EGAC member relations e.g. EOS,GOIEC, etc.	pressures leading to violation of accreditation requirements & Loss of accreditation credibility.	Technical departments & financial department.	3	3	9	Accreditation decision is taken by independent accreditation committee Assessor do not belong to the related body whose lab being assessed	P10G - Decision making and granting accreditation. P7G - Competence and contracting of personnel	2	2	4	No additional action is required
5	Impartiality	Shared resources	Use of assessors belong to EGAC related bodies	Accredited CAB's dissatisfaction, Loss of accreditation credibility	Technical department	4	3	12	EGAC has a form explain the current job for each assessment team member which explain the organization for each of them and EGAC accreditation director with the related technical manager review each assessment report finding to see any kind of	P7G - Competence and contracting of personnel	3	2	6	No additional action is required

Risk ID, according to ISO/IEC 7011:2 017	Context	Source	Description of risk	Impact	Risk Owner	Severity	Likelihood	Risk Index values (RIV)	Treatment action	Implementation in management system	Severity	Likelihood	Risk Index values (RIV)	Need for additional action
6	Impartiality	Finances	Insufficient resources to carry out accreditation activities	Failure to perform accreditation activities in due-time Loss the credibility for EGAC accreditation	All departments	4	3	12	Budget sources (fees, governmental budget, International Cooperation)	1-P15G - Financial & administrative activities 2- EGAC Budget 3- Presidential Decree 248-2006	2	2	4	No additional action is required
7	Impartiality	Training	Specific training may affect the impartiality	Failure of accreditation credibility	All Departments	4	4	16	EGAC does not provide specific training to CABS All training courses provided to CABS are generic training Selection of trainers	EGAC policy of training in QM clause (6.1.3.3).... PGG - Personnel training	2	2	4	No additional action is required
8	Impartiality	Assessors selection	Relation between assessors and CABS	Failure of accreditation credibility	Technical Departments	4	3	12	EGAC ensure that there is no conflict of interest between assessors and CABS EGAC Assessors are not involved in assessment of their own organization Assessors sign Confidentiality and	P9G - Assessment process for CABS and it's related forms. F1P10G_Confidentiality and impartiality agreement	2	2	4	No additional action is required
9	Liability	Liability	A damage may be happen during the accreditation process or damage happen according to unexpected accidents.	Bad effect on the CABS	Administrative and financial departments	3	4	12	1- EGAC has followed the Egyptian Governmental Insurance laws.	EGAC QM Annex (9)	2	2	4	No additional action is required
10	Accreditation Cycle	Assessment programme	Lake in the implementation of the assessment programme	Delay in the implementation of assesment program	Technical department	3	3	9	Monitoring the assesment programme performance	F7P9G_Assessment programme	2	2	4	No additional action is required
11	Information requirements	Confidentiality	Release of CABS information	Loss of CAB trust in accreditation	All Departments	5	2	10	1-Computers are protected against unintended access 2-All Staff members, assessors and committee members sign confidentiality statement 3-EGAC has information requirements which explain the implementation of	1-P2Q - Document and record control. 2-P14IT - Information confidentiality statement requirements. 3-F1P10G_Confidentiality and	4	1	4	No additional action is required

Risk ID. No.	Context according to ISO/IEC 7011:2 017	Source	Description of risk	Impact	Risk Owner	Severity	Likelihood	Risk Index values (RIV)	Treatment action	Implementation in management system	Severity	Likelihood	Risk Index values (RIV)	Needs additional action
12	Resource requirement	Competence of personnel	lack of competence of assessment team	negative effect on efficiency of assessment implementation and consequently accreditation process	Technical departments	5	2	10	Criteria of assessors selection Monitor of assessors performance	P7G - Competence and contracting of personnel F4P7G_Areas of expertise for TLTE, assessor F1P8G, F2P8G, F3P8G& F4P8G_ Appraisal	3	1	3	No additional action is re
13	Resource requirement	Assessor resources	Lack of information about legal requirements and regulations in the abroad country, when performing assessment outside Egypt.	Negative effect on the accreditation process Loss the credibility for EGAC accreditation	Technical department	4	2	8	Adding Legal Expert to the assessment team to advice on the legal requirements in such countries.	P84G - EGAC policy on cross frontier. W114G - Cross frontier and cooperation process.	3	1	3	No additional action is re
14	Relationship	Personnel (Assessors)	Familiarity of EGAC assessors with CABS	Negative effect on the accreditation process Loss the credibility for EGAC accreditation	Technical department	4	3	12	Rotation of Assessment team after each Accreditation cycle EGAC Assessors sign confidentiality and impartiality agreement	P9G - Assessment process for CABS and it's related forms. F1P10G_Confidentiality and impartiality agreement	2	2	4	No additional action is re
15	process requirements	Remote assessment	Lack in use of ICT tools	Affect on quality and results of assessment process.	Technical departments	5	3	15	Awareness of assessors for the use of ICT tools. Agreement with the CABS for the ICT tools in use. Testing of the use of ICT tools with CABS. before the assessment implementation.	*P820G-Remote Assessment *https://egac.gov.eg/	3	1	3	No additional action is re
16	process requirements	Committee Member	Lack of EGAC Committee Member competence and decision makers	Loss in confidence of accreditation decision	Technical department	4	2	8	Criteria of committee members selection. Qualifications of committee members. Monitor of committee members performance.	*P7G - Competence and contracting of personnel. *P10G - Decision making and granting accreditation. F5P8G & F6P8G Appraisal of Committee members	3	1	3	No additional action is re
17	Epidemics	COVID-19	Difficulties in implementation of accreditation process	Failure to perform accreditation activities in-time	Technical & administrative department	4	4	16	EGAC will use a remote technique using ICT to perform accreditation activities	EGAC issued P820G-Remote Assessment	4	3	12	No additional action is re

Risk ID. No.	Context according to ISO/IEC 17011:2017	Source	Description of risk	Impact	Risk Owner	Severity	Likelihood	Risk Index values (RIV)	Treatment action	Implementation in management system	Severity	Likelihood	Risk Index values (RIV)	Need for additional action
18	Resource requirements	Personnel (Staff)	PTP department has only one staff member	Delay in the implementation of assessment program	Technical department (especially PTP department)	4	2	8	1-Request to appoint new employees from Personnel Affairs 2- delegate other employees from other department	1-P7G - Competence and contracting of personnel 2-F1P10G_Confidentiality and impartiality agreement.				

Acceptance by EGAC Accreditation Director.

Signature

Date 16/11/2023

Approval EGAC Executive Director

Signature

Date

Date 16/11/2023

[Handwritten Signature]
 F2P17G
 1 / Oct 2022
 Nov. 25 2023