



## **TWINNING PROJECT FICHE**

### **Strengthening the Institutional Capacity of the Egyptian Accreditation Council EGAC**

**The Support to the Implementation of the Action Plan and  
the Association Agreement Programme (SAAP IV)**

## **Glossary**

AA	Arab Accreditation
ACAA	Agreement on Conformity Assessment and Acceptance
AFRAC	African Accreditation Cooperation
AWA	Assay & Weights Administration
BSI	British Standards Institute
CAB	Conformity Assessment Bodies
CEN	European Committee for Standardization
CPA	Consumer Protection Agency
EA	European co-operation for Accreditation
EGAC	Egyptian Accreditation Council
GLP	Good Laboratory Practice
GOEIC	General Organization for Export and Import Control
ICA	Industrial Control Authority
PTP	Proficiency Testing Providers
MLAs	Multilateral agreements
NB	Notified Bodies
NIS	National Institute for Standards
NQI	National Quality Institute
TDMEP	Trade and Domestic Market Enhancement Program
SAAP	Support to the Association Agreement Program

## TWINNING PROJECT FICHE

### **1. Basic Information**

1.1 Programme: Support to the Association Agreement Program (SAAP)

1.2 Twinning Number: EG/13/ENP/TR/23

1.3 Title: Strengthening the Institutional Capacity of the Egyptian Accreditation Council (EGAC)

1.4 Sector: Trade and Industry

1.5 Beneficiary country: Egypt

### **2. Objectives**

#### **2.1 Overall Objective(s):**

Supporting the enhancement of the Egyptian Quality infrastructure performance within the context of the national reform priorities in line with the EU and international best practices, as well as accelerate the adoption and proper enforcement of a conformity assessment system primarily in the priority sectors identified, pushing the negotiations to sign the Agreement on Conformity Assessment and Acceptance (ACAA).

#### **2.2 Project purpose:**

Providing further support to enhance the technical and institutional capacities of the Egyptian Accreditation Council in its endeavor to extend providing accreditation to different types of Conformity Assessment Bodies and Notified Bodies nationally, regionally, and internationally.

#### **2.3 Contribution to National Quality Plan/Association Agreement/Action Plan**

Egypt is taking serious steps toward strengthening and upgrading the national quality infrastructure to reach international recognition and to sustain the operation of conformity assessment bodies; through restructuring the Egyptian conformity assessment as a decentralised system aligning with global norms and international agreements. Development is carried out for both public and private sector organizations, concerning the activities of quality and conformity assessment systems to increase and raise the competitiveness of Egyptian products to comply with the EU and international requirements.

During the first half of 2012, a Strategic Framework for Economic and Social Development plan until year 2022 was published; this strategic plan requires focusing on developing human resources, the need for an organizational and institutional frame that is encouraging business and trade sectors and the need to review current legislations and regulations.

The Association Agreement (AA) between the European Commission and Egypt entered into force in June 2004 reflecting the approach of the Barcelona Process, as it contains provisions with respect to the three pillars of the Euro-Mediterranean partnership (political, economic and socio-cultural). Its overall objective is to establish the appropriate framework for co-operation and partnership, which will contribute to the economic and social development of Egypt in the context of an endeavor of regional economic integration aiming to create an area of shared economic prosperity.

The twinning project will support the implementation of Article 47 of the Association Agreement which stipulates that both parties shall aim to trim down any major differences in standardization and conformity assessment practice. In this context, the project aims at improving EGAC's role in the area of accreditation of the conformity assessment bodies; in contributing to the reform of the regulatory and institutional framework as well as raising the capacity and awareness of key players in the area of standardization, conformity assessment and accreditation and maintaining the capacities of EGAC to sign EA MLA

Furthermore, the activities of the twinning project are aligned with the objectives of the European Neighbourhood Policy (ENP) Action Plan jointly adopted by Egypt and the EU since March 2007; which introduces a comprehensive policy framework with specific and detailed mechanisms to support economic, political, and social development as well as to improve Egypt's access to the European Single Market. Specifically, this twinning project responds to two topics of the ENP:

- (1) The identification of suitable areas for gradual regulatory upgrading and approximation with EU technical legislation, standards and conformity assessment procedures and;
- (2) Take the necessary steps, with the support of continuing assistance, to complete and upgrade the quality infrastructure and to forward the negotiations of the Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA).

### **3. Description**

#### **3.1 Background and justification:**

##### **3.1.1 Background**

###### ***EU and Egypt Relations***

The EU is Egypt's main trade partner, represents a sum of 40% of Egypt's total trade with the world. From the entry into force of the EU-Egypt Association Agreement in 2004 until 2011 EU-Egypt bilateral trade more than doubled and reached its highest level ever in 2011 (from €11.5 billion to €23.3 billion). The AA establishes a free-trade area between the two partners with the elimination of tariffs on industrial products and significant concessions on agricultural products.

Egypt is a key partner for the EU throughout the Southern Mediterranean region. The main aim of the Euro-Med process is to create a free trade area FTA with Mediterranean countries. The European Commission has set an ambitious objective to improve market access, as well as the progressive economic integration into the EU single market, of the concerned South-Mediterranean partners, including Egypt. For the accomplishment of this objective, on 14 December 2011, the Council of the European Union gave the green light to the European Commission to start the negotiations for **Deep and Comprehensive Free-Trade Agreements (DCFTAs) with Tunisia, Morocco, Jordan and Egypt**. The DCFTAs will go beyond removing only tariffs to cover all regulatory issues relevant to trade, such as investment protection and public procurement.

### ***Related agreements on trade and quality***

The EU recognizes the importance of facilitating trade by eliminating both technical and tariff barriers. For eliminating the tariff barriers the EU concluded several free trade agreements (FTA) from which are the association agreements with its southern Mediterranean neighbors. For facilitating the implementation of the FTA agreements the EU concluded several types of affiliate agreements which are:

- Mutual Recognition Agreements (MRAs) with United States, Canada, Australia, New Zealand, Japan, Israel and Switzerland.
- Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (PECA) which are protocols to the existing Europe Agreements with candidate countries.
- Agreements on Conformity Assessment and Acceptance of Industrial Products (ACAA) for southern and eastern neighbors (*which will be discussed in further details in this document as a core of this project aims*).

The ACAA by which priorities for Commission bilateral and regional trade related activities in the field of mutual recognition agreements and related technical dialogue are proposed. The benefit of such agreements are economic and political for both parties, the access to the EU internal market improved as the Egyptian products are better able to compete within the world market. And to allow further free movement of goods between both sides, signing the ACAA will be an instrument in promoting EU – Egypt Industrial cooperation.

Four conditions should be fulfilled for the creation of a successful adoption of the ACAA, i) adequate infrastructure of standardization, accreditation, conformity assessment and metrology, ii) Adoption of the relevant part of Acquis, iii) technical assistance, iv) formal agreement between the EU and Egypt setting out relationship.

Technical assistance to support an ACAA specification, implementation and follow up is considered one of the responsibilities that Egypt has to undertake prior to its adoption. The twinning project paves the way towards the adoption of ACAA. The ACAA requires the alignment of the partners' horizontal and vertical legislation in the selected priority sectors, and the set up of related implementation infrastructure (standardization, accreditation, metrology, conformity assessment procedures, and a post market surveillance system). ***Egypt has chosen 6 priority sectors*** in agreement with the EU (toys, gas appliances, construction products, electrical appliances, pressure equipment, medical devices, and machinery & vehicles & its parts) that will be tackled during this twinning project activity as justified later .

One of the four conditions to fulfill the creation of a successful ACAA is the presence of an adequate infrastructure in the fields of standardization, accreditation, conformity assessment, and metrology in the partner country; before the formal opening of ACAA negotiations/

implementation. In particular, in the ‘**New Approach**’ sectors<sup>1</sup>, the following requirements would have to be fulfilled:

- The competence of all conformity assessment bodies to be notified must be proven.
- Relevant European harmonized standards should be transposed and all conflicting standards withdrawn;
- A suitable market surveillance system and suitable safeguard procedures must be used.
- Furthermore, any conflicting national procedures such as pre-market authorization schemes would have to be dismantled;

In order to meet Member States’ demands for safe products on the internal market, accreditation should be used to assure the competence of notified conformity assessment bodies in the ACAA countries. The participation of ACAA countries in ongoing work of the international and regional accreditation organizations is equally important. For example, **European co-operation for Accreditation (EA)** has been established by the European Commission as the official European accreditation infrastructure (i.e. regional accreditation), this became effective on 1st April 2009 in Brussels. Further, countries that are outside the EEA or not candidates for EU membership can conclude co-operation agreements with the EA on a bilateral level, with the same content as the multilateral agreements (MLAs) for EA members.

### ***The Quality Set –Up in Egypt***

The quality infrastructure entails four main pillars: standardization, metrology, Accreditation, and market surveillance. Conformity Assessment is related to both Accreditation and Market Surveillance. It’s a fully-fledged scheme that is related and inter-connected. The Egyptian government has been working extensively on the four main pillars.

The Egyptian Quality Infrastructure System is divided among three Ministries and several main institutions; these are the Ministry of Trade and Industry and the Ministry of Scientific Research, Ministry of Supply and Internal trade. The Institutions are as follows:

- The Egyptian Accreditation Council (EGAC), the internationally recognized national accreditation body for Egypt.
- The Egyptian Organization for Standards and Quality (EOS), responsible for the National and International Standards adapted in Egypt. These standards are for specifications, requirements, and guidance.
- The National Institute of Standards (NIS), holder of all of the Egyptian Metrology National Standards.
- Market surveillance:
  - General Organization for Export and Import Control (GOEIC) which is part of the market surveillance in Egypt and responsible for the control of the products coming in or going out of Egypt.
  - Industrial Control Authority ICA which is part of market surveillance in Egypt and

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<sup>1</sup>The New Approach is a legislative technique developed in 1985 by the EU to harmonize the technical regulations and standards of the EC member states in order to assure the free movement of goods among these countries while guaranteeing a high level of safety for consumers.

responsible for the control of the products which in their final steps of production; in the factories.

- Assay & Weights Administration AWA which is also part of the market surveillance in Egypt and is responsible for a big part of the legal metrology in Egypt.
- Consumer Protection Agency CPA which is also part of the market surveillance in Egypt and is about the Law on Consumer Protection and to inform the public of how consumers can protect their rights in case they face any problems when purchasing a product.
- Consumer Protection NGOs which is also part of the market surveillance in Egypt and help the public to protect their rights in the face of any problems with purchasing a product.
- The National Quality Institute (NQI), which act as a horizontal national body in charge of advocacy and awareness for the quality concepts, methodologies, trainings and activities in compliance to international standards.

The quality and accreditation organizational structure in Egypt is as mentioned earlier interlinked and connected; however, when it comes to accreditation, EGAC has the sole responsibility in this context.

### ***The Egyptian Accreditation Council: Organizational Profile***

The Egyptian Accreditation Council (EGAC) was established in 1996 by Presidential Decree number 312/1996 modified in 2006 by the Presidential Decree number 248/2006, which designates EGAC as the sole national body for the assessment and accreditation of conformity assessment bodies including testing and calibration laboratories, inspection bodies as well as certification bodies for products, management systems and personnel.

This Presidential Decree presently entitles EGAC to:

- Achieve international recognition of the Egyptian national infrastructure for quality,
- Enhance the competitiveness of the Egyptian industry,
- Improve the national and international image of Egyptian products.

EGAC is operating under the direction of the Minister of Industry and Foreign Trade and is managed by an Executive Director appointed by the Minister and administered by a board of 14 members, representing stakeholders and concerned bodies. EGAC obtains its financial resources from the allocated government budget, revenues from the delivered services.

Accreditation goes through different levels international, regional, national, and EGAC undertakes the responsibility to present Egypt in this context. As products or services anywhere in the world could be "certified once, accepted everywhere". Thereby creating a framework to support international trade through the removal of technical barriers, thereby;

- On the International Level; EGAC now attained a full recognition of two International organizations: International Laboratory Accreditation Cooperation ILAC and International Accreditation Forum IAF,

- On the Regional Level there are different regional organizations such as APLAC Asia Pacific Laboratory Accreditation Cooperation, IAAC Inter American Accreditation Cooperation, and EA European Accreditation Cooperation. By 2009 EGAC has signed a contract of cooperation with EA and then became an associate member with EA in Nov 2011.

In September 2010, EGAC played an important role in the African region, it hosted and chaired the African Accreditation Cooperation **AFRAC** that was launched from Cairo to promote Quality through accreditation and boost trade within the African Continent. In June 2011, the Arab Accreditation **ARAC** was launched and chaired from Cairo as well to promote Quality and strengthen multilateral trade within the Arab region.

- At the **national level** EGAC is at the top of the hierarchy that assesses and ensures the compliance of the Egyptian conformity assessment bodies with the highest international standards, it is considered as the third-party provides accreditation services for calibration, testing, and medical laboratories, inspection bodies, and certification bodies for compliance with national and international standards of quality published by the International Organization for Standardization and International Electrotechnical Commission (ISO/IEC). It should also be accrediting the Notified Bodies NB in Egypt according to the European Directives as well as the International Standards.

### **3.1.2 Project justification**

Eliminating non-tariff barriers is essential for facilitating movement of goods and services. Standards take a special priority among non-tariff barriers. The incompatible products can be counted as a strong barriers for Egyptian products upon entering the EU market, thus, further mutual recognition is needed on both regional and international level, approximation of laws and regulations, harmonize procedures and recognize standards is required, Improving the quality infrastructure as a whole is mandatory. Accreditation is considered crucial since it aims at ensuring competitiveness in addition to facilitating the access of the product “tested once, accepted everywhere”.

EGAC as the sole accreditation body in Egypt, is planning to expand its current activities, by providing accreditation to notified bodies, and beginning accreditation of personnel certification bodies and product certification bodies, enhancing the efficiency to reach the "critical mass" of customers who would use its services, in order to obtain sustainable financial stability. This will also support in fulfilling the requirements of the ACAA agreement.

From September 2008 to March 2011, EGAC participated in a twinning project entitled “Building the capacity of the Egyptian Accreditation Council to deliver accreditation services” in cooperation with the British Standards Institute **BSI** as a senior partner and the Swedish Board for Accreditation and Conformity Assessment **SWEDAC** as a junior, with a total budget of €1,300,000. As a result of this twinning project, it has been recommended that a second twinning for EGAC should be organized to run in parallel with other related twinning projects supporting the quality infrastructure in Egypt.

The completed project’s main objective was to contribute to the improvement of the Egyptian



Accreditation Council's (EGAC) role in the area of conformity assessment; paving the way for the Agreement on Conformity Assessment and Acceptance (ACAA) being negotiated between Egypt and the EU. The project composed of 3 main components: Legislative Reform, Institution Capacity Building, and External Communications.

The project enabled EGAC to carry out a wide range of assessment activities that are very beneficial to Quality infrastructure reflecting on the Egyptian economy.

Benefiting from the twinning activities, EGAC has developed its technical capacity on strategic planning, accreditation and conformity assessment activities, obtained a full International recognition for formal Multilateral Agreements by ILAC and IAF. Additionally, an external communication plan includes raising the awareness of interested parties on matters related to the EU Internal market and conformity assessment requirements have been prepared.

***New Quality Legislation:*** As one of the major achievements of the previous twinning project, EGAC has succeeded in drafting a new legislation for quality. The new legislation for quality was introduced to Minister of Trade and Industry at that time, he reviewed it and it was about to be introduced to Cabinet but then the Egyptian changes due to the revolution delayed it. However, the new Minister of Industry and Foreign Trade (MIFT) developed a committee to follow up on the requirements of the ACAA. This committee included the heads of the main departments of Industry and Trade in MIFT, e.g. EGAC, Egyptian organization for Standardization EOS, Industrial Control Agency ICA, Trade Agreements sector, Foreign Trade sector. It also included heads of departments from outside MIFT, e.g. National Institute of Standards NIS. This committee reviewed the former preparations for legislations and recalled the quality legislation from EGAC and had it translated to Arabic in order to submit it to MIFT and in turn to the Cabinet for at least a Cabinet Decree. This legislation defines the mission of each component of Egypt's Quality Infrastructure and organizes the inter-relations between them. This will prevent any mix that could happen in their responsibilities and authorities. However due to the recent changes in the official authorities representing the three branches (executive, legislative and judiciary) bodies in the Egypt, among which the Egyptian Parliament EP was dissolved. The new draft law currently under revision of the new Trade and Industry Minister Mr. Hatem Saleh, and it is expected to be in the top agenda of the EP sessions after its formulation.

Based on the ***Recommendations*** of the completed project; other areas within the scope of EGAC were proposed to be addressed for improvement. The final report of the EGAC twinning 2009-2011 strongly recommended that further assistance be given to EGAC to adjust the harmonization of vertical legislation with EU accreditation laws which are represented in the rules and regulations of the European Cooperation for accreditation EA; and also to enable EGAC to be able to accredit Notified Bodies in the areas agreed in the ACAA; in addition, a particular area of concern should be given to proficiency testing area. This will certainly need considerable additional support and expertise. A number of useful steps have been taken such as the introduction to the OECD Good Laboratory Practice (GLP). However, further work to introduce in full-fledged GPL it is needed.

The following elements influenced the decision to proceed with Phase II support to EGAC as a twinning initiative:

Firstly, the necessary criteria for a twinning are met since the assignment is acquis related. Egypt is working on ACAA negotiations priority sectors, which required approximation of EU laws and regulations in related area. Furthermore, EGAC has the capacity (staff, space, skills including language skills) and demonstrated track-record to effectively co-operate with twinning partners.

EU public sector experience of similar service providers is critically required for the implementation of activities. Twinning will be a collectively integrated experience, that covers all the aspects of the required experience including: knowledge of best practices, laws and regulations of the EU, technical and practical experience, interrelations with other EU organizations, internal training and appraisal of the organization personnel, and experience in dealing with the regional and international organizations (like EA). This will only be available through a sound twinning project with a gradual plan for experience transfer that includes all types of learning communication starting from awareness, through classroom study, up to study cases in the MS expert organization premises, group interactions with the MS expert organization and joint assessments in the required field.

***This follow-up twinning project is expected to*** assist in interpreting related standards, ensuring transparency of the operations performed (including accreditation) and results provided by EGAC, to complement EA requirements. The project will also contribute in establishing and assessing the competence of the Notified Bodies based on ACAA's agreed priority sectors, in addition to providing support establishing and accrediting Proficiency Testing Providers PTP, increase awareness among stakeholders with the concept of Liability Insurance policies for CABs.

***This twinning project is expected to support EGAC to:***

Introducing EA requirements for the purpose of signing EA MLA:

The previous twinning focused on the harmonization of the horizontal legislation related to the quality infrastructure system setting a clear separation between the Quality infrastructure related bodies, during this project will focus on harmonization vertical legislation related to accreditation in compliance with EA requirements, that is in line with EU regulation (EC) No 765/2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products.

EGAC as an associate member with European Cooperation for accreditation EA will need to harmonize with EA requirements in order to attain regional recognition and benefits of the EA MLA. EA MLA is an agreement signed between the EA accreditation body members to recognize the equivalence, reliability and therefore acceptance of the certificates issued by the accredited conformity assessment bodies CAB (certifications, inspections, calibrations and tests) across Europe and the neighboring countries. This will reduce costs and ease exports and imports through reducing or eliminating the need for additional testing, inspection or auditing in another country. The CAB is ***accredited once, accepted everywhere.***

The strength of the EA MLA is maintained through a peer evaluation process. The purpose of these on-site evaluations is to verify the accreditation body signatories' continuing competence and conformity with the internationally accepted criteria.

This twinning project is required to support the EGAC to sign the EA MLA through the evaluation by EA against the international standard ISO/IEC 17011, other related criteria and requirement documents from EA, and applicable criteria on behalf of European Union Regulators and Industrial Schemes. As MLA eliminates the need for suppliers of products or services to be certified in each country where they sell their products or services, and therefore provide a means for goods and services to cross borders to Europe and throughout the world which is essential for Egyptian products and supports further FTA. Also, it delivers confidence in the service supplied by accredited laboratories, inspection and certification bodies, thereby providing the framework for goods and services to cross borders in Europe and throughout the world, and acting as a "passport for trade". The relevant EA documents are:

- 1- Procedural and Policy documents Series 2
- 2- Application documents for Accreditation bodies Series 3
- 3- Application documents for Laboratories Series 4
- 4- Application documents for Inspection bodies Series 5
- 5- Application documents for Certification of Products Series 6
- 6- Application documents for Certification of Management Systems Series 7
- 7- Application documents for Certification of Persons Series 8

Liability insurance is an EA requirement for accreditation of laboratories, although it is not required by the international standard or ILAC requirements. This is a principal that needs to be spread between the laboratories in Egypt, especially the accredited ones. The concept of liability insurance is not well known within the laboratories, there are ways that the concept of liability insurance can be introduced. The laboratories will be required to maintain liability insurance coverage for the activities undertaken. Although under the EA MLA the level of insurance cover held by the laboratories is not to be approved by the accreditation bodies, yet it still has to be existent.

EA General Assembly holds its meeting twice a year in parallel with technical meetings, during which a new EA MLA signatory is announced in the fields of calibration, testing, and inspection. As for members they are obligated to agree on the set of measurements and rules as well as to be aware with the amendments of EU related legislations. By now, amongst the 35 EA Full Members, 33 ABs are signatories to the EA MLA, out of which 26 have signed for all scopes. And amongst the 13 EA Associate Members, 4 are signatories to the EA MLA through a bilateral agreement with EA: ISRAC (Israel), TUNAC (Tunisia), NAAU (Ukraine) and BATA (Bosnia-Herzegovina).

During the project EGAC delegates will be coached, transferring the MS expertise about the effective participation in these meetings, i.e. teaching the EGAC delegates how to effectively participate in the technical research of the documents and how to initiate technical remarks and inquiries. This will represent a step forward towards the signing of the EA MLA.

Assessing the competence of the Notified Bodies in the priority sectors agreed upon in ACAA:

Egypt is focusing on a set of priority sectors<sup>2</sup> and works with bodies that conduct the conformity assessment activities as Notified Bodies. These notified bodies are designated to carry out conformity assessment according to an EU directive and the relevant updated standards (ISO 17065 for product certification bodies, ISO 17020 for inspection bodies, and ISO 17025 for testing laboratories). Notification of new Notified Bodies and their withdrawal are the responsibility of the notifying economy. The project will assist in introducing, supporting the technical capacities and awareness of the New Approach Directives. Notified bodies shall give **the products CE Markings**, which is a declaration that the product complies with the **essential requirements** of the relevant European **health, safety and environmental** protection legislations. In practice there are many **EU Product Directives**, which contain the "essential requirements" or "performance levels" that are specified by **Harmonized Standards** to which the products must conform. A **harmonized standard** is established and published by a European Standards Organization, such as the European Committee for Standardization **CEN**.

It is expected that a competent Notified Bodies in the priority sections were assessed and identified during the project life time.

Proficiency Testing Providers were identified and assessed:

The primary aim of proficiency testing is to provide a quality assurance tool for individual laboratories to enable them to compare their performance with similar laboratories, to take any necessary remedial action, and facilitate improvement, no good operational schemes for proficiency testing exists in Egypt at the present time. A number of potential PT providers with some scheme trails are developing recently, but the requirements of proficiency test providers, to be able to well serve testing and calibration laboratories, coincide with the requirements of the accreditation of PT Providers according to ISO 17043 is required. In order to achieve the Accreditation of Proficiency testing providers, the new potential PT providers required to be more acquainted with the accreditation necessities and at the same time EGAC staff and assessors need to have a developed structure for the accreditation of Proficiency testing providers, along with hands-on experience at EA PT providers, and a follow-up on achievements through joint assessments with EA ABs.

Assessing the compliance of Research Studies Centers against GLP requirements of OECD:

For any new product to be introduced in the Egyptian market or exported to EU markets, it has to be tested against hazards on health or environmental safety (non-clinical) by specialized centers, which are limitedly available in Egypt, the on hand products in the market do not comply with GLP<sup>3</sup> principles.

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<sup>2</sup> The 6 priority sectors agreed between Egypt and EU regarding the ACAA (toys, gas appliances, construction products, electrical appliances, pressure equipment, medical devices, and machinery & vehicles & its parts)

<sup>3</sup> Good Laboratory Practice: embodies a set of principles that provides a framework within which studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the HAZARDS and RISKS to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides.

In EU and many other parts of the world it is a regulatory requirement that studies undertaken to demonstrate the health or environmental safety of new chemical or biological substances should be conducted in compliance with the principles of GLP. GLP helps assure Regulatory Authorities that the data submitted is a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments.

It is recognized that it is important to ensure that the Ministry of Health of Population is involved in further development of the GLP landscape in Egypt. A co-ordination mechanism to allow for linkages between the policy/regulatory process and capacity to endorse will be set up prior to commencement of this component.

The assurance of the involvement of Ministry of Health and Population MHP while introducing the GLP is taking into consideration, since EGAC has been delegated for the accreditation (compliance assessment) activity of medical analysis laboratories according to ISO 15189, ISO/IEC 17025 standard, moreover, EGAC emphasizes on the need for further assessment against GLP which is not applied yet in such laboratories, on the other hand EGAC still lack the capabilities to carry out this kind of assessment, that is going to be tackled during the project in cooperation with MHP.

Moreover, the awareness of GLP principles & requirements is an essential part of this twinning project to support the capacities of EGAC's staff and the research centers in the field of pharmaceuticals and cosmetic. Trainings and awareness sessions expected to be held along with an on-ground experience by visiting the EA GLP accredited study centers in EU to transfer know how and have a complete joint assessments with EA ABs on the accrediting the research study centers.

The four components identified and justified above are expected to support the EGAC in the ACAA negotiations and implementation procedures by supporting the requirements that are needed for Egypt to be able to negotiate ACAA agreement.

### **3.2 Linked activities (other international and national initiatives):**

Within the framework of the European Union-Egypt ENP Action Plan the present project should particularly link with the following projects:

A number of projects financed by EU have been contributing for development and strengthening of the Egypt quality infrastructure institutions (standardization, metrology, and accreditation):

In the past years a twinning project was executed to support the quality infrastructure in Egypt. In March 2011, a two and a half year project entitles "Building the Capacity of the Egyptian Accreditation Council to Deliver Accreditation Services" was completed.

**Metrology** is a key component of the quality infrastructure, as a complementary action a **twinning project with the National Institute for Standards NIS** is expected to commence in October 2013, aiming at strengthening the institutional and technical capacity of NIS as the primary holder of metrology in line with the relevant European best practices in standards, norms and processes in the field. The expected results of NIS upcoming twinning project are grouped in two main headings as follows:

Results (1) relating to the legal approximation conforming to the model employed in the organization of the EU internal market. Results (2) relating to the infrastructure capacity building implementation and improving quality management system.

**In Standardization**, as another key component in the QI, there is a program entitled “**Trade and Domestic Market Enhancement Programme TDMEP**” with the Ministry of Industry and Foreign Trade, with a total amount of 20 million. The overall objective of the programme is to assist the Ministry and its stakeholders in the implementation and execution of key policy reforms in order to sustain economic development and further integrate Egypt into the global and regional economy. The program's main objective lies under the importance of increasing Egypt's benefit from international trade policy and agreements foster the industrial policy. The programme includes 2 components 1) Foreign trade and trade agreements. 2) Industrial policy and quality infrastructure. Implementation of the programme is due to commence in first half of 2013. The EGAC twinning will work in close collaboration with the TDMEP, in particular in areas related to enhancement of capacity of potential clients of EGAC services in the filed of notified bodies and proficiency testing.

**TAIEX related activities:** two seminars were held on “New legislation in the Internal Market” for 1 day on the 16 April, 18<sup>th</sup> of November 2010. Expert visit introducing the ISO/IEC 17025 & ILAC Guide G19:2002 Accreditation of forensic laboratories between the period 12<sup>nd</sup> - 23rd of February 2012.

### **3.3 Results:**

This project will lead to the following four main results:

#### **Result I: EA requirements for the purpose of signing EA MLA were introduced**

- Guidance introduced on the EA requirements (vertical legislation harmonization) for the accreditation bodies to be in line with EU laws of accreditation, represented in the rules and regulations of European Cooperation for accreditation EA assist in signing EA's MLA.
- Awareness offered to the EGAC stakeholders & customers on the requirements for the accredited bodies to be in line with their peers of the accredited bodies by ABs recognized by EA
- The principle of **Liability Insurance** introduced to EGAC accredited laboratories.
- Experience provided in interpreting related standards, ensuring complete knowledge of the requirements of the operations performed (including assessments) and results provided by EGAC to agree with EA requirements.
- Special Experience provided for EGAC to have hands-on experience in the accreditation process according to EA requirements.
- EA GA and its technical committees experience offered for EGAC staff through guided participation in these EA activities, in order to get the required familiarity and involvement in EA processes to assist in signing of EA MLA.

**Result II: competent Notified Bodies in the priority sections were assessed and identified.**

- New Approach Directives related to ACAA priority sectors (6 sectors) introduced to the stakeholders and to EGAC (toys and electrical appliances...etc.) beside the requirements to get CE marking, product safety directives, and harmonized standards.
- Technical guidance introduced on the new directives for CABs related to the priority sectors and according to the updated standards (product certification bodies- ISO 17065, inspection bodies- ISO 17020, and testing laboratories- ISO 17025), to be able to act as a notified bodies.
- Evaluation conducted for the CABs related to the priority sectors and the relevant standards leading to the selection of the potential notified bodies.
- Special guidance provided for EGAC staff & assessors to enable them to assess notified bodies according to the priority sectors in the above mentioned fields.
- Technical experience transferred from EA ABs on conducting real assessment of notified bodies, in the priority sectors, offered for EGAC staff & assessors in the above mentioned fields.
- Hands-on experience on the accreditation process offered to EGAC staff and assessors in assessing new potential/ established notified bodies in Egypt, in the priority sectors of the above mentioned fields.

**Result III: Proficiency Testing Providers were identified and assessed**

- Technical guidance on the requirements of proficiency testing PT providers related to the priority sectors according to ISO 17043 offered for the potential providers to be able to develop their own PT schemes.
- Evaluation conducted for the providers in the priority sectors leading to the selection of the potential PT providers.
- Technical guidance provided for EGAC staff & assessors to enable them to assess the PT providers according to the ISO 17043 in the priority sectors.
- Special experience transferred from to EGAC staff & assessors on conducting real assessment of PT providers in the priority sectors.
- Hands-on experience during the accreditation process offered from EA ABs' experts to EGAC staff and assessors in assessing new potential/ established PT providers in Egypt in the priority sectors.

**Result IV: A Research Study Centers were assessed and compliance with GLP requirements of OECD**

- Good Laboratory Practice (GLP) principles & requirements introduced to EGAC staff.
- GLP principles introduced to the stakeholders and related research centers to be aware with the GLP concept.

- Guidance provided for EGAC staff & assessors to enable them to assess the competence of research centers according to GLP principles.
- Technical experience transferred from EA ABs to EGAC staff & assessors on conducting real assessment of the competence of the research centers according to GLP principles.

### **3.4 Activities:**

#### **A.0 General Activities**

##### **A.0.1 Kick-off Event**

**Method:** The first month of the project will be used to allow the setting of the Resident Twinning Adviser (RTA) in Egypt. The RTA will have to be placed in his/her office at EGAC. S/he will be introduced to the beneficiary BC stakeholders of the project and to his counterparts and staff. S/he will also hire an Assistant (RTA Assistant) through an appropriate selection procedure.

A one-day kick-off meeting will be organized in the first month aiming at launching and presenting the project's main objective and activities that are expected to be achieved to the stakeholders within the life time of the project, in order to guarantee large public information a press coverage, press releases and brochure will be concluded.

**Benchmarks:** Stakeholders, media and public informed about the start and content of the project

##### **A.0.2 Final Closing Conference**

**Method:** During the last two months of the project, a closing conference will be organized at which the results of the project will be presented to the general audience. The state of play in the areas of the project's interventions will be discussed with the beneficiary, the Government, the civil society and other donors and stakeholders. The conference will be concluded with relevant recommendations for possible follow-up and lessons learnt for similar projects and how to achieve sustainability.

**Benchmarks:** Closing Conference organized,  
Recommendations and Lessons learnt formulated and discussed  
Stakeholders, media and public informed about the results of the project at its end.

### **Component 1 : Introducing EA requirements for the purpose of signing EA MLA**

#### **1.1 Organize Training on EA Procedural & Applications series**

**Method:** Experts will support introducing the EA vertical requirements for the accreditation of conformity assessment bodies CABs on EA procedural and application documents (7 series: 2-8) which offers additions/ differences from ILAC and IAF policies, procedures, and guidelines for accreditation purposes through 4 days training programs on (inspection, laboratories, certification) providing the necessary materials. This is to be carried out through 6 training programs for 3 days, 20 attendees each.

**Benchmarks:** 7 training programs carried out, material disseminated



## **1.2 Organize Workshops on EA Procedural & Applications series**

**Method:** Experts will support introducing EA vertical requirements to EGAC stakeholders and CABs about the accreditation on EA application documents (5 series: 4-8) which offers additions/ differences from ILAC and IAF policies, procedures, and guidelines for accreditation purposes through 5 workshops; 1 day each, and 50 attendees.

**Benchmarks:** 5 workshops carried out (50 attendees each), material disseminated

## **1.3 Organize Seminars on Liability Insurance**

**Method:** Experts will support introducing Liability Insurance to EGAC accredited laboratories through 3 seminars; 100 attendees, for 1 day each.

**Benchmarks:** 2 seminars carried out (100 attendees each), material disseminated

**Target Audience:** stake holders, field related bodies and other interested parties.

**Objectives:** increase awareness of Egyptian stakeholders of the impact of the Liability Insurance

**Focus Areas:** Liability Insurance required by EU Regulations and directives.

## **1.4 Conduct Study visits to EA ABs for EGAC Delegates**

**Method:** After introducing EA vertical requirements, 12 EGAC delegates (staff and assessors) will be given an opportunity of a study visit to EA ABs (2 study visits; 7 EGAC staff and assessors, for 4 days each visit). The possibilities of sharing experience and learning from one another with sophisticated ABs during accreditation for the right interpretation of the requirements of the operations performed (including assessments) and the results provided by the AB to agree with EA requirements.

They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of conformity assessment and accreditation (1 day for pre-discussions and 3 days for observing full assessment).

**Benchmarks:** 2 Study visit reports (to be submitted in two weeks after the visit)

## **1.5 Establish a joint assessments with EA ABs using EA rules**

**Method:** Experts will assess existing assessment (5 assessments for 5 places; for 4 days each), and give advice for improvement when necessary. Discuss the existing needs with the EGAC assessors, the priority requirements shall be described in the recommendations and submitted in written form together with a report on the performance of the assessors.

As a result of the analysis will address important gaps in EGAC's application of EA requirements.

**Benchmarks:** 5 assessment reports delivered.

## **1.6 EA Couching the experience of Technical Committees and GA**

**Method:** EGAC 16 delegates will be couching through guided participation in the meetings of the EA organization's general assembly's GA that is held twice in the year (2 delegates in 2 GAs 2 day each) and the relevant technical committees (2 delegates in 4 technical committee meeting of 2 days each) about the accreditation in order to gain the required familiarity and involvement in

EA processes to enable the signing of EA MLA.

**Benchmarks:** 4 technical committee minutes reports, 2 GA resolutions reports.

**Component II : Establishing and assessing the competence of the Notified Bodies in the priority sections.**

**2.1 Organize Awareness Workshops on notified bodies principles & benefits.**

**Method:** Experts will support introducing the New Approach Directives related to ACAA priority sectors (6 sectors: toys and electrical appliances...) to the stakeholders and EGAC, including the necessary requirements to get CE marking, product safety directives, and harmonized standards. It is to be held in 6 workshops; 1 day, inviting 50 relevant customers & stakeholders each.

**Benchmarks:** 6 workshops carried out, (50 attendees each), material disseminated.

**2.2 a- Organize Training on notified and notifying bodies principles & benefits**

**Method :** Experts will conduct special 18 training programs for 3 days (20 attendees each), on the updated standards (product certification bodies- ISO 17065, inspection bodies- ISO 17020, and testing laboratories- ISO 17025) in the priority sectors (6 sectors: toys and electrical appliances...), to be aware with the new standards and to be able to act as notified bodies.

**Benchmarks:** 18 Training programs carried out, 360 certificates issued

**b- Conduct Evaluation of the trainees from item 2.2**

**Method:** Experts assigned to achieve activity 2.2 will conduct special evaluation of the attendees (along side with the training) through discussions during the program, from the priority sectors and the relevant standards in order to select the potential notified bodies in the relevant 6 priority sectors. Experts will stay for one more day after the program to discuss with EGAC relevant managers.

**Benchmarks:** 3 potential notified bodies selected

**2.3 Organize Special Training for EGAC staff & assessors**

**Method:** Experts will conduct special training programs (6 training programs; 3 days, and 20-25 attendees each) for EGAC staff & assessors on the updated standards (product certification bodies- ISO 17065, inspection bodies- ISO 17020, and testing laboratories- ISO 17025) in the priority sectors (6 sectors: toys and electrical appliances...), in order for them to become assessors for the notified bodies.

**Benchmarks:** 6 Training programs carried out, ~ 150 certificates issued

**2.4 Conduct Study visits to EA ABs assessing notified bodies**

**Methods:** After training on EA notified bodies assessor requirements, (2 study visits; 9 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit for a real

assessments of EA ABs in the six priority sectors, with the possibilities of sharing experience and learning from one another within sophisticated ABs during accreditation process and the results provided by AB in accordance with EA notified bodies requirements.

They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of conformity assessment and accreditation (1 day for pre-discussions and 3 days for observing full assessment).

**Benchmarks:** 2 Study visit reports (to be submitted in two weeks after the visit)

### **2.5 Establish Joint assessments with EA ABs for the potential notified bodies.**

**Method:** Experts will analysis existing assessments of the new potential notified bodies in the priority sectors of the above mentioned fields (6 assessments; 2 EA AB experts, for 4 days each), and give advice for improvement when necessary. Discussing the existing needs with the EGAC assessors, highlighting the priority requirements shall be described in the recommendations and submitted in written form together with a report on the performance of the assessors. Discussion should be held to identify the needs.

Results of the analysis will allow EGAC counterpart to address important gaps in EGAC's application of EA requirements of notified bodies.

**Benchmarks:** 6 assessment reports delivered.

### **2.6 Organize Awareness Conferences on new developments in the area of notification**

**Method:** Experts will support introducing the new developments in the area of notification and New Approach Directives related to ACAA priority sectors (6 sectors: toys and electrical appliances...) to the stakeholders and to EGAC staff & assessors. It is to be held in 2 conferences; 1 day, and 200 relevant customers, stakeholders & EGAC staff and assessors each.

**Benchmarks:** 2 conferences carried out, (200 attendees each), material disseminated.

**Target Audience:** EGAC stakeholders, relevant Egyptian institutions.

**Objectives:** outline New Approach Directives related to ACAA priority sectors

**Focus Areas:** new developments in the area of notification under the Global new Approach principles.

## **Component III: Establishing and Accrediting Proficiency Testing Providers**

### **3.1 a-Organize Training on Proficiency Testing Provider requirements**

**Method :** Experts will conduct special training programs (1 training program; 2 EA AB expert, 3 days, and 20 attendees) on the updated standards for the requirements of proficiency testing providers from the priority sectors according to ISO 17043 offered for the potential providers in order for them to be able to develop their own PT schemes.

**Benchmarks:** 1 Training programs carried out, 20-25 certificates issued

### **b- Conduct Evaluation of the trainees from item 3.1**

**Method:** after completion of activity 3.1 will, experts will conduct special evaluation of the attendees (along side with the training) through discussions during the program, from the priority sectors in order to select the potential proficiency testing providers. Experts will stay for one more day after the program to discuss with EGAC relevant managers.

**Benchmarks:** 1 days over the training program attended, 3 potential notified bodies selected

### **3.2 Organize Special Training for EGAC staff & assessors**

**Method:** EA AB experts will conduct special training programs, one of them is advanced (2 training programs; 2 experts, 3 days, and 20-25 attendees each) for EGAC staff & assessors on the updated standard (PT providers- ISO 17043), in order for them to become assessors for the proficiency testing providers preferably in the priority sectors.

**Benchmarks:** 2 Training programs carried out, ~ 50 certificates issued

### **3.3 Conduct Study visits to EA ABs assessing notified bodies**

**Methods:** After training on the EA proficiency testing providers assessor requirements, (1 study visits; 6 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit to EA ABs during real assessments on proficiency testing providers, with the possibilities of sharing experience and learning from one another with sophisticated ABs during accreditation and the results provided by the AB in accordance with EA proficiency testing providers requirements.

They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of conformity assessment and accreditation (1 day for pre-discussions and 3 days for observing full assessment).

**Benchmarks:** 1 Study visit reports (to be submitted in two weeks after the visit)

### **3.4 Establish Joint assessments with EA ABs for the potential notified bodies.**

**Method:** Experts will assess existing assessments of the new potential/ established PT providers in the priority sectors by EGAC staff and assessors (3 assessments; for 4 days each), and give advice for improvement when necessary. Discuss the existing needs with the EGAC assessors, the priority requirements shall be described in the recommendations and submitted in written form together with a report on the performance of the assessors. Discussion should be held for the needs.

Results of the analysis will allow EGAC counterpart to address important gaps in EGAC's application of EA requirements of PT providers.

**Benchmarks:** 3 assessment reports delivered.

**Component IV: Introducing the OECD requirements against GLP to Research Study Centers:**

**4.1 Organize Training on GLP principles & requirements**

**Method:** Experts will conduct training programs (1 training program; 3 days, and 20-25 attendees of EGAC staff & customers) on the updated standards for the requirements of GLP by OECD; introducing GLP principles and highlighting the requirements needed to apply, giving examples in at least two fields (pharmaceuticals & cosmetics) offered for the research centers in order for them to be able to get assessed for compliance with the GLP principles & requirements.

**Benchmarks:** 1 Training program carried out, 25 certificates issued

**4.2 Organize Workshops on GLP principles & requirements**

**Method:** Experts will support introducing the GLP principles to the stakeholders and to research centers, including the requirements to be assessed for compliance with the GLP from OECD requirements. It is to be held in 2 workshops; 1 day, and 50 relevant customers & stakeholders each.

**Benchmarks:** 2 workshops carried out, (50 attendees each), material disseminated.

**4.3 Organize Training on GLP compliance assessment**

**Method:** EA AB experts will support introducing the GLP principles to EGAC staff & assessors, including the requirements to be assessed for compliance with the GLP from OECD requirements. It is to be held in 1 training program; 3 days, and 20 attendees. Examples will be introduced in at least two fields (pharmaceuticals & cosmetics).

**Benchmarks:** 1 training program carried out, 20 certificates issued, material disseminated.

**4.4 Conduct Study visits to EA GLP accredited study centers**

**Methods:** After training on the GLP assessment requirements, (1 study visits; 6 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit to EA ABs during real assessments on GLP compliant study centers, with the possibilities of sharing experience and learning from one another with sophisticated ABs during assessment and the results provided by the AB in accordance with GLP of OECD requirements.

They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of research centers and their assessment (1 day for pre-discussions and 3 days for observing full assessment).

**Benchmarks:** 1 Study visit reports (to be submitted in two weeks after the visit)

### **3.5 Means/ Input from the MS Partner Administration:**

#### **3.5.1 Profile and tasks of the Project Leader**

The Project Leader (PL) will be responsible for the overall planning and implementation of the thrust of member states' inputs in this Twinning project. The PL will be expected to devote a minimum of 3 days per month to the project, in addition to one visit to the beneficiary every 3 months. In addition, he will coordinate, from the Member state side, the Project steering Committee (PSC), which will meet in Egypt every three months. In co-operation with the PL counterpart, the PL will be responsible for the organization of the PSC which includes the RTA and representatives of PAO and the EU Delegation.

##### ***The PL's profile:***

The PL is expected to fill the following profile:

- Have a university degree or higher in an area relevant for the scope of this twinning initiative. Have at least 12 years of management experience, 6 years of them in the field of accreditation and conformity. Having more years of experience in the field of accreditation and conformity would be an asset;
- Have at least 5 years in an active senior management position in the Member State institution for accreditation;
- Experience in the field international projects, and national quality infrastructures would be an asset;
- Have experience in the implementation of some New Approach Directives, experience in the neighborhood policy countries will be an asset;
- He has to have excellent command of English.

##### ***The PL's tasks:***

The main tasks of the PL will be:

- To ensure the overall coordination, guidance, and monitoring of the project and the achievement of mandatory results;
- To coordinate and co-chairing the project steering committee meetings, and to work on a regular basis with the Egyptian Project Leader and the BC staff to implement the project and coordinate activities in the BC;
- To contribute in providing technical and logistical support during the implementation of the project, as well as monitoring the outputs and inputs and managing the budget;
- To prepare the project progress reports with support of RTA;
- To be responsible for the timely achievement of the project results;
- To provide legal and technical advice and analysis whenever needed.

### **3.5.2 Profile and tasks of the Resident Twinning Adviser**

One Resident Twinning Adviser (RTA) over a period of 24 months as well as medium/short term experts will implement the above-listed components. The RTA has the responsibility to guide the work of the team and provide support in elaboration, implementation, auditing and peer-evaluation as well as in liaising with the MS on participation of Egypt's delegates in EA & international events.

The Resident Twinning Adviser (RTA) will manage this project on day to day basis.

#### ***The RTA's profile:***

The RTA is expected to fill the following profile:

- Have a university degree or higher relevant related areas
- At least 10 years of management experience 8 years of them in the field accreditation and conformity. Having more years of experience in the field accreditation and conformity would be an asset Experience on EU-funded projects, New Approach Directives, notified bodies and Proficiency Testing.
- Sound knowledge of relevant EU legislative and institutional requirements related to the various components of this project;
- Wide knowledge of related good practice/EU Acquis and demonstrated experience in the different accreditation activities;
- Solid knowledge of accreditation and conformity assessment legislation, work methods and procedures;
- Previous experience in project management would be an asset;
- Working on similar projects in EU neighboring countries would be an asset;
- Experience in implementation, policy setting, institutional capacity building, awareness raising and training components of management systems according to ISO/IEC 17011, ISO/IEC 17025, ISO/IEC 17020, and ISO/IEC 17065 or the equivalent standards;
- Good knowledge about GLP of OECD would be an asset.
- Good training, public speaking, diplomatic and written communication skills;
- Excellent command of spoken and written English;
- Excellent computer literacy (Word, Excel, Power Point);

#### ***The RTA's Tasks:***

- Overall supervision of the project implementation and coordination of all activities, as well as management of the project administration;
- Coordination of the activities of the team members in line with the agreed work programs to enable timely completion of project outputs;
- Provide technical input to the project whenever needed and provision of advice in all components of the project: notified bodies (product certification, inspection bodies, testing laboratories), PT providers, and GLP compliant research centers;
- Liaise with MS and BC Project Leaders and daily contacts with BC RTA counterpart;
- Co-preparation of project progress reports with Project Leader;
- Arranging internships and study tours in the EU for staff of the MS;
- Liaise Awareness raising and Communications;

- Liaison with other relevant projects and Egyptian institutions.

The RTA will have a full-time assistant (RTA assistant) for the entire duration of the project and for the purposes of translation, interpretation and with regards to general project duties assigned by the RTA as required.

### **3.5.3 Profile and tasks of the short-term experts**

#### ***Tasks of medium and short term expertise***

Terms of Reference for short-term adviser(s) will be elaborated by Project Leader/RTA at the work plan preparation stage.

The exact number of STEs per activity should be agreed during the contract negotiation process.

#### ***Profile of short-term expertise***

There should be a pool of short/medium term experts for the duration of the project. STEs should be identified by the Project Leader/RTA and have to be agreed with the Beneficiary administration in the course of designing and delivery of the project.

#### **The STEs shall have the following common profile:**

- a university degree in a relevant subject;
- a minimum of five years experience in their respective field, more years of experience will be an asset;
- an excellent command of written and spoken English;
- Experience in EU neighboring countries or in other international projects relating to quality infrastructure development/management would be an advantage.
- good communicators and motivators with good monitoring skills;
- Good writing, training and presentation skills,
- Experience of external/internal/technical/Lead assessors.

#### **For STEs conducting conferences, seminars, or workshops, they need to also have:**

- Familiarity with various approaches in implementation of the EU legislation as well as EA & international accreditation documents.

#### **In order to achieve the result No 1, STEs shall in addition have the following**

- Very good knowledge about the specific EA vertical requirements for the accreditation of conformity assessment bodies CABs on EA procedural and application documents (7 series: 2-8 mentioned above) and the relevant ILAC and IAF policies, procedures, and guidelines for accreditation purposes;
- Very good experience about the updated requirements for the Liability Insurance by EA;
- Very good experience about AE's technical committees and general assembly activities;

#### **In order to achieve the result No 2, STEs shall in addition have the following**

- Very good knowledge about the specific New Approach Directives related to Egypt's



selected ACAA priority sectors as mentioned above (6 sectors: toys and electrical appliances...), including the requirements to get CE marking, product safety directives, and harmonized standards;

- Very good experience about the relevant standards: ISO/IEC 17065, ISO/IEC 17020, and ISO/IEC 17025 or their equivalent. The updated knowledge about these standards and their application in the above mentioned priority sectors' directives is required;

**In order to achieve the result No 3, STEs shall in addition have the following**

- Very good knowledge about the specific updated standards for the requirements of proficiency testing providers from the priority sectors (mentioned above) according to ISO 17043;
- Very good experience about the relevant activities of the PT and PT schemes with experience of piloting or running inter laboratory comparisons;

**In order to achieve the result No 4, STEs shall have**

- Very good knowledge about the specific updated standard for the requirements of GLP of OECD, introducing GLP principles and highlighting the requirements needed to apply it;
- Very good experience about the assessment of relevant research centers for compliance with the GLP principles & requirements, giving examples in at least two fields (pharmaceuticals & cosmetics).

In addition to their missions in Egypt, the short-term experts are expected to contribute actively to elaborating the programs of the foreseen study visits and joint assessments. They are also expected to actively elaborate the coaching activities for gaining the EA committees & GA experience.

#### **4. Institutional Framework**

The direct beneficiary institution is the Egyptian Accreditation Council (EGAC) with headquarters in Cairo.

EGAC, established as an accreditation body since 1996, was in 2006 designated as the sole accreditation body at national level to perform accreditation of laboratories and conformity assessment bodies.

EGAC is headed by the Minister of Trade and Industry, governed by a board of 14 representatives of stakeholders and concerned bodies and has financial resources originating from the government budget, from revenues of services provided as well as from donations.

#### **5. Budget**

The maximum estimated budget allocated for this Twinning project is € 1,120,000

#### **6. Implementation Arrangements**

## 6.1 Implementing Agency responsible for tendering, contracting and accounting

The Programme Administration Office (PAO), Ministry of International Cooperation, is the contracting authority in charge of all the activities and administrative management of the programme managing several projects, where this project is under the same umbrella. The PAO will be the responsible institution for the management of this twinning project.

It will manage the tenders, contracts and payments and this, in accordance with the provisions of ex-ante control under decentralized management defined in the Practical Guide to contract procedures financed from the General Budget of the EC in the context of external actions.

### Contact person at the PAO:

Name: Ambassador Gamal Bayoumi , Programme Director  
Title: Projects Manager Support to the EU - Egypt Association Agreement (SAAP)  
Ministry of International Cooperation  
9, Abd El Kadar Hamza Str.  
Garden City, apt. 401  
CAIRO – EGYPT  
Tel: +202 792 34 38  
Fax: +202 792 05 83  
Email: [gbayoumi@ee-aa.net](mailto:gbayoumi@ee-aa.net)

## **6.2 Main counterpart in the BC, Egyptian Project Leader**

The Egyptian Project Leader (PL) will act as the counterpart of the Member State PL. In close cooperation with him/her, the Egyptian PL ensures the overall steering and co-ordination of the project, the operational dialogue and the backing at political level. The PL's seniority will ensure his ability to mobilise the necessary staff in support of the efficient implementation of the project. He will also coordinate the Project Steering Committee (PAC) from the Egyptian side.

Mahmoud Eltayeb  
Executive Director  
Egyptian Accreditation Council, EGAC  
Borg Reiad El-Maadi (1), Kornish El-Nile, El-Maadi, Cairo, Egypt.  
Tel: +(202) 25275224, +(202) 25275225, +(202) 25275227.  
Fax: +(202) 25275226.  
Website: [www.egac.gov.eg](http://www.egac.gov.eg)  
Email: [egac2000@idsc.net.eg](mailto:egac2000@idsc.net.eg)  
[meltayeb@idsc.net.eg](mailto:meltayeb@idsc.net.eg)

### RTA Counterpart

The RTA Counterpart will work with the RTA on a daily basis to ensure proper coordination and implementation of all the activities of the project and achieve an efficient transfer of knowledge. He will be responsible, together with the RTA, of finalising the reports to be submitted to the PLs for the Project Steering Committee. His profile should be as follows:

Mohamed Adel Rezk  
Accreditation Director  
Egyptian Accreditation Council, EGAC  
Borg Reiad El-Maadi (1), Kornish El-Nile, El-Maadi, Cairo, Egypt.  
Tel: +(202) 25275224, +(202) 25275225, +(202) 25275227.  
Fax: +(202) 25275226.  
Website: [www.egac.gov.eg](http://www.egac.gov.eg)  
Email: [adelrezk@idsc.net.eg](mailto:adelrezk@idsc.net.eg)  
[maar01@link.net](mailto:maar01@link.net)

Senior management of EGAC will ensure that appropriate staff is made available to work with the Member State partner. They will also make sure that the Member State partner is provided with legislation and other documents necessary for the implementation of the project. EGAC will ensure adequate support and basic equipment for the work of the full team of experts. This includes office space, phone and fax, access to Internet and translation (when necessary).

#### Indicators of Achievement

When drafting the work plan for this project, the partners (EGAC and the selected Member State) will develop a set of measurable performance indicators/benchmarks, on the basis of those given in the logical framework (see annex 1) and the commonly agreed activities and outputs. In order to meet the specific objectives, the partners may propose alternative or complementary activities and outputs to those identified in the previous sections.

### **6.3 Contracts**

A new Financial Regulation applicable to the general budget of the European Union entered into force on 1st January 2013<sup>4</sup>. This implies several changes to the Twinning contract templates. An updated version of the Twinning Manual and of its Annexes, incorporating these changes, is in preparation and shall be published soon on EuropeAid website<sup>5</sup>. The Twinning contract that shall be signed as a result of the present procedure shall follow the templates of the updated Twinning Manual and Annexes.

The signature of the Twinning contract is subject to the approval of the addendum to the PE I of

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<sup>4</sup> Financial Regulation: Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:298:0001:0096:EN:PDF>

Rules of Application: Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:362:FULL:EN:PDF>

<sup>5</sup> [http://ec.europa.eu/europeaid/where/neighbourhood/overview/twinning\\_en.htm](http://ec.europa.eu/europeaid/where/neighbourhood/overview/twinning_en.htm)

the SAAP IV.

## **7. Implementation Schedule (indicative)**

<b>7.1 Launching of the call for proposals</b>	(July 2013)
<b>7.2 Start of project activities</b>	(December 2013)
<b>7.3 Project completion</b>	(November 2015)
<b>7.4 Duration of the execution period</b>	(24 Months)

## **8. Sustainability**

The sustainability of the project will be achieved through a smooth and timely implementation of the project activities and availability of trained personnel in the accreditation infrastructure. The workshops, seminars, on--job coaching and mentoring should take into account an opportunity for train-the-trainer approach, it may entail a multiplier effect and ensure the sustainability of methodologies developed and the longevity of the standards which are established for the priority areas.

It is necessary to apply a training approach characterized by focusing on cases in the local context. Furthermore, needs of the local and international businesses in internationally acceptable certificates as well as needs of public authorities in third party evaluation and participation in (inter)national accreditation activities are expected to contribute to maintaining high level services on a constant basis in the EGAC.

The training documents, recommendations should be regularly updated beyond the duration of the project. Direct peer-to-peer and expert-to-expert working relations should be established as well. Constant monitoring of developments shall be ensured through provision of short evaluation sheets (or questionnaires) surveying how Egyptian participants appreciate of the content, method, applicability and transferability of topics.

## **9. Crosscutting issues**

Consumer protection through upgrading the products standards, and quality, by improve the accreditation of more conformity assessment bodies insure on the applying of the safety standards , is expected to have a clear and positive impact on reducing consumer health risks.

Guaranteeing the safety and environmental friendly aspects for the products of the potential targets behind this project, the health safety and protection are to be ensured. As an accreditation body for management systems and environmental testing laboratories, EGAC is one of the many players for the protection of a clean and sustainable environment.

The principle of equal opportunity will be integrated into all stages of the project implementation. Practices in ensuring equitable gender participation in the project will be guaranteed. Accordingly, the project will seek to ensure that there is equal treatment accorded to male and female staff in EGAC and the other stakeholders participating in the project activities and training programs.

The main criteria for staff recruitment will be appropriate qualifications and experience in similar projects, not sex or age. Both men and women will have equal opportunities.

## **10. Conditionality and sequencing**

There is no precondition set for this twinning project.

### **ANNEXES TO PROJECT FICHE**

1. Logical framework matrix.
2. Purposes of the study visits.

## ANNEX I - LOGFRAME PLANNING MATRIX

### Twining Fiche ” Building the Capacity of the Egyptian Accreditation Council- PHASE II”

Overall objective	Objectively verifiable indicators	Sources of Verification	Assumptions/Risks
<p><b>Supporting the performance of the Egyptian Quality infrastructure within the context of the national reform priorities and in line with the EU and international best practices. This will eventually entail complementing efforts undertaken to push the negotiations of the Agreement on Conformity Assessment and Acceptance (ACAA).</b></p>	<ul style="list-style-type: none"> <li>• Egyptian regulations related to accreditation are Harmonized with EU legislations</li> <li>• MLA with EA is concluded.</li> <li>• Proficiency Testing schemes established</li> <li>• Trade between Egypt and EU increased (by at least 1%)</li> </ul>	<ul style="list-style-type: none"> <li>• Amendments in legislations</li> <li>• Reports of the Ministries responsible for trade and Industry including publication of technical regulations</li> <li>• EU annual progress report</li> <li>• ILC or PT reports</li> <li>• statistical reports (trade sector)</li> <li>• Conference/meetings reports and photos</li> <li>• 2 related international meetings attended</li> </ul>	<ul style="list-style-type: none"> <li>• Political commitment given the long legislation processes.</li> </ul>
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions/Risks
<p><b>Providing further support to enhance the technical and institutional capacities of the Egyptian Accreditation</b></p>	<ul style="list-style-type: none"> <li>• EGAC Institutional capacity developed</li> <li>• EA requirements were</li> </ul>	<ul style="list-style-type: none"> <li>• EGAC annual performance reports</li> <li>• European Cooperation for</li> </ul>	<ul style="list-style-type: none"> <li>• The Concept of accreditation is fully spread within related stakeholders.</li> </ul>

<p><b>Council in its endeavor to extend providing Accreditation services to different types of Conformity Assessment Bodies and Notified Bodies nationally, regionally, and internationally.</b></p>	<p>identified.</p> <ul style="list-style-type: none"> <li>• Scopes of internationally recognized services extended in 6 priority sectors of ACAA</li> <li>• Measurement procedures developed and approved.</li> <li>• 3 Notified bodies were assessed</li> </ul>	<p>Accreditation EA.</p> <ul style="list-style-type: none"> <li>• Assessment report to present the gaps need to be filled</li> <li>• Reports of peer assessors or certificates of scopes of accreditation.</li> <li>• Certificates of training</li> <li>• Training material</li> </ul>	<ul style="list-style-type: none"> <li>• Government's commitment to introduce the EU principles for Conformity assessment activities under accreditation.</li> <li>• Delays in case of adopting the EA requirements (preparation and modification). Unsuccessful results in international comparisons.</li> </ul>
Results	Indicators	Sources of Verification (SoV)	Assumptions/Risks
<p><b><u>Result I: EA requirements for the purpose of signing EA MLA are introduced</u></b></p>	<p>-EGAC experts aware of the EA requirements.</p> <p>- A complete introduction to EA requirements</p> <p>-An assessment regarding the gaps need to be filled according to the EA requirements were introduced.</p> <p>-EGAC accredited laboratories became aware with the liability insurance</p>	<p>- trainings provided</p> <p>- EA list of requirements document</p> <p>- MS experts' assessment reports.</p> <p>-training provided</p>	<p>Strong will towards modifications and the necessary resources availability to meet the EA requirements</p>
<p><b><u>Result II: competent Notified Bodies in the priority sectors</u></b></p>	<p>- Related stakeholders became aware with the new</p>	<p>-Training sessions , attendance</p>	<p>- Difficulty to identify the potential notified bodies to be</p>

<p><b><u>are assessed and identified.</u></b></p>	<p>approaches of ACAA in regards to 6 priorities.</p> <ul style="list-style-type: none"> <li>- 3 Notified bodies are assessed.</li> </ul>	<p>list</p> <ul style="list-style-type: none"> <li>-Assessment by MS experts</li> <li>-Real assessment observation to a MS notified bodies</li> </ul>	<p>accredited.</p> <ul style="list-style-type: none"> <li>- Necessary local resources available</li> </ul>
<p><b><u>Result III: Proficiency Testing Providers are identified and assessed</u></b></p>	<ul style="list-style-type: none"> <li>- A potential proficiency testing providers in the priority sectors evaluated, as a step to build PT scheme.</li> <li>-EGAC staff is aware of evaluation techniques for PT providers according to ISO 17043 in the priority sectors.</li> </ul>	<ul style="list-style-type: none"> <li>-<i>Training course conducted</i></li> <li>- Evaluation prepared to identify the potential PT providers.</li> <li>- Training Evaluations on PT techniques</li> </ul>	<ul style="list-style-type: none"> <li>-Clear understanding of the evaluation and assessed process.</li> <li>- Availability of resources</li> </ul>
<p><b><u>Result IV: A Research Study Centers were assessed and compliance with GLP requirements of OECD</u></b></p>	<ul style="list-style-type: none"> <li>-Awareness of the Research Centers and related stakeholders about the GLP is raised.</li> <li>-Efficient EGAC staff experts able to assess the research centers</li> </ul>	<ul style="list-style-type: none"> <li>- Training course. list of attendance</li> <li>- Seminar and conference statements and publications</li> </ul>	<ul style="list-style-type: none"> <li>- Availability of resources</li> </ul>
<p><b>Activities</b></p>			



Component 1 : Introducing EA requirements for the purpose of signing EA MLA

<p><b>1.1 Organize Training on EA Procedural &amp; Applications series</b></p>	<p>7 Trainings held</p> <p>At least 140 (7*20) participants are trained and aware of the EA policies and guidelines</p>	<p>Training material</p> <p>Certificates</p>	<p>Commitment to provide premises for trainings and seminars</p> <p>Commitment of the experts and the trainee/rs</p>
<p><b>1.2 Organize Workshops on EA Procedural &amp; Applications series</b></p>	<p>5 workshops carried out 100(5*50) participants for BC and relevant bodies aware with EA vertical requirements ,Procedures and applications</p>	<p>Material were disseminated</p>	<p>Commitment to provide premises for trainings and seminars</p> <p>Commitment of the experts and the trainee/rs</p>
<p><b>1.3 Organize Seminars on Liability Insurance</b></p>	<p>2 Seminars held for 1 day introducing liability Insurance with 100 attendees each ,</p>	<p>Press releases and statements providing the necessary materials</p>	<p>Commitment to provide premises for trainings and seminars</p> <p>Commitment of the experts and the trainee/rs</p>
<p><b>1.4 Conduct Study visits to EA ABs for EGAC Delegates</b></p>	<p>12 EGAC delegates aware with EA vertical requirements through 2 study visit to EA</p>	<p>Mission and study visit report</p>	<p>Commitment to support trainers travelling documents</p>

	ABs;		Commitment of the experts and the trainee/rs
<b>1.5 Establish joint assessments with EA ABs using EA rules</b>	<p>Assessment (5 assessments for 5 places, for 4 days each),</p> <p>- giving recommendations for improvement and discuss the existing needs with the EGAC assessors, gaps addressed in EGAC's application of EA requirements</p>	<p>Assessment reports including recommendations of gaps in EGAC application of EA requirements</p>	-Cooperation of available staff to provide the necessary information
<b>1.6 EA Coaching the experience of Technical Committees and General assembly GA</b>	<p>Effective participation during the GA familiar with EA processes to enable the signing of EA MLA.</p> <p>- 2 delegates attended 2 Gas and 4 technical committee meetings</p>	Mission reports	

Component II : Establishing and assessing the competence of the Notified Bodies in the priority sections.

<p><b>2.1 Organize Awareness Workshops on notified bodies principles &amp; benefits.</b></p>	<p>6 workshops for 1 day held covering 6 priority areas for at least 50 participants in each (from NB) are trained and aware of the notification principles and benefits</p>	<p>-Certificates and Material delivered  - evaluation sheets</p>	<p>- Availability of resources and competent staff form Notified bodies</p>
<p><b>2.2 a Organize Training on notified and notifying bodies principles &amp; benefits</b></p>	<p>Efficient notified bodies through 18 Training courses are held , with at least 20 participants are trained for each for 4 days and 20 attendees each) on the updated standards (product certification bodies- ISO 17065, inspection bodies- ISO 17020, and testing laboratories- ISO 17025)</p>	<p>Training Certificates  Training Material</p>	<p>Commitment to provide premises for trainings and seminars  Commitment of the experts and the trainee/rs</p>
<p><b>b- Conduct Evaluation of the trainees from item 2.2a</b></p>	<p>At least 3 Efficient potential notified bodies are identified (along side with the training),</p>	<p>Training evaluation sheets</p>	<p>Commitment of the experts and the trainee/</p>

<b>2.3 Organize Special Training for EGAC staff &amp; assessors</b>	6 training programs; for 3 days, and 20-25 attendees each) on the updated standards (product certification bodies- ISO 17065, inspection bodies- ISO 17020, and testing laboratories- ISO 17025) in the priority sectors (6 sectors: toys and electrical appliances...)	Training attendance sheet	level, competence of BC staff is adequate
<b>2.4 Conduct Study visits to EA ABs assessing notified bodies</b>	9 EGAC staff and assessors will be capable to do real assessment, sharing experience and learning from one another with sophisticated ABs during accreditation and the results provided by the AB in accordance with EA notified bodies requirements.  2 study visits; for 4 days each visit)	mission reports	Receiving travel documents on time
<b>2.5 Establish Joint assessments with EA ABs for the potential</b>	6 assessments of the new potential notified bodies in the priority sectors of the above	Assessments reports	The cooperation of the involved stakeholders to provide the necessary

<b>notified bodies.</b>	mentioned fields presented with; advice for improvement, for 4 days each		information
<b>2.6 Organize Awareness Conferences on new developments in the area of notification</b>	<p>New developments in the area of notification and New Approach Directives introduced related to ACAA priority sectors (6 sectors: toys and electrical appliances</p> <p>By hold 2 Conference for 1 day with 100 relevant customers, stake holders &amp; EGAC staff for each.</p>	Related materials and Statement disseminated	Commitment to provide premises for trainings and seminars
<i><u>Component III : Establishing and Accrediting Proficiency Testing Providers</u></i>			
<b>3.1 a- Organize Training on Proficiency Testing Provider requirements.</b>  <b>b- Conduct Evaluation of the trainees from item 3.1</b>	<p>Potential PT providers aware with updated standards on the priority sectors according to ISO 17043 offered through 1 training program; for 4 days, for 20 attendees)</p> <p>- 3 notified bodies evaluated</p>	<p>Training material disseminated</p> <p>Training certificate disseminated</p> <p>Training evaluation sheet</p>	Commitment to provide premises for trainings and seminars

	and selected		
<b>3.2 Organize Special Training for EGAC staff &amp; assessors</b>	PT providers' assessors aware with updated standard (PT providers- ISO 17043) introduced, through 2 training programs, for 3 days, for 20-25 attendees each.	Training material disseminated  Training certificates	
<b>3.3 Conduct Study visits to EA ABs assessing notified bodies</b>	6 EGAC staff and assessors capable to do real assessment on proficiency testing providers, through 1 study visits; , for 4 days each visit)	Mission report	
<b>3.4 Establish Joint assessments with EA ABs for the potential notified bodies.</b>	3 assessments presented; for 4 days each, including recommendations for improvement when necessary.	Assessment reports	
<i>Component IV: Introducing the OECD requirements against GLP to Research Study Centers:</i>			
<b>4.1 Organize Training on GLP principles &amp; requirements</b>	1 training program implemented ; for 3 days, 20-25 attendees on the updated	Training material disseminated  Training certificates	Availability of resources, suitable premises/venue

	standards for the requirements of GLP by OECD on at least two fields (pharmaceuticals & cosmetics)		
<b>4.2 Organize Workshops on GLP principles &amp; requirements</b>	2 Work shop held for 1 day on introducing the GLP principles to the stakeholders and to research centers, and 50 relevant customers & stakeholders each	Material disseminated Attendance list	
<b>4.3 Organize Training on GLP compliance assessment</b>	1 training program held for 1 day, for 20 attendees in at least two fields (pharmaceuticals & cosmetics).	Training material disseminated	Available of local resources
<b>4.4 Conduct Study visits to EA GLP accredited study centers</b>	1 study visits; 6 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit to EA ABs during real assessments on GLP compliant study centers.	Mission report	

## Annex II: Purposes for the study visits

- 1- The plan set for the trainings are realistic diagram designed to fulfill the needs required, as it gradually raises the level of transfer of the expertise from the MS agency experts to EGAC as follows:
  - a. Seminars and awareness for EGAC staff, assessors and customers of EGAC. (Conducted in Egypt).
  - b. General class room training for selected number of staff and assessors/ potential bodies. (Conducted in Egypt).
  - c. Evaluation of the potential bodies trainees. (Conducted in Egypt).
  - d. Special class room training (higher level training) for selected number of staff and assessors. (Conducted in Egypt).
  - e. Study visits to observe the MS agency during real assessments "*hands-on expertise transfer*" for a very limited number from those who have been trained on the general and specialized training. (Conducted in the MS).
  - f. Joint assessment with the MS agency experts which is "*On Job Training*". (Conducted in Egypt).
  - g. Awareness conferences for the Egyptian market on new developments in the area. (Conducted in Egypt).
  
- 2- Study visits are appropriately inserted as the best way to exchange and get detailed information, and gain experience, sharing of best practice and research, addition to understanding about different systems applied on the ground as well as drafting of comparisons/differences, exchanging different point of views, discovering and accepting other ways of seeing things and many other positive aspects.
  
- 3- As it is explained above it is steady transfer of experience from MS to EGAC and its customers for the assist in the purpose of approximation with EU rules and regulation in the related component fields. It also a step by step planning, where each step depends on the previous one. EGAC gains this gradual experience applying this approach of planning from the previous very successful twinning project, the reason behind each visit is justified in details as follows:

Component	Further Justification
<b><i>Component 1 : Introducing EA requirements for the purpose of signing EA MLA</i></b>	
<p><b>1.7 Conduct Study visits to EA ABs for EGAC Delegates</b></p> <p><b>Method:</b> After introducing EA vertical requirements, 12 EGAC delegates (staff and assessors) will be given an opportunity of a study visit to EA ABs (2</p>	<p>1- Actually the study visits of this component has been cut down to its minimum, as we have seven series of documents for the EA "European Accreditation Cooperation" that are used to run its work and the work of all the accreditation bodies ABs of the MSs.</p> <p>2- Since EGAC is an associate member of EA, but</p>



<p>study visits; 7 EGAC staff and assessors, for 4 days each visit). The possibilities of sharing experience and learning from one another with sophisticated ABs during accreditation for the right interpretation of the requirements of the operations performed (including assessments) and the results provided by the AB to agree with EA requirements.</p> <p>They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of conformity assessment and accreditation (1 day for pre-discussions and 3 days for observing full assessment).</p> <p><b>Benchmarks:</b> 2 Study visit reports (to be submitted in two weeks after the visit)</p>	<p>could not join the multi-lateral arrangement (MLA) with it yet. EGAC needs to understand the practical use of these rules in the EA ABs so that it will have the necessary experience in applying these documents.</p> <ol style="list-style-type: none"> <li>3- So the group has 7 members because each one will be responsible for gaining the experience on one of the document series.</li> <li>4- The two visits are for giving another set of the members to gain this experience and complete whatever was not gained by the 1<sup>st</sup> group.</li> </ol>
<p><b>1.6 EA Couching the experience of Technical Committees and GA</b></p> <p><b>Method:</b> EGAC 16 delegates will be couched through guided participation in the meetings of the EA organization’s general assembly’s GA that is held twice in the year (2 delegates in 2 GAs 2 day each) and the relevant technical committees (2 delegates in 4 technical committee meeting of 2 days each) about the accreditation in order to gain the required familiarity and involvement in EA processes to enable the signing of EA MLA.</p> <p><b>Benchmarks:</b> 4 technical committee minutes reports, 2 GA resolutions reports.</p>	<ol style="list-style-type: none"> <li>1- The active participation in the general assemblies of EA and its technical committees is a crucial element in EGAC's strive to join EA's MLA. This active participation requires the experience of an experienced EA AB expert who will be coaching EGAC's delegates through these meeting in order to give them the experience of how to effectively participate.</li> <li>2- This kind of experience cannot be transferred except through this kind of coaching and during the actual meetings, which are also very short in time.</li> <li>3- The active participation in these committees and these meetings is a requirement of EA to sign its MLA. It is also a step on the active participation in EA's activities; like the peer evaluation and being members in the technical committees.</li> </ol>
<p><b>Component II: Establishing and assessing the competence of the Notified Bodies in the priority sections.</b></p>	
<p><b>2.5 Conduct Study visits to EA ABs assessing notified bodies</b></p> <p><b>Methods:</b> After training on EA notified bodies</p>	<ol style="list-style-type: none"> <li>1- The notified bodies act in 3 different fields (testing, inspection, &amp; product certification) and these fields are included in the 6 priority sector chosen by Egypt</li> </ol>

<p>assessor requirements, (2 study visits; 9 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit for a real assessments of EA ABs in the six priority sectors, with the possibilities of sharing experience and learning from one another within sophisticated ABs during accreditation process and the results provided by AB in accordance with EA notified bodies requirements.</p> <p>They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of conformity assessment and accreditation (1 day for pre-discussions and 3 days for observing full assessment).</p> <p><b>Benchmarks:</b> 2 Study visit reports (to be submitted in two weeks after the visit)</p>	<p>each with a different directive. So this makes 18 different kinds of expertise.</p> <ol style="list-style-type: none"> <li>2- We have 2 visits, each one with 9 EGAC staff and assessors, so that each delegate will be responsible for gaining the experience of one of the required expertise.</li> <li>3- The training in this component as shown above is gradually increasing so that we can be sure that all the required experience transfer becomes possible.</li> </ol>
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***Component III: Establishing and Accrediting Proficiency Testing Providers***

<p><b>3.4 Conduct Study visits to EA ABs assessing notified bodies</b></p> <p><b>Methods:</b> After training on the EA proficiency testing providers assessor requirements, (1 study visits; 6 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit to EA ABs during real assessments on proficiency testing providers, with the possibilities of sharing experience and learning from one another with sophisticated ABs during accreditation and the results provided by the AB in accordance with EA proficiency testing providers requirements.</p> <p>They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of conformity assessment and accreditation (1 day for pre-discussions and 3 days for observing full assessment).</p>	<ol style="list-style-type: none"> <li>1- The proficiency testing bodies act in 6 different main testing fields (chemical, mechanical, physical, electromagnetic, environmental &amp; medical). So this makes 6 different kinds of expertise.</li> <li>2- We have 1 visit, with 6 EGAC staff and assessors, so that each delegate will be responsible for gaining the experience of one of the required expertise.</li> <li>3- The training in this component as well as the others is gradually increasing so that we can be sure that all the required experience transfer becomes possible.</li> </ol>
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<p><b>Benchmarks:</b> 1 Study visit reports (to be submitted in two weeks after the visit)</p>	
<p><b>Component IV: Introducing the OECD requirements against GLP to Research Study Centers:</b></p>	
<p><b>4.4 Conduct Study visits to EA GLP accredited study centers</b></p> <p><b>Methods:</b> After training on the GLP assessment requirements, (1 study visits; 6 EGAC staff and assessors, for 4 days each visit) will be given an opportunity of a study visit to EA ABs during real assessments on GLP compliant study centers, with the possibilities of sharing experience and learning from one another with sophisticated ABs during assessment and the results provided by the AB in accordance with GLP of OECD requirements.</p> <p>They will use a period of 4 days to get the familiarity and discuss the enforcement issues, organization and management of research centers and their assessment (1 day for pre-discussions and 3 days for observing full assessment).</p> <p><b>Benchmarks:</b> 1 Study visit reports (to be submitted in two weeks after the visit)</p>	<ol style="list-style-type: none"> <li>1- The GLP research centers act in many different research fields. So we need different kinds of expertise.</li> <li>2- We have 1 visit, with 6 EGAC staff and assessors, so that each delegate will be responsible for gaining the experience of one or more of the required expertise.</li> <li>3- The training in this component as well as the others is gradually increasing so that we can be sure that all the required experience transfer becomes possible.</li> </ol>