Activity 1.5 ME

Work in new areas

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Work methodology

Interactive management of activities between all personnel involved in this part of the project and the expert to assess the needs of MOLDAC for accreditation in the medical areas; analysis of the achieved objectives and provide effective tools to bridge the gap.

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Expert and participant presentation

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Accreditation

The accreditation process is conducted by an authoritative body against nationally and internationally recognised standards. Accreditation is the independent and impartial evaluation of an organisation competence in relation to specific activities or services.

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Role of the accreditation

1) The primary purpose of health and social care accreditation is to ensure that users of the service receive a consistent high level of care, with quality patient outcomes at its core.

2) Accreditation creates an essential framework for health and social care providers to improve their processes and environment, which stimulates continuous quality improvement to the patient experience, and results in increased confidence in the outcomes.

3) Accreditation bodies, which have been evaluated by peers as competent, sign arrangements that enhance the acceptance of accreditation of these services.

4) Organisations linked to the IAF MLA and ILAC MRA systems demonstrate a commitment to excellence, efficiency and assurance in the provision of health and social care, reinforcing the mutual international recognition of services.

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General Information

Medical areas approached to the accreditation to respect local and/or national prescription and guarantee high quality to the customers. First of all It is necessary define :

- Accreditation scope;
- Reference standards and EA/ILAC documents concerned;
- Regulatory documents
- MOLDAC documents **available** and applicable;

Accreditation scope

The scope of accreditation of a laboratory is the formal and precise statement of the activities which the laboratory is accredited for. It is as such the result of a combination of information (scope parameters) concerning the field of activity (e.g. testing, calibration), the product/object tested or calibrated and the methods and procedures used. The assessment (and reassessment) of the scope of accreditation represents the core of the accreditation process and may be defined as the set of operations carried out by the Accreditation Body in order to ensure, with an adequate degree of confidence, that the laboratory has the competence to provide reliable services within the defined scope ***(ILAC – G18:04/2010)***

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Reference Standards

- **EN ISO 17025: 2005**
- **EN ISO 13485: 2012**

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ISO 17025:2015

This International Standard specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

This International Standard is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

This International Standard is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by this International Standard, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

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EN ISO 13485:2012

Is a standard that represents the requirements for a comprehensive quality management system for the design and manufacture medical devices

Compliance with ISO 13485 is often seen as the first step in achieving compliance with European regulatory requirements. The conformity of Medical Devices and In-vitro Diagnostic Medical Device according to European Union 93/42/EEC, 90/385/EEC and 98/79/EEC must be assessed before sale is permitted.

The preferred method to prove conformity is the certification of the Quality Management System according ISO 9001 and/or ISO 13485 and ISO 14971 by a Notified Body .

The result of a positive assessment is the certificate of conformity allowing the CE mark and the permission to sell the medical device in the European Union.

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EA documents

EA-INF/01: 2015

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ILAC documents

Promotional Brochures– General ILAC brochures or promotional publications. In addition to English, several of these documents, promoting laboratory accreditation, are available in Arabic, Chinese, English, French, German, Hindi, Japanese, Korean, Persian, Portuguese, Russian and Spanish.

Guidance Documents (G- Series) – Guidance documents for accreditation bodies and accredited organisations. These guidance documents may provide information on the interpretation of accreditation criteria for specific applications.

Policy Documents (P Series)– Procedural and policy publications for the operation of the ILAC Arrangement, and which form part of the criteria for ILAC Arrangement evaluations.

Rules Documents (R Series)– Rules (Requirements) documents including the Articles and Bylaws and other documents covering the operation of ILAC as an incorporated entity. Documents in this category were previously published as S Series documents.

Joint ILAC/IAF Documents (A Series) – Joint IAF and ILAC documents used for the evaluation of regions, unaffiliated bodies and inspection bodies.

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Regulatory documents

Regional and nationals documents;

European documents:

Regulations relating to the safety and performance of medical devices in the EU were harmonised in the 1990s, following the New Approach legislative principles. The core legal framework consists of three directives:

Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)

Council Directive 93/42/EEC on Medical Devices (MDD) (1993)

Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDMD) (1998)

They aim of these Directives is to ensure a high level of protection for human health and safety and a good functioning of the Single Market. These three main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47/EC.

The original Directives have been amended several times and a consolidated version is available.

MOLDAC documents

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ACCREDIA documents

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GAP ANALYSIS

In management literature, gap analysis involves the comparison of actual performance with potential or desired performance.

If an organization does not make the best use of current resources, or forgoes investment in capital or technology, it may produce or perform below its potential. This concept is similar to an economy's being below their possibilities .

Gap analysis identifies gaps between the optimized allocation and integration of the inputs (resources), and the current allocation-level. This may reveal areas that can be improved.

Gap analysis involves determining, documenting, and approving the difference between requirements and current capabilities.

Gap analysis naturally flows from benchmarking and from other assessments. First of all it necessary to verify if it is possible to compare that expectation with the company's current level of performance.

This comparison becomes the gap analysis. Such analysis can be performed at the strategic or at the operational level of an organization.

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TO DEVELOP A BETTER PROCESS (identification of the needs)

- Identify the existing process:
- Identify the existing outcome:
- Identify the desired outcome:
- Identify the process to achieve the desired outcome:
- Identify and document the gap:
- Develop the means to fill the gap:
- Develop and prioritize requirements to bridge the gap

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Involved personnel

Technical Personnel
Administrative Personnel