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Possibility of Implementing International Standard ISO 17025 in Food Analysis Laboratories/Market Research and Consumer Protection Center/Study Case

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Abstract: **The aim of the study was to prove if it is possible to implement ISO/IEC 17025 in one of the laboratories of Market Research and Consumer Protection Center (MRCPC) at the University of Baghdad, specifically in Atomic Absorption laboratory (AA lab). Work plan has prepared under the supervision of the top management of MRCPC. Quality Management System (QMS) according to ISO/IEC 17025 has suggested establishing in AA lab, and the estimated time was calculated in two years. A diagnose of actual situation of AA lab has done by quality manager of MRCPC, both of management requirements and technical requirements have analyzed according to ISO/IEC 17025 and it reported in this work. Problems encountered are described in this work and solutions are suggested.**

Keywords: **ISO 17025, Food Analysis, Laboratories.**

1. INTRODUCTION

Universities have always played a big role to develop the country, especially in developing country, as Iraq. Universities are basically teaching and research institution aimed at qualifying human resources and producing knowledge. At Baghdad University, We also respond to the demands of society**,** interacting with other institutions and companies to reduce the gap between innovation and technological application and to make the university closer to productive sector (1).

Therefore, we are in MRCPC decided to respond these demands through the implementing of the international standard ISO 17025 in one of our laboratories, specifically in Atomic Absorption laboratory (AA lab).

Working to implement this standard led us at first, to understand ISO 17025, especially, that this subject is new starting in Iraq, there are a lot of organizations and institutions has started to introduce this standard in its organizations, so we as a higher education institution decided to be one of these organizations.

We asked ourselves, about our ability to do this work, especially that this subject need experience, how to implement this international standard, and in fact, we don't have any anterior experience, and certainly, there are some difficulties when we will start in this work, it seems to begin from zero, but we except this challenge to achieve the objectives of our university indicated anterior (2).

We thought at first to read carefully ISO 17025, and to understand its paragraphs. Quality manager is designated by the superior management of MRCPC to lead this mission.

ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. It is the basis for accreditation from an accreditation body. ISO/IEC 17025 was published in 2005. There are two main clauses in ISO/IEC 17025 – Management Requirements and Technical Requirements. Management requirements are related to the operation and effectiveness of the quality management system within the laboratory, and this clause has similar requirements to ISO

9001 (3). Technical requirements address the competence of staff; testing methodology; equipment and quality; and reporting of test and calibration results.

Analytical testing laboratories seeking ISO/IEC 17025 will be impacted in multiple areas. The main difference between good analytical practices and formal accreditation is the amount of documentation to be developed. There is no doubt that any good analytical laboratory uses qualified analysts, checks the performance of equipment used for testing, and validates analytical methods. However, many times the outcome of the tests is not fully documented. ISO/IEC 17025 accreditation requires formal documentation for nearly everything. It is similar to operating in a regulated environment – 'what is not documented is a rumor,' and is viewed by assessors as 'not being done.'(4).

2. THE ORGANIZATION (AA LAB) AND ITS STRUCTURE IN THE UNIVERSITY

Atomic Absorption laboratory (AA lab) is one of MRCPC laboratories, it was established in 2010 after the equipment (AA 7000) and its accessories have entrance in service (5). We have documented a procedure method for testing each of food and liquids samples, and it has been written to be one of the laboratory documents required to ISO 17025.

AA lab is concerned of testing chemical elements (Cd, Pb, Cu, Fe, Co, As, Ni, Cr, Hg, Ag, V, Mn, Bi, Sn, Li, Mo) by Atomic Absorption Machine model AA-7000. AA lab headed by the superior director of the center and above the supervision of the head of the Department of Evaluation of Goods and Services, laboratory hold legally responsible. The staff of the laboratory consists of 3 persons; one of them is the laboratory manager (Figure 1).

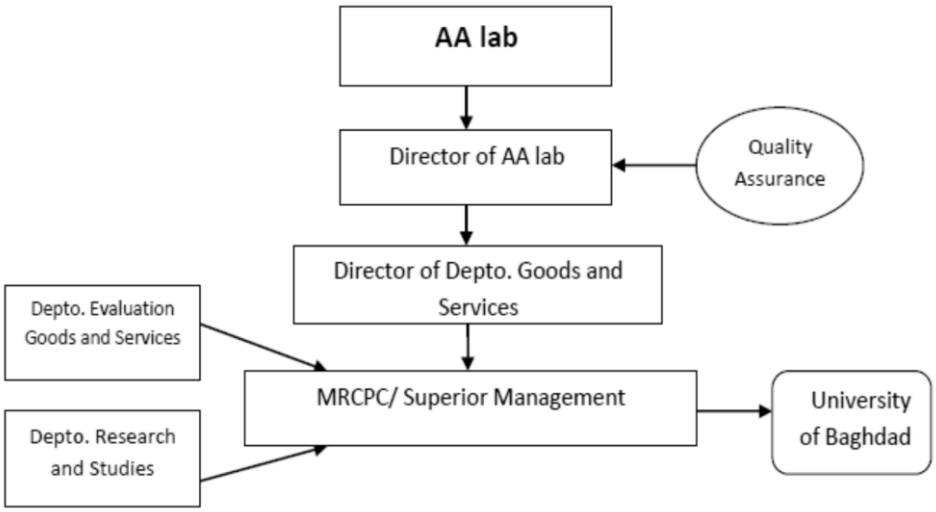

Figure 1: Organizational structure of MRCPC

3. BENEFITS OF IMPLEMENTING ISO/IEC 17025 IN AA LAB

Implementing ISO/IEC 17025 has benefits for laboratories, but the work and costs involved should be considered before proceeding. In AA lab, yet, we have not finished calculating the cost of implementing ISO 17025, and it will be done later.

Implementing ISO/IEC 17025 as part of laboratory quality initiatives provides both laboratory and business benefits such as:

• Having access to more contracts for testing and/or calibration. Some public and private organizations only give contracts to accredited laboratories. Accreditation will also help to get more contracts from organizations that don't mandate accreditation, but do give preference to accredited laboratories in competitive situations.

• Improved national and global reputation and image of the laboratory.

• Continually improving data quality and laboratory effectiveness.

• Having a basis for most other quality systems related to laboratories, such as Good Manufacturing Practices and Good Laboratory Practices.

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4. REQUIREMENTS TO IMPLEMENT ISO/IEC 17015 IN AA LAB

Beside of management requirements and technical requirements needed to implement ISO/IEC 17025 in AA lab, there are a specific requirement should be taken in account and it will be included:

• Sampling should be performed according to a sampling plan, and all sample details should be documented.

• Samples should be uniquely identified and the sample integrity should be protected during transport and storage.

• The quality of test results should be monitored.

• Test reports should include test results as well as an estimation of the overall measurement uncertainty. The report should also include either detailed information about the sample and test conditions, or a link to a reference document.

• Records should be properly maintained to ensure data integrity and availability.

Some requirements impact more and it need to do correctly:

• All analytical methods and procedures should be validated. This includes methods and procedures for sampling, testing and data evaluation.

• Equipment used for sampling and testing should be calibrated, tested, and well maintained. Material such as calibration standards should be qualified and traceable to System International (SI) units or to certified reference material. Nonconforming test results should be documented and controlled.

• People should be qualified for their assigned tasks through education, experience, or training.

• Environmental conditions such as temperature, humidity, and electromagnetic interference should be monitored and controlled.

• All routine tasks should be performed according to written procedures (6).

5. PREPARING PLAN WORK

A plan work has been prepared before starting to implement ISO 17025 in AA lab, the plan was prepared by the Quality Manager in MRCPC, and it discussed with the committee of evaluation Quality in MRCPC (quality manager, director of the laboratories and with the superior management of the center). The plan includes the following:

Rehabilitation the infrastructure of AA lab according ISO 17025:

The period suggested to achieve this work was 3 months from 2015-01-01 to 2015-03-31 and it is totally achieved. The changing of the infrastructure of the laboratory included repairing of laboratory walls, ventilation, lightning and reorganization of the laboratory equipment's.

Starting to implement ISO 17025 in AA lab:

The period suggested to realize the work will be 21 months, from 2015-04-01 to 2016-12-31, both of clause 4 and 5 of ISO 17025 has been started to implement in AA lab, our experience led us to read the international standard ISO 17025 before starting the work, and to understand all of its paragraphs, to implement it correctly. Also we proposed to explain the requirements of this standard to all of our laboratory personal staff, and specifically to AA lab personal, this subject was discussed with the laboratories director and with the superior management of MRCPC. Finally we suggested establishing a quality management system included all of the documents required in this standard. This work was designated to the quality manager of MRCPC to be the leader of this project (7).

Establishing an internal audit to check and to improve our QMS including management and technical requirements of ISO 17025:

We have suggested to put a schedule to improve periodically our QMS, this work is designated to the committee of evaluation quality in MRCPC and under the supervision of the top management, it proposed to achieve an internal audit each six months, that enable us to check, correct and to improve our work achieved during 2015 (8).

Sending an application of accreditation to the national accreditation body:

Firstly, we need to call Iraqi Accreditation System (IQAS) to realize pre-assessment to our work in AA lab. IQAS always find noncompliance in the first assessment for accreditation, and when all of IQAS assessments will finished, we can send an application for accreditation our laboratory (9).

6. DIAGNOSE OF THE ACTUAL SITUATION OF AA LAB ACCORDING TO ISO 17025

A diagnose has realized by quality manager of MRCPC, to check the actual situation of AA lab, both of management and technical requirements which are given in clause 4 and 5 of ISO 17025 are compared with what it implemented of these clauses in AA laboratory. We found that most of these requirements are presented already in AA lab, others need to develop according to ISO 17025 (table 1, 2).

Table 1: Compared of management requirements in AA lab according to ISO 17025

Clause 4: Management Requirements	
4.1. Organization	AA Laboratory
4.2. Management System	In processing (QMS) has started to establish in AA lab.
4.3. Document Control -General	Regulations and standard are presented, Measurement procedures are presented and they are specific for each of food and liquids samples. Calibration document of equipment are presented, other calibration documents are not presented and it done by other organization outside MRCPC. Drawings, software are presented. Specifications, instructions and manuals are in processing.
4.4. Review of Requests, Tenders, and Contracts	AA lab has the capability and resources to meet customer requests. Methods to be used in tests are defined, documented and understood by lab personal. Test methods selected is capable of meeting the customers, requirements.
4.5. Subcontracting of Tests and Calibrations	Normally, AA lab satisfies the test requests of postgraduate students, researchers and some of other customers. Yet, there is no subcontracting of test presented in AA lab.
4.6. Purchasing Services and Supplies	AA lab has a policy and procedures for selecting and purchasing of services and supplies, it uses that affect the quality of the tests. In AA lab there is a qualified technique lab nominated by the top director of MRCPC, realize the operations of selecting and purchasing supplies of AA lab.
4.7. Service to the Customer	AA lab has a good cooperation with his customers from postgraduate students, researchers and other customers. It gives advice to his customers concerning samples and its ideal and standard conditions. Other help or advices requested by customer will answer with transparency by lab personal.
4.8. Complaints	AA lab has a policy and procedures for the resolution of complaints received from customers. AA lab investigates all customer complaints and record that by lab personal and a corrective actions taken by the laboratory when it needed.
4.9. Control of Nonconforming Testing and/or Calibration Work	AA lab has a policy and procedures and it will be implemented when any aspect of testing or work results, do not confirm with own procedures or the agreed requirements of customers.
4.10. Improvement	AA lab will continually improve the effectiveness of the management system which is now in establishing, through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
4.11. Corrective Action	AA lab has a policy and procedure and, it designated appropriate authorities for implementing corrective when nonconforming work or departures from the policy and procedures in the management system or technical operations have been identified.
4.12. Preventive Action	Needed improvement and potential sources of nonconformities, either technical or concerning the management system have been identified in AA lab.
4.13. Control of Records	AA lab has started to establish and maintain procedures for identification,

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	collection, indexing, access, filing, storage, maintains and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.
4.14. Internal Audits	AA lab has established a schedule for internal audits of its activities to verify that its operations continue to comply with the requirements of the management system of ISO/IEC 17025. The internal audit is the responsibility of the committee of quality in MRCPC and it requested by the top management of MRCPC.
4.15. Management Reviews	The superior management of MRCPC shall periodically conduct a review of the laboratory management system and testing activities, in a accordance with a predetermined schedule, to insure their continuing suitability and effectiveness, and to introduce necessary changes or improvement.

Table 2: Compared of technical requirements in AA lab according to ISO 17025

Clause 5: Technical requirements	
5.1. General	AA lab has taken in account those factors that determine the correctness and reliability of tests and calibrations performed by a laboratory: human factors, accommodation and environmental conditions, test and calibration methods and methods of validation, equipment, measurement traceability, sampling and the handling of test and calibration items.
5.2. Personnel	AA lab is ensured of the competence of all personal who operate in the equipment (AA 7000) and perform tests and calibration in this lab, evaluate test results, and sign test and calibration reports. Periodically training concerning ISO 17025 has suggested by quality manager to all lab personal.
5.3. Accommodation and Environmental Conditions	AA lab has prepared all environmental conditions to facilitate correct performance of the tests and calibration, included sampling conditions.
5.4. Test and Calibration Methods and Validation Method	AA lab has a standard method used for testing food and has another method used for testing liquids, both methods are documented and available for personal lab. AA lab has also use instructions of equipment documented and available to personal lab.
5.5. Equipment	AA lab has furnished with all items of sampling, measurement and test equipment required for the correct performance of tests and calibration (including sampling, preparation of test and calibration items, processing and analysis of test and calibration data.
5.6. Measurement Traceability	All equipment used for test, including equipment for subsidiary measurement (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test or sampling has calibrated before being put into service. AA labs have established program and procedure for the calibration of its equipment.
5.7. Sampling	AA lab has a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing. The sampling plan as well as the sampling procedure is available at the location where sampling is undertaken. The sampling processes address the factors to be controlled to ensure the validity of the test and calibration results.
5.8. Handling Test and Calibration Items	AA lab have procedures for the transportation, receipt, handling, protection, storage, retention and disposal of test items, including all provisions necessary to protect the integrity of the test item, and to protect the interests of the laboratory and the consumer.
5.9. Assuring the Quality of Test and Calibration Results	AA lab has quality control procedures for monitoring the validity of tests undertaken. Results data is recorded in such a way that trends are detectable, where practicable, statistical techniques are applied for reviewing of the results.
5.10. Reporting of Results	AA lab reported accurately, clearly and objectively the results of each test undertaken in the lab. The results reported in a test report, including all of the information requested by the consumer and necessary for the interpretation of the test results and all information required by the method used.

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7. ESTABLISHING QUALITY MANAGEMENT SYSTEM FOR AA LAB

At Baghdad University, and specifically in AA lab / MRCPC, the establishing of Quality Management System (QMS) faced problems from the beginning, these problems due to university structure, activities and functions (e.g. the functions and responsibilities of the technical staff, which are usually varied and diffuse).

Important factor for a successful QMS includes, the acceptance and commitment by the laboratory staff beside the superior management, we noticed that our management has accepted the new change that we want to achieve, but we need an extensive training of ISO 17025 to the laboratory staff, to enable them to understand and to implement this standard correctly.

Implementing of QMS in AA lab in the university is different from doing it in those laboratories that basically provide services, and it is considered a difficult task. The provision of testing services is not a priority in the university environments, the staff performance is commonly measured based on their teaching activities and publication, and the laboratories are shared with the research and teaching activities (10).

8. PRELIMINARY ASSESSMENTS OF QMS

AA lab may request a preliminary assessment from an accreditation body, or dry-run assessment of its laboratory quality management system, prior to the accreditation assessment. In our case we suggested to contact with Iraqi Accreditation System (IQAS), This will give the accreditation body an opportunity to identify, in advance, any weaknesses that may exist in our laboratory management system.

During the preliminary assessment, IQAS will send an assessment team to our laboratory. The team, composed of competent assessors, will assess AA lab, management system, records and other documentation, alerting us to any concerns that may interfere with a successful accreditation assessment.

The main advantage of a preliminary assessment that, it allows to AA lab to correct any potential problems before the accreditation assessment begins. But we should remember that a preliminary assessment is not required for ISO/IEC 17025 accreditation. It is strictly optional, depending upon of laboratory need.

While a preliminary assessment is optional, it is recommended. In the long run, it can save time and money by revealing deficiencies or nonconformities that, if corrected before the accreditation assessment, can save the expense of follow-up actions (11).

9. PREPARING FOR ACCREDITATION

AA lab will be ready for accreditation after the implementing of ISO/IEC 17025 included quality management system which will be achieved as it mentioned in the plan work, documentation should include the following:

Quality Manual: Outlining how AA laboratory conforms to the standard;

Procedures: Describing how the system functions;

Work Instructions: Defining specific job activities affecting the quality of calibration or testing;

Quality Documentation: Documents, which explain how quality will be, managed for individual calibration or testing projects or contracts, as well as other types of specific documents;

Quality Records: Various records including charts, files, inspection and testing records, assessment results, and any other records of objective evidence.

10. PROBLEMS AND SOLUTIONS DURING THE IMPLEMENTATION OF ISO 17025 IN AA LAB

The first problem we faced, that in research center such as MRCPC and at the university, the staff have various duties, it divided between research, teaching and another duties, this matter makes that the personals concerned in the subject of implementing ISO 17025 in the laboratory, have not enough time to develop the work quickly and to implement the standard in a good time (12). In others organizations, when it decided to implement a quality standard e.g. ISO 9001 or

ISO 17025, there is a specific department related of implementing the quality, consist of personals that are good qualified and trained in quality issues.

At MRCPC, we designated one person to be the quality manager to achieve this job, beside his other duties. This matter will not prevent us to achieve the work, but the work will do slowly. Certainly it takes time to write e.g. quality manual, standard procedures and other work instructions and documents. We suggested to the superior management of MRCPC to collaborate with other organization such as Center of Standardization and Quality Control-Ministry of Planning, Iraq (COSQC) to help us to achieve this work. The superior management has accepted that, but there are problems concerning the cost of hiring qualified personals to check and prove our work, it costs money to pay to hiring personals and yet we do not have any finance resource to do that.

We have a plan to contact with our university to finance this project, because the cost of implementing a QMS according ISO 17025 and its requirements, cannot achieve only with our efforts, it is a nested work requires efforts of more than one hand plus economic finance.

11. RESULTS AND CONCLUSIONS

A diagnose of actual situation of AA lab has done by quality manager of MRCPC to check and to prove that what is our laboratory (AA lab) towards ISO 17025 , both of management requirements and technical requirements have analyzed according to ISO/IEC 17025 and the results reported in this work (table 1 and table 2). Most of conditions given in clause 4 and 5 of ISO 17025 are implemented already in AA lab, others need to develop, so it is possible to implement ISO 17025 and to have the accreditation of AA lab in the indicated time.

Management system policy related to quality has been issued under the authority of top management. QMS and its documents is starting to write (Quality Manuel, Procedures and instructions). All documents will be communicated, available, understood and implemented by laboratory personal when it will be finished proximally in the end of 2016.

The cost of implementation of ISO 17025 is needed to study seriously; we proposed to have the finance from Baghdad University for completing our work and having the accreditation of AA lab.

Efforts from more than one hand are needed for establishing effective quality management system (QMS) in the atomic absorption laboratory (AA lab), in our plan work we need 2 years to the end of 2016 for completing our QMS included personal lab training.

Cooperation with other organizations put into our account, we are looking for cooperation with IQAS to help us in the subject of accreditation, we will apply that, in continuing with establishing our QMS implemented in AA lab.

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