Unclassified

(2015)

Organization for Economic Co-operation and Development 21-Dec-2015

According to criteria of OECD ON
TESTING AND CALIBRATION
Number 1
GUIDANCE DOCUMENT FOR GOOD IRAQI LAB –HIGHER EDUCATION

GUIDANCE DOCUMENT ON IRAQI GLP

GLP

FOR IRAQI LAB
BAGHDAD -DEC. 2015

Content

Preface:

One of the supervision and the scientific evaluation directorate duties is to build a quality standards based on international standards to improve the educational process in public and private universities and colleges. In line with the mentioned above, The laboratory accreditation department has formed a committee of specialized academic staff responsible for putting Iraqi good laboratory practice (IGLP), based on the requirements of the (OECD) in order to enhance the level of the laboratories of the educational institutions.

1. Scope

Principles of IRAQI GOOD LABORATORY PRACTICE (IRAQI GLP) should apply to non-clinical safety testing of test items contained in pharmaceutical products, cosmetic products, veterinary drugs, food and feed additives, and industrial chemicals.

These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms.

The responsibilities of a test items are to obtain data on their properties and /or their safety with respect to human health and / or environment.

It is possible to apply all standards and requirements, which are concerning good laboratory in field of educational laboratories for improving the educational product of student's quality according to the customer's satisfaction and the requirements of the labor market.

2. The aim of GLP

The aim of GLP principles is to promote the development of quality test data, i.e.: there is a Quality Assurance program that the quality assurance responsibility is being performed in compliance with of GLP principles. In addition to that, comparable quality of test data forms is the basis for the mutual acceptance of data among countries and the measure certainly applies to the development and improvement of educational laboratories in scientific universities.

3. Definitions of Terms

5.1 ***Good Laboratory Practice (GLP)***

Is a quality system concerned with the organizational process and conditions of non-clinical health and environmental safety studies which are planned, performed, monitored, recorded, monitored, archived and reported.

3.2 ***Test Facility***

Staff, premises and operational units those are necessary for conducting the non-clinical health and environmental safety.

Multi –site studies: which are conducted at more than one site.

3.3 ***Test site***

Defined as all locations of study, which a phase is conducted.

3.4 ***Test facility management***

Staff who have the authority and formal responsibility for the organization and functioning of the test facility according to GLP.

3.5 ***Sponsor***

Is an entity which commissions, supports and/or submits a non –clinical health and environmental safety study.

3.6 Study Director

Is the individual responsible for overall conduct of non-clinical health and environmental safety study.

3.7 ***Principal Investigator***

Defined as an individual, for a multi –site study, acts on behalf of the study Director. He has defined responsibility for delegated phases of the study.

3.8 ***Quality Assurance Program***

Is "a defined system", including personal, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.

3.9 ***Standard Operating Procedures (SOPs)***

Is document of procedures, which describe how to perform tests or activities. Normally, is not specified in detail in study plans or test guidelines

3.10 ***Master schedule***

Is a compilation of information to assist in the assessment of workload and for the tracking of studies at test facility.

3.11 ***Test item***

It is an article of study subject.

3.12 ***Reference Item***

Defined as an article used to provide the basis for comparison with test item.

3.13 ***Batch***

Defined as a specific quantity /or many test item/ or reference item which is produced through a cycle of manufacture. It could be expected as designated uniform character.

3.14 ***Vehicle***

Defined as any agent, which serves as a carrier used for mixing .In addition to disperse the test item or facilitate the administration /application to the test system.

4. The benefits of "good laboratory practices" (GLP)

1. Improve the level of educational laboratories.
2. Increase the confidence in the test and measurement results.
3. Increase the confidence of the educational institution administration in the quality of the educational performance of their product.
4. Adjust the corresponding procedure is not for calibration or testing through the procedural way of corrective action and preventive action.
5. Achieve continuous development and improvement.

5. The clauses of GLP:

5.1. The first clause (Organization and personify)

***Include*:** administration, responsibilities, undertaking, studies, research, Workers, leadership laboratory, customer satisfaction, build the capacity of workers to take responsibility *must apply the following standards*.

Standard:

1. Identify tasks, duties, responsibilities, powers (i.e.: job description) and strictly of staff in laboratory. Those data be documented and declare.
2. Laboratory quality checks policy placed including the role and responsibilities of all employees towards quality results. Customer satisfaction should be declared for Lab entrances.
3. Laboratory administration announces its pledge before the Supreme Administrative authorities and the beneficiary in the educational institution in the investigation to ensure the quality of training for students and that the documents and declare the pledge.
4. Pledge includes the ability of the laboratory management to secure all the requirements of good laboratory practice in the effectiveness of the laboratory and activate the scientific procedures according to requirements OF GLP standards.
5. Be best scientific practices and selected by the laboratory management, according to accurate study.
6. Identification the principles using the laboratory management in quality control through laboratory tests, implementation, monitoring, recording and archiving.
7. Laboratory management vision, mission and goals of laboratories with common goals made in accordance with the jurisdiction.
8. Administrative structure to identify and laboratory quality management representative and the location of the laboratory of the educational system

5.2. The second clause (Quality Assurance Program)

Include: Individuals responsible for quality assurance, Training, Accuracy, Self-Assessment, and Audit ***must apply the following standards***.

Standard:

1. Laboratory Department is working to develop an effective plan for self-assessment and analysis of the results of effects.
2. Plan placed semi-annual comprehensive internal audit of the program in the procedures and practices laboratory / lab.
3. Personnel training strictly to apply the set requirements and quality assurance in the laboratory and all laboratory practices.
4. Play an active role managing the lab to monitor the analytical results “incorrect”, and then put corrective measures in addition to its commitment to the development and application management system to achieve improvement.
5. Laboratory administration working to be a program of the daily work with systematic and structured to achieve technical competence in performing practices, tasks and functions assigned to workers and referred to the distribution of rules and responsibilities in the quality manual.

6. Activating the conducting review of laboratory within a half-yearly: which determine the deviations in performance to reach the development in their actions, solutions and processing. Audit report included Development and improvement in performance of safety of Lab when there is a change in planning, implementing and management.

5.3. The third clause (Facilities)

Include: Safety measures and Environmental, Infrastructure, Personal protective equipment, Collective protection systems infrastructure requirements, Laboratory Standards ***must apply the following standards***.

Standard:

1. Lock individual protection kits for students in the laboratory and trained to use them.
2. Life insurance protection organizations of good ventilation, lighting, grounding ground, fire alarm system, sensors, self-extinguishing and according to the characteristics of the laboratory and into its programs and Severity.
3. Guidance signs and warning safety laboratory placed inside and outside the laboratory to raise awareness of the risks.
4. Secure first aid and guidance in emergency situations when dealing with chemical risk or physical risk, Biologic risk, mechanical or electric risk.
5. Ensure sufficient space in laboratory design in terms of the number of students and laboratory experiments and is designed in accordance with the National Standards stated in the Ministry of Higher Education and Scientific Research.
6. Training of laboratory personnel and supervisors on the use of fire, and according to the characteristics and the area of use.
7. Be containers of the closed type and there is a program to remove its contents after each exercise laboratory actual day.
8. To ensure that the maintenance of ventilation systems and lighting program according to the degree of risk or laboratory setting a timetable for the maintenance of Prevention and treatment.
9. Laboratory is divided into reception models and analyzes laboratory room and another room.

5.4. The fourth clause (Equipment, Reagents and Materials)

Include: Hardware, standard solutions, laboratory materials, Calibration, storage, encoding system ***must apply the following standards***.

Standard:

1. Encoding instruments and equipment and record all the required data such as (the manufacturer, year of manufacture, company name ... etc).
2. Placed timetable for calibration of instruments and laboratory equipment.
3. Own with instruments and equipment for the program to build a central database on a laboratory level data subject.
4. Stored laboratory chemicals and biological materials in accordance with the storage system and the world are chemicals and biological coding system according to (NEPA) American's system for protection from fires and accidents.
5. Reservation standard solutions in accordance with the conditions record set in the driver setups and calibration requirements (catalogs) and within the specified degrees of heat.

6. Is secured to maintain instruments after conducting scientific practices and methods according to the chosen style catalogs saved.
7. Standard solutions, coding, and taking into account what determines the dates of their powers.

5.5. The fifth clause (Test Systems)

Include: Physical Sciences, chemical, Biological, Construction, Engineering, Tests, Chemical tests, Physical tests, Biological tests, Laboratory experiments, Construction engineering tests ***must apply the following standards***.

Standard:

1. Evaluation of methods of work in the examination and testing and its provisions.
2. Conduct laboratory experiments to determine accurately the conditions of the requirements.
3. Train employees on laboratory practices are accurately and efficiently test Aladah understanding and documenting performance results.
4. Takes care of minute actions in modeling and coding style and methods of sampling and down to the tests.
5. Ensure the cleanliness of the machinery and equipment, glassware and concentrations of solutions and the area of its kind and used carefully.
6. From time to time test specifications and their impact on the quality of the results.
7. Insurance fully tests methods and methods of alternative tests.
8. Identification within the scientific audit reports within the most appropriate way to be selected to simulate a practical way and using other methods of laboratory results in accuracy in comparison.
9. Be sure of the validity of the standard solutions and solutions within specific concentrations prepared to conduct experiments, as well as survey samples and transplantation procedures in accordance with the specific controls in ways t0 that laboratory examination.

5.6. The Sixth clause (Test and Reference item)

Include: Modeling, Environmental conditions of standard sample, Calibration, Choices, Overall risk, Controls and inspection instructions and calibration, procedures ***must apply the following standards***.

Standard:

1. The laboratory has a clear policy and procedures for scientific testing or calibration and be specific responsibilities and powers at work and that the administration be subject to the evaluation of the procedure.
2. In the case of non-conforming action is applied to adjust the corrective action and re-work the experience of new and implementation of the evaluation to measure and identify possible sources in the reasons for non-conformity.
3. Laboratory administration is working to implement preventive action after all corrective action to prevent potential sources of non-conformity occur in the future and that preventive action be available for those working in the laboratory to raise the level of student performance. 4. Uses laboratory methods and procedures for all tests / calibrations within the scope of work (modeling, trading, transportation, storage, destroyed).

5. Insurance scientific procedures and in particular training for supervisors and associate in the laboratory and improve the efficiency of the performance of reduction of various risks to students.
6. includes good laboratory facilities (the correct performance of the tests and calibrations, including the modeling process and the tests and calibrations) in other sites of educational institutions.

7. Laboratory Department monitors and controls the environmental conditions such as sterilization, dust, gases and radiation, humidity, heat and noise and vibrations during a laboratory practices by students in the important part of the standards of good laboratory.

5.7. The seventh clause (standard operating procedures):

Include: standard operating procedures, Application, Transparency, Results, standard solution for calibration ***must apply the following standards***.

Standard:

1. The selection and laboratory screening and review operating procedures periodically in accordance with the accreditation of good laboratory requirements.
2. Can be locked and determine the environmental conditions and safety through the implementation of laboratory practices by the management of the laboratory for students.
3. Laboratory practices (operating procedures) and easy to apply, transparent and understandable for students in work steps and the achievement of results and goals.
4. Laboratory practices are considered an essential part of the program and practical course within the scientific aspect of the students.
5. Depends on the Standard solutions for calibration of instruments before starting on a laboratory practices by students.
6. Documented observations and negative indicators through executive action by the students and the development of preventive and corrective actions to prevent their occurrence.

5.8. The Eighth clause (performance of study)

Include: Data, Procedures, Results, Requirements, Plans, Events, Targets ***must apply the following standards***.

Standard:

1. Placed an annual plan to evaluate the performance of employees in laboratories and activity.
2. There are laws and instructed in the field of evaluating the performance and equalization of opportunities for Student in the laboratory and be disciplined performance requirement strongly binding instructions.
3. Laboratory management looking for performance evaluation program as a means to raise the efficiency of workers and supervisors within the laboratory to give a good opportunity to excel and take advantage of the opportunity to quality performance to satisfy the needs and wishes of the students as one of the goals of the laboratory management in the application of quality management system.
4. Evaluation and study performance are objectively and fully to build a base corrective actions to coincide with the type and size of the negative indicators and the obstacles so as not to represent a deficiency in the implementation of the duties and activities (laboratory practices).

5. There are specific criteria and minute competent in evaluating the performance of the activity in Lab as well as its employees and care about future trends for the development of performance evaluation system.

5.9. Ninth clause (Report of Results)

Include: Audit, Calibration, Self Assessment, Performance, Information, Results, Tests, Deviations ***must apply the following standards***.

Standard:

1. Our laboratory procedures and to adjust the appropriate facilities and avoid the error in the results of the test and inspection and calibration or during data recording and operations and results.
2. Laboratory Department is working on the calendar uncertainty in the results.
3. Laboratory Department is working on an analysis of data and a set of documents and the corrective action on the results is identical or unacceptable.
4. For purpose of the laboratory results management in a transparent and clear and unambiguous and objectively in accordance with the instructions of the instruction and management of the institution in the relevant test methods and inspection and calibrated and the results included in the report.
5. Recording and documenting deviations in the results or the exceptions and determine the reasons for the screening method or modeling or testing or calibration.
6. Design of results report and certificates, should be designed for each type of test and calibration or already executed.
7. Comparison of results obtained with the methods of other practices.
8. Laboratory management conducting the formal Calendar of factors indicator in the results.

5.10. Tenth clause(archival -storage of records and reports)

Include: Control of documents, Control of Records, Review reports, Audit reports, Reports Results, instructions, Criteria, Legislation or reference documents, Test methods, Evidence Quality ***must apply the following standards***.

Standard:

1. Implemented laboratory management procedural way to control of the legal and technical documentation and reference and the evidence and reports of all kinds.
2. Laboratory management carry out method procedural to set seven records in accordance with the specific requirements of the standards (GLP).
3. Laboratory management is working on the periodic review of the documents and marking the important ones and take action and solutions for the development and improvement.
4. Laboratory management decent on uses tamps colored according to special technical contexts release documents and draft documents and cancellations to characterize the documents and achieve quality performance in use.

6. Procedural modalities required for good laboratory practices (GLP)

First . Administrative procedural methods

1. Corrective action.
2. Preventive action.
3. Adjust the records and documents.
4. Internal Audit.
5. Management Review.

Second . Technical procedural methods

1. General requirements.
2. Workers in the laboratory / training.
3. Equipment and environmental conditions.
4. Test and calibration methods and make sure it is correct.
5. Setup.

Thirdly. The evidence required

1. Test methods and test any laboratory practices guide
2. Working instruction manual.
3. Procedures Guide.
4. Quality manual

7. Set Records:

NO:	Build of records	Which does not exceed
1	Record set documents	Seven years
2	Record set internal audit (audits)	Ten years
3	Record set Calibration	By the operational life of the device
4	Record set setups	Twenty years
5	Record set Training	Five years
6	Adjust the periodic reviews scored	Five years
7	Corrective action record set	Five years

8. Data Weights

- Number of clauses = 10
- Number of standards = 71
- Weights of administrative requirements = 45%
- Weights of technical requirements = 55%

One criterion of value out of weight of 100% = 1,408

Table of weight:

No:	Clause	Weight	Standard
1	First	8 × 1,408 = 11,264 ≈ 11,000	Administrative
2	Second	6 × 1,408 = 8,448 ≈ 8,000	Administrative
3	Third	9 × 1,408 = 12,672 ≈ 13,000	Administrative
4	Fourth	7 × 1,408 = 9,8568 ≈ 10,000	Technician
5	Fifth	9 × 1,408 = 12,672 ≈ 13,000	Technician
6	Sixth	7 × 1,408 = 9,8568 ≈ 10,000	Technician
7	Seven	6 × 1,408 = 8,448 ≈ 8,000	Technician
8	Eight	5 × 1,408 = 7,04 ≈ 7,000	Administrative
9	Nine	10 × 1,408 = 14,08 ≈ 14,000	Technician
10	Tenth	4 × 1,408 = 5,632 ≈ 6,000	Administrative
Summation		100%	