

Conference Paper

Basic Requirements of Laboratory Operation for Halal Analysis

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Abstract

Analysis of halal food requires that the laboratories conductive the tests adhere to international guidelines and standards. Common worldwide guidelines and standards for laboratory include the 'International Organization for Standardization 17025' (ISO 17025), the 'Good Manufacturing Practice' (GMP), and 'Good Laboratory Practice' (GLP). In halal analysis, the laboratory shall comply with ISO 17025, GMP, and 'Good Hygiene Practice' (GHP) as stated in the 'Manual Procedure for Malaysia Halal Certification' (MPPHM). This article discusses the basic requirements for laboratory practises, specifically for halal analysis. The study compares these international guidelines with 'Malaysia Halal Standards' to demonstrate that these international standards are combined with Islamic practices to produce valid test results using globally recognized best-practices. This promotes confidence in the halal laboratory's work both nationally and internationally, and will thus improve international trade.

Keywords: Halal analysis, ISO 17025, GMP, GLP, laboratory operation.

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1. Introduction

A laboratory can be defined as a controlled room or building in which scientific equipment are equipped to perform an experiment, research, analysis, calibration, or measurement. The laboratory is responsible for analyzing samples to detect, identify, and quantify contaminant; as well as for analyzing specimens in food-borne illness outbreaks [1]. In halal analysis, most of the analytical methods are currently focused on porcine DNA detection and alcohol content. The analysis must be carried out at recognized laboratories which are usually accredited based on 'International Organization for Standardization 17025' (ISO 17025) [2].

As one of the key players in the global halal industry, the current recognized Malaysia halal laboratories are laboratories under the Department of Chemistry, Ministry of Health's laboratories, the one-stop center halal laboratory known as 'Malaysia Halal Analysis Center' (MyHAC), and lastly 'Halal Panel Laboratory' appointed by Department of Islamic Development Malaysia (JAKIM) [1]. Whether the halal laboratory is for business

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or work for a government, its operation is totally depending on international guideline and standard to ensure the validity of the test result. Moreover, all the practices of international guideline and standard promote confidence, traceability, and cooperation between laboratories as well as other bodies, to call for a wider acceptance of test results between countries.

Instances for international guideline and standard for laboratory operation are various [3, 4], but the most common and related to the laboratory are 'Good Laboratory Practice' (GLP) [5–7], 'Good Manufacturing Practice' (GMP) [3, 8, 9], and 'International Organization for Standardization 17025' (ISO 17025) [10]. GLP is more convenient as it does not depend on laboratory specific functions, but a common practice that a laboratory should have. GMP is more applicable for manufacturing laboratory to ensure the quality and integrity of produced products according to quality standards. Generally, GMP covers:

1. Salient element of hygiene;
2. Handling of equipment which covers 'Design Qualification' (DQ), 'Installation Qualification' (IQ), 'Operational Qualification' (OQ), and 'Performance Qualification' (PQ);
3. Facility of premises, for instances designated area and ventilation system;
4. Personnel practices and competency;
5. Cleaning practices, for instances scheduled waste, spillage, and contamination;
6. Document practices.

Another international standard such as ISO 17025 is specifically for testing and calibration laboratory. There is a similarity in term of practices between GLP, GMP, and ISO 17025; however, the ISO 17025 is more stringent. By practicing the ISO 17025, the laboratory operation shall cover:

1. Laboratory Policies such as impartiality and confidentiality;
2. Organization structure that explains the relationship between management, technical operation, and support service;
3. Resources, for instances personnel, facilities, and equipment;
4. Processing system, for instances receiving and handling sample, technical report, handling complaint, nonconforming work, and reporting;
5. Management system, for instances control of records and documents, action and risk assessment, corrective action, audits, and management reviews.

If the laboratory operates with specific functions, for instance, finished drug products, the ‘United States Pharmacopeia’ (USP), ‘British Pharmacopeia’ (BP), or ‘Japanese Pharmacopeia’ (JP) are those relevant guidelines for the laboratory operation, specifically on analytical procedures [3].

In a case of halal laboratory, there 15 Malaysia Standards pertaining to halal [11]. Malaysian Halal Standards have been recognized internationally and have gained trust from countries of the Organization of Islamic Cooperation (OIC) as the leading halal standard among Muslim countries [12]. Table 1 shows the list of Malaysia Halal Standards:

TABLE 1: List of Malaysia Halal Standards.

No.	Document Title	Code
1	Halal Food – General Requirements	MS1500:2019
2	Halal Pharmaceuticals - General Guidelines	MS 2424:2012
3	Halal Cosmetic - General Guidelines (First Revision)	MS 2634:2019
4	Islamic Consumer Goods - Part 2: Usage of Animal Bone, Skin and Hair – General Guidelines	MS 2200-2:2012
5	Halal Supply Chain Management System - Part 1: Transportation - General Requirements (First Revision)	MS 2400-1:2019
6	Halal Supply Chain Management System - Part 2: Warehousing - General Requirements (First Revision)	MS 2400-2:2019
7	Halal Supply Chain Management System - Part 3: Retailing - General Requirements (First Revision)	MS 2400-3:2019
8	Quality Management Systems - Requirements from Islamic Perspectives	MS 1900:2005
9	Shariah-Based Quality Management Systems - Requirements with Guidance (First Revision)	MS 1900:2014
10	Value-Based Management System - Requirements from An Islamic Perspective	MS 2300:2009
11	Islamic And Halal Principles - Definitions and Interpretations on Terminology	MS 2393: 2013
12	Halal Packaging - General Guidelines	MS 2565: 2014
13	Halal Chemicals for Use in Potable Water Treatment - General Guidelines	MS 2594:2015
14	Muslim Friendly Hospitality Services – Requirements	MS 2610:2015
15	Detection of Porcine DNA - Test Method - Food and Food Products	MS 2627:2017

The main objective of standardization is to ensure everyone adheres to the same procedures or product specifications, which in return facilitate logistical procedures, trade, prevent consumer deception, and improve product quality. By that, halal laboratory must follow standard sampling procedures that conforms to the standard protocol according to ISO 17025 accreditation and must be carried out by qualified personnel in the dedicated and well-equipped laboratory [1]. Unfortunately, none of the Malaysia Halal Standards can be used as a guideline for halal laboratory operation; however, the related guideline to the halal laboratory operation is stated in the ‘Manual Procedure for Malaysia Halal Certification’ (MPPHM) as follow:

'9.3 Sampling, iv. The laboratory analysis shall be carried out at government laboratories which are accredited based on ISO/ IEC 17025 for the related analytical scope. Currently, the laboratory under the Department of Chemistry Malaysia is the official laboratory for Malaysia Halal Certification.' [2].

Generally, there are various standards and practices that may suit different laboratory needs. In this regard, the objective of this paper is to explain the basic requirement for halal laboratory operation which covers facility and environment of laboratory, handling of equipment, personnel, and good document practice based on the GLP, GMP, and ISO 17025. Details of these three international guidelines and standards can be referred to the original documents or official website.

2. Methodology

This study used a library study that collects information which are relevant to the research objective. Instances of library study are reference to authoritative sources of standards and guidelines (such as MPPHM and ISO 17025), journals, and websites to obtain information related to the study. This paper also reviews available documents as stated in Table 1 for basic laboratory operation, which comply with the need to conduct halal analysis.

3. Facility and Environmental Condition of Halal Laboratory

According to GLP, GMP, and ISO 17025 standard, the facility and environmental condition of the halal laboratory must be properly designed for its intended purpose [5, 8, 10]. Instances for the factors are, but not limited to, microbial contamination, dust, electromagnetic disturbance, radiation, humidity, electrical supply, temperature, sound, and vibration [10]. In this case, the halal laboratory shall be well-designed by considering the location of designated areas such as separation of species or test items, quarantine of animals, routine or specialized equipment room, safe sanitary storage of waste, bedding, supplies, storage, and equipment [6].

For instance, in the case of genomic and proteomic laboratory, contamination area shall be at the edge of the halal laboratory to prevent the hazardous chemicals from contaminating the entire halal laboratory. This contamination area shall be closed to the preparation area to ease experimental activity. However, for tissue culture laboratory, the preparation area shall be isolated and equipped with an air blower cabinet at

the entrance to prevent contamination. Therefore, there is no specific design for halal laboratory as each laboratory depends on its function. The layout and design are subjective as long as the position of each designated area is appropriately justified.

The specialized equipment room is indirectly covered in the GLP, GMP and ISO 17025. This area is dedicated to high-end equipment such as liquid chromatography-mass spectrometry (LCMS), high performance liquid chromatography (HPLC), and gas chromatography-mass spectrometry (GCMS). These equipment require specific controlled room temperature, usually around $21 \pm 2^\circ\text{C}$ with low humidity around $65 \pm 5\%$. The controlled room condition is required for heat-generated equipment such as LCMS, GCMS, chiller, freezer, oven, etc.

Moreover, proper ventilation is crucial as equipment such as LCMS and GCMS may produce hazardous gases during operation. For mass spectrometer equipment (LCMS and GCMS), those machines operate with turbo pump to achieve high vacuum condition inside the equipment; hence dedicated ventilation is required for the equipment. Another function of the specialized equipment room is to protect an analyst from an indirect hazard such as the irritating sound produced by equipment such as LCMS, GCMS, chiller, and freezer.

4. Handling of Equipment

In order to produce reliable test results, equipment shall be qualified and the person in charge shall be well-trained. The personnel factor will be covered in section **4. Personnel** in detail. Generally, analytical equipment qualification consists of four procedures of GMP namely, Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) [9, 13]. Equipment qualification is a documented evidence that an instrument performs suitably for its intended purpose, and properly maintained as well as calibrated. Each stage for the qualification of equipment (DQ, IQ, OQ, PQ) has its own timing and applicability with common activities as well.

4.1. Design Qualification, (DQ).

The DQ is an initial step for equipment qualification in which the particular requirement related to the specifications of equipment is achieved between supplier and halal laboratory. The specification should define the capabilities (e.g. capacity, speed, temperature

range, etc.), requirement (e.g. size and electrical power), and additional features of the equipment.

Timing and applicability: Before purchasing a new type of equipment.

Common activities of DQ:

1. Assurance from a vendor.
2. Assurance from manufacturer.
3. Document checking for instrument's specification.

4.2. Installation Qualification, (IQ).

The IQ ensures that the equipment is properly installed and documented. There are several documents that should be documented and attached as appropriate such as purchased order, equipment manuals, equipment drawings (specification), unit verification, preventive maintenance verification, standard operating procedure verification, calibration report, electrical requirement, and spare parts.

Timing and applicability: During installation of equipment.

Common activities of IQ:

1. Checking installation location and floor space.
2. Checking power, gas supply, and other energy resources.
3. Checking utility, facility, and environment.
4. Checking network and data storage.
5. Assembly and installation.
6. Verifying connections and communications with peripheral units
7. Installation verification.
8. Gathering all manuals and certificates of conformity.

4.3. Operational Qualification, (OQ).

The OQ is performed to test that the equipment operates in accordance with the manufacturer's specification and as per halal laboratory requirement. All the equipment's

items are tested individually, and their performance is documented. The test parameter is various depending on the equipment.

Timing and applicability: After installation or major repair of equipment.

Common activities of OQ:

1. Checking display units and signaling LEDs.
2. Checking temperature controls, fluctuations, alarms, and protection systems.
3. Pressure or vacuum controlling system.
4. Fan and fan speed controller.
5. Card readers and access controller.

4.4. Performance Qualification, (PQ).

The PQ is the final step for equipment qualification procedure. Rather than testing each individual item as in OQ, all items of the equipment are tested together through a certain process and the performance is documented.

Timing and applicability: After installation and periodically at specified interval.

Common activities of PQ:

1. Performing preventive maintenance and repair.
2. Preparing Standard Operating Procedure (SOP) for equipment operation, calibration, maintenance, and acceptance criteria.
3. Performing performance check by using calibrant or universal chemical standard.

4.5. Preventive Maintenance and Calibration

Most of the regulatory authorities such as the Food and Drug Administration (FDA) require the laboratory to maintain their equipment [5, 6]. It is mandatory to perform timely calibration program as well as preventive maintenance (PM). These activities keep the equipment working in optimum condition and extending the shelf life to ensure the best performance of the equipment.

Calibration can be defined as standard operations to verify the data or value obtained from the equipment by comparing with traceable standard materials. The calibration detects and reports the equipment's error and does not involve any adjustment. Information from calibration helps analyst to make an adjustment of data or value to true

value after being compared to the traceable standard. Table 2 shows the common equipment in halal laboratory that need calibration. All calibration periods suggested are subjected to respective manufacturer or equipment manual.

TABLE 2: Guideline for calibration of equipment used on a halal laboratory.

Equipment	External calibration period	Internal calibration period	Parameter to check
Water purification	Yearly	Weekly	Conductivity and pH
Micro-pipette	3 years	Every 3 months	Volume accuracy
Balance	3 years	Weekly	Zero-point, accuracy, level
Freezer	3 years	Daily	Visual, thermal stability
HPLC	Yearly	Not related	Injection volume, flow rate, column temperature, pump pressure, autosampler temperature
LCMS	Yearly	Not related	Injection volume, flow rate, column temperature, pump pressure, autosampler temperature, mass per charge range
GCMS	Yearly	Not related	Injection volume, flow rate, column temperature, autosampler temperature, mass per charger range

Meanwhile, PM is a service and care activities performed by competent personnel to ensure the equipment is working satisfactorily before any failure occur. The PM can be performed daily, weekly, monthly or yearly based on necessity. Both the calibration and PM programs must be planned and documented as mentioned in ISO 17025. This is crucial to notify other person about the date for next calibration or PM, thus the activities are not overlooked and have a comprehensive detail. All the records should be in narrative form instead of shorthand writing or bullet, but in a simple table form.

5. Personnel

Personnel can be divided into two categories which are technical and competent personnel. Indirectly, competent personnel is also technical personnel. This is because competent personnel is knowledgeable in term of laboratory operation such as handling each equipment, operating the equipment, running the test method, etc. However, technical personnel’s knowledge is limited that restrict the personnel to only certain laboratory operation.

According to ISO 17025, both technical and competent personnel require continuous training as a requirement for competency [10]. The training can be obtained from in-house or external training to refresh the knowledge and skill of the personnel, thus

maintaining the quality of work leading to validity of the test result. Common trainings for competency are listed as below:

1. Internal verification for micropipette, balance, oven, chiller, and freezer.
2. Internal check for micropipette, balance, oven, chiller, and freezer.
3. Handling and operating of particular equipment such as LCMS, HPLC, and GCMS.

Moreover, the halal laboratory shall have a procedure and retain records for determining the competence requirements, selection of personnel, training of personnel, supervision of personnel, authorization of personnel, and monitoring competence of personnel [10].

6. Good Document Practice, (GDP).

Daily operation of halal laboratory deals with data and activities. All of the data and activities need to be recorded or documented as required in GLP, GMP, and ISO 17025 [5, 6, 8]. Record is permanent handwriting in official form, worksheet, or checklist which indicates proof of having done the activity as per relevant document. On the other hand, document is a written procedure or detailed policies of company such as SOP and protocols.

The main objective of GDP is to prevent error in communication and permit tracking for certain activity. Besides, GDP minimizes dependence on persons as the execution for certain activity is clearly explained in the document. Instances for important documents for halal laboratory operation are policies, SOP, working instruction, manuals, validation protocols, forms, and records.

7. Conclusion

There are many guidelines and standards available worldwide. A laboratory applies some guidelines and standards for its own operation which is only applicable to specific area or test. Regardless of guidelines and standards, the main objective of any guidelines and standards is to maintain laboratory quality with regard to the validity of test results. In quality management system of halal laboratory, all factors of halal laboratory operation such as the organization structure, laboratory environment, communication, record-keeping, competency as well as knowledge of staff, processes, and procedures need to be addressed properly and efficiently to assure halal laboratory

quality. When the halal laboratory operation is organized into an understandable and workable structure based on the international guideline and standard, the level of inaccuracy in any halal laboratory operation can be avoided. The 99% of accuracy at certain halal laboratory operation may at first be acceptable, but the resulting 1% of cumulative error from each factor of halal laboratory operation can become major impact in halal laboratory quality, specifically the validity of test results.

Conflict of Interest

All authors declare no conflict of interest.

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