BIOGENIX

POLICY AND PROCEDURE FOR DOCUMENT CONTROL

	NAME	DESIGNATION	SIGNATURE	DATE
Prepared by	MS. PREETY RAHEJA	QUALITY MANAGER		30/06/2020
Reviewed by	DR. JULIET TEDDY	DEPUTY DIRECTOR		01/07/2020
Approved by	DR. SALLY ABDULLA IBRAHIM	LABORATORY DIRECTOR		01/07/2020

1. TABLE OF CONTENT

2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4. POLICY STATEMENT

Document control is done following this procedure.

5. PURPOSE

The purpose of this procedure is to provide a uniform and consistent method for the identification, collection, indexing, filing, access, storage, maintenance, retention and disposition of quality records. This procedure is with accordance to clause no: 4.13 of ISO 15189:2012 Medical Laboratory –Requirements for quality and competence

6. SCOPE

5.1. This procedure applies to all the records related to quality management system in BIOGENIX laboratory.

5.2. BIOGENIX Staff

7. DEFINITIONS

7.1. Document: a paper or set of papers with written or printed information;
7.2. Archive: documents that are no longer need to use regularly;
7.3. Retention: continued use, existence, or possession of something.

8. ACRONYMS

8.1. DOH: Department of Health AbuDhabi

9. RESPONSIBILITIES

The responsibilities are shared at all level as mentioned below, management and director responsibility, quality manager responsibility and staff responsibility to control of document and records.

9.1. Laboratory director and Laboratory Management:

9.1.1. The Lab. director and Management is responsible for the approval of documents, record and forms;

9.1.2. Overseeing the accurate and complete creation of records;

9.1.3. Lab director and management is responsible to inform the staff in timely manner about any new or changed documents happened at DOH or any external service agreement and supplier or referral or referring lab.;

9.1.4. Ensuring that staff members has immediate access to current copies of the documents required to perform their duties;

9.1.5. Make sure hard copies are up to date with Quality manual, Procedures and master Index.

9.1.6. Responsible for storing the documents.

9.2. Quality manager responsibilities are:

9.2.1. Numbering new procedures and records;

9.2.2. Uploading, publishing and auditing document control system for recent activity as it pertains to the laboratory's electronic documents;

9.2.3. Archiving and retiring old procedures;

9.2.4. Ensuring the destruction of documents when appropriate and reporting to the lab director;

9.2.5. Storage and ability to retrieve of all required documents and records**;**

9.2.6. To maintain the master list of documents and distribution control list that indicates the status and distribution of all documents under the document control system. Prompt removal of obsolete documents from the workplace;

9.3. BIOGENIX laboratory Staff responsibilities:

9.3.1. The staffs are responsible for security of the documents related to their sections.

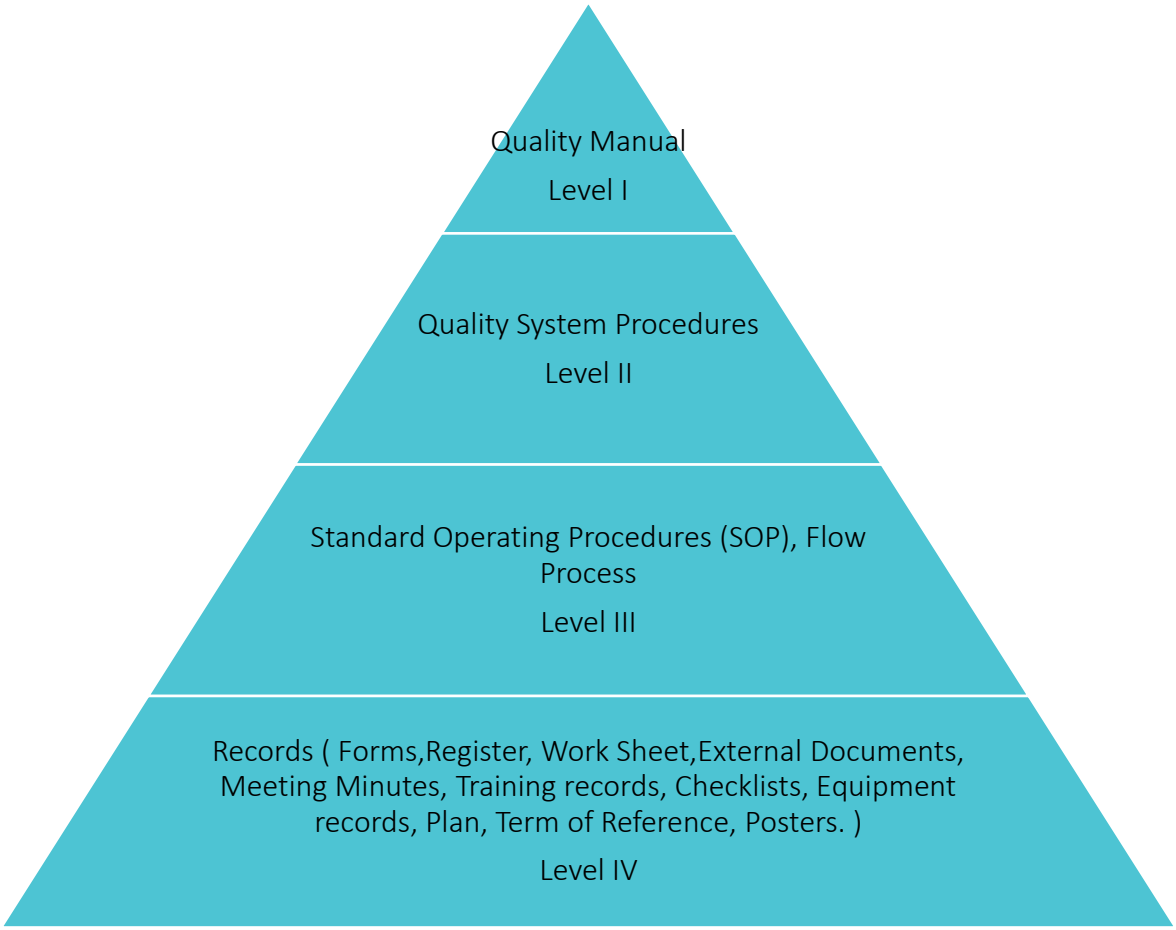
9.3.2. Reading and understanding all documents pertaining to their jobs;

9.3.3. Upon receiving any new documents, staff reads and put their signature with date and returns back to quality manager to keep a record.

10. PROCEDURE

10.1. Document & Record Organization

10.1.1. Documents are controlled by dividing in different levels as follows:



10.2. Document Format

Document initiated in the laboratory follows the lab format and style as per laboratory Document Control procedure. The Laboratory has defined a numbering scheme for unique identification of documents pertaining to the Quality management system.

10.3. Document Reference number:

10.3.1. The reference number indicates the name of the BIOGENIX with the two alphabets "BG" followed by slash (/).

10.3.2. The next digits identify the level of the document such as. PP/ SOP/REC followed by Slash (/).

10.3.3. The Next two-three digits identify the department such as GEN/HR/CHE/HEM etc.

10.3.4. The department is followed by procedure number digits that represent serial number.

10.3.5. Please see the example for reference number:

Policy Procedure Reference number: BG/PP/GEN/001

SOP Reference number: BG/SOP/HEM/001

Records Reference number: BG/REC/GEN/ 001

10.3.6. The External documents are numbered as EX DOC followed by number digit that represent serial number e.g. **EX DOC 1**

10.4. Version Number - All laboratory documents has its current version number listed on each page. Documents with minor changes have the same version number. Such changes that don't affect the performance of the procedure are held until next version is released or when review is due; whichever is closer documents with major changes have a new version number. If such changes are critical they are processed once requested Quality manager uploads revised document and update review dates and version number on procedure. It's the quality manager responsibility to notify staff of new or changed procedures and /or records either by email or during meetings.

10.4.1. Date on Documents: Dates on all laboratory documents is in standardized format (dd/mm/yyyy).

10.4.2. Document content

10.4.2.1. Policies and procedures for laboratory have: name and logo of the laboratory is in English. Title of the document, Department, Document control, Date of effectivity, Revision Date, Next Revision Date, Total Pages and Version Number.

10.4.2.2. Procedure Template (Quality)

The template of the procedure follows DOH template consists of:

a) **Policy Statement**
b) Purpose of the procedure
c) Scope
d) Target audience
e) Definitions
f) Acronym
g) Responsibility
h) Procedure
i) Cross Reference
j) Appendix

10.4.2.3. SOP Template (Technical)

a) Purpose of examination
b) Principle and method of the procedure used for examinations;
c) Performance characteristics;
d) Type of sample;
e) Patient preparation;

f) Type of container and additives;
g) Required equipment and reagents;
h) Environmental and safety controls;
i) Calibration procedures;
j) Procedural steps
k) Quality Control process;
l) Interferences
m) Principle of procedure for calculating results/ measurement of uncertainty;
n) Reference Range;
o) Reportable interval of examination results;
p) Instructions for determining quantitative results;
q) Alert / critical value;
r) Laboratory clinical interpretation;
s) Potential sources of variation;
t) Relevant documents and records

10.5. Document preparation, review, approval and re- approval authority

10.5.1. After the preparation and numbering, documents are reviewed and verified;

10.5.2. All documents are approved before implementation (Laboratory Director is authorized signatory). No document is issued and used without approval**.**

10.5.3. All the documents are reviewed every two years as per DOH guidelines.

10.5.4. After review and approval these documents are then entered in the master list of documents along with their version number by the quality manager and issued to the concerned personnel as per distribution list.

10.6. Document Identifier:

All documents are identified to include:

10.6.1. Title
10.6.2. Unique Identifier on each page
10.6.3. Version number
10.6.4. Page number to the total number of pages (e.g.: Page1 of 5/Page2 of 5)

10.7. Approved by and approval date at the footer of each page;

10.8. Identifications of Changes in Documents

10.8.1. Any staff member may suggest or identify changes to existing or new laboratory document by filing the **DOCUMENT CHANGE FORM**

10.8.2. If there is any addition or deletion in document, it is declared in amendment sheet as well.

10.8.3. The Document Change Form is signed by the concerned staff that wants change and sent to quality manager and then the changes are reviewed and approved by lab. Director.

10.8.4. After the approval, quality manger incorporates the changes in the concerned document and describes the changes on the document change form.

10.8.5. The version number of the corresponding document is incremented, and the Laboratory Director approves the revised document.

10.8.6. The revised document is then distributed to all concerned by Quality Manager. Document Distribution list and the obsolete document retrieved by Quality Manager.

10.9. Retention, Disposal and storage of records:

BIOGENIX laboratory is required to maintain medical records for specified period as per DOH, ISO and CLSI Standards, requirements documented in table below. The BIOGENIX Laboratory follows the longer period which ever may the guidelines. The Quality manager is fully responsible for the retention of the records & Lab. Coordinator is supportive service for maintaining the record retention practices.

Management practices as per the following:

10.9.1. Implement record retention and storage practices.

10.9.2. Ensure that record management, retention and storage procedures are consistent with the procedure.

10.9.3. Educate staff in understanding record retention and storage practices.

10.9.4. Ensure the confidentiality of records/information during storage.

10.9.5. Ensure that storage systems are equipped with environmental control, applicable safety & security measures.

Retention and disposal as per DOH Standards

Type of Medical Record / Health Information (if applicable)	**Minimum Retention Period of Medical Record/Health Information from date of last attendance**	**Disposal Schedule**
Records of Royal Patients	Indefinite	Do not destroy
Records of VIP Patients	Indefinite	Do not destroy
Records of UAE Nationals	Indefinite	Do not destroy
Records of Expatriates (excluding medico legal cases)	7 Years	Destroy after completion of 7 years from last Attendance/visit or last access on behalf of the patient

patient Visit Registration	Indefinite	Do not destroy
Infection Control Registers	Indefinite	Do not destroy
Medical Imaging/Lab/other Investigations Registers	Indefinite	Do not destroy
Vaccination Registers	Indefinite	Do not destroy

Retention of Documents and record as per CLSI Standards

PT Record Retention Requirements	
Laboratory Record	**Period of Retention**
Proficiency Testing Results (copies of what was submitted to the PT provider)	2 years
Attestation Statement	2 years
Proficiency Testing Evaluations	2 years
All other PT related forms	2 years

Test Record Retention Requirements	
Laboratory Record	**Period of Retention**
Test Requisitions	2 years
Test Records	2 years
Test Reports	2 years

Equipment Records Retention Requirements	
Laboratory Record	**Period of Retention**
Discontinued procedures	2 years
Method Performance Specifications	2 years

Equipment Maintenance and Function Checks	2 years
Calibration and Calibration Verification	2 years
Control Procedures (e.g., daily QC records)	2 years
Remedial Action - errors in reported results (both the original and corrected report)	2 years

10.10. Obsolete / Permanent Disposal of Documents:

The systematic permanent disposal of medical records that have been maintained for the prescribed retention period is the overall responsibility of BIOGENIX laboratory management and Quality manager. The purpose of disposal is to permanently remove records from active use. Following steps are adopted by the management before destruction of medical record:

Medical record that is scheduled for disposal is stamped obsolete, keeps a hard copy with quality manger and placed in a secure location to guard against unauthorized or inappropriate access.

We are disposing the documents by shredding which are approved for destruction after completing the retention period, which is destroyed, under the supervision of laboratory staff.

10.11. External Origin Documents

Following documents used in the laboratory **is of External Origin;**

- Legislation and Regulations
- Customer Supplies documents including agreements
- Kit Inserts
- Calibration Certificates

10.11.1. These external origin documents need neither to be numbered nor to be approved by a competent authority.

10.11.2. Quality manager enter in the master list of external origin documents.

10.12. Manual/File labeling:

The records are properly filled and indexed for easy retrieval and safe storage. The files/Manual used in laboratory has the following labeling format: Name of the file/ Number of the file.

10.13. Document availability to staff:

10.13.1. Documents are available to all staffs as appropriate;

10.13.2. Control master copy of the manual, lab procedures, standard operating procedures, LIS and safety procedures are available in the main laboratory and in area of usage;

10.13.3. All current and previous version are in master list and is accessible only by Quality manager and Lab Director;

10.14. Document control log:

Quality manager maintains document control log for all the Procedures, records, SOP's etc. Refer to Document control list for all the current documents.

11. CROSS REFERENCE

11.1. HAAD standards for retention of medical records
11.2. HAAD Standard for Medical Laboratories
11.3. ISO 15189:2012 MEDICAL LABORATORY Requirement for Quality and Competence
11.4. CLSI Guidelines for Development of Lab Documents and records

12. RELEVANT DOCUMENTS & RECORDS

12.1. BG/REC/GEN/036 Document Control List
12.2. BG/REC/GEN/038 Distribution list
12.3. BG/REC/GEN/037 Document change form