



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

MAR 01 2022

ADMINISTRATIVE ORDER

No. 2021-~~0007~~ 2022-0007

SUBJECT: Philippine Standards on the Retention Period of Documents, Records, Slides and Specimens in Clinical Laboratories

I. RATIONALE

Cognizant of its role to provide an effective and efficient Quality Management System (QMS) in Clinical Laboratories and to set a framework to strengthen the development, implementation, and evaluation of the health policies, programs, and plans by RA No. 11223 or “Universal Health Care Act,” the Department of Health (DOH) promulgated this Order by providing a comprehensive set of quality standards on the Retention Period of Documents, Records, Slides, and Specimens in Clinical Laboratories. In addition to the mandate of the National Archives of the Philippines Act of 2007 to review and update all health records, policies shall be developed to protect all public documents, records, and other pertinent materials of archival value prior to its disposal. Thus, meetings with the Technical Working Group (TWG) established through DPO 2018-1602 entitled “Creation of a TWG to Formulate AO on the Establishment of Retention Period for Documents, Records, Slides, and Specimen in Clinical Laboratory” were held to establish the national standards on the minimum retention period referenced from international laboratory standards such as temporary storage in accessible and suitable environment to ensure a secure, safe-keeping repertoire. This also cites the recently-issued Records Disposition Schedule by the National Archives of the Philippines (NAP) dated ~~January 5, 2021~~ *May 26, 2021*.

Provisions under this Order comply with the requirements stated in the assessment and inspection tool for the issuance and renewal of license to operate (LTO) of clinical laboratories by the Health Facilities and Services Regulatory Bureau (HFSRB) pursuant to A.O. No. 2021-0037, “New Rules and Regulations governing the Regulation of Clinical Laboratories in the Philippines”. Further, this Order also follows the roles and responsibilities of the Office for Health Laboratories stipulated under DO No. 2021-0421 entitled “Creation of the Office for Health Laboratories under the Health Facilities and Infrastructure Development Team to Institutionalize the Philippine Health Laboratory System”, pending the enactment of the Philippine Center for Disease Control and Prevention.

II. OBJECTIVES

A. General Objective:

This Order shall provide guidance on the national standards on the minimum retention period of documents, records, slides and specimens in all clinical and public health laboratories.

B. Specific Objectives:

1. To establish retention period guidelines on documents, records, slides and specimens according to its storage condition and to prevent overloading of the storage capacity of laboratories; and
2. To ensure compliance of retention protocols as part of the minimum standards and inspection tool in licensing a clinical laboratory by HFSRB.

III. SCOPE AND COVERAGE

This Order shall apply to all clinical and public health laboratories in the country, including government- and private-owned, clinical and anatomic pathology, institution-based and free-standing, general and special laboratory, primary, secondary, or tertiary laboratories, and laboratories with limited service capability.

IV. DEFINITION OF TERMS

1. **Clinical Laboratory** – refers to a facility that is involved in the (a) pre-analytical, (b) analytical, and (c) post-analytical procedures, where tests are done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis and treatment of diseases. These tests include, but are not limited to the following disciplines: clinical chemistry, hematology, immunohematology, microbiology, immunology and serology, clinical microscopy, histopathology (cytology), toxicology, endocrinology, molecular, and nuclear diagnostics.
2. **Documents** – refer to written information regarding policies, processes and procedures in the clinical laboratory to communicate effectively to all laboratory staff and users, which need to be updated or maintained when necessary.
3. **Records** – refer to the collected information produced by the laboratory in the process of performing and reporting laboratory tests that are permanent and are easily retrieved by the laboratory staff.
4. **Retention Period** – refers to the specific period of time established by the DOH as the lifespan of documents, records, slides and specimens after which they are deemed ready for permanent storage or disposal in accordance with the statutory and regulatory requirements.
5. **Slides** – refer to thin flat pieces of glass used to hold a portion of tissues or body fluids for examination under the microscope.
6. **Specimens** – refer to portions of human body fluids or tissues taken for examination, study or analysis of one or more quantities assumed to apply as a whole.

V. GENERAL GUIDELINES

- A. The DOH shall institutionalize the minimum standard retention period of documents, records, slides, and specimens in clinical laboratories in the country as



stated in **Annex A** of this Order and as guided by the approved Records Disposition Schedule (RDS) by the National Archives of the Philippines as disseminated through the Department Circular 2021-0226 entitled "Dissemination of the Approved Records Disposition Schedule (RDS)."

- B. All clinical laboratories shall establish their own archive to safeguard its documents, records, slides, and specimens, including paraffin blocks, in a safe environment, protected from loss and destruction and secured from theft and tampering. For records, slides, and specimens classified for permanent preservation, a repository shall be made available for permanent storage of important data.
- C. Pursuant to RA No. 10173 or the Data Privacy Act of 2012, all clinical laboratories shall ensure privacy or confidentiality by allowing authorized personnel only for clinical laboratory management on accessing laboratory documents and records.

VI. SPECIFIC GUIDELINES

- A. All clinical laboratories shall implement the guidelines on the retention period as stated in this issuance;
- B. The clinical laboratories shall conduct a regular inventory of retained specimens for the biosafety and biosecurity of the laboratory;
- C. The clinical laboratories shall create their own institutional policies and procedures and adopt them to their respective Standard Operating Procedures (SOPs) based on the minimum retention period of documents, records, slides and specimens as patterned to this Order;
- D. The head of laboratory shall ensure institutional policies for all documents, records, slides and specimens are maintained and available for the particular time frames as specified in this Order if the Clinical Laboratory ceases its operation;
- E. A dedicated space in the health facility shall be ensured for a suitable archive for placement of documents, records, slides and specimens within the premises or an off-site area within the vicinity of the Clinical Laboratory, provided that it is stated in their own internal policies;
- F. The DOH together with the NAP shall permit the use of electronic laboratory documents and records provided that it is accessible and retrievable by the authorized user.

VII. ROLES AND RESPONSIBILITIES

- A. Office for Health Laboratories (OHL) shall:
 - 1. Provide technical assistance in the development and updating of standards on retention period of clinical laboratory documents, records, slides and specimens; and
 - 2. Coordinate with HFSRB, NAP and the different clinical and public health laboratories in implementing and updating this Order, as deemed necessary.
- B. Health Facilities and Services Regulatory Bureau (HFSRB) shall:



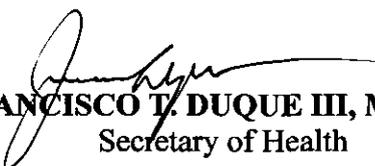
1. Enforce compliance to the retention period of documents, records, slides and specimens and its manner of disposal during inspection for issuance or renewal of LTO of clinical laboratories

C. Clinical and Public Health Laboratories shall:

1. Include the provisions of this issuance in their respective SOPs;
2. Adopt the time period for retention of their laboratory documents, records, slides and specimens based on **Annex A** of this issuance;
3. Provide a suitable archive of documents, records, slides and specimens within the clinical laboratory premises as to prevent damage, deterioration, loss and misuse of clinical laboratory information pursuant to the Data Privacy Act of 2012;
4. Document an inventory or reports of laboratory documents, records, slides and specimens periodically as part of their own SOPs; and
5. Comply with the standards of the retention period of documents, records, slides and specimens to ensure efficient and effective QMS in Clinical Laboratories and as part of the requirements of issuance and renewal of LTO and inspection tool by the HFSRB.

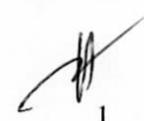
VIII. EFFECTIVITY

This Order shall take effect fifteen (15) days after publication by the DOH, or in a newspaper of general circulation, and upon filing of three (3) certified copies of this Order with the Office of the National Administrative Register of the University of the Philippines Law Center.


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

List of Retention Period based on its category:

A.	<u>DOCUMENTS AND RECORDS:</u>	<u>Retention Period</u>			<u>Remarks</u>
		<u>Active</u>	<u>Storage</u>	<u>Total</u>	
1	Analytical Systems and Quality Improvement Files:				
	Annual Review of Policies, Processes and Procedures Records	2 years		2 years	
	Equipment and Instrument Preventive Maintenance Records	2 years		2 years	After equipment has been returned / rendered unserviceable
	Inspection, Audit and Assessment Records	5 years		5 years	
	Management Review Records	2 years		2 years	
	Method Manuals (Work Instructions) and Laboratory Worksheet	2 years		2 years	After procedure has been discontinued
	Method / Process Validation Records	2 years		2 years	
	Qualification, Competency and Training of Laboratory Staff Records	3 years		3 years	After last day of employment
	Quality Control Records	2 years		2 years	
	Qualification System Assessment and Proficiency Testing Records (e.g. NEQAS)	5 years		5 years	
	Reagents, Materials and Supplies Records	2 years		2 years	
	Registration and Referral Records	2 years		2 years	
	Specimen Rejection Records	1 year		1 year	
	Supplier Qualification Records	2 years		2 years	



	Waste Disposal Records	2 years		2 years	
2	Clinical Laboratory Files:				
	Blood Bank Records:				
	a. Donor	5 years	5 years	10 years	
	b. Recipient and other Patients	5 years	5 years	10 years	
	c. Permanent Deferral Donor	Permanent**			
	Clinical Laboratory Employees' Signature Initials	2 years	3 years	5 years	After updated
	Laboratory Test Filled-Out Requisition Forms (Clinical Laboratory Request)	2 years		2 years	
	Record Book:				After date of last entry
	a. General Laboratory Test Results	5 years		5 years	
	b. General Patient Registry (Accession)	5 years	5 years	10 years	
3	Laboratory Test Reports:				
	Clinical Laboratory	2 years		2 years	
	Cytogenetics	10 years	10 years	20 years	
	Cytology	5 years	5 years	10 years	
	Drug Test Reports:				
	a. Negative	2 years		2 years	
	b. Positive with Medico-legal Concerns	Permanent**			
	Medico-legal	Permanent**			
	Surgical Pathology	5 years	5 years	10 years	

4	Special Laboratory Files:				
	Flow Cytometry Histograms and Dot Plots	5 years	5 years	10 years	
	Electrophoresis	1 year		1 year	
	Cytogenetic Diagnostic Images (Digitized, Prints or Negatives)	10 years	10 years	20 years	
	Forensic Autopsy Gross Photographs or Negatives	Permanent**			

*Adopted from the approved Records Disposition Schedule (RDS) by the National Archives of the Philippines as disseminated through the Department Circular 2021-0226.

**Permanent records are those with enduring value and classified in the Records Disposition schedule that have been selected for permanent preservation (National Archives of the Philippines).

B.	<u>SLIDES, SMEARS AND PARAFFIN BLOCKS</u>	<u>Retention Period</u>
1	Anatomic Pathology:	
	Forensic Autopsy Stained Slides and Paraffin Blocks	Permanent
	Surgical Pathology and Immunohistochemistry Stained Slides and Paraffin Blocks	10 years
	Tissue Frozen Section Stained Slides and Stained Smears	10 years
2	Cytogenetics:	
	Permanently Stained Slides	3 years
3	Cytology:	
	Cytology Negative / Unsatisfactory Stained Slides	5 years
	Cytology Positive / Suspicious Stained Slides	10 years
	Fine Needle Aspiration Biopsy Stained Slides	10 years
	Gynecologic Stained Slides	5 years
4	Hematology:	
	Bone Marrow Smears	10 years
	Bone Marrow Tissue Biopsy Slides and Paraffin Blocks	10 years
	Malaria Stained Smears	1 year

	Other Body Fluids Slides for Cell Counting	7 days
	Peripheral Blood Slides (Abnormal)	1 year
	Peripheral Blood Slides (Normal)	7 days
5	Microbiology:	
	AFB-stained Smears	1 year
	Grams and Trichome Stained Slides	7 days
	KOH Slides	7 days
C.	<u>SPECIMENS</u>	<u>Retention Period</u>
1	Anatomic Pathology:	
	Body Fluids for Cytology	7 days, Refrigerated
	Formalin-fixed representative tissues suitable for DNA Analysis	Permanent
	Thin Prep Aliquot Tubes	30 days, Room Temperature
	Wet and Formalin-fixed Tissues for Forensic Autopsy	1 year after completion of final report
	Wet and Formalin-fixed Tissues for Routine Histopathology (Benign)	2 weeks after completion of final report
	Wet and Formalin-fixed Tissues for Routine Histopathology (Malignant)	4 weeks after completion of final report
2	Blood Banking and Transfusion Medicine:	
	ABO Blood Typing (EDTA-Whole Blood and Serum)	7 days
	Crossmatch Unit Segments from blood donor units and recipients	7 days post-transfusion
	Direct Antiglobulin Test	7 days
	Serum with positive antibody screening test	1 year, Frozen

3	Clinical Chemistry and Immunology / Serology	
	Immunofixation Gels	1 year, Room Temperature
	Other Body Fluids (Pleural / Peritoneal / Pericardial Fluid)	1 week, Refrigerated
	Serum / Plasma	1 week, Refrigerated
4	Clinical Microscopy:	
	24-hour Urine, aliquot	1 day, Refrigerated
5	Drug Testing and Toxicology:	
	Body fluids and tissues for toxicology (with medico-legal concerns)	Permanent
	Urine (Negative Screening Test)	5 days, Frozen
	Urine (Positive Screening Test)	1 year, Frozen
6	Hematology:	
	Anti-coagulated (Heparinized or EDTA) Whole Blood	24 hours, Room Temperature
	Plasma for Coagulation Testing	24 hours, Room Temperature
7	Microbiology:	
	Blood cultures	7 days inside the machine
	Culture Swabs	1 day, Room Temperature
	Sputum	1 day, Refrigerated
	Urine for culture	1 day, Refrigerated
8	Molecular Laboratory:	
	Nasal and Oropharyngeal Swabs (Abnormal)	30 days, Frozen
	Nasal and Oropharyngeal Swabs (Normal)	1 day, Frozen

	Other Tissue Swabs for viral isolation	30 days, Refrigerated
	Serum / Plasma	1 week, Refrigerated



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