



Guidelines for Regulating Pathology Laboratory Good Practices



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Introduction

City Cancer Challenge (C/Can) and its network of partners support cities as they strengthen the quality of cancer care infrastructure.

By the end of 2019, seven C/Can cities had identified priority projects to develop and harmonise the quality of core cancer diagnostic and treatment services in pathology, radiology, nuclear medicine, surgery, radiotherapy, medical oncology, and palliative and supportive care.

In all cities, the local technical and executive committees have prioritised action to improve harmonisation and the quality of pathology diagnosis and proposed policy solutions to address common and persistent challenges, including the absence of written standard operating procedures and the variability of pathology laboratory practices in the city.

Throughout the first cycle of technical assistance projects in C/Can's cities (2018-2019), the need was identified to develop guidance on the core elements that should be considered by the pathology technical groups when formulating local policy solutions to advance city projects and ensure that new cities joining C/Can benefit from what others have considered, developed and learned.

The present document is expected to provide a starting point for local pathology professionals to assemble and work together and standardise practices in public and private laboratories in their respective cities, regardless of their size or location. The primary aim is to increase the quality control of laboratory services provided to the local community.

The recommendations outlined in this document were developed by Dr Beatriz Hornburg, a pathologist and external expert nominated by the American Society for Clinical Pathology (ASCP) to assist the pathology city project team in Asunción, Paraguay, in consultation with the C/Can team. The content of the document was generated as a result of various technical meetings between Dr Hornburg, the C/Can pathology project team in Asunción, Paraguay and the C/Can Technical Assistance team. The document has been reviewed by three external independent senior pathologists: Dr Dan Scungio, Dr Jeannette Guarner and Dr Darryl Elzie, nominated by the ASCP, and their comments and suggestions have been extremely helpful in making the document as practical and comprehensive as possible.

INTERPRETING THIS DOCUMENT

The recommendations outlined in this publication are expected to be interpreted, analysed, and tailored taking into account the local context and the need to build a multisectoral and multidisciplinary consultative process within the city.

This document proposes core elements that should be included as the minimal requirements in draft regulations (or equivalent) to ensure alignment and adherence to important pathology good practices in all laboratories in C/Can cities. The regulatory elements recommended in this framework are the most critical that every laboratory, public and private, should comply with to ensure good laboratory performance.

The guidelines outlined in this document are intended to be used by local project teams to develop a first draft to ensure adherence to their city pathology laboratory good practices manual. It must be discussed and adapted according to local needs and other related local laws and regulations.

The contents described in the document should be kept in draft city regulations, since they are considered as the core items for the quality pathology services. However, increasing the number of items as needed by the local situation is encouraged if the local city pathology teams consider there is capacity and knowledge installed to implement those requirements widely in their cities.

Scope and aim of the regulatory framework

The regulatory system may vary, depending on the city and jurisdiction. In some countries, the term regulation (or norm) may be preferred and attainable, while in other cities, developing guidelines to encourage best practices may be the only option. The local project teams in each city should take this into account when defining the purpose and the aim of the document and adopt the most relevant terminology accordingly.

The regulatory framework should define the requirements for the operation of anatomic pathology laboratories, cytopathology laboratories, including diagnostic tests procedures, whether for clinical assistance or research purposes, techniques and methods developed within these institutions and their respective collection station(s) (where applicable), known collectively as pathology laboratories. Aspects related to transporting human biological material are approached as well.

The local project teams should consult with local policy and regulatory experts in developing their draft regulatory frameworks so as to ensure adherence to local standards, norms, and regulations.

COMPONENTS OF THE DRAFT REGULATORY FRAMEWORK

- › A definition of the appropriate regulatory body responsible to oversee and ensure the implementation of the new regulatory framework. The approval of such a regulatory framework should be done, at least, by the city health surveillance body. However, the higher the authority sought to implement the framework, such as state or provincial government, or even the ministry of health, would be optimal, if feasible.
- › An approval mechanism for the operation of services that perform laboratory activities, such as anatomic pathology laboratories, cytopathology laboratories, and their related collection station(s).
- › The obligation of pathology laboratories to meet the requirements outlined in the new regulatory framework proposal, including the length of time from the date of its publication to adapt and adopt existing relevant regulation(s) (or equivalent).
- › A definition of the scope of the regulatory framework, including stating that the regulation (or equivalent) applies to individuals and legal entities directly or indirectly involved in the operation of the anatomic pathology laboratory, cytopathology and collection station in diagnostic procedures and laboratory tests and clinical research in pathology or cytopathology, as well as in the transport of human biological material collected.
- › A description of non-compliance consequences and possible implications with other local norms and regulations.

The following sections include the core elements that are recommended to be included as minimal requirements when drawing up draft regulations (or equivalent) to ensure alignment and adherence to important pathology best practices in all laboratories in a specific city. The regulatory elements suggested in this framework are the most critical that every laboratory, public and private, should comply with to ensure best practice.

01 Operational parameters

1.1 Pathology laboratories must operate in compliance with quality requirements that guarantee to clients that the procedures and processes performed are within the specifications proposed in the draft regulatory framework.

1.2. Pathology laboratories that carry out research activities must submit their projects for consideration and approval by the respective research ethics committees. Similarly, when laboratories agree to serve as biobanks or biorepositories for outside research, they must ensure that these research projects are also submitted to the local research ethics committees.

1.3. The anatomic pathology, cytopathology laboratories and collection station must have an official operating license and its updates issued by the competent health surveillance agency, in accordance with the local laws and regulations; otherwise they are not allowed to function or provide services to the community.

02 Operational requirements

2.1. No health service covered should operate without being in accordance with the requirements established in the proposed regulatory framework and licensed by the local health authority.

2.2. The health service must have an internal quality manual or manual of activities and respective standard operating procedures (SOP) which should include, at the very least, the following topics [1]:

- › Patient registration with instructions for care, preparation, and collection of patients' specimens and respective relevant clinical data.
- › Instructions for collecting, sending, and storing specimens, acceptance and rejection criteria, transport, preparation, stability, preservation, and disposal.
- › Procedural descriptions for preparing and processing samples for diagnostic interpretation.
- › Equipment operation, with their preventive and corrective maintenance as well as cleaning instructions.

- › Preparation, preservation, and storage of reagents and dyes.
- › Archives – designated facility, room or area, room temperature control, entrance control.
- › Procedures for internal and external and or interlaboratory quality control programs for professional qualifications.
- › Quality assurance procedures according to the pathology laboratory good practices manual.
- › Health care, safety and environmental technical regulations in force.
- › Employee and, where applicable, other collaborators training and continuing education programs.
- › A health services waste management plan, in accordance with local legislation. If there is no specific local legislation, laboratories are advised to create such regulation, along with other health care services, discarding criteria based on international standards for human and environmental safety. The WHO's safe management of wastes from health-care activities [2] [3] may be used as a guide.
- › Hospitals, clinics, and medical services in which specimens are collected for anatomopathological, cytopathological, and similar tests must have patients' free and informed consent form regarding the sending of their specimen(s) to the respective diagnostic services [4] [5]. This item relates to patients' safety and their right to know where their samples will be analysed, thus securing the sample traceability from the beginning of its collection until the release of the pathology report and final storage.

2.3. Support activities/processes that are not performed directly by the laboratory may be outsourced through a service provision contract and must be clearly described within the laboratory internal quality manual or manual of activities, as well as be clearly explained to the patient with a free informed consent form [4] [5].

03 Organisation and procedures

3.1. The pathology laboratory director must assure that the laboratory's internal quality manual contains policies and SOP clearly indicated and ensure that these are used to provide adequate laboratory services to the community [6].

3.2. The pathology laboratory must have its opening hours posted in an appropriate place and visible to the public [7].

3.3. The pathology laboratory operating license issued by the competent local authority should be visible to the public.

04 Human resources

4.1. The pathology laboratory, including its respective collection station(s), must operate under the supervision of a professional legally qualified as a laboratory director [1] [8] [7].

4.2. In the absence of a laboratory director, the health service must have a legally qualified substitute professional, with the same basic qualifications, which must be stated in the laboratory's Quality Manual [9].

4.3. The pathology laboratory director should only exercise responsibility for up to two establishments [1] [4] [6] [7]. The laboratory director should exercise responsibility for only two health services if the route between the establishments does not exceed 1 (one) hour or 50 km. The laboratory director must clearly designate his/her substitute, therefore assuring that the laboratory activities will not be unsupervised.

4.4. The laboratory director will have his/her role established through an employment contract or service provision contract, signed between the establishment and the respective professional or, in a proprietorship official document, if the laboratory director is one of the partners [1].

4.5. All laboratory employees or collaborators must be bound to the health service by formal contract, as established by local laws and regulations [1] [7].

05 Occupational health and safety

5.1. The pathology laboratory must guarantee a safe and healthy work environment for all staff, regardless of the employment relationship. A healthy work environment means well-preserved facilities, well-organised workspace, good technical conditions, and good air quality, all with the goal of improving the workforce's quality of life, while reducing or eliminating work-related risks and preventing accidents [7]. If there are local ministry of labour regulations or those by a similar organ to protect occupational health and workers' safety, they should be adhered to.

5.2. The pathology laboratory must adopt occupational health and safety measures, giving priority to collective and individual protection, according to the characteristics and risk factors in the workplace [1] [7]. Local biosafety laws or regulations should be adhered to, were applicable.

5.3. The pathology laboratory must develop and implement an environmental risk prevention program (ERPP) in accordance with the regulatory standards of the labour ministry, if available [7]. If no regulation is in force, it is suggested that the conditions outlined in this document to be followed.

5.3.1. The ERPP must contain an inventory of all chemical products, including reagents and in-house solutions, as well as their residues. It must be clearly indicated in the program which chemicals are hazardous to workers (see local biosafety laws for health services). The laboratory must have a policy or SOP in case of accidents involving chemical products.

5.4. The pathology laboratory must provide medical examinations in the following situations, according to local law, when applicable.

- a. When an employee is hired.
- b. Throughout the period of their contract.
- c. When returning to work after an absence, regardless of its cause.
- d. Internal job change.
- e. Before dismissal from the laboratory services.

5.5. The pathology laboratory must guarantee the proper functioning of collective protection equipment (CPE) at all times, as well as its certification, through qualification and periodic maintenance, either preventive or corrective [7].

5.5.1. The pathology laboratory must have properly functioning emergency showers and eye washers installed in areas where chemicals are manipulated and used.

5.5.2. The pathology laboratory must provide its workers with personal protective equipment (PPE) appropriate to the risks to which they are exposed, ensure that it is mandatory to use it in the work environment, and provide replacement whenever necessary, in accordance with the relevant local norms and regulations.

5.5.2.1 Personal protective equipment (PPE) must be officially certified by a competent entity that confirms and approve their production and quality criteria, according to international safety regulations, (e.g. ISO norms for masks production and quality specifications).

5.5.3. When employees leave the workplace, they must remove PPE and laboratory coats.

5.6. The pathology laboratory should ensure that all workers or collaborators, whether self-employed or outsourced, have access to an active immunisation program against tetanus, diphtheria, hepatitis B, free of charge, in compliance with the local guidelines and recommendations of the relevant health authorities, with reinforcements and serological test control, when appropriate. The immunisation program must be started when the health professional is admitted to work, regardless of whether the nature of the function is administrative or technical.

5.7. The pathology laboratory must ensure that all workers receive initial and continuous training, containing at least: knowledge of routines defined by the SOP, work process, health risks and problems, collective and individual protection measures used in the laboratory, as well as rules and procedures adopted in case of incidents or accidents. These training must be officially documented, citing the type and subject of training, with the name of the instructor and a list of presence signed by the trainees [7].

5.7.1. The pathology laboratory must ensure that workers are engaged in writing and following instructions, and or SOP, easy to understand and in accessible language, on the topics specified in the previous item. The pathology laboratory can select someone to coordinate the actions for quality system implementation and improvement, however the engagement of the staff in

helping to write the internal procedures and documents, as well as record necessary data on forms and datasheets is very important to feed the system. Therefore, they will participate and gain interest in setting up and implementing quality processes.

5.8. Every pathology laboratory must be equipped with the necessary material to provide first aid, considering the characteristics of the activities performed [7].

5.8.1. The first aid material must be kept in an appropriate place, under the care of a person or persons trained for this purpose.

5.9. The pathology laboratory must implement a procedure of medical and nursing care for emergencies in case of employee exposure to potentially infectious biological material, hazardous chemicals, or when other accidents occur, as well as procedures for accompanying and monitoring exposed workers [10] [7]. The Laboratory does not necessarily need to have an emergency unit within its premises but must ensure a sequence of actions and procedures in case an employee is exposed to a hazardous chemical or biological material and is required to access an emergency service.

5.10. In cases of accidents, incidents, or damage to employee's health, even if there is no need to leave work, the employer must proceed with social security and epidemiological notification in accordance with local laws and regulations.

5.11. The pathology laboratory must guarantee effective and continuous actions to control vectors and urban pests, preventing their attraction, shelter, access, and or their proliferation to the laboratory's premises.

5.11.1. Chemical control of pests, when necessary, must be carried out by an authorised establishment that holds a sanitary and environmental license and must use household cleaning products.

5.12. The pathology laboratory must develop and implement a waste management plan [7] [9] in accordance with local laws and regulations.

06 Functional structure of the facility

6.1. The pathology laboratory must meet general and specific construction standards, as outlined under local legislation and regulations on physical infrastructure for health services.

6.2. Architectural projects for the construction, expansion, or adaptation of the laboratory must be analysed and approved by the competent authority, in accordance with current laws and regulations. Usually, this item is submitted to local city halls and health surveillance agencies. If there are no such requirements, this item may be left out of the regulatory framework.

6.3. A pathology laboratory installed in new buildings, or when subject to adaptation and/or extension, must guarantee accessibility to people with disabilities or reduced mobility, including workers, in accordance with local laws and regulations. If there are no relevant local laws and regulations, it is recommended that people with disabilities have full and easy access to the laboratory facilities.

6.4. The pathology laboratory must have a physical area adequate to the intended activities, providing a directional workflow, with performance and security proportional to its complexity and volume, size, and type of specimens tested [7].

6.5. The facility must be equipped with adequate light [11] so that workers are able to perform their activities safely and properly, according to local standards defined by local laws and regulations.

6.6. The facility must be equipped with an efficient and adequate ventilation system that allows workers to perform their activities safely and properly, in accordance with the local laws and regulations [12] [13] [14].

6.6.1. The control standards for room air safety in the gross dissection room and Histology Room (slides preparation) must be in accordance with local laws and regulations [12] [13] [14] [7].

6.7. Maintenance of building facilities must be regularly scheduled, and corrective maintenance must be executed whenever needed, using updated records. The maintenance services may be executed by internal means or by a third-party [7].

6.8. The specimen reception room as well as the reception room and areas open to the public must be separate from technical areas, and whenever possible, from each other, especially when there is a large number of specimens for triage [9] [7].

07 Supplies and equipment

7.1. The pathology laboratory must be properly equipped to carry out the proposed activities, as stated in the operating license issued by the competent health authority.

7.2. The pathology laboratory must have a detailed list of the equipment necessary to carry out the procedures performed. This list may be described in the Quality Manual (QM) directly or in a SOP for equipment, referred to in the QM.

7.3. Equipment can be replaced by others with more advanced technology, provided they are registered with the competent authority.

7.4. The pathology laboratory must maintain records of preventive and corrective maintenance of equipment and instruments according to their specificities and the manufacturer's instructions [7].

7.4.1 - Equipment maintenance or technical assistance must be performed by the manufacturer or legally authorized companies.

7.5. Equipment required to operate at a controlled temperature and/or humidity must be checked daily.

7.6. Reagents must be stored in appropriate conditions according to the manufacturer's specifications (temperature, toxicity, volatility, flammability, and compatibility) [10] [7].

7.7. The manufacturer's recommendations regarding storage and conservation of reagents, dyes, or other supplies used in diagnostic procedures, analyses, or laboratory tests must be diligently followed.

7.8. It is prohibited to use reagents, dyes, or other inputs for any diagnostic purpose, that have passed their expiry date, or that are damaged or adulterated [9] [10] [7] [2].

7.9. The pathology laboratory must guarantee electricity for equipment or critical supplies through a backup system or have a contingency plan that can be immediately activated in an emergency. [11] [7] [2].

08 Biosafety

[15] [7] [2]

8.1. The pathology laboratory must document policies, processes, programs, or any other actions related to biosafety, covering all stages and activities carried out on their premises.

8.2. It is the sole responsibility of the pathology laboratory to comply with all laws and regulations regarding hygiene and safety at work in order to minimise the risks of exposure to pathogens or hazardous chemical products, accidents, and illnesses related to work.

8.3. The pathology laboratory must provide workers with PPE appropriate to the risk they are exposed to, instituting mandatory use in the work environment, in addition to providing replacement whenever necessary. The delivery of PPE must be proven through documented records, preferably with employees' signature, confirming they received the equipment and proper training to use it.

8.3.1. Workers, when leaving the workplace, must take off and properly dispose of PPE and laboratory coats in their work activities.

8.4. The pathology laboratory must ensure the proper functioning of the collective protection equipment (CPE) certified, through qualification and periodic preventive and corrective maintenance.

8.5. The pathology laboratory must ensure that all PPE used is certified by the relevant local authority responsible.

8.6. The working area must have first aid kits, in a visible and easily accessible place, with an instruction manual for emergencies and work safety rules. It is important to keep the first aid kit in a clean location and to check items inside for expiration.

8.7. The pathology laboratory must guarantee effective and continuous action to control vectors and urban pests, with the objective of preventing their attraction, shelter, access, and or their proliferation in the premises of the laboratory's facilities.

8.7.1. Chemical control, when necessary, must be carried out by an authorised establishment that holds a sanitary and environmental license and must use household cleaning products duly registered with the relevant local health authority.

8.8. The pathology laboratory must provide emergency shower and eye washers installed in the technical areas with chemical accident risks.

09 Quality assurance

[1] [9] [10] [7] [16]

9.1. The pathology laboratory should participate in external quality assessment programs, being it through proficiency tests or thoroughly documented interlaboratory diagnostic comparisons programs with laboratories located in the city or elsewhere. [9] [16] [7].

9.1.1. Participation in exchange slides and diagnosis with other pathology laboratories and check diagnostic accordance when there are no specific proficiency tests to a given diagnostic procedure.

9.1.2. Periodic participation of professionals in continuing education programs.

9.1.3. Documentation of appropriate corrective actions when proficiency test results are unacceptable.

9.2. The pathology laboratory must have a record of the internal quality control system, appropriate to routine procedures, which must be carefully executed, as follows:

- › Exchange of information between legally qualified professionals and the pathology laboratory.

- › Control of routine cases.
- › Gauging of devices/equipment.
- › Checking the sensitivity/specificity of reagents and dyes used by their specific controls.
- › Periodic review of operational procedures in, at least, every two (2) years or whenever an alteration to the routine of a specific procedure occurs.
- › A pathologist or cytopathologist must review all unsatisfactory, suspicious, and positive for neoplasia in gynaecological cytology before signing out
- › A pathologist or cytopathologist must review at least 10% of gynaecological cytology tests interpreted as negative for neoplasia by cytotechnician(s) before signing out. (When there is not a cytotechnician, pathologists are advised to create means of reviewing each other cases periodically).
- › A pathologist or cytopathologist must review all gynaecological cytology cases that are suspected for malignancy, or other reasons, cited by cytotechnicians, before signing out; (When there is not a cytotechnician, pathologists are advised to create means of reviewing each other cases periodically).
- › All non-gynaecological cytology cases must be analysed, diagnosed, and sign out by a pathologist or cytopathologist.
- › Correlation between cytological and histopathological specimens from the same anatomical site must be made consistently. For example, gynaecological cytology that tests positive for high intraepithelial squamous lesion and the ensuing uterine cervix biopsy must be correlated in test reports. This is particularly important when there is a discordance between diagnoses, and the reason of this discordance must be explained, which will determine whether the clinical investigation will be continued.
- › Frozen sections must be mounted in permanent slides after diagnosis is issued to the attending physician. Slides from frozen sections and the ensuing surgical specimen must be correlated in the final report.
- › Pathologists must make an effort to foster and participate in tumour boards and other conferences. Cases of interest must have their complete clinical data correlated with their results.
- › Consultation among colleagues in the same service or from external laboratories should be documented and if there is a discordance between diagnosis, correction actions must be taken by altering the diagnostic report. This alteration should be clear in the original report and a comment must be made regarding this alteration.

9.3. There must be a duly identified and documented SOP, in printed and or digital format, as many as needed, according to the laboratory's menu of activities and tests provided to the community, easily accessible to the staff that perform such activities.

9.4. The pathology laboratory must adopt appropriate measures for the internal quality control system and ideal conditions for the staff to work safely [17].

9.5. When using in-house methods to perform a given test, it must be stated in the test report.

9.5.1. The in-house methods must be validated by the laboratory, and this validation system must be documented and verified periodically, at least every two years, or less, according to the complexity of the test [7].

10 Pathology reports

10.1 The pathology laboratory must ensure that test results and reports are released in a timely and confidential manner to the correct patient, to his or her official representative and or to the physician who requested the test [9] [7].

10.2 Reports must be legible, without transcription erasures, written in the official local language, dated and signed by the pathologist/cytopathologist or technical director.

10.2.1. Items to be included in the reports

- › Clear identification of the health service/pathology laboratory.
- › Full address and telephone number of the health service//pathology laboratory (this sometimes includes the name of the hospital and the pathology department).
- › Identification of the technical director and his or her registration number with the local medical council (or according to local law)
- › Identification of the pathologist/cytopathologist who analysed and issued the test report, with his or her respective medical council registration number.
- › Name of the patient and his/her identification number, and local social security number (or equivalent), date of birth, and patient's single code within the pathology laboratory information system. For example, for an endoscopic biopsy, the laboratory identification number received may be B2012345 or C2012345, the letter "B" or "C" relating to the type of test [in this case a biopsy (B) or cytopathology (C) case], the first two numbers relate to the two last numbers of the current year when the biopsy entered the laboratory records, and the last five numbers relate to the entry order of the laboratory records.

- › Date of sample collection (whenever recorded in the test request), date of sample registration in the laboratory information system, and date of issue of the test report. The pathology laboratory should encourage physicians and other auxiliary health professionals to complete the date and time of specimen collection to be able to control adequate fixation time.
- › Specification of the type of test and anatomical site of the biological sample.
- › Gross dissection description and diagnostic conclusion, where applicable.
- › Comments and observations pertinent to the interpretation of the report, where applicable.
- › In the case of cancer, diagnostic conclusion and pertinent synoptic report.
- › Methodology used, where applicable.

10.2.2. When there is a need for rectification in any data contained in the pathology/cytopathology/immunohistochemistry/molecular pathology report, it must be made in the same report, and the rectification must be made clear.

10.2.3. If a review of a given case is needed, whether requested by the patient's doctor or for internal quality control purposes, the number of the previous report must be included.

10.2.4. The delivery of reports must be under a protocol or identification document of the person responsible for the delivery and the person responsible for the reception of the patients' reports. It may be electronically, with an identification password, by mail and or by courier, or to a previously authorized third party.

10.2.5. The pathology laboratory must define which reports are critical or urgent, and if there are unexpected results that must be promptly communicated to clinicians. The process of delivering these results must be clearly described in the SOP [8] [18].

11 Samples and reports, filing and storage

[9] [4] [19] [7]

11.1 - Specimen parts and other biological sample remnants after grossing must be stored for a minimum period of two weeks after the respective definitive diagnostic reports or results are released.

11.2. Paraffin blocks must be stored for at least 10 years [preferably 20 years], in an appropriate place, free of insects, and in a temperature-controlled room to preserve their physical integrity and easy retrieval when needed.

11.3. Histological and cytological slides negative for malignancy must be archived and stored for a recommended minimum period of five years.

11.3.1. Histological and cytological slides positive for malignancy must be archived for a recommended minimum period of 10 years.

11.4. Paper reports should be kept for at least five years, free from insects and protected from light. Electronic/digital reports should be filed for 20 years using appropriate media. Backup restore tests must be executed periodically to verify the integrity of the filed reports.

11.5. Technical documents such as SOPs, work instructions, datasheets, etc., must be filed and kept for at least two years, in chronological order.

11.6. Urgent results, in the scope of perioperative frozen sections or routine tests, can be transmitted verbally, doctor to doctor. This verbal transmission of information must be duly documented in the laboratory information system, citing the date, hour, and content of the diagnostic report.

11.7. Temporary files must maintain the condition of quality, safety, and traceability of the samples and other documents.

12 Waste management

[9] [7] [2]

12.1. Waste management must comply with the provisions of current local laws and regulations and be executed without putting the laboratory staff at risk and should not be a direct source of environmental contamination.

12.2. The responsibility for waste management is attributed to its generator, whether the laboratory, hospital, clinic, or other health service.

12.3 - The pathology laboratory must have an active waste management plan and related actions must be well documented.

13 Transportation of biological specimens

[9] [11] [7]

13.1. The transport of human biological material is subject to local laws and regulations established by the competent authorities, subject to the peculiarities to each type of material and means of transport. Appropriate labelling of the primary and secondary container is particularly important. The primary container must have accurate patient identification, with name, date of birth, and preferably also the local social security number or official identification.

13.2. Procedures that require transportation to a location other than the collection site, require an informed consent form, informing patients or their legal representatives, the destination of their sample, type of test, and indicating the laboratory that will analyse it.

13.2.1. In cases of bidding or invitation letter after the material is collected, the health service that generates the samples will be responsible for the consent form, which may be the same, regardless of the type of sample.

13.3. Third-party companies hired to provide transport are jointly liable for damages resulting from losses, as well as for damages related to carelessness in the custody, conservation, preservation, and transportation of the samples sent for tests while under their care.

14 Collection station

[9]

14.1. The pathology laboratory that works on an outpatient and/or hospital basis is considered a collection station service, characterised by the execution of procedures for collecting human material for the purposes of diagnosis, perioperative diagnoses, and clinical follow-up.

14.2. The collection station, in order to function, must be linked technically and formally to a pathology /cytopathology laboratory and its purpose described in the proper document stating its company of origin.

14.3. The collection station will only be able to function through an operating license issued by the competent health agency in its area of jurisdiction.

14.4. From the organisation:

14.4.1. Requirements for the physical structure of collection stations

- › Reception/waiting area for patients and companions, with a recommended minimum size of 1.2 m² per person.
- › The reception/waiting room and toilets can be shared with another adjacent unit, like collection room, if applicable.
- › Public/patient toilets.
- › Procedures Room: recommended minimum size of 7.5 m², which is mandatory in the units that perform Fine Needle Aspiration (FNA) procedures, and/or gynaecological collection, and or incisional biopsies. When performing gynaecological procedures, an attached toilet must be provided.

- › Classification and distribution of samples (triage) area with a recommended minimum size of 3.0 m² with a cold running water point and respective sink.
- › Supporting areas like waste disposal site, cleaning material deposit, and small kitchen if needed.
- › Equipment: must have a refrigerator to store liquid cytological material or body fluids, if applicable.
- › Installation: sink, eyewash.
- › Cardiac arrest emergency reanimation kit, and ventilation equipment according to local law for inpatient and outpatient small procedures operating room.

14.5. The technical personnel responsible for the collection station must use the pathology laboratory good practices manual and ensure its compliance.

Glossary

Anatomic pathology or pathology: medical specialty that studies and diagnosis diseases based on clinical and morphological correlation by means of macroscopic, microscopic, biochemical, immunologic, and molecular examination of human organs, tissues and cells.

Area: it may be a separate compartment, a closet, or a designated space in a room. There is no presupposed dimension for this area. An open environment, without walls on one or more faces.

Autopsy: a post-mortem examination to discover the cause of death or the extent of disease, performed by a pathologist or forensic physician.

Client: Any user of the pathology laboratory services. These can be patients and their families, physicians, nurses or other professionals interested in the services provided by the laboratories.

Cleaning material deposit (CMD): a room for the storage of appliances, utensils, and cleaning material, equipped with a washing tank.

Critical supply or consumable: one that directly affects the quality of the analysis result.

Cytopathology: a branch of anatomic pathology that deals with manifestations of disease at the cellular level.

Deposit of equipment/materials: a closed area for the storage of pieces of furniture, appliances, equipment, and accessories for eventual use or in maintenance.

Diagnostic services: for the purpose of this document, Diagnostic Services are considered pathology and or cytopathology laboratories with all their related techniques employed in order to perform diagnostic procedures and issuing the respective results in the form of pathology or cytopathology reports.

Diagnostic product for in-vitro use: reagents, standards, calibrators, controls, materials, articles, and instruments, together with instructions for their use, that contribute to carrying out a qualitative, quantitative or semi-quantitative determination of a biological sample and that are not intended to fulfil any anatomical, physical or therapeutic function, which are not ingested, injected or inoculated in human beings and which are used only to prove information about samples obtained from the human organism.

Environment: physically determined and specialised space for the development of a particular activity, characterised by different dimensions and facilities. An environment can consist of a room or an area.

In-house methodology: reagents or analytical systems produced and validated by the laboratory itself, exclusively for its use, in research or diagnostic support.

Informed consent form: a formal document that describes the activity that will be performed to inform the patient about the objective, risks and benefits, as well as the facility where the procedure/test will be performed. The patient must be competent to make a voluntary decision about whether to undergo the procedure or allow the sample transportation to another facility to be submitted to an analysis or analyses that cannot be carried out at the primary institution.

Laboratory director or responsible technician: the medical director of the laboratory is a suitably qualified physician who is legally, morally, and ethically responsible for the scope, standards, and quality of service. The medical director has the knowledge and skills in all areas of practice, including administration, teaching and education, research, and patient care. The director stands responsible for medically useful, accurate information made available in a timely fashion to enhance medical services to patients. The director participates in all managerial decisions and guides the operation of the laboratory ranging from the selection of staff, choice of methods, purchase of equipment, quality assurance, quality control, safety, hours of operation, scheduling of staff, and utilisation management.

Laboratory equipment: generic designation for a device used by the laboratory as an integral part of the analytical process.

Legally qualified professional: professional with higher or technical education with competencies assigned by law.

Operating license: the document issued by the competent state or municipal health agency, which regulates and allows the operation of establishments that carry out activities under the health surveillance regime.

Pathology laboratory: laboratories whose main activity is the exercise of pathology or anatomic pathology, which entails cytopathology, immunohistochemistry, molecular biology, which may be exclusively dedicated to any of these areas. A collection station, defined as a room or rooms dedicated to the collection of samples like cervical cytology or skin biopsy specimens, and being able to transport the collected human biological material, which may or may not be attached to a pathology laboratory.

Quality manual (QM): the collection of operational procedures related to the activities performed by the laboratory to achieve test results, maintenance, archive, and others and the internal policies related to these activities.

Quality Control System (QCS): organisational structure, responsibilities, standardised procedures, processes, and resources for improving quality management to control and improve processes, guaranteeing their results.

Record or register: any document, physical or virtual, destined to write any data or occurrence in the laboratory, such as patient data, reports of accidents, adverse events, etc.

Report or pathology report or cytopathology report: the document generated by the laboratory containing information about the laboratory, the patient, and the data resulting from their tests and the legally qualified professional responsible for the analysis as well as the technical director of the laboratory.

Room: area surrounded by walls along its perimeter and a door, with or without a window.

Sample, specimen, or human biological material: fluids, secretions, tissues, any product of surgical procedure, small or large, and human organs.

Standard Operating Procedure (SOP): the written procedure that defines how to perform any laboratory activity to its full extent, always achieving the same result.

Supporting environment: a room or area that supports environments intended for the purpose of a unit. Example: a chemical hood area supports the staining solutions preparing the area.

Traceability: the ability to recover the history, the raw data related to the tests, and their quality controls, the location of the respective biological samples and their records.

Validation: a procedure that provides evidence that a system performs within quality specifications, in a standardised manner, thus able to release valid results.

Work instructions: any document that serves as a guide or protocol for a determined activity or procedure. Example: the instructions to perform a slide staining.

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