A022

~~Medical laboratories – presentation of the national legislation~~

Accreditation programme for medical laboratories

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1. Introduction

The ISO 15189:2012 standard specifies requirements for quality and competence in medical laboratories that are verified in the course of accreditation.

Medical analyses activities are also framed by a national legislation whose provisions sometimes overlap those of the standard ISO 15189:2012, while adding clarifications or supplementary requirements.

The aim of this annex is:

- To present the national regulation applicable to medical laboratories to the assessors;
- To highlight in particular, the provisions of the *Grand Ducal regulation of 27 May 2004 determining the minimum criteria to be observed in the context of overall operations of a medical laboratory* that constitute supplementary requirements or clarifications with regard to the standard ISO 15189:2012.
- To set out specific provisions relating to the assessment of sampling sites or facilities.

This annex does not release neither OLAS assessors, nor accredited organismes or organisms in the process of accreditation, from following developments of the national legislation.

2. Definitions

The definitions given in procedure *P002* apply.

Laboratory manager "responsable de laboratoire" :

According to the *grand-ducal regulation of 27 May 2004 determining the minimum criteria to be observed in the context of overall operations of a medical analysis laboratory*, the laboratory manager is the person who validates analysis results.

Each laboratory manager must hold a degree in medicine, pharmacy or chamistry. He also has to have undergone specific training, whose contents and conditions are determined by the *grand-ducal regulation of 18 December 1998 establishing the disciplines of biomedical analysis laboratory and regulating the specialized training of laboratory managers*. The authorisation issued by the Minister of Health sets out the disciplines for which the person is authorised to exercise the function of a laboratory manager.

If a laboratory has activities that cover several disciplines of laboratory medicine, it must be led either by a person who has undergone the required training for each concerned activity, or by several persons having each one undergone training for one of the planned activities.

Medical laboratory (Law of 16 July 1984):

Laboratory performing tests that contribute to the prevention, diagnosis and treatment of human diseases or which reveal any other change in the physiological state. These analyses can be performed only in laboratories that meet the conditions laid down by the *law of 16 July 1984 concerning medical laboratories* and under the responsibility of the persons referred to in article 4 of this law. Only these laboratories are authorised to use the name of "laboratoire d'analyses médicales".

Blood Transfusion Centre (GDR of 25 January 2006):

The organism which, approved in accordance with article 4 of the law of 15 March 1979 regulating blood transfusion, is responsible for any aspect of human blood or blood components collection and control,

whatever use they are intended for, and their processing, storage and distribution if intended for transfusion. The present definition does not apply to hospital blood banks.

Hospital blood bank (GDR of 25 January 2006):

A unit of a hospital or a specialised hospital, referred to in article 1 of the law of 28 August 1998 on hospitals, which stores and distributes blood and blood components exclusively intended for use in hospital services, including blood transfusions within hospitals and that can effect compatibility tests.

Tissue bank (Law of 1 August 2007):

A tissue bank or a unit of a hospital or another organism that conducts processing, preservation, storage or distribution of human tissues and cells. Tissue banks may also be responsible for obtaining or controlling of tissues and cells.

In vitro diagnostic medical device (Regulation (EU) 2017/746):

Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

a) concerning a physiological or pathological process or state;
b) concerning congenital physical or mental impairments;
c) concerning the predisposition to a medical condition or a disease;
d) to determine the safety and compatibility with potential recipients;
e) to predict treatment response or reactions;
f) to define or monitor therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices.

Note (Recital 17 of Regulation (EU) 2017/746):
Software, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of an in vitro diagnostic medical device, qualifies as an in vitro diagnostic medical device, while software for general purposes, even when used in a healthcare setting, or software intended for well-being purposes is not an in vitro diagnostic medical device.
The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.

Specimen receptacle (Regulation (EU) 2017/746):

'Specimen receptacle` means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Health institution (Regulation (EU) 2017/746):

An organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.

Examples of health institutions (recital 29 of Regulation (UE) 2017/746)):
Hospitals, laboratories, public health institutes. It should be noted that the concept of 'health institution' does not cover establishments primarily claiming to pursue health interests or healthy lifestyles, such as gyms, spas, wellness and fitness centre.

Incident (Regulation (UE) 2017/746):
Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any harm as a consequence of a medical decision, action taken or not taken on the basis of information or result(s) provided by the device.

Serious incident (Regulation (UE) 2017/746):

Any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person;

b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health;

c) a serious public health threat.

Putting into service (Regulation (EU) 2017/746):

The stage at which a device, other than a device for performance study, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose.

3. Specifi requirements

3.1. Overview of the legislation applicable to medical laboratories :

Hierarchy of legal standards	Medical laboratories			
		Analyses reimbursed by the National Health Fund	**Blood transfusion**	**Human tissues and cells intended for human applications**
EUROPEAN REGULATIONS	Regulation (UE) 2017/746 on *in vitro* diagnostic medical devices			
LAWS	Medical laboratories		Blood transfusion regulation	Human tissues and cells intended for human applications (directive 2004/23/CE)
GRAND DUCAL REGULATIONS	Minimum criteria Disciplines of a medical laboratory Dispositifs médicaux de diagnostic in vitro (directive 98/79/CE)	Classification of acts and services of medical laboratories	Quality and security standards (directive 2002/98/CE)	Technical requirements (directive 2006/86/CE) Traceability requirements (directive 2006/17/CE)
MINISTERIAL REGULATION			Technical requirements concerning blood/ blood components (directives 2004/33/CE et 2011/38/UE) Notification of serious adverse reactions and events (directive 2005/61/CE) Quality system (directive 2005/62/CE)	
AGREEMENTS		Agreement between the FLLAM and the CNS		

All the luxembourgish legislation on health is easily accessible through the Health Code (in French).

3.2. In vitro diagnostic medical devices

3.2.1. In-house medical devices

The grand-ducal regulation of 24 July 2001 on in vitro diagnostic medical devices includes provisions concerning the placing on the market and putting into service of in vitro diagnostic medical devices (hereinafter referred to as “devices”).

The technical specifications applicable to devices in Annex II, List A are laid down in Decisions 2002/364/EC, 2009/108/EC and (EU) 2019/1244.

An in vitro medical device may be put into service only if it complies with the Regulation EU) 2017/746 when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, shall be considered as having been put into service.

However, the requirements of the above-mentioned Regulation shall not apply to devices manufactured and used only within health institutions established in the Union, provided that all of the conditions of **article 5 (5) of Regluation 2017/746** are met. Then, CE marking of internally manufactured products is not required.

Examples of devices involved: FISH probes, PCR primers, culture media, in-house manufactured quality controls.

According to Article 5 (5) of Regulation 2017/746 the following conditions must be met:

a) the devices are not transferred to another legal entity;

b) manufacture and use of the devices occur under appropriate quality management systems;

c) the laboratory of the health institution is compliant with standard EN ISO 15189 or where applicable national provisions, including national provisions regarding accreditation;

d) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;

e) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

f) the health institution draws up a declaration which it shall make publicly available, including:

   (i) the name and address of the manufacturing health institution,
   (ii) the details necessary to identify the devices,
   (iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable,

information on which requirements are not fully met with a reasoned justification therefor;

g) as regards class D devices in accordance with the rules set out in Annex VIII, the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met. Member States may apply this provision also to class A, B or C devices in accordance with the rules set out in Annex VIII;

h) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (g); and

i) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

According to Regulation (EU) 2022/112 of 25 January 2022, points b), c) and e) to i) above shall apply from 26 May 2024; point d) above shall apply from 26 May 2028.

The general safety and performance requirements set out in **Annex I of Regulation 2017/746** do also remain applicable to in-house manufactured devices.

3.2.2. Reactovigilance alerts and material vigilance

According to § 5.3.1.6 of ISO 15189:2012, adverse incidents and accidents that can be attributed directly to specific equipment shall be investigated and reported to the manufacturer and appropriate authorities, as required.

In Luxembourg, the competent authority for medical devices is the Direction de la Santé. In accordance with Article 82 (10) of Regulation 2017/746, any healthcare professional, user or patient can communicate serious incidents to the competent authority via the email address meddevices.vigilance@ms.etat.lu.

3.3. Medical laboratories

The *law of the 16th July 1984 on medical laboratories* sets the general framework for the operation of a medical laboratory.

Thus, the opening and operation of a laboratory for medical analyses must be authorized by the Minister of Health. Furthermore, the law refers to different grand-ducal regulations with regard to particular training required by laboratory managers and minimum criteria concerning personnel, facilities, installations and equipment.

Moreover, the law requires medical laboratories to participate in mandatory quality controls for biomedical analyses. The list of approved providers of proficiency tests and the list of mandatory quality controls are fixed annually by the Minister of Health.

☞ Competent authority: general control of laboratories for biomedical analyses is operated by doctors of the Directorate of Health, pharmacists-inspectors as well as doctors, pharmacists and engineers of the National Laboratory of Health (Laboratoire national de santé).

3.3.1. Medical laboratories – minimum criteria

The *grand-ducal regulation of 27 May 2004 determining the minimum criteria to be observed in the context of overall operations of a medical laboratory* aims to establish the minimum criteria to be met by a medical laboratory. The requirements of the standard ISO 15189 largely cover the provisions of this regulation. However, in some cases the regulation provides additional clarifications, which are detailed below.

§ of the standard ISO 15189 :2012	Article of the GDR of 27 May 2004	Additional requirements of GDR of 27 May 2004
4.1 Organization and management responsibility	Art 2 and 3	• Each laboratory staff member must be able at any time to refer to the laboratory manager. He must be present in his laboratory at the diurnal phases of maximum activity of working days. It must be possible to call him after hours and especially at night when a permanence with qualified personnel is organised in the laboratory. • The laboratory must evaluate the minimum number of staff in relation to the overall volume of analyses performed during the course of the previous calendar year.
4.5 Examination by referral laboratories **4.5** Examination by referral laboratories	Art 12 and 13 Art 12 and 13	• The results of analyses carried out on samples sent by a laboratory to another laboratory must be communicated by the laboratory that conducted the analysis, to the prescribing doctor, to the laboratory having transmitted the samples, and to the patient if request by him. *This provision is completed by the provisions of the recent agreement between the FLLAM and CNS, which states that the laboratory transmitting the analyses is responsible for communicating the results to the prescribing phyisician by integrating the report of the collaboration laboratory as appendix.* • For the transmission of samples between laboratories, the laboratory must use the document as described in annex I of the present regulation.
4.13 Control of records	Art 12	• Nominative and chronological analysis results have to be archived and kept for a period of ten years.
5.1 Personnel	Annex III	• The laboratory shall ensure that measures concerning personal health and safety as well as environmental protection, including the smoking ban and the prohibition of food in premises of blood collection, sample reception and analyses, are applied in accordance with current legislation and, where appropriate, in coordination with the occupational physician and the committee on health, safety and working conditions.

§ of the standard ISO 15189 :2012	Article of the GDR of 27 May 2004	Additional requirements of GDR of 27 May 2004
		• The laboratory must establish and implement the applicable procedures relating to health and safety of staff, e.g. use of gloves, protective glasses, use and change of lab coats, formal ban on pipetting by mouth, no recapping of needles after blood collection, use of hoods when handling hazardous materials or contaminants, and cleaning of working areas by respecting durations of action of disinfectants and decontaminants; • The laboratory must ensure compliance with regulations concerning technical preventive measures for staff depending on the toxicity of the products used and on the classification of germs defined by regulations.
5.2 Accomodation and environmental conditions	Art 5, 7 and 9	• Obligation to have a heated, illuminated and ventilated waiting room; • Obligation to have a ventilated toilet with a sink to wash hands; • Obligation to have premsies accessible to disabled persons; • The blood collection premises must have a chair for collecting the samples from both the left and the right side.
5.3 Laboratory equipment, reagents, and consumables **5.3** Laboratory equipment, reagents, and consumables	Art 10 and 11 Art 10 and 11	• Storage areas for raw materials and/ or toxic or potentially hazardous reagents or contaminants shall be separated. • Conservation areas for biological samples must be different from storage areas. • The laboratory manager shall maintain a list of analyses actually realised with the available equipment and make it available to the competent authorities. • Reagents that were prepared and reconstituted in the laboratory shall bear the date of preparation or reconstitution, as well as their expiry date. The reagents from industrial origin must bear the reception date at the laboratory. • The stability of prepared and reconstituted in the laboratory reagents shall be indicated and verified.
5.4 Pre-examination processes	Art 4, 6 and 10	• Any laboratory shall be indicated to the public by a professional plate at the door of the laboratory premises and of the building in which it is installed. • This plate includes the following information: - The name of the laboratory; - The name(s) of the laboratory manager(s);

§ of the standard ISO 15189 :2012	Article of the GDR of 27 May 2004	Additional requirements of GDR of 27 May 2004
		- The disciplines for which it is authorised to carry out analyses; - The opening and closing hours of the laboratory. • Prescribing information must be collected in computerized form and must include the degree of urgency (in addition to the points listed in §5.4.3 of the standard). • The labeling of specimen containers must be made at the time of sampling by the person who did it. • Labelling must unequivocally state the identity of the patient, the nature of the sample, date and time of collection. If a code bar is used for labeling, it shall not hide the information written in clear as required above.
5.5 Examination processes	Art 10	• The mixture of several samples from different individuals is prohibited for individual medical biology analyses: each biological sample must be treated separately.
5.7 Post-examination processes	Art 12 and 14	• Minimum storage temperature and duration after analysis of certain biological samples depending on the requested examinations: **Biological examinations** / **Temperature** / **Duration** Tumour markers: PSA, ACE, CA 15-3, CA 19-9, CA 125 — - 18° Celsius — 1 year Serology : Bacterial serology — - 18° Celsius — 1 year Viral serology — - 18° Celsius — 1 year Parasitic serology — - 18° Celsius — 1 year Molecular biology: Mycobacteria — - 80° Celsius — 1 year Hepatitis B virus — - 80° Celsius — 1 year Hepatitis C virus — - 80° Celsius — 1 year Chlamydia — - 80° Celsius — 1 year Human Immuno-deficiency Virus — - 80° Celsius — 1 year Prenatal diagnostic: Measurement of fetal trisomy 21 serum markers in maternal blood — - 18 ° Celsius — 1 year Diagnostis of infectious embryofoetopathie — - 80° Celsius — 3 years • Results of biomedical analyses msut be validated by the laboratory manager (*responsable de laboratoire*).
5.8 Reporting of results	Art 12 and Annex III	• The analysis reports must appear on laboratory letterhead paper and be signed by the laboratory manager. The reports shall clearly display the name and address of the laboratory that

§ of the standard ISO 15189 :2012	Article of the GDR of 27 May 2004	Additional requirements of GDR of 27 May 2004
		performed the analysis, as well as the name(s) of the laboratory manager(s) under whose control the analyses were performed. The signatory of the report guarantees the accuracy of these statements. Annex III specifies however that, for hospitalised patients and in the case of urgent analyses, partial results can be transmitted in conditions defined by the biologist and under his responsibility, before overall biological validation of all the requested analysis results. They must be confirmed as soon as the final validation has been issued by a biologist and the attending physician has to be informed about this particularity. In the current state of regulation, any telematics signature must be confirmed by a document containing the analysis results certified by a handwritten signature. However, if the results are transmitted electronically, a process of affixing the signature of the biologist on the report can substitute in first-line a handwritten signature. The software must be designed so that affixing of the signature requires the introduction of the biologists secret code and use of a personal hardware.
5.9 Release of results	Art 12 and Annex III	• The results must be transmitted to the prescribing doctor of the patient and to the patient, if he requests them. • The results can not be given to any third party without the patient's permission. When the patient is a legal incapacitated minor or adult, the results can be transmitted to the legal representative who requests them. The results of biomedical analyses must be validated by the laboratory manager. • The biologist of a health care facility must be able to ensure that the system set up for the delivery of reports to the care units meets the criteria of confidentiality and compliance established in coordination with the clinicians and the management team. If the prescribing physician can consult the lab server or another server dedicated to transmit laboratory results, these must be designed to keep track of the consultation. • If the results are transmitted via a telematic process to another laboratory or to the prescribing physician, the biologist must use a reliable transmission system that ensures compliance of the validation of transmitted results and respect of medical confidentiality. The reception system for analysis reports must respect the confidentiality of medical data. It must allow viewing or printing them only on demand from the prescriber, who must use a PIN code and his personal hardware. Teletransmitted results shall in no case arrive in a place accessible to the public. • If the results are addressed to an operating room or a recovery room, they can be streamed continuously, in order to be accessible directly to surgeons, anesthesiologists and intensivists.

§ of the standard ISO 15189 :2012	Article of the GDR of 27 May 2004	Additional requirements of GDR of 27 May 2004
		• If the results are addressed to a hospital or consulting service, the system shall enable viewing or printing them only on demand of the prescriber, trough the use of a PIN code and a his personal hardware. • When the patient is a legal incapacitated minor or adult, the biologist can give the results only to his legal representative. • If the results can not be reported to the prescribing physician (in case of change of the physician or analyses performed at the initiative of the biologist or added at the request of the patient), the biologist must ask the patient to designate a physician to whom he would like the results to be delivered. If no physician isdesignated, the biologist has to inform the patient himself with even more caution and sensitivity that the results are worrying. Any result of concern that the biologist is brought to give, can only be communicated to the patient in hand and during a private interview. The biologist must encourage the patient to consult a physician as soon as possible.

3.3.2. Disciplines of a medical laboratory

The *grand-ducal regulation of 18 December 1998 establishing the disciplines of a medical laboratory and regulating the specialised training of laboratory managers* defines four disciplines that a medical laboratory may include:

a) **medical chemistry** (covers the domains *MED1 - Biochimie clinique*, *MED3 – Immunologie* et *MED6 - Génétique* defined by OLAS)

b) **hematology** (covers the domains *MED2 – Hématologie* et *MED7 – Biologie de la reproduction* defined by OLAS)

c) **microbiology** (covers the domains *MED4 - Microbiologie médicale* et *MED5 – Sérologie* defined by OLAS),

d) **pathological anatomy** (covers the domain *MED8 - Anatomo-pathologie* defined by OLAS)

According to this grand-ducal regulation, the laboratory managers must obtain an autorisation order of the Minister of Health stating for which disciplines of laboratory medicine their training is recognised.

3.4. Analyses reimbursed by the National Health Fund

3.4.1. Classification of acts and services of medical laboratories

Acts and services of medical laboratories that are supported by the National Health Fund are defined by the grand-ducal regulation of 19 March 1999 concerning the classification of acts and services of medical and clinical biology laboratories supported by health insurance, as amended. The price of an act is determined by multiplying its coefficient by the value of the keyletter "L" negotiated for each year by the signatories of the Convention oncluded in implementation of Article 61 of the Social Insurance Code.

3.4.2. Agreement between the FLLAM and the CNS

The Luxembourgish Federation of Medical Laboratories (FLLAM) is a non-profit association whose purpose is representation and defense of professional, material and moral interests of operators and managers of medical laboratories in the private sector. Within the context of the agreement between the Luxembourgish Federation of Medical Laboratories (FLLAM) and the National Health Fund (CNS), concluded in implementation of Article 61 and following the Social Security Code, the FLLAM however represents all medical laboratories of the outpatient sector, including public laboratories. The agreement applies to all budgeted analyses via the nomenclature of acts and services of medical laboratories.

This agreement requires a certain percentage of accreditation of the activities charged to health insurance. These percentages are related to the number of acts charged to the health insurance. Thus, by the 1st January 2018 latest, all laboratories must prove that they are undertaking an accreditation process, and by 1st January 2019 latest, all laboratories must be accredited against ISO 15189 for at least 50% of their activities charged to the health insurance, 80% in 2021, and 90% in 2023.

Medical laboratories that start their activity after entry into force of this agreement, must commit to starting the process for accreditation of their activities within two years of the beginning of their business and be accredited:

- for 50% of their activities charged to the health insurance within 3 years of the start of operations;
- for 80% of their activities charged to the health insurance within 5 years of the start of operations;
- for 90% of their activities charged to the health insurance within 7 years of the beginning of their activity.

The agreement also lays down the principles and technical details for data transmission, as well as professional ethics, including the formal prohibition to provide the medical corps with computer-based tools for assisting medical prescription.

Furthermore, the agreement allows subcontracting of only maximum 20% of the total amount of analyses supported by health insurance. These 20% relate to turnover and not the number of acts. In case of subcontracting, the laboratory subcontracting the analyses is responsible for communicating the analysis results to the prescribing doctor by integrating the report of the referral laboratory in annex.

3.5. Regulation of blood transfusion

The *law of 15 March 1979 on the regulation of blood transfusion* sets the framework within which blood transfusion can be made in Luxembourg.

Collection of human blood or plasma in view of deliverance in the form of whole blood or its derivatives, as well as import and export of human blood or its derivatives, may only be made by a body specifically approved for that purpose by the Minister of Health. The law foresees that the collection of blood or plasma can only be realised by a medical doctor or under his responsability.

The responsible doctor for the management of a blood transfusion service must have a license to practice, issued by the Ministry of Public Health.

Furthermore, the internal regulation of the authorised body, as well as the price at which whole blood and its derivatives (excluding industrially prepared products) are issued, are subject to the approval of the Minister of Public Health.

The law refers to various grand-ducal regulations for:

- the list of derivatives and blood components that can be imported or exported without approval;
- the technical requirements for the determination of blood groups;
- the tests for monitoring the compatibility of the donor blood and the blood of the recipient and the precautions that shall surround transfusions;
- the qualification criteria for donors and their periodic medical examination;
- the conditions and methods for sampling, handling, preparation, storage, dispensing and delivery of human blood and its derivatives;
- premises where the operations are performed as well as equipment and devices used to perform them.

☞ Competent authority: the Minister of Health is the competent authority responsible for implementing the requirements of this act and its executive regulations. The Minister of Health will designate a qualified medical officer of his department who may at any time conduct monitoring inspections with regard to implementation of the law of 15 March 1979 on the regulation of blood transfusion and its implementing measures.

3.5.1. Quality and safety standards – Blood transfusion

The *grand-ducal regulation of 25 January 2006 setting quality and safety standards for the collection, testing, processing, storage, distribution and transfusion of human blood and blood components* contains provisions regarding the implementation of a quality system, haemovigilance, and the quality and safety of blood and blood components. It indicates the requirements for testing of donated blood as well as labeling requirements.

This grand-ducal regulation transposes the EU directive 2002/98/CE.

3.5.2. Technical requirements concerning blood and blood components

The *ministerial regulation of 14 February 2006 determining certain technical requirements concerning blood and blood components* establishes disclosure requirements to provide to and to get from prospective blood donor, as well as acceptance and exclusion criteria of blood donors.

It also determines the conditions of storage, transportation and distribution to be met for blood and blood components, as well as the requirments for quality control of blood and blood components and for blood grouping.

This grand-ducal regulation transposes the EU directives 2004/33/CE and 2011/38/UE.

3.5.3. Notification of serious adverse reactions and incidents

In order to ensure traceability, the blood transfusion centre, hospital blood banks, hospitals, manufacturers and biomedical research institutions to which blood or blood components may be provided shall keep the data set out in Annex I of the *ministerial regulation of 14 February 2006 determining the requirements for traceability and notification of serious adverse reactions and incidents* on an appropriate and readable storage medium for at least thirty years.

Notification of serious adverse reactions shall be realised by using the notification forms published in annex II of this ministerial regulation.

This grand-ducal regulation transposes the EU directives 2005/61/CE.

3.5.4. Quality system – Blood transfusion centres

The *ministerial regulation of 14 February 2006 determining the standards and specifications relating to a quality system within the blood transfusion centre* defines the requirements that quality systems for blood transfusion centres and hospital blood banks must meet.

These requirements notably concern:

- Personnel,
- Accomodation and laboratory equipment,
- Document control,
- Donor eligibility (according to the ministerial regulation of 14 February 2006 determining certain technical requirements for blood and components),
- Laboratory controls (according to the grand-ducal regulation of 25 January 2006 setting standards of quality and safety for the collection, testing, processing, storage, distribution and transfusion of human blood and blood components),
- Labelling (according to the Ministerial Regulation of 14 February 2006 determining the requirements for traceability and notification of serious adverse reactions and incidents),
- Continual improvement.

This grand-ducal regulation transposes the EU directive 2005/62/CE.

3.6. Human tissues and cells intended for human applications

The *law of 1 August 2007 on human tissues and cells intended for human applications* sets standards of quality and safety for human tissues and cells intended for human applications, in order to ensure a high level of protection of human health. Notably, this law applies to the gametes collected for medically assisted procreation. It does however not apply to blood or blood components.

Before starting any activity, the institutions conducting activities of obtaining, controlling, processing, preservation, storage and distribution, or only one of these activities, require an authorisation by the Minister of Health.

This law establishes for instance traceability requirements, conditions for import or export of tissues and cells, the notification system for serious adverse events and reactions, as well as requirements for procurements form a living or deceased donor.

Each tissue bank shall designate a responsible person who shall at least fulfill the following conditions and qualifications:

- be a doctor, licensed to practice in Luxembourg, or hold a diploma certifying a university course in the field of biology;
- and have experience of at least two years in the relevant fields.

In terms of traceability, it is clarified that tissue banks must keep data necessary to ensure traceability for at least 30 years after clinical use. With regard to gametes collected for medically assisted procreation, these data must be kept for at least 50 years. Data storage may also be performed electronically.

The technical requirements with their subsequent adaptations to scientific and technical progress adopted by the Commission of the European Communities in the following areas, are applicable in Luxembourg upon publication in the Official Journal of the European Union:

- Requirements concerning autorisation of tissue banks;
- Requirements for obtaining human tissues or cells;
- Quality system, including training of personnel;
- Selection criteria for donors of tissues and/or cells;
- Laboratory tests required for donors;
- Procedures for obtaining cells and/or tissues and reception at the tissue bankt;
- Requirements for the preparation process of tissue and cell;
- Processing, storage and distribution of tissues and cells;
- Requirements for direct distribution to the recipient of specific tissues and cells.

☞ Competent authority: the doctors, pharmacists and engineers of the Directorate of Health, as well as the doctors, pharmacists and engineers who are public servants of the National Health Laboratory, are in charge of investigating and recording legal offenses and implemention of its regulations.

This law transposes the EU directive 2004/23/CE.

3.6.1. Technical requirements – tissues and cells of human origin

The *grand-ducal regulation of 30 August 2007 concerning the requirements for traceability, notification of serious adverse reactions and events, as well as certain technical requirements for the coding, processing, preservation, storage and distribution of tissues and cells of human origin* specifies the requirements that tissue banks have to fulfill.

The requirements on agrement, designation, autorisation or licensing of the tissue banks cover:

- Organisation and management
- Personnel
- Laboratory equipment, reagents, and consumables
- Accommodation and environmental conditions
- Documentation and records
- Quality control

The regulation also specifies the requirements to be met by preparation processes at the tissue bank.

In the case of assisted reproduction, any type of misidentification or confusion regarding a gamete or an embryo is considered a serious adverse event. All procurement organisations or persons, or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue bank for investigation and notification to the competent authority.

The tissue banks are required to have procedures in place to communicate without delay the cases of suspected serious adverse incidents, as well as the conclusion of the root cause analysis, to the competent authority. The forms to be used are attached to the regulation.

Annex VI of the regulation contains the minimum data concerning the donor/ recipient that must be kept for a minimum of 30 years.

This regulation transposes EU directive 2006/86/CE.

3.6.2. Traceability requirements - tissues and cells of human origin

The *grand-ducal regulation of 30 August 2007 determining certain technical requirements for the donation, procurement and testing of tissues and cells of human origin* aims to determine the requirements for procurement of tissues and cells of human origin and to lay down the procedures for the donation and procurement of tissues and/or cells, as well as for their reception at the tissue bank.

Annex III of this regulation specifies the selection criteria and laboratory tests required for donors of reproductive cells.

The procedures for donation and obtaining cells and/or tissues are specified in annex IV and include among others the consent and identification of the donor, the documentation to establish for each donor and the contents of the procurement report.

This regulation transposes EU Directive 2006/17/EC.

4. Accreditation process

The provisions of procedure *P002* apply to the planning of assessments.

Audit of sampling sites / blood collection centres

As part of their activities, some medical laboratories may use sample collection centres (blood, urine, stool ...) or other collection sites (company, retirement home, home etc.). This sampling activity is an integral part of activities covered by accreditation.

During the first accreditation cycle, OLAS plans to visit a maximum number of collection centres. If the results of the audits are satisfactory, the number of sample collection centres to be visited per accreditation cycle can be reduced to 10 + 20% of the rest (= 10 + (n-10) / 5) from the first renewal.

When other collection sites exist (company, retirement home, home etc.), one witness is planned at each assessment.

To carry out assessment of sample collection sites, OLAS uses technical (or quality and technical) assessors with the necessary competences to cover the activities related to sampling.