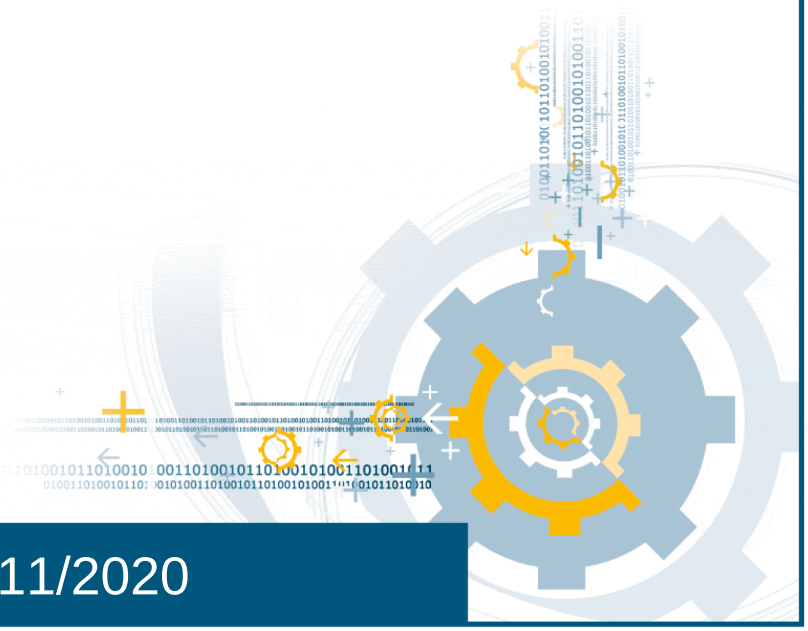
ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS 107:2020

Information Security in the context of Laboratory Accreditation



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Foreword

This Luxembourgish standard (ILNAS 107:2020) has been developed by the working group "Information Security (IS) in Laboratories" set up under the responsibility and chairmanship of the Luxembourg Institute for Standardization, Accreditation, Security and Quality of Products and Services (Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services (ILNAS)).

The reference to this Luxembourgish standard will have to be published in the Official Journal of the Grand Duchy of Luxembourg to receive the status of national standard.

Particular attention is paid to the fact that some of the elements of this document may be subject to intellectual property or similar rights. ILNAS shall not be held responsible for not having identified such property rights and warned of their existence.

This document has been developed in the context of the accreditation of medical laboratories according to ILNAS-EN ISO 15189:2012 and testing and calibration laboratories according to ILNAS-EN ISO/IEC 17025:2017.

Note 1: In this document, texts marked in "*italics"* are extracts from ILNAS-EN ISO 15189:2012 and ILNAS-EN ISO/IEC 17025:2017. The partial publication of these extracts has been approved by ILNAS in its capacity as the Luxembourg Standards Body (Organisme luxembourgeois de normalization (OLN)) and member of the European Committee for Standardization (CEN).

Note 2: Should there be a disagreement in the interpretation or meaning between the English and French versions of this document, the French version published in the Official Journal of the Grand Duchy of Luxembourg prevails.

Introduction

Considering the increasing importance of digitization and the evolution of digital services supporting quality management and management of processes in laboratories, the objectives of this document on information security requirements in laboratories are:

- to offer a more in-depth interpretation of the requirements formulated in the two standards ILNAS-EN ISO 15189:2012 and ILNAS-EN ISO/IEC 17025:2017;
- to propose recommendations for the implementation of adequate information security controls in laboratories, adapted to their needs;
- to focus on the risk-based approach to information security adopted by laboratories;
- to provide more recommendations to the assessors of the Office Luxembourgeois d'Accréditation et de Surveillance (OLAS) for assessing information security aspects in the context of an accreditation assessment.

This document may help laboratories to comply with Article 32 "Security of processing" of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (GDPR) [1].

This document can serve as good practice for public sector laboratories to comply with the amended Law of 14 September 2018 on a transparent and open administration [2].