



NSAI
Standards

Irish Standard
I.S. EN ISO 25237:2017

Health informatics - Pseudonymization (ISO 25237:2017)

I.S. EN ISO 25237:2017

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National Foreword

I.S. EN ISO 25237:2017 is the adopted Irish version of the European Document EN ISO 25237:2017, Health informatics - Pseudonymization (ISO 25237:2017)

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EUROPEAN STANDARD

EN ISO 25237

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2017

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English Version

Health informatics - Pseudonymization (ISO 25237:2017)

Informatique de santé - Pseudonymisation (ISO
25237:2017)

Medizinische Informatik - Pseudonymisierung (ISO
25237:2017)

This European Standard was approved by CEN on 14 December 2016.

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EN ISO 25237:2017 (E)

Contents	Page
European foreword.....	3

European foreword

This document (EN ISO 25237:2017) has been prepared by Technical Committee ISO/TC 215 “Health informatics” in collaboration with Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2017, and conflicting national standards shall be withdrawn at the latest by July 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

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**INTERNATIONAL
STANDARD**

**ISO
25237**

First edition
2017-01

**Health informatics —
Pseudonymization**

Informatique de santé — Pseudonymisation



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Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Abbreviated terms	6
5 Requirements for privacy protection of identities in healthcare	7
5.1 Objectives of privacy protection	7
5.2 General	7
5.3 De-identification as a process to reduce risk	8
5.3.1 General	8
5.3.2 Pseudonymization	8
5.3.3 Anonymization	9
5.3.4 Direct and indirect identifiers	9
5.4 Privacy protection of entities	9
5.4.1 Personal data versus de-identified data	9
5.4.2 Concept of pseudonymization	11
5.5 Real world pseudonymization	13
5.5.1 Rationale	13
5.5.2 Levels of assurance of privacy protection	14
5.6 Categories of data subject	16
5.6.1 General	16
5.6.2 Subject of care	16
5.6.3 Health professionals and organizations	16
5.6.4 Device data	16
5.7 Classification data	17
5.7.1 Payload data	17
5.7.2 Observational data	17
5.7.3 Pseudonymized data	17
5.7.4 Anonymized data	17
5.8 Research data	17
5.8.1 General	17
5.8.2 Generation of research data	18
5.8.3 Secondary use of personal health information	18
5.9 Identifying data	18
5.9.1 General	18
5.9.2 Healthcare identifiers	18
5.10 Data of victims of violence and publicly known persons	19
5.10.1 General	19
5.10.2 Genetic information	19
5.10.3 Trusted service	19
5.10.4 Need for re-identification of pseudonymized data	19
5.10.5 Pseudonymization service characteristics	20
6 Protecting privacy through pseudonymization	20
6.1 Conceptual model of the problem areas	20
6.2 Direct and indirect identifiability of personal information	21
6.2.1 General	21
6.2.2 Person identifying variables	21
6.2.3 Aggregation variables	21
6.2.4 Outlier variables	22
6.2.5 Structured data variables	22
6.2.6 Non-structured data variables	23

ISO 25237:2017(E)

6.2.7	Inference risk assessment	23
6.2.8	Privacy and security	24
7	Re-identification process	24
7.1	General	24
7.2	Part of normal procedures	24
7.3	Exception	24
7.4	Technical feasibility	25
Annex A	(informative) Healthcare pseudonymization scenarios	26
Annex B	(informative) Requirements for privacy risk analysis	39
Annex C	(informative) Pseudonymization process (methods and implementation)	49
Annex D	(informative) Specification of methods and implementation	55
Annex E	(informative) Policy framework for operation of pseudonymization services (methods and implementation)	56
Annex F	(informative) Genetic information	60
Bibliography	61

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

ISO 25237:2017(E)

Introduction

Pseudonymization is recognized as an important method for privacy protection of personal health information. Such services may be used nationally, as well as for trans-border communication.

Application areas include, but are not limited to:

- indirect use of clinical data (e.g. research);
- clinical trials and post-marketing surveillance;
- pseudonymous care;
- patient identification systems;
- public health monitoring and assessment;
- confidential patient-safety reporting (e.g. adverse drug effects);
- comparative quality indicator reporting;
- peer review;
- consumer groups;
- field service.

This document provides a conceptual model of the problem areas, requirements for trustworthy practices, and specifications to support the planning and implementation of pseudonymization services.

The specification of a general workflow, together with a policy for trustworthy operations, serve both as a general guide for implementers but also for quality assurance purposes, assisting users of the pseudonymization services to determine their trust in the services provided. This guide will serve to educate organizations so they can perform pseudonymization services themselves with sufficient proficiency to achieve the desired degree of quality and risk reduction.

Health informatics — Pseudonymization

1 Scope

This document contains principles and requirements for privacy protection using pseudonymization services for the protection of personal health information. This document is applicable to organizations who wish to undertake pseudonymization processes for themselves or to organizations who make a claim of trustworthiness for operations engaged in pseudonymization services.

This document

- defines one basic concept for pseudonymization (see [Clause 5](#)),
- defines one basic methodology for pseudonymization services including organizational, as well as technical aspects (see [Clause 6](#)),
- specifies a policy framework and minimal requirements for controlled re-identification (see [Clause 7](#)),
- gives an overview of different use cases for pseudonymization that can be both reversible and irreversible (see [Annex A](#)),
- gives a guide to risk assessment for re-identification (see [Annex B](#)),
- provides an example of a system that uses de-identification (see [Annex C](#)),
- provides informative requirements to an interoperability to pseudonymization services (see [Annex D](#)), and
- specifies a policy framework and minimal requirements for trustworthy practices for the operations of a pseudonymization service (see [Annex E](#)).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 27799, *Health informatics — Information security management in health using ISO/IEC 27002*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

access control

means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

[SOURCE: ISO/IEC 2382:2015, 2126294]

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