SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 14265:2014

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Zdravstvena informatika - Klasifikacija namenov za obdelavo osebnih zdravstvenih informacij (ISO/TS 14265:2011)

Health Informatics - Classification of purposes for processing personal health information (ISO/TS 14265:2011)

Medizinische Informatik - Klassifikation des Zwecks zur Verarbeitung von persönlichen Gesundheitsinformationen (ISO/TS 14265:2011)

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Informatique de santé - Classification des besoins pour le traitement des informations de santé personnelles (ISO/TS 14265:2011)

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SPÉCIFICATION TECHNIQUE

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CEN ISO/TS 14265

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English Version

Health Informatics - Classification of purposes for processing personal health information (ISO/TS 14265:2011)

Informatique de santé - Classification des besoins pour le traitement des informations de santé personnelles (ISO/TS 14265:2011)

Medizinische Informatik - Klassifikation des Zwecks zur Verarbeitung von persönlichen Gesundheitsinformationen (ISO/TS 14265:2011)

This Technical Specification (CEN/TS) was approved by CEN on 25 June 2012 for provisional application.

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Foreword

The text of ISO/TS 14265:2011 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 14265:2013 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

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ISO/TS 14265 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

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0 Introduction

0.1 Rationale

A fundamental principle underlying the use of personal health data is that it is essential to know the purposes for which data was originally collected and that all subsequent processing activities be the same as, or consistent with, the original purpose. This principle, when applied in conjunction with a standardized list of purposes, forms the foundation for a correspondence of permitted purpose between different users, systems, organizations or policy domains who might need to share personal health information.

Interoperability standards, and their progressive adoption by e-health programmes, are expanding the capacity for organizations to exchange health data. For this to occur on a wide scale, the majority of decisions regarding requests for health data will need to take place automatically. In order that data processing activities (collection, storage, access, analysis, linkage, communication, disclosure and retention) are appropriate, it is important that policies are defined in fully computable ways that are themselves interoperable. Interoperable policies will enable requests between heterogeneous systems and services to be evaluated consistently. In order for automatic processing policies to be defined and operationalized, it is important that governance structures, processes and rules are applied to the design of information and information technology at an enterprise or inter-enterprise level through a number of administrative mechanisms. These mechanisms include enterprise architecture/frameworks, standards, strategy, procedures, laws, regulations, principles and policy, and include operational controls such as committees, budgets, plans, and responsibility agreements (e.g. information sharing agreements, service level agreements and contracts). It is recognized that not all disclosures will take place automatically, and that individual (human) decisions will at times be made, taking policies and governance arrangements into account.

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For ethical and legal reasons, it is normally the case that information is used only for the purpose for which it was collected or created. This purpose can be specified explicitly and consented to. Consent to use data for a particular purpose can also be implied, although it is almost always a requirement that the purposes be declared.

Where data are intended for further and different purposes, a new purpose can require a new consent. For example, in some jurisdictions, data collected for health care cannot automatically be used for research, nor information collected for research used for care, without obtaining new consent. Knowing the purpose for which access to information is intended is essential in order to determine if access to data for processing activities are appropriate.

Increasingly, this problem has become not only one of determining that a user has permission to access particular items of information but also that the user has permission to use them for a specified purpose. It is therefore essential to ensure that the context within which access and use is asserted is the correct one. Purpose (or use, purpose of use, or context of use) when clearly defined, helps to ensure that access to protected information items is granted to properly authorized users under a specific, appropriate and unambiguous policy. The explicit declaration of intended purpose prior to being granted access also helps to ensure that users understand that such access does not imply that use is also permitted for other undeclared, inconsistent purposes. Purpose of use helps bring clarity to situations where there are multiple and potentially conflicting contextually sensitive policies for identical users' access to identical information items.

0.2 Background

ISO/TS 22600-1 defines a generic architectural approach for policy services, and a generic framework for defining policies in a formal way. However, like any generic architecture, a structural framework to support policy interoperability has to be instantiated for use. A policy domain needs also to specify which information properties they wish to take into account when making processing decisions. They need to specify a high level policy model containing those properties, to which all instances of that kind of policy must conform.

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