

DIN EN 14485:2004-03 (E)

Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive; German version EN_14485:2003, text in English

Contents

Page

Foreword	5
Introduction.....	6
1 Scope.....	9
2 Normative references.....	9
3 Terms and definitions	9
4 Abbreviated terms	11
5 General solutions to exchanging personal health data between compliant and non-compliant countries	11
5.1 General approach.....	11
6 Judging the adequacy of data protection.....	12
6.1 General	12
6.2 Content Principles.....	12
6.3 Procedural/Enforcement Mechanisms.....	14
6.4 Third Countries that have ratified the Council of Europe Convention 108	14
6.5 Industry self-regulation	15
7 Making adequate provisions	16
7.1 Introduction	16
7.2 Meeting the "Content Principles"	16
7.3 Providing for the "Procedural/Enforcement Mechanisms"	17
7.3.1 General	17
7.3.2 Providing redress.....	17
7.3.3 Support and help to data subjects	17
7.3.4 Adequate compliance	18
7.3.5 Onward transfers.....	18
7.3.5 Direct marketing and sale of data.....	18
7.4 Overriding law	18
8 Permissible derogations, Articles 26.1 and 26.2.....	19
8.1 Article 26.1	19
8.1.1 General	19
8.1.2 Consent	20
8.2 Article 26.2	20
9 Anonymisation	20
9.1 Definition of personal data.....	20
9.2 Rendering personal data anonymous.....	21
10 Notification to Supervisory Authorities	21
10.1 Introduction	21
10.2 Implementation of Articles 18 to 20.....	21
11 Steps in establishing an international application with adequate data protection safeguards from the view point of an EU data controller.....	22
11.1 Introduction	22
11.2 Step One: Can the data be non-personal?	22
11.3 Step Two: Is the recipient third country an EEA country?	23
11.4 Step Three: Is the recipient country recognised by the Commission as having adequate data protection provisions?	23
11.5 Step Four: Is the recipient organisation in compliance with arrangements formally recognised by the Commission as providing adequate data protection provisions?	24

11.6	Step Five; If the recipient third country is not EEA, has it signed the Council of Europe Convention 108?	24
11.7	Step Six: Is the recipient country applying to become a member of the EU?	24
11.8	Step Seven: Can adequacy of data protection be established?	24
11.9	Step Eight: If adequacy of data protection cannot be established can the derogations in Article 26.1 provide a solution?	24
11.10	Step Nine: If adequacy of data protection cannot be established can the derogation in Article 26.2 regarding contractual clauses provide a solution?	26
11.11	Step Ten: If transfer of personal data health data to the recipient third country is permissible has the recipient implemented adequate security measures and can the application proceed?	26
12	Steps in establishing an international application with adequate data protection safeguards from the viewpoint of a non-EU data controller.....	26
12.1	Establishing data protection adequacy in the EU	26
13	Model contract clauses	27
	Published models	27
14	Security measures	27
14.1	Introduction	27
14.2	General security	28
14.3	Security contracts with processors and with controllers in non-compliant countries	28
14.4	Security policy	28
14.5	Risk analysis	29
14.6	Security organisation and allocation of duties.....	29
14.7	Reporting of security incidents or breaches	29
14.8	Staff and contractor contracts.....	29
14.9	Training and awareness	30
14.10	Transmission of data.....	30
14.11	Limitations of purpose and access.....	30
14.12	Onward transfers	30
14.13	Audit trails	31
14.14	Loss, damage and destruction	31
14.15	Business Continuity Plans.....	31
14.16	Network Security.....	31
14.17	Patients Rights	31
14.18	Compliance.....	32
14.19	Standards.....	32
15	Declaration of grounds on which transfers are to take place	32
15.1	Statement of grounds.....	32
Annex A	(informative) Key primary international documents on data protection.....	33
A.1	EU Data Protection Directive	33
A.1.1	General.....	33
A.1.2	Coverage.....	33
A.1.3	Rules for lawfulness of processing	33
A.1.4	Special categories of processing.....	34
A.1.5	Data subject's rights.....	34
A.1.6	Security of processing	35
A.1.7	Supervisory Authorities	35
A.1.8	Remedies and sanctions.....	35
A.1.9	Transfer of personal data to third countries	35
A.2	Organisation for Economic Co-operation and Development (OECD)	36
A.3	Council of Europe	36
A.4	United Nations General Assembly	37
A.4.1	General.....	37
A.4.2	Principles concerning minimum guarantees that should be provided in any national legislation	37

A.4.3 Application of the Guidelines to personal data files kept by governmental international organisations	38
Annex B (informative) Text of Articles 25 and 26 of the EU Data Protection Directive	39
B.1 Article 25: Principles	39
B.2 Article 26: Derogations	39
Annex C (informative) Text of Article 28 of the EU Data Protection Directive.....	41
Annex D (informative) Questionnaire for Assessing Data Protection Adequacy	43
Annex E (informative) Safe harbour privacy principles	49
Annex F (informative) Standards and sources of advice	52
F.1 EU Security projects	52
F.2 CEN/ISSS.....	52
F.3 Non-CEN Standards	52
F.4 Selected web sites	53
Annex G (informative) Model Declaration of Grounds upon which Transfer of Personal Health Data is Regarded as in Compliance with the EU Data Protection Directive	54
Annex H (informative) Model contractual clauses for controller to controller transfers to a country with inadequate data protection provisions.....	56
H.1 Introduction	56
H.2 Model standard contractual clauses	57
Annex I (informative) Model contractual clauses for controller to processor transfers to a country with inadequate data protection provisions.....	67
I.1 Introduction	67
I.2 Model standard contractual clauses	68
Bibliography.....	76