

Purpose	Document that the data control	ller has implemented adequ	uate measures and that the								
	processing is conducted within	the level of acceptable ris	k.								
	The organizations are obliged	The organizations are obliged to evaluate the probability and consequence of									
	security breaches, and to base the security work on the results of such evaluations										
	measured against the acceptabl	•									
Responsibility	The organization's management	nt is responsible for a risk	assessment being carried								
	out in relation to the processing	g of health and personal da	ıta.								
Execution	The risk assessment shall be ca	arried out prior to the comr	nencement of the								
	processing of health and person	nal data, and in connection	with changes to the								
	processing that may have an in	npact on security.	_								
Scope	All organizations within the he	ealth care sector must cond	uct risk assessments.								
-	Risk assessments shall be adap	oted to the organization's s	ize and the scope of the								
	processing of health and person	nal data.	_								
Target group	□ Organization	☐ Staff/employee									
This fact sheet is	manager/management	Researcher	□ Data processor								
particularly relevant	Person or body	□ Privacy protection	Supplier								
for:	responsible for research	ombudsman									
	Project manager –										
	research										
	Head of security/Security										
	coordinator										
Authority	The Personal Data Regula										
	The Regulations relating to	o interorganizational acces	s to personal health data								
	section 5										
References		Risk assessment of information systems. The Data Inspectorate, Updated: 15									
	Feb 02, Reissued: 6 March										
	The Code of conduct for in		er 6.2 Risk assessment								
	• Fact sheet 5 – Level of acc										
	• <u>www.difi.no</u> with risk asse	essment model									

No	Activity/Description
1	Planning
	a) The management shall develop and adopt a plan for risk assessment in in relation to the processing of health and personal data
	b) Carrying out several smaller risk assessments, rather than a large and extensive one is recommended where possible. This provides a better overview, and the individual risk assessment may be concluded and appropriate measures planned and implemented.
2	Preparing for a risk assessment
	a) Obtain an overview of the processing of health and personal data
	b) Choose the area that is to be assessed (processing, interorganizational access to personal health data, IT system, technical solution, etc)
	c) Prepare, and, if necessary, update the basis for risk assessment, in order that all participants have the same understanding of the area to be assessed
	- Information flow to render visible how health and personal data are being processed
	- Configuration diagram of the technical solution
	d) Preparing proposals concerning threats and unwanted incidents that the working group should consider with regard to processing, process flow, and configuration map
	e) Establish a working group for carrying out the risk assessment. The composition of the group depends on what is to be assessed. It is especially important that daily users of the IT system are involved when the use of IT systems is to be assessed

Activity/Description
f) Adapt the scale of probability and consequences with regard to the level of acceptable
risk
Carrying out the risk assessment
a) Inviting participants to bring forward unwanted incidents they desire assessed
b) The group should go through, and, if necessary, adapt the process flow or configuration diagram
c) Adapt the scale of probability and consequence in line with the group's assessment. The use of a unified internal scale system is recommended. In that way the information security management system becomes an integrated part of the organization's management systems.
d) Document the risk assessment of each individual unwanted incident in line with the scale, consequences, and the magnitude of the consequences, calculate risk (probability multiplied with consequence), existing and proposed measures (NB! Evaluate one unwanted incident at a time) (see the form for risk assessment below). The use of a projector is recommended, in order that all participants may observe what is being documented
e) Indicate if the incident will have an impact on confidentiality, integrity, and availability, in order that a comparison with the predetermined level of acceptable risk is made easier.
Evaluating and recommending new measures
a) Evaluate risk with regard to the determined level of acceptable risk (see Matrix –
evaluating risks below)
b) Prioritize measures where the risk is greater than the level of acceptable risk
c) Develop a plan of action setting out which measures should be implemented when, and who is responsible for doing so. It is important to distinguish between emergency and long-term measures.

## **Example**

The example on the next page shows a suggested form for risk assessment, not the process described above.

In the first example on the next page the risk has been determined as being 8 (probability multiplied by consequence). The matrix below has been taken from *Fact sheet 5 – Level of acceptable risk*, and shows the connection between the level of acceptable risk and the determined risk. The level of acceptable risk in processing health and personal data has been set to 6. The calculated risk of 8 thus exceeds the acceptable risk level, with the consequence that measures must be implemented in order to bring the risk down to an acceptable level (suggested measures are shown in the table on the next page).

y	4 Probable								
bilit	3 Possible								
Probability	2 Less probable			6 <sup>1</sup>	8				
Ъ	1 Improbable								
		1 Insignificant	2 Moderate	3 Serious	4 Critical				
		Consequence							

Table 1 – Evaluating risks

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<sup>&</sup>lt;sup>1</sup> Level of acceptable risk

## Examples of risk assessment forms

## Example 1

RISK ASSESSMENT						
<b>Organization: Dentist Gliset</b>	Organization: Dentist Gliset					
Assessed by: Peder Aas		Date: 12 Feb 2015				
The purpose of the risk assessment:	Availabili	ty and confidentiality				

	Situations considered (unwanted incident/scenario)		Probability			Consequence				Risk level Probability × consequence
		1 = Unlikely	2 = Less likely	3 = Possible	4 = Likely	1 = Insignificant	2 = Moderate	3 = Serious	4 = Critical	Low risk, e.g. risk < 5 Corrective measures not needed.  Medium risk, e.g. between 6 and 8 Corrective measures must be considered.  High risk, e.g. risk > =9 Corrective measures must be taken.
1.	Server containing both current patient records and the backup is stolen from the dental office	1	<b>⊠</b> 2	3	4	1	2	3	4	□Low risk ☑Medium risk □High risk
2.	All data are not backed up prior to the installation of a new version of the electronic patient record	1	2	3	4	1	2	3	4	☐ Low risk☐ Medium risk☐ High risk
3.	Patient identity numbers and personal health data are sent via email	1	2	3	4	1	2	3	4	☐ Low risk☐ Medium risk☐ High risk

_	ption of corrective measures er of priority)	Significance/ Comment	Item no above
1.	Develop procedures for the use of email and provide training in the relevant rules for all employees: sending full personal identity numbers and personal health data via an ordinary email system, either internally or externally, is prohibited	This is a high-frequency risk and the measures will have a significant impact	3
2.	Developing procedures ensuring that a full backup of all data in the electronic patient record is taken prior to the installation of a new version of the system		2
3.	Place the server in a locked room.		1

No	Violation of	Cause / Threat	Unwanted incident	P	Co	R (P×Co)	Possible consequences	Existing measures / Suggested measures	Person responsible / Deadline
1	C, A	Portable computer being stored insecurely in a car or during travelling.  Portable computer holds health and personal data.	Theft of portable computer holding health and personal data.	2	4	8	<ul><li>a) Unauthorised access to the complete set of health and personal data</li><li>b) Interruption to the processing of health and personal data on portable equipment</li></ul>	Existing measures  a) None  Suggested measures  a) Encryption of portable equipment storage media  b) Backup of data stored on portable equipment  c) Possible ban on the processing of health and personal data on portable equipment	
2	С	User lacks training	User sends an SMS informing a patient that a specific medicine has arrived at the pharmacy. The medicine indicates the patient's diagnosis.	2	3	6	a) Violation of the duty of secrecy	Existing measures  a) Procedures for training new employees  Suggested measures  a) Tighten procedures ensuring that new employees receive training  b) Require individuals to sign a document confirming that they have received training	

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No	Violation of	Cause / Threat	Unwanted incident	P	Co	R (P×Co)	Possible consequences	Existing measures / Suggested measures	Person responsible / Deadline
3	I	GP practice burgled Server not secured	Server containing the electronic patient record (including backup) is stolen	1	4	4	<ul><li>a) Unauthorised access to the complete set of health and personal data</li><li>b) Provision of patient care interrupted</li></ul>	Existing measures  a) None  Suggested measures  a) Secure server in locked room  b) Establish backup procedures requiring that the backup is stored separately in a locked and fireproof location	
4	I, A	Backup contents not tested	Backup is discovered to contain no data when an attempt is made to restore the electronic patient record from the backup to the server	1	4	4	<ul><li>a) Provision of patient care interrupted</li><li>b) Patient records contain errors</li></ul>	Existing measures  a) None  Suggested measures  a) Establish procedures for reviewing backup contents  b) Establish procedures for periodically testing that restoring from backup is possible	
5	С	Printer is placed in public area	Visitor (patient or other individual) takes a printout directly from the printer	2	3	6	a) Unauthorized access to health and personal data	Existing measures  a) None  Suggested measures  a) Place the printer in a secure area  b) Acquire technical solution requiring users to authenticate before printouts may be collected	

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No	Violation of	Cause / Threat	Unwanted incident	P	Co	R (P×Co)	Possible consequences	Existing measures / Suggested measures	Person responsible / Deadline
6	A	System configuration is changed without configuration control  Inexperienced individuals carry out software updates	A new version of the electronic patient record is installed, but the system does not work	1	4	4	a) Provision of patient care interrupted	Existing measures  a) None  Suggested measures  a) Establishing procedures for configuration changes, including a requirement that restoring the previous version of the software must be possible	
7	С	Decommissioned equipment is not securely stored  Unauthorized individuals have access to computing equipment containing health and personal data	Computing equipment containing health and personal data ends up in a landfill	1	4	4	b) Unauthorised access to the complete set of health and personal data	Existing measures  a) None  Suggested measures  a) Establishing procedures for decommissioning computing equipment  b) Ensuring that equipment that is to be decommissioned is stored securely	

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