

# DIN EN ISO 27789:2022-01 (E)

## Health informatics - Audit trails for electronic health records (ISO 27789:2021); English version EN ISO 27789:2021

---

<b>Contents</b>		<b>Page</b>
<b>Foreword</b> .....		<b>v</b>
<b>Introduction</b> .....		<b>vi</b>
<b>1</b>	<b>Scope</b> .....	<b>1</b>
<b>2</b>	<b>Normative references</b> .....	<b>1</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>1</b>
<b>4</b>	<b>Abbreviated terms</b> .....	<b>5</b>
<b>5</b>	<b>Requirements and uses of audit data</b> .....	<b>5</b>
5.1	Ethical and formal requirements.....	5
5.1.1	General.....	5
5.1.2	Access policy.....	5
5.1.3	Unambiguous identification of information system users.....	6
5.1.4	User roles.....	6
5.1.5	Secure audit records.....	6
5.2	Uses of audit data.....	6
5.2.1	Governance and supervision.....	6
5.2.2	Subjects of care exercising their rights.....	7
5.2.3	Evidence and retention requirements.....	7
<b>6</b>	<b>Trigger events</b> .....	<b>7</b>
6.1	General.....	7
6.2	Details of the event types and their contents.....	8
6.2.1	Access events to the personal health information.....	8
6.2.2	Query events to the personal health information.....	8
<b>7</b>	<b>Audit record details</b> .....	<b>8</b>
7.1	The general record format.....	8
7.2	Trigger event identification.....	10
7.2.1	Event ID.....	10
7.2.2	Event action code.....	11
7.2.3	Event date and time.....	11
7.2.4	Event outcome indicator.....	12
7.2.5	Event type code.....	12
7.3	User identification.....	12
7.3.1	User ID.....	12
7.3.2	Alternative user ID.....	13
7.3.3	User name.....	13
7.3.4	User is requestor.....	13
7.3.5	Role ID code.....	13
7.3.6	Purpose of use.....	14
7.4	Access point identification.....	15
7.4.1	Network access point type code.....	15
7.4.2	Network access point ID.....	16
7.5	Audit source identification.....	16
7.5.1	Overview.....	16
7.5.2	Audit enterprise site ID.....	17
7.5.3	Audit source ID.....	17
7.5.4	Audit source type code.....	17

7.6	Participant object identification.....	18
7.6.1	Overview .....	18
7.6.2	Participant object type code.....	19
7.6.3	Participant object type code role .....	19
7.6.4	Participant object data life cycle and record entry lifecycle events .....	20
7.6.5	Participant object ID type code.....	22
7.6.6	Participant object Permission PolicySet.....	23
7.6.7	Participant object sensitivity.....	23
7.6.8	Participant object ID.....	24
7.6.9	Participant object name.....	24
7.6.10	Participant object query.....	24
7.6.11	Participant object detail, Participant object description.....	24
<b>8</b>	<b>Audit records for individual events.....</b>	<b>25</b>
8.1	Access events .....	25
8.2	Query events.....	26
<b>9</b>	<b>Secure management of audit data.....</b>	<b>28</b>
9.1	Security considerations.....	28
9.2	Securing the availability of the audit system.....	28
9.3	Retention requirements.....	29
9.4	Securing the confidentiality and integrity of audit trails.....	29
9.5	Access to audit data.....	29
	<b>Annex A (informative) Audit scenarios.....</b>	<b>30</b>
	<b>Annex B (informative) Audit log services.....</b>	<b>36</b>
	<b>Bibliography.....</b>	<b>45</b>