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SR 816.11.n / Anhang 2 der Verordnung des EDI vom ... über das elektronische Patientendossier

Technische und organisatorische Zertifizierungsvoraussetzungen für Gemeinschaften und Stammgemeinschaften

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Anforderungen an Gemeinschaften

1 Verwaltung (Art. 8 EPDV)

1.1 Verwaltung von Gesundheitseinrichtungen (Bst. a und c)

1.1.1 Die Prozesse für den Eintritt und den Austritt von Gesundheitseinrichtungen müssen definiert, dokumentiert, umgesetzt und eingehalten werden.

1.1.2 Der Prozess für den Eintritt von Gesundheitseinrichtungen muss sicherstellen, dass:
1.1.2.1 Vereinbarungen zur Einforderung und Überprüfung von Aufgaben und Pflichten der Gesundheitseinrichtung, mindestens im Bereich Datenschutz und Datensicherheit abgeschlossen werden;
1.1.2.2 die Daten des Abfragedienstes der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV aktualisiert werden;
1.1.2.3 der Prozess «Eintritt von Gesundheitsfachpersonen» (vgl. Ziffer 1.2.2) für alle mit einer Gesundheitseinrichtung eintretenden Gesundheitsfachpersonen ausgelöst wird.

1.1.3 Der Prozess für den Austritt von Gesundheitseinrichtungen muss sicherstellen, dass:
1.1.3.1 der Prozess «Austritt von Gesundheitsfachpersonen» (vgl. Ziffer 1.2.4) für alle mit einer Gesundheitseinrichtung austretenden Gesundheitsfachpersonen ausgelöst wird;
1.1.3.2 sofern sich die austretende Gesundheitseinrichtung keiner anderen Gemeinschaft anschliesst:
1.1.3.2.1 die Dokumente in den Dokumentenablagen der austretenden Gesundheitseinrichtung gelöscht werden;
1.1.3.2.2 die Einträge im Dokumentenregister, die auf Dokumente in den Ablagen der austretenden Einrichtung verweisen, gelöscht werden;
1.1.3.2.3 die betroffenen Patientinnen und Patienten rechtzeitig informiert werden.

1.1.4 Die Gemeinschaft muss für die von ihr registrierten Daten im zentralen Abfragedienst der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV:
1.1.4.1 eine verantwortliche Person benennen;
1.1.4.2 sicherstellen, dass die Aktualität und Korrektheit der Daten:
1.1.4.2.1 der Gesundheitseinrichtungen mindestens halbjährlich überprüft und bestätigt wird;
1.1.4.2.2 der Gruppen von Gesundheitsfachpersonen mindestens vierteljährlich überprüft und bestätigt wird.

1.2 Verwaltung von Gesundheitsfachpersonen (Bst. a bis d)

1.2.1 Die Prozesse für den Eintritt, die Verwaltung und den Austritt von Gesundheitsfachpersonen müssen definiert, dokumentiert, umgesetzt und eingehalten werden.

1.2.2 Der Prozess für den Eintritt von Gesundheitsfachpersonen muss sicherstellen, dass:
1.2.2.1 die Einwilligung der Gesundheitsfachperson zu den spezifischen Richtlinien der Gemeinschaft oder der Gesundheitseinrichtung dokumentiert wird;
1.2.2.2 die Identifikation der Gesundheitsfachperson

1.2.2.2.1 anhand des Identifikationsmittels eines nach Artikel 30 EPDV zertifizierten Herausgebers erfolgt, oder
1.2.2.2.2 den Anforderungen nach Artikel 23 EPDV entspricht;
1.2.2.3 es sich um eine Gesundheitsfachperson nach Artikel 2 Buchstabe b EPDG handelt;
1.2.2.4 das von einem nach Artikel 30 EPDV zertifizierten Herausgeber herausgegebene Identifikationsmittel der Gesundheitsfachperson registriert wird;
1.2.2.5 die Daten des Abfragedienstes der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV aktualisiert werden. Ist die Gesundheitsfachperson in einem eidgenössischen oder kantonalen Berufsregister ((z. B. des Registers über die universitären Medizinalberufe «MedReg», des Registers der Psychologieberufe «PsyReg» oder des Gesundheitsberuferegisters «NAREG») geführt, so sind die entsprechenden Angaben von dort zu übernehmen.

1.2.3 Der Prozess für die Verwaltung von Gesundheitsfachpersonen muss sicherstellen, dass:
1.2.3.1 die Daten des Abfragedienstes der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV aktualisiert werden;
1.2.3.2 der Zugang zum elektronischen Patientendossier überprüft wird;
1.2.3.3 die Zugriffsrechte angepasst werden.

1.2.4 Der Prozess für den Austritt von Gesundheitsfachpersonen muss sicherstellen,:
1.2.4.1 dass die Daten des Abfragedienstes der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV aktualisiert werden;
1.2.4.2 der Zugang zum elektronischen Patientendossier deaktiviert wird;
1.2.4.3 die Zugriffsrechte gelöscht werden.

1.3 Verwaltung von Hilfspersonen von Gesundheitsfachpersonen

1.3.1 Gemeinschaften müssen Prozesse vorsehen, dass Hilfspersonen von Gesundheitsfachpersonen in einem gemeinschaftsinternen Dienst zur Verwaltung von Gesundheitseinrichtungen und Gesundheitsfachpersonen erfasst, verwaltet und gelöscht werden können.

1.3.2 Für die Verwaltung von Hilfspersonen gelten, mit Ausnahme der unten aufgeführten Anforderungen, dieselben Anforderungen wie für Eintritt, die Verwaltung oder den Austritt von Gesundheitsfachpersonen. Ausgenommen sind:
1.3.2.1 die Sicherstellung, dass es sich um eine Gesundheitsfachperson nach Artikel 2 Buchstabe b EPDG handelt;
1.3.2.2 die Aktualisierung des Abfragedienstes der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV.

1.4 Identifikation und Authentisierung (Art. 8 Bst. d)

1.4.1 Für den Zugriff von Gesundheitsfachpersonen auf das elektronische Patientendossier dürfen nur gültige Identifikationsmittel verwendet werden, die von einem nach Artikel 30 EPDV zertifizierten Herausgeber herausgegeben wurden.

1.4.2 Gemeinschaften müssen sicherstellen, dass die eindeutigen Identifikatoren der Identifikationsmittel von Gesundheitsfachpersonen und Hilfspersonen zuverlässig mit der registrierten Identität der jeweiligen Person in der Gemeinschaft verbunden wird.

1.4.3 Gemeinschaften müssen sicherstellen, dass alle technischen Systeme, wie beispielsweise angeschlossene Primärsysteme oder Zugangsportale, die von Gesundheitsfachpersonen oder Hilfspersonen für den Zugriff auf das elektronische Patientendossier genutzt werden:

1.4.3.1 ein starkes Authentifizierungsverfahren nach aktuellem Stand der Technik mit mindestens zwei Authentifizierungsfaktoren als Voraussetzung für die Bearbeitung von Daten des elektronischen Patientendossiers unterstützen.

1.4.3.2 einen vertrauenswürdigen Endpunkt für die sichere Kommunikation mit dem Identitätsdienstleister (Herausgeber des Identifikationsmittels) gemäss Kapitel 3.2 (*P.TrustedCommunityEndpoint*) des Schutzprofils nach Art. 8 EPDV-EDI zur Verfügung stellen.

1.4.4 Gemeinschaften müssen eine so erfolgte Authentifizierung anderer zertifizierter Gemeinschaften und Stammgemeinschaften anerkennen.

1.5 Verwaltung von Gruppen von Gesundheitsfachpersonen (Art. 8 EPDV Bst. a, c, e und f)

1.5.1 Gemeinschaften sind für die Verwaltung der Gruppen von Gesundheitsfachpersonen verantwortlich. Die Richtlinien und Prozesse zur Verwaltung der Gruppen von Gesundheitsfachpersonen müssen definiert, dokumentiert, umgesetzt und eingehalten werden.

1.5.2 Die Prozesse und Richtlinien müssen sicherstellen, dass:

1.5.2.1 die Zusammensetzung der Gruppen für Patientinnen und Patienten jederzeit nachvollziehbar ist;

1.5.2.2 die Patientinnen und Patienten über Eintritte von Gesundheitsfachpersonen in Gruppen von Gesundheitsfachpersonen informiert werden können;

1.5.2.3 die Grössen von Gruppen verhältnismässig bleiben;

1.5.2.4 die Daten im Abfragedienstes der Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV aktualisiert werden.

2 Datenhaltung und Datenübertragung (Art. 9 EPDV)

2.1 Löschen von Daten (Abs. 1 Bst. a und b)

2.1.1 Gemeinschaften müssen Verfahren vorsehen, die sicherstellen, dass:

2.1.1.1 die bei ihnen von den Gesundheitsfachpersonen im elektronischen Patientendossier erfassten Daten nach 10 Jahren vernichtet werden;

2.1.1.2 bei einer Aufhebung des elektronischen Patientendossiers gemäss Artikel 20 Absatz 1 sämtliche Daten vernichtet werden; dabei sind die Daten mindestens aus folgenden

abfragbaren Systemen zu vernichten:

2.1.1.2.1 Dokumentenregister;
2.1.1.2.2 Dokumentenablagen;
2.1.1.2.3 Patientenindex;
2.1.1.2.4 Berechtigungssteuerung;
2.1.1.2.5 internes Zugangsportal.

2.2 Dokumentenablage (Abs. 1 Bst. c)

2.2.1 Gemeinschaften müssen Verfahren vorsehen, die sicherstellen, dass:

2.2.1.1 Dokumente des elektronischen Patientendossiers nur in ausschliesslich für diesen Zweck vorgesehenen Dokumentenablagen gespeichert werden;

2.2.1.2 in den Dokumentenablagen nur die gemäss Anhang 3 der EPDV-EDI zugelassenen Dateiformate gespeichert werden;

2.2.1.3 Dateien im Dateiformat «Portable Document Format» (PDF) nur in der Ausprägung PDF/A-1 oder PDF/A-2 gespeichert werden;

2.2.1.4 als Kodierung von Zeichen in abrufbaren Daten und Dokumenten Unicode UTF-8 verwendet wird.

2.3 Verwaltung auf Wunsch der Patienten (Abs. 2)

2.3.1.1 Gemeinschaften müssen Verfahren vorsehen, damit auf Wunsch der Patientin oder des Patienten bestimmte auf diese oder diesen bezogene Daten (Abs. 2):

2.3.1.1.1 nicht im elektronischen Patientendossier erfasst werden;
2.3.1.1.2 nach Artikel 9 Absatz 1 Buchstabe a weitere 10 Jahre verfügbar bleiben;
2.3.1.1.3 aus dem elektronischen Patientendossier vernichtet werden;

2.3.2 Von den Vorgaben nach Artikel 9 Absätze 1 und 2 EPDV auszunehmen sind Protokolldaten und Daten in den nicht abfragbaren Primärsystemen sowie in Datensicherungen.

2.4 Umsetzung der Vertraulichkeitsstufen (Abs. 3 Bst. a)

2.4.1 Gemeinschaften müssen sicherstellen, dass:

2.4.1.1 die Patientin oder der Patient Daten des elektronischen Patientendossiers den Vertraulichkeitsstufen nach den Vorgaben von Artikel 1 EPDV zuordnen kann. Dies indem die von der Patientin oder dem Patienten über das Zugangsportal der Stammgemeinschaft vorgenommene Zuordnung von Daten des elektronischen Patientendossiers zu einer der vier Vertraulichkeitsstufen, für die jeweiligen bei ihr gespeicherten Dokumente übernommen wird;

2.4.1.2 neu eingestellten Daten die Vertraulichkeitsstufe gemäss Artikel 1 Absatz 2 oder entsprechend der Festlegung des Patienten oder der Patienten nach Artikel 3 Buchstabe c EPDV zugewiesen wird;

2.4.1.3 Gesundheitsfachpersonen neu eingestellten Daten die Vertraulichkeitsstufe «sensible Daten» zuweisen können.

2.5 Durchsetzen der Zugriffsentscheidung (Abs. 3 Bst. a)

2.5.1.1 Gemeinschaften müssen sicherstellen, dass Zugriffe auf Daten ihrer Dokumentenablagen und Dokumentenregister nur gemäss der zuvor eingeholten Zugriffsentscheidung der Stammgemeinschaft erfolgen können.

2.6 Notfallzugriff (Abs. 3 Bst. a)

2.6.1 Hinsichtlich Zugriff in medizinischen Notfallsituationen (Art. 2 Abs. 5 EPDV) müssen Gemeinschaften sicherstellen, dass:

2.6.1.1 vorgängig eine Begründung für den Notfallzugriff angegeben werden muss;

2.6.1.2 ein Notfallzugriff nur nach einer nochmaligen Bestätigung, mittels einer nicht automatisiert reproduzierbaren, manuellen Interaktion der Gesundheitsfachperson möglich ist.

2.6.1.3 die Patientin oder der Patient darüber unverzüglich informiert wird (*Art. 9 Abs. 5 EPDG*);

2.6.1.4 die Information über einen erfolgten Notfallzugriff, sofern sie ausserhalb des elektronischen Patientendossiers elektronisch (z. B. SMS, E-Mail, etc.) übermittelt wird, selbst keine besonders schützenswerten Daten enthält.

2.7 Überprüfung der Berechtigungssteuerung (Abs. 3 Bst. a)

2.7.1.1 Die Berechtigungssteuerung muss die Möglichkeit bieten, dass im Rahmen automatisierter Testszenarien die Korrektheit der Funktionalitäten und Regelauswertungen überprüft werden können.

2.8 Metadaten (Abs. 3 Bst. b)

2.8.1 Gemeinschaften müssen sicherstellen, dass für die Beschreibung der bereitgestellten Dokumente die Metadaten nach Anhang 4 der EPDV-EDI verwendet werden.

2.9 Integrationsprofile (Abs. 3 Bst. d)

Standardschnittstelle zur Identifikationsdatenbank der zentralen Ausgleichsstelle (ZAS)

2.9.1 Die Zugangspunkte der Gemeinschaften müssen sicherstellen, dass sie die von der Zentralen Ausgleichsstelle (ZAS) angebotenen technischen Schnittstellen zur Identifikationsdatenbank (UPI) für die Ausgabe und Nutzung der Patientenidentifikationsnummer gemäss dem Bearbeitungsreglement der ZAS verwenden.

2.9.2 Neben der korrekten technischen Verwendung der Schnittstellen sind auch die organisatorischen Vorgaben gemäss dem Bearbeitungsreglement der ZAS einzuhalten.

Integrationsprofile, nationale Anpassungen der Integrationsprofile und nationale Integrationsprofile

2.9.3 Die Gemeinschaften müssen für die Informationsübertragung die Integrationsprofile nach Artikel 5 Buchstaben a bis c (Integrationsprofile, nationale Anpassungen der Integrationsprofile und nationale Integrationsprofile) im Anhang 5 der EPDV-EDI verwenden.

Akteure und Transaktionen der Integrationsprofile – Gemeinschaftsübergreifende Kommunikation

2.9.4 Die IHE-Akteure *Initiating Gateway* und *Responding Gateway* müssen folgende Transaktionen der Integrationsprofils IHE XCA und IHE XCPD in den Versionen nach Anhang 5 der EPDV-EDI unterstützen:

2.9.4.1 Cross Gateway Query [ITI-38]

2.9.4.2 Cross Gateway Retrieve [ITI-39]

2.9.4.3 Cross Gateway Patient Discovery [ITI-55]

2.9.4.4 Patient Location Query [ITI-56]

Akteure und Transaktionen der Integrationsprofile – Kommunikation beglaubigter Identitäten

2.9.5 Die Gruppierung anderer Akteure mit den IHE-Akteuren *X-Service Provider* und *X-Service User* des IHE-Integrationsprofils IHE XUA richtet sich nach den Vorgaben der nationalen Integrationsprofile und Anpassungen der Integrationsprofile gemäss Anhang 5 der EPDV-EDI und ist dem entsprechend sicherzustellen.

2.9.6 Die IHE-Akteure *X-Service* Provider und *X-Service User* müssen folgende Transaktion des Integrationsprofils IHE XUA in der Version nach Anhang 5 der EPDV-EDI unterstützen:

2.9.6.1 Provide X-User Assertion [ITI-40]

Akteure und Transaktionen der Integrationsprofile – Abfragedienst für Gesundheitseinrichtungen und Gesundheitsfachpersonen

2.9.7 Die IHE-Akteure *Provider Information Consumer* und *Provider Information Source* müssen folgende Transaktionen des Integrationsprofils IHE HPD in der Version nach Anhang 5 der EPDV-EDI unterstützen:

2.9.7.1 Provider Information Query [ITI-58]

2.9.7.2 Provider Information Feed [ITI-59]

Akteure und Transaktionen der Integrationsprofile – Dokumente abrufen

2.9.8 Der IHE-Akteur *Document Consumer* muss folgende Transaktionen des Integrationsprofils IHE XDS in der Version nach Anhang 5 der EPDV-EDI unterstützen:

2.9.8.1 Registry Stored Query [ITI-18]

2.9.8.2 Retrieve Document Set [ITI-43]

Akteure und Transaktionen der Integrationsprofile – Dokumente bereitstellen

2.9.9 Der IHE Akteur *Document Source* muss folgende Transaktionen des Integrationsprofils IHE XDS in der Version nach Anhang 5 der EPDV-EDI unterstützen:

2.9.9.1 Provide and Register Document Set-b [ITI-41]

2.9.9.2 Retrieve Document Set [ITI-43]

Akteure und Transaktionen der Integrationsprofile – Dokumenten-Metadaten mutieren

2.9.10 Der IHE-Akteur *Document Administrator* muss folgende Transaktionen des Integrationsprofils IHE XDS Metadata Update in der Version nach Anhang 5 der EPDV-EDI unterstützen:

2.9.10.1 Update Document Set [ITI-57]

2.9.10.2 Delete Document Set [ITI-62]

Akteure und Transaktionen der Integrationsprofile – Dokumentenregister

2.9.11 Der IHE-Akteur *Document Registry* muss folgende Transaktionen der Integrationsprofile XDS und XDS Metadata Update in den Versionen nach Anhang 5 der EPDV-EDI unterstützen

2.9.11.1 Register Document Set-b [ITI-42]

2.9.11.2 Register Stored Query [ITI-18]

2.9.11.3 Update Document Set [ITI-57]

2.9.11.4 Delete Document Set [ITI-62]

Akteure und Transaktionen der Integrationsprofile – Dokumentenablage

2.9.12 Der IHE-Akteur *Document Repository* muss folgenden Transaktionen des Integrationsprofils IHE XDS in der Version gemäss Anhang 5 der EPDV-EDI unterstützen:
2.9.12.1 Provide and Register Document Set-b [ITI-41]
2.9.12.2 Retrieve Document Set [ITI-43]

Akteure und Transaktionen der Integrationsprofile – Daten für den Patientenindex bereitstellen

2.9.13 Der IHE-Akteur *Patient Identity Source* muss die folgende Transaktion der Integrationsprofile PIX V3 in den Versionen gemäss Anhang 5 der EPDV-EDI unterstützen:
2.9.13.1 Patient Identity Feed HL7 v3 [ITI-44]

Akteure und Transaktionen der Integrationsprofile – Patientenindex bereitstellen und abfragen

2.9.14 Die IHE-Akteure *Patient Demographics Supplier* und *Patient Demographics Consumer* muss die folgende Transaktion des Integrationsprofils PDQ V3 in den Versionen nach Anhang 5 der EPDV-EDI unterstützen:
2.9.14.1 Patient Demographics Query V3 [ITI-47]

Akteure und Transaktionen der Integrationsprofile – Patientenindex verwalten

2.9.15 Der IHE-Akteur *Patient Identifier Cross-reference Manager* muss die folgenden Transaktionen des Integrationsprofils IHE PIX V3 in den Versionen nach Anhang 5 der EPDV-EDI unterstützen:
2.9.15.1 Patient Identity Feed HL7 V3 [ITI-44]
2.9.15.2 PIX V3 Query [ITI-45]
2.9.15.3 PIX V3 Update Notification [ITI-46]

Akteure und Transaktionen der Integrationsprofile – Authentisierung von Systemen und Protokollierung von IHE-Transaktionen

2.9.16 Die Gruppierung anderer Akteure mit den IHE-Akteuren *Secure Application* und *Secure Node grouped with Any IHE Actor* des Integrationsprofils IHE ATNA (resp. der nationalen Anpassung dazu) richtet sich nach den Vorgaben der IHE-Integrationsprofile, der nationalen Integrationsprofile sowie der Anpassungen der Integrationsprofile und ist dem entsprechend sicherzustellen.

2.9.17 Die Akteure in der Rolle *Secure Node grouped with Any IHE Actor* müssen die folgenden Transaktionen des Integrationsprofils IHE ATNA und seiner nationalen Anpassung gemäss Anhang 5 der EPDV-EDI unterstützen:
2.9.17.1 Maintain Time [ITI-1]
2.9.17.2 Authenticate Node [ITI-19]

2.9.18 Die Akteure in der Rolle *Secure Application* müssen die folgende Transaktion des Integrationsprofils IHE ATNA und seiner nationalen Anpassung gemäss Anhang 5 der EPDV-EDI unterstützen:
2.9.18.1 Record Audit Event [ITI-20]

Akteure und Transaktionen der nationalen Integrationsprofile – Autorisierungsentscheid abfragen

2.9.19 Die Gruppierung anderer Akteure mit dem Akteur *Authorization Decision Consumer* des nationalen Integrationsprofils CH:ADR richtet sich nach den dort spezifizierten Vorgaben und ist dem entsprechend sicherzustellen.

2.9.20 Die Akteure *Authorization Decision Provider*, *Authorization Decision Consumer* und *Policy Repository* müssen die Transaktionen des nationalen Integrationsprofils CH:ADR gemäss den technischen Spezifikationen nach Anhang 5 der EPDV-EDI unterstützen.

Akteure und Transaktionen der nationalen Integrationsprofile – Berechtigungskonfiguration managen

2.9.21 Die Akteure *Policy Repository* und *Policy Manager* müssen die Transaktion des nationalen Integrationsprofils CH:PPQ gemäss der technischen Spezifikation nach Anhang 5 der EPDV-EDI unterstützen.

Authentisierung mit gültigen Zertifikaten

2.9.22 Gemeinschaften müssen über ein gültiges elektronisches Zertifikat verfügen, das bei einer nach dem Bundesgesetz vom 19. Dezember 2003 über die elektronische Signatur anerkannten Anbieterin von Zertifikatsdiensten bezogen wurde, für:

2.9.22.1 die gegenseitige Authentisierung ihrer Zugangspunkte;

2.9.22.2 die gegenseitige Authentisierung ihrer Zugangspunkte gegenüber den Abfragediensten nach Artikel 38 Absatz 1 Buchstaben a bis c EPDV;

2.9.22.3 die gegenseitige Authentisierung ihrer Zugangspunkte gegenüber gegenüber der Identifikationsdatenbank der ZAS.

2.9.23 Gemeinschaften müssen für den Datenaustausch mit den Abfragediensten nach Artikel 38 Absatz 1 Buchstabe a die Transaktionen des Integrationsprofils IHE ATNA verwenden.

2.9.24 Gemeinschaften müssen für den Datenaustausch mit der Identifikationsdatenbank der ZAS die Datenaustauschplattform SEDEX (secure data exchange) des Bundesamtes für Statistik verwenden.

Konsistente Zeit der Schweiz

2.9.25 Für Zeitstempel in der Kommunikation und Protokollierung ist die gesetzliche Zeit der Schweiz der METAS zu verwenden. Die Uhren aller relevanten informationsverarbeitenden Systeme müssen mit der gesetzlichen Zeit der Schweiz synchronisiert sein.

2.10 Protokolldaten (Abs. 3 Bst. e)

Anforderungen an das Protokollierungssystem:

2.10.1 Jede Bearbeitung von Daten des elektronischen Patientendossiers ist zu protokollieren und mit Zeitstempel zu versehen.

2.10.2 Die Protokolldaten sind auf das erforderliche Mass zu beschränken und dürfen keine medizinischen Daten enthalten.

2.10.3 Es gelten folgende Anforderungen:

2.10.3.1 vorgesehene Protokollierungen dürfen nicht umgangen werden können;

2.10.3.2 eine nachträgliche Veränderung von Protokolldaten darf nicht möglich sein;
2.10.3.3 bei der Protokollierung muss unterschieden werden zwischen Zugriffen, die aus der Nutzung des elektronischen Patientendossiers resultieren und für Patientinnen und Patienten einsehbar sein müssen sowie technisch-administrativen Zugriffen im Rahmen des Systembetriebs;
2.10.3.4 für Systemadministratoren darf keine Möglichkeit bestehen, die Protokollierung ihrer eigenen Aktivitäten zu löschen oder zu deaktivieren.

2.10.4 Protokolleinträge für die Einsichtnahme durch den Patienten oder die Patientin sind jedes Mal dann zu erzeugen, wenn
2.10.4.1 folgende Daten bearbeitet werden:
2.10.4.1.1 die Dokumente in den Dokumentenablagen;
2.10.4.1.2 die Einträge im Dokumentenregister;
2.10.4.1.3 die Konfiguration der Berechtigungssteuerung;
2.10.4.1.4 die Daten des Patientenindex.
2.10.4.2 folgende Ereignisse auftreten:
2.10.4.2.1 die Authentifizierung am System (Login/Logout);
2.10.4.2.2 erfolgreiche und abgewiesene Versuche auf das System zuzugreifen;
2.10.4.2.3 die Suche nach dem Patientendossier;
2.10.4.2.4 die Suche nach Dokumenten eines Patientendossiers;
2.10.4.2.5 ein erfolgter Notfallzugriff;
2.10.4.2.6 erfolgreiche und abgewiesene Versuche auf Dokumente zuzugreifen;
2.10.4.2.7 die Registrierung eines neuen Identifikationsmittels.

2.10.5 Bei Aufruf einer Suchfunktion muss das Protokoll mindestens enthalten:
2.10.5.1 verwendete Such- bzw. Abfragekriterien (z. B. verwendete Identifikatoren, Name, Geburtsdatum, etc.);
2.10.5.2 Angaben zum Ergebnis der Abfrage (z. B. Anzahl Ergebnisse);
2.10.5.3 etwaige Folgeaktionen (z. B. Auswahl eines Datensatzes aus einer Trefferliste, Druck, Datenexport).

2.10.6 Die Protokolldaten sind 10 Jahre aufzubewahren.

2.10.7 Der Abruf und die Darstellung der Protokollinformationen für die Einsichtnahme durch den Patienten oder die Patientin richtet sich nach den nationalen Anpassungen zum IHE-Integrationsprofil ATNA («Audit Trail Consumption») und dem dort enthaltenen technischen Austauschformat für Protokollinformationen in Anhang 5 der EPDV-EDI.

2.11 Verknüpfung der Patientenidentifikationsnummer mit Dokumenten (Abs. 3)

2.11.1 Gemeinschaften müssen sicherstellen, dass die Patientenidentifikationsnummer der ZAS nicht persistent in den Dokumentenablagen oder Dokumentenregistern gespeichert wird und in den Primärsystemen nicht direkt und dauerhaft mit Dokumenten der Patientinnen und Patienten verknüpft wird.

3 Zugangsportal für Gesundheitsfachpersonen (Art. 10 EPDV)

3.1 Konformität mit gesetzlichen Bestimmungen

3.1.1 Das Zugangsportal für Gesundheitsfachpersonen muss den einschlägigen rechtlichen Anforderungen entsprechen.

3.2 Darstellung

3.2.1 Die Darstellung auf den Benutzeroberflächen des Zugangsportals muss korrekt und vollständig sein und klar erkennen lassen:

3.2.1.1 ob ein Dokument durch eine oder durch den Patienten oder die Patientin selbst bereitgestellt wurde;

3.2.1.2 welche Dokumente von der zugreifenden Gesundheitsfachperson selbst bereitgestellt wurden;

3.2.1.3 welche Dokumente annulliert wurden;

3.2.1.4 welche Versionen eines Dokumentes gegebenenfalls auch vorhanden sind

3.3 Barrierefreiheit

3.3.1 Das Zugangsportal muss:

3.3.1.1 so ausgestaltet sein, dass behinderte oder ältere Gesundheitsfachpersonen dieses barrierefrei nutzen können;

3.3.1.2 den Konformitätsbedingungen gemäss Web Content Accessibility Guidelines (WCAG) 2.0 entsprechen und die Konformitätsstufe AA erreichen.

3.4 Dateiformate: Bereitstellung

3.4.1 Das Zugangsportal muss:

3.4.1.1 die Möglichkeit bieten, die gemäss Anhang 3 der EPDV-EDI zugelassenen Dateiformate bereitzustellen;

3.4.1.2 die Dateien anderer Formate vor dem Abspeichern in der Dokumentenablage in ein zugelassenes Format umwandeln.

3.5 Dateiformate: Abruf

3.5.1 Das Zugangsportal muss:

3.5.1.1 die Möglichkeit bieten, die gemäss Anhang 3 der EPDV-EDI zugelassenen Dateiformate abzurufen;

3.5.1.2 den Abruf von Dateien zum Abspeichern im Primärsystem unterstützen («Download»);

3.5.1.3 die Möglichkeit bieten, ausgewählte Dokumente nicht nur einzeln, sondern auch gesammelt («bulk download») herunterzuladen;

3.5.1.4 strukturierte Daten menschenlesbar, korrekt und vollständig darstellen;

3.5.1.5 die Möglichkeit bieten, dass strukturierte Daten sowohl im Originalformat, als auch als menschenlesbares Format heruntergeladen werden können.

3.5.2 Für den Abruf von Dokumenten zur Darstellung oder zum Abspeichern sind zulässige Obergrenzen für die erlaube Anzahl von Dokumenten pro Zeiteinheit («rate limits») zu definieren, welche beim Überschreiten geeignete Sperr- oder zusätzliche Sicherheitsmassnahmen auslösen.

4 Datenschutz und Datensicherheit (Art. 11 EPDV)

4.1 Anforderungen an Dritte

4.1.1 Die Sicherstellung der Anforderungen dieses Kapitels (Datenschutz und Datensicherheit) liegt auch dann in der Verantwortung der Gemeinschaften, wenn sie Leistungen durch Dritte (Betriebsorganisationen) erbringen lassen.

4.2 Datenschutz- und Datensicherheitsmanagementsystem (Abs. 1)

4.2.1 Gemeinschaften müssen ein Datenschutz- und Datensicherheitsmanagementsystem, wie in der Norm ISO/IEC 27001:2013 definiert, betreiben, dass:

4.2.1.1 alle einzuhaltenden gesetzlichen Anforderungen an die besonders schützenswerten Datenbestände ausdrücklich definiert und auf aktuellem Stand hält;

4.2.1.2 die zur deren Erfüllung notwendigen spezifischen Massnahmen und die für deren Überwachung verantwortlichen Personen festlegt;

4.2.1.3 alle relevanten Aufzeichnungen im Einklang mit gesetzlichen Anforderungen vor Verlust, Zerstörung und Fälschung schützt.

4.2.2 Das Datenschutz- und Datensicherheitsmanagementsystem muss mindestens umfassen:

4.2.2.1 einen von der oder dem Datenschutz- und Datensicherheitsverantwortlichen (vgl. Kap. 4.3) beurteilten Risikokatalog;

4.2.2.2 einen Risikobehandlungsplan;

4.2.2.3 ein aktuell gehaltenes Inventar der folgenden Betriebsmittel (vgl. Kap. 4.8):

4.2.2.3.1 Hardware;

4.2.2.3.2 Software;

4.2.2.3.3 Datenbestände;

4.2.2.3.4 Aufbauorganisation;

4.2.2.3.5 Prozesse.

4.2.3 Sicherheitsrelevante Veränderungen an den Betriebsmitteln sind zu beurteilen und zu dokumentieren.

4.2.4 Mindestens jährlich ist ein Management Review durchzuführen, bei dem die Geschäftsleitung der Gemeinschaft über den Risikokatalog und den Risikobehandlungsplan befindet.

4.3 Datenschutz- und Datensicherheitsverantwortlicher (Abs. 1 Bst. a)

4.3.1 Für das Führen des Datenschutz- und Datensicherheitsmanagementsystems der Gemeinschaft ist ein Datenschutz- und Datensicherheitsverantwortlicher zu benennen und dessen Aufgabenprofil zu definieren, der die Einhaltung der Datenschutz- und Datensicherheitsvorschriften überwacht und:

4.3.1.1 seine Funktion fachlich unabhängig ausüben kann;

4.3.1.2 über die zur Erfüllung seiner Aufgaben erforderlichen Ressourcen verfügt;

4.4 Erkennen von Sicherheitsvorfällen (SIEM) (Abs. 1 Bst. b)

4.4.1 Gemeinschaften müssen:

4.4.1.1 ein System zur Erkennung von und zum Umgang mit Sicherheitsvorfällen (*Security Information and Event Management System* [SIEM]) betreiben, das alle relevanten Systeme der gemeinschaftsinternen Informatikinfrastruktur risikogerecht überwacht, Anomalien im System erkennt und Datenschutz- und Datensicherheitsereignisse aufzeichnet.

4.4.1.2 diese Aufzeichnungen vor Veränderungen und Löschungen schützen.

4.4.1.3 sicherstellen, dass Datenschutz- und Datensicherheitsereignisse angemessen organisatorisch und technisch gemäss Kap. 4.5 adressiert werden.

4.4.2 Das SIEM muss gemeinschaftsspezifisch aufgebaut werden und mindestens die folgenden Muster erkennen und adressieren:

4.4.2.1 Angriffe aus dem Internet auf das Zugangsportal oder auf den Zugangspunkt der Gemeinschaft;

4.4.2.2 unübliche Häufungen schreibender oder lesender Zugriffe auf die Dokumentenablagen, das Dokumentenregister oder den Patientenindex, welche auf eine missbräuchliche Nutzung oder automatisierte Attacke hinweisen;

4.4.2.3 ungewöhnliche und kritische Mutationen von Berechtigungsdaten in der Berechtigungssteuerung, dem Identitäts- und Zugangsmanagement-System (IAM) oder – sofern vorhanden – dem gemeinschaftsinternen Dienst zur Verwaltung von Gesundheitseinrichtungen und Gesundheitsfachpersonen, analog dem Abfragedienst für Gesundheitseinrichtungen und Gesundheitsfachpersonen nach Artikel 40 EPDV («lokaler HPD»).

4.5 Umgang mit Sicherheitsvorfällen (SIEM) (Abs. 1 Bst. b)

4.5.1 Gemeinschaften müssen:

4.5.1.1 formale Verfahren für das unverzügliche Melden von Datenschutz- oder Datensicherheitsereignissen an die vorgegebenen Stellen und für die Eskalation (Meldung an BAG und Zertifizerungsstelle nach Art. 11 Abs. 2) definiert haben sowie deren Einhaltung einfordern und kontrollieren;

4.5.1.2 sicherstellen, dass diese Verfahren und die daraus resultierenden Verpflichtungen allen betroffenen Mitarbeitenden der Gesundheitseinrichtungen sowie der Betriebsorganisationen bekannt sind.

4.5.2 Das SIEM:

4.5.2.1 umfasst Prozesse für den Umgang mit Sicherheitsereignissen;

4.5.2.2 definiert bei sicherheitskritischen Ereignisse einer definierten Stufe mindestens die folgenden Notfallprozesse zur sofortigen Unterbindung sämtlicher Kommunikation:

4.5.2.2.1 wie und unter welchen Bedingungen die Gemeinschaft durch das Sperren des Zugangspunktes der Gemeinschaft von der Bearbeitung von Daten des elektronischen Patientendossiers isoliert wird;

4.5.2.2.2 wie und unter welchen Bedingungen die Gemeinschaft vom Internet isoliert wird;

4.5.2.2.3 wie und unter welchen Bedingungen die Gemeinschaft von einem angebundenen Primärsystem isoliert wird.

4.6 Schutz vor Schadcode (Abs. 1 Bst. b)

4.6.1 Gemeinschaften müssen sicherstellen, dass
4.6.1.1 sie Massnahmen, Verfahren und Systeme zum Schutz bzw. zum Erkennen und Entfernen von Schadsoftware und zur Überwachung von mobilem Programmcode (z. B. Viren) festlegen und umsetzen, respektive einsetzen;
4.6.1.2 die Systemverantwortlichen die Aktualität der eingesetzten Software zur Erkennung und Entfernung von Schadsoftware regelmässig überprüfen.

4.7 Umgang mit Sicherheitsschwachstellen (Abs. 1 Bst. b)

4.7.1 Gemeinschaften müssen über ein Sicherheitsschwachstellenmanagement verfügen, welches Informationen über technische Sicherheitsschwachstellen von verwendeten Informationssystemen rechtzeitig einholt, die Anfälligkeit der Organisation für eine Ausnutzung solcher Sicherheitsschwachstellen bewertet und angemessene Massnahmen für den Umgang mit den damit einhergehenden Risiken ergreift.

4.7.2 Software-Aktualisierungen zur Beseitigung von Sicherheitsschwachstellen (sog. «*Patches*») müssen vor der Installation getestet und auf allfällige unerwünschte Wirkungen hin beurteilt werden.

4.7.3 Steht für die Beseitigung einer Sicherheitsschwachstelle noch kein «*Patch*» zur Verfügung, müssen alternative Sicherheitsmassnahmen in Betracht gezogen werden (z. B. Anpassung der Zugriffskontrollen oder Einschränkung des Netzwerkverkehrs).

4.8 Verwaltung schützenswerter Daten und Systeme (Abs. 1 Bst. c und d)

4.8.1 Gemeinschaften müssen sicherstellen, dass die angeschlossenen Gesundheitseinrichtungen über Regelungen verfügen, dass nur behandlungsrelevante Daten aus der Krankengeschichte der Patientin oder des Patienten im elektronischen Patientendossier zugänglich gemacht werden dürfen.

4.8.2 Gemeinschaften müssen sicherstellen, dass alle schützenswerten Daten, Systeme und Einrichtungen des elektronischen Patientendossiers eindeutig identifiziert, klassifiziert und in einem Inventar erfasst werden.

4.8.3 Im Inventar müssen mindestens folgende Systeme erfasst und verwaltet werden:
4.8.3.1 die Dokumentenablagen;
4.8.3.2 das Dokumentenregister;
4.8.3.3 die Protokollierungssysteme;
4.8.3.4 das System zur Berechtigungssteuerung;
4.8.3.5 das Identitäts- und Zugangsmanagement-System (IAM);
4.8.3.6 der Patientenindex;
4.8.3.7 die datenschutz- oder datensicherheitsrelevanten Datenbestände des Systembetriebs (z.B. Logs, Backups, privilegiertes Zugangs Management für Systemadministratoren).
4.8.3.8 die Primärsysteme mit den Rollen (IHE-Aktoren) *Document Source* und *Document Consumer*. Das Inventar umfasst für diese Elemente zusätzlich mindestens:
4.8.3.8.1 das TLS-Clientzertifikat für die Transportschichtsicherheit (TLS) des jeweiligen IHE-Aktors.

4.8.4 Zu jedem Element im Inventar muss:
4.8.4.1 ein verantwortlicher Eigentümer zugeordnet werden;

4.8.4.2 die ursprüngliche Quelle der enthaltenen Daten ersichtlich sein;
4.8.4.3 das Datum der letzten Bestätigung durch den oder die Datenschutz- und Datensicherheitsverantwortliche geführt werden.

4.8.5 Der oder die Datenschutz- und Datensicherheitsverantwortliche muss das Inventar mindestens jährlich überprüfen.

4.9 Datenschutz- und Datensicherheitsanforderungen für die angeschlossenen Gesundheitseinrichtungen und deren Gesundheitsfachpersonen, sowie Endgeräte (Bst. e)

4.9.1 Gemeinschaften müssen Datenschutz- und Datensicherheitsvorgaben für Gesundheitseinrichtungen und deren Gesundheitsfachpersonen vorsehen, die sicherstellen, dass:
4.9.1.1 die Gesundheitseinrichtungen auf die einzuhaltenden Sicherheitsmassnahmen (vgl. Kapitel 1.1.2.1) hingewiesen werden;
4.9.1.2 die Gesundheitseinrichtungen dazu verpflichten, ihre auf das elektronische Patientendossier zugreifenden Gesundheitsfachpersonen über die Aufgaben, Rechte und Pflichten im Zusammenhang mit der Bearbeitung von Daten des elektronischen Patientendossiers sowie Risiken und Massnahmen bezüglich Datenschutz und Datensicherheit zu informieren und zur Einhaltung der geforderten Massnahmen zu verpflichten. Die Verpflichtung und Information muss mindestens folgende Punkte umfassen:
4.9.1.2.1 den sicheren Umgang mit Identifikationsmitteln und Zugangsdaten;
4.9.1.2.2 die Prinzipien der Beschreibung von bereitzustellenden Dokumenten mit Metadaten;
4.9.1.2.3 die Massnahmen zur sicheren Nutzung von Endgeräten (PC, Smartphone, Tablet, etc.);
4.9.1.2.4 das Verhalten zur Abwehr von an Gesundheitsfachpersonen gerichtete Bedrohungen wie z. B. «Social Engineering», «Phishing», Umgang mit externen Speichermedien, etc.;
4.9.1.2.5 die Kontaktstellen und Verfahren zur Meldung von Datenschutz- und Datensicherheitsvorfällen;
4.9.1.2.6 die Verantwortlichkeiten beim Einsatz von Hilfspersonen.

Sichere Endgeräte für Gesundheitsfachpersonen

4.9.2 Gemeinschaften verpflichten die angeschlossenen Gesundheitseinrichtungen dazu, eine sichere Konfiguration derjenigen Endgeräte sicherzustellen, die von den Gesundheitsfachpersonen für den Zugriff auf das elektronische Patientendossier genutzt werden.

4.9.3 Die Konfiguration der Endgeräte muss mindestens umfassen:
4.9.3.1 den Einsatz einer regelmässig aktualisierten Software gegen Schadprogramme;
4.9.3.2 den Einsatz netzwerktechnischer Schutzsysteme (z. B. Firewalls);
4.9.3.3 eine restriktive Handhabung von Systemadministratorrechten für normale Endsystem-Benutzer;
4.9.3.4 eine regelmässige Aktualisierung des Betriebssystems und sicherheitskritischer Software-Komponenten (z. B. Laufzeitumgebungen wie Java, .Net, etc.).

4.10 Datenschutz- und Datensicherheitsanforderungen an das Personal (Abs. 1 Bst. f)

4.10.1 Gemeinschaften müssen über ein Regelwerk verfügen, in dem die Regeln zur Zugriffskontrolle und Berechtigungen für jeden Benutzer oder jede Benutzergruppe klar

festgelegt und in den entsprechenden informationsverarbeitenden Systemen und Netzwerkdiensten umgesetzt sind.

4.10.2 Gemeinschaften müssen sicherstellen, dass:

4.10.2.1 Personen, die mit Daten oder Systemen des elektronischen Patientendossiers umgehen, für die vorgesehenen Aufgaben kompetent genug sind und ihre Verantwortlichkeiten wahrnehmen können sowie dem Datenschutz und der Datensicherheit bewusst nachkommen;

4.10.2.2 Anforderungen für den Gebrauch geheimer Authentisierungsinformationen, wie z. B. Passwörter, erstellt und kommuniziert werden;

4.10.2.3 Personen, die Zugang zu Daten des elektronischen Patientendossier erlangen könnten, einer der ärztlichen Schweigepflicht analogen Verpflichtungen unterliegen;

4.10.2.4 definierte Prozesse für das Personalmanagement definiert umgesetzt und eingehalten werden.

4.10.3 Gemeinschaften müssen:

4.10.3.1 eine von dem oder der Datenschutz- und Datensicherheitsverantwortlichen der Gemeinschaft visierte Liste aller Personen führen, die – unabhängig von der Rechteverwaltung im elektronischen Patientendossier – Zugriff auf Patientendaten haben («Liste der Schlüsselpersonen»);

4.10.3.2 diese Personen eine Personensicherheitsprüfung (PSP) nach Militärgesetz durchlaufen haben;

4.10.3.3 ein offizielles, festgelegtes Verfahren vorsehen, um disziplinarische Massnahmen oder Sanktionen gegen Mitarbeitende einzuleiten, die gegen den Datenschutz und die Datensicherheit verstossen haben.

4.11 Datenschutz- und Datensicherheitsanforderungen an Dritte (Abs. 1 Bst. f)

4.11.1 Gemeinschaften müssen eine von dem oder der Datenschutz- und Datensicherheitsverantwortlichen visierte Liste mit allen Lieferanten und Dienstleistungserbringern («Dritte») führen, die unter Umständen auf Daten des elektronischen Patientendossiers zugreifen, sie verarbeiten, speichern, weitergeben oder IT-Infrastrukturkomponenten dafür bereitstellen.

4.11.2 Gemeinschaften müssen sicherstellen, kein Datenzugriff durch Intermediäre erfolgt und dass «Dritte», die unter Umständen im Rahmen der Bereitstellung von Dienstleistungen oder Infrastrukturkomponenten auf Daten des elektronischen Patientendossiers zugreifen könnten, dies nur zum Zwecke der Leistungserbringung für die Gemeinschaften tun und Daten des elektronischen Patientendossiers keinesfalls für andere Zwecke weiter verarbeiten oder weitergeben.

4.11.3 Mit Dritten müssen alle relevanten Datenschutz- und Datensicherheitsanforderungen formal festgelegt und in Liefervereinbarungen vereinbart werden.

4.11.4 Die Liefervereinbarungen müssen unmissverständlich die Verpflichtungen und Verantwortlichkeiten zur Erfüllung der relevanten Anforderungen an den Datenschutz und die Datensicherheit festhalten.

4.11.5 Die Liefervereinbarungen müssen mindestens folgende Bestimmungen umfassen:

4.11.5.1 Verpflichtungen des Lieferanten, die relevanten Datenschutz- und Datensicherheitsanforderungen der Gemeinschaft beim Einsatz oder der Bereitstellung von Informations- und Kommunikationstechnologie-Produkten, Personal und/oder Dienstleistungen einzuhalten.

4.11.5.2 Anforderungen und Verfahren für den Umgang mit Datenschutz- und Datensicherheitsvorfällen;
4.11.5.3 die Angabe von Kontaktpersonen für Fragen und bei Vorkommnissen im Bereich Datenschutz- und Datensicherheit;
4.11.5.4 das Recht zur regelmässigen Überprüfung der Lieferantenprozesse und Kontrollmassnahmen im Zusammenhang mit dem Vertrag;
4.11.5.5 die Verpflichtung zur Einhaltung der Datenschutz- und Datensicherheitsanforderungen der Gemeinschaft innerhalb der gesamten Lieferkette weiterzuverpflichten für den Fall, dass die Lieferanten Unterlieferanten beauftragen;
4.11.5.6 die Vorschriften und Kontrollmassnahmen für Unterverträge;
4.11.5.7 die Verpflichtung, die Gemeinschaft über jedwede Änderung in den Vertragsbeziehungen zu involvierten Unterlieferanten zu informieren.

4.12 Überwachung und Überprüfung von Dienstleistungen (Abs. 1 Bst. f)

4.12.1 Die von Dritten und allfälligen Unterlieferanten gelieferten Dienstleistungen, Berichte und Aufzeichnungen müssen von den Gemeinschaften regelmässig überwacht und überprüft werden, so dass sichergestellt ist, dass:
4.12.1.1 die vertraglich festgelegten Bedingungen für den Datenschutz- und die Datensicherheit eingehalten wurden;
4.12.1.2 Datenschutz- und Datensicherheitsvorfälle und -probleme angemessen bearbeitet wurden;
4.12.1.3 Änderungen der Dienstleistungen einem gelenkten Änderungsmanagement unterliegen.

4.13 Meldepflicht für Sicherheitsvorfälle (Abs. 2)

4.13.1 Gemeinschaften müssen formale Verfahren für das unverzügliche Melden von, gemäss dem Datenschutz- und Datensicherheitsmanagementsystem als sicherheitsrelevant eingestuften Vorfällen, an die Zertifizierungsstelle und das BAG definiert haben, sowie deren Einhaltung einfordern und kontrollieren.

4.14 Betriebssicherheit (Abs. 3)

4.14.1 Gemeinschaften müssen sicherstellen, dass:
4.14.1.1 Privilegierte Zugriffe auf die produktive Betriebsumgebung z. B. durch Betriebssystem-, Datenbank- und Applikations-Administratoren:
4.14.1.1.1 eine starke 2-Faktor Authentisierung erfordern;
4.14.1.1.2 durch ein unabhängig administriertes überwacht und protokolliert werden;
4.14.1.1.3 keinen Export von Patientendaten ermöglichen.
4.14.1.2 externe Zugriffe durch Dritte und Nachauftragnehmer und insbesondere privilegierte externe Zugriffe auf die produktive Betriebsumgebung zusätzlich:
4.14.1.2.1 entweder unterbunden oder angemessen geschützt sind;
4.14.1.2.2 überwacht und protokolliert werden;
4.14.1.2.3 nur befristet und bei Bedarf aktiviert werden.
4.14.1.3 Entwicklungs-, Test- und Inbetriebnahme-Aktivitäten neuer Systeme in ihren Umgebungen nachvollziehbar dokumentiert und nach einem kontrollierten Prozess ablaufen;
4.14.1.4 vollständige Backups gemacht werden und dass diese verschlüsselt sind;
4.14.1.5 das Schlüsselmaterial für die Verwaltung der Backups dem 4-Augenprinzip unterliegt;

4.14.1.6 Backups mit einem Zeitstempel versehen werden;
4.14.1.7 Backups integritätsgeschützt auf einem separaten Speicher gespeichert werden und diese nach dem Kopieren vom Netzwerk getrennt werden;
4.14.1.8 die Verfahren zur Systemwiederherstellung ausreichend dokumentiert sind und regelmässig erprobt werden;
4.14.1.9 die technischen Logs keine unverschlüsselten Patientendaten enthalten;
4.14.1.10 Logfiles mit einem Zeitstempel versehen werden und integritätsgeschützt gespeichert werden;
4.14.1.11 Datenträger mit Patientendaten stets korrekt entsorgt und vorgängig alle Daten gelöscht werden;
4.14.1.12 die Systemuhren mit der gesetzlichen Zeit der Schweiz abgeglichen sind;

4.14.2 Die Produktivumgebung der gemeinschaftsinternen Informatikinfrastruktur des elektronischen Patientendossiers muss:
4.14.2.1 von anderen Umgebungen (z. B. Entwicklungs-, Abnahme- und Testumgebungen) isoliert sein;
4.14.2.2 ausschliesslich im Rahmen kontrolliert ablaufender Prozesse mit neuer Software versorgt werden;
4.14.2.3 regelmässig auf Sicherheitsschwachstellen überprüft werden.
4.14.2.4 die erkannten Sicherheitsschwachstellen im Rahmen eines kontrollierten Patch-Management-Prozesses beheben;
4.14.2.5 von anderen Systemen des Betreibers mittels eigener Netwerkzonierung isoliert sein;

4.14.3 Neben der Bearbeitung von Daten des elektronischen Patientendossiers durch Gesundheitsfachpersonen sowie Patienten und Patientinnen sind mindestens folgende Informationen von Ereignissen, die im Rahmen des Systembetriebs auftreten, aufzuzeichnen:
4.14.3.1 Datum, Zeit und Details von Schlüssel-Ereignissen (z. B. Login und Logout);
4.14.3.2 erfolgreiche und abgewiesene Versuche auf das System zuzugreifen;
4.14.3.3 erfolgreiche und abgewiesene Versuche auf Daten oder Dokumente zuzugreifen;
4.14.3.4 Veränderungen an der Systemkonfiguration;
4.14.3.5 die Verwendung von privilegierten Zugriffsrechten;
4.14.3.6 Netzwerkadressen und -protokolle;
4.14.3.7 die Aktivierung und Deaktivierung von Schutz- oder Authentisierungs-Systemen;
4.14.3.8 die Modifikation von Systemberechtigungen und Zugängen;
4.14.3.9 das Anlegen, die Modifikation oder das Löschen von Benutzerkonten («Accounts»);
4.14.3.10 das Kopieren oder Ausdrucken von besonders schützenswerten Informationen.

4.15 Anschaffung, Entwicklung und Instandhaltung von Systemen (Abs. 3)

4.15.1 Gemeinschaften müssen den Datenschutz und die Datensicherheit über den gesamten Lebenszyklus der Systeme des elektronischen Patientendossiers sicherstellen. Dazu müssen formale Prozesse definiert, eingeführt und eingehalten werden für die Dokumentation, die Spezifikation, das Testen, die Qualitätskontrolle und die kontrollierte Umsetzung bei:
4.15.1.1 der Einführung oder der Entwicklung neuer Systeme;
4.15.1.2 grösseren Änderungen oder Entwicklungen an bestehenden Systemen;
4.15.1.3 dem Wechsel der Betriebsplattformen.

4.15.2 Mindestens ist nachzuweisen, dass innerhalb jedes Entwicklungszyklus:
4.15.2.1 Sicherheitsanforderungen bereits in der Planung mittels einer strukturierten Anforderungsanalyse noch vor allfälligen Entwicklungsaufträgen oder Erweiterungen von bestehenden Informationssystemen definiert werden;
4.15.2.2 Änderungen an Systemen einem formalen, dokumentierten Verfahren zur Änderungskontrolle unterliegen;

4.15.2.3 der Zugriff auf den Software-Quellcode beschränkt, kontrolliert und protokolliert wird;
4.15.2.4 Leitlinien für die sichere Entwicklung, auch bei ausgelagerten Systementwicklungstätigkeiten vorhanden sind und im Entwicklungszyklus angewandt und umgesetzt werden;
4.15.2.5 sich in Testumgebungen keine Patientendaten befinden;
4.15.2.6 ausgelagerte Softwareentwicklung durch die Betriebsorganisation überwacht und beaufsichtigt werden.

4.16 Verschlüsselung in der Kommunikation (Abs. 3)

4.16.1 Gemeinschaften müssen sicherstellen, dass jegliche Übertragung von Daten des elektronischen Patientendossiers innerhalb der Gemeinschaft wie auch zwischen Gemeinschaften durch geeignete und dem Stand der Technik entsprechende kryptographische Massnahmen gegen den Verlust der Vertraulichkeit, Authentizität und Integrität abgesichert werden.

4.17 Verschlüsselte Datenspeicherung (Abs. 3)

4.17.1 Besonders schützenswerte Daten des elektronischen Patientendossiers müssen mit geeigneten und dem Stand der Technik entsprechenden kryptographischen Massnahmen verschlüsselt und integritätsgeschützt gespeichert werden.

4.18 Verwaltung kryptographischer Schlüssel (Abs. 3)

4.18.1 Gemeinschaften müssen sicherstellen, dass:
4.18.1.1 Verfahren für die Erzeugung, die Verteilung, die Aktivierung, die Aktualisierung, den Widerruf oder Deaktivierung und die Löschung von kryptographischen Schlüsseln definiert, umgesetzt und kontrolliert werden;
4.18.1.2 die verwendeten kryptographischen Schlüssel gegen Veränderung und Verlust geschützt werden;
4.18.1.3 geheime und private Schlüssel vor unbefugter Benutzung und Offenlegung geschützt werden;
4.18.1.4 Einrichtungen zur Erzeugung, Speicherung und Archivierung von Schlüsseln physisch geschützt werden.

4.19 Kommunikationssicherheit: Verwaltung von Netzwerken (Abs. 3)

4.19.1 Gemeinschaften müssen sicherstellen, dass:
4.19.1.1 Richtlinien zur Netzwerksicherheit definiert, eingehalten und kontrolliert werden;
4.19.1.2 Netzwerke so verwaltet werden, dass Daten des elektronischen Patientendossiers in Anwendungen und Systemen vor unautorisierten Zugriffen geschützt sind;
4.19.1.3 Regelungen der Zuständigkeiten für die Verwaltung von Netzwerken innerhalb einer Gemeinschaft definiert, eingehalten und kontrolliert werden.

4.20 Kommunikationssicherheit: Netzwerkdienste (Abs. 3)

4.20.1 Gemeinschaften müssen sicherstellen, dass durch ein geeignetes Design des Netzwerks und seiner Komponenten sowie durch den geeigneten Aufbau und die Konfiguration der

Netzwerkdienste, die Daten des elektronischen Patientendossiers in Anwendungen und Systemen geschützt sind, indem:

4.20.1.1 geeignete sichere Netzwerkstrukturen festgelegt, durch Netzwerkpläne dargestellt und umgesetzt werden, wodurch dedizierte Gruppen von Informationsdiensten, Benutzern und Informationssystemen in Netzwerken voneinander getrennt gehalten werden können. Insbesondere müssen Firewalls, Router, Switches, etc. und technologische Umsetzungen für Netzwerkdienste derart konfiguriert sein, dass:

4.20.1.1.1 die technischen Schnittstellen der gemeinschaftsinternen Informatikinfrastruktur einer Gemeinschaft («IHE-Services») nur von Systemen aufgerufen werden dürfen, die zu einer zertifizierten Gemeinschaft gehören;

4.20.1.1.2 Systeme, die über das Internet auf einen IHE-Service zugreifen, sich gegenüber den IHE-Services mittels TLS-Serverauthentisierung mit einem gültigen elektronischen Zertifikat authentisieren. Dabei müssen:

4.20.1.1.2.1 für Zugangsportale sowie *Responding Gateways* mindestens öffentliche *Extended-Validation*-TLS-Zertifikate eingesetzt werden;

4.20.1.1.2.2 für andere IHE-Services entweder mindestens öffentliche *Extended-Validation*-TLS-Zertifikate eingesetzt werden oder TLS-Zertifikate, die nur innerhalb der Gemeinschaft gültig sind.

4.20.1.1.3 alle IHE-Services, die aus dem Internet aufrufbar sind, das aufrufende System mittels *TLS-Client-Authentication* authentisieren;

4.20.1.1.4 *Responding Gateways* den Verbindungsaufbau nur zulassen, wenn das aufrufende System zu einer zertifizierten Gemeinschaft gehört;

4.20.1.1.5 alle gemeinschaftsinternen IHE-Services, die nicht aus dem Internet aufgerufen werden können, den Verbindungsaufbau nur zulassen, wenn das aufrufende System zur eigenen zertifizierten Gemeinschaft gehört und im Inventar der eigenen Gemeinschaft registriert und vom ISBO der Gemeinschaft akzeptiert wurde;

4.20.1.2 die hierzu eingesetzten Verfahren (z. B. Client-Server-Zertifikate, IP- oder MAC-Adress-Filter) dokumentiert werden.

4.20.2 Gemeinschaften müssen:

4.20.2.1 alle Systeme mit persistent gespeicherten Daten des elektronischen Patientendossiers der Gemeinschaft (namentlich Dokumentenregister, Dokumentenablage, Berechtigungssteuerung und Patientenindex) netzwerktechnisch von allen anderen Systemen separieren, die ein tieferes Sicherheitsniveau aufweisen;

4.20.2.2 die hierzu eingesetzten Verfahren (z. B. Netzwerksegmentierung mittels Firewalls) dokumentieren.

4.20.3 Gemeinschaften müssen insbesondere das zum Schutz des Zugangsportals implementierte Sicherheitsdispositiv dokumentieren. Die Dokumentation umfasst mindestens:

4.20.3.1 die Netzwerktopologie und das Ausweisen der sog. «demilitarisierten Zone» (DMZ);

4.20.3.2 die Versionen und Release-Stände der auf der Web-Application-Firewall (WAF) und dem Webserver eingesetzten Software sowie verwendeter sicherheitsrelevanter Softwarekomponenten Dritter;

4.20.3.3 die vorgesehenen Massnahmen für die Erkennung und Behandlung von Angriffen und Sicherheitsschwachstellen.

4.21 Ablauf von Netzwerk-Sitzungen («*Session timeout*») (Abs. 3)

4.21.1 Inaktive Netzwerk-Sitzungen müssen nach einer definierten Inaktivitätsperiode (20 Minuten bei Patienten, 2 Stunden bei Gesundheitsfachpersonen) beendet werden.

4.21.2 Die Authentisierung auf den Zugangsportalen und Endgeräten muss vor dem nächsten Zugriff erneut durchgeführt werden, wenn während 20 Minuten bei Patienten, beziehungsweise 2 Stunden bei Gesundheitsfachpersonen keine Interaktion des Benutzers mit dem elektronischen Patientendossier stattfand.

4.22 Zwischenspeicher (Abs. 3)

4.22.1 Elemente der gemeinschaftsinternen Informatikinfrastruktur, die der Übermittlung von Dokumenten des elektronischen Patientendossiers dienen (namentlich die Zugangspunkte), dürfen diese nicht persistent speichern.

4.23 Verfügbarkeit (Abs. 3)

4.23.1 Gemeinschaften müssen sicherstellen, dass:

4.23.1.1 die technischen Dienste zur Nutzung des elektronischen Patientendossiers vor Unterbrechungen geschützt sind, so dass grössere Störungen nur eingeschränkte und vertraglich vereinbarte Auswirkungen auf die Informationsverarbeitungssysteme haben und eine rechtzeitige Wiederaufnahme sämtlicher Dienste sichergestellt werden kann;

4.23.1.2 die exponierten technischen Dienste der Informatikinfrastruktur eine vertraglich vereinbarte Verfügbarkeit über die Zeit von mindestens 98%, sowie unter Last aufweisen;

4.23.1.3 alle über das Internet erreichbaren Schnittstellen des elektronischen Patientendossiers gegen sog. *Denial-of-Service* (DoS)-Angriffe geschützt sind;

4.23.1.4 sie über erprobte Prozesse verfügen, die es erlauben, die Zeit für die Wiederherstellung nach dem Verlust von Informationswerten, die zum Beispiel in Folge von Naturkatastrophen, Unfällen, Anwendungs-, System- und Geräteausfällen oder mutwilligen Beschädigungen entstehen könnten, durch eine Kombination vorbeugender und wiederherstellender Massnahmen auf ein akzeptables Niveau zu minimieren.

4.24 Datenspeicher unter Schweizer Rechtshoheit (Abs. 4)

4.24.1 Die Gemeinschaft muss sicherstellen, dass der Betrieb der gemeinschaftsinternen Datenspeicher des elektronischen Patientendossiers (insbesondere Dokumentenablagen, Dokumentenregister, Patientenindex) von juristischen Personen erbracht wird, die:

4.24.1.1 unter Schweizer Recht sind;

4.24.1.2 für die Erbringung der Leistung ausschliesslich unter Schweizer Recht handeln;

4.24.1.3 sich zur Mehrheit in Schweizer Eigentum befinden;

4.24.1.4 die Leistung gesamtheitlich innerhalb der Schweizer Landesgrenzen erbringen.

5 Kontaktstelle für Gesundheitsfachpersonen (Art. 12 EPDV)

5.1.1 Die Gemeinschaften müssen für die Gesundheitsfachpersonen eine Kontaktstelle («*Service-Desk*») bezeichnen, die diese im Umgang mit dem elektronischen Patientendossier unterstützt.

5.1.2 Gemeinschaften müssen mindestens sicherstellen, dass:

5.1.2.1 die Mitarbeitenden des «Service-Desk» ihre Aufgaben, Rechte und Pflichten sowie die Risiken und die Massnahmen bezüglich Datenschutz und Datensicherheit kennen;

5.1.2.2 die Mitarbeitenden mit Zugriff auf Daten des elektronischen Patientendossiers sorgfältig ausgewählt werden und einer der ärztlichen Schweigepflicht analogen Verpflichtung unterstehen;

5.1.2.3 die Einwilligung der Mitarbeitenden zu den spezifischen Richtlinien der Gemeinschaft dokumentiert wird;

5.1.2.4 Remote-Zugriffe für Support-Tätigkeiten auf die Endgeräte der Gesundheitsfachpersonen ausschliesslich mit Kenntnis und Einwilligung der jeweiligen Gesundheitsfachperson erfolgen können und automatisch dokumentiert werden.

Zusätzliche Anforderungen für Stammgemeinschaften

6 Information der Patientin oder des Patienten (Art. 14 EPDV)

6.1 Die Information der Patientin oder des Patienten nach Artikel 14 EPDV muss mindestens folgende Punkte umfassen:

6.1.1 Informationen über den Zweck des elektronischen Patientendossiers.

6.1.2 Informationen zu den Grundzügen der Datenbearbeitung, mindestens über:
6.1.2.1 den Verbleib der Dokumente in den Primärsystemen und Dokumentenablagen;
6.1.2.2 das Recht auf Widerruf der vermuteten Einwilligung zur Bereitstellung von Dokumenten im Behandlungsfall sowie auf die Löschung bestimmter Dokumente;
6.1.2.3 die Möglichkeiten und Funktionen des Zugangsportals für Patientinnen und Patienten;
6.1.2.4 die Möglichkeit zur Einsichtnahme in die Protokollinformationen;
6.1.2.5 die Möglichkeit, einen Stellvertreter oder eine Stellvertreterin zu benennen;
6.1.2.6 die Möglichkeit, Gesundheitsfachpersonen nach Artikel 3 Buchstabe h EPDV zur Weitergabe von Zugriffsrechten zu ermächtigen.

6.1.3 Informationen zu den Folgen der Einwilligung und der Möglichkeit des Widerrufs, mindestens über:
6.1.3.1 die Freiwilligkeit der Einwilligung;
6.1.3.2 die Tatsache, dass nur ein Patientendossier gleichzeitig geführt werden kann;
6.1.3.3 die Modalitäten der Vergabe und Verwendung der Patientenidentifikationsnummer;
6.1.3.4 die Möglichkeit, die Stammgemeinschaft zu wechseln und die damit verbundenen Konsequenzen für den Datenverbleib sowie für allfällige Stellvertretungen und ermächtigte Gesundheitsfachpersonen;
6.1.3.5 die Möglichkeit des formlosen Widerrufs ohne Angabe von Gründen;
6.1.3.6 die Möglichkeit, nach einem Widerruf erneut ein elektronisches Patientendossier eröffnen zu können, dem eine neue Patientenidentifikationsnummer zugeordnet wird;

6.1.4 Informationen zu den Möglichkeiten der Erteilung von Zugriffsrechten nach den Artikeln 1 bis 3 EPDV, mindestens über:
6.1.4.1 die nach der Eröffnung geltenden Einstellungen für Zugriffsrechte von Gesundheitsfachpersonen und der Vertraulichkeitsstufe von Dokumenten;
6.1.4.2 die Möglichkeiten der Vergabe, Anpassung und des Entzugs von Zugriffsrechten an Gesundheitsfachpersonen und Gruppen von Gesundheitsfachpersonen;
6.1.4.3 die Möglichkeit, dass auch von den Gesundheitsfachpersonen registrierte Hilfspersonen mit dem Zugriffsrecht der verantwortlichen Gesundheitsfachperson zugreifen können;
6.1.4.4 die Möglichkeit des Zugriffs von Gesundheitsfachpersonen in medizinischen Notfallsituationen und die Möglichkeit, den Zugriff in medizinischen Notfallsituationen einzuschränken, zu erweitern oder ganz auszuschliessen;
6.1.4.5 die Möglichkeit einzelne Gesundheitsfachpersonen vollständig vom Zugriff auszuschliessen (Ausschlussliste);
6.1.4.6 die Möglichkeit für Mitarbeitende des «Service-Desks» Remote-Zugriffe auf die Endgeräte der Patienten oder der Patientin durchzuführen, sofern er oder sie die Einwilligung dazu

erteilt hat.

6.1.5 Informationen zu den empfohlenen Datenschutz- und Datensicherheitsmassnahmen, mindestens über:

6.1.5.1 die möglichen Restrisiken und die vorgesehenen Massnahmen bezüglich Datenschutz und Datensicherheit;

6.1.5.2 die sichere Authentisierung und den Umgang mit Identifikationsmitteln und Zugangsdaten;

6.1.5.3 die Prinzipien der Beschreibung von bereitzustellenden Dokumenten mit Metadaten;

6.1.5.4 die Massnahmen für eine sichere Nutzung von Endgeräten (PC, Smartphone, Tablet, etc.);

6.1.5.5 die Verhaltensempfehlungen zur Abwehr von patientengerichteten Bedrohungen wie z. B. «*Social Engineering*», «Phishing», etc.

7 Einwilligung (Art. 15 EPDV)

7.1 Die Prozesse für die Erstellung eines elektronischen Patientendossiers müssen definiert, dokumentiert, umgesetzt und eingehalten werden.

7.1.1 Der Prozess zur Erstellung eines elektronischen Patientendossiers muss sicherstellen, dass eine Einwilligung zur Eröffnung eines elektronischen Patientendossiers mit einer eigenhändigen Unterschrift des Patienten oder der Patientin eingeholt wird.

8 Verwaltung (Art. 16 EPDV)

8.1 Eintritt und Austritt von Patientinnen und Patienten (Abs. 1 Bst. a)

8.1.1 Die Prozesse für die Verwaltung von Patientinnen und Patienten müssen definiert, dokumentiert, umgesetzt und eingehalten werden. Die Prozesse müssen insbesondere sicherstellen, dass:

8.1.1.1 die jeweiligen Prozesse zur Sicherstellung Vorgaben nach den Buchstaben b–e definiert, dokumentiert, umgesetzt und eingehalten werden.

8.2 Identifikation der Patientinnen und Patienten (Abs. 1 Bst. b)

8.2.1 Die Prozesse zur Identifikation der Patientinnen und Patienten müssen definiert, dokumentiert, umgesetzt und eingehalten werden.

8.2.2 Der Prozess zur Identifikation einer Patientin oder eines Patienten muss sicherstellen, dass:

8.2.2.1 die Identifikation des Patienten oder der Patientin (Bst. b):

8.2.2.1.1 anhand des Identifikationsmittels eines nach Artikel 30 zertifizierten Herausgebers erfolgt, oder

8.2.2.1.2 den Anforderungen nach Artikel 23 Absatz 1 EPDV entspricht;

8.2.2.2 ein elektronisches Patientendossier nur dann neu erstellt wird, wenn zuvor sichergestellt wurde, dass zu der betreffenden Person nicht bereits ein elektronisches Patientendossier besteht;

8.2.2.3 der Patient oder die Patientin im Patientenindex der Stammgemeinschaft angelegt wird;

8.2.2.4 das Identifikationsmittel des Patienten oder der Patientin eindeutig mit seinem oder ihrem

elektronischen Patientendossier verknüpft wird (Bst. c);

8.2.2.5 eine Patientenidentifikationsnummer nach den Vorgaben der Artikel 5 und 6 EPDV angefordert und dem zu erstellenden elektronischen Patientendossiers korrekt zugeordnet wird (Bst. d);

8.2.2.6 die demographischen Daten der Identifikationsdatenbank der zentralen Ausgleichsstelle (ZAS) in den Patientenindex der Stammgemeinschaft übernommen werden (Bst. d);

8.3 Identifikation und Authentisierung (Abs. 1 Bst. c)

8.3.1 Für den Zugriff von Patientinnen und Patienten auf das elektronische Patientendossier dürfen nur gültige Identifikationsmittel verwendet werden, die von einem nach Artikel 30 zertifizierten Herausgeber herausgegeben wurden.

8.3.2 Gemeinschaften müssen sicherstellen, dass die eindeutigen Identifikatoren der Identifikationsmittel von Patientinnen und Patienten sowie deren allfälligen Stellvertreterinnen und Stellvertretern zuverlässig mit der registrierten Identität der jeweiligen Person in der Gemeinschaft verbunden wird.

8.3.3 Gemeinschaften müssen sicherstellen, dass die Zugangsportale:

8.3.3.1 ein starkes Authentifizierungsverfahren nach aktuellem Stand der Technik mit mindestens zwei Authentifizierungsfaktoren als Voraussetzung für die Bearbeitung von Daten des elektronischen Patientendossiers unterstützen.

8.3.3.2 einen vertrauenswürdigen Endpunkt für die sichere Kommunikation mit dem Identitätsdienstleister (Herausgeber des Identifikationsmittels) gemäss Kapitel 3.2 (*P.TrustedCommunityEndpoint*) des Schutzprofils nach Art. 8 EPDV-EDI zur Verfügung stellen.

8.4 Wechsel der Stammgemeinschaft (Bst. e)

8.4.1 Die Prozesse zum Wechsel der Stammgemeinschaft durch einen Patienten oder eine Patientin müssen definiert, dokumentiert, umgesetzt und eingehalten werden.

8.4.2 Der Prozess zum Wechsel der Stammgemeinschaft muss sicherstellen, dass:

8.4.2.1 die individuelle Konfiguration der Berechtigungssteuerung in die neue Stammgemeinschaft überführt und von dieser übernommen werden kann. Dabei sind die Vorgaben zum technischen Format im nationalen Integrationsprofil CH:PPQ gemäss Anhang 5 der EPDV-EDI einzuhalten;

8.4.2.2 die Ermächtigung einer Gesundheitsfachpersonen gemäss Artikel 3 Buchstabe h EPDV aufgehoben wird;

8.4.2.3 die Möglichkeiten des Zugriff durch allfällige Stellvertreter oder Stellvertreterinnen eines Patienten oder einer Patientin aufgehoben wird.

8.5 Durchsetzen der Zugriffsentscheidung zur Bearbeitung der Berechtigungskonfiguration (Abs. 2): Zugriffsrechte (Art. 2 EPDV Abs. 1) und Optionen der Patientinnen und Patienten (Art. 3 EPDV)

8.5.1 Stammgemeinschaften müssen sicherstellen, dass eine Bearbeitung der Konfiguration der Berechtigungssteuerung nur gemäss der zuvor eingeholten Zugriffssentscheidung erfolgen kann.

8.6 Berechtigungssteuerung (Abs. 2): Zugriffsrechte (Art. 2 EPDV Abs. 1 bis 4)

8.6.1 Patientinnen und Patienten müssen die Möglichkeit haben, die Zugriffsrechte für Gesundheitsfachpersonen und Gruppen von Gesundheitsfachpersonen zu vergeben und anzupassen. Dabei sind die Vorgaben von Artikel 2 Absätze 1 bis 4 EPDV einzuhalten.

8.6.2 Die einzuhaltenden Vorgaben betreffen insbesondere:
8.6.2.1 die Möglichkeit Zugriffsrechte einzelnen Gesundheitsfachpersonen oder Gruppen von Gesundheitsfachpersonen Zugriffsrechte nach Artikel 1 Absatz 1 zuzuweisen;
8.6.2.2 die Gültigkeit der vergebenen Zugriffsrechte bis zum Entzug durch die Patientin oder den Patienten;
8.6.2.3 die korrekte Umsetzung der mit dem Ein- oder Austritt einer Gesundheitsfachperson in eine Gruppe von Gesundheitsfachpersonen verbundenen Veränderungen der Zugriffsrechte nach Artikel 2 Absatz 4 EPDV, inklusive der Berücksichtigung allfälliger an sie individuell erteilter Zugriffsrechte;

8.7 Optionen der Patientinnen und Patienten (Art. 3 EPDV)

8.7.1 Stammgemeinschaften müssen sicherstellen, dass:
8.7.1.1 Patientinnen und Patienten die Optionen nach den Vorgaben von Artikel 3 EPDV nutzen können;
8.7.1.2 die Vorgaben von Artikel 3 korrekt umgesetzt werden.

8.7.2 Die einzuhaltenden Vorgaben betreffen die korrekte Umsetzung:
8.7.2.1 von zeitlich beschränkten Zugriffsrechten nach Artikel 3 Buchstabe a EPDV;
8.7.2.2 der Einschränkung, der Erweiterung und des Ausschlusses von Notfallzugriffen;
8.7.2.3 der Festlegung welche Vertraulichkeitsstufe neu eingestellten Daten zugewiesen wird;
8.7.2.4 des Ausschlusses einzelner Gesundheitsfachpersonen vom Zugriff auf das elektronische Patientendossier;
8.7.2.5 der Deaktivierung der Information nach Artikel 8 Buchstabe f;
8.7.2.6 der Festlegung, dass Gesundheitsfachpersonen, die in eine Gruppe von Gesundheitsfachpersonen eintreten, nicht automatisch das mit der Gruppe verbundene Zugriffsrecht erhalten;
8.7.2.7 der Benennung einer Stellvertretung;
8.7.2.8 der Ermächtigung von Gesundheitsfachpersonen zur Weitergabe ihrer Zugriffsrechte nach Massgabe von Buchstabe h EPDV;
8.7.2.9 die korrekte Auswertung der geltenden Berechtigungsregeln.

8.8 Stellvertretung (Art. 16 Abs. 3)

8.8.1 Stammgemeinschaften müssen der Patientin oder dem Patienten die Möglichkeit bieten, eine Stellvertretung zu benennen.

8.8.2 Die Stellvertreterin oder der Stellvertreter muss mittels eigenem Identifikationsmittel, das von einem nach Artikel 30 zertifizierten Herausgeber herausgegeben wurde, auf das elektronische Patientendossier der vertretenen Person zugreifen.

8.8.3 Die Stammgemeinschaft muss sicherstellen, dass:
8.8.3.1 die Identifikation des Stellvertreters oder der Stellvertreterin

8.8.3.1.1 anhand des Identifikationsmittels eines nach Artikel 30 zertifizierten Herausgebers erfolgt, oder
8.8.3.1.2 den Anforderungen nach Artikel 23 Absatz 1 EPDV entspricht;
8.8.3.2 die rechtlichen Voraussetzungen für die Wahrnehmung der Stellvertretung erfüllt sind;
8.8.3.3 die Stellvertretung nach Artikel 14 EPDV über die Grundzüge der Datenbearbeitung sowie die Möglichkeiten, Rechte und Pflichten im Zusammenhang mit der Nutzung des elektronischen Patientendossiers informiert wird;
8.8.3.4 das Identifikationsmittel der Stellvertretung, das von einem nach Artikel 30 EPDV zertifizierten Herausgebers herausgegeben wurde, eindeutig und korrekt mit dem elektronischen Patientendossier der vertretenen Person verknüpft wird;
8.8.3.5 dass der Zugang des Stellvertreters oder der Stellvertreterin zum elektronischen Patientendossier nur für die Dauer der Stellvertretung besteht.

9 Zugangsportal für Patientinnen und Patienten (Art. 17 EPDV)

9.1 Konformität mit gesetzlichen Bestimmungen

9.1.1 Das Zugangsportal für Patientinnen und Patienten muss den einschlägigen rechtlichen Anforderungen entsprechen.

9.1.2 Das Zugangsportal muss Patientinnen und Patienten und den nach Artikel 3 Buchstabe h EPDV ermächtigten Gesundheitsfachpersonen die Möglichkeit bieten, die Berechtigungssteuerung unter Einhaltung der Vorgaben von Artikel 1 bis 3 EPDV umzusetzen.

9.1.3 Das Zugangsportal muss hinsichtlich der Verwendung von Patientendaten mindestens folgende Rahmenbedingungen erfüllen:
9.1.3.1 die von den Patienten in Bereichen ausserhalb des elektronischen Patientendossiers bereitgestellten Daten dürfen nur dann im elektronische Patientendossier erfasst werden, wenn die Patientin oder der Patient dazu ihre oder seine Einwilligung erteilt hat;
9.1.3.2 die vom Patienten oder von der Patientin selbst bereitgestellte Daten müssen immer direkt, d.h. ohne Verwendung intermediärer Speicher im elektronischen Patientendossier erfasst werden können;
9.1.3.3 die Daten des elektronischen Patientendossiers dürfen nicht automatisch und nicht ohne explizite Einwilligung des Patienten oder der Patientin in funktionelle Bereiche «ausserhalb» des elektronischen Patientendossiers überführt werden.

9.2 Darstellung

9.2.1 Die Darstellung auf der Benutzeroberfläche des Zugangsportals muss korrekt und vollständig sein und klar erkennen lassen:
9.2.1.1 ob ein Dokument durch eine Gesundheitsfachpersonen oder durch den Patienten oder die Patientin selbst bereitgestellt wurde;
9.2.1.2 welche Dokumente von der Patientin oder dem Patienten selbst bereitgestellt wurden;
9.2.1.3 welche Dokumente annulliert wurden;
9.2.1.4 welche Versionen eines Dokumentes gegebenenfalls auch vorhanden sind.
9.2.1.5 welche Gesundheitsfachpersonen über welche Zugriffsrechten verfügen;
9.2.1.6 welche Dokumente welcher Vertraulichkeitsstufe zugeordnet sind;

9.2.2 Für die Darstellung der in Anhang 3 der EPDV-EDI vorgegebenen Metadaten auf der Benutzeroberfläche des Zugangsportals sind die dort vorgegebenen Begriffe («defined terms») gemäss gewählter Spracheinstellung zu verwenden.

9.3 Barrierefreiheit

9.3.1 Das interne Zugangsportal muss:
9.3.1.1 so ausgestaltet sein, dass behinderte oder ältere Patientinnen und Patienten dieses barrierefrei nutzen können;
9.3.1.2 den Konformitätsbedingungen gemäss Web Content Accessibility Guidelines (WCAG) 2.0 entsprechen und die Konformitätsstufe AA erreichen.

9.4 Dateiformate: Bereitstellung

9.4.1 Das Zugangsportal muss:
9.4.1.1 die Möglichkeit bieten, die gemäss Anhang 3 der EPDV-EDI zugelassenen Dateiformate bereitzustellen;
9.4.1.2 die Dateien anderer Formate vor dem Abspeichern in der Dokumentenablage in ein zugelassenes Format umwandeln.

9.5 Dateiformate: Abruf

9.5.1 Das Zugangsportal muss:
9.5.1.1 die Möglichkeit bieten, die gemäss Anhang 3 der EPDV-EDI zugelassenen Dateiformate abzurufen;
9.5.1.2 den Abruf von Dateien zum Abspeichern im Primärsystem unterstützen («Download»);
9.5.1.3 die Möglichkeit bieten, ausgewählte Dokumente nicht nur einzeln, sondern auch gesammelt («bulk download») herunterzuladen;
9.5.1.4 strukturierte Daten menschenlesbar, korrekt und vollständig darstellen;
9.5.1.5 die Möglichkeit bieten, dass strukturierte Daten sowohl im Originalformat, als auch als menschenlesbares Format heruntergeladen werden können.

9.5.2 Für den Abruf von Dokumenten zur Darstellung oder zum Abspeichern sind zulässige Obergrenzen pro Zeiteinheit («rate limits») zu definieren, welche beim Überschreiten geeignete Sperr- oder zusätzliche Sicherheitsmassnahmen auslösen.

9.6 Protokolldaten (Bst. c)

9.6.1 Patientinnen und Patienten müssen die Möglichkeit haben, Protokolldaten für ihr oder sein elektronisches Pateientendossier aus allen Gemeinschaften und Stammgemeinschaften in einer für sie lesbaren Form einzusehen.

10 Verfügbarkeit der von Patientinnen oder Patienten erfassten Daten (Art. 18 EPDV)

10.1 Dokumentenablagen für Dokumente von Patientinnen und Patienten

10.1.1 Stammgemeinschaften müssen dedizierte gemeinschaftsinterne Dokumentenablagen für die durch Patientinnen oder Patienten selbst erfassten Dokumente bereitstellen.

10.1.2 Die Dokumente dürfen keiner Löschungsfrist unterliegen.

10.1.3 Der dafür vorgesehene Speicherplatz muss mindestens 2 Gigabyte umfassen.

10.1.4 Stammgemeinschaften müssen ein Kapazitätsmanagement für den verfügbaren Speicherplatz für die durch Patientinnen und Patienten erfassten Dokumente führen.

10.2 Offline-Archivierung von Dokumenten und Metadaten

10.2.1 Patientenbezogene Daten und deren Metadaten müssen den Patientinnen und Patienten in einem interoperablen gängigen elektronischen Format zur Verfügung gestellt werden können.

10.2.2 Dabei sind Verfahren vorzusehen, die es ermöglichen festzustellen, ob die Daten seit der Verfügungsstellung verändert wurden.

10.2.3 Stammgemeinschaften müssen sicherstellen, dass Daten, die erneut im elektronischen Patientendossier verfügbar gemacht werden sollen, unverändert geblieben sind.

11 Kontaktstelle für Patientinnen und Patienten (Art. 19 EPDV)

11.1.1 Stammgemeinschaften müssen für die Patientinnen und Patienten eine Kontaktstelle («*Service-Desk*») bezeichnen, die sie im Umgang mit dem elektronischen Patientendossier unterstützt.

11.1.2 Stammgemeinschaften müssen mindestens sicherstellen, dass:

11.1.2.1 die Mitarbeitenden des «Service-Desk» ihre Aufgaben, Rechte und Pflichten sowie die Risiken und die Massnahmen bezüglich Datenschutz und Datensicherheit kennen;

11.1.2.2 die Mitarbeitenden mit Zugriff auf Daten des elektronischen Patientendossiers sorgfältig ausgewählt werden und einer der ärztlichen Schweigepflicht analogen Vereinbarung unterstehen;

11.1.2.3 die Einwilligung der Mitarbeitenden des Service-Desk zu den spezifischen Richtlinien der Stammgemeinschaft dokumentiert wird;

11.1.2.4 Remote-Zugriffe für Support-Tätigkeiten auf die Endgeräte der Patientinnen und Patienten ausschliesslich mit Kenntnis und Einwilligung der jeweiligen Gesundheitsfachperson erfolgen können und automatisch dokumentiert werden.

12 Aufhebung des elektronischen Patientendossiers (Art. 20 EPDV)

12.1.1 Stammgemeinschaften müssen Prozesse zur Aufhebung des elektronischen Patientendossiers aufgrund von Widerruf, Nichtgebrauch und Tod der Patientin oder des Patienten definiert, dokumentiert, umgesetzt und eingehalten haben.

12.2 Bedingungen zur Aufhebung des elektronischen Patientendossiers (Abs. 1)

12.2.1 Der Prozess zur Aufhebung des elektronischen Patientendossiers muss ausgelöst werden, wenn:
12.2.1.1 die Patientin oder der Patient die Einwilligung zu dessen Führung widerruft;
12.2.1.2 während 10 Jahren niemand darauf zugreift; oder
12.2.1.3 die Patientin oder der Patient verstorben ist.

12.3 Aufhebung des elektronischen Patientendossiers (Abs. 2)

12.3.1 Der Prozess zur Aufhebung des elektronischen Patientendossiers muss sicherstellen, dass:
12.3.1.1 das aufzuhebende elektronische Patientendossier korrekt identifiziert wird;
12.3.1.2 sämtliche Zugriffsrechte auf das entsprechende Patientendossier unverzüglich entzogen werden;
12.3.1.3 sämtliche Daten des entsprechenden Patientendossiers nach Artikel 9 Absatz 1 Buchstabe b vernichtet werden;
12.3.1.4 alle Gemeinschaften und Stammgemeinschaften innert angemessener Frist über die Aufhebung des elektronischen Patientendossiers informiert werden;
12.3.1.5 die ZAS innert angemessener Frist über die Aufhebung des elektronischen Patientendossiers informiert wird.

12.4 Widerruf der Einwilligung zur Führung eines elektronischen Patientendossiers (Abs. 2 Bst. a)

12.4.1 Der Prozess zur Aufhebung des elektronischen Patientendossiers aufgrund Widerruf muss, in Ergänzung zu Kap. 12.3, zudem sicherstellen, dass:
12.4.1.1 der Widerruf rechtsgültig dokumentiert wird;
12.4.1.2 die Widerrufserklärung während zehn Jahren aufbewahrt wird.

12.4.2 Es muss sichergestellt werden, dass:
12.4.2.1 die Identifikation der widerrufenden Person
12.4.2.1.1 anhand des Identifikationsmittels eines nach Artikel 30 zertifizierten Herausgebers erfolgt, oder
12.4.2.1.2 den Anforderungen nach Artikel 23 Absatz 1 EPDV entspricht;
12.4.2.2 die widerrufende Person über die Folgen des Widerrufs informiert wurde;

12.5 Schliessen bei Nichtgebrauch (Abs. 2 Bst. b)

12.5.1 Der Prozess zur Aufhebung des elektronischen Patientendossiers aufgrund Nichtgebrauch nach Artikel 20 Absatz 1 Buchstabe b muss, in Ergänzung zu Kap. 12.3, zudem sicherstellen, dass:

12.5.1.1 die Patientin oder der Patient drei Monate vor der Aufhebung darüber informiert wird.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI

Bundesamt für Gesundheit BAG
Direktionsbereich Gesundheitspolitik

Metadaten

Ausgabe: 1.0 22.03.2016
Inkrafttreten: ...

Zu verwendende Metadaten im elektronischen Patientendossier

1 Attribute-Liste

1. Rolle des Autors
2. Medizinische Fachrichtung des Autors
3. Verfügbarkeitsstatus des Dokumentes
4. Dokumentenklasse
5. Vertraulichkeitsstufe
6. Format des Dokumentes
7. Typ der Gesundheitseinrichtung
8. Sprache des Dokumentes
9. MIME Typ des Dokumentes
10. Medizinische Fachrichtung der in dem Dokument erfassten Daten
11. Geschlecht der Patientin oder des Patienten
12. Typ des Dokumentes

Bei den meisten Attributen und entsprechender Liste von zugelassenen Werten wird eine eindeutige OID (Object Identifier) zugeordnet, welche ebenfalls zu verwenden ist. Die OIDs sind technische Identifikatoren, welche von den IT-Systemen für eine eindeutige Zuordnung der Attribute und Werte genutzt werden müssen.

1.1 Rolle des Autors

Nationale OID: 2.16.756.5.30.1.127.3.10.1.1.3

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
40001	Pharmacist	Apothekerin/Apotheker		
40002	Physician	Ärztin/Arzt		
40003	Chiropractor	Chiropraktorin/Chiropraktiker		
40004	Dietitian	Ernährungsberaterin/Ernährungsberater		
40005	Midwife	Hebamme		
40006	Complementary therapist	Komplementärmedizinerin/ Komplementärmediziner /		
40007	Patient	Patientin/Patient		
40008	Professional nurse	Pflegefachperson		
40009	Psychologist	Psychologin/Psychologe		
40010	Social Worker	Sozialdienst-Mitarbeiterin/Mitarbeiter		
40011	Other Therapist	Therapeutin/Therapeut		
40012	Dentist	Zahnärztin/Zahnarzt		
40900	Unknown	Unbekannt		
40999	Other	Andere		

1.2 Medizinische Fachrichtung des Autors

Nationale OID: 2.16.756.5.30.1.127.3.10.1.1.4

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
50001	Internal medicine specialist	Fachärztin/Facharzt für Allgemeine Innere Medizin		
50002	Anesthesiologist	Fachärztin/Facharzt für Anästhesiologie		
50003	Occupational therapist	Fachärztin/Facharzt für Arbeitsmedizin		
50004	Surgeon	Fachärztin/Facharzt für Chirurgie		
50005	Dermatologist	Fachärztin/Facharzt für Dermatologie und Venerologie		
50006	Endocrinologist	Fachärztin/Facharzt für Endokrinologie / Diabetologie		
50007	Gastroenterologist	Fachärztin/Facharzt für Gastroenterologie		
50008	Obstetrician and gynecologist	Fachärztin/Facharzt für Gynäkologie und Geburtshilfe		
50009	Hematologist	Fachärztin/Facharzt für Hämatologie		
50010	Cardiovascular surgeon	Fachärztin/Facharzt für Herz- und thorakale Gefässchirurgie		
50011	Infectious disease specialist	Fachärztin/Facharzt für Infektiologie		
50012	Cardiologist	Fachärztin/Facharzt für Kardiologie		
50013	Pediatrician	Fachärztin/Facharzt für Kinder- und Jugendmedizin		
50014	Child and adolescent psychiatrist	Fachärztin/Facharzt für Kinder- und Jugendpsychiatrie und -psychotherapie		
50015	Pediatric surgeon	Fachärztin/Facharzt für Kinderchirurgie		
50016	Clinical pharmacologist	Fachärztin/Facharzt für Klinische Pharmakologie und Toxikologie		
50017	Oral and maxillofacial surgeon	Fachärztin/Facharzt für Mund-, Kiefer- und Gesichtschirurgie		
50018	Nephrologist	Fachärztin/Facharzt für Nephrologie		
50019	Neurosurgeon	Fachärztin/Facharzt für Neurochirurgie		
50020	Neurologist	Fachärztin/Facharzt für Neurologie		
50021	Nuclear medicine specialist	Fachärztin/Facharzt für Nuklearmedizin		
50022	Ophthalmologist	Fachärztin/Facharzt für Ophthalmologie		
50023	Orthopedic surgeon	Fachärztin/Facharzt für Orthopädische Chirurgie und Traumatologie des Bewegungsapparates		
50024	Otorhinolaryngologist	Fachärztin/Facharzt für Oto-Rhino-Laryngologie		
50025	Medical pathologist	Fachärztin/Facharzt für Pathologie		
50026	Rehabilitation physician	Fachärztin/Facharzt für Physikalische Medizin und Rehabiliation		
50027	Plastic surgeon	Fachärztin/Facharzt für Plastische, Rekonstruktive und Ästhetische Chirurgie		
50028	Pulmonologist	Fachärztin/Facharzt für Pneumologie		
50029	Preventive medicine specialist	Fachärztin/Facharzt für Prävention und Gesundheitswesen		
50030	Psychiatrist	Fachärztin/Facharzt für Psychiatrie und Psychotherapie		

50031	Radiologist	Fachärztin/Facharzt für Radiologie		
50032	Radio-Oncologist	Fachärztin/Facharzt für Radio-Onkologie / Strahlentherapie		
50033	Rheumatologist	Fachärztin/Facharzt für Rheumatologie		
50034	Tropical medicine specialist	Fachärztin/Facharzt für Tropen- und Reisemedizin		
50035	Urologist	Fachärztin/Facharzt für Urologie		
50036	Angiologist	Fachärztin/Facharzt für Angiologie		
50037	Intensive care specialist	Fachärztin/Facharzt für Intensivmedizin		
50038	Geneticist	Fachärztin/Facharzt für Medizinische Genetik		
50039	Medical oncologist	Fachärztin/Facharzt für Medizinische Onkologie		
50040	Pharmacologist	Fachärztin/Facharzt für Pharmazeutische Medizin		
50041	Forensic medicine specialist	Fachärztin/Facharzt für Rechtsmedizin		
50042	Hand surgeon	Fachärztin/Facharzt für Handchirurgie		
50043	Neuropathologist	Fachärztin/Facharzt für Neuropathologie		
50044	Dentist	Zahnärztin/Zahnarzt		
50045	Retail pharmacist	Apothekerin/Apotheker in Offizinpharmazie		
50046	Hospital pharmacist	Apothekerin/Apotheker in Spitalpharmazie		
50047	Dietician/public health nutritionist	Ernährungsberaterin/Ernährungsberater		
50048	Paramedic	Rettungssanitäterin/Rettungssanitäter		
50049	Chiropractor	Chiropraktorin/Chiropraktiker		
50050	Psychotherapist	Psychotherapeutin/Psychotherapeut		
50051	Clinical psychologist	Klinischer Psychologe/Klinische Psychologin		
50052	Health psychologist	Gesundheitspsychologin/Gesundheitspsychologe		
50053	Music therapist	Musiktherapeutin/Musiktherapeut		
50054	Midwife	Hebamme		
50055	Physiotherapist	Physiotherapeutin/Physiotherapeut		
50056	Laboratory technician - analysist	Biomedizinische Analytikerin/Biomedizinischer Analytiker		
50057	Medical X-ray technician	Radiologietechnologin/Radiologietechnologe		
50058	Diabetes dietitian	Diätologin/Diätologe		
50059	Occupational therapist	Ergotherapeutin/Ergotherapeut		
50060	Speech/language therapist	Logopädin/Logopäde		
50061	Orthoptist	Orthoptistin/Orthoptist		
50062	Professional nurse	diplomierte Pflegefachfrau/diplomierter Pflegefachmann		
50063	Professional nurse (Bachelor degree)	diplomierte Pflegefachfrau/diplomierter Pflegefachmann mit akademischem pflegefachlichem Abschluss (Bachelor)		
50064	Professional nurse (Master degree)	diplomierte Pflegefachfrau/diplomierter Pflegefachmann mit akademischem pflegefachlichem Abschluss (Master)		
50065	Specialized nurse	diplomierte Pflegefachfrau/diplomierter Pflegefachmann mit Zusatz- oder		

		Spezialfunktion, z.B. IPS, Anästhesie (NDS)		
50066	Specialized nurse (additional qualification)	diplomierte Pflegefachfrau/diplomierter Pflegefachmann mit fachvertiefendem NDK und weiteren Zusatzausbildungen wie Diabetesberaterin, Stillberaterin etc.		
50067	Nursing assistant	Pflegefachfrau/Pflegefachmann mit Attestabschluss		
50068	Health specialist (swiss federal certificate of competence)	Fachfrau/Fachmann Gesundheit, FaGe mit eidg. Fähigkeitszeugnis		
50069	Masseur	Heilmasseurin/Heilmasseur		
50070	Perfusionist	Kardiotechnikerin/Kardiotechniker		
50071	Health advisor	Gesundheits- und Sozialberaterin/-Berater		
50072	Audiologist	Hörgeräteakustiker/in		
50073	Clinical immunologist	Fachärztin/Facharzt für Allergologie und Immunologie		
50074	Allergist	Fachärztin/Facharzt für Allergologie		
50075	Pharmaceutical assistant	Pharma-Assistentin / Pharma-Assistent		
50900	Unknown	Unbekannt		
50999	Other	andere gesundheitsbezogene Fachrichtung		

1.3 Verfügbarkeitsstatus des Dokumentes

Keine OID notwendig

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
urn:oasis:names:tc:ebxml-regrep:StatusType:Approved	Approved	genehmigt		
urn:oasis:names:tc:ebxml-regrep:StatusType:Deprecated	Deprecated	abgelehnt		

1.4 Dokumentenklasse

Nationale OID: 2.16.756.5.30.1.127.3.10.1.3

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
70001	Notes on Consultations	Konsultationseinträge/-Notizen		
70002	Progress Notes	Verlaufseinträge/-Notizen		
70003	Notes on Procedures	Interventionseinträge/-Notizen		
70004	Tests/Procedure Requests	Untersuchungs-/ Prozedur-Anforderungen		
70005	Clinical Care Referrals	Zuweisungen/Überweisungen		
70006	Episode Summary Reports	Zusammenfassende Berichte		
70007	Progress Reports	Verlaufs-Berichte		
70008	Diagnostic Test Results	Diagnostische Untersuchungsbefunde		
70009	Notifications	Meldungen		

70010	Historic Overviews	Zusammenfassungen der Krankengeschichte		
70011	Present State Summaries	Zusammenfassungen aktueller Zustand		
70012	Care Plans	Behandlungspläne, Behandlungsschemata		
70013	Alerts	Warnungen /Risiken		
70020	Scanned Documents	Gescannte Dokumente		
70021	Data from Patient	Eigene Daten des Patienten		
70999	Other Composition	anderweitige Dokumente		

1.5 Vertraulichkeitsstufe

Nationale OID: 2.16.756.5.30.1.127.3.10.1.5

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
30002	Useful medical data	nützliche Daten		
30003	Medical data	medizinische Daten		
30004	Sensitive data	sensible Daten		
30005	Secret data	geheime Daten		

1.6 Format des Dokumentes

Keine OID notwendig

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
urn:che:epd:EPD_Basic_Document	EPD basic document	EPD Dokument		
urn:che:epd:2.16.756.5.30.1.1.1.1.3.5	eVaccination record	eImpfdossier		
urn:ihe:rad:1.2.840.10008.5.1.4.1.1.88.59	IHE KOS document	KOS Dokument		

1.7 Typ der Gesundheitseinrichtung

Nationale OID: 2.16.756.5.30.1.127.3.10.1.11

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
20001	Diagnostic institution	Institut für medizinische Diagnostik		
20002	Accident and Emergency department	Notfall- / Rettungsdienste		
20003	Health Authority	Gesundheitsbehörde		
20004	Private home-based care	Organisation für Pflege zu Hause		

20005	Hospital	stationäre Einrichtung / Spital		
20006	Military health services	Armeeärztliche Dienste		
20007	Prison health services	Gesundheitseinrichtung in der Haftanstalt		
20008	Nursing home	Sozio-Medizinische Institution		
20009	Pharmacy	Apotheke		
20010	Ambulatory care site	Ambulante Einrichtung, inkl. Ambulatorium		
20011	Free-standing rehabilitation clinic	Organisation für stationäre Rehabilitation		
20012	Residential institution	zu Hause		
20900	Unknown	Unbekannt		
20999	Other	Andere Gesundheits-Organisation		

1.8 Sprache des Dokumentes

OID für IETF RFC 3066: 1.3.6.1.2.1.101.1.1.3.1.1

Interationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
de-CH	German	Deutsch		
fr-CH	French	Französisch		
it-CH	Italian	Italienisch		
rm	Rhaeto-Romanic	Rätoromanisch		
en-US	English	Englisch		

1.9 MIME Typ des Dokumentes

OID für HL7 MIME MediaType: 2.16.840.1.113883.6.10

Interationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
multipart/x-hl7-cda-level1	CDA Level 1 Multipart	CDA Level 1 Multipart		
text/xml	XML-Text	XML-Text		
application/pdf	PDF	PDF		
application/dicom	DICOM	DICOM		
audio/mpeg	MPEG audio layer 3	MPEG audio layer 3		
video/mpeg	MPEG Video	MPEG Video		
image/tiff	TIFF Image	TIFF Image		
image/jpeg	JPEG Image	JPEG Image		
text/plain	Plain Text	Plain Text		
multipart/x-hl7-cda-level1	CDA Level 1 Multipart	CDA Level 1 Multipart		
text/xml	XML-Text	XML-Text		
application/pdf	PDF	PDF		
application/dicom	DICOM	DICOM		
audio/mpeg	MPEG audio layer 3	MPEG audio layer 3		

1.10 Medizinische Fachrichtung der in dem Dokument erfassten Daten

Nationale OID: 2.16.756.5.30.1.127.3.10.1.18

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
10001	Allergology	Allergologie		
10002	General medicine	Allgemeinmedizin		
10003	Anesthetics	Anästhesiologie		
10004	Angiology	Angiologie		
10005	Clinical pharmacology	Pharmakologie		
10006	Occupational medicine	Arbeitsmedizin		
10007	Chiropraxy	Chiropraktik		
10008	Surgery	Chirurgie		
10009	Dermatology	Dermatologie und Venerologie		
10010	Endocrinology	Endokrinologie/Diabetologie		
10011	Occupational therapy	Ergotherapie		
10012	Unit of dietetics and nutrition	Ernährungsberatung		
10013	Geriatric medicine	Geriatrie		
10014	Gastroenterology	Gastroenterologie		
10015	Obstetrics and gynecology	Gynäkologie und Geburtshilfe		
10016	Cardiac surgery	Herz- und Gefässchirurgie		
10017	Infectious diseases (specialty)	Infektiologie		
10018	Internal medicine	Innere Medizin		
10019	Intensive care service	Intensivmedizin		
10020	Cardiology	Kardiologie		
10021	Complementary therapy service	Komplementärmedizin		
10022	Pediatric specialty	Pädiatrie		
10023	Psychology service	Psychologie		
10024	Laboratory Service	Labormedizin		
10025	Speech and language therapy service	Logopädie		
10026	Clinical genetics	Medizinische Genetik		
10027	Oral and maxillofacial surgery	Mund-, Kiefer- und Gesichtschirurgie		
10028	Nephrology	Nephrologie		
10029	Neurosurgery	Neurochirurgie		
10030	Neurology	Neurologie		
10031	Nuclear medicine - specialty	Nuklearmedizin		
10032	Ophthalmology	Ophthalmologie		
10033	Trauma and orthopedics	Orthopädie und Traumatologie		
10034	Osteopathy	Osteopathie		
10035	Oto-Rhino-Laryngology	Oto-Rhino-Laryngologie		
10036	Palliative medicine	Palliativmedizin		
10037	Pathology	Pathologie		
10038	Nursing service	Pflege		

10039	Physical medicine	Physikalische Medizin		
10040	Physiotherapy	Physiotherapie		
10041	Plastic surgery	Plastische, Rekonstruktive und Ästhetische Chirurgie		
10042	Pneumology	Pneumologie		
10043	Podiatry service	Podologie		
10044	Preventive medicine	Prävention		
10045	Psychiatry and Psychotherapy	Psychiatrie und Psychotherapie		
10046	Psychosomatic medicine	Psychosomatik		
10047	Radiology - specialty	Radiologie		
10048	Radiation oncology AND/OR radiotherapy	Radio-Onkologie/Strahlentherapie		
10049	forensic medicine	Rechtsmedizin		
10050	Rehabilitation - specialty	Rehabilitation		
10051	Emergency medical services	Notfall und Rettungsmedizin		
10052	Rheumatology	Rheumatologie		
10053	Thoracic surgery	Thoraxchirurgie		
10054	Blood transfusion (specialty)	Transfusionsmedizin		
10055	Tropical medicine	Tropen- und Reisemedizin		
10056	Urology	Urologie		
10057	Odontology	Zahnheilkunde		
10058	Clinical hematology	Hämatologie		
10059	Clinical immunology/allergy	Immunologie		
10900	unknown	Unbekannt		
10999	other	Andere nicht näher spezifizierte medzinische Fachrichtung		

1.11 Geschlecht der Patientin oder des Patienten

OID für HL7 administrative sex: 2.16.840.1.113883.12.1

Internationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
F	Female	weiblich		
M	Male	männlich		
O	Other	andere		

1.12 Typ des Dokumentes

Nationale OID: 2.16.756.5.30.1.127.3.10.1.27

Nationaler Code	Englische Bezeichnung	Deutsche Bezeichnung	Französische Bezeichnung	Italienische Bezeichnung
60001	Privacy policy acknowledgment Document	Patienteneinwilligung für die Verwendung der elektronischen Daten		
60002	Patient Consent	Patienteneinwilligung		
60003	Advance directive status	Patientenverfügung		
60004	Patient Summary document	Patient Summary (medizinische Zusammenfassung)		
60005	Medication summary Document	Medikamentenliste (aktuell)		
60006	Prescription For Medication Document	elektronisches Rezept		
60007	Admission request Document	Zuweisungsschreiben/Einweisungsschreiben		
60008	Physician consulting Initial evaluation note	Eintrittsbericht		
60009	Physician Discharge concise summary	Kurz-Austrittsbericht (ärztlich)		
60010	Physician Discharge summary	Austrittsbericht (lang-ärztlich)		
60011	nurse discharge concise summary	Kurz-Austrittsbericht (pflegerisch)		
60012	nurse discharge summary	Austrittsbericht (lang-pflegerisch)		
60013	Provider-unspecified Transfer summary	Verlegungsbericht		
60014	Obstetrics and Gynecology Discharge summary	Verlaufs- / Austrittsbericht Gynäkologie und Geburtshilfe		
60015	Overall Plan of Care/Advance Care Directives	Pflegeplan (allgemein)		
60016	nursing note	Pflegebericht		
60017	Referral note	Konsilauftrag (allgemein)		
60018	laboratory order	Laborauftrag		
60019	pathology order	Pathologieauftrag		
60020	Requested imaging studies information Document	Radiologieauftrag		
60021	Consult Note	Konsultationsbericht		
60022	Diagnostic studies.non-lab	Untersuchungsbefund (allgemein)		
60023	Laboratory report	Labor-Befund		
60024	Diagnostic Imaging Report	Radiologie-Befund		
60025	Pathology studies	Pathologie-Befund		
60026	Bone marrow Pathology biopsy report	Knochenmark-Biopsie-Befund		
60027	Tissue Pathology biopsy report	Histologie-Befund		
60028	Cardiac catherization	Herzkatheter-Befund		

	study			
60029	Heart US	Echokardiographie-Befund		
60030	Pulmonary function report	Lungenfunktions-Befund		
60031	Physical therapy consult note	Physiotherapiebericht		
60032	Anesthesiology Note	Anästhesie Bericht		
60033	Surgery Surgical operation note	OP-Bericht		
60034	Wound care management Note	Wundbefund		
60035	Provider-unspecified ED Progress note	Notfallbericht		
60036	Provider-unspecified Progress note	klinisches Verlaufsblatt		
60037	Cardiology Hospital Progress note	Kardiologie Verlaufs-Bericht		
60038	Intensive care Unit Progress Note	Kurve Intensivstation		
60039	Conclusions (interpretation) document	Beschlussprotokoll		
60040	Photographic image Unspecified body region Document	Nicht spezifizierte Bilddaten		
60041	Radiology studies	Radiologische Bilddaten		
60042	Infectious disease Diagnostic study note	Meldung übertragbare Erkrankung		
60043	Vaccination record	elektronisches Impfdossier		
60044	Emergency record	Notfall-Ausweis		
60045	Treatment scheme	Behandlungsschema		
60046	Allergy record	Allergie-Ausweis		
60047	Birth certificate document	Geburtsanzeige		
60048	Eligibility acknowledgement	Kostengutsprache		
60049	Audit trail	Protokolldaten		
60900	Unknown	Unbekannt		
60999	Other	Andere nicht näher spezifiziert		

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Eidgenössisches Departement des Innern EDI

Bundesamt für Gesundheit BAG
Direktionsbereich Gesundheitspolitik

SR 816.11.n / Anhang 5 der Verordnung des EDI vom ... über das elektronische Patientendossier

Nationale Anpassungen der Integrationsprofile nach Artikel 5 Buchstabe b EPDV-EDI

National extensions to the IHE Technical Framework

Ausgabe: 1.0 22.03.2016
Inkrafttreten: ...

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National Extensions

The national extensions documented in this section shall be used in conjunction with the definitions of integration profiles, actors and transactions provided in Volumes 1 through 3 of the IHE IT Infrastructure Technical Framework. This section includes extensions and restrictions to effectively support the regional practice of healthcare in Switzerland. It also translates a number of English terms to ensure correct interpretation of requirements of the IT Infrastructure Technical Framework.
This IT Infrastructure national extension document was authored under the supervision of the Federal Office of Public Health (FOPH), eHealth Suisse and IHE Suisse in order to fulfil the Swiss regulations. See also Ordinance to the Federal Act on the Electronic Health Record, published in the Official Compilation of Federal Legislation[1] (available in German, French and Italian).

[1] German: https://www.admin.ch/opc/de/classified-compilation/20111795/index.html
French: https://www.admin.ch/opc/fr/classified-compilation/20111795/index.html
Italian: https://www.admin.ch/opc/it/classified-compilation/20111795/index.html

1.1 Definitions of terms

1.1.1 Electronic patient dossier (EPD)

The object of the Federal Law on Electronic Health Records (FLEHR) is to define the conditions for processing data and documents relating to electronic health records. Using electronic health records, healthcare professionals can access data relevant to treatment of their patients that was compiled and decentrally recorded by healthcare professionals involved in the treatment process. Healthcare professionals may save this data if necessary in their practice and hospital information systems outside of the electronic health records. To access electronic health records, healthcare professionals must join a certified community, which is an association of healthcare professionals and their institutions, and their patients must grant them the necessary access rights. In addition, the electronic health record also allows patients to view their data, to make their own data accessible and to manage the allocation of access rights. Healthcare professionals may only process data in electronic health records with the consent of the patient. Patients have the option of granting individual and graded access rights.
Notation of this term in the following text: **EPD**

1.1.2 EPD circle of trust

From an organizational perspective and in terms of the FLEHR, communities are an association of healthcare professionals and their institutions. Communities who want to participate in the Swiss EPD must comply with the certification requirements as laid down in the implementing provisions for the FLEHR. Such communities and, in particular, their gateways will be listed in a community portal index provided by the FOPH and therefore form a circle of trust by mutual recognition of their conformity related to data protection and data privacy. Furthermore, all required central services are also part of this circle of trust.
Notation of this term in the following text: **EPD circle of trust**

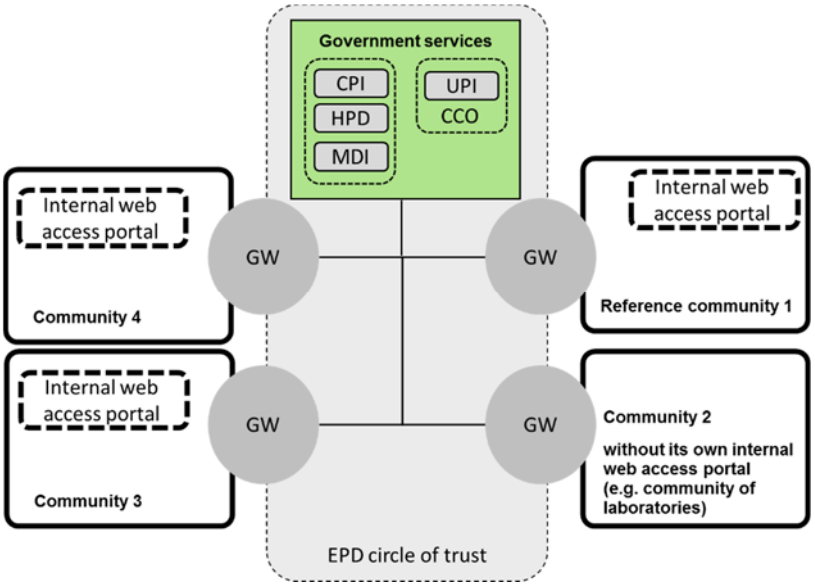

Figure 1: Swiss EPD circle of trust

Legend:

- GW: Gateway
- CPI: Community / Portal Index
- UPI: Unique Person Identification
- HPD: Healthcare Provider Directory
- MDI: Metadata Index-Service

1.1.3 Reference community

If a patient decides to open an EPD, she or he first chooses a community that manages all of his current consents and access right configurations to be used by other EPD users (in essence healthcare professionals) while accessing his personal EPD. Consents and access rights for one patient are managed by exactly one community in the EPD circle of trust.
Although the term home community is used by IHE in a slightly different way, the current specification states this consent and access right management community as reference community.
Cross-community accesses to documents within the EPD are only permitted when the initiating user gets permission by the access rights defined by the patient. Although cross-community accesses may occur between each community within the EPD circle of trust regardless whether it is the patient's reference community or not, the responding community must always apply the current access right settings managed by the reference community.
The patient may change his reference community at any time (for example, when moving to another residence).
Notation of this term in the following text: **referenceCommunity**

1.1.4 Patient Identifiers (EPD-PID, MPI-PID)

Communities in the EPD circle of trust use the national EPD patient identifier (EPD-PID) only for cross-community communication. The federal Central Compensation Office (CCO)[2] is the institution which issues EPD-PID's. CCO is the only institution which is allowed to correlate the Social Security Number (AVN13) with the EPD-PID. There is no correlation possible back from the EPD-PID to the Social Security Number. This is political intention in order to achieve highest possible patient privacy.
Within a community patients are identified by a MPI-PID which is managed by a community Master Patient Index (MPI). Primary Systems may correlate their local patient identifier with the MPI-PID. For cross-community communication the gateways may correlate the MPI-ID to the EPD-PID.

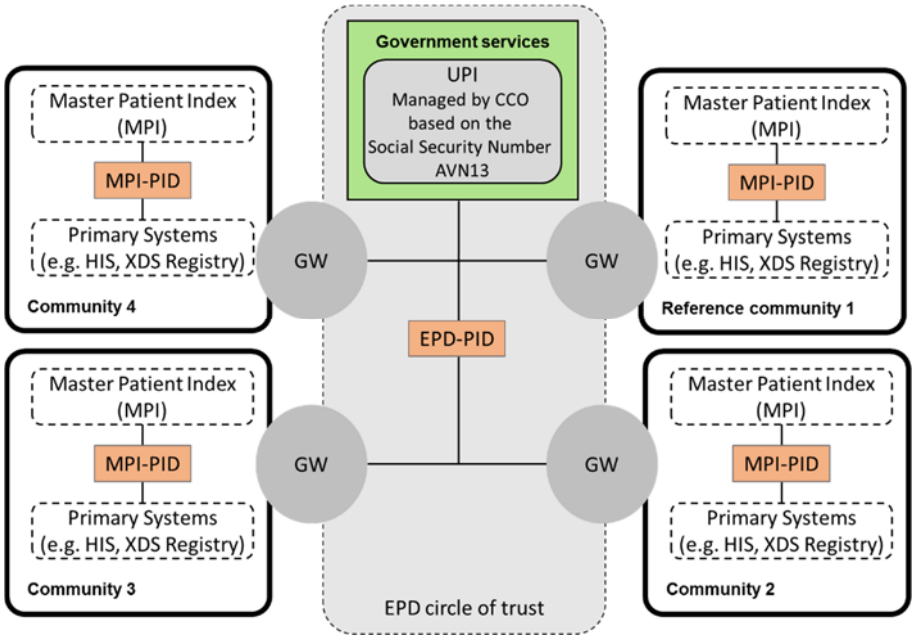

Figure 2 Swiss Patient Identifiers

1.2 IHE Suisse Scope of precisions

The extensions, restrictions and translations specified apply to the following IHE IT Infrastructure Integration profiles:

- IT Infrastructure: Consistent Time (CT)
- IT Infrastructure: Audit Trail and Node Authentication (ATNA)

[2] http://www.zas.admin.ch/index.html

- IT Infrastructure: Cross-Community Access (XCA)
- IT Infrastructure: Patient Identifier Cross-Reference HL7 V3 (PIXv3)
- IT Infrastructure: Patient Demographic Query HL7 V3 (PDQv3)
- IT Infrastructure Technical Framework Supplement: Cross-Community Patient Discovery (XCPD)
- IT Infrastructure Technical Framework Supplement: Healthcare Provider Directory (HPD)

1.3 Requirements on CT Profile for Swiss Time Service

ITI TF-1 does not specify any NTP Servers. The following Time Service MUST be used by all actors in the Swiss EPD circle of trust.

- Maintain Time [ITI-1]
  ntp.metas.ch MUST be used as Time Service.

1.4 Requirements on ATNA, XDS.b and XCA Profiles for Audit Trail Consumption

1.4.1 Introduction

The FLEHR requires a patient access on the complete audit trail within the EPD circle of trust. The access to the audit trail will be provided by certified web access portals for patients.
The present national extension will use and precise the existing transactions and content profiles of the Audit Trail and Node Authentication (ATNA), Cross-Enterprise Document Sharing (XDS.b) and Cross-Community Access (XCA) integration profiles in order to achieve the Swiss regulation needs on the audit trail access by patients.
This figure shows all relevant actors and transactions for the present national extension:

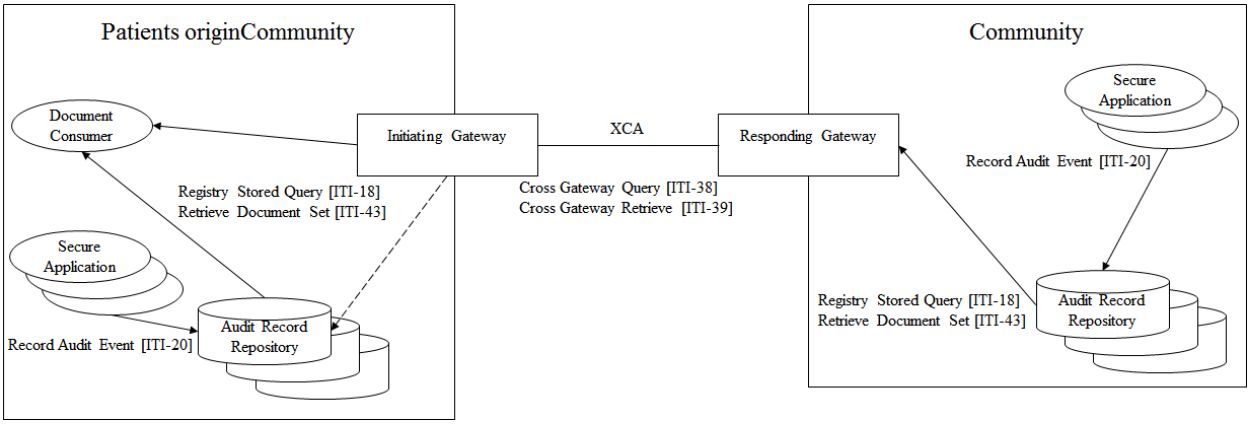

Figure 3: Big picture – actors and transactions

This figure shows all relevant content profiles for the present national extension:

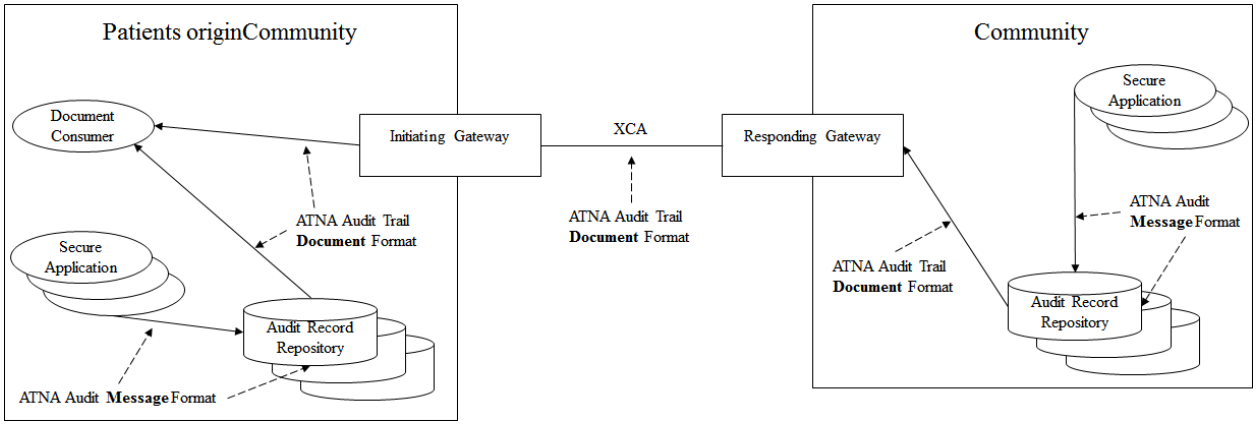

Figure 4: Big picture – content profiles

1.4.2 Actors

1.4.2.1 XDS.b Document Consumer

The following option MUST be implemented by all web access portal providers for patients in the Swiss EPD circle of trust:

- On-Demand Documents Option (see ITI TF-2a, 3.18.4.1.2.5)

These actors MUST …

- combine all Audit Trail Message entries of all Audit Trail Document entries into one single document of type ATNA Audit Trail Document Format (see chapter 1.4.4.2 on page 23). Relevant transactions:
  - Registry Stored Query [ITI-18] transaction that uses the parameters described in chapter “1.4.3.1.1 Parameters for stored query FindDocuments” on page 10.
  - Retrieve Document Set [ITI-43] transaction performed against an Audit Record Repository using a document UUID received by a previously executed by a Registry Stored Query mentioned before.
- translate the coded information into the language preferred by the user when provide it to the user through the UI or other results like reports. Translations MUST fulfil the following requirements:
  - Translations in German, French and Italian MUST be supported. Other language translations are permitted but remain in the responsibility of the software vendor.
  - Translations for coded values from the Swiss Metadata Value-Set[3] must match the translations provided in the Swiss Metadata Value-Set.
  - Translations for coded values mentioned in the present national extensions MUST be used.
  - No translation is required for narrative text.

1.4.2.2 XCA Initiating Gateway

The following option MUST be implemented by all community gateways in the Swiss EPD circle of trust:

- On-Demand Documents Option (see ITI TF-2a, 3.18.4.1.2.5)

These actors basically relay the XDS.b Registry Stored Query [ITI-18] and XDS.b Retrieve Document Set [ITI-43] transactions to XCA Cross Gateway Query [ITI-38] and XCA Cross Gateway Retrieve [ITI-39] as described in IHE ITI TF-2.

[3] <TODO: Laid down in the Departmental Ordinance on the Electronic Health Record and published elsewhere>

If the homeCommunityId represents the local community and the parameter $XDSDocumentEntryTypeCode contains the value 60049 (Audit trail), these actors MUST initiate a Registry Stored Query to all local ATNA Audit Repositories.
See also chapter “1.4.3.1.1 Parameters for stored query FindDocuments” on page 10.

1.4.2.3 XCA Responding Gateway

The following option MUST be implemented by all community gateways in the Swiss EPD circle of trust:

- On-Demand Documents Option (see ITI TF-2a, 3.18.4.1.2.5)

These actors basically relay the XCA Cross Gateway Query [ITI-38] and XCA Cross Gateway Retrieve [ITI-39] to XDS.b Registry Stored Query [ITI-18] and XDS.b Retrieve Document Set [ITI-43] transactions as described in ITI TF-2.
If the parameter $XDSDocumentEntryTypeCode contains the value 60049 (Audit trail), these actors MUST initiate a Registry Stored Query to all local ATNA Audit Repositories.
See also chapter “1.4.3.1.1 Parameters for stored query FindDocuments” on page 10.

1.4.2.4 ATNA Secure Application

The following transactions are declared as optional in ITI TF-1 but are REQUIRED by the present national extension:

- Maintain Time [ITI-1]
  See chapter “1.3 Requirements on ” on page 7.
- Record Audit Event [ITI-20]
  The Audit Message Format described in chapter “1.4.4.1 ATNA Audit Message Format” on page 13 MUST be used.

This behaviour MUST be implemented by all applications in the Swiss EPD circle of trust that are requesting, consuming or producing health information of patients having an EPD.

1.4.2.4.1 Audit messages

All ATNA Secure Application actors are required to record the audit messages defined by the IHE actor they are grouped with as described in the IHE Technical Framework.
In case these audit messages do not fulfil the requirements described in chapter “1.4.4.1 ATNA Audit Message Format” on page 13, ATNA Secure Application actors within the Swiss EPD circle of trust MUST record an additional audit message as described in chapter “1.4.4.1 ATNA Audit Message Format” on page 13 for each transaction concerning a patient having an EPD.

1.4.2.5 ATNA Audit Record Repository

ATNA Audit Record Repository actors within the Swiss EPD circle of trust MUST …

- support the following options and transactions:
  (see chapter “1.4.3 Transactions” starting on page 10 for detailed descriptions)
  - On-Demand Documents Option (see ITI TF-2a, 3.18.4.1.2.5).
  - XDS.b Registry Stored Query [ITI-18].
  - XDS.b Retrieve Document Set [ITI-43].
- be able to receive and store audit messages of Audit Message Format described in chapter “1.4.4.1 ATNA Audit Message Format” on page 13 by the Record Audit Event [ITI-20] which is based on the preferred Audit Message Format by IHE ATNA (see ITI TF-2a, chapter 3.20.7.1).
- be able to perform the Retrieve Document Set transaction for all On-Demand documents specified by document and repository UUIDs created by a previously Registry Stored Query transaction.
- have assigned a unique repository ID within the community (similar to XDS.b Document Repository actors).

1.4.3 Transactions

1.4.3.1 Registry Stored Query [ITI-18]

See ITI TF-2a, chapter “3.18.4.1.2.3 Query Request Parameters – Coding Style”. The query parameters described in the following chapter MUST be used for Audit Trail Consumption.

1.4.3.1.1 Parameters for stored query FindDocuments

ITI TF-2a specifies the query parameters for a stored query “FindDocuments” (see ITI TF-2a 3.18.4.1.2.3.7.1). The stored query “FindDocuments” MUST be used using the following parameters in order to retrieve Audit Trails within the Swiss EPD circle of trust.
The mentioned Swiss Metadata Value-Set can be found in appendix 3 of the Departmental Ordinance on the Electronic Health Record.

Table 1: Parameters for stored query FindDocuments

Element Name Attribute	Card.	Original descriptions	Swiss National Extension
$XDSDocumentEntryPatientId XDSDocumentEntry.patientId	[1..1]	The format of the patientId value is CX. See also ITI TF-3, 4.2.3.2.16	No further refinement.
$XDSDocumentEntryClassCode XDSDocumentEntry.classCode	[0..*]	The code specifying the high-level use classification of the document type (e.g., Report, Summary, Images, Treatment Plan, Patient Preferences, Workflow). See also description 1 below and ITI TF-3, 4.2.3.2.3	This value MUST represent the following value from the Swiss Metadata Value-Set “epd_xds_classCode” (2.16.756.5.30.1.127.3.10.1.3): DTC90 (Other Composition)
$XDSDocumentEntryTypeCode XDSDocumentEntry.typeCode	[0..*]	The code specifying the precise type of document from the user perspective. See also description 1 below and ITI TF-3, 4.2.3.2.25	This value MUST represent the following value from the Swiss Metadata Value-Set “epd_xds_typeCode” (2.16.756.5.30.1.127.3.10.1.27): 60049 (Audit Trail)
$XDSDocumentEntryPracticeSettingCode XDSDocumentEntry.practiceSettingCode	[0..*]	The code specifying the clinical specialty where the act that resulted in the document was performed (e.g., Family Practice, Laboratory, Radiology). See also description 1 below and ITI TF-3, 4.2.3.2.17	When specified, this value MUST represent a value from the Swiss Metadata Value-Set “epd_xds_practiceSettingCode” (2.16.756.5.30.1.127.3.10.1.18)
$XDSDocumentEntryCreationTimeFrom Lower value of XDSDocumentEntry.creationTime	[0..1]	creationTime represents the time the author created the document. See also description 6 below and ITI TF-3, 4.2.3.2.6	MUST NOT be specified ([0..0]).
$XDSDocumentEntryCreationTimeTo Upper value of XDSDocumentEntry.creationTime	[0..1]		
$XDSDocumentEntryServiceStartTimeFrom Lower value of	[0..1]	Represents the start time of the service	Used to specify the start time of the desired audit trail message to be returned.

Element Name **Attribute**	**Card.**	**Original descriptions**	**Swiss National Extension**
XDSDocumentEntry.serviceStartTime		being documented took place (clinically significant, but not necessarily when the document was produced or approved). See also ITI TF-3, 4.2.3.2.19	All audit trail messages having the @EventDateTime (AuditMessage/EventIdentification) equals or newer MUST be returned by the Audit Record Repository actor.
$XDSDocumentEntryServiceStartTimeTo Upper value of XDSDocumentEntry.serviceStartTime	[0..1]		MUST NOT be specified ([0..0]).
$XDSDocumentEntryServiceStopTimeFrom Lower value of XDSDocumentEntry.serviceStopTime	[0..1]	Represents the stop time of the service being documented took place (clinically significant, but not necessarily when the document was produced or approved). See also ITI TF-3, 4.2.3.2.20	MUST NOT be specified ([0..0]).
$XDSDocumentEntryServiceStopTimeTo Upper value of XDSDocumentEntry.serviceStopTime	[0..1]		Used to specify the stop time of the desired audit trail message to be returned. All audit trail messages having the @EventDateTime (AuditMessage/EventIdentification) equals or older MUST be returned by the Audit Record Repository actor.

Element Name Attribute	Card.	Original descriptions	Swiss National Extension
$XDSDocumentEntryHealthcareFacilityTypeCode XDSDocumentEntry.healthcareFacilityTypeCode	[0..*]	This code represents the type of organizational setting of the clinical encounter during which the documented act occurred. See also description 1 below and ITI TF-3, 4.2.3.2.11	When specified, this value MUST represent a value from the Swiss Metadata Value-Set “epd_xds_healthcareFacility-TypeCode” (2.16.756.5.30.1.127.3.10.1.11)
$XDSDocumentEntryEventCodeList XDSDocumentEntry.eventCodeList	[0..*]	This list of codes represents the main clinical acts, such as a colonoscopy or an appendectomy being documented. See also description 1, 3 below and ITI TF-3, 4.2.3.2.8	No further refinement.
$XDSDocumentEntryConfidentialityCode XDSDocumentEntry.confidentialityCode	[0..*]	The code specifying the security and privacy tags of the document. See also description 1 below and ITI TF-3, 4.2.3.2.5	This value MUST represent the following value from the Swiss Metadata Value-Set “epd_xds_confidentialityCode” (2.16.756.5.30.1.127.3.10.1.5): 30005 (very restricted)
$XDSDocumentEntryAuthorPerson XDSDocumentEntry.author	[0..*]	Represents the humans and/or machines that authored the document. See also description 4 below and ITI TF-3, 4.2.3.2.1	No further refinement.
$XDSDocumentEntryFormatCode XDSDocumentEntry.formatCode	[0..*]	The code specifying the detailed technical format of the document. See also description 1 below and ITI TF-3, 4.2.3.2.9	This value MUST represent the following value from the Swiss Metadata Value-Set “epd_xds_formatCode” (2.16.756.5.30.1.127.3.10.1.9): urn:che:epd:EPD_Basic_Document <*TODO OID to be registered for the content profile. As soon as it is registered change the format code to urn:che:epd:urn:che:epd:2.16.756.5.30…*>
$XDSDocumentEntryStatus XDSDocumentEntry.status	[1..*]	Represents the status of the DocumentEntry. A DocumentEntry shall have one of two availability statuses: Approved: The document is available for patient care. Deprecated: The document is obsolete. See also ITI TF-3, 4.2.3.2.2	While audit trail entries may not be deprecated, the following value MUST be used: urn:oasis:names:tc:ebxml-regrep:StatusType:Approved
$XDSDocumentEntryType XDSDocumentEntry.objectType	[0..*]	The objectType attribute reflects the type of DocumentEntry As described in Section 4.1.1, there are two	While queries to audit trails are On-Demand documents, the following value MUST be used: urn:uuid:34268e47-fdf5-41a6-ba33-82133c465248 (On-Demand)

Element Name Attribute	Card.	Original descriptions	Swiss National Extension
		DocumentEntry types: Stable Document Entry and On-Demand Document Entry. See also description 5 below and ITI TF-3, 4.2.3.2.30	

Descriptions from ITI TF-2a, 3.18.4.1.2.3.7.1:

1. Shall be coded according to specification in Section 3.18.4.1.2.3.4 Coding of Code/Code-Scheme.
2. Supports AND/OR semantics as specified in Section 3.18.4.1.2.3.5.
3. The value for this parameter is a pattern compatible with the SQL keyword LIKE which allows the use of the following wildcard characters: % to match any (or no) characters and _ to match a single character. The match shall be applied to the text contained in the Value elements of the authorPerson Slot on the author Classification (value strings of the authorPerson sub-attribute)
4. See Section 3.18.4.1.2.3.6.2
5. CreationTimeFrom and CreationTimeTo are ignored when evaluating an On-Demand Document Entry's selection for inclusion in the query response.

1.4.3.1.2 Response

ATNA Audit Record Repository actors within the Swiss EPD circle of trust MUST…

1. create a virtual document UUID and return it as one single document entry in the result (On-Demand Document) and
2. cache all audit messages matched by the filter parameters in order to provide them by the retrieve Document Set transaction using the corresponding document UUID in the ATNA Audit Trail Document Format. Caching is REQUIRED for 8 hours. Later accesses to the corresponding document UUID MUST fail.

1.4.3.2 Retrieve Document Set [ITI-43]

ATNA Audit Record Repository actors within the Swiss EPD circle of trust MUST return the audit messages matched by the filter parameters in the query of the corresponding document UUID. The contents of the document returned MUST exactly conform to the state at the point of time of the stored query FindDocuments execution.

1.4.3.3 Record Audit Event [ITI-20]

The ATNA Audit Message Format described in chapter 1.4.4.1 starting on page 13 MUST be used for all events for patients having an EPD.

1.4.4 Content profiles

1.4.4.1 ATNA Audit Message Format

IHE ITI TF-2a references to several Audit Message Formats (see ITI TF-2a, 3.20.7) and prefers use of the DICOM schema for audit records generated by all IHE actors (see ITI TF-2a, 3.20.7.1). ATNA Secure Application actors within the Swiss EPD circle of trust MUST record an audit message for each transaction concerning a patient having an EPD using the mentioned DICOM schema.
The schema can be found in the DICOM Standard, Part 15 Annex A.5 (available from: http://dicom.nema.org/medical/dicom/current/output/chtml/part15/sect_A.5.html).
Detailed contents to be provided by all ATNA Secure Application actors within the Swiss EPD circle of

trust are described in the following chapter.

1.4.4.1.1 Detailed AuditMessage definitions

The detailed specifications for IHE actor audit message requirements specified within the IHE integration profiles MUST be used with the following specification.

Table 2: Detailed AuditMessage definitions

Element Name	Card.	Original descriptions	Swiss National Extension
AuditMessage [1..1] (root element)			
AuditMessage/EventIdentification [1..1] (type: EventIdentificationContents)			
@EventActionCode (type: xs:token)	[0..1]	Indicator for type of action performed during the event that generated the audit. C= Create R= Read U= Update D= Delete E= Execute	No further refinement.
@EventDateTime (type: xs:dateTime)	[1..1]	Universal coordinated time (UTC), i.e., a date/time specification that is unambiguous as to local time zones The time at which the audited event occurred. See Section A.5.2.5	Date and time format following ISO 8601 MUST be used. Indication of the time zone in Switzerland during the daylight-savings time (summer): UTC +2 hours and during normal time (winter): UTC +1 hour. Sample daylight-savings time: 2016-08-10T20:29:10+02:00 Sample normal time: 2016-02-10T20:29:10+01:00

Element Name	Card.	Original descriptions	Swiss National Extension
@EventOutcomeIndicator (type: xs:token)	[1..1]	Indicates whether the event succeeded or failed. When a particular event has some aspects that succeeded and some that failed, then one message shall be generated for successful actions and one message for the failed actions (i.e., not a single message with mixed results). 0= Nominal Success (use if status otherwise unknown or ambiguous) 4=Minor failure (per reporting application definition) 8=Serious failure (per reporting application definition) 12=Major failure (reporting application now unavailable)	No further refinement.
EventID (type: CodedValueType)	[1..1]	Identifier for a specific audited event … The identifier for the family of event. E.g., "User Authentication"; Extended by DICOM using DCID (400)	No further refinement.
EventTypeCode (type: CodedValueType)	[0..*]	Identifier for the category of event. The specific type(s) within the family applicable to the event, e.g., "User Login". Note: DICOM/IHE defines and uses this differently than RFC-3881. Extended by DICOM using DCID (401).	No further refinement.
EventOutcomeDescription	[0..1]	N/A	No further refinement.
AuditMessage/ActiveParticipant [1..1] (type: ActiveParticipantContents)			
@UserID (type: text)	[1..1]	Unique identifier for the user actively participating in the event. If the participant is a person, then the User ID shall be the identifier used for that person on this particular system, in the form of loginName@domain-name. If the participant is an identifiable process, the UserID selected shall be one of the identifiers used in the internal system logs. See also A.5.2.1	No further refinement.
@AlternativeUserID (type: text)	[0..1]	Alternative unique identifier for the user. If the participant is a person, then Alternative User ID shall be the identifier used for that person within an enterprise for authentication purposes, for example, a Kerberos	No further refinement.

Element Name	Card.	Original descriptions	Swiss National Extension
		Username (user@realm). If the participant is a DICOM application, then Alternative User ID shall be one or more of the AE Titles that participated in the event. See also A.5.2.2	
@UserName (type: text)	[0..1]	A human readable identification of the participant. If the participant is a person, the person's name shall be used. If the participant is a process, then the process name shall be used. See also A.5.2.3	If the participant is a person, the person's name MUST be specified as follows: [<title>]<family name> <given name>
@UserIsRequestor (type: xs:Boolean)	[1..1]	Indicator that the user is or is not the requestor, or initiator, for the event being audited. Used to identify which of the participants initiated the transaction being audited. If the audit source cannot determine which of the participants is the requestor, then the field shall be present with the value FALSE in all participants. The system shall not identify multiple participants as UserIsRequestor. If there are several known requestors, the reporting system shall pick only one as UserIsRequestor.	No further refinement.
@NetworkAccessPointID (type: xs:token)	[0..1]	An identifier for the network access point of the user device This could be a device id, IP address, or some other identifier associated with a device. See also A.5.2.4	No further refinement.
@NetworkAccessPointTypeCode	[0..1]	An identifier for the type of network access point. 1= Machine Name, including DNS name 2= IP Address 3= Telephone Number 4= Email address 5= URI (user directory, HTTP-PUT, ftp, etc.) See also A.5.2.4	No further refinement.
RoleIDCode (type: CodedValueType)	[0..*]	Specification of the role(s) the user plays when performing the event, as assigned in role-based access control security Extended by DICOM using DCID (402) Usage of this field is refined in the individual message descriptions below. Other additional roles may also	When describing a human user's participation in an event, this value MUST represent a value from the Swiss Metadata Value-Set "epd_xds_authorRole" (2.16.756.5.30.1.127.3.10.1.1.3)

Element Name	Card.	Original descriptions	Swiss National Extension
		be present, since this is a multi-valued field. ITI TF-2a, 3.20.7.7: RoleIDCode is a CodedValueType. When describing a human user's participation in an event, this value should represent the access control roles/permissions that authorized the event/trans. Use of standards based roles/permissions is preferable to site or application specific. As RFC3881 indicates Many security systems are unable to produce this data, hence it is optional. For example: at a site "St Fraser" they have defined a functional role code "NURSEA" for attending nurse. This can be represented as EV("NURSEA", "St Fraser", "Attending Nurse") Candidate standards based structural/functional role codes can be found at ISO, HL7, ASTM, and various other sources.	
MediaIdentifier/MediaType (type: CodedValueType)	[0..1]	When importing or exporting data, e.g., by means of media, the UserID field is used both to identify people and to identify the media itself. See also A.5.2.1	When importing or exporting data, this value MUST represent either a unique media identifier or at least a unique media type (e.g., DVD, paper, film). Currently there is no Swiss Metadata Value-Set available for media types, but as soon as there is one, it MUST be used when describing media types.
AuditMessage/AuditSourceIdentification [1..1] (type: AuditSourceIdentificationContents)			
@code (type: xs:token)	[1..1]	1= End-user display device, diagnostic device 2= Data acquisition device or instrument 3= Web Server process or thread 4= Application Server process or thread 5= Database Server process or thread 6= Security server, e.g., a domain controller 7= ISO level 1-3 network component 8= ISO level 4-6 operating software 9= other Other values are allowed if a codeSystemName is present.	No further refinement.
other-csd-attributes	N/A	See descriptions for attribute group other-csd-attributes.	
@AuditEnterpriseSiteID	[0..1]	Logical source location within the healthcare enterprise network, e.g., a hospital or other provider location within a multi-entity provider group. Serves to further qualify the Audit Source ID, since Audit Source ID is not required to be globally unique.	[1..1] The GLN of the audit source MUST be specified. Audit sources may apply for a GLN. When presenting to the user, the GLN details MUST be provided[4].

[4] There exists a Webservice at the Refdata foundation which might be used: http://refdatabase.refdata.ch/Service/Partner.asmx?WSDL (see also http://www.refdata.ch/content/page_1.aspx?Nid=60&Aid=636&ID=296)

Element Name	Card.	Original descriptions	Swiss National Extension
@AuditSourceID (type: xs:token)	[1..1]	Identifier of the source. The identification of the system that detected the auditable event and created this audit message. Although often the audit source is one of the participants, it could also be an external system that is monitoring the activities of the participants (e.g., an add-on audit-generating device).	A meaningful description of the audit source, comprehensible for the patient / citizen must be specified.
AuditSourceTypeCode (type: xs:token)	[0..*]	Code specifying the type of source Used as defined in RFC 3881: 1= End-user display device, diagnostic display 2= Data acquisition device or instrument 3= Web server process 4= Application server process 5= Database server process 6= Security server, e.g., a domain controller 7= ISO level 1-3 network component 8= ISO level 4-6 operating software 9= External source, other or unknown type E.g., an acquisition device might use "2" (data acquisition device), a PACS/RIS system might use "4 "(application server process).	No further refinement.
AuditMessage/ParticipantObjectIdentification [0..*] (type: ParticipantObjectIdentificationContents)			
@ParticipantObjectID (type: xs:token)	[1..1]	Describes the identifier that is contained in Participant Object ID. Values may be drawn from those listed in RFC 3881 and DCID (404), as specified in the individual message descriptions.	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.
@ParticipantObjectTypeCode (type: xs:token)	[0..1]	1= Person 2= System object 3= Organization 4= Other	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.

Element Name	Card.	Original descriptions	Swiss National Extension
@ParticipantObjectTypeCodeRole (type: xs:token)	[0..1]	1= Patient 2= Location 3= Report 4= Resource 5= Master File 6= User 7= List 8= Doctor 9= Subscriber 10= guarantor 11= Security User Entity 12= Security User Group 13= Security Resource 14= Security Granulatiry Definition 15= Provider 16= Report Destination 17= Report Library 18= Schedule 19= Customer 20= Job 21= Job Stream 22= Table 23= Routing Criteria 24= Query	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.
@ParticipantObjectDataLifeCycle (type: xs:token)	[0..1]	1= Origination, Creation 2= Import/ Copy 3= Amendment 4= Verification 5= Translation 6= Access/Use 7= De-identification 8= Aggregation, summarization, derivation 9= Report 10= Export 11= Disclosure 12= Receipt of Disclosure 13= Archiving 14= Logical deletion 15= Permanent erasure, physical destruction	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.

Element Name	Card.	Original descriptions	Swiss National Extension
@ParticipantObjectSensitivity (type: xs:token)	[0..1]	Denotes policy-defined sensitivity for the Participant Object ID such as VIP, HIV status, mental health status, or similar topics. Used as defined in RFC 3881.	The current confidentiality code of the object MUST be specified when the object is a document in the EPD. This value MUST represent a value from the Swiss Metadata Value-Set “epd_xds_confidentialityCode” (2.16.756.5.30.1.127.3.10.1.5) in the HL7 CNE datatype format. The following sequences are required: CNE.1: Code national CNE.2: Text in ge, fr or it CNE.7: Publication date of the value-set in the format YYYYMMDD CNE.14: OID of the value-set Sample: 30003^medical data^^^^^ 20150702^^^^^^^ 2.16.756.5.30.1.127.3.10.1.5
ParticipantObjectIDTypeCode (type: CodedValueType)	[1..1]	Describes the identifier that is contained in Participant Object ID. Values may be drawn from those listed in RFC 3881 and DCID (404), as specified in the individual message descriptions.	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.
ParticipantObjectName (type: xs:token) Or ParticipantObjectQuery (type: xs:base64Binary)	[1..1]	An instance-specific descriptor of the Participant Object ID audited, such as a person's name. Or The actual query for a query-type participant object. Usage refined by individual message descriptions	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.

Element Name	Card.	Original descriptions	Swiss National Extension
ParticipantObjectDetail (type: ValuePair)	[0..*]	Implementation-defined data about specific details of the object accessed or used. Used as defined in RFC 3881. Note 1: The value field is xs:base64Binary encoded, making this attribute suitable for conveying binary data. Note 2: optional details, these can be extensive and large.	No further refinement. To be used as specified in the IHE actor audit message requirements specified within the IHE integration profiles.
ParticipantObjectDescription (type: xs:token)	[0..*]	Optional descriptive text	No further refinement. When used, it MUST be specified in the preferred language by the patient / citizen (see also chapter 1.4.2.1 on page 8).
DICOMObjectDescriptionContents	[0..1]	These are extensions made by DICOM to RFC-3881 schema for use describing DICOM objects. See descriptions for group DICOMObjectDescriptionContents.	
CodedValueType			
@csd-code (type: xs:token)	[1..1]	N/A	The code MUST be unique within the OID specified with @codeSystemName.
other-csd-attributes	N/A	See descriptions for attribute group other-csd-attributes	
other-csd-attributes			
@codeSystemName (type: xs:token)	[1..1]	codeSystemName is either an OID or String. OID pattern="[0-2]((\.0)|(\.[1-9][0-9]*))*"	An OID MUST be used.
@displayName (type: xs:token)	[0..1]	N/A	The name of the code system specified by the OID must be specified in the patient's preferred language. It MUST be a valuable translation of the original OID description in the ISO/IEC 9834-1 registration authority.
@originalText (type: xs:token)	[0..1]	Note: this also corresponds to DICOM "Code Meaning"	The name of the element must be specified in the patient's preferred language. It MUST be a valuable translation of the element's original text.
DICOMObjectDescriptionContents			
MPPS	[0..*]	DICOM extension. An MPPS Instance UID(s) associated with this participant object.	No further refinement.
Accession	[0..*]	DICOM extension. An Accession Number(s) associated with this participant object.	No further refinement.
SOPClass	[1..1]	DICOM extension. The UIDs of SOP classes referred to in this participant object. Required if ParticipantObjectIDTypeCode is (110180, DCM, "Study Instance UID")	No further refinement.

Element Name	Card.	Original descriptions	Swiss National Extension
		and any of the optional fields (AccessionNumber, ContainsMPPS, NumberOfInstances, ContainsSOPInstances,Encrypted, Anonymized) are present in this Participant Object. May be present if ParticipantObjectIDTypeCode is (110180, DCM, "Study Instance UID") even though none of the optional fields are present.	
ParticipantObjectContainsStudy	[0..1]	DICOM extension. A Study Instance UID, which may be used when the ParticipantObjectIDTypeCode is not (110180, DCM, "Study Instance UID").	No further refinement.
Encrypted	[0..1]	DICOM extension. A single value of True or False indicating whether or not the data was encrypted. Note: If there was a mix of encrypted and non-encrypted data, then create two event reports.	No further refinement.

Element Name	Card.	Original descriptions	Swiss National Extension
Anonymized	[0..1]	DICOM extension. A single value of True or False indicating whether or not all patient identifying information was removed from the data.	No further refinement.

See also Appendix A – AuditMessage schema starting on page 45.

1.4.4.2 ATNA Audit Trail Document Format

Following the Swiss regulations, any patient has the right to access the audit trail of his own EPD. While the audit trails are stored in multiple Audit Record Repositories in multiple communities, the purpose of the ATNA Audit Trail Document Format is to combine all Audit Trail entries of all Documents returned by Registry Stored Queries [ITI-18] that used the parameters described in chapter “1.4.3.1.1 Parameters for stored query FindDocuments” on page 10 into one single document. Detailed contents to be provided by all ATNA Audit Record Repository actors within the Swiss EPD circle of trust are described in the following chapter.

1.4.4.2.1 Detailed AuditTrail definitions

Table 3: Detailed AuditTrail definitions

Element Name	Card.	Description
AuditTrail [1..1] (root element)		
AuditMessage	[1..*]	An AuditTrail consist of one to many AuditMessage elements. See chapter “1.4.4.1.1 Detailed AuditMessage definitions” starting on page 14.

See also Appendix B – AuditTrail schema on page 52.

1.4.5 Translations

This chapter specifies the translations in German, French and Italien. These translations MUST be while presenting the audit trail to the user. Other translations are optional (see also chapter 1.4.2.1 on page 8).

1.4.5.1 EventActionCode

Table 4: Translations for EventActionCode

Code	English	German	French	Italian
C	Create	Erstellen	<*TODO*>	<*TODO*>
R	Read	Lesen	<*TODO*>	<*TODO*>
U	Update	Aktualisieren	<*TODO*>	<*TODO*>
D	Delete	Löschen	<*TODO*>	<*TODO*>
E	Execute	Ausführen	<*TODO*>	<*TODO*>

1.4.5.2 EventOutcomeIndicator

Table 5: Translations for EventOutcomeIndicator

Code	English	German	French	Italian
0	Nominal Success	Erfolgreich	<*TODO*>	<*TODO*>
4	Minor failure	Fehlgeschlagen	<*TODO*>	<*TODO*>
8	Serious failure	Schwerwiegender Fehler	<*TODO*>	<*TODO*>
12	Major failure	Fataler Fehler	<*TODO*>	<*TODO*>

1.4.5.3 NetworkAccessPointTypeCode

Table 6: Translations for NetworkAccessPointTypeCode

Code	English	German	French	Italian
1	Machine Name	Gerätename	*<TODO>*	*<TODO>*
2	IP Address	IP-Adresse	*<TODO>*	*<TODO>*
3	Telephone Number	Telefonnummer	*<TODO>*	*<TODO>*
4	Email address	e-Mail Adresse	*<TODO>*	*<TODO>*
5	URI	URI	URI	URI

1.4.5.4 AuditSourceIdentification code

Table 7: Translations for AuditSourceIdentification code

Code	English	German	French	Italian
1	End-user display device, diagnostic device	*<TODO>*	*<TODO>*	*<TODO>*
2	Data acquisition device or instrument	*<TODO>*	*<TODO>*	*<TODO>*
3	Web Server process or thread	*<TODO>*	*<TODO>*	*<TODO>*
4	Application Server process or thread	*<TODO>*	*<TODO>*	*<TODO>*
5	Database Server process or thread	*<TODO>*	*<TODO>*	*<TODO>*
6	Security server, e.g., a domain controller	*<TODO>*	*<TODO>*	*<TODO>*
7	ISO level 1-3 network component	*<TODO>*	*<TODO>*	*<TODO>*
8	ISO level 4-6 operating software	*<TODO>*	*<TODO>*	*<TODO>*
9	Other	*<TODO>*	*<TODO>*	*<TODO>*

1.4.5.5 AuditSourceTypeCode

Table 8: Translations for AuditSourceTypeCode

Code	English	German	French	Italian
1	End-user display device, diagnostic display	*<TODO>*	*<TODO>*	*<TODO>*
2	Data acquisition device or instrument	*<TODO>*	*<TODO>*	*<TODO>*
3	Web server process	*<TODO>*	*<TODO>*	*<TODO>*
4	Application server process	*<TODO>*	*<TODO>*	*<TODO>*
5	Database server process	*<TODO>*	*<TODO>*	*<TODO>*
6	Security server, e.g.,	*<TODO>*	*<TODO>*	*<TODO>*
7	ISO level 1-3 network component	*<TODO>*	*<TODO>*	*<TODO>*
8	ISO level 4-6 operating software	*<TODO>*	*<TODO>*	*<TODO>*
9	External source, other or unknown type	*<TODO>*	*<TODO>*	*<TODO>*

1.4.5.6 ParticipantObjectTypeCode

Table 9: Translations for ParticipantObjectTypeCode

Code	English	German	French	Italian
1	Person	*Person*	*<TODO>*	*<TODO>*
2	System object	Systemobjekt		
3	Organization	Organisation		
4	Other	Andere		

1.4.5.7 ParticipantObjectTypeCodeRole

Table 10: Translations for ParticipantObjectTypeCodeRole

Code	English	German	French	Italian
1	Patient	*<TODO>*	*<TODO>*	*<TODO>*
2	Location	*<TODO>*	*<TODO>*	*<TODO>*
3	Report	*<TODO>*	*<TODO>*	*<TODO>*
4	Resource	*<TODO>*	*<TODO>*	*<TODO>*

5	Master File	<TODO>	<TODO>	<TODO>
6	User	<TODO>	<TODO>	<TODO>
7	List	<TODO>	<TODO>	<TODO>
8	Doctor	<TODO>	<TODO>	<TODO>
9	Subscriber	<TODO>	<TODO>	<TODO>
10	Guarantor	<TODO>	<TODO>	<TODO>
11	Security User Entity	<TODO>	<TODO>	<TODO>
12	Security User Group	<TODO>	<TODO>	<TODO>
13	Security Resource	<TODO>	<TODO>	<TODO>
14	Security Granulatiry Definition	<TODO>	<TODO>	<TODO>
15	Provider	<TODO>	<TODO>	<TODO>
16	Report Destination	<TODO>	<TODO>	<TODO>
17	Report Library	<TODO>	<TODO>	<TODO>
18	Schedule	<TODO>	<TODO>	<TODO>
19	Customer	<TODO>	<TODO>	<TODO>
20	Job	<TODO>	<TODO>	<TODO>
21	Job Stream	<TODO>	<TODO>	<TODO>
22	Table	<TODO>	<TODO>	<TODO>
23	Routing Criteria	<TODO>	<TODO>	<TODO>
24	Query	<TODO>	<TODO>	<TODO>

1.4.5.8 ParticipantObjectDataLifeCycle

Table 11: Translations for ParticipantObjectDataLifeCycle

Code	English	German	French	Italian
1	Origination, Creation	<TODO>	<TODO>	<TODO>
2	Import/ Copy	<TODO>	<TODO>	<TODO>
3	Amendment	<TODO>	<TODO>	<TODO>
4	Verification	<TODO>	<TODO>	<TODO>
5	Translation	<TODO>	<TODO>	<TODO>
6	Access/Use	<TODO>	<TODO>	<TODO>
7	De-identification	<TODO>	<TODO>	<TODO>
8	Aggregation, summarization, derivation	<TODO>	<TODO>	<TODO>
9	Report	<TODO>	<TODO>	<TODO>
10	Export	<TODO>	<TODO>	<TODO>
11	Disclosure	<TODO>	<TODO>	<TODO>
12	Receipt of Disclosure	<TODO>	<TODO>	<TODO>
13	Archiving	<TODO>	<TODO>	<TODO>
14	Logical deletion	<TODO>	<TODO>	<TODO>
15	Permanent erasure, physical destruction	<TODO>	<TODO>	<TODO>

1.5 Requirements on PIXv3 for Patient Identity Feed

This section corresponds to the transaction Patient Identity Feed HL7 V3 [ITI-44] of the IHE IT Infrastructure Technical Framework. This transaction is used by the Patient Identity Source, Patient Identifier Cross-reference Manager and Document Registry Actors. With the PIXv3 Patient Identity Feed a primary system can register a local identifier within the MPI.

1.5.1 Message Semantics

1.5.1.1 Major Components of the Patient Registry Record Added/Revised Messages

PersonalRelationship
This is used for sending information pertaining to the mother's maiden name. See also IHE ITI TF-2b, chapter 3.44.4.1.2.1. In Switzerland the fathers and mothers name can be added here to.
Message Information Model
The Message Information Model for both the Patient Activate and Patient Revise messages, as it is described in IHE ITI TF-2b, Table 3.44.4.1.2-1 is further restricted for use in an MPI within the EPD on the following attributes:

Table 12 Patient Active and Revise Model Attributes

PRPA_HD201301IHE Patient Activate/Revise	**This HMD extract defines the message used to report that a new patient record was added, or a patient record was updated. Derived from Figure 3.44.4.1.2-1 (PRPA_RM201301IHE)**	**Swiss National Extension**
Patient	The primary record for the focal person in a Patient Identity Source.	
classCode [1..1] (M) Patient (CS) {CNE:PAT}	Structural attribute; this is a "patient" role.	No further refinement.
id [1..*] (M) Patient (SET<II>)	Identifiers designated by this patient identity source for the focal person.	No further refinement.
statusCode [1..1] Patient (CS) {CNE:active, fixed value= "active"}	A value specifying the state of this record in a patient registry (based on the RIM role class state-machine). This record is active.	No further refinement.
confidentialityCode [0..*] Patient (SET<CE>) {CWE:Confidentiality}	Value(s) that control the disclosure of information about this living subject as a patient.	No further refinement.
veryImportantPersonCode [0..1] Patient (CE) {CWE:PatientImportance}	A code specifying the patient's special status granted by the scoper organization, often resulting in preferred treatment and special considerations. Examples include board member, diplomat.	No further refinement.

PRPA_HD201301IHE Patient Activate/Revise	**This HMD extract defines the message used to report that a new patient record was added, or a patient record was updated. Derived from Figure 3.44.4.1.2-1 (PRPA_RM201301IHE)**	**Swiss National Extension**
Person	A subtype of LivingSubject representing a human being either Person.name or Patient.id must be non-null.	
classCode [1..1] (M) Person (CS) {CNE:PSN, fixed value= "PSN"}	Structural attribute; this is a "person" entity.	No further refinement.
determinerCode [1..1] (M) Person (CS) {CNE:INSTANCE, fixed value= "INSTANCE"}	Structural attribute; this is a specific person.	No further refinement.
name [1..*] Person (BAG<PN>)	Name(s) for this person.	The birth name is passed with the qualifier BR (HL7V3_Edition2012/infrastructure/ datatypes_r2/datatypes_r2.html#dt-DSET).
telecom [0..*] Person (BAG<TEL>)	Telecommunication address(es) for communicating with this person.	No further refinement.
administrativeGenderCode [0..1] Person (CE) {CWE:AdministrativeGender}	A value representing the gender (sex) of this person. Note: this attribute does not include terms related to clinical gender which is a complex physiological, genetic and sociological concept that requires multiple observations in order to be comprehensively described.	No further refinement.
birthTime [0..1] Person (TS)	The date and time this person was born.	No further refinement.
deceasedInd [0..1] Person (BL)	An indication that this person is dead.	No further refinement.
deceasedTime [0..1] Person (TS)	The date and time this person died.	No further refinement.
multipleBirthInd [0..1] Person (BL)	An indication that this person was part of a multiple birth.	No further refinement.
multipleBirthOrderNumber [0..1] Person (INT)	The order in which this person was born if part of a multiple birth.	No further refinement.
addr [0..*] Person (BAG<AD>)	Address(es) for corresponding with this person.	No further refinement.
maritalStatusCode [0..1] Person (CE) {CWE:MaritalStatus}	A value representing the domestic partnership status of this person.	No further refinement.
religiousAffiliationCode [0..1] Person (CE) {CWE:ReligiousAffiliation}	A value representing the primary religious preference of this person.	MUST NOT be used.
raceCode [0..*] Person (SET<CE>) {CWE:Race}	A set of values representing the races of this person.	MUST NOT be used.
ethnicGroupCode [0..*] Person (SET<CE>) {CWE:Ethnicity}	A set of values representing the ethnic groups of this person.	MUST NOT be used.

PRPA_HD201301IHE Patient Activate/Revise	**This HMD extract defines the message used to report that a new patient record was added, or a patient record was updated. Derived from Figure 3.44.4.1.2-1 (PRPA_RM201301IHE)**	**Swiss National Extension**
OtherIDs	Used to capture additional identifiers for the person such as a Drivers' license or Social Security Number. Please see notes above in the Major Components section on the use of OtherIDs.	If patient is already registered in a community, the MPI-PID MUST be provided here. The EPD-PID MAY be added here.
classCode [1..1] (M) Role (CS) {CNE:ROL}	Structural attribute. This can be any specialization of "role" except for Citizen, or Employee.	No further refinement.
id [1..*] (M) Role (SET<II>)	One or more identifiers issued to the focal person by the associated scopingOrganization (e.g., a Driver's License number issued by a DMV).	No further refinement.
PersonalRelationship	A personal relationship between the focal living subject and another living subject.	
classCode [1..1] (M) Role (CS) {CNE:PRS, fixed value= "PRS"}	Structural attribute; this is a "personal relationship" role.	No further refinement.
id [0..*] Role (SET<II>)	Identifier(s) for this personal relationship.	No further refinement.
code [1..1] (M) Role (CE) {CWE:PersonalRelationshipRoleType}	A required value specifying the type of personal relationship between the relationshipHolder and the scoping living subject drawn from the PersonalRelationshipRoleType domain, for example, spouse, parent, unrelated friend.	No further refinement. Codes: FTH: Father MTH: Mother
statusCode [0..1] Role (CE) {CWE:RoleStatus}	A value specifying the state of this personal relationship (based on the RIM Role class state-machine), for example, following divorce a spouse relationship would be "terminated".	No further refinement.
effectiveTime [0..1] Role (IVL<TS>)	An interval of time specifying the period during which this personal relationship is in effect, if such time is applicable and known.	No further refinement.
Citizen	Used to capture person information relating to citizenship.	
classCode [1..1] (M) Role (CS) {CNE:CIT, fixed value= "CIT"}	Structural attribute; this is a "citizen" role.	No further refinement.
id [0..*] Role (SET<II>)	Identifier(s) for the focal person as a citizen of a nation.	No further refinement.
effectiveTime [0..1] Employee (IVL<TS>)	An interval of time specifying the period during which this employment relationship is in effect, if such time limit is applicable and known.	No further refinement.
Nation	A politically organized body of people bonded by territory and known as a nation.	
classCode [1..1] (M) Organization (CS) {CNE:NAT, fixed value= "NAT"}	Structural attribute; this is a 'nation' type of entity.	No further refinement.
determinerCode [1..1] (M) Organization (CS) {CNE:INSTANCE, fixed value= "INSTANCE"}	Structural attribute; this is a specific entity.	No further refinement.
code [1..1] (M) Organization (CD) {CWE:NationEntityType}	A value that identifies a nation state.	No further refinement.
name [0..1]	A non-unique textual identifier or moniker for this	No further refinement.

PRPA_HD201301IHE Patient Activate/Revise	**This HMD extract defines the message used to report that a new patient record was added, or a patient record was updated. Derived from Figure 3.44.4.1.2-1 (PRPA_RM201301IHE)**	**Swiss National Extension**
Organization (ON)	nation.	
Employee	A relationship of the focal person with an organization to receive wages or salary. The purpose of this class is to identify the type of relationship the employee has to the employer rather than the nature of the work actually performed. For example, it can be used to capture whether the person is a Military Veteran or not.	
classCode [1..1] (M) Employee (CS) {CNE:EMP}	Structural attribute; this is an "employee" role.	No further refinement.
statusCode [0..1] Employee (CS) {CNE:RoleStatus}	A value specifying the state of this employment relationship (based on the RIM Role class state-machine), for example, active, suspended, terminated.	No further refinement.
statusCode [0..1] Employee (CS) {CNE:RoleStatus}	A value specifying the state of this employment relationship (based on the RIM Role class state-machine), for example, active, suspended, terminated.	No further refinement.
effectiveTime [0..1] Employee (IVL<TS>)	An interval of time specifying the period during which this employment relationship is in effect, if such time limit is applicable and known.	No further refinement.
occupationCode [0..1] Employee (CE) {CWE:EmployeeOccupationCode}	A code qualifying the classification of kind-of-work based upon a recognized industry or jurisdictional standard. OccupationCode is used to convey the person's occupation as opposed to jobClassCode (not used in this transaction) which characterizes this particular job. For example, it can be used to capture whether the person is a Military Veteran or not.	No further refinement.
BirthPlace	The birthplace of the focal living subject.	
classCode [1..1] (M) Birthplace (CS) {CNE:BIRTHPL}	Structural attribute; this is a "birthplace" role.	No further refinement.
id [0..*] Birthplace (SET<II>)	A living subject's birth place represented by a unique identifier.	No further refinement.
addr [0..*] Patient (BAG<AD>)	A living subject's birth place represented as an address. Note: Either BirthPlace.addr or an associated Place.name must be valued.	No further refinement.
classCode [1..1] (M) Birthplace (CS) {CNE:BIRTHPL}	Structural attribute; this is a "birthplace" role	No further refinement.
LanguageCommunication	A language communication capability of the focal person	
languageCode [1..1] (M) LanguageCommunication (CE) {CWE:HumanLanguage}	A value representing a language for which the focal person has some level of proficiency for written or spoken communication. Examples: Spanish, Italian, German, English, American Sign.	No further refinement.
preferenceInd [0..1] LanguageCommunication (BL)	An indicator specifying whether or not this language is preferred by the focal person for the associated mode.	No further refinement.

1.6 Requirements on PIXv3 Profile for Patient Identifier Cross-reference Query

This section corresponds to transaction PIXv3 Query [ITI-45] of the IHE IT Infrastructure Technical Framework. This transaction is used by the Patient Identifier Cross-reference Consumer and Patient Identifier Cross-reference Manager Actors. With the PIXv3 Query a primary system can query with the local identifier the MPI and get the corresponding MPI-PID and the EPD-PID.

1.6.1 Message Semantics

1.6.1.1 Major Components of the Patient Registry Query by Identifier

DataSource Parameter
This parameter specifies the assigning authority/authorities of the Patient Identity Domain(s) whose identifiers need to be returned. The DataSource Parameter MUST be specified to the assigning authority/authorities of the MPI-PID in the affinity domain. See also ITI TF-2b, chapter 3.45.4.1.2.1

1.6.2 Return Corresponding Identifiers

1.1.1.1 Major Components of the Get Corresponding Identifiers Query Response

The otherId MUST contain the EPD-PID. See also ITI TF-2b, chapter 3.45.4.2.2.1

1.7 Requirements on PDQv3 Profile for Patient Demographics Query

This section corresponds to Patient Demographics Query HL7 V3 transaction [ITI-47] of the IHE Technical Framework. This transaction is used by the Patient Demographics Consumer and Patient Demographics Supplier Actors.

1.7.1 Message Semantics

1.7.1.1 Major Components of the Patient Registry Query by Demographics

The PatientTelecom Query Parameter MUST NOT be used.

1.7.1.1.1 Additional components for the Swiss National Extension

MothersName Parameter
This optional parameter specifies the name of the mother of the person whose information is being queried. For this parameter item, a single person name (PN) data item shall be specified in the Person.value attribute. Within the PN data type, the given name and family name may be specified. If the sender needs to indicate that the name parts specified are not limited to an exact match, then the use attribute of the value element shall be set to "SRCH".

FathersName Parameter
This optional parameter specifies the name of the father of the person whose information is being queried. For this parameter item, a single person name (PN) data item shall be specified in the Person.value attribute. Within the PN data type, the given name and family name may be specified. If the sender needs to indicate that the name parts specified are not limited to an exact match, then the use attribute of the value element shall be set to "SRCH".

1.7.1.2 Message Information Model

The Message Information Model for both the Patient Activate and Patient Revise messages is described in IHE ITI TF-2b, Table 3.47.4.1.2-1. Within the Swiss national extensions the following sections MAY additionally be included:

Table 13: Patient Demographics Query – Swiss national extension sections

PRPA_HD201306IHE Patient Registry Query by Demographics	**This HMD extract defines the message used to query a patient registry for records matching a set of demographics information.** **Derived from Figure 3.47.4.1.2-1 (PRPA_RM201306IHE)**	**Swiss National Extension**
MothersName	N/A	Design Comments: This query parameter is the name of a focal person's mother. It is included as a parameter because it is a common attribute for confirming the identity of persons in some registries. This parameter does not map to a single RIM attribute, instead, in RIM terms Mother's name is the person name part of "family“ for the person who is the player in a PersonalRelationship of type of "mother" to the focal person.
value [1..1] ParameterItem (PN)	N/A	Design Comments: A person name. In this case it may consist of only the given name part, the family name part, or both.
semanticsText [1..1] ParameterItem (ST) {default= "Person.MotherName"}	N/A	These static values MUST be used.
FathersName	N/A	Design Comments: This query parameter is the name of a focal person's father. It is included as a parameter because it is a common attribute for confirming the identity of persons in some registries. This parameter does not map to a single RIM attribute, instead, in RIM terms Father’s name is the person name part of "family" for the person who is the player in a PersonalRelationship of type of "father" to the focal person.
value [1..1] ParameterItem (PN)	N/A	Design Comments: A person name. In this case it may consist of only the given name part, the family name part, or both.
semanticsText [1..1] ParameterItem (ST){default= "Person.Father.Name"}	N/A	These static values MUST be used.

1.7.2 Patient Demographics Query Response

1.7.2.1 Expected Actions

The Patient Demographics Supplier shall perform the matching of patient data based on the query parameter values it receives. The information provided by the Patient Demographics Supplier to Patient Demographics Consumers is a list of possible matching patients from the patient information source associated with the value that the Consumer sent in the Device class of the transmission wrapper of the query message. See also IHE ITI TF-2b, chapter 3.47.4.2.3.
The Message Information Model for both the Patient Registry Find Candidates Response messages, as it is described in IHE ITI TF-2b, Table 3.47.4.2.2-8: is further restricted for use in an MPI within the EPD on the following attributes:

Table 14: Message Information Model for Patient Registry Find Candidates

PRPA_HD201310IHE Patient Registry Find Candidates Response	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query. Derived from Figure 3.47.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
Patient	The primary record for the focal person in a Patient Demographics Supplier.	
classCode [1..1] (M) Patient (CS) {CNE:PAT}	Structural attribute; this is a "patient" role.	No further refinement.
id [1..*] (M) Patient (SET<II>)	Patient identifiers. Patient Identifiers from different Identity Domains may be contained either here, or in the OtherIDs.id attributes, but not in both places. At least one Patient Identifier shall be present in this attribute.	No further refinement. Note: The EPD-PID should be added in OtherIDs.id.
statusCode [1..1] Patient (CS) {CNE:active, fixed value= "active"}	A value specifying the state of this record in a patient registry (based on the RIM role class state-machine). This record is active.	No further refinement.
confidentialityCode [0..*] Patient (SET<CE>) {CWE:Confidentiality}	Value(s) that control the disclosure of information about this living subject as a patient.	No further refinement.
veryImportantPersonCode [0..1] Patient (CE) {CWE:PatientImportance}	A code specifying the patient's special status granted by the scoper organization, often resulting in preferred treatment and special considerations. Examples include board member, diplomat.	No further refinement.
Person	A subtype of LivingSubject representing a human being either Person.name or Patient.id must be non-null.	
classCode [1..1] (M) Person (CS) {CNE:PSN, fixed value= "PSN"}	Structural attribute; this is a "person" entity.	No further refinement.
determinerCode [1..1] (M) Person (CS) {CNE:INSTANCE, fixed value= "INSTANCE"}	Structural attribute; this is a specific person.	No further refinement.
name [1..*] Person (BAG<PN>)	Name(s) for this person.	The birth name is passed with the qualifier BR (HL7V3_Edition2012/ infrastructure/datatypes_r2/ datatypes_r2.html#dt-DSET).
telecom [0..*] Person (BAG<TEL>)	Telecommunication address(es) for communicating with this person.	No further refinement.
administrativeGenderCode [0..1] Person (CE) {CWE:AdministrativeGender}	A value representing the gender (sex) of this person. Note: this attribute does not include terms related to clinical gender which is a complex physiological, genetic and sociological concept that requires multiple observations in order to be comprehensively described.	No further refinement.
birthTime [0..1] Person (TS)	The date and time this person was born.	No further refinement.
deceasedInd [0..1] Person (BL)	An indication that this person is dead.	No further refinement.
deceasedTime [0..1] Person (TS)	The date and time this person died.	No further refinement.
multipleBirthInd [0..1] Person (BL)	An indication that this person was part of a multiple birth.	No further refinement.
multipleBirthOrderNumber [0..1] Person (INT)	The order in which this person was born if part of a multiple birth.	No further refinement.
addr [0..*] Person (BAG<AD>)	Address(es) for corresponding with this person.	No further refinement.
maritalStatusCode [0..1] Person (CE) {CWE:MaritalStatus}	A value representing the domestic partnership status of this person.	No further refinement.
religiousAffiliationCode [0..1] Person (CE) {CWE:ReligiousAffiliation}	A value representing the primary religious preference of this person.	MUST NOT be used.

PRPA_HD201310IHE **Patient Registry Find Candidates Response**	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query.** **Derived from Figure 3.47.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
raceCode [0..*] Person (SET<CE>) {CWE:Race}	A set of values representing the races of this person.	MUST NOT be used.
ethnicGroupCode [0..*] Person (SET<CE>) {CWE:Ethnicity}	A set of values representing the ethnic groups of this person.	MUST NOT be used.
OtherIDs	Used to capture additional identifiers for the person such as a Drivers' license or Social Security Number.	The EPD-PID MAY be added here.
classCode [1..1] (M) Role (CS) {CNE:ROL}	Structural attribute. This can be any specialization of "role" except for Citizen, or Employee.	No further refinement.
id [1..*] (M) Role (SET<II>)	One or more identifiers issued to the focal person by the associated scopingOrganization (e.g., identifiers from a different Patient Identity Domain).	No further refinement.
PersonalRelationship	A personal relationship between the focal living subject and another living subject.	
classCode [1..1] (M) Role (CS) {CNE:PRS, fixed value= "PRS"}	Structural attribute; this is a "personal relationship" role.	No further refinement.
id [0..*] Role (SET<II>)	Identifier(s) for this personal relationship.	No further refinement.
code [1..1] (M) Role (CE) {CWE:PersonalRelationshipRoleType}	A required value specifying the type of personal relationship between the relationshipHolder and the scoping living subject drawn from the PersonalRelationshipRoleType domain, for example, spouse, parent, unrelated friend.	No further refinement. Codes: FTH: Father MTH: Mother
Citizen	Used to capture person information relating to citizenship.	
classCode [1..1] (M) Role (CS) {CNE:CIT, fixed value= "CIT"}	Structural attribute; this is a "citizen" role.	No further refinement.
id [0..*] Role (SET<II>)	Identifier(s) for the focal person as a citizen of a nation.	No further refinement.
Nation	A politically organized body of people bonded by territory and known as a nation.	
classCode [1..1] (M) Organization (CS) {CNE:NAT, fixed value= "NAT"}	Structural attribute; this is a 'nation' type of entity.	No further refinement.
determinerCode [1..1] (M) Organization (CS) {CNE:INSTANCE, fixed value= "INSTANCE"}	Structural attribute; this is a specific entity.	No further refinement.
code [1..1] (M) Organization (CD) {CWE:NationEntityType}	A value that identifies a nation state.	No further refinement.
name [0..1] Organization (ON)	A non-unique textual identifier or moniker for this nation.	No further refinement.

PRPA_HD201310IHE Patient Registry Find Candidates Response	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query. Derived from Figure 3.47.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
Employee	A relationship of the focal person with an organization to receive wages or salary. The purpose of this class is to identify the type of relationship the employee has to the employer rather than the nature of the work actually performed. For example, it can be used to capture whether the person is a Military Veteran or not.	
classCode [1..1] (M) Employee (CS) {CNE:EMP}	Structural attribute; this is an "employee" role.	No further refinement.
statusCode [0..1] Employee (CS) {CNE:RoleStatus}	A value specifying the state of this employment relationship (based on the RIM Role class state-machine), for example, active, suspended, terminated.	No further refinement.
occupationCode [0..1] Employee (CE) {CWE:EmployeeOccupationCode}	A code qualifying the classification of kind-of-work based upon a recognized industry or jurisdictional standard. OccupationCode is used to convey the person's occupation as opposed to jobClassCode (not used in this transaction) which characterizes this particular job. For example, it can be used to capture whether the person is a Military Veteran or not.	No further refinement.
LanguageCommunication	A language communication capability of the focal person.	
languageCode [1..1] (M) LanguageCommunication (CE) {CWE:HumanLanguage}	A value representing a language for which the focal person has some level of proficiency for written or spoken communication. Examples: Spanish, Italian, German, English, American Sign.	No further refinement.
preferenceInd [0..1] LanguageCommunication (BL)	An indicator specifying whether or not this language is preferred by the focal person for the associated mode.	No further refinement.
QueryMatchObservation	Used to convey information about the quality of the match for each record.	
classCode [1..1] (M) Observation (CS) {CNE:http://hl7.org/v3ballot2007may/html/infrastructure/vocabulary/ActClass.htm - ActClass, default= "OBS"}	Structural attribute – this is an observation.	No further refinement.
moodCode [1..1] (M) Observation (CS) {CNE:http://hl7.org/v3ballot2007may/html/infrastructure/vocabulary/ActMood.htm - ActMood, default= "EVN"}	Structural attribute – this is an event.	No further refinement.
code [1..1] (M) Observation (CD) {CWE:QueryMatchObservationType}	A code, identifying this observation as a query match observation.	No further refinement.
value [1..1] (M) QueryMatchObservation (INT)	A numeric value indicating the quality of match for this record. It shall correspond to the MinimumDegreeMatch.value attribute of the original query, and it shall have the same meaning (e.g., percentage, indicating confidence in the match).	No further refinement.

1.7.2.1.1 Special handling for more attributes requested

If there are more than 5 matches zero matches a special handling like in the XCPD transaction (see IHE ITI TF-2b, chapter 3.55.4.2.2.6) is necessary.
The Responding Gateway has the option of informing the Initiating Gateway when additional demographic attributes may result in a match. This would most often be used in cases where the security and privacy policies do not allow release of patient data unless and until there is a level of assurance that the same patient is referenced. In this case the Responding Gateway cannot return a matching patient or patients because the level of assurance is not great enough. If the Initiating Gateway was able to specify further demographic attributes the Responding Gateway might have

greater assurance of the match and thus be able to return the match information.
To indicate this situation in its response the Responding Gateway codes a DetectedIssueEvent within the controlActProcess element, where the code in the actOrderRequired element references one of the coded elements described in Table 15 . There may be as many triggerFor elements, each of them containing an ActOrderRequired element, as needed to code the attributes which would increase the assurance of the match. The codeSystem for these code elements is <*TODO oid to be registered*> instead of 1.3.6.1.4.1.19376.1.2.27.1 as described in IHE ITI TF-2b, Table 3.55.4.4.2-4.

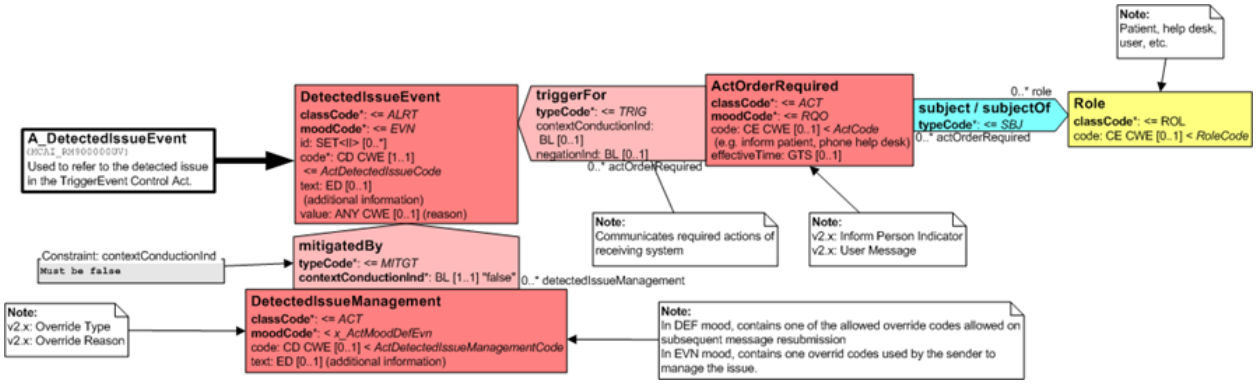

Figure 5: XCPD – RMIM for DetectedIssueEvent

Table 15: Coded Values for actOrderRequired code (codeSystem=<*TODO oid to be registered*>)

Value for code	Meaning of code
LivingSubjectAdministrativeGenderRequested	Requests the LivingSubjectAdministrativeGender attribute be specified
PatientAddressRequested	Requests the PatientAddress attribute be specified
LivingSubjectBirthPlaceNameRequested	Requests the LivingSubjectBirthPlaceName attribute be specified
BirthNameRequested	Requests the Birth Name attribute be specified
MothersNameRequested	Requests the Mothers Name attribute be specified
FahtersNameRequested	Requests the Fathers Name attribute be specified

The following example shows part of a response requesting the PatientAddress and PatientTelecom attributes.

```
<detectedIssueEvent classCode="ALRT" moodCode="EVN">
 <code code="ActAdministrativeDetectedIssueCode"
codeSystem="2.16.840.1.113883.5.4"/>
 <triggerFor typeCode="TRIG">
 <actOrderRequired classCode="ACT" moodCode="RQO">
  <code code="PatientAddressRequested” codeSystem="<TODO>" />
 </actOrderRequired>
 </triggerFor>
 <triggerFor typeCode="TRIG">
 <actOrderRequired classCode="ACT" moodCode="RQO">
  <code code=" LivingSubjectAdministrativeGenderRequested” codeSystem="<TODO>"/>
 </actOrderRequired>
 </triggerFor>
</detectedIssueEvent>
```

The different return cases should be handled equivalent to the XCPD cases in IHE ITI TF-2b, chapter 3.55.4.2.3 Expected Actions.

1.8 Requirements on XCPD Profile for Cross-Community Patient Discovery

XCPD is used in Switzerland for resolving the national patient identifier (EPD-PID) into the community identifiers (MPI-PID) in another affinity domain/community. The Query can either return an exact match or no match.

1.8.1 Modes and Options

The Cross Gateway Patient Discovery transaction [ITI-55] has several modes. For the EPD only the Shared/National Patient Identifier Query mode MUST be used. Other modes as defined in this transaction (see also IHE ITI TF-2b, chapter 3.55.1) MUST NOT be used.
The Health Data Locator and Revoke Option of the Patient Location Query transaction [ITI-56] MUST NOT be used.[5]

1.8.2 Cross Gateway Patient Discovery Request

Caching
The Initiating Gateway may specify a duration value in the SOAP Header element of the request. This value suggests to the Responding Gateway a length of time that the Initiating Gateway recommends caching any correlation resulting from the interaction. This values MUST NOT exceed 3 days. See also IHE ITI TF-2b, chapter 3.55.4.1.

1.8.2.1 Major Components of the Patient Registry Query by Demographics

LivingSubjectId Parameter is the only allowed query Parameter. All other parameter in IHE ITI TF-2b, chapter 3.55.4.1.2.1 MUST NOT be used.
The LivingSubjectId Parameter MUST contain the EPD-PID.
Reverse Cross-Gateway Queries
Reverse Cross-Gateway Queries MUST NOT be used (see IHE ITI TF-2b, chapter 3.55.4.1.2.4).

1.8.3 Cross Gateway Patient Discovery Response

Caching
The Responding Gateway may specify a duration value in the SOAP Header element of the response. This value suggests to the Initiating Gateway a length of time that the Responding Gateway recommends caching any correlation resulting from the interaction. This values MUST NOT exceed 3 days. See also IHE ITI TF-2b, chapter 3.55.4.2.

1.8.3.1 Major Components of the Patient Registry Find Candidates Response Message

The QueryMatchObservation class is used to convey information about the quality of the match for the record returned by the query response. This value MUST state 100 for an exact match.
The Message Information Model for the Patient Registry Find Candidates Response message is further restricted within the EPD:

Table 16: Message Information Model for Patient Registry Find Candidates

[5] http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_XCPD_HDL_Revoke_Option.pdf

PRPA_HD201310IHE **Patient Registry Find Candidates Response**	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query.** **Derived from Figure 3.55.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
Patient	The primary record for the focal person.	
classCode [1..1] (M) Patient (CS) {CNE:PAT}	Structural attribute; this is a "patient" role.	No further refinement.
id [1..1] (M) Patient (SET<II>)	The Patient Identifier to be used in subsequent XCA Cross Gateway Query transactions related to this patient when sent to the Responding Gateway sending the response. All other patient identifiers shall be specified in the OtherIDs.id attribute.	The MPI-PID MUST be returned if there is a match from the EPD-PID.
statusCode [1..1] Patient (CS) {CNE:active, fixed value= "active"}	A value specifying the state of this record in a patient registry (based on the RIM role class state-machine). This record is active.	No further refinement.
confidentialityCode [0] Patient (SET<CE>) {CWE:Confidentiality}	Value(s) that control the disclosure of information about this living subject as a patient.	MUST NOT be used.
veryImportantPersonCode [0] Patient (CE) {CWE:PatientImportance}	A code specifying the patient's special status granted by the scoper organization, often resulting in preferred treatment and special considerations. Examples include board member, diplomat.	MUST NOT be used.
Person	A subtype of LivingSubject representing a human being either Person.name or Patient.id must be non-null.	
classCode [1..1] (M) Person (CS) {CNE:PSN, fixed value= "PSN"}	Structural attribute; this is a "person" entity.	No further refinement.
determinerCode [1..1] (M) Person (CS) {CNE:INSTANCE, fixed value= "INSTANCE"}	Structural attribute; this is a specific person.	No further refinement.
name [1] Person (BAG<PN>) {null, fixed value nullFlavor="NA"}	Name(s) for this person. Fixed to be null, <name nullFlavor="NA"/>, request contains only a patient identifier and no demographic data.	No further refinement.
telecom [0] Person (BAG<TEL>)	Telecommunication address(es) for communicating with this person.	MUST NOT be used.
administrativeGenderCode [0] Person (CE) {CWE:AdministrativeGender}	A value representing the gender (sex) of this person. Note: this attribute does not include terms related to clinical gender which is a complex physiological, genetic and sociological concept that requires multiple observations in order to be comprehensively described.	MUST NOT be used.
birthTime [0] Person (TS)	The date and time this person was born.	MUST NOT be used.
deceasedInd [0] Person (BL)	An indication that this person is dead.	MUST NOT be used.
deceasedTime [0] Person (TS)	The date and time this person died.	MUST NOT be used.

PRPA_HD201310IHE **Patient Registry Find Candidates Response**	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query.** **Derived from Figure 3.55.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
multipleBirthInd [0] Person (BL)	An indication that this person was part of a multiple birth.	MUST NOT be used.
multipleBirthOrderNumber [0] Person (INT)	The order in which this person was born if part of a multiple birth.	MUST NOT be used.
addr [0] Person (BAG<AD>)	Address(es) for corresponding with this person.	MUST NOT be used.
maritalStatusCode [0] Person (CE) {CWE:MaritalStatus}	A value representing the domestic partnership status of this person.	MUST NOT be used.
religiousAffiliationCode [0] Person (CE) {CWE:ReligiousAffiliation}	A value representing the primary religious preference of this person.	MUST NOT be used.
raceCode [0] Person (SET<CE>) {CWE:Race}	A set of values representing the races of this person.	MUST NOT be used.
ethnicGroupCode [0] Person (SET<CE>) {CWE:Ethnicity}	A set of values representing the ethnic groups of this person.	MUST NOT be used.
OtherIDs	Used to capture additional identifiers for the person such as a Drivers' license or Social Security Number.	
classCode [1..1] (M) Role (CS) {CNE:ROL}	Structural attribute. This can be any specialization of "role" except for Citizen, or Employee.	MUST NOT be used
id [1] (M) Role (SET<II>)	One or more identifiers issued to the focal person by the associated scopingOrganization (e.g., identifiers from a different Patient Identity Domain).	MUST NOT be used.
PersonalRelationship	A personal relationship between the focal living subject and another living subject.	
classCode [1..1] (M) Role (CS) {CNE:PRS, fixed value= "PRS"}	Structural attribute; this is a "personal relationship" role.	MUST NOT be used.
id [0..*] Role (SET<II>)	Identifier(s) for this personal relationship.	MUST NOT be used.
code [1..1] (M) Role (CE) {CWE:PersonalRelationshipRoleType}	A required value specifying the type of personal relationship between the relationshipHolder and the scoping living subject drawn from the PersonalRelationshipRoleType domain, for example, spouse, parent, unrelated friend.	MUST NOT be used.
Citizen	Used to capture person information relating to citizenship.	
classCode [1..1] (M) Role (CS) {CNE:CIT, fixed value= "CIT"}	Structural attribute; this is a "citizen" role.	MUST NOT be used.
id [0..*] Role (SET<II>)	Identifier(s) for the focal person as a citizen of a nation.	MUST NOT be used.
Nation	A politically organized body of people bonded by territory and known as a nation.	
classCode [1..1] (M) Organization (CS) {CNE:NAT, fixed value= "NAT"}	Structural attribute; this is a 'nation' type of entity.	MUST NOT be used.
determinerCode [1..1] (M) Organization (CS) {CNE:INSTANCE, fixed value= "INSTANCE"}	Structural attribute; this is a specific entity.	MUST NOT be used.

PRPA_HD201310IHE **Patient Registry Find Candidates Response**	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query.** **Derived from Figure 3.55.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
code [1..1] (M) Organization (CD) {CWE:NationEntityType}	A value that identifies a nation state.	MUST NOT be used.
name [0..1] Organization (ON)	A non-unique textual identifier or moniker for this nation.	MUST NOT be used.
Employee	A relationship of the focal person with an organization to receive wages or salary. The purpose of this class is to identify the type of relationship the employee has to the employer rather than the nature of the work actually performed. For example, it can be used to capture whether the person is a Military Veteran or not.	
classCode [1..1] (M) Employee (CS) {CNE:EMP}	Structural attribute; this is an "employee" role.	MUST NOT be used.
statusCode [0..1] Employee (CS) {CNE:RoleStatus}	A value specifying the state of this employment relationship (based on the RIM Role class state-machine), for example, active, suspended, terminated.	MUST NOT be used.
occupationCode [0..1] Employee (CE) {CWE:EmployeeOccupationCode}	A code qualifying the classification of kind-of-work based upon a recognized industry or jurisdictional standard. OccupationCode is used to convey the person's occupation as opposed to jobClassCode (not used in this transaction) which characterizes this particular job. For example, it can be used to capture whether the person is a Military Veteran or not.	MUST NOT be used.
LanguageCommunication	A language communication capability of the focal person.	
languageCode [1..1] (M) LanguageCommunication (CE) {CWE:HumanLanguage}	A value representing a language for which the focal person has some level of proficiency for written or spoken communication. Examples: Spanish, Italian, German, English, American Sign.	MUST NOT be used.
preferenceInd [0..1] LanguageCommunication (BL)	An indicator specifying whether or not this language is preferred by the local person for the associated mode.	MUST NOT be used.
QueryMatchObservation	Used to convey information about the quality of the match for each record.	
classCode [1..1] (M) Observation (CS) {CNE:http://hl7.org/v3ballot2007may/html/infrastructure/vocabulary/ActClass.htm - ActClass, default= "OBS"}	Structural attribute – this is an observation.	No further refinement.

PRPA_HD201310IHE **Patient Registry Find Candidates Response**	**This HMD extract defines the message used to return records from a patient registry in response to a Find Candidates Query.** **Derived from Figure 3.55.4.2.2-1 (PRPA_RM201310IHE)**	**Swiss National Extension**
moodCode [1..1] (M) Observation (CS) {CNE:http://hl7.org/v3ballot2007may/html/infrastructure/vocabulary/ActMood.htm - ActMood, default= "EVN"}	Structural attribute – this is an event.	No further refinement.
code [1..1] (M) Observation (CD) {CWE:QueryMatchObservationType}	A code, identifying this observation as a query match observation.	No further refinement.
value [1..1] (M) QueryMatchObservation (INT)	A numeric value indicating the quality of match for this record. It shall correspond to the MinimumDegreeMatch.value attribute of the original query, and it shall have the same meaning (e.g., percentage, indicating confidence in the match).	This value MUST state 100 for a match, 0 otherwise.

1.9 Requirements on HPD Profile for Replication

1.9.1 Introduction

The Healthcare Provider Directory (HPD) profile is extended to support the incremental replication of the entire directory or part of it to a second directory (across organizational boundaries). This extension will support the integration of multiple Swiss organizations with a single national HPD service, providing them with the support for the asynchronous synchronization of the directory content, without scarifying their operational independence.
This extension also defines some content profiles to ease the integration between communities, by limiting the value-set of several attributes, e.g. identifiers, organization types, provider types, etc.

1.9.2 Use-case: Provider information replication

Table 17: Use-case: Provider information replication

Scenario	A *Provider Information Consumer* is used to feed a second directory based on changes applied to *Provider Information Directory*.
Triggering event	A new provider is published to the *Provider Information Directory*.
Involved actors	*Provider Information Directory, Provider Information Consumer.*
Short description	The *Provider Information Consumer* issues a *Provider Information Delta Download* transaction to retrieve valid mutations from the *Provider Information Directory*.
Pre-conditions	The actor is authenticated and authorized to communicate with the *Provider Information Directory*.
Post-conditions	The content of the *Provider Information Directory* is unchanged and the replication at the *Provider Information Consumer* is updated.
Activities flow	1. Based on a timer (or on a notification), the *Provider Information Consumer* issues a *Provider Information Delta Download* transaction to download all delta changes since the last successful transaction; 2. Optionally, some filtering criteria are processed.

1.9.3 Actors / Transactions

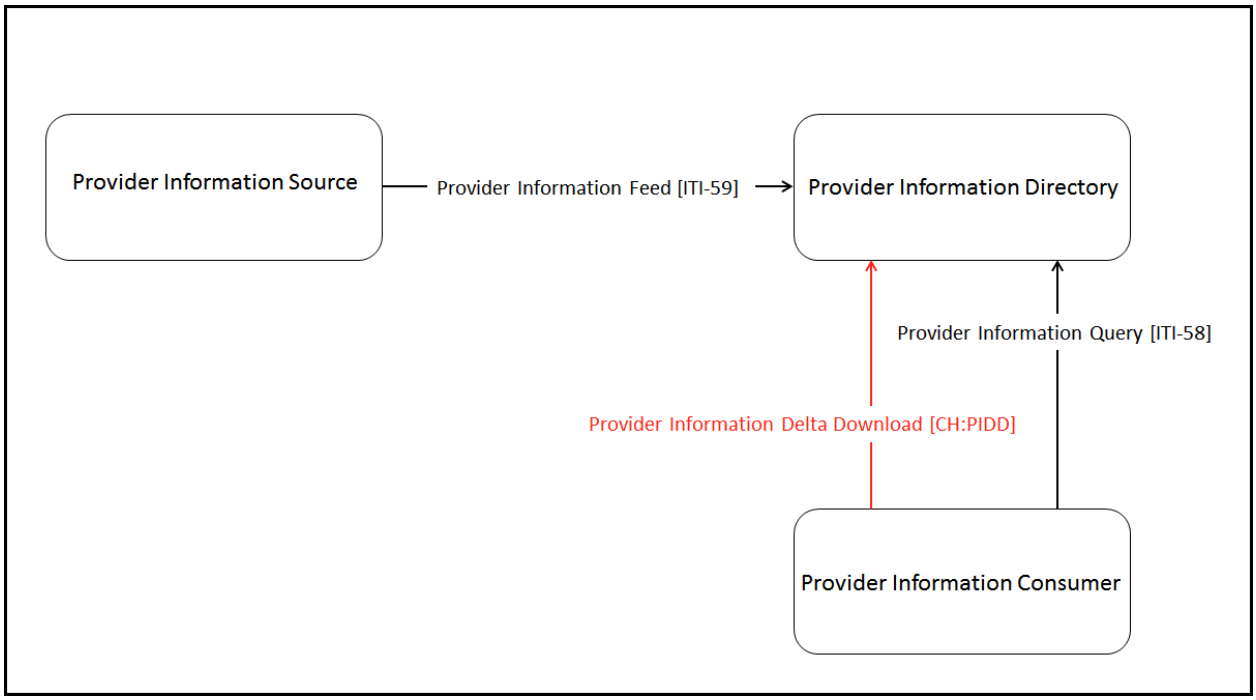

Figure 6: Swiss extended HPD Actors / Transactions

1.9.3.1 Provider Information Directory

The Provider Information Directory is extended with the following option:

- Provider Information Delta Download Option

This option requires the implementation of the Swiss Provider Information Delta Download [CH:PIDD] transaction.

1.9.3.2 Provider Information Consumer

The Provider Information Consumer is extended with the following option:

- Provider Information Delta Download Option

This option requires the implementation of the Swiss Provider Information Delta Download [CH:PIDD] transaction.

1.9.4 Transactions

1.9.4.1 Provider Information Delta Download (CH:PIDD)

This transaction schema extends the DSMLv2 interface by supporting an additional SOAP schema (see Appendix C – Provider Information Delta Download schema on page 53) and an additional wsdl operation:

```
<operation name="ProviderInformationDownloadRequest">
  <soap:operation soapAction="urn:ihe:iti:hpd:2010:ProviderInformationDownloadRequest" />
    <input>
     <soap:body use="literal" />
  </input>
  <output>
    <soap:body use="literal" />
  </output>
</operation>
```

1.9.4.1.1 Interaction Diagram

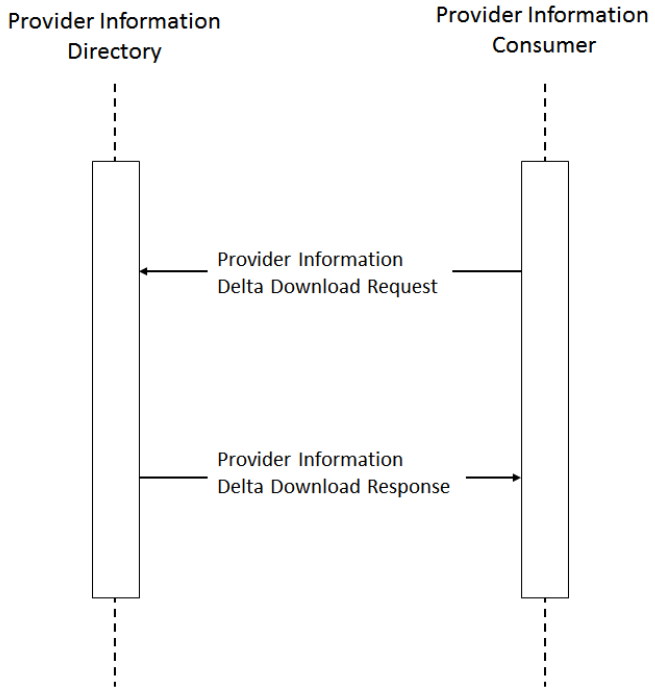

Figure 7: Provider Information Delta Download (CH:PIDD) interaction diagram

1.9.4.1.2 Provider Information Delta Download Request

Provider Information Consumer initiates a Provider Information Delta Download Request to the Provider Information Directory. This request includes:

- A required **fromDate** parameter to define the inclusive range starting date of the requested transactions sequence;
- An optional **toDat** parameter to define the inclusive range ending date of the requested transactions sequence (default: now);
- An optional **filterMyTransactions** boolean parameter to manage the the server side filtering of the author issued transactions (default: true);

1.9.4.1.3 Provider Information Delta Download Response

The response message contains a sequence of DSMLv2 batchRequest elements.

1.9.5 Message Semantics

1.9.5.1 HPD Schema Content

1.9.5.1.1 Identifiers

Organizational (e.g. hospitals) and Individual (health professionals) providers are identified by a Global Location Number (GLN).
A GLN number is a GTIN-13 digits unique number distributed by GS1 (http://www.gs1.ch/), where the first 12 digits are identifying the entity and the 13th is a check digit that can be used to validate manual inputs. In Switzerland GLN's can be obtained from the Refdata foundation[6] at no costs.
The format to persist identifiers for both organizational and individual providers is:
`Issuing Authority:Type:ID:Status`

Example (for an individual provider):
`GS1:GLN:9085632587458:active`

[6] http://www.refdata.ch/content/partner_d.aspx?Nid=6&Aid=908&ID=412

1.9.5.1.2 Attributes

Some additional restrictions apply to the Swiss national extension of the IHE ITI HPD Profile to ensure a better quality of the data. The following sections report the list of attributes supported, together with some indications on the deviations from the original HPD profile and ISO standard for both organizational and individual providers.

Conventions:
Optionality column (?): O=optional, R=required, R2=required if available;
Cardinality column (#): S=Single-valued, M=Multi-valued;
Deviations from the HPD profile are **highlighted**.

Table 18: Swiss refined HPD Organizational provider attributes

HPD profile [1]			**Swiss National Extension**		
Attribute name	**?**	**#**	**?**	**#**	***Notes***
Unique Entity Identifier	R	S	R	S	*Auto-generated*
Org Identifiers	R	M	R	**S**	GLN
Org Names	R	M	R	M	Legal name(s)
Org Known Names	R2	M	R2	M	Other name(s)
Org Type	O	M	**R**	M	HealthCareFacilityCode value [App. A-1]
Org Type description	O	M	O	M	HealthCareFacilityCode display name [App. A-1]
Org Status	O	S	O	S	Possible values: *Active, Inactive*
Org Supported Lang.	O	M	O	M	Encoded using ISO-639-1
Org Specialty	O	M	**R2**	M	PracticeSettingCode value [App. A-2]
Org Relationships	O	M	**R**	M	Reference to community or parent org.

NOTE: HPD profile or ISO standard format restrictions are not reported here; more information on these restrictions and on additional attributes are available in the IHE ITI TF-2b, Table 3.58.4.1.2.2.3-1: Organizational Provider Mapping applies.

Table 19: Swiss refined HPD Individual provider attributes

HPD profile [1]			**Swiss National Extension**		
Attribute name	**?**	**#**	**?**	**#**	***Notes***
Unique Entity Identifier	R	S	R	S	*Auto-generated*
Provider Identifiers	R	M	R	**S**	GLN
Provider Type	R	M	R	M	IndProviderTypeCode value [App. A-3]
Provider Type descript.	R	M	R	M	IndProviderTypeCode display name [App. A-3]
Provider Status	O	S	O	S	Possible values: *Active, Inactive*
Provider Primary Name	R	S	R	S	i.e. provider display name
Provider First Name	R2	M	**R**	M	Actual first name
Provider Last Name	R	M	R	**S**	Actual last name
Provider Known Names	R	M	R	M	Composed name string (e.g. title, first name,...)
Provider Supported Lang.	O	M	O	M	Encoded using ISO-639-1
Provider Gender	O	S	O	S	RFC 2985
Provider Specialty	O	M	O	M	AuthorSpecialtyCode value [App. A-4]
Provider Relationships	O	M	**R**	**M**	Reference to community or parent org.

NOTE: HPD profile or ISO standard format restrictions are not reported here; more information on these restrictions and on additional attributes are available in the IHE ITI TF-2b, Table 3.58.4.1.2.2.2-1: Individual Provider Mapping applies.

Appendices

Appendix A – AuditMessage schema (AuditMessage.xsd)

This XML schema is identical to the DICOM A.5.1-1 Audit Message Schema, which is provided in Relax NG Compact format.

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema
  xmlns:xs="http://www.w3.org/2001/XMLSchema"
  elementFormDefault="qualified">
  <!--
  This defines the coded value type. The comment shows a pattern that can be used to further
  constrain the token to limit it to the format of an OID.  Not all schema software
  implementations support the pattern option for tokens.
  -->
  <!-- The basic message -->
  <xs:element name="AuditMessage">
    <xs:complexType>
      <xs:sequence>
        <xs:element ref="EventIdentification"/>
        <xs:element maxOccurs="unbounded" ref="ActiveParticipant"/>
        <xs:element ref="AuditSourceIdentification"/>
        <xs:element minOccurs="0" maxOccurs="unbounded" ref="ParticipantObjectIdentification"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="EventIdentification" type="EventIdentificationContents"/>
  <xs:element name="ActiveParticipant" type="ActiveParticipantContents"/>
  <xs:element name="AuditSourceIdentification" type="AuditSourceIdentificationContents"/>
  <xs:element name="ParticipantObjectIdentification"
type="ParticipantObjectIdentificationContents"/>

  <xs:complexType name="EventIdentificationContents">
    <xs:sequence>
      <xs:element ref="EventID"/>
      <xs:element minOccurs="0" maxOccurs="unbounded" ref="EventTypeCode"/>
      <xs:element minOccurs="0" ref="EventOutcomeDescription"/>
    </xs:sequence>
    <xs:attribute name="EventActionCode">
      <xs:simpleType>
        <xs:restriction base="xs:token">
          <xs:enumeration value="C"/>
          <xs:enumeration value="R"/>
          <xs:enumeration value="U"/>
          <xs:enumeration value="D"/>
          <xs:enumeration value="E"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:attribute>
    <xs:attribute name="EventDateTime" use="required" type="xs:dateTime"/>
    <xs:attribute name="EventOutcomeIndicator" use="required">
      <xs:simpleType>
        <xs:restriction base="xs:token">
          <xs:enumeration value="0"/>
          <xs:enumeration value="4"/>
```

```
        <xs:enumeration value="8"/>
        <xs:enumeration value="12"/>
      </xs:restriction>
    </xs:simpleType>
  </xs:attribute>
</xs:complexType>

<xs:attributeGroup name="other-csd-attributes">
  <xs:attribute name="codeSystemName" use="required" type="xs:token"/>
  <xs:attribute name="displayName" type="xs:token"/>
  <xs:attribute name="originalText" use="required" type="xs:token"/>
</xs:attributeGroup>

<xs:attributeGroup name="CodedValueType">
  <xs:attribute name="csd-code" use="required" type="xs:token"/>
  <xs:attributeGroup ref="other-csd-attributes"/>
</xs:attributeGroup>

<xs:element name="EventID">
  <xs:complexType>
    <xs:attributeGroup ref="CodedValueType"/>
  </xs:complexType>
</xs:element>

<xs:element name="EventTypeCode">
  <xs:complexType>
    <xs:attributeGroup ref="CodedValueType"/>
  </xs:complexType>
</xs:element>

<xs:element name="EventOutcomeDescription" type="xs:string"/>

<xs:complexType name="AuditSourceIdentificationContents">
  <xs:sequence>
    <xs:element minOccurs="0" maxOccurs="unbounded" ref="AuditSourceTypeCode"/>
  </xs:sequence>
  <xs:attribute name="code" use="required">
    <xs:simpleType>
      <xs:union memberTypes="xs:token">
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="1"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="2"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="3"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="4"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
```

```
          <xs:restriction base="xs:token">
            <xs:enumeration value="5"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="6"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="7"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="8"/>
          </xs:restriction>
        </xs:simpleType>
        <xs:simpleType>
          <xs:restriction base="xs:token">
            <xs:enumeration value="9"/>
          </xs:restriction>
        </xs:simpleType>
      </xs:union>
    </xs:simpleType>
  </xs:attribute>
  <xs:attribute name="codeSystemName" type="xs:token"/>
  <xs:attributeGroup ref="other-csd-attributes"/>
  <xs:attribute name="AuditEnterpriseSiteID" type="xs:token"/>
  <xs:attribute name="AuditSourceID" use="required" type="xs:token"/>
</xs:complexType>

<xs:element name="AuditSourceTypeCode" type="xs:token"/>

<xs:complexType name="ActiveParticipantContents">
  <xs:sequence>
    <xs:element minOccurs="0" maxOccurs="unbounded" ref="RoleIDCode"/>
    <xs:element minOccurs="0" ref="MediaIdentifier"/>
  </xs:sequence>
  <xs:attribute name="UserID" use="required"/>
  <xs:attribute name="AlternativeUserID"/>
  <xs:attribute name="UserName"/>
  <xs:attribute name="UserIsRequestor" use="required" type="xs:boolean"/>
  <xs:attribute name="NetworkAccessPointID" type="xs:token"/>
  <xs:attribute name="NetworkAccessPointTypeCode">
    <xs:simpleType>
      <xs:restriction base="xs:token">
        <xs:enumeration value="1"/>
        <xs:enumeration value="2">
          <xs:annotation>
            <xs:documentation>Machine Name, including DNS name</xs:documentation>
          </xs:annotation>
        </xs:enumeration>
        <xs:enumeration value="3">
          <xs:annotation>
            <xs:documentation>IP Address</xs:documentation>
          </xs:annotation>
        </xs:enumeration>
        <xs:enumeration value="4">
```

```
          <xs:annotation>
            <xs:documentation>Telephone Number</xs:documentation>
          </xs:annotation>
        </xs:enumeration>
        <xs:enumeration value="5">
          <xs:annotation>
            <xs:documentation>Email address</xs:documentation>
          </xs:annotation>
        </xs:enumeration>
      </xs:restriction>
    </xs:simpleType>
  </xs:attribute>
</xs:complexType>

<xs:element name="RoleIDCode">
  <xs:complexType>
    <xs:attributeGroup ref="CodedValueType"/>
  </xs:complexType>
</xs:element>

<xs:element name="MediaIdentifier">
  <xs:complexType>
    <xs:sequence>
      <xs:element ref="MediaType"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

<xs:element name="MediaType">
  <xs:complexType>
    <xs:attributeGroup ref="CodedValueType"/>
  </xs:complexType>
</xs:element>

<xs:attributeGroup name="ValuePair">
  <xs:annotation>
    <xs:documentation>URI (user directory, HTTP-PUT, ftp, etc.)</xs:documentation>
  </xs:annotation>
  <xs:attribute name="type" use="required" type="xs:token"/>
  <xs:attribute name="value" use="required" type="xs:base64Binary"/>
</xs:attributeGroup>

<xs:group name="DICOMObjectDescriptionContents">
  <xs:sequence>
    <xs:element minOccurs="0" maxOccurs="unbounded" ref="MPPS"/>
    <xs:element minOccurs="0" maxOccurs="unbounded" ref="Accession"/>
    <xs:element ref="SOPClass"/>
    <xs:element ref="ParticipantObjectContainsStudy"/>
    <xs:element minOccurs="0" ref="Encrypted"/>
    <xs:element minOccurs="0" ref="Anonymized"/>
  </xs:sequence>
</xs:group>

<xs:element name="MPPS">
  <xs:complexType>
    <xs:attribute name="UID" use="required" type="xs:token"/>
  </xs:complexType>
</xs:element>

<xs:element name="Accession">
```

```
  <xs:complexType>
    <xs:attribute name="Number" use="required" type="xs:token"/>
  </xs:complexType>
</xs:element>

<xs:element name="SOPClass">
  <xs:complexType>
    <xs:sequence>
      <xs:element minOccurs="0" maxOccurs="unbounded" ref="Instance"/>
    </xs:sequence>
    <xs:attribute name="UID" type="xs:token"/>
    <xs:attribute name="NumberOfInstances" use="required" type="xs:integer"/>
  </xs:complexType>
</xs:element>

<xs:element name="Instance">
  <xs:complexType>
    <xs:attribute name="UID" use="required" type="xs:token"/>
  </xs:complexType>
</xs:element>

<xs:element name="ParticipantObjectContainsStudy">
  <xs:complexType>
    <xs:sequence>
      <xs:element minOccurs="0" maxOccurs="unbounded" ref="StudyIDs"/>
    </xs:sequence>
  </xs:complexType>
</xs:element>

<xs:element name="StudyIDs">
  <xs:complexType>
    <xs:attribute name="UID" use="required" type="xs:token"/>
  </xs:complexType>
</xs:element>

<xs:element name="Encrypted" type="xs:boolean"/>

<xs:element name="Anonymized" type="xs:boolean"/>

<xs:complexType name="ParticipantObjectIdentificationContents">
  <xs:sequence>
    <xs:element ref="ParticipantObjectIDTypeCode"/>
    <xs:choice>
      <xs:element ref="ParticipantObjectName"/>
      <xs:element ref="ParticipantObjectQuery"/>
    </xs:choice>
    <xs:element minOccurs="0" maxOccurs="unbounded" ref="ParticipantObjectDetail"/>
    <xs:element minOccurs="0" maxOccurs="unbounded" ref="ParticipantObjectDescription"/>
    <xs:group ref="DICOMObjectDescriptionContents"/>
  </xs:sequence>
  <xs:attribute name="ParticipantObjectID" use="required" type="xs:token"/>
  <xs:attribute name="ParticipantObjectTypeCode">
    <xs:simpleType>
      <xs:restriction base="xs:token">
        <xs:enumeration value="1"/>
        <xs:enumeration value="2"/>
        <xs:enumeration value="3"/>
        <xs:enumeration value="4"/>
      </xs:restriction>
    </xs:simpleType>
```

```
  </xs:attribute>
  <xs:attribute name="ParticipantObjectTypeCodeRole">
    <xs:simpleType>
      <xs:restriction base="xs:token">
        <xs:enumeration value="1"/>
        <xs:enumeration value="2"/>
        <xs:enumeration value="3"/>
        <xs:enumeration value="4"/>
        <xs:enumeration value="5"/>
        <xs:enumeration value="6"/>
        <xs:enumeration value="7"/>
        <xs:enumeration value="8"/>
        <xs:enumeration value="9"/>
        <xs:enumeration value="10"/>
        <xs:enumeration value="11"/>
        <xs:enumeration value="12"/>
        <xs:enumeration value="13"/>
        <xs:enumeration value="14"/>
        <xs:enumeration value="15"/>
        <xs:enumeration value="16"/>
        <xs:enumeration value="17"/>
        <xs:enumeration value="18"/>
        <xs:enumeration value="19"/>
        <xs:enumeration value="20"/>
        <xs:enumeration value="21"/>
        <xs:enumeration value="22"/>
        <xs:enumeration value="23"/>
        <xs:enumeration value="24"/>
      </xs:restriction>
    </xs:simpleType>
  </xs:attribute>
  <xs:attribute name="ParticipantObjectDataLifeCycle">
    <xs:simpleType>
      <xs:restriction base="xs:token">
        <xs:enumeration value="1"/>
        <xs:enumeration value="2"/>
        <xs:enumeration value="3"/>
        <xs:enumeration value="4"/>
        <xs:enumeration value="5"/>
        <xs:enumeration value="6"/>
        <xs:enumeration value="7"/>
        <xs:enumeration value="8"/>
        <xs:enumeration value="9"/>
        <xs:enumeration value="10"/>
        <xs:enumeration value="11"/>
        <xs:enumeration value="12"/>
        <xs:enumeration value="13"/>
        <xs:enumeration value="14"/>
        <xs:enumeration value="15"/>
      </xs:restriction>
    </xs:simpleType>
  </xs:attribute>
  <!-- spelling correction!!
  ParticipantObjectSensistity seems to be wrong.
  Using ParticipantObjectSensitivity instead
  -->
  <xs:attribute name="ParticipantObjectSensitivity" type="xs:token"/>
</xs:complexType>

<xs:element name="ParticipantObjectIDTypeCode">
```

```
    <xs:complexType>
      <xs:attributeGroup ref="CodedValueType"/>
    </xs:complexType>
  </xs:element>

  <xs:element name="ParticipantObjectName" type="xs:token"/>

  <xs:element name="ParticipantObjectQuery" type="xs:base64Binary"/>

  <xs:element name="ParticipantObjectDetail">
    <xs:complexType>
      <xs:attributeGroup ref="ValuePair"/>
    </xs:complexType>
  </xs:element>

  <xs:element name="ParticipantObjectDescription" type="xs:token"/>

</xs:schema>
```

Appendix B – AuditTrail schema (AuditTrail.xsd)

Includes the AuditMessage schema, introduced in chapter “1.4.4.1.1 Detailed AuditMessage definitions” starting on page 14.
See also Appendix A – AuditMessage schema starting on page 45.

```
<?xml version="1.0" encoding="UTF-8"?>
<xs:schema
  xmlns:xs="http://www.w3.org/2001/XMLSchema"
  elementFormDefault="qualified">

  <xs:include schemaLocation="AuditMessage.xsd"/>

  <xs:element name="AuditTrail">
    <xs:complexType>
      <xs:sequence>
        <xs:element minOccurs="1" maxOccurs="unbounded" ref="AuditMessage"/>
      </xs:sequence>
    </xs:complexType>
  </xs:element>

</xs:schema>
```

Appendix C – Provider Information Delta Download schema (PIDD.xsd)

```
<?xml version="1.0" encoding="UTF-8"?>
<xsd:schema targetNamespace="urn:ehealth-suisse:names:tc:CS:1" xmlns="urn:ehealth-
suisse:names:tc:CS:1" elementFormDefault="qualified">
  <xsd:element name="downloadRequest" type="DownloadRequest" />
  <xsd:element name="downloadResponse" type="DownloadResponse" />

  <!-- **** Download Request **** -->
  <xsd:complexType name="DownloadRequest">
    <xsd:sequence>
      <xsd:element name="authRequest" type="dsml:AuthRequest" minOccurs="0" maxOccurs="1" />
    </xsd:sequence>
    <xsd:attribute name="requestID" type="xsd:string" use="optional" />
    <xsd:attribute name="fromDate" use="required">
      <xsd:simpleType>
        <xsd:restriction base="xsd:dateTime" />
      </xsd:simpleType>
    </xsd:attribute>
    <xsd:attribute name="toDate" use="optional">
      <xsd:simpleType>
        <xsd:restriction base="xsd:dateTime" />
      </xsd:simpleType>
    </xsd:attribute>
    <xsd:attribute name="filterMyTransactions" use="optional" default="true">
      <xsd:simpleType>
        <xsd:restriction base="xsd:boolean" />
      </xsd:simpleType>
    </xsd:attribute>
  </xsd:complexType>

  <!-- **** Download Response **** -->
  <xsd:complexType name="DownloadResponse">
    <xsd:sequence>
      <xsd:element ref="dsml:batchRequest" maxOccurs="unbounded" minOccurs="0" />
    </xsd:sequence>
    <xsd:attribute name="requestID" type="xsd:string" use="optional" />
  </xsd:complexType>

</xsd:schema>
```

Glossary

The IHE Glossary can be found as an appendix to the *IHE Technical Frameworks General Introduction*.
See also chapter “1.1 Definitions of terms” on page 5.

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Direktionsbereich Gesundheitspolitik

SR 816.11.n / Anhang 5 der Verordnung des EDI vom ... über das elektronische Patientendossier

Nationale Integrationsprofile nach Artikel 5 Buchstabe c EPDV-EDI

Authorization Decision Request (CH:ADR) and Privacy Policy Query (CH:PPQ)

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1 Introduction

The Swiss Electronic Health Record (EPD) depends on an IHE XDS and multi-community based system where the patient not only consents to the creation and use of the record, but does so by explicitly defining access rules through a patient portal.

The patient's privacy choices (concerning access to his health record) are stored by the community where the patient has established his EPD (reference community) and MUST be respected by all participating systems. It has been specified for the Document Registries to act as Policy Enforcing Service Providers in terms of a XACML PEP. However, as the rules to be enforced MAY not be available to the Document Registry of a community, the XACML PDP needs to be implemented as its own separated actor to establish interoperability regarding policy enforcements. Furthermore, Policy Repositories themselves (XACML PAP) are specified to act as a Policy Enforcing Service Provider.

The complexity and flexibility of access rule definitions that were granted to patients by law, require the Patient Portals to act as Policy Managers that use an API into Policy Repositories to add, query, update and delete policies. There is a lack of interoperability standards regarding this use case.

1.1 Definitions of terms

1.1.1 Electronic patient dossier (EPD)

The object of the Federal Law on Electronic Health Records (FLEHR) is to define the conditions for processing data and documents relating to electronic health records. Using electronic health records, healthcare professionals can access data relevant to treatment of their patients that was compiled and decentrally recorded by healthcare professionals involved in the treatment process. Healthcare professionals may save this data if necessary in their practice and hospital information systems outside of the electronic health records. To access electronic health records, healthcare professionals must join a certified community, which is an association of healthcare professionals and their institutions, and their patients must grant them the necessary access rights. In addition, the electronic health record also allows patients to view their data, to make their own data accessible and to manage the allocation of access rights. Healthcare professionals may only process data in electronic health records with the consent of the patient. Patients have the option of granting individual and graded access rights.
Notation of this term in the following text: **EPD**

1.1.2 EPD circle of trust

From an organizational perspective and in terms of the FLEHR, communities are an association of healthcare professionals and their institutions. Communities who want to participate in the Swiss EPD must comply with the certification requirements as laid down in the implementing provisions for the FLEHR. Such communities and, in particular, their gateways will be listed in a community portal index provided by the FOPH and therefore form a circle of trust by mutual recognition of their conformity related to data protection and data privacy. Furthermore, all required central services are also part of this circle of trust.
Notation of this term in the following text: **EPD circle of trust**

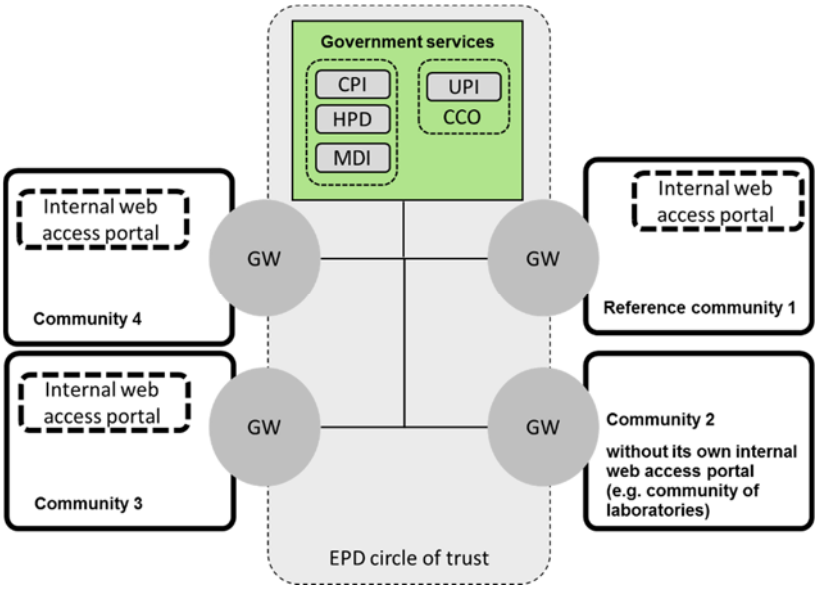


Figure 1: Swiss EPD circle of trust

Legend:

- GW: Gateway
- CPI: Community / Portal Index
- UPI: Unique Person Identification
- HPD: Healthcare Provider Directory
- MDI: Metadata Index-Service

1.1.3 Reference community

If a patient decides to open an EPD, she or he first chooses a community that manages all of his current consents and access right configurations to be used by other EPD users (in essence healthcare professionals) while accessing his personal EPD. Consents and access rights for one patient are managed by exactly one community in the EPD circle of trust.
Although the term home community is used by IHE in a slightly different way, the current specification states this consent and access right management community as reference community.
Cross-community accesses to documents within the EPD are only permitted when the initiating user gets permission by the access rights defined by the patient. Although cross-community accesses may occur between each community within the EPD circle of trust regardless whether it is the patient's reference community or not, the responding community must always apply the current access right settings managed by the reference community.
The patient may change his reference community at any time (for example, when moving to another residence).
Notation of this term in the following text: **referenceCommunity**

1.1.4 Patient Identifiers (EPD-PID, MPI-PID)

Communities in the EPD circle of trust use the national EPD patient identifier (EPD-PID) only for cross-community communication. The federal Central Compensation Office (CCO)[1] is the institution which issues EPD-PID's. CCO is the only institution which is allowed to correlate the Social Security Number (AVN13) with the EPD-PID. There is no correlation possible back from the EPD-PID to the Social Security Number. This is political intention in order to achieve highest possible patient privacy.
Within a community patients are identified by a MPI-PID which is managed by a community Master Patient Index (MPI). Primary Systems may correlate their local patient identifier with the MPI-PID. For

[1] http://www.zas.admin.ch/index.html

cross-community communication the gateways may correlate the MPI-ID to the EPD-PID.

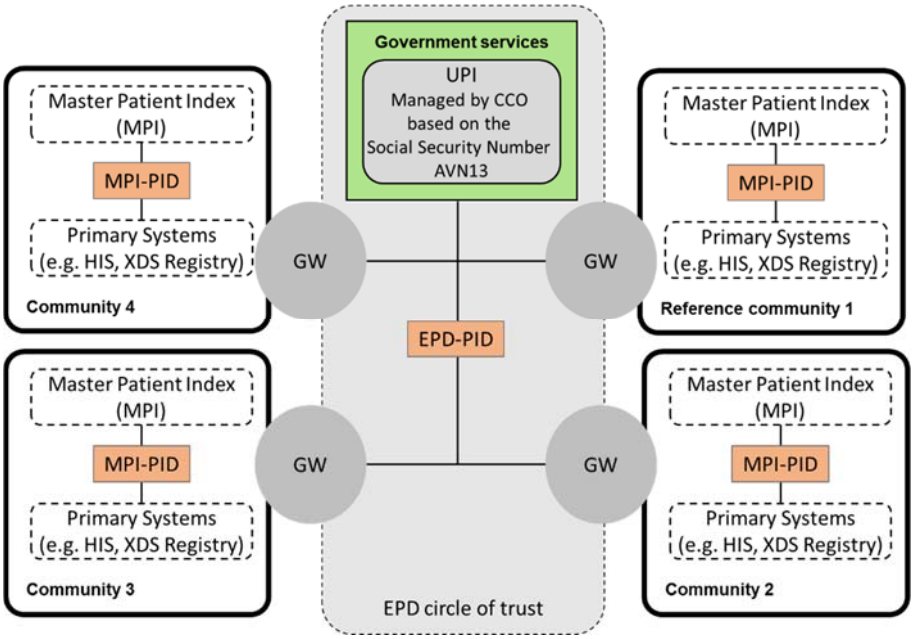


Figure 2 Swiss Patient Identifiers

1.1.5 Terminology

The key words “MUST”, “MUST NOT”, “REQUIRED”, “SHALL”, “SHALL NOT”, “SHOULD”, “SHOULD NOT”, “RECOMMENDED”, “MAY”, and “OPTIONAL” in this document are to be interpreted as described in [RFC2119].

2 Volume 1 – Integration Profiles

2.1 Overview

The **Authorization Decision Request (ADR)** may be understood as a subsequent process to IHE XUA. XUA formulates the user's identity (SAML assertion) that is trying to access data through a corresponding transaction. ADR takes the information provided by the identity assertion of a transaction and formulates a decision request query by a description of the subject (who), action (how), resource (what) and environment (when). The response contains an access decision for each resource.

The **Privacy Policy Query (PPQ)**, however, may rather be understood similar to XDS transactions. A Policy Manager applies PPQ transactions to add, query, update and delete policies held by the Policy Repository. PPQ is the pre-requisite for Patient Portals to manipulate the policies, authorization decisions are finally based on. It is important to understand that PPQ transactions underlie the same access control mechanisms as XDS transactions do. Therefore XUA identity assertions MUST be provided, so that the Policy Repository can verify (through a subsequent ADR transaction) whether the access control mechanism allows the changes.

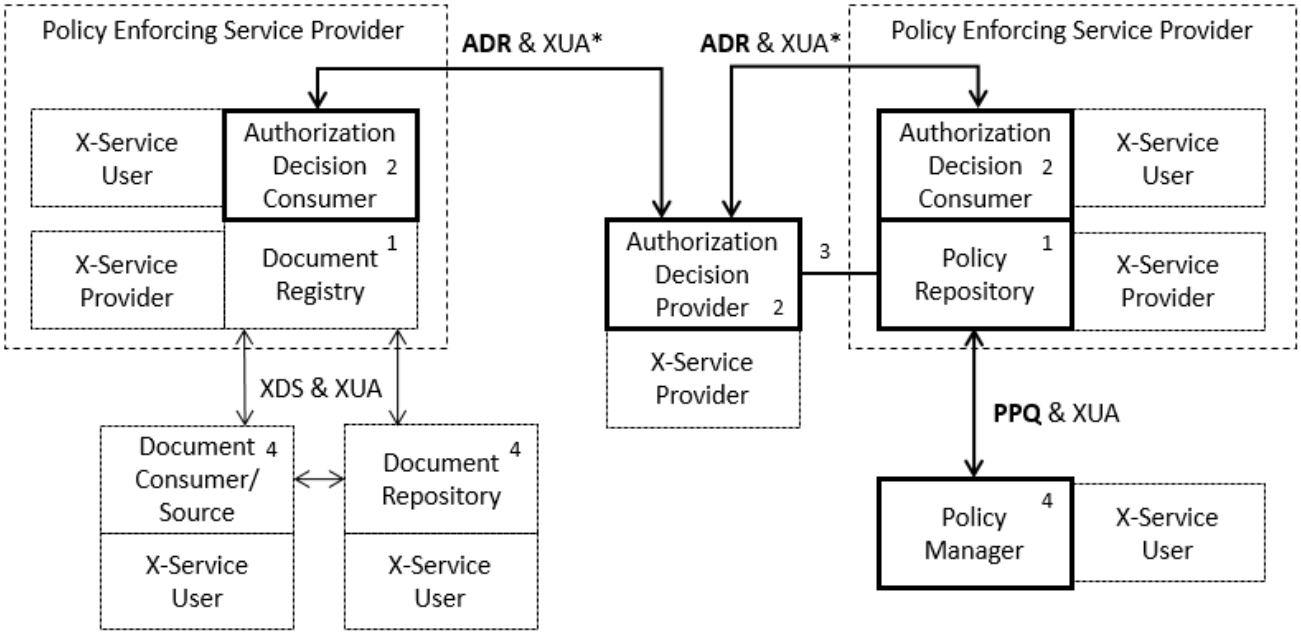


*Figure 3: ADR and PPQ Actors - shows the actors directly involved in the ADR and PPQ Profile and the relevant transactions between them. If needed for context, other actors that MAY be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes. *) The ADR transaction MUST provide a XUA identity assertion of the current user mainly for auditing reasons.*

1. Document Registries, Repositories and Policy Repositories MUST be grouped with the ADR Authorization Decision Consumer and XUA X-Service Provider actors to become Policy Enforcing Service Providers.
2. ADR transactions are protected by XUA as well, which requires the Authorization Decision Consumer to be grouped with the X-Service User actor and the Authorization Decision Provider to be grouped with the X-Service Provider actor (marked with *)
3. The ADR Authorization Decision Provider SHOULD be grouped with a Policy Repository or requires privileged access to the policies stored by the Policy Repository.
4. A Policy Manager applies PPQ transactions to add, query, update and delete policies stored by the Policy Repository. Document Consumers apply XDS Registry Stored Query

transactions to retrieve document metadata. Document Repositories apply XDS Register Document Set transactions due to XDS Provide and Register transactions by a Document Source. All three are grouped with the XUA X-Service User Actor.

2.2 EPD XUA Requirements for XDS and PPQ

A SAML 2.0 **<Assertion>** is added to the WS-Security context of the SOAP Header of each transaction message to communicate entities (user identities) that initiated those transactions. This is a pre-requisite for subsequent Authorization Decision Query Requests.

```
<wsse:Security xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
  <saml2:Assertion xmlns:saml2="urn:oasis:names:tc:SAML:2.0:assertion"
    xmlns:xs="http://www.w3.org/2001/XMLSchema" ID="_37d8092df99f08cd8435ac29a7062092"
    IssueInstant="2014-04-09T19:10:00.294Z" Version="2.0">
    <!--Identity Claims-->
  </saml2:Assertion>
</wsse:Security>
```

Listing 1: The WS Security context of the SOAP header with the SAML2 Assertion element. For simplicity the identity claims are not shown.

The EPD SAML 2.0 <Assertion> has the child elements **<Issuer>**, **<Signature>**, **<Subject>**, **<Conditions>, <AuthnStatement>** and **<AttributeStatement>**. The <AttributeStatement> element caries a number of attributes that reflect the identity claims being made.

The EPD requires the following details to be claimed within the assertion:

<Issuer> the system that issued the token and therefore confirms that the identified user was properly authenticated and that the attributes included in the token are accurate. For further details see [SAML 2.0].

```
<saml2:Issuer>urn:e-health-suisse:xua:gemeinschaft:ksa</saml2:Issuer>
```

<Signature> an X.509 signature by a trusted entity (XUA Assertion Provider) to guaranty the confidentiality of the claims being made and unaltered content of the assertion. For further details see [SAML 2.0].

```
<ds:Signature xmlns:ds="http://www.w3.org/2000/09/xmldsig#">
      <ds:SignedInfo>
        <ds:CanonicalizationMethod Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#"/>
        <ds:SignatureMethod Algorithm="http://www.w3.org/2001/04/xmldsig-more#rsa-sha256"/>
        <ds:Reference URI="#_37d8092df99f08cd8435ac29a7062092">
          <ds:Transforms>
            <ds:Transform Algorithm="http://www.w3.org/2000/09/xmldsig#enveloped-signature"/>
            <ds:Transform Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#">
              <ec:InclusiveNamespaces xmlns:ec="http://www.w3.org/2001/10/xml-exc-c14n#" PrefixList="xs"/>
            </ds:Transform>
          </ds:Transforms>
          <ds:DigestMethod Algorithm="value="http://www.w3.org/2001/04/xmlenc#sha256"/>
          <ds:DigestValue>NRrlqwGn8o9tO0DlkYbOaXNqlM0=</ds:DigestValue>
        </ds:Reference>
      </ds:SignedInfo>
 <ds:SignatureValue>dbBafjF2NPY0Y73uWztQvRpda5DOV8BrPYL5KlCx8yvnEBZ9TQrKnjwhcE=</ds:SignatureValue>
  <ds:KeyInfo>
    <ds:X509Data>
      <ds:X509Certificate>
        <!-- X.509 Certificate -->
      </ds:X509Certificate>
    </ds:X509Data>
  </ds:KeyInfo>
</ds:Signature>
```

Listing 2: The Signature Element of the WS Security context providing the details of signature algorithm used. For simplicity the X.509 certificate is not shown.

<Subject> identifies the Requester Entity (Who is asking for access?). This element SHALL have the following SAML 2.0 **<NameID>** child element with the following attributes:

@Format=" urn:oasis:names:tc:SAML:2.0:nameid-format:persistent" and **@NameQualifier="urn:e-health-suisse:epd-pid"** in case of a patient or **@NameQualifier="urn:gs1:gln"** in case of a professional or **@NameQualifier="urn:e-health-suisse:custodian-id"** in case of a custodian or guardian, who's been assigned to manage a patient's Health Record.
The Value of this element SHALL convey the subject identifier.

<Subject> SHALL have a second child element **<SubjectConfirmation>** with the following attribute:
@Method="urn:oasis:names:tc:SAML:2.0:cm:bearer"

```
<saml2:Subject>
  <saml2:NameID Format="urn:oasis:names:tc:SAML:2.0:nameid-format:persistent"
                NameQualifier="urn:e-health-suisse:gln">4567</saml2:NameID>
  <saml2:SubjectConfirmation Method="urn:oasis:names:tc:SAML:2.0:cm:bearer"/>
</saml2:Subject>
```

Listing 3: Subject element of the SAML assertion providing the ID and the name qualifier of the requesting subject.

<Conditions> specifying a validity period (time stamps) to prevent "replay" of the assertion while attributes MAY have changed. The time period MUST be defined between a minimum of 5 seconds and a maximum of 10 minutes.
An audience restriction (urn:e-health-suisse:token-audience:all-communities) specifies the intended recipient or system the assertion SHALL be valid for.
The reuse of the token (signed SAML identity assertion) MAY be denied by

setting a <OneTimeUse> element. For further details see [SAML 2.0].

```
<saml2:Conditions NotBefore="2016-02-09T19:10:00.294Z" NotOnOrAfter="2016-02-09T19:15:00.294Z">
  <saml2:AudienceRestriction>
    <saml2:Audience>urn:e-health-suisse:token-audience:all-communities</saml2:Audience>
  </saml2:AudienceRestriction>
</saml2:Conditions>
```

Listing 4: The condition element of the SAML 2 assertion defining the assertion life time.

<AuthnStatement> specifying the authentication procedure by which the entity's identity (e.g. a user) was verified. For further details see [SAML 2.0].

```
<saml2:AuthnStatement AuthnInstant="2016-02-09T19:10:00.294Z">
  <saml2:AuthnContext>
<saml2:AuthnContextClassRef>urn:oasis:names:tc:SAML:2.0:ac:classes:PasswordProtectedTransport</saml2:AuthnContextClassRef>
  </saml2:AuthnContext>
</saml2:AuthnStatement>
```

Listing 5: The authentication statement providing the authentication procedure used by the requesting system.

<AttributeStatement> identifies the Requester Entity's attributes / identity claims. There are six mandatory **<Attribute>** child elements as follows.
There SHALL be one <Attribute> element with the attribute:
@Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id"
The **<AttributeValue>** child element SHALL convey the subject's real world name as plain text as defined by IHE XUA.

There SHALL be one <Attribute> elements with the attribute:
@Name="urn:oasis:names:tc:xacml:2.0:subject:role"
The **<AttributeValue>** child element SHALL convey a coded value of the subject's **<Role>**. There are four roles to be distinguished within the EPD: "Patient(in)", "Behandelnde(r)", "Hilfsperson" and "Stellvertreter(in)".

There SHALL be one or more <Attribute> elements with the attribute:
@Name="urn:oasis:names:tc:xspa:1.0:subject:organization"
The **<AttributeValue>** child element SHALL convey a plain text the subject's organization is named by.

There SHALL be one or more <Attribute> elements with the attribute:
@Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id"
The **<AttributeValue>** child element SHALL convey the ID of the subject's organization or group that is identified by a GLN within the EPD's Healthcare Organizations Index (HOI). The value's syntax SHALL be a URN: urn:gs1:gln:<*GLN*>, e.g. urn:gs1:gln:7609999999999.

There SHALL be an <Attribute> element with the attribute:
@Name="urn:oasis:names:tc:xacml:2.0:resource:resource-id"
The **<AttributeValue>** child SHALL convey the EPD-PID identifier of the patient's record the current transaction is related to.
(syntax as used in iti-18 XDSDocumentEntryPatientId)

.

There SHALL be an <Attribute> element with the attribute:
@Name=" urn:oasis:names:tc:xspa:1.0:subject:purposeofuse"
The **<AttributeValue>** child element SHALL convey a coded value of the current transaction's **<PurposeOfUse>**. There are two values to be distinguished within the EPD: "Normalzugriff", "Notfallzugriff" (displayName).

```
<saml2:AttributeStatement>
  <saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:subject-id">
    <saml2:AttributeValue>Hans Muster</saml2:AttributeValue>
  </saml2:Attribute>
  <saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:subject:role">
    <saml2:AttributeValue>
      <Role xmlns="urn:hl7-org:v3" xs:type="CE“
            code=“1"
            codeSystem="2.16.756.5.30.1.127.3.10.xx.xx.xx"
            codeSystemName="eHealth Suisse EPD Akteure"
            displayName=“Patient(in)"/>
    </saml2:AttributeValue>
  </saml2:Attribute>
  <saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization">
    <saml2:AttributeValue>Kantonspital Aarau</saml2:AttributeValue>
  </saml2:Attribute>
  <saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:organization-id">
    <saml2:AttributeValue>urn:e-health-suisse:gln:92375058</saml2:AttributeValue>
  </saml2:Attribute>
  <saml2:Attribute Name="urn:oasis:names:tc:xacml:2.0:resource:resource-id">
   <saml2:AttributeValue>8901^^^&amp;amp;2.16.756.5.30.1.127.3.10.x.xx&amp;amp;ISO</saml2:AttributeValue>
  </saml2:Attribute>
  <saml2:Attribute Name="urn:oasis:names:tc:xspa:1.0:subject:purposeofuse">
    <saml2:AttributeValue>
      <PurposeOfUse xmlns="urn:hl7-org:v3" xs:type="CE"
                    code=“1"
                    codeSystem="2.16.756.5.30.1.127.3.10.xx.xx.xx"
                    codeSystemName="eHealth Suisse Verwendungszweck"
                    displayName=“Normalzugriff"/>
    </saml2:AttributeValue>
  </saml2:Attribute>
</saml2:AttributeStatement>
```

Listing 6: The SAML 2 attribute statement with the IHE XUA attribute claims.

2.3 Authorization Decision Query

This supplement defines new functionalities for XDS-based communities concerning the enforcement of access policies. They are applied to the clinical data stored by an XDS Document Registry, as well as to the access policies themselves, which are stored in a Policy Repository.

2.3.1 Motivation

The Document Registry, as the only system with knowledge of all clinical documents (and which only exists once) within communities (affinity domains), is generally thought of as an appropriate actor to enforce access rules on stored metadata. It is common that the Document Registry is inherently combined with the ability to make authorization decisions, which postulates access to the rules to be enforced and the ability to interpret them. As this is not necessarily given in all XDS environments, a separation of actors for decision making and enforcement, as well as the development of corresponding transactions greatly enhances interoperability. This is by no means a new idea, as the XACML standard as well as existing IHE profiles (SeR) envision the same concept and therefore will be adopted and adapted by ADR.
More generally, ADR enables a policy enforcing service provider (e.g. a Document Registry or a Policy Repository) to retrieve access decisions from an authority with access to the rules and the ability to interpret them.

2.3.2 Objectives and Constraints

The objective of the ADR Profile is the definition of a mechanism to request authorization decisions and convey the results between the actors “Authorization Decision Consumer” and “Authorization Decision Provider”. Both are to be interpreted as specific implementations of PEP and PDP as defined by the XACML specification. There is a considerable overlap of concepts and use cases with the existing IHE Secure Retrieve (SeR) Profile. The following specification is based on IHE SeR, which was adapted to the needs of the actors and use cases of ADR. Transport, transaction types and content shall be based on the same standards and technologies as far as possible.
Two new actors and a new ADR-specific Authorization Decision Query transaction are being introduced. This profile describes how a Policy Enforcing Service Provider can request authorization decisions on certain resources and actions depending on user entities, a patient’s record and other parameters allowed by the underlying standards.
Summarized, the constraints upon which this profile is developed are:

- The XACML data-flow model serves as the underlying processing model.
- There are Authorization Decision Providers acting as XACML PDPs with access to the policies and the capability to perform access decisions on.
- The policies are stored in a Policy Repository acting as XACML PAP.
- Policy enforcing service providers (e.g. Document Registries) act as XACML PEPs by implementing the Authorization Decision Consumer and the corresponding enforcement of a decision.
- The transactions between the profile’s actors rely on SAML 2.0 profile of XACML v2.0.
- Policy enforcing service providers are grouped with a XUA X-Service Provider actor and therefore are capable of processing identities communicated in a SAML identity assertion.

2.3.3 Actors / Transactions

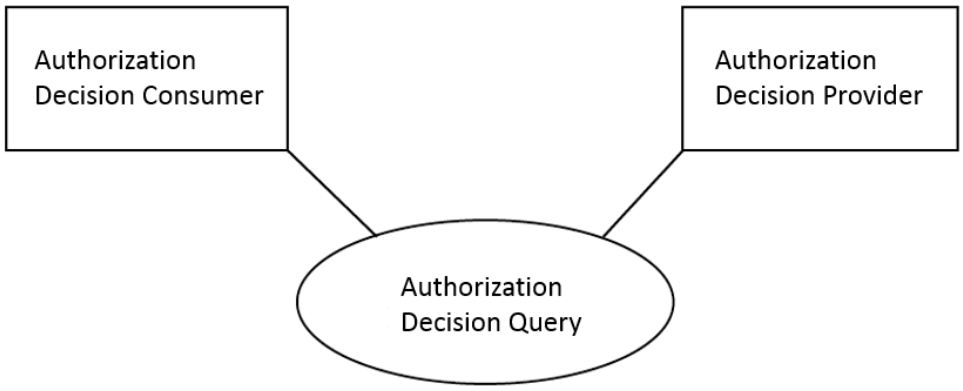


Figure 4: Diagram of actors involved in the ADR profile.

Actor:	Authorization Decision Provider
Role:	This actor accesses and interprets rules/policies and permits or denies access to resources.
Actor:	Authorization Decisions Consumer
Role:	This actor queries for authorization decisions.

Table 1 Actor Roles

2.4 Privacy Policy Query

This supplement defines new functionalities for XDS-based communities concerning the management of access policies in terms of updating or modifying policies as well as querying policies from and adding policies to a Policy Repository through a Policy Manager.

2.4.1 Motivation

The EPD defines the Policy Repository to act as XACML PAP that holds the access rules for the entire record as defined by the patient. Communities offering that service can be chosen by the patient to serve as the holder of that information (referenceCommunity). The community also provides a Patient Portal to allow the corresponding management of that information by the patient.
For the EPD, patients have extensive choices regarding their privacy preferences. There is a base rule stack, which defines a number of general access levels; the patient has a choice to grant to individual providers. A corresponding rule stack on top of the base rule stack MUST be allowed for the patient to be created, retrieved, manipulated and deleted. In addition to that, the patient MAY even define who has access not only to the record's documents but also to the patient's access rule stack including the ability to modify it.
The complexity and flexibility REQUIRED, can hardly be facilitated by existing standards. There are simpler approaches existing (e.g. IHE BPPC) to allow the expression of privacy choices by formulating consent to a set of fixed access policies (Allow publishing? Allow access during normal treatment? Allow break-the-glass?). However, allowing the patient to express specific rules for individual documents, providers and organizations requires a richer user experience and the ability to retrieve, change and delete individual rules. This implies using an API approach instead of a document-centric approach.

2.4.2 Objectives and Constraints

The objective of PPQ is the definition of actors and transactions to convey access policies from a Patient Portal to the referenceCommunity. Two new actors "Policy Manager" and "Policy Repository" are introduced. While the Policy Repository may be interpreted as a specific implementation of a XACML PAP, no analogy to the Policy Manager actor is defined in XACML. Therefore the Policy Manager is being introduced as an entirely new PPQ actor.
This profile describes how Policy Managers query, add, update and delete policies, allowing a Health

Record user to manage access rights according to the freedom of choice that was granted to the patient by Swiss regulations.
Constraints upon which this profile is developed are:

- The development of transactions between the profile's actors relies on SAML 2.0 and XACML SAML extension types, elements and protocols as specified in OASIS SAML 2.0 profile of XACML v2.0.
- The Policy Repository itself acts as a Policy Enforcing Service Provider being grouped with a XUA X-Service Provider actor. Therefore it is capable of processing identities communicated in a SAML identity assertion.
- The Policy Repository responds to PPQ Requests according to the result of ADR (transaction is allowed or not allowed to be performed).
- Respectively, Policy Managers are grouped with a XUA X-Service User to convey the current user's identity.

2.4.3 Actors / Transactions

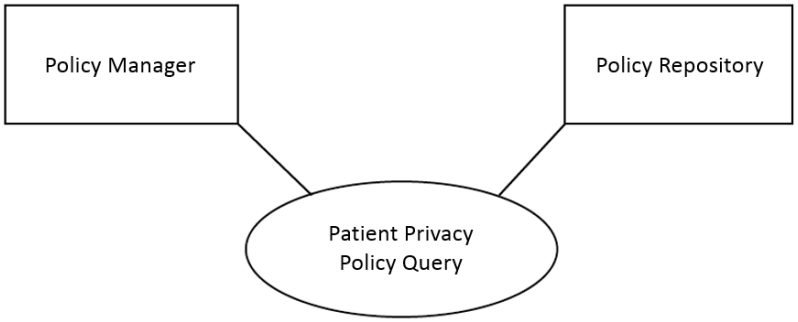


Figure 5: Actors involved in the PPQ profile.

Actor:	Policy Manager
Role:	This actor queries for existing policy sets, adds new policy sets, updates or deletes existing policy sets.
Actor:	Policy Repository
Role:	This actor acts as a XACML Policy Administration Point

Table 2: Actor Roles of the PPQ profile.

3 Volume 2 – Transactions

3.1 Authorization Decision Query

3.1.1 Scope

This transaction is used by the Authorization Decisions Consumer to query for authorization decisions, granted and managed by the Authorization Decisions Provider.
The Authorization Decisions Consumer asks for authorizations based on: the requester entity (**Subject**), the **Resources** available to be accessed by the Subject depending on the **Action** that was initiated, each completed by further context parameters.
This transaction is based on SOAP v1.2 exchange protocol and Synchronous Web services (See ITI TF-2x: Appendix V).

3.1.2 Referenced Standards

OASIS SOAP v1.2
OASIS Security Assertion Markup Language (SAML) v2.0
OASIS eXtensible Access Control Markup Language (XACML) v2.0
OASIS Multiple Resource Profile of XACML v2.0
OASIS SAML 2.0 profile of XACML v2.0
OASIS Cross-Enterprise Security and Privacy Authorization (XSPA) Profile of SAML v2.0 for Healthcare Version 2.0 (not normative)

3.1.3 Interaction Diagram

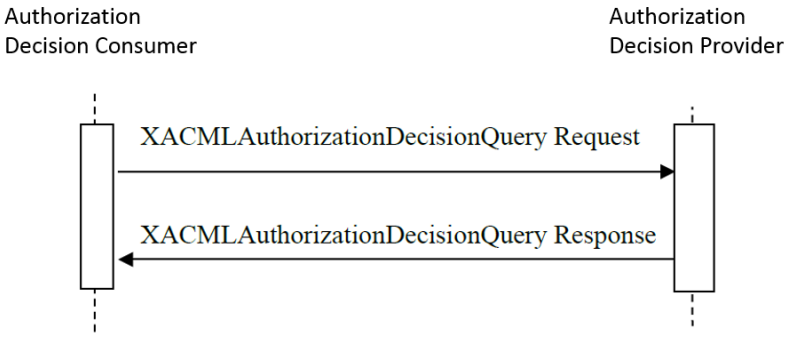


Figure 6: Sequence diagram of the XACMLAuthzDecisionQuery transaction of the ADR profile.

3.1.4 XACMLAuthzDecisionQuery Request

This message enables the Authorization Decisions Consumer to query the Authorization Decisions Provider for authorizations. This message relies on the SAML v2.0 extension for XACML and uses the element <XACMLAuthzDecisionQuery> to convey the Resource metadata, Subject identifier and Actions. The Authorization Decisions Consumer can ask for authorization regarding a number Resources in one query as the request message complies with the Multiple Resource Profile of XACML v2.0. Actors involved support XUA and use SAML identity assertions to identify entities (See ITI TF-1: 39.5 and 39.6). SAML attribute elements SHALL be mapped into XACML context attribute elements as defined in SAML 2.0 profile of XACML v2.0.

3.1.5 Trigger Events

The Authorization Decision Consumer of the EPD sends this message when it needs to verify whether there is an authorization to disclose specific Resources to an entity requesting them; e.g. to allow or deny access to and the manipulation of policies stored by a policy repository or to allow or deny access to document metadata stored in a Document Registry based on the entry's confidentiality code. In addition to that the Authorization Decision Consumer of the EPD sends this message when it needs to verify whether there is an authorization to persist specific Resources e.g. to allow or deny storage of document metadata in a Document Registry based on the entry's confidentiality code. The trigger events are:

- The grouped XDS Document Registry receiving a Registry Stored Query Request [ITI-18] and a Provide X-User Assertion [ITI-40] transaction, that identifies the specific requester entity within a SAML assertion, from an XDS Document Consumer;
- The grouped XDS Document Registry receiving a Register Document Set-b [ITI-42] and a Provide X-User Assertion [ITI-40] transaction, that identifies the specific requester entity within a SAML assertion, from an XDS Document Repository;
- The grouped PPQ Policy Repository receiving a Privacy Policy Query transaction (see this document) and a Provide X-User Assertion [ITI-40] transaction from a PPQ Policy Manager that identifies the specific requester entity within a SAML assertion.

3.1.6 Message Semantics

3.1.6.1 ADR due to XDS Registry Stored Query [ITI-18]

For the XDS Registry Stored Query related access decision enforcement, the EPD relies on the XDS Confidentiality Code within the document metadata to be accessed to represent a subset of the patient's health record. The Authorization Decisions Consumer MUST create one request to query for an access decision for each subset (rather than the actual document metadata objects), before providing the corresponding document metadata to a consumer. Therefore one of the attributes of each Resource within the Request must be a XDS confidentiality code defining the subset for an access decision to be made on (details below).

ADR due to XDS Register Document Set-b [ITI-42]

For the XDS Register Document Set related access decision enforcement, the EPD relies on the XDS Confidentiality Code within the document metadata to be stored in the patient's Health Record. The Authorization Decisions Consumer (Document Registry) MUST create one request to query for an access decision for each Confidentiality Code, before allowing the Register transaction to a Document Repository. One of the attributes of each Resource within the Request must be a XDS confidentiality code for an access decision to be made on (details below).

3.1.6.2 ADR due to PPQ

The EPD allows patients and their guardians to manage the patient's Health Record access rights. In addition to that, the patient may allow a professional to delegate his access rights to another professional if necessary.

In the case of ADR due to PPQ an access decision must be requested for each actual object (Resource) that access is being requested for (not a class of objects as it is the case for ADR due to XDS). Each Resource represents a policy set that's being queried, added, deleted or updated by a PPQ transaction. An access decision is to be requested for each of these Resources before the corresponding action can be granted (or has got to be denied, depending on the decision).

A professional may only delegate access rights to another professional not exceeding her or his own access level that was initially granted by the patient. The access level to be granted is encoded within the value of the referenced-policy-set attribute. Therefore, in case of ADR due to PPQ, one of the attributes of each Resource must be a referenced policy set (details below).

3.1.6.3 Semantics

The XACMLAuthzDecisionQuery Request message SHALL use SOAP v1.2 message encoding. The WS-Addressing Action header SHALL have this value:

urn:e-health-suisse:2015:policy-enforcement:AuthorizationDecisionRequest

The recipient of the Authorization Decision Query SHALL be identified by the WS-Addressing To header (URL of the endpoint).

A SAML 2.0 Identity Assertion SHALL be conveyed within the WS-Security Security header.

```
<soap:Envelope xmlns:soap=http://schemas.xmlsoap.org/soap/envelope/
        xmlns:wsa=http://www.w3.org/2005/08/addressing xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance
        xmlns:wsse=http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd
        xmlns:ds=http://www.w3.org/2000/09/xmldsig# xmlns:xacml-saml="urn:oasis:xacml:2.0:saml:assertion:schema:os"
        xmlns:xacml-samlp="urn:oasis:xacml:2.0:saml:protocol:schema:os"
        xmlns:saml="urn:oasis:names:tc:SAML:2.0:assertion" xmlns:xacml="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
        xmlns:epd="urn:e-health-suisse:2015:policy-administration"
        xmlns:xacml-context="urn:oasis:names:tc:xacml:2.0:context:schema:os" xmlns:hl7="urn:ihe-d:hl7-org:v3"
        xsi:schemaLocation="http://schemas.xmlsoap.org/soap/envelope/ http://schemas.xmlsoap.org/soap/envelope/
                http://www.w3.org/2005/08/addressing urn:e-health-suisse:2015:policy-administration
                epd-policy-administration-combined-schema-1.0-local.xsd ws-addr.xsd ">
  <soap:Header>
    <wsa:Action>urn:e-health-suisse:2015:policy-enforcement:AuthorizationDecisionRequest</wsa:Action>
    <wsa:MessageID>urn:uuid:e4bb38c7-e546-4bb1-8d68-2bccf783dfbf</wsa:MessageID>
    <wsa:To>https://e-health-suisse-adr-provider.ch</wsa:To>
    <wsse:Security>
      <saml:Assertion>
        <!--SAML Assertion as described above-->
      </saml:Assertion>
    </wsse:Security>
  </soap:Header>
  <soap:Body>
   <!—ADR TRANSACTION PAY LOAD-->
  </soap:Body>
</soap:Envelope>
```

Listing 7: The SOAP envelope with the security header and the transaction payload of the ADR transactions. For better reading placeholder are used for the SAML assertions and the transaction payload.

The body of the message SHALL use an **<XACMLAuthzDecisionQuery>** element (defined in the SAML 2.0 Profile for XACML v2.0) to convey a <Request> with the Authorization Query parameters (Subject, Resource, Action, Environment). This element SHALL contain the following attribute:
@ReturnContext SHOULD be set to "**false**" because the content of the XACMLAuthzDecisionQuery Request is not needed within the Authorization Result.
@InputContextOnly SHALL be set to "**false**", as the Authorization Decision Provider may have further information and rules, other than the parameters included in the request, to determine a decision. This should not be restricted by the Authorization Decision Consumer.
This profile does not define further constraints for other attributes of this element (see OASIS SAML 2.0 profile of XACML v2.0 for details).

```
<soap:Body>
  <xacml-samlp:XACMLAuthzDecisionQuery InputContextOnly="false" ReturnContext="false"
  ID="_682fee8b-46c0-442a-8c54-fd9d656412fc" Version="2.0" IssueInstant="2016-02-09T09:30:10.5Z">
    <xacml-context:Request>
      <!--Request Parameters-->
    </xacml-context:Request>
  </xacml-samlp:XACMLAuthzDecisionQuery>
</soap:Body>
```

Listing 8: The SOAP body element for the XACMLAuthzDecisionQuery transaction. For better reading a placeholder is used for the request parameter.

The <XACMLAuthzDecisionQuery> element SHALL have only one child element **<Request>.** This element SHALL comply with OASIS Multiple Resource Profile of XACML v2.0. This element SHALL have the XACML child elements **<Subject>, <Resource>, <Action> and <Environment>**. <Request> and all subsequent elements, attributes and values comply to the namespace xmlns:xacml-context="urn:oasis:names:tc:xacml:2.0:context:schema:os". The namespace is left out of the following examples for better readability.

```
<soap:Body>
  <XACMLAuthzDecisionQuery>
    <Request>
      <Subject>
        <!--Attributes-->
      </Subject>
      <Resource>
        <!--Attributes-->
      </Resource>
      <Resource>
        <!--There can be more than one Resource-->
      </Resource>...
      <Action>
        <!--Attribute-->
      </Action>
      <Environment/>
    </Request>
  </XACMLAuthzDecisionQuery>
</soap:Body>
```

Listing 9: The schematic payload of the XACMLAuthzDecisionQuery request. For better reading placeholder are used for the XACML request elements.

<Subject> identifies the Requester Entity. It SHALL have at least the following **<Attribute>** child elements:

@AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id" and **@DataType="http://www.w3.org/2001/XMLSchema#string"**.
The **<AttributeValue>** child element SHALL convey the subject identifier. This element SHALL have the same value of the /Subject/NameID element conveyed within the SAML assertion.

@AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id-qualifier" and **@DataType=" http://www.w3.org/2001/XMLSchema#string"**.
The **<AttributeValue>** child element SHALL convey the subject ID qualifier. This element SHALL have the same value as the /Subject/NameID/@NameQualifier conveyed within the SAML assertion, e.g. **urn:e-health-suisse:epd-pid** in case of a patient or guardian or **urn:gs1:gln** in case of a professional or auxiliary person.

@AttributeId="urn:ihe:iti:xca:2010:homeCommunityId" and **@DataType="http://www.w3.org/2001/XMLSchema#anyURI"**.
The **<AttributeValue>** child element SHALL convey the home community id. This value is not necessarily conveyed within the XUA SAML assertion. It SHALL be set to the OID of the Authorization Decision Consumer's community.

@AttributeId="urn:oasis:names:tc:xacml:2.0:subject:role" and **@DataType="urn:hl7-org:v3#CV"**.
The **<AttributeValue>** child element SHALL convey the coded value for the subject's role. This element SHALL have the same value as the

/AttributeStatement/Attribute[@name=”urn:oasis:names:tc:xacml:2.0:subject:role”]/AttributeValue conveyed within the SAML assertion.

@AttributeId=”urn:oasis:names:tc:xacml:2.0:subject:organization-id” and **@DataType=” http://www.w3.org/2001/XMLSchema#anyURI”**.
The **<AttributeValue>** child element SHALL convey the organization identifier. This element SHALL have the same value as the organization-id conveyed within the SAML assertion.

@AttributeId=”urn:oasis:names:tc:xacml:2.0:subject:purposeofuse” and **@DataType=”urn:hl7-org:v3#CV”**.
The **<AttributeValue>** child element SHALL convey the coded value for the subject’s purpose of use. This element SHALL have the same value of the <AttributeStatement>/<Attribute>/<AttributeValue> element **@PurposeOfUse** conveyed within the SAML assertion.

```
<Request>
  <Subject>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id"
               DataType="http://www.w3.org/2001/XMLSchema#string">
      <Attribute>4567</AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:1.0:subject:subject-id-qualifier"
               DataType="http://www.w3.org/2001/XMLSchema#string">
      <AttributeValue> urn:e-health-suisse:epd-pid</AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:ihe:iti:xca:2010:homeCommunityId"
               DataType="http://www.w3.org/2001/XMLSchema#anyURI">
      <AttributeValue>1.2.756.113619.20.2.6.1</AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:2.0:subject:role“
               DataType="urn:hl7-org:v3#CV">
      <AttributeValue>
        <hl7:CodedValue code=“1" codeSystem="2.999.8" displayName=“Patient(in)"/>
      </AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:2.0:subject:organization-id"
               DataType="http://www.w3.org/2001/XMLSchema#anyURI">
      <Attribute Value>urn:e-health-suisse:gln:92375058</AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:2.0:subject:purposeofuse"
               DataType="urn:hl7-org:v3#CV">
      <AttributeValue>
        <hl7:CodedValue code="1" codeSystem=" 2.16.756.5.30.1.xxx" displayName=“Normalzugriff"/>
      </AttributeValue>
    </Attribute>
</Subject>
  <Resource/>
  <Action/>
  <Environment/>
</Request>
```

Listing 10: Example of the subject attributes elements of the XACMLAuthzDecisionQuery request.

<Resource> identifies the object (ADR due to PPQ) or class of objects (ADR due to XDS) an Authorization Decision is requested for. It SHALL at least have the following **<Attribute>** child elements. The Authorization Decisions Provider MAY ignore any attribute not defined in this specification.

@AttributeId=”urn:oasis:names:tc:xacml:1.0:resource:resource-id” and **@DataType=”http://www.w3.org/2001/XMLSchema#anyURI”**.
The **<AttributeValue>** child element SHALL convey the resource identifier.

For ADR due to XDS [ITI-18] and [ITI-42] there are always exactly four Resources to be identified, each representing a class of documents: useful, medical, sensitive and confidential documents. The value MUST be constructed dynamically containing the patient’s national identifier extension that was conveyed in the SAML assertion of the XDS transaction identifying the resource (resource-id). The four resource identifiers for ADR due to XDS are:
urn:e-health-suisse:2015:epd-subset:4567:useful,
urn:e-health-suisse:2015:epd-subset:4567:medical,
urn:e-health-suisse:2015:epd-subset:4567:sensitive and
urn:e-health-suisse:2015:epd-subset:4567:confidential with 4567 as an example value of the patient ID.

For ADR due to PPQ an Authorization Decision MUST be requested for each object itself, not a class of objects. In that case the value is the uuid of a Policy Set the Entity (Subject) is asking access for by a PPQ query, add, update or delete policy, e.g.: **c969c7cd-9fe9-4fdc-83c5-a7b5118922a3**.
Therefore, for ADR due to PPQ, there is not a fixed number of <Resource>s (with corresponding Resource IDs) to be specified within the request.

@AttributeId=”urn:e-health-suisse:2015:epd-pid” and **@DataType=”urn:hl7-org:v3#II”**.
The **<AttributeValue>** child element SHALL convey the patient’s national identifier that was conveyed in the SAML assertion of the XDS transaction identifying the resource (resource-id).

For ADR due to XDS each Resource element MUST also contain the actual confidentiality code corresponding to the resource-id as another attribute: **@AttributeId=”urn:ihe:iti:xds-b:2007:confidentiality-code”** and **DataType=”urn:hl7-org:v3#CV”**.
The **<AttributeValue>** child element SHALL convey a confidentiality code, e.g. **<hl7:CodedValue code="2" codeSystem="2.999.1" displayName="useful data"/>**.

Example for one of the four Resource elements in case of ADR due to XDS [ITI-18]/[ITI-42]:

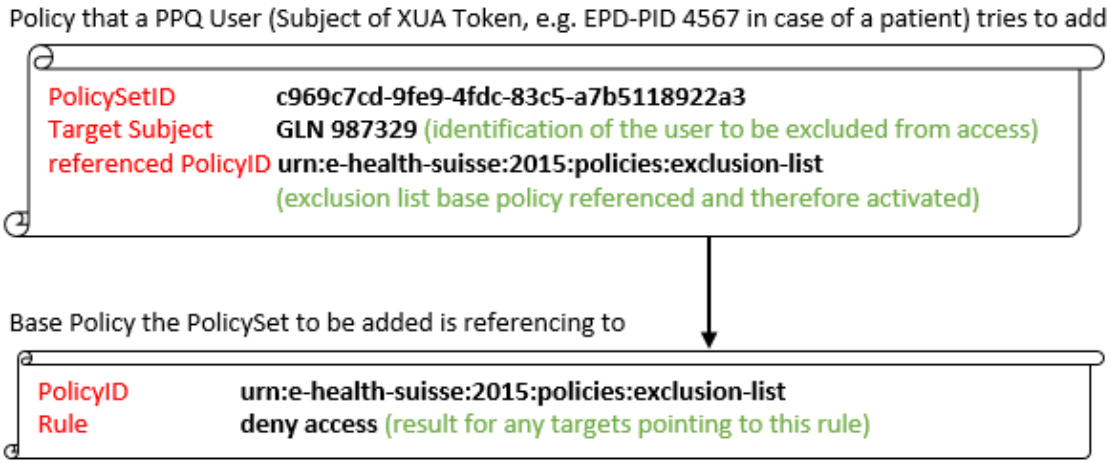
```
<Request>
  <Subject/>
  <Resource>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:1.0:resource:resource-id“
               DataType="http://www.w3.org/2001/XMLSchema#anyURI">
      <AttributeValue>urn:e-health-suisse:2015:epd-subset:8901:useful</AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:e-health-suisse:2015:epd-pid“
               DataType="urn:hl7-org:v3#II">
      <AttributeValue><hl7:InstanceIdentifier root="2.999.1" extension=“8901"/></AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:ihe:iti:xds-b:2007:confidentiality-code“
               DataType="urn:hl7-org:v3#CV">
      <AttributeValue>
        <hl7:CodedValue code="2" codeSystem="2.999.2" displayName=“useful data"/>
      </AttributeValue>
    </Attribute>
  </Resource>
  <Resource>
    <!-- resource element for medical documents corresponding to the example above -->
  </Resource>
  <Resource>
    <!-- resource elements for sensitive documents corresponding to the example above -->
  </Resource>
  <Resource>
    <!-- resource elements for confidential documents corresponding to the example above -->
  </Resource>
  <Action/>
  <Environment/>
</Request>
```

Listing 11: Example of the resource attributes of the XACMLAuthzDecisionQuery request payload. For better reading the part for one confidentiality code is shown in detail, while for the other confidentiality codes placeholders are used.

For ADR due to PPQ each Resource element MUST also contain the **referenced** policy **within** the policy set to be potentially returned, added, updated or deleted (according to the first resource attribute).
@AttributeId=”urn:e-health-suisse:2015:policy-attributes:referenced-policy-set” and **DataType=”urn:hl7-org:v3#CV”**.
The **<AttributeValue>** child element SHALL convey the Policy Identifier that is being referenced within the Policy Set to be queried, added, updated or deleted, e.g. **urn:e-health-suisse:2015:policies:exclusion-list**.

The following example is to clarify this requirement:
If a user (e.g. a patient) tries to add a policy set with ID c969c7cd-9fe9-4fdc-83c5-a7b5118922a3 (as in @AttributeId=”urn:oasis:names:tc:xacml:1.0:resource:resource-id”) that adds somebody (e.g. GLN 7609999999999) to the exclusion list, the policy set will contain a reference to another policy from the base configuration, which will have the policy set ID urn:e-health-suisse:2015:policies:exclusion-list. That’s the value to be included within the Resource attribute @AttributeId=”urn:e-health-suisse:2015:policy-attributes:referenced-policy-set”.

An illustration of the usecase:



Correspondingly, the Resource element of an ADR due to PPQ transaction (to verify if the PPQ user 4567 may be allowed to perform this transaction) SHALL be constructed as in the following example:

```
<Request>
  <Subject/>
  <Resource>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:1.0:resource:resource-id“
               DataType="http://www.w3.org/2001/XMLSchema#anyURI">
      <AttributeValue>c969c7cd-9fe9-4fdc-83c5-a7b5118922a3</AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:e-health-suisse:2015:epd-pid“
               DataType="urn:hl7-org:v3#II">
      <AttributeValue><hl7:InstanceIdentifier root="2.999.1" extension="4567"/></AttributeValue>
    </Attribute>
    <Attribute AttributeId="urn:e-health-suisse:2015:policy-attributes:referenced-policy-set"
               DataType="urn:hl7-org:v3#CV">
      <AttributeValue>urn:e-health-suisse:2015:policies:exclusion-list</AttributeValue>
    </Attribute>
  </Resource>
  <Resource>
    <!—further resource elements-->
  </Resource>
  <Action/>
  <Environment/>
</Request>
```

Listing 12: Example of resource attributes of the XACMLAuthzDecisionQuery request payload for ADR due to PPQ to request an authorization decision for access to the patient's policy configuration.

<Action> identifies the transaction being performed by the Requester Entity. The <Action> element SHALL have one **<Attribute>** child element:

@AttributeId="urn:oasis:names:tc:xacml:1.0:action-id" and
@DataType="http://www.w3.org/2001/XMLSchema#anyURI".
The **<AttributeValue>** child element SHALL convey the action identifier:
urn:e-health-suisse:2015:policy-administration:PolicyQuery or
urn:e-health-suisse:2015:policy-administration:AddPolicy or
urn:e-health-suisse:2015:policy-administration:UpdatePolicy or
urn:e-health-suisse:2015:policy-administration:DeletePolicy for ADR due to PPQ or
urn:e-health-suisse:2015:action:RegistryStoredQuery for ADR due to XDS ITI-18 or
urn:e-health-suisse:2015:action:RegisterDocumentSet for ADR due to XDS ITI-42.

```
<Request>
  <Subject/>
  <Resource/>
  <Action>
    <Attribute AttributeId="urn:oasis:names:tc:xacml:1.0:action-id"
               DataType="http://www.w3.org/2001/XMLSchema#anyURI">
      <AttributeValue>urn:e-health-suisse:2015:policy-administration:AddPolicy</AttributeValue>
    </Attribute>
  </Action>
  <Environment/>
</Request>
```

Listing 13: Example of the action setting of XACMLAuthzDecisionQuery request for ADR due to PPQ.

<Environment> The EPD does not specify any <Environment> parameters within the XACMLAuthzDecisionQuery. Therefore this child element MAY be empty: **<Environment />**. The Authorization Decision Provider MAY ignore any attribute in this section when arriving at an authorization decision. However, there is a constraint to the use of <Environment> in case of inputContextOnly of <XACMLAuthzDecisionQuery> was set to true. In that case, current time and date MUST be provided as attributes of <Environment>.

3.1.7 Expected Actions

The Authorization Decisions Provider SHALL return Authorization Decisions that match the XACML Query parameters according to the rules defined in XACML policies.

The Authorization Decision Provider SHALL produce a XACMLAuthzDecisionQuery Response message that conveys the results of the evaluation of the patient's policies against the request. One result for each Resource SHALL be included in the response message.

3.1.8 XACMLAuthzDecisionQuery Response

The XACMLAuthzDecisionQuery Response message is created by the Authorization Decisions Provider in response to the XACMLAuthzDecisionQuery Request. This message conveys to the Authorization Decisions Consumer the results of the evaluation made by the Authorization Decisions Provider. For each Resource specified within the Request message, the Authorization Decisions Provider provides an Authorization Result that SHALL be used by the Authorization Decisions Consumer to determine which of the requested objects are to be returned or transactions to be allowed in response to the corresponding initial transactions. This message relies on OASIS SAML 2.0 profile of XACML v2.0 protocol standard. Authorization Results are conveyed using the XACMLAuthzDecisionStatement.

3.1.9 Trigger Events

This message is created by the Authorization Decisions Provider after the evaluation of the XACMLAuthzDecisionQuery Request message. The Authorization Decision Provider MUST only return Authorization Decisions applicable to the request.

3.1.10 Message Semantics

The XACMLAuthzDecisionQuery Response message is based on OASIS SAML 2.0 profile of XACML v2.0.
The WS-Addressing Action header of the SOAP message SHALL be:
urn:e-health-suisse:2015:policy-enforcement:XACMLAuthzDecisionQueryResponse

As defined in OASIS SAML 2.0 profile of XACML v2.0, the XACML Authorization Statement is conveyed within a SAML v2.0 Assertion. The Assertion does not need to be signed. In case of all Resources resulting in a decision of “Indeterminate” (details below), the SAML /Status/**StatusCode** of the Assertion shall be the same as the /Result/Status/StatusCode/@Value of the Response: urn:e-health-suisse:2015:error:not-holder-of-patient-policies. Otherwise the SAML /Status/**StatusCode** of the Assertion SHALL be supplied as defined in section 7.3.1 of OASIS SAML 2.0 profile of XACML v2.0.
The **<Issuer>** of the Authorization Assertion MUST identify the Authorization Decisions Provider. For the EPD this ID is specified to be the home community ID of the Authorization Decision Provider community encoded as an URN, e.g.
<saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.99</saml:Issuer>.

```
<soap:Body>
  <saml:Assertion
   xmlns:xacml-samlp="urn:oasis:xacml:2.0:saml:protocol:schema:os"
   xmlns:xacml-saml="urn:oasis:xacml:2.0:saml:assertion:schema:os" xmlns:saml="urn:oasis:names:tc:SAML:2.0:assertion"
   xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance xmlns:xacml="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
   xmlns:xacml-context="urn:oasis:names:tc:xacml:2.0:context:schema:os" xmlns:hl7="urn:ihe-d:hl7-org:v3"
   xsi:schemaLocation="urn:oasis:xacml:2.0:saml:assertion:schema:os access_control-xacml-2.0-saml-assertion-schema-os.xsd
   urn:ihe-d:hl7-org:v3 ihe-d-xacml-hl7-datatypes-base-1.0.xsd" ID="_79f6b857-f5ad-4b38-bebe-ef51aa9949b8"
   Version="2.0" IssueInstant="2016-02-05T09:30:10.5Z">
    <saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.999.1.1</saml:Issuer>
    <saml:Status>
      <samlp:StatusCode>urn:oasis:names:tc:SAML:2.0:status:Success</samlp:StatusCode>
    </saml:Status>
    <saml:Statement xsi:type="xacml-saml:XACMLAuthzDecisionStatementType">
    <xacml-context:Response>
        <!--Decision Result per Resource-->
      </xacml-context:Response>
    </saml:Statement>
  </saml:Assertion>
</soap:Body>
```

Listing 14: Schematic payload of the XACMLAuthzDecisionQuery response. For better reading the

details of the response is suppressed and shown in the listings below.
As specified in the OASIS multiple resource profile of XACML v2.0, the XACML **<Response>** element SHALL contain a **<Result>** element for each **<Resource>** element contained within the XACMLAuthzDecisionQuery Request message. Each <Result> element SHALL contain a @**ResourceId** attribute that identifies which Resource an Access Decision belongs to. A child element **<Decision>** holds the actual decision value.
In case of the decision code of a Result equaling to “Deny”, “Permit” or “NotApplicable”, the /Result/Status/**StatusCode**/@Value attribute SHALL equal to "urn:oasis:names:tc:xacml:1.0:status:ok". In case of “Indeterminate” it SHALL equal to “urn:e-health-suisse:2015:error:not-holder-of-patient-policies”.
<Response> and all subsequent elements, attributes and values comply to the namespace xmlns:xacml-context="urn:oasis:names:tc:xacml:2.0:context:schema:os". The namespace is left out of the following examples for better reading purposes.

```
<Response>
  <Result ResourceId="e693657c-50be-46a6-bdcd-05269147f357">
    <Decision>Deny</Decision>
    <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
  <Result ResourceId="1c9fa73c-2b9c-41b2-a814-f9164e073c15">
    <Decision>Permit</Decision>
    <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
  <Result ResourceId="c969c7cd-9fe9-4fdc-83c5-a7b5118922a3">
    <Decision>Permit</Decision>
    <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
</Response>
```

Listing 15: Example for a response to an ADR due to PPQ request.

```
<Response>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:useful">
    <Decision>Permit</Decision>
    <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:medical">
    <Decision>Permit</Decision>
    <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:sensitive">
    <Decision>NotApplicable</Decision>
    <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:confidential">
    <Decision>NotApplicable</Decision>
   <Status>
      <StatusCode Value="urn:oasis:names:tc:xacml:1.0:status:ok"/>
    </Status>
  </Result>
</Response>
```

Listing 16: Example for a Response to an ADR due to XDS message if 4567 was the patient ID (EPD-PID) of the Health Record to be accessed.

As defined in the XACML v2.0 standard, there are four possible values associated with the **<Decision>**. The Authorization Decisions Provider shall use these values as described below:

- **Permit**: if the evaluation was successful and the Subject is authorized to perform the Action on the Resource;
- **Deny:** if the evaluation was successful and the Subject is explicitly not authorized to perform the Action on the Resource.
- **NotApplicable**: if the evaluation was successful, but the Subject is not authorized to perform the Action on the Resource. E.g. a Permit decision can be determined on the Resource “useful data”, but no permit or deny decision can be determined for the other resources in the request. The decision code for the other resources MUST be NotApplicable.
- **Indeterminate**: if the evaluation succeeded, but access to the requested Resource is not managed by the Authorization Decisions Manager, or if the evaluation failed. The EPD specifically defines this decision code to be returned, if access rights for a given patient are not managed in the associated Policy Repository and therefore cannot be determined by the Authorization Decision Provider. To distinguish between those two cases, clients may evaluate the /Result/Status/StatusCode/@Value attribute, which has to equal "urn:e-health-suisse:2015:error:not-holder-of-patient-policies" if the Policy Repository is not responsible for holding the given patient policies.

```
<Response>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:useful">
    <Decision>Indeterminate</Decision>
    <Status>
      <StatusCode Value="urn:e-health-suisse:2015:error:not-holder-of-patient-policies"/>
      <StatusMessage>Gemeinschaft ist nicht die Stammgemeinschaft des Patienten</StatusMessage>
    </Status>
  </Result>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:medical">
    <Decision>Indeterminate</Decision>
    <Status>
      <StatusCode Value="urn:e-health-suisse:2015:error:not-holder-of-patient-policies"/>
      <StatusMessage>Gemeinschaft ist nicht die Stammgemeinschaft des Patienten</StatusMessage>
    </Status>
  </Result>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:sensitive">
    <Decision>Indeterminate</Decision>
    <Status>
      <StatusCode Value="urn:e-health-suisse:2015:error:not-holder-of-patient-policies"/>
      <StatusMessage>Gemeinschaft ist nicht die Stammgemeinschaft des Patienten</StatusMessage>
    </Status>
  </Result>
  <Result ResourceId="urn:e-health-suisse:2015:epd-subset:4567:confidential">
    <Decision>Indeterminate</Decision>
    <Status>
      <StatusCode Value="urn:e-health-suisse:2015:error:not-holder-of-patient-policies"/>
      <StatusMessage>Gemeinschaft ist nicht die Stammgemeinschaft des Patienten</StatusMessage>
    </Status>
  </Result>
</Response>
```

Listing 17: The response to a XACMLAuthzDecisionQuery in the case when the patient's policies are not known in the requested community, i.e. when the requested community is not the patients referenceCommunity.

3.1.11 Expected Actions

When the Policy Enforcing Service Provider receives a XACMLAuthzDecisionQuery Response, it SHALL enforce the decision results according to the following EPD policy.

If a **Deny** or **NotApplicable** decision is returned, the

- XDS Document Registry SHALL not disclose the related document metadata in response to ITI-18;
- XDS Document Registry SHALL not store any document metadata from a submission set containing a document that has a confidentiality code for which such a decision was returned and return a XDS registration failure to the XDS Document Repository in response to ITI-42;
- PPQ Policy Repository SHALL not allow the initial PPQ transaction, respectively not return the policy data or make the requested changes to the policies.

If a **Permit** decision is returned, the

- XDS Document Registry SHALL disclose the document metadata with the given confidentiality code in response to ITI-18;
- XDS Document Registry SHALL perform the initiated transaction for a submission set containing documents with a corresponding confidentiality code as long as all of the documents of a submission set have a confidentiality code that was permitted by the ADR Response (otherwise see “Deny or NotApplicable” above);
- Policy Repository shall perform the initiated transactions, respectively return the policy data that has been queried for.

If **Indeterminate** is returned, the

- XDS Document Registry MUST request a decision from another Authorization Decisions Provider (XADR as defined below). If there is no Authorization Decisions Provider that returns Deny, NotApplicable or Permit, then the Document Registry SHALL not disclose any document metadata in response to ITI-18 or not perform the ITI-42 transaction respectively.
- PPQ Policy Repository SHALL not allow the initial PPQ transaction, respectively not return the policy data or make the requested changes to the policies.

3.1.12 Enforcement of XDS Retrieve Document Set transactions

The Retrieve of a document MUST be enforced according to the access rights formulated by the patient. If the document metadata of a document cannot be accessed by a user, a Retrieve of the corresponding document MUST be denied by the Document Repository. To implement this functionality, it is recommended for the Document Repositories to initialize a XDS Registry Stored Query [ITI-18] GetDocuments ObjectRef), combined with the XUA Identity Token provided by the Document Consumer [ITI-40], before supplying the document to the Consumer. If the corresponding Document Id is included in the XDS Registry Stored Query Response, the Document SHALL be supplied to the Document Source. If the corresponding Document Id is not included in the XDS Registry Query Response, the Document SHALL NOT be supplied to the Document Source.
The IHE SeR Profile may provide further guidance on the enforcement of access rights concerning the XDS Retrieve Document Set transaction.

3.1.13 Security Considerations

The Authorization Decisions Query transaction requires TLS communication between actors involved. This transaction mandates the creation of Authorizations associated at least with the Requester Entity and with the document metadata (confidentiality code) requested. If additional parameters need to be associated to the authorization, then the same parameters SHALL be provided within the Authorization Decisions Query transaction.

3.1.14 Authorization Decisions Consumer Audit Message

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV (110112, DCM,"Query")
	EventActionCode	M	E = Execute
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	EV("ADR", "e-health-suisse", "Authorization Decisions Query")
Source (Authorization Decisions Consumer) (1)			
Destination (Authorization Decisions Consumer) (1)			
Query Parameters (1..n)			
Requester Entity (1)			
Authorization Result (1..n)			

Source: AuditMessage/ ActiveParticipant	*UserID*	*U*	*not specialized*
	AlternativeUserID	MC	the process ID as used within the local operating system in the local system of logs
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110153, DCM, "Source")
	NetworkAccessPointTypeCode	U	"1" for machine (DNS) name "2" for IP address
	NetworkAccessPointID	U	The machine name or IP address, as specified in DICOM PS 3.15 A.5.3.

Destination: AuditMessage/ ActiveParticipant (1)	UserID	M	Authorization Decisions Provider SOAP URI
	AlternativeUserID	U	the process ID as used within the local operating system in the local system of logs
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110152, DCM, "Destination")
	NetworkAccessPointTypeCode	U	"1" for machine (DNS) name "2" for IP address
	NetworkAccessPointID	U	The machine name or IP address, as specified in DICOM PS 3.15 A.5.3.

Requester Entity: AuditMessage/ ParticipantObjectIdentification (1)	ParticipantObjectTypeCode	M	"1" (person)
	ParticipantObjectTypeCodeRole	M	"11" (security user entity)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV("ADR", "e-health-suisse", "Authorization Decisions Query")
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	M	The Requester Entity (identified in the Attribute with AttributeId

			urn:oasis:names:tc:xacml:1.0:subject:subject-id)
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

Query Parameters: AuditMessage/ ParticipantObjectIdentification (1..n)	ParticipantObjectTypeCode	M	“2” (SYSTEM)
	ParticipantObjectTypeCodeRole	M	“24” (query)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“ADR”, “e-health-suisse”, “Authorization Decisions Query”)
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	*M*	*not specialized*
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	M	Resource-ID
	ParticipantObjectDetail	*U*	*not specialized*

Authorization Result: AuditMessage/ ParticipantObjectIdentification (1..n)	ParticipantObjectTypeCode	M	**“**2” (SYSTEM)
	ParticipantObjectTypeCodeRole	M	“13” (security resource)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“ADR”, “e-health-suisse”, “Authorization Decisions Query”)
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	M	Resource-ID
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	*U*	*not specialized*
	ParticipantObjectDetail	M	Decision Code (Permit, Deny, NotApplicable, Indeterminate)

3.1.15 Authorization Decisions Provider Audit Message

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV (110112, DCM,“Query”)
	EventActionCode	M	E = Execute
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	EV(“ADR”, “e-health-suisse”, “Authorization Decisions Query”)
Source (Authorization Decisions Provider) (1)			
Destination (Authorization Decisions Provider) (1)			
Query Parameters (1..n)			
Requester Entity (1)			
Authorization Result (1..n)			

Source: AuditMessage/ ActiveParticipant	*UserID*	*U*	*not specialized*
	AlternativeUserID	MC	the process ID as used within the local operating system in the local system of logs
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110153, DCM, “Source”)
	NetworkAccessPointTypeCode	U	“1” for machine (DNS) name “2” for IP address
	NetworkAccessPointID	U	The machine name or IP address, as specified in DICOM PS 3.15 A.5.3.

Destination: AuditMessage/ ActiveParticipant (1)	UserID	M	Authorization Decisions Provider SOAP URI
	AlternativeUserID	U	the process ID as used within the local operating system in the local system of logs
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110152, DCM, “Destination”)
	NetworkAccessPointTypeCode	U	“1” for machine (DNS) name “2” for IP address
	NetworkAccessPointID	U	The machine name or IP address, as specified in DICOM PS 3.15 A.5.3.

Requester Entity: AuditMessage/ ParticipantObjectIdentification (1)	ParticipantObjectTypeCode	M	“1” (person)
	ParticipantObjectTypeCodeRole	M	“11” (security user entity)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“ADR”, “e-health-suisse”, “Authorization Decisions Query”)
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	M	The Requester Entity (identified in the Attribute with AttributeId urn:oasis:names:tc:xacml: 1.0:subject:subject-id)
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

Query Parameters: AuditMessage/ ParticipantObjectIdentification (1..n)	ParticipantObjectTypeCode	M	“2” (SYSTEM)
	ParticipantObjectTypeCodeRole	M	“24” (query)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“ADR”, “e-health-suisse”, “Authorization Decisions Query”)
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	*M*	*not specialized*
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	M	Resource-ID
	ParticipantObjectDetail	*U*	*not specialized*

Authorization Result: AuditMessage/ ParticipantObjectIdentification (1..n)	ParticipantObjectTypeCode	M	**“**2” (SYSTEM)
	ParticipantObjectTypeCodeRole	M	“13” (security resource)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“ADR”, “e-health-suisse”, “Authorization Decisions Query”)
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	M	Resource-ID
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	*U*	*not specialized*
	ParticipantObjectDetail	M	Decision Code (Permit, Deny, NotApplicable, Indeterminate)

3.2 Cross-Community Authorization Decision Request (XADR)

Within the EPD, the patient's Health Record access rights are to be stored within the patient's referenceCommunity only. However, each XDS Document Registry MUST act as Policy Enforcing Service Provider, even if the patient's Health Record access rights are not stored within the same community.
That means, any Authorization Decision Consumer grouped with a XDS Document Registry SHALL ask each Authorization Decision Provider, even outside their home community, until a response includes a decision code other than NotApplicable. The XADR request follows the same specification as ADR above. Only the service endpoint of an XADR Authorization Decision Provider will be outside of the community of the Authorization Decision Consumer. There may be strategies to be implemented to reduce the number of necessary service calls, which are out of scope of this specification.
For the Authorization Decision Consumer, grouped with a PPC Policy Repository, this is not a requirement, as patient access rights are always managed by a community specific Policy Manager. In that case, the Authorization Decision Provider is always grouped with the Policy Repository of the Policy Managers community, and therefore is the only source of an ADR due to PPC access decision.

3.3 Privacy Policy Query (PPQ)

3.3.1 Scope

These transactions are used by the Policy Manager to add, query, update or delete authorization policies (respectively XACML policy sets) stored in a Policy Repository.
This transaction is based on SOAP v1.2 exchange protocol and Synchronous Web services (See ITI TF-2x: Appendix V).

3.3.2 Referenced Standards

OASIS SOAP v1.2
OASIS Security Assertion Markup Language (SAML) v2.0
OASIS SAML 2.0 profile of XACML v2.0
OASIS eXtensible Access Control Markup Language (XACML) v2.0
OASIS Multiple Resource Profile of XACML v2.0

3.3.3 Interaction Diagrams

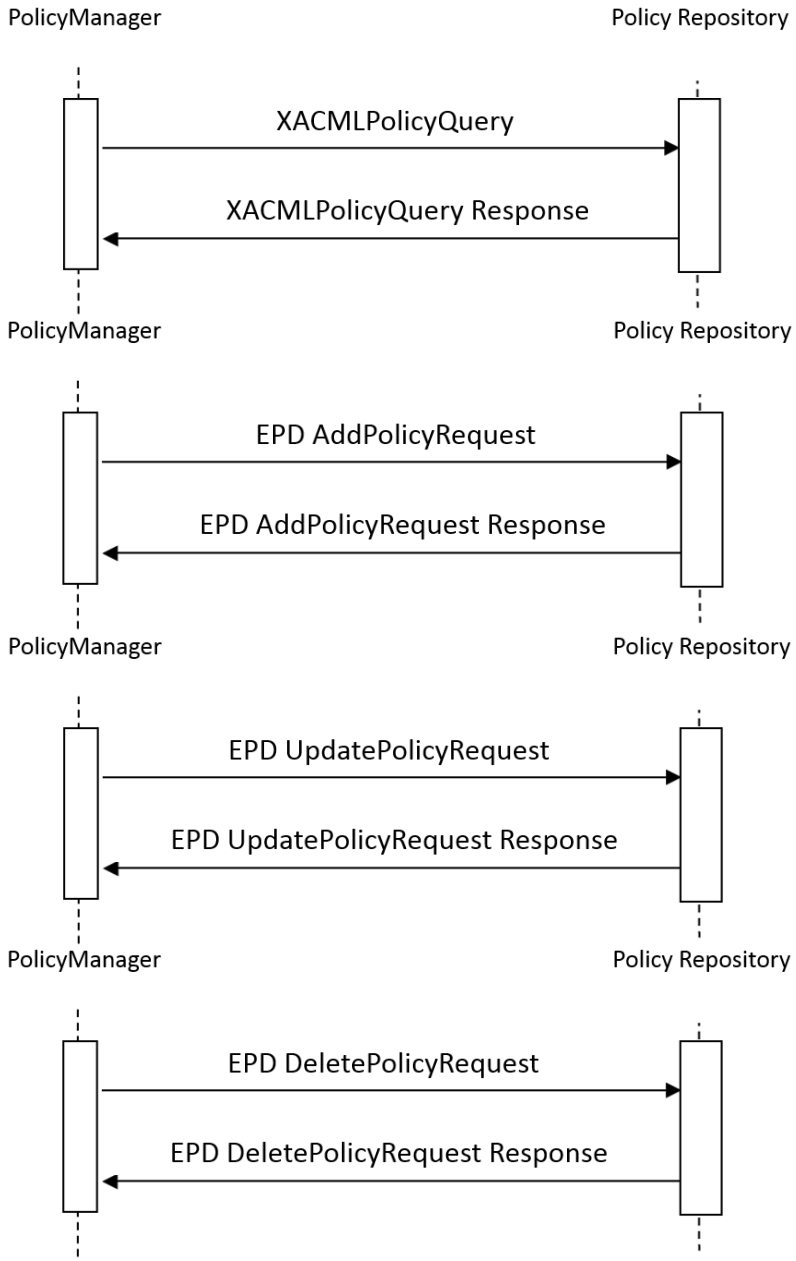


Figure 7: Sequence diagrams for the transactions of the PPQ profile to query, add, update and remove elements of the patient's privacy policy.

3.3.4 Message Semantics SOAP

PPQ Request messages SHALL use SOAP v1.2 message encoding.
The Addressing Action header of the SOAP message SHALL be:
urn:e-health-suisse:2015:policy-administration:PolicyQuery or
urn:e-health-suisse:2015:policy-administration:AddPolicy or
urn:e-health-suisse:2015:policy-administration:UpdatePolicy or
urn:e-health-suisse:2015:policy-administration:DeletePolicy, depending on the corresponding trigger event.
The recipient of the PPQ Request SHALL be identified by the WS-Addressing To header (URL of the endpoint).
A SAML 2.0 Identity Assertion SHALL be conveyed within the WS-Security Security header.

```
<soap:Envelope xmlns:soap=http://schemas.xmlsoap.org/soap/envelope/
               xmlns:wsa=http://www.w3.org/2005/08/addressing xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance
               xmlns:wsse=http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd
               xmlns:ds=http://www.w3.org/2000/09/xmldsig# xmlns:xacml-saml="urn:oasis:xacml:2.0:saml:assertion:schema:os"
               xmlns:xacml-samlp="urn:oasis:xacml:2.0:saml:protocol:schema:os"
               xmlns:saml="urn:oasis:names:tc:SAML:2.0:assertion" xmlns:xacml="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
               xmlns:epd="urn:e-health-suisse:2015:policy-administration"
               xmlns:xacml-context="urn:oasis:names:tc:xacml:2.0:context:schema:os" xmlns:hl7="urn:ihe-d:hl7-org:v3"
               xsi:schemaLocation="http://schemas.xmlsoap.org/soap/envelope/ http://schemas.xmlsoap.org/soap/envelope/
                                   http://www.w3.org/2005/08/addressing urn:e-health-suisse:2015:policy-administration
                                   epd-policy-administration-combined-schema-1.0-local.xsd ws-addr.xsd ">
  <soap:Header>
    <wsa:Action>urn:e-health-suisse:2015:policy-administration:PolicyQuery</wsa:Action><!--or-->
    <wsa:Action>urn:e-health-suisse:2015:policy-administration:AddPolicy</wsa:Action><!--or-->
    <wsa:Action>urn:e-health-suisse:2015:policy-administration:UpdatePolicy</wsa:Action><!--or-->
    <wsa:Action>urn:e-health-suisse:2015:policy-administration:DeletePolicy</wsa:Action>
    <wsa:MessageID>urn:uuid:feafcab1-1f9d-4d46-8321-8af925f55f13</wsa:MessageID>
    <wsa:To>urn:e-health-suisse:2015:actor:EpdPolicyRepository</wsa:To>
    <wsse:Security>
      <saml:Assertion>
        <!--SAML Assertion as described above-->
      </saml:Assertion>
    </wsse:Security>
  </soap:Header>
  <soap:Body>
    <!—PPQ TRANSACTION PAY LOAD-->
  </soap:Body>
</soap:Envelope>
```

Listing 18: The SOAP envelope with the security header, the SAML assertions and the transaction payload of the PPQ request. For better reading placeholder are used for the SAML assertions and the transaction payload.

PPQ Response messages SHALL use SOAP v1.2 message encoding.
The Addressing Action header of the SOAP message SHALL be:
urn:e-health-suisse:2015:policy-administration:PolicyQueryResponse or
urn:e-health-suisse:2015:policy-administration:AddPolicyResponse or
urn:e-health-suisse:2015:policy-administration:UpdatePolicyResponse or
urn:e-health-suisse:2015:policy-administration:DeletePolicyResponse, depending on the corresponding trigger event.
The recipient of the PPQ Response SHALL be identified by the WS-Addressing To header (URL of the endpoint).

```
<soap:Envelope xmlns:soap=http://schemas.xmlsoap.org/soap/envelope/
               xmlns:wsa=http://www.w3.org/2005/08/addressing xmlns:xsi=http://www.w3.org/2001/XMLSchema-instance
               xmlns:wsse=http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd
               xmlns:ds=http://www.w3.org/2000/09/xmldsig# xmlns:xacml-saml="urn:oasis:xacml:2.0:saml:assertion:schema:os"
               xmlns:xacml-samlp="urn:oasis:xacml:2.0:saml:protocol:schema:os"
               xmlns:saml="urn:oasis:names:tc:SAML:2.0:assertion" xmlns:xacml="urn:oasis:names:tc:xacml:2.0:policy:schema:os"
               xmlns:epd="urn:e-health-suisse:2015:policy-administration"
               xmlns:xacml-context="urn:oasis:names:tc:xacml:2.0:context:schema:os" xmlns:hl7="urn:ihe-d:hl7-org:v3"
               xsi:schemaLocation="http://schemas.xmlsoap.org/soap/envelope/ http://schemas.xmlsoap.org/soap/envelope/
                                   http://www.w3.org/2005/08/addressing urn:e-health-suisse:2015:policy-administration
                                   epd-policy-administration-combined-schema-1.0-local.xsd ws-addr.xsd ">
  <soap:Header>
   <wsa:Action>urn:e-health-suisse:2015:policy-administration:PolicyQueryResponse</wsa:Action><!--or-->
   <wsa:Action>urn:e-health-suisse:2015:policy-administration:AddPolicyResponse</wsa:Action><!--or-->
   <wsa:Action>urn:e-health-suisse:2015:policy-administration:UpdatePolicyResponse</wsa:Action><!--or-->
   <wsa:Action>urn:e-health-suisse:2015:policy-administration:DeletePolicyResponse</wsa:Action>
   <wsa:MessageID>urn:uuid:03010066-ba69-43d9-82b1-bb740f8c9a79</wsa:MessageID>
    <wsa:To>urn:e-health-suisse:2015:actor:EpdPolicyManager</wsa:To>
  </soap:Header>
  <soap:Body>
   <!—PPQ RESPONSE PAY LOAD-->
  </soap:Body>
</soap:Envelope>
```

Listing 19: The SOAP envelope with the transaction payload of the PPQ response. For better reading a placeholder is used the response payload.

3.3.5 XACMLPolicyQuery

This message enables the Policy Manager to query the Policy Repository for existing policies of a patient.
This message relies on SAML 2.0 profile of XACML v2.0.
Actors involved support XUA and use SAML identity assertions to identify current user entities for subsequent access enforcement.

3.3.6 Trigger Events

The Policy Manager sends this message when it needs to retrieve existing XACML policies or policy sets of a patient stored by a Policy Repository (of the patient's referenceCommunity).

3.3.7 Message Semantics

This message relies on a SAML v2.0 extension protocol element <xacml-samlp:XACMLPolicyQuery> (as specified in OASIS SAML 2.0 profile of XACML v2.0 to convey a **<Request>**, constructed by the XACML 2.0 policy schema. Following the XACML syntax, the Policy Manager asks for XACML Policies and Policy Sets that match a top-level **<Target>** constructed by a number of **<Resources>**. For the EPD, the patient identified by a patient ID (EPD-PID) is included as a Resource Attribute to be queried for (all policies matching that Resource SHALL be returned if allowed). The Policy Manager MAY query for single Policies too. In that case a Policy ID is required as the match target of the query.

```
<soap:Body>
  <xacml-samlp:XACMLPolicyQuery ID="357cf1d7-d87a-45f5-95ab-e91cbf68a7ad" Version="2.0"
                                IssueInstant=" 2016-02-09T09:30:10.5Z ">
   <xacml-context:Request>
    <xacml:Target>
      <xacml:Resources>
        <xacml:Resource>
          <xacml:ResourceMatch MatchId="urn:hl7-org:v3:function:II-equal">
            <xacml:AttributeValue DataType="urn:hl7-org:v3#II">
              <hl7:InstanceIdentifier root="2.999.1" extension="4567"/>
            </xacml:AttributeValue>
            <xacml:ResourceAttributeDesignator DataType="urn:hl7-org:v3#II"
                                               AttributeId="urn:ihe:iti:xds-b:2007:patient-id"/>
          </xacml:ResourceMatch>
        </xacml:Resource>
      </xacml:Resources>
    </xacml:Target>
   </xacml-context:Request>
  </xacml-samlp:XACMLPolicyQuery>
</soap:Body>
```

Listing 20: Example for the SOAP body element of a XACMLPolicyQuery payload with the XACML syntax to match all patient privacy policies of a specific patient, identified by the patient id.

3.3.8 Expected Actions

The Policy Repository SHALL return all XACML Policies or Policy Sets that match a specific Resource Attribute within their top-level <Target> element.

3.3.9 ACMLPolicyQuery Response

The XACMLPolicyQuery Response message is created by the Policy Repository in response to the XACMLPolicyQuery Request. In conformance to SAML 2.0 profile of XACML v2.0, the Policy Repository SHALL produce a SAML Assertion response message that conveys the resulting Policies and Policy Sets within a Policy Statement.

3.3.10 Trigger Events

This message is created by the Policy Repository after the evaluation of a XACMLPolicyQuery Request message. The Policy Repository identifies Policy Sets applicable to be returned to the requester.

3.3.11 Message Semantics

The **XACMLPolicy <Assertion>** as specified in OASIS SAML 2.0 Profile of XACML v2.0, is conveyed within a XACMLPolicy **<Response>**. The Assertion does not need to be signed.
The **<Issuer>** of the Assertion MUST identify the Policy Repository. For the EPD this ID is specified to be the home community ID of the Authorization Decision Provider community encoded as an URN, e.g.
<saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.99</saml:Issuer>. The SAML **StatusCode** of the /Assertion/Status of the Response SHALL be conveyed as defined in OASIS SAML 2.0 Profile of XACML v2.0, Section 7.3.2.

```
<soap:Body>
  <samlp:Response ID="4v7a68d0-5d67-557e-def4-8e5858676abc2" Version="2.0"
                  IssueInstant=" 2016-02-09T09:30:10.5Z ">
    <saml:Assertion ID="3b5a66d0-5d86-477e-afc4-8e561084edc9" Version="2.0"
                  IssueInstant=" 2016-02-09T09:30:10.5Z ">
      <saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.999.1</saml:Issuer>
      <saml:Status>
        <samlp:StatusCode>urn:oasis:names:tc:SAML:2.0:status:Success</samlp:StatusCode>
      </saml:Status>
      <saml:Statement xsi:type="xacml-saml:XACMLPolicyStatementType">
        <!—XACML Policy-->
      </saml:Statement>
    </saml:Assertion>
  </samlp:Response>
</soap:Body>
```

Listing 21: Structure of the SOAP body element of the response to a XACMLPolicyQuery. A placeholder is used for the XACML policies returned by the Policy Repository.

3.3.12 EPD AddPolicyRequest and EPD UpdatePolicyRequest

This message enables the Policy Manager to add or update XACML policies, respectively existing XACML Policy Sets of a patient.
This message relies on SAML 2.0 Profile of XACML v2.0.
Actors involved support XUA and use SAML identity assertions to identify current user entities for subsequent access enforcement.

3.3.13 Trigger Events

The Policy Manager sends these messages when it needs to add new or update existing patient-specific policy sets stored within the Policy Repository (of a patient's referenceCommunity).

3.3.14 Message Semantics

This message relies on an EPD specific transaction schema (epd-policy-administration-combined-schema-1.0-local.xsd) as the SAML 2.0 profile of XACML v2.0 does not provide a transaction type and schema REQUIRED by these requests. It uses the element **<AddPolicyRequest>** or **<UpdatePolicyRequest>** to identify the transaction and convey the request.
Otherwise it relies on the very same specification and concepts as the XACMLPolicyQuery Response message does. XACML Policies or Policy Sets to be added or updated are conveyed using a SAML **<Statement>** of type **XACMLPolicyStatementType** within a XACML Policy SAML **<Assertion>** as specified in OASIS SAML 2.0 profile of XACML v2.0. The Assertion does not need to be signed. The **<Issuer>** of the Assertion SHALL identify the Policy Manager. For the EPD this ID is specified to be the home community ID of the Authorization Decision Provider community encoded as an URN, e.g. **<saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.98</saml:Issuer>.**

```
<soap:Body>
  <epd:AddPolicyRequest> <!--or-->
  <epd:UpdatePolicyRequest>
    <saml:Assertion ID="_3b5a66d0-5d86-477e-afc4-8e561084edc9" Version="2.0"
                    IssueInstant="2016-02-09T09:30:10.5Z">
      <saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.98</saml:Issuer>
      <saml:Statement xsi:type="xacml-saml:XACMLPolicyStatementType">
        <!—XACML Policy-->
      </saml:Statement>
    </saml:Assertion>
  </epd:AddPolicyRequest> <!--or-->
  </epd:UpdatePolicyRequest>
</soap:Body>
```

Listing 22: Structure of the SOAP body element of the response to an AddPolicyRequest, with the policy to be conveyed injected in the Statement as denoted by the placeholder.

3.3.15 Expected Actions

The Policy Repository SHALL return a status according to the success or failure of the transaction as defined below.

3.3.16 EPD AddPolicyRequest Response and EPD UpdatePolicyRequest Response

The EPD AddPolicyRequest Response or EPD UpdatePolicyRequest Response message is created by the Policy Repository in response to the EPD AddPolicyRequest or EPD UpdatePolicyRequest message.
An EPD specific transaction EPD PolicyRepositoryResponse is applied to report a general success or failure code. A soap fault MUST be reported back to the Policy Manager in case an EPD UpdatePolicyRequest cannot be executed due to unknown Policy or Policy Set IDs.

3.3.17 Trigger Events

This message is created by the Policy Repository after the EPD AddPolicyRequest or EPD UpdatePolicyRequest have been executed or refused to be executed.

3.3.18 Message Semantics

The EPD specific transaction **<PolicyRepositoryResponse>** conveys a status **urn:e-health-suisse:2015:response-status:success** or **urn:e-health-suisse:2015:response-status:failure**.

```
<soap:Body>
  <epd:PolicyRepositoryResponse status="urn:e-health-suisse:2015:response-status:success"/>
</soap:Body>
```

```
<soap:Body>
  <epd:PolicyRepositoryResponse status="urn:e-health-suisse:2015:response-status:failure"/>
</soap:Body>
```

Listing 23: Status element of the response to a request to add or to update a policy.

In case of an update failure due to unknown Policy Set IDs a soap **<Fault>** with a **<faultcode>** value **epd-policy-administration:UnknownPolicySetId** is to be returned to the Policy Manager.

```
<soap:Body>
  <soap:Fault>
    <faultcode>epd-policy-administration:UnknownPolicySetId</faultcode>
    <faultstring>The PolicySet with the given PolicySet ID does not exist</faultstring>
  </soap:Fault>
</soap:Body>
```

Listing 24: The soap fault element with error message in the case of an failure of the update request.

3.3.19 EPD DeletePolicyRequest

This message enables the Policy Manager to delete XACML Policies or Policy Sets from a Policy Repository.
This message relies on SAML 2.0 profile of XACML v2.0.
Actors involved support XUA and use SAML identity assertions to identify current user entities for subsequent access enforcement (See ITI TF-1: 39.5 and 39.6).

3.3.20 Trigger Events

The Policy Manager sends these messages when it needs to delete existing patient-specific policy sets stored within the Policy Repository (of a patient's referenceCommunity).

3.3.21 Message Semantics

This message relies on an EPD specific transaction schema (epd-policy-administration-combined-schema-1.0-local.xsd) as the SAML 2.0 profile of XACML does not provide a transaction type and schema REQUIRED by this requests. It uses the element **<DeletePolicyRequest>** to identify the transaction and convey the request.
Otherwise it relies on the same specification and concepts as the XACMLPolicyQuery Response message, EPD AddPolicyRequest and EPD UpdatePolicyRequest do. However, there is no Statement type specified to convey the information needed by this transaction. Policies or Policy Sets to be deleted are to be identified by a corresponding ID that is to be conveyed using an EPD specific SAML **<Statement>** of type **XACMLPolicySetIdReferenceStatementType** (as defined in epd-policy-administration-combined-schema-1.0-local.xsd) within a XACML Policy SAML **<Assertion>**. The Assertion does not need to be signed.
The **<Issuer>** of the Assertion SHALL identify the Policy Manager. For the EPD this ID is specified to be the home community ID of the Authorization Decision Provider community encoded as an URN, e.g.
<saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.98</saml:Issuer>.

```
<soap:Body>
  <epd:DeletePolicyRequest>
    <saml:Assertion ID="_3b5a66d0-5d86-477e-afc4-8e561084edc9" Version="2.0"
                    IssueInstant="2016-02-09T09:30:10.5Z">
      <saml:Issuer NameQualifier="urn:e-health-suisse:community-index">urn:oid:2.98</saml:Issuer>
      <saml:Statement xsi:type="epd:XACMLPolicySetIdReferenceStatementType">
        <xacml:PolicySetIdReference>10a3f268-d9d6-4772-b908-9d8521161</xacml:PolicySetIdReference>
      </saml:Statement>
    </saml:Assertion>
  </epd:DeletePolicyRequest>
</soap:Body>
```

Listing 25: Example of the SOAP body for a EPD DeletePolicyRequest, where the policy set to be removed from the patients policy configuration is referenced by ID.

3.3.22 Expected Actions

The Policy Repository SHALL return a status according to the success or failure of the transaction as defined below.

3.3.23 EPD DeletePolicyRequest Response

The EPD DeletePolicyRequest Response message is created by the Policy Repository in response to the EPD DeletePolicyRequest.
An EPD specific transaction EPD PolicyRepositoryResponse is applied to report a general success or failure code. A soap fault MUST be reported back to the Policy Manager in case an EPD DeletePolicyRequest cannot be executed due to unknown Policy or Policy Set IDs.

3.3.24 Trigger Events

This message is created by the Policy Repository after the EPD DeletePolicyRequest or have been executed or refused to be executed.

3.3.25 Message Semantics

The EPD specific transaction **<PolicyRepositoryResponse>** conveys the status **urn:e-health-suisse:2015:response-status:success** or **urn:e-health-suisse:2015:response-status:failure**.

```
<soap:Body>
  <epd:PolicyRepositoryResponse status="urn:e-health-suisse:2015:response-status:success"/>
</soap:Body>
```

```
<soap:Body>
  <epd:PolicyRepositoryResponse status="urn:e-health-suisse:2015:response-status:failure"/>
</soap:Body>
```

Listing 26: Status element of the response to a request to add or to update a policy.

In case of an update failure due to unknown Policy Set IDs a soap **<Fault>** with a **<faultcode>** value **epd-policy-administration:UnknownPolicySetId** is to be returned to the Policy Manager.

```
<soap:Body>
  <soap:Fault>
    <faultcode>epd-policy-administration:UnknownPolicySetId</faultcode>
    <faultstring>The PolicySet with the given PolicySet ID does not exist</faultstring>
  </soap:Fault>
</soap:Body>
```

Listing 27: The soap fault element with error message in the case of a failure of the delete request.

3.3.26 Security Considerations

Relevant Security Considerations are defined in ITI TF-1: 39.5. The Privacy Policy Query transactions require TLS communication between actors involved. Relevant XDS Affinity Domain Security background is discussed in the XDS Security Considerations Section (see ITI TF-1: 10.7). The Actors involved SHALL record audit events according to the following:

3.3.27 Policy Manager Audit Message

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV (110112, DCM,“Query”)
	EventActionCode	M	E = Execute
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	EV(“PPQ”, “e-health-suisse”, “Privacy Policy Query Policy Query”) *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Add Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Update Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Delete Policy”)*
Source (Policy Manager) (1)			
Human Requestor (0..n)			
Destination (Document Registry) (1)			
Audit Source (Document Consumer) (1)			
Patient (0..1)			
Query Parameters(1..n)			

Source: AuditMessage/ ActiveParticipant	*UserID*	*U*	*not specialized*
	AlternativeUserID	M	the process ID as used within the local operating system in the local system of logs
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110153, DCM, “Source”)
	NetworkAccessPointTypeCode	U	“1” for machine (DNS) name “2” for IP address
	NetworkAccessPointID	U	The machine name or IP address.

Human Requestor (if known) AuditMessage/ ActiveParticipant	UserID	M	Identity of the human that initiated the transaction.
	AlternativeUserID	*U*	*not specialized*
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	U	Access Control role(s) the user holds that allows this transaction.
	NetworkAccessPointTypeCode	NA	
	NetworkAccessPointID	NA	

Destination AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI.
	AlternativeUserID	U	not specialized
	UserName	U	not specialized
	UserIsRequestor	U	not specialized
	RoleIDCode	U	EV(110152, DCM, “Destination”)
	NetworkAccessPointTypeCode	M	“1” for machine (DNS) name, “2” for IP address
	NetworkAccessPointID	M	The machine name or IP address.

Audit Source AuditMessage/ AuditSourceIdentification	*AlternativeUserID*	*U*	*not specialized*
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*

Patient (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (person)
	ParticipantObjectTypeCodeRole	M	“11” (patient)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	*not specialized*
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	M	The patient ID in HL7 CX format.
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

Query Parameters: AuditMessage/ ParticipantObjectIdentification (1..n)	ParticipantObjectTypeCode	M	“2” (SYSTEM)
	ParticipantObjectTypeCodeRole	M	“24” (query)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“PPQ”, “e-health-suisse”, “Privacy Policy Query Policy Query”) *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Add Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Update Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Delete Policy”)*
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	*M*	*not specialized*
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	M	PolicySetId (PatientId for query all policies of a patient)
	ParticipantObjectDetail	*U*	*not specialized*

3.3.28 Policy Repository Audit Message

	Field Name	**Opt**	**Value Constraints**
Event	EventID	M	EV (110112, DCM,“Query”)
	EventActionCode	M	E = Execute
	EventDateTime	*M*	*not specialized*
	EventOutcomeIndicator	*M*	*not specialized*
	EventTypeCode	M	EV(“PPQ”, “e-health-suisse”, “Privacy Policy Query Policy Query”) *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Add Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Update Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Delete Policy”)*
Source (Policy Manager) (1)			
Destination (Policy Repository) (1)			
Audit Source (Policy Repository) (1)			
Patient (0..1)			
Query Parameters (1..n)			

Source: AuditMessage/ ActiveParticipant	UserID	*M*	*not specialized*
	AlternativeUserID	U	*not specialized*
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110153, DCM, “Source”)
	NetworkAccessPointTypeCode	M	“1” for machine (DNS) name “2” for IP address
	NetworkAccessPointID	U	The machine name or IP address.

Destination: AuditMessage/ ActiveParticipant	UserID	M	SOAP endpoint URI.
	AlternativeUserID	M	the process ID as used within the local operating system in the local system of logs
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*
	RoleIDCode	M	EV (110152, DCM, “Destination”)
	NetworkAccessPointTypeCode	U	“1” for machine (DNS) name “2” for IP address
	NetworkAccessPointID	U	The machine name or IP address.

Audit Source AuditMessage/ AuditSourceIdentification	*AlternativeUserID*	*U*	*not specialized*
	UserName	*U*	*not specialized*
	UserIsRequestor	*U*	*not specialized*

Patient (AuditMessage/ ParticipantObjectIdentification)	ParticipantObjectTypeCode	M	“1” (person)
	ParticipantObjectTypeCodeRole	M	“1” (patient)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	*not specialized*
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	M	The patient ID in HL7 CX format.
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	*U*	*not specialized*
	ParticipantObjectDetail	*U*	*not specialized*

Query Parameters: AuditMessage/ ParticipantObjectIdentification	ParticipantObjectTypeCode	M	“2” (SYSTEM)
	ParticipantObjectTypeCodeRole	M	“24” (query)
	ParticipantObjectDataLifeCycle	*U*	*not specialized*
	ParticipantObjectIDTypeCode	M	EV(“PPQ”, “e-health-suisse”, “Privacy Policy Query Policy Query”) *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Add Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Update Policy”)* *EV*(“PPQ”, “e-health-suisse”, *“Privacy Policy Query Delete Policy”)*
	ParticipantObjectSensitivity	*U*	*not specialized*
	ParticipantObjectID	*M*	*not specialized*
	ParticipantObjectName	*U*	*not specialized*
	ParticipantObjectQuery	M	PolicySetId (PatientId for query all policies of a patient)
	ParticipantObjectDetail	*U*	*not specialized*

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Direktionsbereich Gesundheitspolitik

SR 816.11.n / Anhang 8 der Verordnung des EDI vom ... über das elektronische Patientendossier

Vorgaben für den Schutz der Identifikationsmittel

Protection Profile for Electronic Means and their Authentication Procedures

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Version: 1.0 22.03.2016

Inkrafttreten: …

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PP Introduction

The Swiss Federal Law on Electronic Health Records (FLEHR) requires a strong authentication of identity for patients and healthcare professionals in order to access the Swiss Electronic Health Record (EHR). The Federal Council sets the requirements in relation to electronic identities and the issuing process for Electronic Identification Means (EIM) in detail. In this regard, EIM are used to identify patients and healthcare professionals to access the Swiss national electronic health record (EHR) via an access portal that is operated by communities (association of health professionals) and reference communities (communities with additional responsibilities related to the establishment of an account for the Electronic Patient Record). To assure a high confidence in the claimed identity of patients and healthcare professionals, the related processes for instantiation and issuance of identification means such as identity proofing and verification or credential issuance have to comply with the requirements for the level of assurance 3 as defined in ISO/IEC 29115:2013

The Protection Profile for Electronic Identification Means and their Authentication Procedures is based on the Regulations on the Electronic Patient Record (EPDV). It defines a set of requirements that are expected to be fulfilled by all products that can perform electronic identification and authentication to access the Swiss national EHR. The evaluation of EIM according this protection profile is part of the certification process of communities and reference communities, respectively.

1.1 PP Reference

Title:	Protection Profile for Electronic Identification Means and their Authentication Procedures
Version:	1.0
Date:	23.03.2016
Issuer:	Swiss Federal Office of Public Health
Evaluation Assurance Level	The assurance level for this PP is EAL2
CC Version	V3.1 Revision 4

1.2 TOE Overview

This protection profile defines the security objectives and requirements for EIM including their authentication procedures required to access the Swiss national EHR.

1.2.1 TOE definition

The Target of Evaluation (TOE) addressed by this protection profile comprises the components that are relevant to instantiate as an EIM towards relying parties (RP) in the EPDV context, namely it provides the following:

- An Identity Provider (IdP) for identification and authentication of registered users.
- Web services / middleware / internet visible access portal for authentication provided by IdP.
- Web service / middleware to create secure channel between IdP and service provider (i.e. community portal for patients and healthcare professionals) provided by IdP.
- Web service / middleware provided by service provider (i.e. community portal for patients and healthcare professionals) to receive authorization response from secure channel from IdP.
- Devices of multiple variety (e.g. smartcard, mobile devices) carrying tokens (e.g. application on mobile device) and/or credentials (e.g. public and secret key material, authentication credentials).
- Secure handover of randomized and time limited session from service provider to device (e. g. secure browser redirect or equivalent level)

1.2.2 TOE Usage

Electronic identification means comprises one or more token that are secured by a device. Each token may hold a credential, that is used by the IdP to authenticate the user's identity based on possession and control of the corresponding token. Figure 1 shows the steps required to authenticate patients and healthcare processionals to an access portal of communities.

In the first step, the holder of the token authenticates himself to the IdP (1) which provides a defined interface for that purpose. Specifically, this means an IdP-initiated approach where the IdP refers to service provider or relying party and, thus, the claimant may choose a specific context (2). In the next step, the IdP verifies the credentials of that user and after successful verification, the IdP transmits a proof of identity to the access providing system of the (reference-) community (3). The connection between IdP and service provider (SP) has to be established via secure channel. This channel shall also be used for initial notification of an approved patient's identity to the reference community of the patient. Although the IdP authorizes patients and healthcare professionals in order to grant access to the EHR, fine-grained permission control is left to the reference community.

To access the EHR, the session has to be handed over from the service provider to the IdP or the user's device (3,4). Afterwards, the user has access via the interface to the services authorized for this user in the (reference-) community.

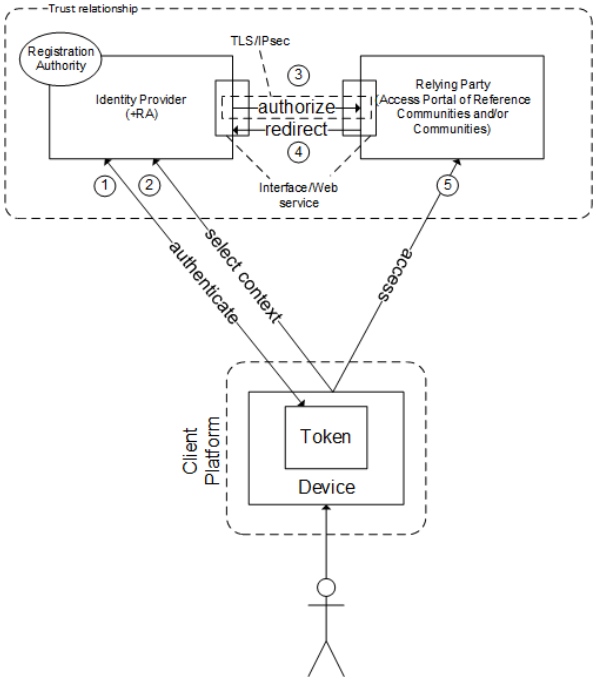

Figure 1 Usage of the TOE

1.3 Operational Environment

EIM have to be compliant with a specific level of assurance (LoA 3) as defined by ISO/IEC 29115:2013 [9]. It is assumed that EIM meet all necessary requirements related to enrolment, credential management and entity authentication such that there is a high confidence in the claimed or asserted identity of patients and healthcare professionals being allowed to access the EHR.

1.4 Physical Protection of the TOE

The physical protection is mainly provided by the TOE environment. This specifically covers the following scenarios:

- Access to the TOE infrastructure is not sufficiently restricted and the attacker gains unauthorized access to the server environment.
- The device is stolen and manipulated an attacker.

1.5 Assets

The assets to be protected by the TOE are data listed in Table 1. Assets of the TOE are divided into TSF and User data and the security services provided by the TOE as defined above. The data assets known to the TOE environment like public keys shall be protected by the TOE environment as well.

TSF data / User Data	Data	Description
User data	Device / Token with secret/public credential	A device that carries a secret/public credential of an individual user • Disseminated beforehand in a rollout process • Activation data or password is only known to the user Note that the device could be of multiple variety (e. g. Chipcard, Handheld-Device, Harddisk).
User data	Activation data for token	An activation secret for the token.
User data	Credential for web portal	A credential that is used for additional login into the access portal of the reference community.
User data	Secret and private credential of the user (on token)	The token stores secret and private credential of a user to authenticate the user has to be stored in a confidential and integrity protected way by the TOE.
User data	Reference of user credential	The IdP stores reference of the credential of a user to authenticate the user has to be stored in a confidential and integrity protected way by the TOE.
User data	Token output / authenticator	Authentication data that is transferred from the Token to the IdP Raw or transformed, e.g. in form of a cryptographic expression
User data	Identification Data	A unique tuple that identifies a user e.g. GLN, given birthname, birthdate, etc.
TSF data	Cryptographic Key Material for Channels	All cryptographic key material that is used to establish secure channels for communication between parts of the TOE or between the TOE and other trusted components as well as the browser.
TSF data	Claimant ID	A unique ID provided by the IdP to identify the claimant unanimously.
TSF data	Assertion Data	Any SAML assertion defined and generated by the TOE.

Table 1 Assets of the TOE divided into TSF and User data.

1.6 External Entities and Subjects

This protection profile considers the following subjects and external entities:

Entity	Description
User	A patient, a patient's representative, a Healthcare professional or an authorized supportive persons with access to the EDP, i.e. that have a identification token beforehand.
Trusted Users	Administrators, Operators and Security Information Officers that have privileged access rights to the EIM platform.
Temporary privileged users	Users that might have temporary privileged access rights, e.g. developers, support persons and auditors.
Test users and functional users	Technical users that might exist for management of the platform.
Attacker	A human, or a process acting on his behalf, located outside the TOE. The main goal of the attacker is to access or modify security relevant data.
Service Provider (Relying Party)	Data storage and infrastructure on (reference-) community site that is connected to the EIM and provides the access control for identified users (authorization control in accordance with the regulation). Additionally a secure channel exists between the (reference-) community infrastructure and the EIM.
RA (Registration Authority)	A trusted entity that establishes and vouches for the identity of a Subscriber/Claimant to an IdP. The RA may be an integral part of an IdP, or it may be independent of an IdP, but it has a relationship to the IdP(s).
IdP (Identity Service Provider)	A trusted entity that issues or registers subscriber tokens and issues electronic credentials to subscribers. The IdP may encompass Registration Authorities and verifiers that it operates. An IdP may be an independent third party, or may issue credentials for its own use.
Subscriber/Claimant	A user after successful identification and registration.
Client_Platform	The platform environment from which the user requests an identification process at the IdP. (e.g. for a user's PC with browser for redirect to the community access portal and a connected mobile device with the token).
Service desk	Portal within the IdP for user help and revocation requests

Table 2 External Entities and Subjects

2 Conformance Claims

- This PP has been developed using Version 3.1 R4 [1], [2], [3] of Common Criteria [CC].
- This PP does not claim conformance to any other PP.
- This PP requires strict conformance of any PP/ST to this PP.

This PP claims an assurance package EAL2 as defined in [CC] Part 3 for product certification.

3 Security Problem Definition

The Security Problem Definition is the part of a PP, which describes

- Assumptions on security relevant properties and behavior of the TOE's environment;
- Organizational security policies, which describe overall security requirements defined by the organization in charge of the overall system including the TOE. In particular this may include legal regulations, standards and technical specifications;
- Threats against the assets, which shall be averted by the TOE together with its environment.

3.1 Assumptions

Assumption	**Description**
A.Personal	It is assumed that background verification checks on all candidates for employment, contractors, and third party developers are carried out in accordance with relevant laws, regulations and ethics, and proportional to the business requirements, the classification of the information to be accessed, and the perceived risks. It is assumed that all employees and contractors understand their information security responsibilities, are authorized and trained for the roles for which they are considered and are aware of information security threats. Healthcare professionals and patients are assumed to always act with care and read the existing guidance documentation of the corresponding part of TOE. It is assumed, that holders of devices/tokens and other computing platforms keep secret activation/authentication data confidential, ensuring that it is not divulged to any other parties and avoid keeping a record on paper, in a software file or on a hand-held device, unless this can be stored securely and the method of storing has been approved.
A.AccessManagement	An Access Management is in place to control the allocation of access rights for authorized user access and to prevent unauthorized access to information systems and physical premises.
A.Physical	It is assumed, that the components of the TOE except for the enrolled device/token are operated in a secure area and protected against physical manipulations.
A.Monitoring	It is assumed, that information processing systems on the service providing part of the TOE are monitored and user activities, physical access to secure areas, exceptions, and information security events are recorded to ensure that information system problems are identified.

	It is assumed that the clocks of all relevant information processing systems are synchronized with an agreed accurate time source.
A.Malware	It is assumed, that that information processing systems on the service providing part of the TOE and its computing environment is protected against malware based on a malware detection and repair system service and information security awareness is introduced and practiced. It is also assumed, that a vulnerability management to prevent exploitation of technical vulnerabilities is established and maintained.
A.ClientPlatform	It is assumed, that the computing environment on which a part of the TOE is installed or interacts and has access to the services provided by the TOE, is protected against malware, its components have a current patch status and is not used in the administrator mode. It is assumed, that this computing environment is a general home-type environment. This means low physical security measures.
A.Identification	It is assumed that the claimant is carefully identified and well informed concerning practicing security awareness.
A.CredentialHandling	It is assumed that a mechanism to ensure that a credential is provided to the correct entity or an authorized representative is implemented. It is assumed that procedures ensure that a credential or means to generate a credential are only activated, if it is under the control of the intended entity. Therefore the device/token is protected against unauthorized access with activation data only known to the claimant. In the case of revocation due to compromise or loss of device/token, it is assumed, that the claimant informs immediately the service desk of the IdP through appropriate channels.
A.TrustedCommunityEndpoint	It is assumed, that the community provides a trusted endpoint for defined secure communication with the IdP.

Table 3 Assumptions

3.2 Organizational Security Policies (P)

The TOE and/or its environment shall comply with the following Organizational Security Policies (P) as security rules, procedures, practices, or guidelines imposed by an organization upon its operation.

Policy	Description
P.Audit	The security relevant events (internal to the TOE or due to the communication flows) shall be recorded and maintained and reviewed. The audit trail analysis is executed in order to hold the authorized users accountable for their actions and to trace attack attempts from networks. At minimum, the following items should be logged: - user IDs - dates, times, and details of key events - terminal identity - records of successful and rejected system access attempts - changes to system configuration - use of privileges network addresses and protocols
P.Crypto	State of the art recommended cryptographic functions shall be used to perform all cryptographic operations (e.g. NIST or other applicable guidance and recommendations). At least the following or stronger cryptographic algorithms shall be used: - SHA-2 - AES: n ≥ 256 - RSA: n ≥2048 - ECDSA: n ≥ 224
P.AccessRights	A defined management of admission to TOE and network resources shall be established that grants authenticated users access to specific resources based on policies and permission levels, assigned to users or user groups. The access control shall include an authentication, which proves the identity of the user or client entity attempting to log in. Administrative privileges allow users the right to make any and all changes on the TOE, including setting up accounts for other users and change SFR specific settings. The allocation and use of system administration privileges shall be more restricted and controlled.
P.Hardening	A defined policy for hardening the TOE shall be established and processes shall be implemented for securing the systems within the TOE by reducing its vulnerability. To achieve this, an effective vulnerability and patch management shall be established, unnecessary software shall be removed, unnecessary services shall disabled or removed and access rights and access to resources shall be strongly restricted and controlled.
P.Assertion	SAML-Token has to comply with the specification given in section 6.3. The IdP information processing system shall contain a component to generate unique reference identifiers. A time restricted SAML-Token issued by the IdP shall be digitally signed with an enhanced signature by a certified certificate service provider.
P.TrustedCommunityEndpoint	A trusted community endpoint for the secure communication between the IdP and the Community shall be established as defined in section 6.3.

Table 4 Description of the organizational security policies the TOE and its environment shall comply with

3.3 Threats

This section describes the threats to be averted by the TOE independently or in collaboration with its IT environment. These threats result from the assets protected by the TOE and the method of OE's use in the operational environment. The threats described in chapter 10.3 of the ISO/IEC 29115 are fully covered and extended by the following threats.

Threat	**Assets/ Security Goals / Adverse Action / Attacker**
T.CompromiseToken/Credential Compromise of a device/token and their credentials	Asset: Secret and private credential of the claimants device/token Security goal: The TOE and therefore all assets of the TOE Adverse action: Exposition of credential stored on a device/token - An attacker causes a IdP to create a credential based on a fictitious subscriber/claimant - An attacker alters information as it passes from the enrolment process to the credential creation process. - An attacker obtains a credential that does not belong to him and by masquerading as the rightful claimant causes the IdP to activate the credential. - An attacker has access to secret credentials stored on a device/token of a registered claimant with a weak credential protection mechanism and is therefore able to export or copy these secret credentials. Subsequently he is able to use these secret credentials for masquerading the rightful claimant (direct use or duplication of the token). - An attacker has either direct access to the activation data by breaking a weak protection mechanism or he can apply analytical methods outside the authentication mechanism (offline guessing) supported by a weak protection mechanism of the device/token. - An attacker can capture activation data or credentials by sending disguised malware as applications (e.g. keystroke logging software), which can be stored on a device. - The dissemination of revocation information is not timely leading to a threat of device/token with revoked credentials still being able to authenticate before the IdP updates the latest revocation information. Attacker: An Attacker alters information during the enrolment process of a device/token or gains access to a credential of a registered claimant and impersonates him or her either by credential tampering, credential disclosure, credential duplication, delayed credential revocation or offline guessing.
T.Token/CredentialTheft	Asset: Secret and private credential of the claimants device/token Security goal: The TOE and therefore all assets of the TOE

	Adverse action: A device/token that generates or contains credentials is stolen by an attacker Attacker: If an attacker also knows the activation data or has direct access to the activation data by breaking a weak protection mechanism or can apply analytical methods outside the authentication mechanism (offline guessing) favored by a weak protection mechanism of the device/token, he gain an authenticated access to the TOE and therefore all assets of the TOE.
T.WebPlatformAttacks	Asset: The TOE and therefore all assets of the TOE. Security goal: Confidentiality and integrity of the assets. Adverse action:. - Application functions related to authentication and session management are often not implemented correctly, allowing attackers to compromise passwords, keys, or session tokens, or to exploit other implementation flaws to assume other users' identities. - Cross-Site-Scripting (XSS) flaws occur whenever an application takes untrusted data and sends it to a web browser without proper validation or escaping. XSS allows attackers to execute scripts in the claimant's browser which can hijack user sessions, deface web sites, or redirect the user to malicious sites. - A Cross-Site Request Forgery attack (CSRF) forces a logged-on claimant's browser to send a forged HTTP request, including the claimant's session cookie and any other automatically included authentication information, to a vulnerable web application. This allows the attacker to force the claimant's browser to generate requests the vulnerable application thinks are legitimate requests from the claimant. - Injection flaws, such as SQL, OS-Command-Shell, XPATH and LDAP injection occur when untrusted data is sent to an interpreter as part of a command or query. The attacker's hostile data can trick the interpreter into executing unintended commands or accessing data without proper authorization. - Web applications frequently redirect and forward users to other pages and websites, and use untrusted data to determine the destination pages. Without proper validation, attackers can redirect claimants to phishing or malware sites, or use forwards to access unauthorized pages. - Most web applications verify function level access rights before making that functionality visible in the UI. However, applications need to perform the same access control checks on the server when each function is accessed. If requests are not verified, attackers will be able to forge requests in order to access functionality without proper authorization.

	Attacker: - Not correctly implemented authentication and session managements allow an attacker either capture or bypass the authentication methods that are used by a web application. He is able to compromise passwords, keys, or session tokens, or to exploit other implementation flaws to assume other users identities (Unencrypted connections, predictable login credentials, vulnerable and unprotected session handling, no or too long timeouts, etc.) - An attacker can inject untrusted snippets of JavaScript into an application without validation. This JavaScript is then executed by the claimant who is visiting the target site. There are 3 primary types: In Reflected XSS, an attacker sends the claimant a link to the target application through email, social media, etc. This link has a script embedded within it which executes when visiting the target site. In Stored XSS, the attacker is able to plant a persistent script in the target website which will execute when anyone visits it. With DOM Based XSS, no HTTP request is required, the script is injected as a result of modifying the DOM of the target site in the client side code in the claimant's browser and is then executed. - Cross-Site Request Forgery (CSRF) is a web application vulnerability that makes it possible for an attacker to force a claimant to unknowingly perform actions while they are logged into an application. Attackers commonly use CSRF attacks to target sites such as cloud storage, social media, banking and on-line shopping, because of the user information and actions available in these applications. - All injection attacks involve allowing untrusted or manipulated requests, commands, or queries to be executed by a web application. An attacker wants to perform SQL inject they could write a SQL query to replace or concatenate an existing query used by the application, using specific characters like to bypass the existing query-logic. For an OS commanding injection an attacker can include a shell command within their injection using specific characters to include attacker's commands. Each attack could be tailored to the attacker's goal, the target server's infrastructure, and which inputs can bypass the application's existing logic. XPATH is the query language used to parse and extract specific data out of XML documents, and by injecting malicious input into an XPATH query, an attacker can alter the logic of the query. This attack is known as XPATH injection. - Applications that redirect after a successful authentication to another location by sending a redirect header to the client in an HTTP/HTTPS response, an attacker can without proper validation redirect claimants to phishing or malware sites, or use forwards to access unauthorized pages. - The web application needs to verify the request at the UI level, as well as the backend function level. An attacker will ignore the UI and a forge requests that access unauthorized functionality.

T.SpoofingAndMasquerading	Asset: The TOE and therefore all assets of the TOE. Security goal: The confidentiality and integrity of the assets. Adverse action: Spoofing and masquerading refer to situations in which an attacker impersonates another entity in order to launch attacks against network hosts, steal data, spread malware or bypass access controls. This may be done by making use of the credential(s) of an entity or otherwise posing as an entity (e.g. by forging a credential). Attacker: An attacker impersonates an entity spoofs one or more biometric characteristics that matches the pattern of the entity (by creating a “gummy” finger, recording voice, etc.) IP spoofing attacks can be used to overload targets with traffic or bypassing IP address-based authentication, when trust relationships between machines on a network and internal systems are in place. Such spoofing attacks impersonate machines with access permissions and bypass trust-based network security measures. An attacker spoofs a MAC address by having its device broadcast a MAC address that belongs to another device that has permissions on a particular network. In a DNS server spoofing attack, an attacker is able to modify the DNS server in order to reroute a specific domain name to a different IP address. This attack can also be used to masquerade a legitimate IdP with an attackers IdP or masquerade a legitimate software publisher responsible for downloading on-line software applications and/or updates by a faked downloading service.
T.SessionHijacking	Asset: Credentials, Session-IDs and other user data Security goal: The confidentiality and integrity of the assets Adverse action: An Attacker is able to intercept successful authentication exchange transactions between the claimant and the IdP and to steal or predict valid session data to gain compromised/unauthorized access to the web portal of the service provider. Without effective countermeasures, such attacks could be successfully performed using methods like Session Sniffing, Client-side attacks (XSS, malicious JavaScript Codes, Trojans, etc), Man-in-the-middle attacks, Man-in-the-browser attacks. Attacker: An Attacker is able to take over an already authenticated session by eavesdropping on or predicting the value of authentication data used to mark HTTP/HTTPS requests sent by the claimant to the IdP and subsequently gain compromised/unauthorized access to the web portal of the service provider. An attacker logs into a vulnerable application, establishing a valid

	session ID that will be used to trap the claimant. He then convinces the claimant to log into the same application, using the same session ID, giving the attacker access to the claimants account through this active session.
T.OnlineGuessing	Asset: User credentials Security goal: The confidentiality of assets Adverse action: An Attacker performs repeated logon trials by guessing possible values of the token authenticator. Attacker: An Attacker navigates to a web page and attempts to log in using brute force methods based on specific dictionaries.
T.ReplayAttack	Asset: Credentials, authentication exchange data Security goal: The confidentiality of assets Adverse action: An Attacker is able to replay previously captured messages (between a legitimate Claimant and an IdP) to authenticate as that Claimant to the IdP. Attacker: An Attacker captures a Claimant's credential or session IDs from an actual authentication session, and replays it to the IdP to gain access at a later time.
T.Eavesdropping	Asset: Credentials, authentication exchange data and other user data Security goal: The confidentiality of communication channels and assets of the TOE Adverse action: An Attacker listens passively to the authentication transaction to capture information which can be used in a subsequent active attack to masquerade as the Claimant. A way to achieve this, the attacker positions himself in between the Claimant and the IdP, so that he can intercept the content of the authentication protocol messages. The Attacker typically impersonates the IdP to the Claimant and simultaneously impersonates the Claimant to the IdP. Conducting an active exchange with both parties simultaneously may allow the Attacker to use authentication messages sent by one legitimate party to successfully authenticate to the other. Attacker: An Attacker captures the transmission credentials or Session IDs

	from a Claimant to a IdP.
T.Configuration	Asset: The TOE and therefore all assets of the TOE. Security Goal: Confidentiality and integrity of the assets. Adverse action: An unauthenticated or authenticated attacker might exploit a weakness resulting from a wrong configuration setting, incomplete deployment or not up-to-dated software (libraries, frameworks, and other software modules, almost always running with full privileges) of TSF components of the TOE (applications, frameworks, application servers, web servers, database servers and platforms) Attacker: An unauthenticated or authenticated attacker is able to exploit a weakness by wrong configuration setting, incomplete deployment or not up-to-dated software to expose confidential information about user data or TSF data.
T.DoS	Asset: The TOE and therefore all assets of the TOE. (The availability of the TOE). Security goal: The Denial of Service (DoS) attack is focused on making TSF components of the TOE (site, application, server) unavailable for the purpose there were designed. Adverse action: An attacker is able to manipulate network packets, programming, logical, or resources handling vulnerabilities, etc. Attacker: An (unauthenticated) attacker is able to start a DoS attack on the external interfaces of the TOE (namely browser interface and web service) so that a service receives a very large number of requests and may cease to be available to legitimate users. An (unauthenticated) attacker is also able to stop a service, if a programming vulnerability is exploited or to slow down using too much service handles.

Table 5 Threats

4 Security Objectives

This chapter describes the security objectives for the TOE and the security objectives for the TOE environment.

4.1 Security Objectives for the TOE

This section describes the security objectives for the TOE and addresses the aspects of identified threats to be countered by the TOE and organizational security policies to be met by the TOE. The security objectives describe the protection of the primary assets as User Data and the secondary assets as TOE security functions data (TSF data) against threats identified in TOE environment.

O.Integrity	The TOE shall protect against either intentional or accidental violation of user and TSF data integrity (the property that data has not been altered in an unauthorized manner) or violation of system integrity (the quality that a system has when it performs its intended function in an unimpaired manner, free from unauthorized manipulation).
O.Confidentiality	The TOE shall protect user and TSF data against intentional or accidental attempts to perform unauthorized access. The TOE shall protect confidentiality of user and TSF data in storage, during processing and while in transit.
O.Availability	The TOE shall ensure the availability of services provided by the TOE and the TSF to authorized users (e.g. the IdP is unavailable to subscribers as a consequence of a DoS attack or insufficient scalability).
O.Accountability	The TOE shall trace all actions of an entity uniquely to that entity. The TOE shall record user activities, exceptions, and information security events and shall keep these for an agreed period to assist in future investigations and in access control monitoring.
O.Authentication	Towards the service provider: All messages between IdP and their relaying parties shall be digitally signed to guarantee the authenticity and validity shall be time limited. Towards the client platform: The TOE shall provide either a token with two or more authentication factors (multifactor token) or a combination of a single-factor token and at least another token transmitted on a separate channel for authentication. The factors shall comply with the requirements of ISO 29115.
O.Secure_Communication	The TOE shall support secure communication for protection of the confidentiality and the integrity of the user data and TSF data received or transmitted. Further nonces, challenges or timeliness shall be used for freshness of each transaction.
O.Cryptographic_Functions	The TOE shall provide means to encrypt and decrypt user data and TSF data to maintain confidentiality, integrity and accountability and allow for detection of modification of user data that is transmitted within or outside of the TOE.
O.Access_Control	The TOE shall enable access control on all objects under the control of the TOE (e.g. assets) as well as the TSF and ensure authorized use while preventing unauthorized use.

4.2 Security Objectives for the operational environment

This section describes security objectives that the TOE should address in the operational environment to solve problems with regard to the threats and organizational security policies defined as the security problems. In addition, the security objectives stated herein shall all be derived from the assumptions.

OE.HR-Security	Security roles and responsibilities of employees, contractors and third party users shall be defined and documented in accordance with the organization's information security policy. A written and signed agreement is mandatory as part of contractual obligation for employees, contractors and third party users. Conditions of their employment contract shall state their and the organization's responsibilities for information security. All employees of the organization and, where relevant, contractors and third party users shall receive appropriate awareness training and regular updates in organizational policies and procedures as relevant for their job function. Responsibilities and defined processes shall be in place to ensure an employee's, contractor's or third party user's exit from the organization and that the return of all assets and the removal of all access rights are completed. The following controls shall be fulfilled: [ISO/IEC 27001:2013][8]: A.7 Human resource security
OE.Access_ManagementSystem	Secure Operation of the TOE requires an access-management-system for which an access control policy shall be established, documented and reviewed based on business and information security requirements. Access to systems and applications shall be restricted in accordance with the access control policy. A formal user registration and de-registration process shall be implemented to enable assignment of access rights. The allocation and use of privileged access rights shall be restricted and controlled. Password management systems shall be interactive and shall ensure strong passwords. The following controls shall be applied and fulfilled: - [ISO/IEC 27001:2013]: A.9 Access Control
OE. SecureAreas and Equipment	Critical or sensitive information processing facilities of the IdP shall be housed in secure areas, protected by defined security perimeters, with appropriate security barriers and entry controls. They shall be physically protected from unauthorized access, damage and loss including safeguard supporting facilities, such as the electrical supply and cabling infrastructure. The following controls shall be applied and fulfilled: - [ISO/IEC 27001:2013]: A.11 Physical and environmental security
OE.Configuration and ChangeManagement	In order to ensure the integrity of information processing systems of the IdP, there shall be established strict controls over the implementation of changes. Formal change

	control procedures shall be enforced. They should ensure that security and control procedures are not compromised, that support programmers are given access only to those parts of the system necessary for their work, and that formal agreement and approval for any change is obtained. Defined policies and configuration procedures or systems shall be established to keep control of all implemented software as well as the system documentation. The following controls shall be applied and fulfilled: - [ISO/IEC 27001:2013]: A.12.1.2 Change management - [ISO/IEC 27001:2013]: A.12.5 Control of operational software
OE.Malware and Vulnerability Management	The information processing systems of the IdP shall be protected against malicious code and based on malware code detection, security awareness, and appropriate system access and change management controls. Information resources to be used to identify relevant technical vulnerabilities and to maintain awareness have to be defined and made available. When a potential technical vulnerability has been identified, associated risks shall be identified and the following actions shall be taken: - patching the vulnerable systems or - turning off services or capabilities related to the vulnerability - adapting or adding access controls, e.g. firewalls - increased monitoring to detect actual attacks - raising awareness of the vulnerability The following controls shall be applied and fulfilled: - [ISO/IEC 27001:2013]: A.12.2 Protection from malware - [ISO/IEC 27001:2013]: A.12.6 Technical vulnerability management
OE.Logging and Monitoring	The information processing systems of the IdP shall be monitored and information security events shall be recorded. Operator logs and fault logging shall be used to ensure information system problems are identified. Logging facilities and log information should be protected against tampering and unauthorized access. The clocks of all relevant information processing systems shall be synchronized with an accepted Swiss time source to ensure the accuracy of audit logs. The following controls shall be applied and fulfilled: - [ISO/IEC 27001:2013]: A.12.4 Logging and monitoring
OE.Network Security	A policy concerning the use of networks and network services shall exist and implemented. All authentication methods with respect to the security requirements used to control access by remote users shall be defined and documented. Groups of information services, users, and information processing systems in the IdP shall be segregated on networks. Routing controls shall be implemented for networks to ensure that information processing systems connections and information flows do not breach the access control policies. The following controls shall be applied and fulfilled:

	- [ISO/IEC 27001:2013]: A.13.1 Network security management
OE.Identification and IdentityManagement	Secure Operation of the TOE requires the following steps taken beforehand regarding an Identification- and Identity-Management-System: 1. Before a claimant (subscriber) enters into a contractual relationship with a Registration Authority [RA], he shall be informed of the precise terms and conditions by the RA regarding the use of the device/token. 2. The RA shall perform all identity proofing in accordance with the published identity proofing policy and ensure, that subscribers are properly identified and registered. 3. The RA shall accept requests with qualified digital signatures for claimants possessing valid certificates. 4. The RA shall record the signed agreement with the claimant (subscriber). 5. Records with the actions of the RAs and IdPs, shall be stored in corresponding event journals. 6. Communications between the RA and the IdP shall be authenticated and secure. 7. If external RAs are used, a documented process for validating and authorising external registration authorities respecting the information security requirements shall be implemented. 8. The IdP shall provide a policy for managing the identity information lifecycle 9. Processes to maintain the accuracy of the identity information and controls to verify policies, regulations, business requirements and to improve processes shall be established by the IdP. 10. Policies to specify the conditions and procedures to archive identity information shall be established by the IdP. 11. The IdP shall provide policies to specify the conditions and procedures to initiate deletion of identity information. The following controls shall be fulfilled: - [ISO/IEC 29115:2013]: 10.1 Threats to, and controls for, the enrolment phase - [ISO/IEC 24760-2:2015][10]: 6.2 Access policy for identity information - [ISO/IEC 24760-2:2015]: 6.3.1 Policy for identity information life cycle - [ISO/IEC 24760-2:2015]: 6.3.2 Conditions and procedure to maintain identity information - [ISO/IEC 24760-2:2015]: 6.3.5 Identity information quality and compliance - [ISO/IEC 24760-2:2015]: 6.3.6 Archiving information - [ISO/IEC 24760-2:2015]: 6.3.7 Terminating and deleting identity information
OE.Credential Management	1. The IDP shall establish procedures to ensure that the individual who receives the device/token is the same individual who participated in the registration procedure. 2. For issuing a device/token, procedures shall be established, which allow the subscriber to authenticate

	the IdP as the source of the delivered device/token and to check its integrity. 3. The IdP shall revoke a device/token based on a unique identifying attribute in a token or in a credential (e.g. serial number) within a specific time period as defined by a corresponding policy or immediately, when stolen or compromised. An on-line revocation/status checking availability shall be implemented and maintained as well as a web site, on which revocation requests can be submitted in an authenticated manner (security questions, out-of-band notification, etc.) by the claimants. The following controls shall be applied and fulfilled: - [ISO/IEC 29115:2013]: 10.2 Threats to, and controls for, the credential management phase
OE.Operations Security	To ensure correct and secure operations of information processing systems, the IdP shall also implement, maintain and control processes according to the following security controls of the ISO/IEC 27001 Standard: - [ISO/IEC 27001:2013]: A. 12.3 Backup - [ISO/IEC 27001:2013]: A.14.2.1 Secure development policy - [ISO/IEC 27001:2013]: A.14.2.5 Secure system engineering principles - [ISO/IEC 27001:2013]: A.15 Supplier relationships - [ISO/IEC 27001:2013]: A.16 Information security incident management - [ISO/IEC 27001:2013]: A.18.1.3 Protection of records - [ISO/IEC 27001:2013]: A.18.1.4 Privacy and protection of personally identifiable information - [ISO/IEC 27001:2013]: A. 18.2.2 Compliance with security policies and standards
OE.User Security Awareness	1. The RA shall inform the claimant/subscriber through an agreement to submit accurate and complete information to the legal requirements according EPDV, particularly within the registration process. 2. The RA shall inform the claimant/subscriber through an agreement to protect his device/token and furthermore to: - use the device/token only for authentication and in accordance with any other limitations notified to the claimant/subscriber - exercise care to prevent unauthorised use of its device/token 3. The RA shall inform the claimant/subscriber through an agreement and to notify the IdP without any reasonable delay, if any of the following events should occur before the end of the validity period: - the claimant's device/token has been lost, stolen or potentially compromised - control over the claimant's device/token has been lost due to a compromised activation data or other reasons. 4. Claimants shall be aware to communicate revocation requests through protected and authenticated channels with an appropriate user authentication and validation (security questions, out-of-band notification,

	etc.). 5. The RA shall made aware the claimant/subscriber of his responsibilities for maintaining effective access controls, particularly regarding the use of his activation data. 6. The RA shall made aware, that the claimant/subscriber shall keep his computing environment on which the part of the TOE is installed or interacts integer. To achieve this requirement, an anti-virus and personal firewall shall be installed and kept up to date. The entire computing environment shall be updated with the last patches und security updates. The claimant shall be aware and extremely cautious when downloading and/or running executable content such as programs, scripts, macros, add-ons, apps, etc. in order to prevent attacks on the integrity of the computing environment.

Table 6 Security Objectives for the operational environment

4.3 Security Objectives rationale

This chapter describes rationales for the effectiveness of the security objectives stated above for individual parameters of the security problem definition.

4.3.1 Overview

	O.Integrity	O.Confidentiality	O.Availability	O.Accountability	O.Authentication	O.Secure_Communication	O.Cryptographic_Functions	O.Access_Control	OE.HR-Security	OE.Access_ManagementSystem	OE. SecureAreas and Equipment	OE.Configuration and ChangeManagement	OE.Malware and Vulnerability Management	OE.Logging and Monitoring	OE.Network Security	OE.Identification and IdentityManagement	OE.Credential Management	OE.Operations Security	OE.User Security Awareness
P.Audit	X	X		X										X					
P.Crypto	X	X				X	X								X				
P.AccessRights		X			X			X		X									
P.Hardening													X						
T.CompromiseToken/Credential	X	X			X	X	X												X
T.Token/CredentialTheft								X									X		X
T.WebPlatformAttacks						X						X	X	X	X				

	O.Integrity	O.Confidentiality	O.Availability	O.Accountability	O.Authentication	O.Secure_Communication	O.Cryptographic_Functions	O.Access_Control	OE.HR-Security	OE.Access_ManagementSystem	OE. SecureAreas and Equipment	OE.Configuration and ChangeManagement	OE.Malware and Vulnerability Management	OE.Logging and Monitoring	OE.Network Security	OE.Identification and IdentityManagement	OE.Credential Management	OE.Operations Security	OE.User Security Awareness
T.SpoofingAndMasquerading	X	X		X	X	X								X					
T.SessionHijacking	X	X				X									X				
T.Online_Guessing				X	X									X					
T.ReplayAttack				X		X								X					
T.Eavesdropping		X				X									X				
T.Configuration									X			X							
T.DoS			X									X	X		X				
A.Personal																			
A.AcccessManagement																			
A.Physical																			
A.Monitoring														X					
A.Malware													X						
A.Identification																X			
A.Credential Handling																	X		
A.SystemOperation																		X	
A.Client_Platform																			X

Table 7 Rationale for the security objectives

4.3.2 Countering the threats

4.3.2.1 **T.CompromiseToken/Credential**

The threat **T.CompromiseToken/Credential** addresses all compromises of a device/token and their credentials meaning that an attacker gains access to a credential of a registered claimant and impersonates him or her either by credential tampering, credential disclosure, credential duplication, delayed credential revocation or offline guessing.

The protection against this threat is mainly achieved by the security objectives **O.Integrity** by ensuring TSF data integrity, **O.Confidentiality** by ensuring that TSF Data has not been altered in an unauthorized manner, **O.Authentication** by ensuring authenticity and a strong authentication with regard to the client platform, **O.Secure_Communication** by protection of confidentiality and integrity of the received and transmitted user and TSF data and **O.Cryptographic_Functions** by encryption of TSF and User data of the TOE. Furthermore, the security objective for the operational environment **OE.User Security Awareness** shall ensure that the claimant/subscriber is aware of his responsibilities for maintaining effective access controls and obligations with regard to stolen, lost or compromised devices/tokens.

4.3.2.2 **T.Token/CredentialTheft**

The threat **T.Token/CredentialTheft** describes the situation where the token or device has been stolen by an attacker. The attacker then gains access to the TSF data for instance by knowing the activation data and therefore gains access to the TOE.

This threat is countered by the security objectives **O.Access_Control** and the objectives for the TOE environment **OE.Credential Management** and **OE.User Security Awareness**. The objective **O.Access_Control** sets the requirements to prevent unauthorized use by the establishment of access control of all objects under the control of the TOE and the TSF. The objective for the TOE environment **OE.Credential Management** shall ensure secure issuing procedures regarding the device and token and procedures for immediate revocation of stolen or lost devices/tokens.

4.3.2.3 **T.WebPlatformAttacks**

The threat **T.WebPlatformAttacks** addresses incorrect or faulty implementation of application functions related to authentication and session management that allows an attacker to compromise passwords, keys or session tokens by using exploits such as Cross-Site-Scripting, Cross-Site Request Forgery attacks or Injection exploits.

The protection against this threat is achieved by the security objectives **O.Secure_Communication** and the objectives for the TOEs environment **OE.Configuration and ChangeManagement**, **OE.Malware and Vulnerability Management** and **OE.Network Security**. The objective **OE.Malware and Vulnerability Management** ensures that information processing systems are protected against malicious code and that appropriate measures such as malware code detection are in place beside appropriate system access and change management controls. The objective **OE.Network Security** counters this threat by ensuring the security of information in networks and the protection of connected services from unauthorized access. The objective **OE.Configuration and ChangeManagement** counters this threat by ensuring that security and control procedures are not compromised, that support programmers are given access only to those parts of the system necessary for their work, and that formal agreement and approval for any change is obtained.

4.3.2.4 T.SpoofingAndMasquerading

The threat **T.SpoofingAndMasquerading** refers to situations in which an attacker impersonates another entity in order to launch attacks against network hosts, steal data, spread malware or bypass access controls. This may be done by making use of the credential(s) of an entity or otherwise posing as an entity (e.g. by forging a credential).

The protection against this threat is mainly achieved by the security objectives **O.Integrity**, **O.Confidentiality**, **O.Accountability**, **O.Authentication**, **O.Secure_Communication** and the objective for the TOE environment **OE.Logging and Monitoring**. The objectives **O.Integrity** and **O.Confidentiality** shall ensure that TSF data has not been accessed or altered in an unauthorized manner such that the attacker will not be able to masquerade as the owner of the token/device. The objective **O.Accountability** shall ensure that all actions of an entity specifically to establish future investigations and access control monitoring. The objective **O.Authentication** requires any message to be digitally signed and **O.Secure_Communication** that secure communication is supported by the TOE. The objective **OE.Logging and Monitoring** further requires logs and fault logging to ensure information that system problems are identified.

4.3.2.5 T.SessionHijacking

The threat **T.SessionHijacking** addresses the situation where an attacker is able to intercept successful authentication exchange transactions between the claimant and the IdP and to steal or predict valid session data to gain compromised/unauthorized access to the web portal of the service provider.

The protection against this threat is achieved by the security objectives **O.Integrity**, **O.Confidentiality**, **O.Secure_Communication** providing integrity secured, confidential secure channels between the trusted entities. Further it is ensured by the objective for the TOE environment **OE.Network Security**.

4.3.2.6 **T.Online_Guessing**

The threat **T.Online_Guessing** addresses guessing of the token authenticator for instance by using brute force methods based on specific dictionaries.

The protection of this threat is achieved by the objectives **O.Accountability**, ensuring unique tracing of all actions to an entity and **O.Authentication** requiring use of a multi-authentication factor token and supportively the objective for the TOE environment **OE.Logging and Monitoring**.

4.3.2.7 T.ReplayAttack

The threat **T.ReplayAttack** addresses replaying of previously captured messages between the claimant and the IdP in order to authenticate as that claimant.

The protection of this threat is achieved by the security objectives **O.Accountability**, **O.Secure_Communication**, specifically providing nonces or challenges to prove the freshness of the transaction and supportively the objective for the TOE environment **OE.Logging and Monitoring**.

4.3.2.8 **T.Eavesdropping**

The threat **T.Eavesdropping** addresses passively listening to authentication transactions and to capture information that can be used in a subsequent active attack to masquerade as the claimant.

The protection of this threat is achieved by the security objectives **O.Confidentiality**, **O.Secure_Communication**, specifically encrypting all communication appropriately and supportively the objective for the TOE environment **OE.Network Security**.

4.3.2.9 **T.Configuration**

The threat **T.Configuration** addresses exploiting of weaknesses resulting from a wrong configuration setting, incomplete deployment or not up-to-date software of TSF

The protection of this threat is achieved by the security objectives for the TOE environment **OE.HR-Security** and **OE.Configuration and ChangeManagement**.

4.3.2.10 **T.DoS**

The threat **T.DoS** addresses denial of service attacks focussing on TSF in order to make them unavailable.

The protection of this threat is achieved by the security objectives **O.Availability** and the objectives for the TOE environment **OE.Configuration and ChangeManagement**, **OE.Malware and Vulnerability Management** and **OE.Network Security**.

5 Security Requirements

5.1 Overview

The CC allows several operations to be performed on functional components: refinement, selection, assignment, and iteration are defined in chapter C.4 of part 1 of the CC. Each of these operations is used in this PP.

The refinement operation is used to add detail to a requirement, and thus further restricts a requirement. Refinement of security requirements is (1) denoted by the word “refinement” in a footnote and the added/changed words are in bold text, or (2) included in text as underlined text and marked by a footnote. In cases where words from a CC requirement were deleted, a separate attachment indicates
10 the words that were removed.

The selection operation is used to select one or more options provided by the CC in stating a requirement. Selections that have been made by the PP authors are denoted as underlined text and the original text of the component is given by a footnote. Selections to be filled in by the ST author appear in square brackets with an indication that a selection is to be made, [selection:], and are italicized.

The assignment operation is used to assign a specific value to an unspecified parameter, such as the length of a password. Assignments that have been made by the PP authors are denoted by showing as underlined text and the original text of the component is given by a footnote. Assignments to be filled in by the ST author appear in square brackets with an indication that an assignment is to be made [assignment:], and are italicized.

20 ## 5.2 Security Functional Requirements for the TOE

This section on security functional requirements (SFR) for the TOE is divided into sub-section following the main security functionality.

5.2.1 Security audit automatic response (FAU_ARP)

FAU_ARP.1 Security alarms

FIA_ARP.1.1	The TSF shall take [one or more of the following actions: audible alarm, SNMP trap, log, email with or without attachments, page to a pager, SMS, visual alert to notify the administrator’s designated personnel and generate an audit record] upon detection of a potential security violation.
Hierarchical to:	No other components.
Dependencies:	**FAU_SAA.1 Potential violation analysis**
Application note:	This requirement applies only for the IdP. Additionally, the security alarms have to be integrated in the monitoring processes of the computing environment of the TOE.

5.2.2 Audit Data Generation (FAU_GEN)

FAU_GEN.1 Audit Generation

FAU_GEN.1.1	The TSF shall be able to generate an audit record of the following auditable events:

a) Start-up and shutdown of the audit functions;

b) All auditable events for the not specified[1] level of audit; and

c) *Auditable events listed in the table below:*[2]

Event	Additional Details	Entity
Any event	- Time the event (e.g. request) received	IdP Activity Log
Authenticated successful	- Remote logname/identity - IP address - Claimant ID, if the request was authenticated - First line of request. - Final status. - Size of response in bytes. - Referrer header field	IdP Activity Log
Authenticated unsuccessful	- Remote logname/identity - IP address - First line of request. - Final status. - Size of response in bytes. - Referrer header field	IdP Activity Log
Logged in successful	- Name of the Trusted User, Temporary privileged user - Name and role of the operator	IdP Activity Log
Logged out successful	- Name of the Trusted User, Temporary privileged user - Name and role of the operator	IdP Activity Log
Logon failure	- Name of the Trusted User, Temporary privileged user - Name and role of the operator	IdP Activity Log
Creation of a new claimant	- n/a	IdP Activity Log
Deletion of a claimant	- n/a	IdP Activity Log
Locking of a claimant	- n/a	IdP Activity Log
Successful and rejected	- Name of the subject and	IdP Activity

[1] [selection, choose one of: minimum,basic, detailed, not specified]

[2] [assignment: other specifically defined auditable events]

data and other resource access attempts if applicable	the resources	Log
Changes to system configuration	- Name of the Trusted User - Name and role of the operator	IdP Activity Log
Privileged actions (e.g. password change)	- Name of the Trusted User, Temporary privileged user - Name and role of the operator	IdP Activity Log
Use of system utilities and applications	- Name of the subject and the resources	IdP Activity Log
Alarms raised by the access control system	- Entity	IdP Activity Log
Activation and de-activation of protection systems	- Name of the Trusted User - Name and role of the operator	IdP Activity Log
Incidents	- Source - Number of changes - Analysis – list of suspicious actions - Event Tree: process, file, registry and network events - Timeline: timeline of suspicious actions - Geography: suspected locations of suspicious events - Configuration: host system identification details, running applications, service handles, processes, threads	IdP Incidents Alerts

FAU_GEN.1.2 The TSF shall record within each audit record at least the following information:

a) Date and time of the event, type of event, subject identity (if applicable), and the outcome (success or failure) of the event; and

b) For each audit event type, based on the auditable event definitions of the functional components included in the PP, additional details specified below:[3]

- files accessed (if applicable)
- programs/utilities used
- use of privileged accounts, e.g. supervisor, root, administrator;

[3] [assignment: other audit relevant information]

- system start-up and stop;
- I/O device/connector attachment/detachment;
- failed or rejected user actions;
- failed or rejected actions involving data and other resources;
- access policy violations and notification
- console alerts or messages;
- system log exceptions;
- network management alarms;
- alarms raised by the access control system;
- changes to, or attempts to change, system security settings and controls

Hierarchical to: No other components.

Dependencies: **FPT_STM.1 Reliable time stamps**

Application note: These requirements apply only to the IdP and shall be integrated into the logging and monitoring concept of the computing environment of the TOE.

5.2.3 Security audit analysis (FAU_SAA)

FAU_SAA.1 Potential violation analysis

FAU_SAA.1.1 The TSF shall be able to apply a set of rules in monitoring the audited events and based upon these rules indicate a potential violation of the enforcement of the SFRs.

FAU_SAA.1.2 The TSF shall enforce the following rules for monitoring audited events:

a) Accumulation or combination of defined auditable events given in the following table[4] known to indicate a potential security violation

b) none[5].

No.	Operation	Potential violation analysis list
1	Authentication	Claimant ID mismatch
2		Authentication attempt with revoked claimant ID
3		Authenticator Token mismatch
4		Authentication error
5		Communication channel not trusted or broken
6		Communication channel with weak encryption
7		Enumerating of access portal
8		DoS-Attack on access portal
9		System alerts
10		Certificate validation and path failures

[4] [assignment: subset of definedauditable events]

[5] [assignment: any other rules]

11		Assertion scheme mismatch
12		Digital signature verification failure

Hierarchical to: No other components.

Dependencies: **FAU_GEN.1 Audit Generation**

Application note: These requirements apply only to the IdP and shall be integrated into the operation security concept of the computing environment of the TOE

5.2.4 Security audit review (FAU_SAR)

FAU_SAR.1 Audit review

FAU_SAR.1.1 The TSF shall provide Trusted Users and/or Temporary privileged users[6] with the capability to read incident reports and the IdP Activity Log[7] from the audit records.

FAU_SAR.1.2 The TSF shall provide the audit records in a manner suitable for user to interpret the information.

Hierarchical to: No other components.

Dependencies: **FAU_GEN.1 Audit Generation**

Application note: These requirements apply only on the IdP and shall be integrated into the logging and monitoring concept of the computing environment of the TOE.

5.2.5 Security audit event storage (FAU_STG)

FAU_STG.1 Protected audit trail storage

FAU_STG.1.1 The TSF shall protect the stored audit records in the audit trail from unauthorized deletion.

FAU_ STG.1.2 The TSF shall be able to prevent[8] unauthorized modifications to the stored audit records in the audit trail.

Hierarchical to: No other components.

Dependencies: **FAU_GEN.1 Audit Generation**

Application note: These requirements apply only to the IdP and shall be integrated into the operation security concept of the computing environment of the TOE

[6] [assignment: authorised users]

[7] [assignment: list of audit information]

[8] [selection, choose one of: prevent, detect]

5.2.6 Management of security attributes (FMT_MSA)

FMT_MSA.1 Management of security attributes

FMT_MSA.1.1	The TSF shall enforce the access control SFP[9] to restrict the ability to query, delete[10] the security attributes Reference of the user credential, Claimant ID, Identification Data[11] to Trusted User[12].
Hierarchical to:	No other components.
Dependencies:	[FDP_ACC.1 Subset access control, or FDP_IFC.1 Subset information flow control] FMT_SMR.1 Security roles FMT_SMF.1 Specification of Management Functions
Application note:	

FMT_MSA.3 Static attribute initialisation

FMT_MSA.3.1	The TSF shall enforce the access control SFP[13] to provide restrictive[14] default values for security attributes that are used to enforce the SFP.
FMT_MSA.3.2	The TSF shall allow the Security Information Officers[15] to specify alternative initial values to override the default values when an object or information is created.
Hierarchical to:	No other components.
Dependencies:	FMT_MSA.1 Management of security attributes FMT_SMR.1 Security roles
Application note:	

[9] [assignment: access control SFP(s), information flow control SFP(s)]

[10] [selection: change_default, query, modify, delete, [assignment: other operations]]

[11] [assignment: list of security attributes]

[12] [assignment: the authorised identified roles]

[13][assignment: access control SFP, information flow control SFP]

[14] [selection, choose one of: restrictive, permissive, [assignment: other property]]

[15] [assignment: the authorised identified roles]

5.2.7 Access control functions (FDP_ACF)

FDP_ACF.1 Security attribute based access control

FDP_ACF.1.1	The TSF shall enforce the access control SFP[16] to objects based on the following: User, Trusted User, Temporary privileged users, User data, and for each, the SFP-relevant security attributes, or named groups of SFP-relevant security attributes[17].
FDP_ACF.1.2	The TSF shall enforce the following rules to determine if an operation among controlled subjects and controlled objects is allowed: Authenticated successful, Authenticated unsuccessful, Logged in successful, Logged out successful, Logon failure, Creation of a new claimant, Deletion of a claimant, Locking of a claimant, Successful and rejected data and other resource access attempts if applicable[18].
FDP_ACF.1.3	The TSF shall explicitly authorize access of subjects to objects based on the following additional rules: none[19].
FDP_ACF.1.4	The TSF shall explicitly deny access of subjects to objects based on the following additional rules: none[20].
Hierarchical to:	No other components.
Dependencies:	FDP_ACC.1 Subset access control FMT_MSA.3 Static attribute initialization
Application note:	These requirements apply only to the IdP and shall be integrated into the access management system of the computing environment of the TOE.

5.2.8 Access control policy (FDP_ACC)

FDP_ACC.1 Subset access control

FDP_ACC.1.1	The TSF shall enforce the access control SFP[21] on User, Trusted User, Temporary privileged users, User data and operations among subjects and objects

[16] [assignment: access control SFP]

[17] [assignment: list of subjects and objects controlled under the indicated SFP, and for each, the SFP-relevant security attributes, or named groups of SFP-relevant security attributes]

[18] [assignment: rules governing access among controlled subjects and controlled objects using controlled operations on controlled objects]

[19] [assignment: rules, based on security attributes, that explicitly authorise access of subjects to objects]

[20] [assignment: rules, based on security attributes, that explicitly deny access of subjects to objects]

[21] [assignment: access control SFP]

covered by the SFP[22].

Hierarchical to: No other components.

Dependencies: FDP_ACF.1 Security attribute based access control

Application note:

5.2.9 Inter-TSF TSF data consistency (FPT_TDC)

FPT_TDC.1 Inter-TSF basic TSF data consistency

FDP_TDC.1.1 The TSF shall provide the capability to consistently interpret Assertion Data[23] when shared between the TSF and another trusted IT product.

FPT_TDC.1.2 The TSF shall use OASIS Security Assertion Markup Language (SAML) V2.0[24] when interpreting the TSF data from another trusted IT product.

Hierarchical to: No other components.

Dependencies: No dependencies.

Application note:

5.2.10 Import from outside of the TOE (FDP_ITC)

FDP_ITC.2 Import of user data with security attributes

FDP_ITC.2.1 The TSF shall enforce the access control SFP(s)[25] when importing user data, controlled under the SFP, from outside of the TOE.

FDP_ITC.2.2 The TSF shall use the security attributes associated with the imported user data.

FDP_ITC.2.3 The TSF shall ensure that the protocol used provides for the unambiguous association between the security attributes and the user data received.

FDP_ITC.2.4 The TSF shall ensure that interpretation of the security attributes of the imported user data is as intended by the source of the user data.

FDP_ITC.2.5 The TSF shall enforce the following rules when importing user data controlled under the SFP from outside the TOE: none[26].

Hierarchical to: No other components.

Dependencies: [FDP_ACC.1 Subset access control, or
FDP_IFC.1 Subset information flow control]
[FTP_ITC.1 Inter-TSF trusted channel, or

[22] [assignment: list of subjects, objects, and operations among subjects and objects covered by the SFP]

[23] [assignment: list of TSF data types]

[24] [assignment: list of interpretation rules to be applied by the TSF]

[25] [assignment: access control SFP(s) and/or information flow control SFP(s)]

[26] [assignment: additional importation control rules]

FTP_TRP.1 Trusted path]
FPT_TDC.1 Inter-TSF basic TSF data consistency

Application note:

5.2.11 Cryptographic key management (FCS_CKM)

FCS_CKM.1 Cryptographic key generation

FCS_CKM.1.1 The TSF shall generate cryptographic keys in accordance with a specified cryptographic key generation algorithm [defined by the following standards: ETSI TS 102 176-1 [5], NIST Special Publication 800-133 [6], NIST Special Publication 800-56A, NIST Special Publication 800-56B [7][27] and specified cryptographic key sizes [asymmetric (RSA): 2048 - 4096 Bit, elliptic curve (EC): n ≥ 224, symmetric: ≥ 256 bits, any key sizes of algorithms providing comparable cryptographic strength][28] that meet the following: none[29].

Hierarchical to: No other components.

Dependencies: [FCS_CKM.2 Cryptographic key distribution, or
FCS_COP.1 Cryptographic operation]
FCS_CKM.4 Cryptographic key destruction

Application note:

FCS_CKM.3 Cryptographic key access

FCS_CKM.3.1 The TSF shall perform import the user data with security[30] in accordance with a specified cryptographic key access method import through a secure channel[31] that meets the following: GlobalPlatform Card Specification v.2.3 [14], TLSv1.2 [11], other secure means with defined descriptions[32].

Hierarchical to: No other components.

Dependencies: [FDP_ITC.1 Import of user data without security
attributes, or
FDP_ITC.2 Import of user data with security
attributes, or

[27] [assignment:cryptographic key generation algorithm]

[28] [assignment: cryptographic key sizes]

[29] [assignment: list of standards]

[30] [assignment: type of cryptographic key access]

[31] [assignment: cryptographic key access method]

[32] [assignment: list of standards]

FCS_CKM.1 Cryptographic key generation]
FCS_CKM.4 Cryptographic key destruction

Application note:

FCS_CKM.4 Cryptographic key destruction

FCS_CKM.4.1	The TSF shall destroy cryptographic keys in accordance with a specified cryptographic key destruction method physically overwriting the keys with random numbers[33] that meets the following: none[34].
Hierarchical to:	No other components.
Dependencies:	[FDP_ITC.1 Import of user data without security attributes, or FDP_ITC.2 Import of user data with security attributes, or FCS_CKM.1 Cryptographic key generation]
Application note:	The key destruction method shall be applied on volatile key fragments after a cryptographic operation for authentication purposes. This requirement shall not be applied on libraries for standard communication security applications (e.g. TLS, IPsec).

5.2.12 Cryptographic operation (FCS_COP)

FCS_COP.1(1) Cryptographic operation (Symmetric Key Cryptographic Operation)

FCS_COP.1.1(1)	The TSF shall perform data encryption and decryption operations[35] in accordance with a specified cryptographic algorithm AES[36] with a cryptographic key size 256 bits[37] that meets the following: none[38].
Hierarchical to:	No other components.
Dependencies:	[FDP_ITC.1 Import of user data without security attributes, or FDP_ITC.2 Import of user data with security attributes, or

[33] [assignment: cryptographic key destruction method]

[34] [assignment: list of standards]

[35] [assignment: list of cryptographic operations]

[36] [assignment: cryptographic algorithm]

[37] [assignment: cryptographic key sizes]

[38] [assignment: list of standards]

FCS_CKM.1 Cryptographic key generation]
FCS_CKM.4 Cryptographic key destruction

FCS_COP.1(2) Cryptographic operation (Asymmetric Key operations)

FCS_COP.1.1(2)	The TSF shall perform data encryption and decryption[39] in accordance with a specified cryptographic algorithm RSA, Diffie-Hellman, ElGamal, EC and comparable algorithms[40] and cryptographic key size 2048 - 4096 Bit, n ≥ 224[41] that meet the following: PKCS#1 v1.5, PKCS#1 v2.1[42].
Hierarchical to:	No other components.
Dependencies:	[FDP_ITC.1 Import of user data without security attributes, or FDP_ITC.2 Import of user data with security attributes, or FCS_CKM.1 Cryptographic key generation] FCS_CKM.4 Cryptographic key destruction
Application note:	Additionally to the listed cryptographic algorithms, other algorithms are admitted if they provide comparable cryptographic strength.

FCS_COP.1(3) Cryptographic operation (HASH function)

FCS_COP.1.1	The TSF shall perform a HASH operation[43] in accordance with a specified cryptographic algorithm [SHA-256, SHA-512[44]] with a cryptographic key size none[45] that meets the following: FIPS PUB 180-3[46].
Hierarchical to:	No other components.
Dependencies:	[FDP_ITC.1 Import of user data without security attributes, or FDP_ITC.2 Import of user data with security attributes, or FCS_CKM.1 Cryptographic key generation]

[39] [assignment: list of cryptographic operations]

[40] [assignment: cryptographic algorithm]

[41] [assignment: cryptographic key sizes]

[42] [assignment: list of standards]

[43] [assignment: list of cryptographic operations]

[44] [assignment: cryptographic algorithm]

[45] [assignment: cryptographic key sizes]

[46] [assignment: list of standards]

FCS_CKM.4 Cryptographic key destruction

Application note:

5.2.13 Authentication failures (FIA_AFL)

FIA_AFL.1 Authentication failure handling

FIA_AFL.1.1 / IdP	The TSF shall detect when an administrator configurable positive integer within the range of 1 - 20[47] unsuccessful authentication attempts occur related to authentication on the IdP portal or system[48].
FIA_AFL.1.1 / Device/Token	The TSF shall detect when a certain number of[49] unsuccessful authentication attempts occur related to RAD/Activation (5 attempts are allowed) and PUK (authentication (10 attempts are allowed) if provided[50].
FIA_AFL.1.2 / IdP	When the defined number of unsuccessful authentication attempts has been met or surpassed[51], the TSF shall display warning message, stop the function of user authentication for 10 minutes and generate audit data to the event[52].
FIA_AFL.1.2 / Device/Token	When the defined number of unsuccessful authentication attempts has been met or surpassed[53], the TSF shall block the RAD/Activation[54].
Hierarchical to:	No other components.
Dependencies:	**FIA_UID.1 Timing of identification**

Application note:

5.2.14 User authentication (FIA_UAU)

FIA_UAU.1 Timing of authentication

FIA_UAU.1.1	The TSF shall allow all functions allowed to be performed by the non authenticated user according to the defined authentication sequence with corresponding secure authentication process states[55] on behalf of the user to be performed before the user is authenticated.

[47] [selection: [assignment: positive integer number], an administrator configurable positive integer within[assignment: range of acceptable values]]

[48] [assignment: list of authentication events]

[49] [selection: [assignment: positive integer number], an administrator configurable positive integer with-in[assignment: range of acceptable values]]

[50] [assignment: list of authentication events]

[51] [selection: met, surpassed]

[52] [assignment: list of actions]

[53] [selection: met, surpassed]

[54] [assignment: list of actions]

[55] [assignment: list of TSF mediated actions]

FIA_UAU.1.2	The TSF shall require each user to be successfully authenticated before allowing any other TSF-mediated actions on behalf of that user.
Hierarchical to:	No other components.
Dependencies:	**FIA_UID.1 Timing of identification**
Application note:	

FIA_UAU.2 User authentication before any action

FIA_UAU.2.1	The TSF shall require each user to be successfully authenticated before allowing any other TSF-mediated actions on behalf of that user.
Hierarchical to:	FIA_UAU.1 Timing of authentication.
Dependencies:	**FIA_UID.1 Timing of identification**
Application note:	

FIA_UAU.3 Unforgeable authentication

FIA_UAU.3.1	The TSF shall *detect and prevent* use of authentication data that has been forged by any user of the TSF.
FIA_UAU.3.2	The TSF shall detect and prevent[56] use of authentication data that has been copied from any other user of the TSF.
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	

FIA_UAU.5 Multiple authentication mechanisms

FIA_UAU.5.1	The TSF shall provide at least a 2-factor authentication mechanism using a combination of the following possible authentication components: a) Username and Passphrase or activation data, b) Software/Hardware token verification data, c) Biometric credentials[57] to support user authentication.
FIA_UAU.5.2	The TSF shall authenticate any user's claimed identity according to the following rules: The TOE first verifies the first one authentication component and then verifies the second one authentication component. If each verification of the two chosen

[56] [selection: detect, prevent]

[57] [assignment: list of multiple authentication mechanisms]

	authentication components has been successfully performed, further TSF-mediated actions are allowed.[58]
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	These SFRs refer to the ability for one of many authentication schemes to be specified, and to the ability for the TSF to authenticate a claimant based on the data passed through any of these schemes. The access web portal of the IdP use an authenticated secure channel to protect authentication/verification data transactions based on TLS 1.2 with at least one server-side certificate authentication.

FIA_UAU.7 Protected authentication feedback

FIA_UAU.7.1	The TSF shall provide only obscured feedback[59] to the user while the authentication is in progress.
Hierarchical to:	No other components.
Dependencies:	**FIA_UID.1 Timing of identification**
Application note:	Obscured feedback implies the TSF does not produce a visible display of any authentication data entered by a user, such as through a keyboard or another entering device (e.g., echo the password). It is acceptable that some indication of progress be returned instead.

5.2.15 User identification (FIA_UID)

FIA_UID.1 Timing of identification

FIA_UID.1.1	The TSF shall allow access to the public web portal of the IdP (restricted to the functions and resources accessible to the subscriber/claimant according to the access control policy assigned for that purpose)[60] on behalf of the user to be performed before the user is identified.
FIA_UID.1.2	The TSF shall require each user to be successfully identified before allowing any other TSF-mediated actions on behalf of that user.
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	

[58] [assignment: rules describing how the multiple authentication mechanisms provide authentication]

[59] [assignment: list of feedback]

[60] [assignment: list of TSF-mediated actions]

5.2.16 Management of functions in TSF (FMT_MOF)

FMT_MOF.1 Management of security functions behaviour

FMT_MOF.1.1	The TSF shall restrict the ability to modify the behavior of, enable, disable[61] the functions according to table under FMT_SMF.1 {a ..o}[62] to [Administrators, Operators].
FMT_MOF.1.2	The TSF shall restrict the ability to enable, disable[63] the functions according to table under FMT_SMF.1 {p ..q}[64] to Subscriber/Claimant[65].
Hierarchical to:	No other components.
Dependencies:	FMT_SMR.1 Security roles FMT_SMF.1 Specification of Management Functions
Application note:	

5.2.17 Revocation (FMT_REV)

FMT_REV.1 Revocation

FMT_REV.1.1	The TSF shall restrict the ability to revoke security attributes[66] associated with the users[67] under the control of the TSF to the authorized claimants[68].
FMT_REV.1.2	The TSF shall enforce rules a) The TSF shall revoke immediately the authentication associated with security b) The authorized claimant can revoke the authentication processes activated by the subscriber/claimant and the registration authority[69].
Hierarchical to:	No other components.
Dependencies:	**FMT_SMR.1 Security roles**
Application note:	The IdP has to make available a revocation service using the ocsp protocol

[61] [selection: determine the behaviour

of, disable, enable, modify the behaviour of]

[62] [assignment: list of functions]

[63] [selection: determine the behaviour

of, disable, enable, modify the behaviour of]

[64] [assignment: list of functions]

[65] [assignment: the authorised identified roles]

[66] [assignment: list of security attributes]

[67] [selection: users, subjects, objects, [assignment: other additional resources]]

[68] [assignment: the authorised identified roles]

[69] [assignment: specification of revocation rules]

5.2.18 Security management roles (FMT_SMR)

FMT_SMR.1 Security roles

FMT_SMR.1.1 The TSF shall maintain the roles

- Administrators,
- Operators,
- Maintenances,
- Claimant,
- and further authorized roles (e.g. supervisors)[70]

FMT_SMR.1.2 The TSF shall be able to associate users with roles.

Hierarchical to: No other components.

Dependencies: **FIA_UID.1 Timing of identification**

Application note:

5.2.19 Specification of Management Functions (FMT_SMF)

FMT_SMF.1 Specification of Management Functions

FMT_SMF.1.1 The TSF shall be capable of performing the following security management functions: [71]

	Management Function	**Entity**
a)	Management of Security Attributes Objects and credentials	IdP Device/Token
b)	Management of Claimant Security Attributes	IdP
c)	Management of Authentication Data	IdP
d)	Management of Audit Trail	IdP
e)	Management of Audited Events	IdP
f)	Management of TOE Access Banner	IdP
g)	Management of Role Definitions, including Role Hierarchies and constraints	IdP
h)	Management of access control and its policy	IdP
i)	Management of TOE configuration data	IdP
j)	Management of cryptographic network protocols	IdP
k)	Management of cryptographic keys	IdP
l)	Management of digital certificates	IdP
m)	Management of identification and authentication policy	IdP
n)	Management of identity	IdP
o)	Management of session services	IdP
p)	Management of device/token	Device/Token
q)	Management Reference authentication data [RAD]	Device/Token

Hierarchical to: No other components.

Dependencies: No dependencies.

[70] [assignment: the authorised identified roles]

[71] [assignment: list of management functions to be provided by the TSF]

Application note:

5.2.20 Replay detection (FPT_RPL)

FPT_RPL.1 Replay detection

FPT_RPL.1.1	The TSF shall detect replay for the following entities: TSF data and security attributes[72].
FPT_RPL.1.2	The TSF shall perform reject data; and audit event[73] when replay is detected.
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	

5.2.21 Time stamps (FPT_STM)

FPT_STM.1 Reliable time stamps

FPT_STM.1.1	The TSF shall be able to provide reliable time stamps.
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	These requirements apply only on the IdP and shall be integrated into the logging and monitoring concept of the computing environment of the TOE.

5.2.22 Limitation on scope of selectable attributes (FTA_LSA)

FTA_LSA.1 Limitation on scope of selectable attributes

FTA_LSA.1.1	The TSF shall restrict the scope of the session security attributes cookies, session-IDs[74], based on user identity, originating location, time of access[75].
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	

5.2.23 Confidentiality of exported TSF data (FTP_ITC)

FTP_ITC.1 Inter-TSF confidentiality transmission

FTP_ITC.1.1	The TSF shall provide a communication channel between itself and another trusted IT product that is logically distinct from other communication channels and provides assured identification of its end points and protection of the channel data from modification or disclosure.

[72] [assignment: list of identified entities]

[73] [assignment: list of specific actions]

[74] [assignment: session security attributes]

[75] [assignment: attributes]

FTP_ITC.1.2	The TSF shall permit the TSF[76] to initiate communication via the trusted channel.
FTP_ITC.1.3	The TSF shall initiate communication via the trusted channel for secure communication of assertions and user data.[77]
Hierarchical to:	No other components.
Dependencies:	No dependencies.
Application note:	This is to protect the transmission between the IdP and the associated RP.The TSF shall only use TLS 1.2 (RFC 5246 [11]) or IPsec with IKEv2 (RFC 4301 [12], RFC 7296 [13]).

[76] [selection: the TSF, another trusted IT product]

[77] [assignment: list of functions for which a trusted channel is required].

5.3 Security Requirements Rationale

	O.Integrity	Q.Confidentiality	O.Availability	O.Accontability	O.Authentication	O.Secure_Com-munication	O.Crypto-graphic_Func-tions	O.Access_Con-trol	OE.HR_Security	OE.Acces_Man-agementSystem	OE.SecureAreas and Equipment	OE.Configration *and* ChangeManage-	OE.Malware and velnerability Managmenet	OE.Logging and Monitorung	OE.Netswork Security	OE.Identification and IdentityMan-agement	OE.Credential Management	OE.Operations Security	OE.User responsibilities
FAU_ARP.1			X	X															
FAU_GEN.1			X	X															
FAU_SAA.1			X	X															
FAU_SAR.1	X		X	X															
FAU_STG.1	X		X																
FCS_CKM.1							X												
FCS_CKM.3		X			X	X	X	X											
FCS_CKM.4		X					X												
FCS_COP.1		X				X	X												
FDP_ACC.1				X			X	X											
FDP_ACF.1				X				X											
FDP_ITC.2	X	X				X		X											
FIA_AFL.1			X		X		X	X											
FIA_UAU.1				X	X		X	X											
FIA_UAU.2					X			X											
FIA_UAU.3	X				X			X											
FIA_UAU.5					X			X											
FIA_UAU.7		X			X			X											
FIA_UID.1				X	X	X		X											
FMT_MSA.1					X		X	X											

	O.Integrity	Q.Confidentiality	O.Availability	O.Accontability	O.Authentication	O.Secure_Com-munication	O.Crypto-graphic_Func-tions	O.Access_Con-trol	OE.HR_Security	OE.Acces_Man-agementSystem	OE.SecureAreas and Equipment	OE.Configration *and* ChangeManage-	OE.Malware and velnerability Managemenet	OE.Logging and Monitorung	OE.Netswork Security	OE.Identification and IdentityMan-agement	OE.Credential Management	OE.Operations Security	OE.User responsibilities
FMT_MSA.3					X		X	X											
FMT_MOF.1								X											
FMT_REV.1	X		X	X	X			X											
FMT_SMF.1				X	X	X	X	X											
FPT_RPL.1			X	X	X	X													
FTA_LSA.1	X				X	X	(X)	X											
FTP_ITC.1	X	X			X	X	X												
FPT_TDC.1	X			X															
FMT_SMR.1				X	X			X											
FPT_STM.1	X			X															

5.4 Security Assurance Requirements Rationale

The Evaluation Assurance Level for this Protection Profile is **EAL2**.
The reason for choosing assurance level EAL 2 is that this Protection Profile shall provide reasonable assurance for auditing the Electronic Means of Identification in the context of the Federal Act on Electronic Health Records and its regulations.

6 Appendix

6.1 Mapping from English to German/French terms

Term	German	French
Reference community	Stammgemeinschaft	Communauté de référence
Community	Gemeinschaft	Communauté
Healthcare professional	Gesundheitsfachperson	Professionnel de la santé
Electronic identification means	Identifikationsmittel	Moyen d'identification
Regulation on the Electronic Patient Record	Verordnung über das elektronische Patientendossier	Ordonnance sur le dossier électronique du patient
Claimant	Anspruchsberechtigter	Ayant droit
Token	Identifizierungsmerkmal	Caractéristiques d'identification
Credential	Berechtigungsnachweis	Référence d'authentification
Federal Act on Electronic Health Records	Bundesgesetz über das elektronische Patientendossier	Loi fédérale sur le dossier électronique du patient

6.2 Tables

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6.3 References

[1] Common Criteria for Information Technology Security Evaluation, Part 1: Introduction and general model; Version 3.1, Revision 3, Final, July 2009

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[13] RFC 7296: Internet Key Exchange Protocol Version 2 (IKEv2)

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6.4 SAML Specification

Note: The specification will be drafted during or subsequently to appraisal.