Electronic Health Record Lifecycle Model Release 1

Draft Standard for Trial Use

Health Level Seven Electronic Health Record Technical Committee
27 January 2008

Key References

1) HL7 EHR Interoperability Model Release 1 (EHR/IM), Draft Standard for Trial Use, published February 2007
2) HL7 EHR System Functional Model (EHRS/FM), Normative Standard, published February 2007
3) ISO 18307, Health Informatics – Interoperability and Compatibility in Messaging and Communication Standards, 2001
4) ISO 18308, Health Informatics – Requirements for an Electronic Health Record Reference Architecture, 2004
5) ISO 20514, Health Informatics – Electronic Health Record Definition, Scope and Context, 2005
6) ISO 21089, Health Informatics – Trusted End-to-End Information Flows, 2004

Definitions

EHR	Electronic Health Record
EHRS	Electronic Health Record System
EHR TC	Health Level Seven Electronic Health Record Technical Committee

Section 1: Background

In recent years “interoperability” has been a topic of great interest to the healthcare community. Many interoperability definitions have been offered, multiple interoperability claims have been made. The HL7 EHR TC has taken a particular interest to ensure that EHR interoperability is not just a byword but that industry consensus could be achieved regarding “What is EHR interoperability?” and that EHR interoperability could in fact be manifested via testable conformance criteria.

The first crucial step is to achieve an industry consensus agreement. This is the purpose of the HL7 EHR Interoperability Model (EHR/IM). It offers a set of EHR interoperability assertions and characteristics. Assertions express foundational concepts. Characteristics describe pertinent qualifiers and have testable conformance criteria (to allow validation of actual EHR records).

As the interoperability characteristics of EHR records were established, it was apparent that interoperability was not fulfilled at a single instance in time. Indeed the entire record lifecycle is within the scope of interoperability, starting at the point of record origination with vital continuity assured through subsequent record related events.

Section 2: Purpose

The HL7 EHR Lifecycle Model supplements the HL7 EHR Interoperability Model, building on the Act Record as a common record unit of the EHR. The EHR/IM formalizes the EHR Act Record, as a persistent record of acts (actions) occurring in health(care) delivery. The EHR/LM formalizes events in the Act Record lifecycle.

The following example illustrates how the EHR Record lifecycle propagates downstream via EHR record flows from the source System (from ISO 21089, “Health Informatics – Trusted End-to-End Information Flows”).

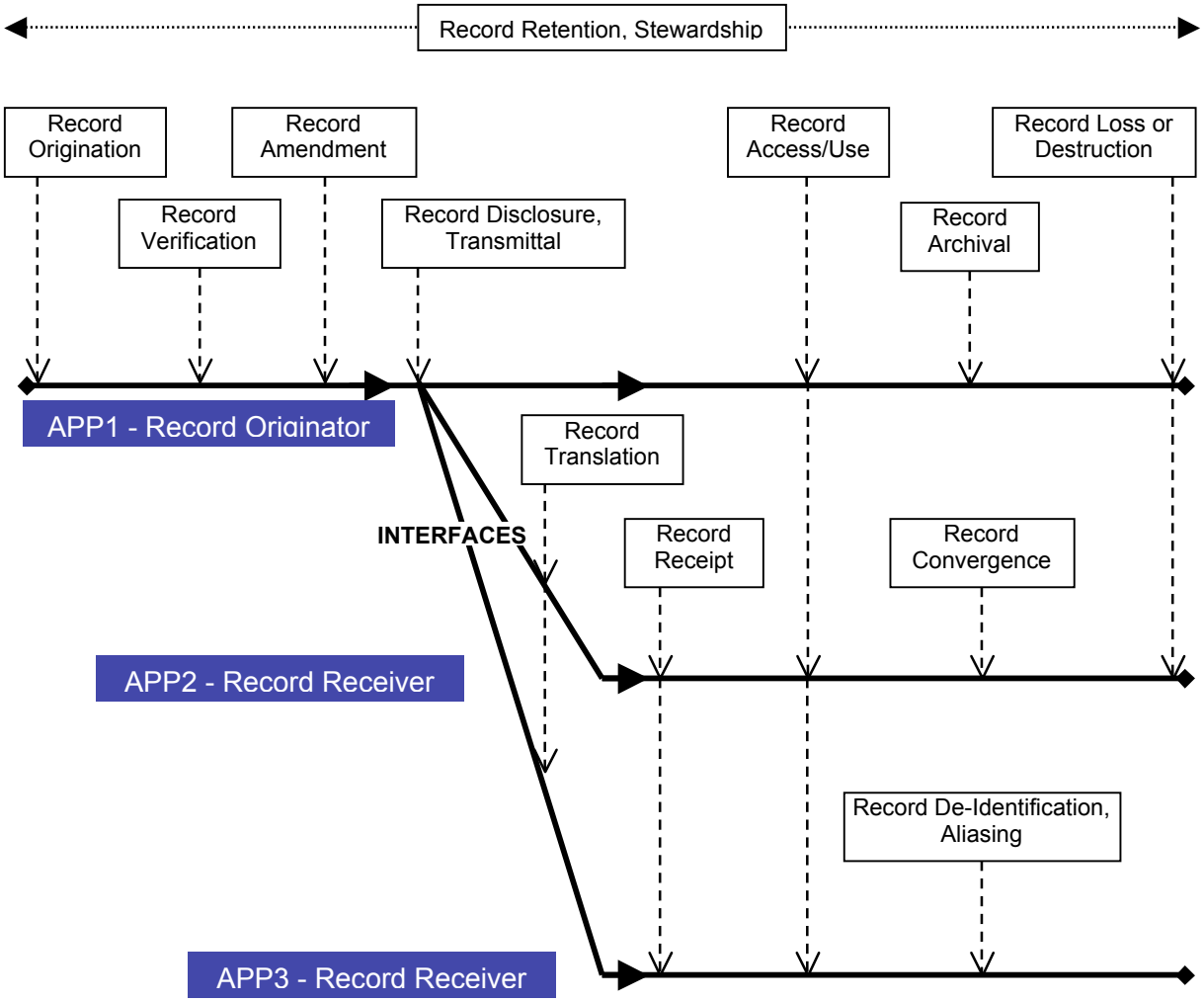


Figure 1: From ISO 21089, "Health Informatics – Trusted End-to-End Information Flows"

Section 3: Objectives

Objectives for the EHR Lifecycle Model are to:

- Establish **a common industry reference** for the EHR Act Record lifecycle.
- Establish **a requirements-first standard specification** for EHR Act Record lifecycle.
- Establish a model that is focused on **lifecycle events of EHR Act Records** as a supplement to the HL7 EHR Interoperability Model (focused on the interoperability characteristics of EHR Records) and its companion, the HL7 EHR-S Functional Model (focused on functional characteristics of EHR Systems).
- Establish **testable conformance criteria for EHR Systems and EHR Records** – at key points/events in the Act Record lifecycle.
- Establish a **framework to promote legally qualified EHR Act Records**.
- Specify the context of EHR Act Record **flow and lifecycle,** including origination, retention, amendment, interchange, protection, access, and use.
- Specify the EHR Act Record in context as an **immediate record (documentation) of the health(care) delivery process**, integral to work flow and concurrent to clinical practice.
- Specify **What** (i.e., EHR Act Record Lifecycle Characteristics) and **Why** (i.e., Rationale), but **not HOW** (i.e., Architectures and Implementations).
- Establish an industry consensus EHR Act Record lifecycle specification that is **technology-, vendor-, and product-neutral**.
- Leverage the **HL7 v3 Reference Information Model** to describe the primary EHR Act Record classes of Act, Actor, Role, and Participation.
- Leverage the HL7/ANSI **open consensus standards development process** to achieve industry collaboration and agreement.
- Ballot and publish a **draft standard for trial use** (DSTU) as precedent to a **full normative standard**.
- Enable **conformance profiles** specific to care settings, realms, products, implementations, and uses.

Section 4: Health(care) Delivery

The HL7 EHR Interoperability Model establishes the following frame of reference for health(care) delivery and the health record. From EHR/IM, Section 1:

- Health(care) delivery occurs at points along a time continuum.
- The Health Record documents health(care) along the time continuum.

Section 5: The Health(care) Act

In EHR/IM Section 2, the health(care) Act includes these key aspects:
- An Act is a discrete action, service or event occurring in the course of health(care) delivery.
- An Act is an accountable unit of health(care) delivery.
- Health(care) delivery is comprised of Acts.
- An Act has associated facts, findings, and observations.
- An Act may be patient specific or not.
- An Act has Actor(s), in roles and with specific participations.
- An Act occurs at a specific date/time and has an elapsed time.

Section 6: The Act Record

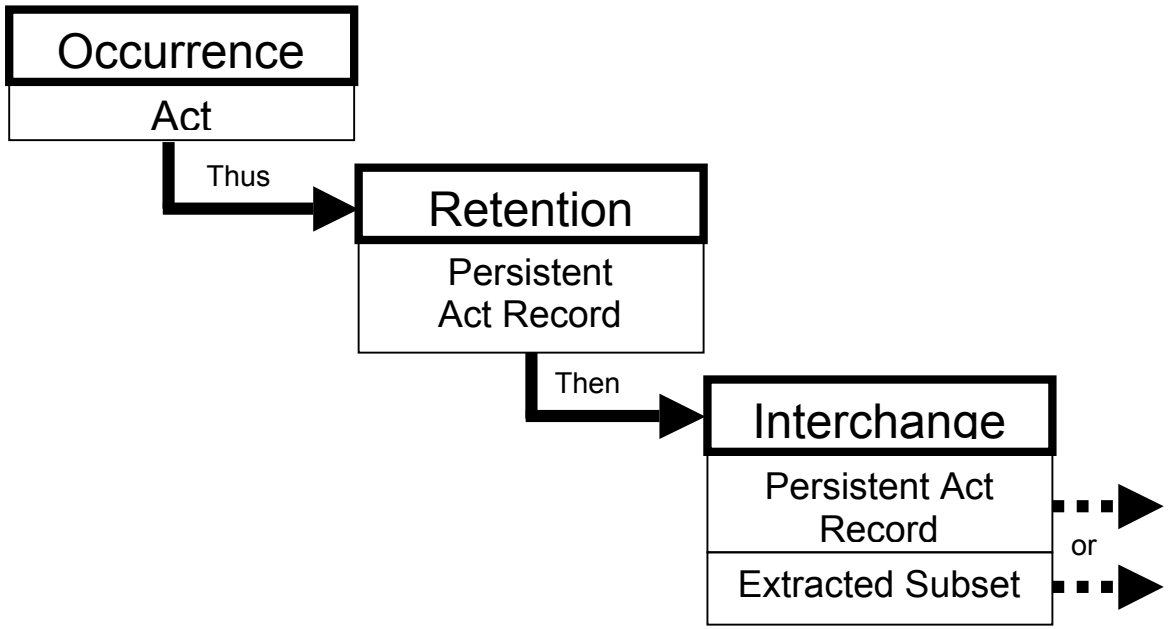
In EHR/IM Section 3, the Act Record is described in the following terms:
- An Act is documented by an Act Record instance.
- An Act/Act Record instance is uniquely identifiable.
- An Act Record is persistent legal evidence of Act occurrence.
- An Act Record is a unit of record of the Health Record.

EHR entry [is that] portion of an electronic health record documenting part or all of a delivered or intended care activity, a clinical observation or a statement concerning health status or needs, and which is to be managed as a whole from an EHR repository and life-cycle perspective.

NOTE: The scope of the EHR Lifecycle Model is intentionally constrained to EHR entries committed to persistent storage in the EHR. Interim data or records, initiated or in process but not yet ready for persistent storage, is out of scope.

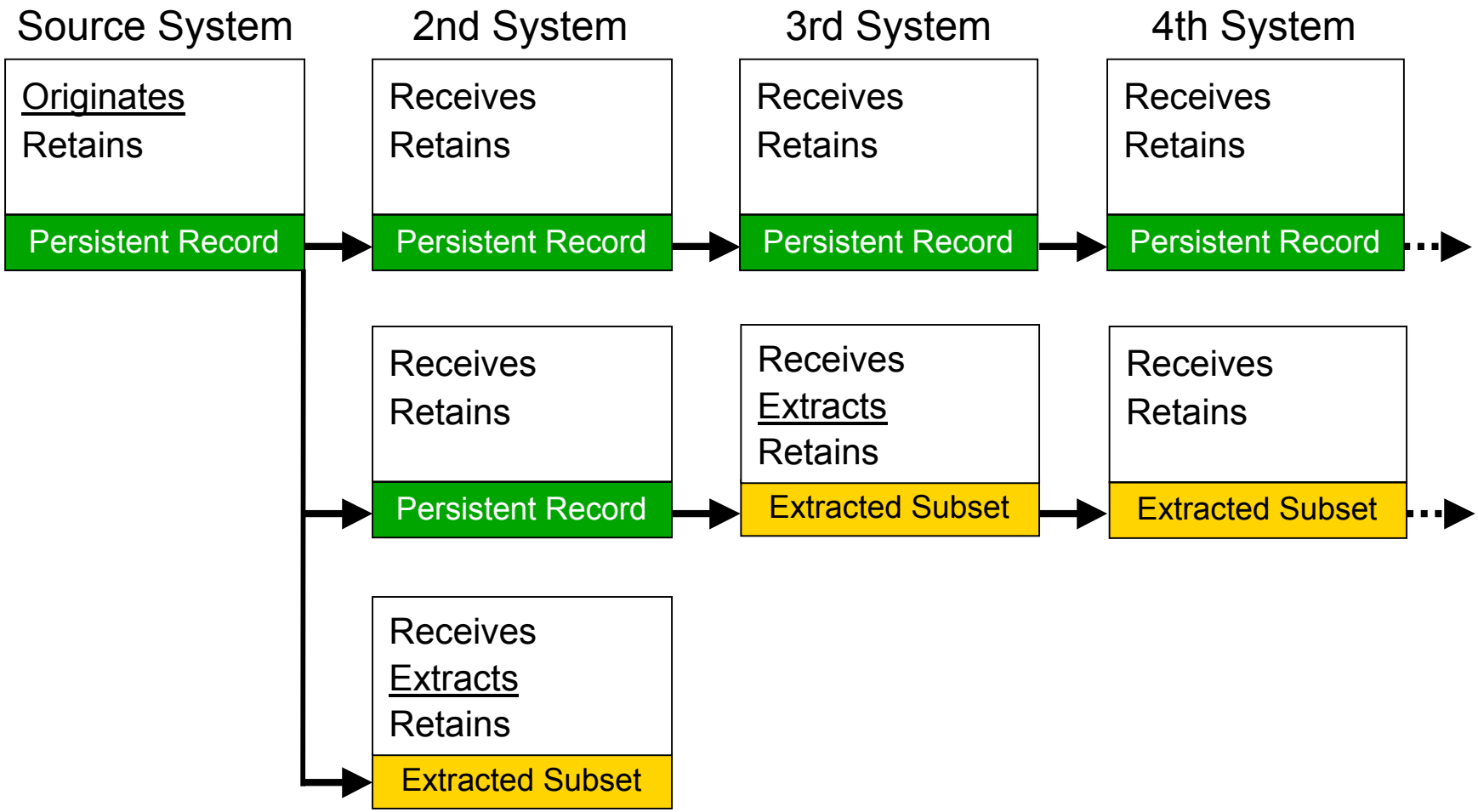
Section 7: The Act/Act Record Paradigm

The following depicts the progression of an Act, documented/evidenced by an Act Record, retained and persisted by the Source System then interchanged (if appropriate) as an indivisible Act Record or its proper subset.



Section 8: The Act Record Interchange Paradigm

The following offers a simple example of how Act Records are interchanged from their Source System downstream to additional Receiver Systems, either as persistent indivisible Act Records or proper subsets thereof.



Section 9: Events in the Act Record Lifecycle

To fulfill its purpose as documentation and persistent evidence of the Act, the Act Record must be retained without alteration. The seminal event in the lifecycle comes at the point where the Act Record is originated and retained (by the source System). Immediately or over the course of time, additional lifecycle events may occur. The following identifies key points/events in the Act Record lifecycle:

ID	Act Record Lifecycle Event
1	Originate Record
2.1	Amend Record Content
2.2	Translate Record Content
3.1	Verify Record Content
3.2	Ensure/Attest Record as Complete
3.3	Ensure/Attest Record as Accurate
4	Access/View Record Content
5.1	Transmit and/or Disclose Record(s) – Original and Amendment(s)
5.2	Transmit and/or Disclose Record(s) – Most Recent Amendment
6.1	Receive and Retain/Persist Record(s) – from external source
6.2	Receive Record(s) – from external source – no persistence
7.1	De-identify or Alias Record(s)
7.2	Re-identify Record(s)
8	Converge Record(s)
9	Archive Record(s)
10	Destroy or Identify Record(s) as Missing
11	Deprecate Record(s)

For any given Act Record instance, the first event (Originate and Retain/Persist Record) is the only one required. Other events are invoked when appropriate.

Section 10: EHR Lifecycle Event Initiators

Act Record lifecycle events may be initiated by an actor: user or medical device; or automatically by rules-based algorithm. The following offers examples of both initiators:

Initiator (Actor)	By	Act example(s)
User	Command	Patient registration, admit/check-in, assessment, order, observation, diagnostic test, therapy, care, procedure, authorization etc.
Medical Device	Rule-based algorithm	Monitored parameters, test results, etc.
System	Rule-based algorithm	Notification, alert, reminder, report, etc.

Section 11: Description of EHR Lifecycle Events

EHR lifecycle events include the following. In each case below the "System" is the EHR or other healthcare system in which the event defined by the "When: clause is performed. The specific business rules and authorizations governing these lifecycle events are often prescribed by jurisdictional or local policies, and are beyond the scope of this Model.

11.1 Event: Originate and Retain/Persist Record

- When: Act Record is originated – typically during the course of the Act itself, to document the Act.
- Act Record content is the responsibility of authorized Author(s).
- The originating System is responsible for Act Record retention and persistence.
- The System is responsible for initiating an audit/trace event showing Act Record origination.

11.2.1 Event: Amend Record Content

- When: Act Record content is modified (from its original or previous retained state) – typically after conclusion of the Act, to correct, update or complete content.
- Amended Act Record content is the responsibility of authorized amending Author(s).
- The amendment becomes part of the Act Record revision history, where the original content and any previous amendments are retained without alteration.
- After amendment, the System is responsible for retention of the Act Record and its revision history.

- The System is responsible for initiating an audit/trace event showing Act Record amendment.

11.2.2 Event: Translate Record Content

- When: Act Record content is amended to include translation of content – typically to transform coded data from one coding/classification scheme to another, also from one human language to another.
- Translated (amended) Act Record content is the responsibility of the System – which invokes mapping/translation rules for each relevant record attribute.
- The translation amendment becomes part of the Act Record revision history, where original content and any previous amendments are retained without alteration.
- After translation amendment, the System is responsible for retention of the Act Record and its revision history (including the translation event).
- The System is responsible for initiating an audit/trace event showing Act Record translation amendment.

11.3.1 Event: Verify Record Content

- When: Act Record content is verified – typically after conclusion of the Act, to ensure content is sufficient and appropriate.
- Verified Act Record content is the responsibility of authorized Reviewer(s). The Reviewer may be a supervisor, proctor, preceptor or other designated individual.
- The System is responsible for initiating an audit/trace event showing Act Record verification.

11.3.2 Event: Ensure/Attest Record as Complete

- When: Act Record content is attested complete – typically during/after conclusion of the Act.
- Attested Act Record content is the responsibility of authorized Author(s).
- The System is responsible for initiating an audit/trace event showing Act Record attested complete.

11.3.3 Event: Ensure/Attest Record as Accurate

- When: Act Record content is attested accurate – typically during/after conclusion of the Act.
- Attested Act Record content is the responsibility of authorized Author(s).
- The System is responsible for initiating an audit/trace event showing Act Record attested accurate.

11.4 Event: View/Access Record Content

- When: Act Record content is viewed or accessed.
- Viewed Act Record content is the responsibility of authorized User(s).

- The System is responsible for initiating an audit/trace event showing Act Record viewed/accessed.

11.5.1 Event: Transmit and/or Disclose Record(s) – Original and Amendment(s)
- When: Act Record(s) transmitted and/or disclosed – typically to an external entity or system.
- Transmittal includes original Act Record(s) and corresponding amendment(s), if any.
- Transmittal of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) transmitted/disclosed.

11.5.2 Event: Transmit and/or Disclose Record – Most Recent Amendment
- When: Act Record(s) transmitted and/or disclosed – typically to an external entity or system.
- Assumes original Act Record and any preceding amendments have already been transmitted.
- Transmittal of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) transmitted/disclosed.

11.6.1 Event: Receive and Retain/Persist Record(s)
- When: Act Record(s) received – typically from an external system.
- Receipt of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) received and retained.

11.6.2 Event: Receive Record(s) – from external source – no persistence
- When: Act Record(s) received – typically from an external system.
- Receipt of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System may be responsible for initiating an audit/trace event showing Act Record(s) received.

11.7.1 Event: De-identify or Alias Record(s)
- When: Act Record(s) de-identified or aliased.
- Aliasing allows records to be later re-identified.
- De-identification or aliasing of Act Record(s) may be initiated by User command.
- De-identification or aliasing of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) de-identified or aliased.

11.7.2 Event: Re-identify Record(s)

- When: Act Record(s) re-identified.
- Re-identification of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) re-identified.

11.8 Event: Converge Record(s)

- When: Act Record(s) converged through derivation, summarization or aggregation.
- Convergence of Act Record(s) may be initiated by User command and/or rules-based algorithm.
- Convergence of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) converged.

11.9 Event: Archive Record(s)

- When: Act Record(s) archived – typically to off-line (less readily available) storage media.
- Archival of Act Record(s) may be initiated by User command.
- Archival of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) archived.

11.10 Event: Destroy or Identify Record(s) as Missing

- When: Act Record(s) destroyed or identified as missing.
- Destruction typically occurs after conclusion of the legal retention period.
- Destruction of Act Record(s) may be initiated by User command.
- Destruction of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) destroyed or identified as missing.

11.11 Event: Deprecate Record(s)

- When: Act Record(s) are deprecated, if found to be improperly identified or otherwise invalid.
- Deprecation of Act Record(s) may be initiated by User command.
- Deprecation of Act Record(s) is the responsibility of the System – which invokes relevant rules.
- The System is responsible for initiating an audit/trace event showing Act Record(s) deprecated.

Section 12: System Roles in the EHR Lifecycle

The Act Record lifecycle may occur within a single System or may occur across Systems. System roles of the EHR Lifecycle Model include:

- Source Application or EHR System, acting as the initial point of Act Record origination and retention;
- Mediator (e.g., an interface engine or NHIN services), acting as the exchange broker for Act Record(s);
- Receiver Application or EHR System, acting as secondary point of Act Record capture and retention.

Except for content translation, this Lifecycle Model assumes that the Act Record may only be verified, attested or amended by events occurring in the Source System. The following table shows the applicability of EHR lifecycle events to System roles of source, mediator and receiver:

ID	Act Record Lifecycle Event	Applicability		
		Source System – Application or EHRS	**Mediator: e.g., Interface Engine or NHIN services**	**Receiver System – Application or EHRS**
1	Originate and Retain/Persist Record	X		
2.1	Amend Record Content	X		
2.2	Translate Record Content	X	X	X
3.1	Verify Record Content	X		
3.2	Ensure/Attest Record as Complete	X		
3.3	Ensure/Attest Record as Accurate	X		
4	Access/View Record Content	X	X	X
5.1	Transmit or Disclose Record(s) – Original and Amendment(s)	X	X	
5.2	Transmit and/or Disclose Record(s) – Most Recent Amendment	X		
6.1	Receive and Retain/Persist Record(s) – from external source			X
6.2	Receive Record(s) – from external source – no persistence		X	X
7.1	De-identify or Alias Record(s)	X	X	X
7.2	Re-identify Record(s)	X	X	X
8	Converge Record(s)	X	X	X

ID	Act Record Lifecycle Event	Applicability		
		Source System – Application or EHRS	**Mediator: e.g., Interface Engine or NHIN services**	**Receiver System – Application or EHRS**
9	Archive Record(s)	X		X
10	Destroy or Identify Record(s) as Missing	X		X
11	Deprecate Record(s)	X		
	Record/Data Flow		→	

Section 13: Audit and Traceability

Most Act Record lifecycle events carry the requirement to be auditable/traceable, as follows:

Event ID	Point in Act Record Lifecycle	Typical Audit/Trace Point?
1	Originate and Retain/Persist Record	Yes
2.1	Amend Record Content	Yes
2.2	Translate Record Content	Yes
3.1	Verify Record Content	Yes
3.2	Ensure/Attest Record as Complete	Yes
3.3	Ensure/Attest Record as Accurate	Yes
4	Access/View Record Content	Yes
5.1	Transmit and/or Disclose Record(s) – Original and Amendment(s)	Yes
5.2	Transmit and/or Disclose Record – Most Recent Amendment	Yes
6.1	Receive and Retain/Persist Record(s) – from external source	Yes
6.2	Receive Record(s) – from external source – no persistence	No
7.1	De-identify or Alias Record(s)	Yes
7.2	Re-identify Record(s)	Yes
8	Converge Record(s)	Yes
9	Archive Record(s)	Yes
10	Destroy or Identify Record(s) as Missing	Yes
11	Deprecate Record(s)	Yes

Section 14: Conformance Criteria

Conformance criteria are the result of distilling business and technical requirements into testable metrics. The EHR record lifecycle is manifest both in: a) EHR (or other) System functions; and b) EHR Record content. The following specifies conformance criteria with this dual perspective:

ID	Act Record Lifecycle Event	EHR (or other) System – Requirements and Conformance Criteria The System (source, mediator or receiver)…	EHR Act Record – Requirements and Conformance Criteria The Act Record…
1	Originate and Retain/Persist Record	1) **Shall** permit the origination of a record associated with each health(care) Act/Action, hereinafter an Act Record. 2) **Shall** ensure Act Record subject is identified: e.g., patient. 3) **Shall** ensure that Act Record author(s) are identified and authorized. 4) **Shall** ensure Act and Act Record are uniquely identified. 5) **Shall** capture Act context in the Act Record, including who, what, when, where, per right column (→). 6) **Shall** persist and retain the Act Record. 7) **Shall** create a persistent audit log of Act Record origination and retention. Reference: EHRS/FM DC.1, DC.1.1.1, DC.1.1.3.2, DC.1.3.3, DC.1.8.4, DC.1.8.5, DC.2, DC.2.3.2, DC.2.4.5.1-2, DC.3, DC.3.1.1, DC.3.1.3, DC.3.2.2-4, S.1, S.2, S.3, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.8, IN.1.9, IN.2.1, IN.2.2, IN.2.5.1-2	1) **Shall** have a unique identifier. [EHR/IM 3.1] 2) **Shall** specify who: subject/patient. [EHR/IM 2.4.1, 3.6.1] 3) **Shall** specify who: Act Record author [EHR/IM 3.8.1] 4) **Shall** specify who: Act participant. [EHR/IM 2.5] 5) **Shall** specify who: originating System. [EHR/IM 3.9] 6) **Shall** specify what: Act or action performed or provided. [EHR/IM 2] 7) **Shall** specify when: Act date/time and duration. [EHR/IM 3.11.1-2] 8) **Shall** specify when: Act record origination date/time. [EHR/IM 3.11.3] 9) **Shall** specify where: Act location. [EHR/IM 3.12.1] 10) **Shall** specify where: Act record origination location. [EHR/IM 3.12.2] 11) **Shall** specify where: Act record device and network address. [EHR/IM 3.13] 12) **Shall** include audit trail event for Act Record origination. [EHR/IM 3.19.2] 13) **Should** include original author's signature [EHR/IM 3.16] Reference: ISO 21089-2004, Section 12.2.2,

ID	Act Record Lifecycle Event	EHR (or other) System – Requirements and Conformance Criteria The System (source, mediator or receiver)…	EHR Act Record – Requirements and Conformance Criteria The Act Record…
2.1	Amend Record Content	1) **Shall** permit amendment of an Act Record. 2) **Shall** ensure Act Record subject is identified: e.g., patient. 3) **Shall** ensure that Act Record amendment author(s) are identified and authorized. 4) **Shall** ensure Act and Act Record and each amendment are uniquely identified. 5) **Shall** capture amendment context in the Act Record, including who, what, when, where, per right column (→). 6) **Shall** retain – without alteration – all original Act Record content. 7) **Shall** create a persistent audit log of each Act Record amendment. Reference: EHRS/FM DC.1, DC.1.1.1, DC.1.1.3.2, DC.1.3.3, DC.1.8.4, DC.1.8.5, DC.2, DC.2.3.2, DC.2.4.5.1-2, DC.3, DC.3.1.1, DC.3.1.3, DC.3.2.2-4, S.1, S.2, S.3, S.3.1.5, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.8, IN.1.9, IN.2.1, IN.2.2, IN.2.5.1-2	1) **Shall** specify who: Act Record amendment author. [EHR/IM 3.8.2] 2) **Shall** specify who: amending System. [EHR/IM 3.9] 3) **Shall** specify when: Act record amendment date/time. [EHR/IM 3.11.4] 4) **Shall** specify where: Act record amendment location. [EHR/IM 3.12.3] 5) **Shall** specify where: Act record amendment device and network address. [EHR/IM 3.13] 6) **Shall** retain – without alteration – all original and previously amended content. [EHR/IM 3.10] 7) **May** include reason for amendment. [EHR/IM 3.10.1] 8) **Shall** include audit trail event for Act Record amendment. [EHR/IM 3.19.2] 9) **Should** include amending author's signature [EHR/IM 3.16] Reference: ISO 21089-2004, Section 12.3.2.
2.2	Translate Record Content	1) **Shall** permit Act Record content to be translated: a) from one coding/classification scheme to another; b) from one human language to another. 2) **Shall** capture translation context in the Act Record, including who, what, when, where, per right column (→). 3) **Shall** retain – without alteration – all original Act Record content. 4) **Shall** create a persistent audit log of Act Record translation. Reference: EHRS/FM DC.1, DC.2, DC.3, S.1, S.2,	1-7) per Act Record amendment above. 8) **Shall** include audit trail event for Act Record content translation. [EHR/IM 3.19.2] Reference: ISO 21089-2004, Sections 12.3,2 and 12.4.

ID	Act Record Lifecycle Event	EHR (or other) System – Requirements and Conformance Criteria The System (source, mediator or receiver)…	EHR Act Record – Requirements and Conformance Criteria The Act Record…
		S.3, S.3.1.5, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.8, IN.1.9, IN.2.2, IN.2.5.1-2, IN.4.1-3, IN.5.1-2	
3.1	Verify Record Content	1) **Shall** permit Act Record content to be verified, e.g., by supervisor, proctor, preceptor. 2) **Shall** capture verification context in the Act Record, including who, what, when, where, per right column (→). 3) **Shall** create a persistent audit log of Act Record verification. Reference: EHRS/FM DC.1, DC.1.8.3, DC.2, DC.3, S.1, S.2, S.3, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.8, IN.1.9, IN.2.2, IN.2.5.1-2	1) **Shall** specify who: Act Record reviewer/verifier. [EHR/IM 3.8.2] 2) **Shall** specify who: verification System. [EHR/IM 3.9] 3) **Shall** specify when: Act record verification date/time. [EHR/IM 3.11.4] 4) **Shall** specify where: Act record verification location. [EHR/IM 3.12.3] 5) **Shall** specify where: Act record verification device and network address. [EHR/IM 3.13] 6) **Shall** include audit trail event for Act Record verification. [EHR/IM 3.19.2] Reference: ISO 21089-2004, Section 12.2.2.
3.2	Ensure/Attest Record as Complete	1) **Shall** permit Act Record content to be attested as complete. 2) **Shall** capture attestation context in the Act Record, including who, what, when, where, per right column (→). 3) **Shall** create a persistent audit log of Act Record completeness attestation. Reference: EHRS/FM DC.1, DC.1.8.5, DC.2, DC.3, S.1, S.2, S.3, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.8, IN.1.9, IN.2.2	1-5) Per Act Record verification above. 6) **Shall** include audit trail event for Act Record attested complete. [EHR/IM 3.19.8] Reference: ISO 21089-2004, Section 12.2.2.
3.3	Ensure/Attest Record as Accurate	1) **Shall** permit Act Record content to be attested as accurate. 2) **Shall** capture attestation context in the Act Record, including who, what, when, where, per right column (→).	1-5) Per Act Record verification above. 6) **Shall** include audit trail event for Act Record attested accurate. [EHR/IM 3.19.8] Reference: ISO 21089-2004, Section 12.2.2.

ID	Act Record Lifecycle Event	EHR (or other) System – Requirements and Conformance Criteria The System (source, mediator or receiver)…	EHR Act Record – Requirements and Conformance Criteria The Act Record…
		3) **Shall** create a persistent audit log of Act Record accuracy attestation. Reference: EHRS/FM DC.1, DC.1.1.3.2, DC.1.8.5, DC.2, DC.3, S.1, S.2, S.3, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.8, IN.1.9, IN.2.2	
4	Access/View Record Content	1) **Shall** permit Act Record content to be accessed/viewed by authorized users. 2) **Should** create a persistent audit log of Act Record access/view. Reference: EHRS/FM DC.1, DC.1.1.3.1, DC.1.1.4, DC.1.1.5, DC.1.8.3, DC.1.8.5, DC.2, DC.3, S.1, S.2, S.3, IN.1.1, IN.1.2, IN.1.3, IN.1.5, IN.1.9, IN.2.1, IN.2.2, IN.2.5.1-2	1) **May** embed access controls to allow permitted Act Record access/view. [EHR/IM 3.18.1] 2) **Should** include audit trail event for Act Record access/view. [EHR/IM 3.19.3] Reference: ISO 21089-2004, Section 12.5.
5.1	Transmit or Disclose Record(s) – Original and Amendment(s)	1) **Shall** permit Act Record(s) to be transmitted/disclosed to external systems, including original and amendment(s), if any 2) **Shall** create a persistent audit log of Act Record transmittal or disclosure. Reference: EHRS/FM DC.1, DC.2, DC.3, DC.3.1.1, DC.3.1.3, DC.3.2.2-4, S.1, S.2, S.2.1.2, S.2.2, S.2.2.1-3, S.3, S.3.3.3-6, S.3.6, IN.1.1, IN.1.2, IN.1.6, IN,1.7, IN.1.9, IN.2.1, IN.2.2, IN.2.3, IN.2.5.1-2, IN.4.1-3, IN.5.1-2	1) **Shall** include audit trail event for Act Record transmittal/disclosure. [EHR/IM 3.19.5] Reference: ISO 21089-2004, Section 12.8.1.
5.2	Transmit and/or Disclose Record – Most Recent Amendment	1) **Shall** permit most recent Act Record amendment to be transmitted/disclosed to external systems 2) **Shall** create a persistent audit log of Act Record transmittal or disclosure. Reference: as per 5.1 above	1) **Shall** include audit trail event for Act Record transmittal/disclosure. [EHR/IM 3.19.5] Reference: ISO 21089-2004, Section 12.8.1.

ID	Act Record Lifecycle Event	EHR (or other) System – Requirements and Conformance Criteria The System (source, mediator or receiver)…	EHR Act Record – Requirements and Conformance Criteria The Act Record…
6.1	Receive and Retain/Persist Record(s) – from external source	1) **Shall** permit Act Record(s) to be captured from external systems. 2) **Shall** retain a persistent copy of the Act Record(s). 3) **Shall** create a persistent audit log of Act Record(s) receipt and retention. Reference: EHRS/FM DC.1.1.3.1, DC.3.1.1, DC.3.1.3, DC.3.2.2-4, S.3.1.4, S.3.1.5, S.3.3.3-6, IN.1.1, IN.1.2, IN.1.6, IN,1.7, IN.1.9, IN.2.1, IN.2.2, IN.2.3, IN.2.5.1-2, IN.4.1-3, IN.5.1-2	1) **Shall** include audit trail event for Act Record receipt. [EHR/IM 3.19.6] Reference: ISO 21089-2004, Section 12.9.
6.2	Receive Record(s) – from external source – no persistence	1) **Shall** permit Act Record(s) to be captured from external systems. 2) May create a persistent audit log of Act Record(s) receipt. Reference: EHRS/FM DC.1.1.3.1, DC.3.1.1, DC.3.1.3, DC.3.2.2-4, S.3.1.4, S.3.1.5, S.3.3.3-6, IN.1.1, IN.1.2, IN.1.6, IN,1.7, IN.1.9, IN.2.1, IN.2.2, IN.2.3, IN.2.5.1-2, IN.4.1-3, IN.5.1-2	1) May include audit trail event for Act Record receipt. [EHR/IM 3.19.6] Reference: ISO 21089-2004, Section 12.9.
7.1	De-identify or Alias Record(s)	1) **Shall** permit Act Record(s) to be de-identified or aliased. 2) **Shall** create a persistent audit log of Act Record(s) de-identified or aliased. Reference: EHRS/FM S.1.5, S.2, S.2.2, IN.1.1, IN.1.2, IN.1.9, IN.2.1, IN.2.2, IN.2.3, IN.2.5.1-2	1) **Shall** include audit trail event for Act Record de-identification or aliasing. [EHR/IM 3.19.7] Reference: ISO 21089-2004, Section 12.6.1.
7.2	Re-identify Record(s)	1) **Shall** permit Act Record(s) to be re-identified, if previously aliased. 2) **Shall** create a persistent audit log of Act Record(s) re-identified. Reference: EHRS/FM IN.1.1, IN.1.2, IN.1.9, IN.2.2	1) **Shall** include audit trail event for Act Record re-identification. [EHR/IM 3.19.7] Reference: ISO 21089-2004, Section 12.6.2.

ID	Act Record Lifecycle Event	EHR (or other) System – Requirements and Conformance Criteria The System (source, mediator or receiver)…	EHR Act Record – Requirements and Conformance Criteria The Act Record…
8	Converge Record(s)	1) **Shall** permit Act Record(s) to be converged, including derivation of content, summarization, aggregation. 2) **Shall** create a persistent audit log of Act Record(s) re-identified. Reference: EHRS/FM…	1) **Shall** include audit trail event for Act Record transmittal/disclosure. Reference: ISO 21089-2004, Section 12.7.
9	Archive Record(s)	1) **Shall** permit Act Record(s) to be archived for long-term retention. 2) **Shall** create a persistent audit log of Act Record(s) archived. Reference: EHRS/FM DC.1.1.1, IN.1.1, IN.1.2, IN.2.1, IN.2.2, IN.2.5.1-2	1) **Shall** include audit trail event for Act Record archival. Reference: ISO 21089-2004, Section 12.10.
10	Destroy or Identify Record(s) as Missing	1) **Shall** permit Act Record(s) to be permanently destroyed in accordance with legal retention requirements. 2) **Shall** create a persistent audit log of Act Record(s) loss or destruction. Reference: EHRS/FM S.2.2, IN.1.1, IN.1.2, IN.2.1, IN.2.2, IN.2.5.1-2	1) **Shall** include audit trail event for Act Record destruction. Reference: ISO 21089-2004, Section 12.11.
11	Deprecate Record(s)	1) **Shall** permit Act Record(s) to be deprecated if improperly identified or otherwise invalid. 2) **Shall** create a persistent audit log of Act Record(s) deprecation. Reference: EHRS/FM DC1.1.1	1) **Shall** include audit trail event for Act Record deprecation. Reference: ISO 21089-2004, Section 12.