Section Lifecycle-2 – EHR Lifecycle Model – System Roles, Audit, Event Criteria

Section x: 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

ID	Act Record Lifecycle Event	Applicability		
		Source System – Application or EHRS	**Mediator: e.g., Interface Engine or NHIN services**	**Receiver System – Application or EHRS**
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
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 y: 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 z: 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.