| **Section/ID#:**  **Type:**  **Name:** | **Conformance Criteria** | **See**  **Also** | **R1.1 Row#** | **R2 Row#** | **Chg Indic** |
| --- | --- | --- | --- | --- | --- |
| **IN 10** |  | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Record Entry Lifecycle and Management** |
| Actions are taken to support patient health. Actions are taken in provision of healthcare to individuals. Actions are taken as the result of rules-based EHR System algorithms.  Actors (i.e., patients, providers, users, systems) take Actions. (Consider Actions generically to encompass tasks, acts, procedures or services performed or rendered.)  Actions have corresponding Entries in the EHR Record, i.e., Action instances correspond to Record Entry instances. (The relationship of Actions and corresponding Record Entries may be one to one, many to one or even one to many.)  Actions have associated metadata (such as who, what, when, where, how, under what conditions, in what context). The corresponding Record Entry captures this metadata along with other Action facts, findings and observations.  Each Record Entry also includes its own provenance metadata such as who (author) and when (documented). The EHR System manages all Action-related Record Entries, according to scope of practice, organizational policy and jurisdictional law.  Actions and related Record Entries capture a chronology of patient health and healthcare and also a chronology of operations and services provided in a healthcare enterprise.  Record Entries reflect changes in health information from the time it was created, to the time it was amended, sent, received, etc. In this manner, each Record Entry serves as persistent evidence of an Action taken, enabling providers to maintain comprehensive information that may be needed for legal, business, and disclosure purposes. To satisfy these purposes, Record Entries must also be retained and persisted without alteration.  Record Entries have both a lifespan and a lifecycle. Lifecycle Events include originate/retain, amend, verify, attest, access/view, transmit/receive, and more. Lifecycle Events occur at various points in a Record Entry lifespan, always starting with a point of origination and retention (i.e., when the Entry is first created and stored).  Record Entries may be encapsulated to bind author/system/time signatures to data and metadata content.  A Record Entry may have a pre and post Event state if content is modified. In this case, the original Record Entry is preserved (with signature binding) and a new Entry is created (with new signature binding).  Record Lifecycle Events may also create an entry in a Record Audit Log.  The EHR System manages Record Lifecycle Events for each Record Entry, including pre and post Event record states, continuity and related Record Audit Logs.  Action examples include: (1) In the direct care of a patient, a healthcare professional creates or amends health information to be contained in a history and physical; (2) A medical device can supply the EHR system with a test result; (3) The EHR system can alert the healthcare professional of a potential drug-drug interaction.  As described here, the lifecycle of Record Entries is intentionally scoped to those required for persistent storage. |  |  |  |  |  |
| **IN 10.1** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Originate and Retain Action Record Entry** |
| **Statement:**  Originate, retain and persist an Action Record Entry  **Description:**  Occurs when Record Entry is originated – typically during the course of an Action itself, to document the Action.  • Record Entry content is the responsibility of authorized Author(s).  • The originating System is responsible for Record Entry retention and persistence.  • The System is responsible for initiating an audit/trace event showing Record Entry origination.  **Reference: ISO 21089-2004, Section 12.2.2** | 1. The system **SHALL** provide the ability to originate a Record Entry instance corresponding to an Action instance. |  |  |  |  |
| 2. The system **SHALL** create a uniquely identifiable Record Entry. |  |  |  |  |
| 3. The system **SHALL** identify the patient or individual subject of the Action and the corresponding Record Entry. |  |  |  |  |
| 4. The system **SHALL** identify Actor(s) who/which performed the Action. |  |  |  |  |
| 5. The system **SHALL** capture the date/time and duration of the Action. |  |  |  |  |
| 6. The system **SHOULD** capture the physical location of the Action. |  |  |  |  |
| 7. The system **SHALL** identify Record Entry author. |  |  |  |  |
| 8. The system **SHALL** identify Record Entry system (of origination). |  |  |  |  |
| 9. The system **SHOULD** capture the digital signature of the Record Entry author, binding signature to data and metadata content. |  |  |  |  |
| 10. The system **SHALL** capture Record Entry date/time. |  |  |  |  |
| 11. The system **SHOULD** capture Record Entry device and network address. |  |  |  |  |
| 12. The system **SHALL** comply with IN.2.2.x, Record Origination Audit Trigger. |  |  |  |  |
| 13. The system **SHALL** manage the Record Entry as a persistent, indelible data object. |  |  |  |  |
| **IN 10.2** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Amend Action Record Entry Content** |
| **Statement:**  Amend content of an Action Record Entry  **Description:**  Occurs when Record Entry content is modified (from its original or previous retained state) – typically upon conclusion of an Action, to correct, update or complete content.  • Amended Record Entry 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.  **Reference: ISO 21089-2004, Section 12.3.2** | 1. The system SHALL provide the ability to amend Record Entry content. |  |  |  |  |
| 2. The system **SHALL** retain the original and all previously amended versions of the Record Entry, without alteration. |  |  |  |  |
| 3. The system **SHALL** create a new uniquely identifiable version of the Record Entry, incorporating amended content. |  |  |  |  |
| 4. The system **SHALL** identify the patient or individual subject of amended Record Entry. |  |  |  |  |
| 5. The system **SHALL** identify Record Entry amendment author. |  |  |  |  |
| 6. The system **SHALL** identify Record Entry amendment system. |  |  |  |  |
| 7. The system **SHOULD** capture the digital signature of the Record Entry amendment author, binding signature to new data and metadata content. |  |  |  |  |
| 8. The system **SHALL** capture Record Entry amendment date/time. |  |  |  |  |
| 9. The system **SHOULD** capture Record Entry amendment device and network address. |  |  |  |  |
| 10. The system **SHALL** comply with IN.2.2.x, Record Amendment Audit Trigger. |  |  |  |  |
| 11. The system **SHALL** manage the Record Entry amendment as a persistent, indelible data object, along with its revision history. |  |  |  |  |
| **IN 10.3** | DC.1, DC.2, DC.3, 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.2.2, IN.2.5.1-2, IN.4.1-3, IN.5.1-2 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Translate Action Record Entry Content** |
| **Statement:**  Translate content of an Action Record Entry  **Description:**  Occurs when Record Entry 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) Record Entry content is the responsibility of translating System – which invokes  mapping/translation rules for each relevant record attribute.  • The translation amendment becomes part of the Record Entry revision history, where original content and  any previous amendments are retained without alteration.  • After translation amendment, the System is responsible for retention of the Record Entry and its revision  history (including the translation event).  • The System is responsible for initiating an audit/trace event showing Record Entry translation amendment.  **ISO 21089-2004, Sections 12.3,2 and 12.4.** | 1. The system **SHOULD** provide the ability to translate coded Record Entry content from one coding/classification system to another. |  |  |  |  |
| 2. The system **MAY** provide the ability to translate Record Entry content from one human language to another. |  |  |  |  |
| **Criteria 2-11 as per Section IN.10.2 above, Amend Action Record Entry Content, substituting “translation” for “amendment”.** |  |  |  |  |
| **IN 10.4** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Verify Action Record Entry Content** |
| **Statement:**  Verify content of Action Record Entry  **Description:**  Occurs when Record Entry content is verified – typically after conclusion of an Action, to ensure content is sufficient and appropriate.  • Verified Act Record content is the responsibility of authorized Reviewer(s). The Reviewer may be someone other than the originating author, i.e., a supervisor, proctor, preceptor or other designated individual.  • The System is responsible for initiating an audit/trace event showing Act Record verification.  **Reference: ISO 21089-2004, Section 12.2.2.** | 1. The system **SHALL** provide the ability to verify Record Entry content. |  |
| 2. The system **SHALL** identify the patient or individual subject of verified Record Entry. |
| 3. The system **SHALL** identify Record Entry verification author. |
| 4. The system **SHALL** identify Record Entry verification system. |
| 5. The system **SHOULD** capture the digital signature of the Record Entry verification author, binding signature to new data and metadata content. |
| 6. The system **SHALL** capture Record Entry verification date/time. |
| 7. The system **SHOULD** capture Record Entry verification device and network address. |
| 8. The system **SHALL** comply with IN.2.2.x, Record Verification Audit Trigger. |
| 9. The system **SHALL** manage the Record Entry verification as a persistent, indelible data object. |
| **IN 10.5** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Ensure/Attest Action Record Entry Content Complete** |
| **Statement:**  Attest content complete for Action Record Entry  **Description:**  Occurs when Record Entry content is attested complete – typically during/after conclusion of an Action.  • Attested Record Entry content is the responsibility of authorized Author(s).  • The System is responsible for initiating an audit/trace event showing Record Entry attested complete.  **Reference: ISO 21089-2004, Section 12.2.2.** | 1. The System SHALL provide the ability to attest to completeness of Record Entry content. |  |  |  |  |
| **Criteria 2-9 as per Section 10.4 above, Verify Action Record Entry Content, substituting “attestation” for “verification”.** |  |  |  |  |
| **IN 10.6** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Ensure/Attest Action Record Entry Content Accurate** |
| **Statement:**  Attest content accurate for Action Record Entry  **Description:**  Occurs when Record Entry content is attested accurate – typically during/after conclusion of an Action.  • Attested Record Entry content is the responsibility of authorized Author(s).  • The System is responsible for initiating an audit/trace event showing Record Entry attested accurate.  **Reference: ISO 21089-2004, Section 12.2.2.** | 1. The System SHALL provide the ability to attest to accuracy of Record Entry content. |  |  |  |  |
| **Criteria 2-9 as per Section 10.4 above, Verify Action Record Entry Content, substituting “attestation” for “verification”.** |  |  |  |  |
| **IN 10.7** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **View/Access Action Record Entry Content** |
| **Statement:**  View/Access content of Action Record Entry(ies)  **Description:**  Occurs when Record Entry(ies) is viewed or accessed.  • Viewed Record Entry content is the responsibility of authorized User(s).  The System is responsible for initiating an audit/trace event showing Record Entry viewed/accessed.  **Reference: ISO 21089-2004, Section 12.5.** | 1. The system MAY embed masks to limit access to Record Entry content to authorized individuals. |  |  |  |  |
| 2. The system **SHALL** provide the ability to view/access Record Entry content. |  |  |  |  |
| 3. The system **SHALL** identify the patient or individual subject of accessed Record Entry. |  |  |  |  |
| 4. The system **SHALL** identify Record Entry access individual. |  |  |  |  |
| 5. The system **SHALL** identify Record Entry access system. |  |  |  |  |
| 6. The system **SHALL** capture Record Entry access date/time. |  |  |  |  |
| 7. The system **SHOULD** capture Record Entry access device and network address. |  |  |  |  |
| 8. The system **SHALL** comply with IN.2.2.x, Record Access Audit Trigger. |  |  |  |  |
| **IN 10.8** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Transmit and/or Disclose Action Record Entry(ies)** |
| **Statement:**  Transmit/Disclose content of Action Record Entry(ies)  **Description:**  Occurs when Record Entry content is transmitted and/or disclosed – typically to an external entity or system.  • Transmittal includes original Record Entry(ies) and corresponding amendment(s), if any.  • Transmittal of Record Entry(ies) is the responsibility of the System – which invokes relevant rules.  • The System is responsible for initiating an audit/trace event showing Record Entry(ies) transmitted/disclosed.  **Reference: ISO 21089-2004, Section 12.8.1.** | 1) The system **SHALL** provide the ability to transmit Record Entry(ies) to external systems. |  |  |  |  |
| 2) The system **SHALL** comply with IN.2.2.x, Record Transmit Audit Trigger. |  |  |  |  |
| **IN 10.9** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Receive and Retain/Persist Action Record Entry(ies)** |
| **Statement:**  Receive and retain/persist content of Action Record Entry(ies)  **Description:**  Occurs when Record Entry content is 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.  **Reference: ISO 21089-2004, Section 12.8.1.** | 1) The system **SHALL** provide the ability to receive and retain/persist Record Entry(ies) from external systems. |  |  |  |  |
| 2) The system **SHALL** comply with IN.2.2.x, Record Receipt Audit Trigger. |  |  |  |  |
| **IN 10.10** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **Receive Record Action Record Entry(ies) – without persistence** |
| **Statement:**  Receive content of Action Record Entry(ies) without retention or persistence  **Description:**  Occurs when Record Entry content is 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.  **Reference: ISO 21089-2004, Section 12.9.** | 1) The system SHOULD provide the ability to receive Record Entry(ies) from external systems without persisting content. |  |  |  |  |
| 2) The system SHALL comply with IN.2.2.x, Record Receipt Audit Trigger. |  |  |  |  |
| **IN 10.12** | 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 | **Function**  **Level**  **See Also** |  |  |  |
| **Header** |
| **De-identify or Alias Action Record Entry(ies)** |
| **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.**  **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: ISO 21089-2004, Section 12.6.1.** | **1) Shall include audit trail event for Act Record deidentification**  **or aliasing. [EHR/IM 3.19.7]** |  |  |  |  |
| **IN 10.13** | IN.1.1, IN.1.2, IN.1.9, IN.2.2 | **Function**  **Level**  **See**  **Also** |  |  |  |
| **Header** |
| **Re-identify Record(s)** |
| **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**  **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.**  **ISO 21089-2004, Section 12.6.2.** | **1) Shall include audit trail event for Act Record reidentification.**  **[EHR/IM 3.19.7]** |  |  |  |  |
| **IN 10.14** | None specified | **Function**  **Level**  **See**  **Also** |  |  |  |
| **Header** |
| **Converge Record(s)** |
| **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.**  **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.**  **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:**  **ISO 21089-2004, Section 12.7.** | **1) Shall include audit trail event for Act Record**  **transmittal/disclosure.** |  |  |  |  |
| **IN 10.15** | DC.1.1.1, IN.1.1, IN.1.2,  IN.2.1, IN.2.2, IN.2.5.1-2 | **Function**  **Level**  **See**  **Also** |  |  |  |
| **Header** |
| **Archive Record(s)** |
| **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.**  **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.**  **ISO 21089-2004, Section 12.10.** | **1) Shall include audit trail event for Act Record archival.** |  |  |  |  |
| **IN 10.16** | S.2.2, IN.1.1, IN.1.2, IN.2.1,  IN.2.2, IN.2.5.1-2 | **Function**  **Level**  **See**  **Also** |  |  |  |
| **Header** |
| **Destroy or Identify Record(s) as Missing** |
| **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.**  **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.**  **ISO 21089-2004, Section 12.11.** | **1) Shall include audit trail event for Act Record destruction.** |  |  |  |  |
| **IN 10.17** | DC1.1.1 | **Function**  **Level**  **See**  **Also** |  |  |  |
| **Header** |
| **Deprecate Record(s)** |
| **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.**  **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.**  **ISO 21089-2004, Section 12.** | **1) Shall include audit trail event for Act Record**  **deprecation.** |  |  |  |  |
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