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CDA Document Receiver Requirements

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Related Documents:

The table below lists other related documents, which should be understood in the context of this document:

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| Ref No | Doc Reference Number | Title | Version |
|  |  |  |  |

Glossary of Terms

|  |  |  |
| --- | --- | --- |
| Term | Abbreviation | What it stands for |
| CDA | CDA | Clinical Document Architecture – an HL7 standard for the structure (format, content) of clinical documents |
| CDA Document | - | An instance of a clinical document in CDA format |
| CRE Type |  | A Care Record Element categorisation predominantly designed for use with the Summary Care Record held on PSIS but also for more general use |
| Domain Message Specification | DMS | A set of documented requirements related to a specific messaging domain covering a range of messages interactions between systems across that domain. This is the successor to the MIM (Message Implementation Manual) that covered many different domains which reached version 8 – all further developments being spawned off into their own domains to become DMSs. |
| Data Transfer Service | DTS | A Store and Collect mail facility operated by BT and now part of the range of ‘Spine’ services |
| Interoperability Tool-Kit | ITK | Interoperability Tool-Kit – a set of technical standards covering the exchange of messages between the messaging components of systems. |
| Point to Point | P2P | Refers to sending messages directly from one system to another either directly or via an intermediary service such as DTS or TMS – in the case of TMS the message travels through TMS to another end point and not to any central sine service |
| Trading Partner | TP | A system and/or organisation which the host system exchanges messages with. An organisation may have many systems each with their own identifier which equates to a Trading Partner ID. A system (with a single Trading Partner ID) may support multiple organisations. Examples include the 5 character cipher used to identify GP systems and NHAIS systems for NHAIS registration links, 15-char EDI Sender/recipient IDs used in Pathology messaging, a Spine ASID, etc. |
| Trading Partner ID | TP | An identifier for a system to identify itself uniquely within messages it sends and/or receives messages electronically with other systems. |

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Contents

[1 Introduction 5](#_Toc388614443)

[1.1 Purpose 5](#_Toc388614444)

[1.2 Audience 5](#_Toc388614445)

[1.3 Document Scope 5](#_Toc388614446)

[1.4 Document Topology 6](#_Toc388614447)

[1.5 Background 6](#_Toc388614448)

[1.6 Definitions 7](#_Toc388614449)

[1 Operating Model 8](#_Toc388614450)

[1.1 Overview of Operating Principles 8](#_Toc388614451)

[2 Validation Requirements 9](#_Toc388614452)

[2.1 ‘Recipient’ Validation 9](#_Toc388614453)

[2.2 Duplicate Document Check 9](#_Toc388614454)

[2.3 Replacement and Nullification Validation 10](#_Toc388614455)

[3 Application Level Processing Requirements 11](#_Toc388614456)

[3.1 Patient Validation 11](#_Toc388614457)

[4 User Processing Requirements 14](#_Toc388614458)

[4.1 Patient Matching 17](#_Toc388614459)

[4.2 User Configuration 20](#_Toc388614460)

[4.3 CDA Document Display 21](#_Toc388614461)

[4.4 Action Management 24](#_Toc388614462)

[4.5 Message Handling 29](#_Toc388614463)

[4.6 Filing 32](#_Toc388614464)

[4.7 Patient Record 41](#_Toc388614465)

[4.8 System Reporting 42](#_Toc388614466)

[4.9 Audit Requirements 42](#_Toc388614467)

[Appendix A. Replacement and Nullification Addendum 43](#_Toc388614468)

# Introduction

This document specifies the processing requirements for systems receiving CDA documents as illustrated in Figure 1. It covers the interface between the ‘MHS’ and the clinical application represented by the yellow circle with the dashed edge.

 Figure 1: CDA Interoperability Architecture

## Purpose

The purpose of this document is to provide detailed system requirements to system developers. It must be read and understood within the context provided by the other documents published in the CDA Interoperability baseline.

## Audience

The audience for this document is primarily system architects, system developers and other supplier staff involved with the design, build and test of systems that will be receiving CDA documents across the architecture illustrated in Figure 1. As the requirements are mostly generic in nature, much of the functionality described within will be equally applicable to other received clinical documents and clinical message processing.

## Document Scope

The scope of this document covers the processing of a received message containing a CDA document from the point at which the Message Handling System has received an incoming message and performed the necessary transport layer validation (and acknowledgment) and is about to pass it over to the clinical application for processing, through to the point at which the document has been processed by users of the clinical application and the document and/or contents now form part of the local patient record.

## Document Topology

The diagram below illustrates the scope of the baseline documentation defining requirements across the generic CDA interoperability environment with the area covered by this document circled. Suppliers must read associated documentation from this CDA interoperability baseline in order to comply with the overall requirements for CDA interoperability.



Figure 2: CDA Interoperability Documentation Model

## Background

The requirements within this document have been drawn from the following sources:

* ‘EDI-Related Application Functionality in GP Clinical Systems: User Requirements v1.0’ published for the GP-Provider Links Project in 1996
* ‘best of breed’ implementations across clinical systems receiving report style messages
* Various requirements documents published by NHS CFH relating to ‘Spine messaging’ over TMS and CDA documentation published by NHS CFH as part of the Summary Care Record Release 2 requirements

## Definitions

Where used in this document set, the keywords MUST, SHOULD and MAY are to be interpreted as follows:

* **MUST**: This word, or the terms "**REQUIRED**" or "**SHALL**", means that the definition is an absolute` requirement of the specification.
* **SHOULD**: This word, or the adjective "**RECOMMENDED**", means that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications **MUST** be understood and carefully weighed before choosing a different course.
* **MAY**: This word, or the adjective “**OPTIONAL**”, means that an item is truly optional. One implementer may choose to include the item because a particular implementation requires it or because the implementer feels that it enhances the implementation while another implementer may omit the same item. An implementation which does not include a particular option **MUST** be prepared to interoperate with another implementation which does include the option, though perhaps with reduced functionality. In the same vein an implementation which does include a particular option **MUST** be prepared to interoperate with another implementation which does not include the option (except, of course, for the feature the option provides).
* **SHOULD NOT**: This phrase, or the phrase "**NOT RECOMMENDED**" mean that there may exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behaviour described with this label.

# Operating Model

## Overview of Operating Principles

This section provides a high level overview of the principles guiding the intended use of CDA Documents.

The following principles govern the use of the CDA documents:

* The CDA documents may be created in any care environment that would ordinarily produce the communication domains covered by the scope of this document.
* The CDA documents may be accessed and viewed from any system sending the document or any system receiving the document provided that the user accessing the document has the necessary access rights to do so.
* The CDA documents will be produced in order to summarise a Patient’s episode of care, they are not intended to capture detailed operational care information.
* The CDA Documents should serve as freestanding documents in their own right.

# Validation Requirements

This section deals with the validation of received CDA documents prior to passing them on for application and user processing – it is essentially a ‘pre-processing’ stage undertaken automatically by the system to detect errors that would either result in the document not being passed on for further application or user processing, or errors that need to be flagged to users.

## ‘Recipient’ Validation

The system must apply basic header validation to check that the system is the intended recipient.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR01** | The system **MUST** validate ‘recipient’ information contained in the CDA Document ‘header’ information to check that the identified recipient organisation, person or other recipient type supported by the system.  | Must |
| CR01.1 | When the above organisation check fails the system **MUST** automatically ‘reject back to sender’ with an appropriate error code indicating ‘Unrecognised recipient organisation’ (See ‘Point to Point Error Codes’ document) and log the error in the message logs. | Must |
| CR01.2 | When the above person check fails the system **MUST** flag the item for investigation by a system administrator who can either (a) ‘reject back to sender’ with an appropriate error code indicating ‘Unrecognised recipient person’ (See ‘Point to Point Error Codes’ document) or (b) accept the message and pass it through to the application for processing. The message logs MUST indicate the received state and selection made. | Must |

## Duplicate Document Check

The system must apply basic header validation to check that the document received is not a duplicate, i.e. has not been received before.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR05** | The system **MUST** check that the CDA Document ID (‘CliniclDocument.ID’) of the received document has not been received before. If this check fails the system **MUST** return a negative Application/Business Acknowledgement with an appropriate error code indicating ‘Duplicate Document ID received’. (See ‘Point to Point Error Codes’ document) | Must |
| CR05.1 | The system **MUST** flag the item accordingly in the message log indicating that it is a duplicate. | Must |

## Replacement and Nullification Validation

The system must check that when a replacement CDA document has been received that a version of the document it is replacing has been received by the system previously and if not, to flag the Document accordingly. The system must also apply the checks to nullification messages received for CDA documents.

Note that there are valid situations where this can occur, e.g. the earlier version of the document was sent by paper, and as such the receiving system must accept the document with a warning to make users aware of the situation.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR10** | If a Replacement CDA document is received the system **MUST** apply the following validation checks:* Check that a version of the document being replaced has been previously received

If the check fails the system **MUST** flag the item with a warning indicating that the document being replaced has not been previously received and pass the document through to the ‘Inbox’ for user processing. | Must |
| **CR11** | If a Replacement CDA document is received the system **MUST** apply the following validation checks:* Check that the version of the new document is greater than the latest previously received document with the same SetID

If the check fails the system **MUST** return a negative Application/Business Acknowledgement indicating that the ‘Document version precedes current version’ (see Point to Point Error Codes document).  | Must |
| **CR12** | If a Nullification message is received for a CDA document the system **MUST** apply the following validation checks:* Check that a version of the document (i.e. a document with the same SetID) being nullified (withdrawn) has been previously received

If the check fails the system **MUST** flag the item with a warning indicating that the document being nullified has not been previously received and send back a negative Application/Business Acknowledgement to the sender with an error code indicating ‘nullified document SetID not recognised’ (See Point to Point Error Codes' document. | Must |

# Application Level Processing Requirements

The requirements in this section cover the second processing stage following the pre-processing validation stage described in the previous section. It deals with situations where the system (application) can either process the document automatically without user intervention or provides some further pre-processing needed for user processing in the next stage.

## Patient Validation

The requirements in the section ONLY apply to situations where the patient the document relates to is expected to be present in the system. (e.g. a report about a patient event/care episode sent to the patient’s registered GP Practice or a community nursing team providing services to the patient with an ongoing duty of care.

In these situations the system can perform certain automated actions and generate automated responses back to the sender (e.g. the patient is no longer registered with this GP Practice). Care needs to be taken to ensure that inappropriate rejections are not generated (e.g. if the patient demographics sent do not enable any potential matching records to be found that doesn’t necessarily mean that the patient record does not exist on the system.)

In the GP Practice scenario, it is possible for a CDA document to be received for a patient who has left the GP Practice and the sender should have sent the document to the patient’s new GP Practice. Even in this situation it may be clinically relevant to pass this document onto the local clinician who initiated the care event or to the patients’ GP (in the local system) as there may an ongoing duty of care. It may also be appropriate to pass the document on to someone internally as there could be urgent actions that need carrying out.

In such situations systems should (1) reject the document by sending a negative Application/Business Acknowledgement back to the sender so that they know the patient has changed practice and (2) place the document in the system ‘Inbox’ to allow it to be viewed by a suitable clinician and to perform any subsequent actions (as appropriate). The reviewing clinician may decide it is appropriate to send the document on to the patient’s new GP practice (if this is technically possible) and in order to support this effectively, GP systems (only) are required to provide a ‘Forward’ function. (See ‘Forward Message’ requirement below.).

This is a potentially complex area and differs across system settings. Suppliers building solutions to meet these requirements should discuss their approach with the Authority in order to agree a consistent approach across systems.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR30** | Upon receipt of a CDA document for a patient whose record should be present and ‘active’ in the system, the system **SHOULD** send a negative Application/Business Acknowledgement back to the sender with an appropriate error code(see Point to Point Error Codes document for details) as follows:1. ‘patient record not present in system’
2. ‘patient not registered here’
3. ‘patient has moved to new GP practice’

Note: error 3 applies to GPs systems only. | Should |
| **CR31** | If the receiving system is a GP system and the patient was previously registered here but has since moved onto a new practice (i.e. they have been ‘deducted’ or a GP2GP record transfer has recently taken place and a deduction is expected), the system **MUST** provide the ability to notify the practice administrator and support the notification to the new practice following clinical review of the message. Note: The Requesting GP has a clinical responsibility of care for the patient and programme of care that they have initiated. | Must |
| CR31.1 | The system **MUST**, by querying PDS and SDS, ascertain whether the patient’s new Practice system is capable of receiving the message interaction associated with the CDA document over TMS. The new practice code MUST be retrieved from the patient’s PDS record. The interaction check **MUST** check for the presence of the InteractionID against the MHS entry for the new practice.  | Must |
| CR31.2 | If the patient’s new practice does support the interaction, the system **MUST** provide a ‘Forward to New Practice’ (or equivalent) option from the CDA document clinical review screen (i.e. where a clinician can read the document and decide whether it is appropriate to forward the document to the new practice).  | Must |
| CR31.3 | If a user selects the ‘Forward to New Practice’ option the system **MUST** send the CDA document to the new practice over TMS. The ‘to’ and ‘from’ identifiers, i.e. ASID, PartyKey, values in the ebXML header and HL7 header **MUST** be set correctly to reflect the new Sending system (this system) and the new Receiving system (the new Practice system).The contents of the CDA document itself, including the sender and receiver attributes, **MUST NOT** be altered in any way, i.e. the CDA document **MUST NOT** be changed in any way. | Must |
| CR31.4 | If a CDA Document is forwarded to another Practice the system **MUST** clearly indicate that this has been done. | Must |

# User Processing Requirements

This section covers all the requirements once an inbound CDA document has passed through the MHS and application validation checks and, as far as can be ascertained by these pre-processing stages, is a valid document for authorised users to process. The diagram below illustrates a generic processing flow diagram showing the various paths a document can take, the users involved and the various actions that certain users can perform.

**CDA Document Lifecycle**

A typical lifecycle for a received report style CDA Document is

* Received and validated by MHS
* Passed to Application
* Validated by Application
* Matched to a Patient Record
* Assigned to a clinician[[1]](#footnote-1) for review
* Additional actions assigned to other users
* Clinical[[2]](#footnote-2) Review marked as completed
* Document and/or subset of the document is filed into the patient record
* Other actions completed
* Processing complete

Exceptional conditions include ‘rejecting the document back to the sender’ (and deleting it); undoing action assignments, undoing patient matching.

The system should provide facilities for managers to monitor the progress of document processing and to identify delays and the process must have facilities to cope with staff being absent.



**Patient Matching**

Once the necessary validation has been performed by the MHS and/or the application, the CDA document is ready for processing by users. There are certain actions that the system must perform prior to presentation to a user, the first of these being for the system to attempt to find a matching local patient record for all ‘Report style’ CDA Documents, i.e. where the document is reporting about events that have occurred to a patient who the receiver has a relationship with, i.e. the patient record should exist locally. The system will, using demographic information contained in the document, which will vary depending on aspects such as whether the sender and receiver are PDS connected, and what information the sender has about the patient, use this information to automatically, without any user initiation or intervention, locate a matching patient record in the local patient index. An automatic match will only succeed if there is one candidate record found and if not the patient matching process will be deferred to a user initiated manual matching processes using local search functions and received data (see Patient Matching section below).

(Note: This version of the requirements does not cover the creation of a new record, i.e. where the receiver is not always expecting to have a local patient record for the patient subject of the CDA document. (e.g. a referral). This will be detailed in a future release of the requirements.).

**List Functions**

The system needs to provide an ‘list’ type facility ,which could be workflow, task list, inbox type functionality. A ‘list’ is a generic term applied to a means for a user to show clinical communications they need to action, the implementation method and design is up to the supplier within the remit of the requirements detailed in this document.

One of the concepts associated with this generic ’list’ functionality is that there are also individual user, or team, views of the messages to be processed. Users of individual or team ‘lists’ would see items assigned to them/their team. The system ‘list’ view is mainly for assignment and management purposes and not for clinical processing. A user would generally only have access to their ‘list’ view, or if a member of a team, to the team ‘list’ also. Users may also have deputies for times when they are away and a deputy will be able to deal with any items during those times. The system must control access to the documents in the inbox in such a way that only users authorised to access clinical[[3]](#footnote-3) data are allowed to view the contents of documents and other users (e.g. administration staff) are only able to see sufficient summary information to carry out administration tasks (e.g. assign clinical reviewer, match patient).

**User Configuration**

In order to process documents safely, certain types of users are required to review received documents and as a result they, or other users, may need to carry out certain actions (e.g. contact the patient and ask them to make an appointment, refer patient to service x). In some organisations it is more appropriate for teams to be assigned a review or resulting action. Where individuals can be assigned tasks it is important for the system to handle situations where that user is unavailable (e.g. on leave) and thus all users must have deputies assigned (individuals or teams).

**Action Management**

There will typically be many actions or tasks performed by the organisation receiving a CDA document. This will usually commence with a clinical review undertaken by a clinician who will decide what to file in the patient record and what other actions need undertaking. In many cases, a received document will be addressed to an individual user (e.g. a GP, nurse, consultant) and the system can automatically assign the ‘clinical review’ action to that user (assuming they have been correctly and uniquely identified in the document). In other cases, an authorised user, who may be a healthcare professional or an administrator, will need to assign a document to a user for clinical review. If the user is known to be ‘away’ the system should send the document to their deputy.

The system should support the creation of user-defined actions so that organisations can configure the system to reflect the way they work. Actions should have default time periods and overdue actions need to be pro-actively identified by the system to prevent delays in patient care.

**Reviewing Documents**

The person reviewing the document must have the necessary privileges to access the entire contents of the document, including any attachments.

**Filing Documents**

The system must provide flexible facilities to allow a user to decide what to file into the patient record and what additional entries to add to the patient record as a result. This may simply be adding the whole document to the record or could involve the addition of problem codes, diagnosis codes, procedure codes, changes to medication, and referrals for further care or treatment, with or without parts of the received CDA document. (Note: There is no requirement to systematically process any data held in a CDA Document – it is expected in this release of the requirements that the act of ‘filing’ is ‘manual’ and under user control, (e.g. cutting and pasting, etc, as required in order to perform the task.))

Documents may be filed into the patient record pending completion of the clinical review so that the latest patient information is available to users.

**Handling Attachments**

The later variants of the CDA document messages allow the inclusion of binary objects (files) such as radiology images with a Radiology Report, PDF versions of a Discharge letter. The system needs to make these available to users for viewing and adding to the patient record.

**Processing Complete**

Once all actions have been completed and filing is complete, the system should regard the processing as completed and move the document into a ‘completed’ area (or equivalent concept) to make more efficient use of the inbox (e.g. it would only contain items requiring some type of action).

## Patient Matching

The requirements in this section relate to the situation where a CDA Document has been received which contains information about an event(s) related to a patient (e.g. a Discharge Report, an Out of Hours Report) and thus there is an assumption that the system which receives the document contains a record for the patient and the organisation is expecting to receive such a document as part of its care provision to the patient. The requirements in this section do not apply to the receipt of ‘request’ style documents such as Referrals where the patient record may not exist.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR40** | The system **MUST**, using data contained with the CDA document, attempt an AUTOMATIC MATCH (without any user initiation or intervention) to locate a single matching local patient record.  | Must |
| CR40.1 | <<REMOVED>> |  |
| CR40.2 | If the only patient detail included in a CDA document is the NHS number and the system is NOT connected to PDS, the system **MUST** attempt to locate a matching local patient record by NHS number alone. If a SINGLE match is found this can be considered a successful ’Automated match’.If the NHS number is ‘unverified (a different OID is used) the system **MUST** flag the automated match in such a way that users are aware on the match being performed using an unverified NHS number and manual confirmation should be undertaken. | Must |
| CR40.3 | When the patient demographic information contained in the CDA document includes the patient’s verified or unverified NHS number AND other demographic information, the system **MUST** attempt to locate a matching local patient record by the following ‘Exact match with NHS number’ algorithm:*An exact match requires the NHS number AND the Date of Birth to match a SINGLE local record (where these additional demographics are present)*Any failure (e.g. no results or more than one result) of the ‘Exact match’ algorithm **MUST** result in an unsuccessful Automated match. | Must |
| CR40.4 | <<removed>> |  |
| **CR41** | The CDA document **MUST** be flagged with the status of the automatic match attempt, i.e. successful or unsuccessful.  | Must |
| CR41.1 | If unsuccessful, the CDA document MUST be marked for Manual Patient Matching. | Must |
| **CR42** | The system **MUST** provide a MANUAL PATIENT MATCH facility for users to manually match a CDA document to a local patient record.  | Must |
| CR42.1 | The manual patient matching facility **MUST** display all the patient demographics present in the CDA document (i.e. within the ‘Patient’ (NHS number only) or ‘PatientUniversal’ templates) and **MUST**, by default, copy relevant values into the local search parameters. | Must |
| CR42.1.1 | If an attachment is also present in the CDA document the system **MAY** allow users authorised to view clinical content to view the attachment to assist with patient matching as it may contain patient demographics (e.g. a PDF letter about a patient) | May |
| CR42.2 | The system **MUST** display the following minimum patient demographic information fields during the matching process:* NHS Number
* Local Patient Identifier
* Surname/family name
* First Forename
* Other forenames
* Title
* Sex
* Date of Birth
* Home address (or other address if home address not present)
* Post Code
 | Must |
| CR42.3 | The manual patient matching facility **MUST** allow the user to enter appropriate search criteria, adding additional data or changing or deleting data copied from the patient template of the CDA document and to perform a search of the local records.NB. The CDA Document must not be changed as a result of changing the search criteria. | Must |
| CR42.4 | The system **MUST** present a list of candidate matching records displaying appropriate data clearly indicating for each data item whether the local data matches the data from the CDA document or not. | Must |
| CR42.5 | The user **MUST** be able to select a local record from the list and this **MUST** be recorded as a successful ‘manual match’. | Must |
| CR42.6 | The system **MAY** allow an authorised user to view the contents of the CDA document to assist with patient matching. | May |
| **CR43** | If a matching patient record cannot be found when it is expected to be present[[4]](#footnote-4), an authorised user **MUST** have the option to ‘Reject’ the CDA document and send a negative Application/Business Acknowledgement back to the sender with a suitable error code indicating “patient record not in system”. (See ‘Point to Point Error Codes’) | Must |
| **CR44** | If a matching patient record cannot be found when it is expected to be present[[5]](#footnote-5), an authorised user **MUST** have the option to ‘Delete’ the CDA document. The system **SHOULD** prevent a CDA document from being deleted before a rejection is carried out (see previous requirement). | Must |
| **CR45** | The Audit Trail for the CDA document **MUST** indicate the date and time the patient match took place and who performed the matching (i.e. the system via automatic patient match or an identified User) | Must |
| **CR46** | It **MUST** be possible to reverse both an automatic patient match and a manual patient match as long as the document or any data within has not been filed into the patient record. | Must |
| **CR47** | If an automatically matched patient is a synthetic patient the system **MUST** retain the match but mark the item for manual processing and require the user to confirm the automated match against a synthetic patient. Note : A synthetic patient is a patient record that exists in live systems for testing and commissioning. The synthetic patient has no reference to any real patient alive or dead. | Must |
| CR47.1 | If a manually matched patient is a synthetic patient the system **MUST** inform the user of their selection and ask them to confirm their selection. | Must |

## User Configuration

In order to ensure the safe and timely processing of received CDA documents, all users who could be assigned an action relating to the processing of a document (e.g. perform clinical review, contact patient) need to have deputies so that in their absence, the deputy can perform these actions to ensure no delays occur.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR50** | The system **MUST**, with respect to the assignment of actions relating to CDA document processing, allow a deputy to be assigned to a user such that the deputy can carry out any actions assigned to the User on their behalf (e.g. when they are on leave). | Must |
| **CR51** | The assignment of deputies **MUST** only be undertaken by the User themselves or by other users with specific access rights to do so (e.g. System Administrator) | Must |
| **CR52** | A deputy **MUST** be able to access any “list” assigned to the User who they are deputy for. This **SHOULD** be done by either providing access to the persons Inbox or by selecting to display such items in the deputies “list”. | Must |
| CR52.1 | A User accessing an item in the role of deputy **MUST** ONLY have their own access rights, e.g. if a clinician with full access to clinical data contained in a CDA document has a deputy who does not have access to clinical data in a CDA document, the deputy **MUST** NOT be permitted to access the CDA document as if they were the clinical user. | Must |
| **CR53** | It **SHOULD** be possible to record, for any user, whether they have access (subject to access controls) only to items assigned to:* themselves only
* their team
* all items (as listed in the System “list”)
 | Should |

## CDA Document Display

The system will need to provide several different views of a CDA document depending on the access rights of individual users and what data they wish to view. The simplest distinction is to provide an administrative view of the document which does not display any clinical content (except for document type) and a clinical[[6]](#footnote-6) view which displays all clinical data which may comprise structured coded data and text data. There will also probably be an Inbox List view showing high level summary administrative data (see Inbox Functionality above) and a full message view for diagnostic and audit purposes.

The MIM 7 CDA documents and the DMS CDA documents (updated MIM 7) are structurally different. The MIM 7 variant is constrained to not allow any attachments to be included and for the ‘StructuredBody’ Act to only be XML whereas the DMS variants allow the use of a ‘NonXMLBody’ Act to hold binary files or attachments such as PDF files; for attachments to be embedded within a ‘CodedEntry’ Act and for native clinical codes and translated codes (SNOMED CT) to be used. The system needs to handle these variations and therefore the requirements below are written to ensure correct support for the DMS message variants as a MIM 7 CDA Document is just a subset of these.

Also, see further sections on ‘Handling Structured Data’ and ‘Handling Attachments’ below.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR55** | For the purposes of the requirements in this section the system **MUST** regard all contents of the StructuredBody and Non-XML StructuredBody as the parts of a CDA document containing Clinical Data[[7]](#footnote-7). The other parts of the CDA document, also known as Header information, **MUST** be regarded as Administrative Data. | Must |
| CR55.1 | The system **MUST** ONLY display Clinical Data within a CDA Document to users who, through their RBAC profile[[8]](#footnote-8) (national or local), have the right to view a patient’s medical record. | Must |
| CR55.2 | The system **MUST** display Administrative Data within any CDA Document to any user who, through their RBAC profile, have the right to view a patient’s administrative data (e.g. ‘B0820 View Patient Demographics’).  | Must |
| **CR56** | The system **MUST** comply with the rendering requirements within the CDA Document Technical Requirements document when displaying any CDA Document data. | Must |
| **CR57** | When displaying Clinical Data, the system **MUST**, with the exception of the patient banner, display Clinical Data first and **SHOULD** **NOT** include Administrative Data in the clinical view of the document. Administrative Data **MUST** be available to the user should they wish to display it (e.g. by use of a separate tab). | Must |
| **CR58** | The system **MUST** be able to display all data in a CDA document view showing all Administrative and Clinical Data to authorised users who have access to Audit Trails. Such display **MUST** also include appropriate audit data | Must |
| **CR59** | The system **MAY** provide full CDA document view showing all Administrative and Clinical Data to other authorised users (e.g. system administrators) where such access is required and suitable RBAC profiles exist. | May |
| **CR60** | When listing a CDA Document matched against a synthetic patient the system **MUST** make this clear when listing the document in a “list”.When the system displays a CDA Document for a synthetic patient the system **MUST** display a user warning indicating that the document is for a synthetic patient. The patient banner **MUST** also indicate that synthetic status of a patient record. Note: A synthetic patient is a patient record that has been created for live testing of systems. This patient record is not related to any person dead or alive. | Must |
| **CR61** | When users have added Clinical or Administrative notes/comments (see later) to a document the system **MUST** ensure that these are only accessible to users who have the appropriate access rights. | Must |
| **CR62** |  | REMOVED |
| **CR63** | It **MUST** be possible to open the patient record from the CDA Document display/view screen (subject to the user having the necessary access rights) | Must |
| **CR64** | When displaying a CDA Document the system **MUST** clearly show to the user the status of:* the clinical review (unassigned, assigned, completed)
* the filing status (unfiled, filed)
* whether any actions are overdue
* the overall status (open, completed)
 | Must |
| **CR65** | When displaying a CDA Document the system **MUST** clearly show the SNOMED CT coded representation of the document, i.e. the ‘displayname’ attribute of the ‘ClinicalDocument’ Act.See the ‘CDA Technical Requirements’ document, section 3.1, about future developments in this area. | Must |

## Action Management

The system needs to provide some basic action management facilities in order to support the safe processing of CDA Documents within the organisation domain. There are two mandatory actions and these are ‘clinical review’ (i.e. perform a clinical review of the contents of the document and make decisions about any further actions that need to be taken) and ‘file’ (i.e. add the document to the patient’s record). In this context, ‘file’ means that the clinical review has been completed and the document can be added to the patient record – systems may add a document to the patient record prior to the clinical reviewing being completed but the system must indicate this pending situation. A system may provide any number of further actions and may re-word these actions as long as the semantics and resulting functions are the same.

In order to support ongoing actions and the communications between users carrying out actions, the system must provide a facility for users to add notes/comments that is separate to the content of the CDA Document but associated with it.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR70** | The system **MUST** support the assignment of a ‘clinical review’ action to a CDA Document for one or more users to undertake. | Must |
| CR70.1 | The system **MUST NOT** automatically mark the clinical review as complete as a result of the reviewing clinician(s) displaying the document. The reviewing clinicians(s) **MUST** be provided with suitably labelled options to ‘complete the clinical review’ or ‘skip/defer clinical review’.  | Must |
| **CR71** | The system **MUST** support a ‘file’ action being carried out by any user who has the necessary RBAC activity (i.e. ‘(B0380) Perform Detailed Care Record’).  | Must |
| CR71.1 | The system **MAY** provide facilities to file documents into the patient record pending completion of the clinical review. If this is supported the system **MUST** clearly indicate that the document is awaiting completion of the clinical review (e.g. ‘review pending’) and once the clinical review has been completed the status of the document MUST be updated to remove the ‘review pending’ status. | May/Must |
| CR71.2 | The system **MAY** provide a single option to ‘complete clinical review and file into patient record’  | May |
| **CR72** | The system **SHOULD** allow user-defined actions to be added to the system. | Should |
| **CR73** | The system **MUST** support a default time period for each action type to be performed before the action becomes ‘overdue’. When assigning an action the system **MUST** default to the default time period (added to today’s date) but **MUST** allow the person assigning the action to overwrite the default and enter time period manually. | Must |
| CR73.1 | The system **SHOULD** take into account non-working days when calculating ‘due by’ dates and when calculating whether an action is overdue. The system **SHOULD** support, in its configuration settings, the recording of non-working days. | Should |
| **CR74** | When any action assigned to a CDA document becomes overdue, this **MUST** be indicated clearly on ALL Inbox views listing CDA Documents. | Must |
| **CR75** | The system **MUST** provide a facility to list ALL CDA Documents with overdue actions. This **SHOULD** be configurable by user(s), user type, team, action type, etc. | Must |
| **CR76** | The system **MAY** provide facilities for users to create action templates for specific document types or recipients, e.g. a Discharge Report from Oncology to be sent to the patient’s usual GP and copied ‘for information’ to all other GPs, a community nursing assessment to be sent to the nursing team. | May |
| **CR77** | A user performing an action associated with a CDA document **MUST** be able to view and add comments to the Administrative and Clinical Notes/Comments area subject to their access rights. These **MUST** NOT alter the document in any way but **MUST** be stored as additional associated data to the main CDA document | Must |

### Clinical Review

The ‘clinical review’ is a particular type of action that can be assigned to a received CDA document and is one of two mandatory actions that must be supported by the system (the other being ‘File). All CDA documents must be assigned to a competent user for clinical review. This could be undertaken by an individual, more than one individual or an assigned to a team for review.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR80** | The system **MUST** support the concept of a ‘clinical review’ action being assigned to every received CDA document. | Must |
| CR80.1 | The system **MUST** prevent users who do not have sufficient privileges (e.g. RBAC activity ‘B0360 View Detailed Health Record’) to access the full CDA document, from being assigned this action. | Must |
| **CR81** | The system **MUST** support one or more users being assigned to perform the ‘clinical review’ action for a CDA document. | Must |
| **CR82** | The system **MUST**, using information contained in the CDA Document ’recipient’ section support the routing of a message to the intended recipient via an automated process or through a guided process with user interaction. | Must |
| **CR83** | The system **MUST** support the concept of a ‘clinical review’ action being manually assigned to a CDA document. | Must |
| CR83.1 | The system **MUST** ONLY allow a user to assign this action to another user(s) if the user gaining the action has sufficient access rights to at least view CDA Document Administrative Data. | Must |
| **CR84** | The system **MUST** allow a clinical review action to be assigned whether the CDA document has been matched to a patient record or not. (NB It may be necessary to access the clinical content of a CDA document to gain access to further demographic data to assist with patient matching) | Must |
| **CR85** | The system **MUST** NOT allow a clinical review to be marked as completed until the document has been matched to a patient record. | Must |
| **CR86** | A user assigned the ‘clinical review’ action **MUST** be able to record that the review has been completed. | Must |
| CR86.1 | The system **SHOULD** prevent the clinical review from being marked as completed if the full contents of the CDA document have not been displayed to the user. | Should |
| **CR87** | If more than one user has been assigned the clinical review action, the action **SHOULD** not be regarded as complete until ALL users have marked the action as complete. | Should |
| **CR88** | The system **SHOULD** support other clinical users being assigned ‘for information’ type actions such that other clinicians may view the CDA document but without any need to perform a clinical review upon it. | Should |
| **CR89** | The system **MUST** provide facilities for an authorised user to add clinical notes/comments to the document. These **MUST** NOT alter the document in any way but **MUST** be stored in additional associated data to the main document | Must |
| CR89.1 | All entries made by users in the Clinical Notes/Comments section **MUST** be attributed to the user who made them (e.g. prefixed by username/initials). | Must |
| CR89.2 | Users without access to Clinical Data **MUST** NOT be able to access Clinical Notes/Comments | Must |

## List Functionality

It is important that clinical users have means to be able to progress clinical communications (e.g. received documents) The system has the concept of “list functionality” which could be an inbox, workflow or task list from which it is clear what the user needs to action to be able to progress the clinical communication. The implementation method of this within the suppliers control and design ensuring the that it is clear on what actions need to be taken and the status of messages through the stages of its lifecycle.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR95A** | List all documents/messages received by the system to leave the practice and organise to make optimal use of this list by any combination of the following mechanisms:• Pre-defined views to display to a User all received documents/messages indicating the status (i.e. whether the message/document has been actioned e.g. a task has been generated, or is awaiting a batch process) • Sorting/ordering – ad-hoc re-ordering of the content of a list chronologically by date/time created, date/time received and by any particular information about the message/document• Filtering and grouping – identifying a subset of the list based on the message/document type, messaging mechanism, generator, recipient organisation, Patient details and validation status and by any particular information about the message/document | Must |
| **CR95** | The system **MUST** support the concept of a **“list”**for all clinical correspondence/documents received either by messaging, scanning, email or other mechanisms. Note: Inbox, Workflow or task list is not limiting the implementation approach from the supplier. How this is delivered is open to the supplier’s choice of design, referred to a “list” in the requirements below. | Must |
| CR95.1 | The “list” facility **MUST** be appropriately named. | Must |
| CR95.2 | If the “list” is shared with administrative correspondence/documents for the attention of non-clinical staff, it **MUST** be possible to filter the “list” to show ONLY clinical documents or ONLY administrative documents[[9]](#footnote-9). | Must |
| **CR96** | The system **MUST** support the concept of an individual **User “list”** containing all clinical documents for the attention of that user. | Must |
| CR96.1 | If a clinical User’s “list” can contain non-clinical correspondence/documents, it **MUST** be possible to filter the contents to show ONLY clinical documents or ONLY other documents. | Must |
| **CR97** | The system **MAY** support the concept of a Team “list”. If so then it **MUST** provide facilities to filter by clinical and non clinical contents | May |
| CR97.1 | A Team “list” **MUST** contain all clinical documents/correspondence assigned to the team. | Must |
| CR97.2 | A Team “list” **MUST** contain clinical documents/correspondence assigned to individual members of the team unless the system supports the concept of ‘for the addressee only’ or equivalent functionality. | Must |
| **CR98** | For each System, User of Team (if supported) “list”, the system **MUST** support the concept of a Completed / Actioned Items which **MUST** contain items from the System/User/Team “list” for which all actions have been completed, i.e. the System/User/Team “list” **MUST** ONLY contain items for which an action is outstanding. | Must |
| **CR99** | The “list” (and Completed / Actioned Items) view **MUST** ONLY display ‘header’ information and **MUST** NOT any Clinical Data content. (See CDA Document Technical Requirements for a list of ‘Header’ fields.) (See Viewing Requirements below)‘Clinical Data’ **MUST** be defined as any data within the ‘StucturedBody’ or ‘NonXMLBody’ Act (or subsidiary components) of a CDA document. | Must |
| **CR100** | In addition to the Header items, the “list”x view **MUST** indicate the following ’document status’ field:* Whether the item has been matched to a patient or not and whether this was done automatically or performed manually
* Whether the item has been assigned to a User for clinical review
* Whether the clinical review has been completed
* Whether any ‘actions’ have been assigned to this item
* Whether any ‘actions’ are overdue
* Whether the document has been filed to the patient record
* Whether the document has been received from an unrecognised sender
* Whether the document is an unrecognised CDA document type
 | Must |
| CR100.1 | If necessary, the system **MUST** provide facilities to view the Header items and document status items in full if it is not possible to view all items in the default list view. | Must |
| **CR102** | It **SHOULD** be possible to order the “list” (and Completed / Actioned Items) view typically using the following fields:* Date/Time received
* Sender / Author
* Patient
* Document Type
* Clinical Reviewer
 | Should |
| **CR103** | It **SHOULD** be possible to filter the “list” (and Completed Items) typically using thefollowing fields* Patient matching status – auto, manual, unmatched
* Date/time range
* Sender /Author
* Patient
* Document Type
* Clinical Reviewer
* Review Status – unassigned, assigned, complete
* Action Status – none assigned, assigned awaiting completion, one or more overdue, all actions complete
* Filing status – awaiting filing, filed.
 |  |
| **CR104** | The system **SHOULD** display the current status of an item in the “list” as its status changes (i.e. as functions are carried out and actions performed) using suitable ‘refresh’ functions. | Should |
| **CR105** | The system **MUST** provide the ability to ‘Display’ the full CDA document from the “list”View to allow authorised users to view the contents of the document. This **MUST** be controlled via standard RBAC facilities which will determine which users have access to clinical data. | Must |
| **CR106** | The system **MUST** display a CDA Document according to the ‘CDA Document Technical Requirements’ document. | Must |
| **CR107** | The system **SHOULD** provide a facility to add Administrative notes/comments to a CDA document WITHOUT changing the CDA document itself ( e.g. they should be in addition to it, like an electronic ‘post-it’ note). | Should |
| CR107.1 | All entries made by users in the Administrative Notes/Comments section **MUST** be attributed to the user who made them (e.g. prefixed by username/initials). | Must |
| **CR108** | It **SHOULD** be possible to open the patient record from the “list” for the selected item in the “list” (subject to the user having the necessary access rights) | Should |
| **CR109** | It **MUST** be possible to search for all “list” and Completed / Actioned items for a specified patient and for the subsequent list to have all the “list” functions specified in this document made available to the user (subject to the necessary access rights). | Must |

## Filing

The system needs to provide facilities for a user to add/link the whole or selected parts of CDA Document to one or more existing or new entries in the patient record (e.g. problem, diagnosis, treatment/care plan, consultation, encounter, medication record). For example, it could allow a user to cut and paste part of the document into an existing entry, to create a new entry linked to the document and to create a new diagnosis entry also linked to the document. The system must not restrict the number of entries within the patient record that can be ‘linked to’ the CDA document as there are many situations where multiple entries would need to be created in the record as a result of the information in the document. The ‘link’ is required so that any entries associated with the document can be identified if the document is subsequently replaced or withdrawn.

The generic CDA Document model allows for three sub-sections of a StructuredBody, these being ‘SectionChoice’ containing formatted text, ‘CodedEntry’ containing clinical codes and ‘CRETypeListChoice containing links to map a CodedEntry to a CREType.

The ‘CodedEntry’ element may contain an embedded attachment. A CDA Document may contain a NonXMLBody Act containing a binary object (file) in place of the StructuredBody Act.

At the time of writing the only two CRETypes are allowed to be used in CDA Documents, these are *Drugs and Allergies* and *Medications*.

In addition to the above there exists a clear principle provided by Authority clinicians regarding the processing of clinical data received within a CDA Document:

**There is no requirement for automated transfer of clinical data from a received CDA document to local care records**. **Local systems must not allow data transfer to take place without the audited involvement of a clinical user.**

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR115** | The system **MUST** provide facilities for a user to add and/or link the whole and/or selected parts of CDA Document to one or more existing or new entries in the patient record. A user adding or updating such entries **MUST** have the ability to link the entry to the source CDA Document, e.g. through appropriate systematic linking to the CDA Document SetID and Document ID.(Note: For future support of replacement and nullification documents it will be necessary to trace clinical entries associated with a replaced or nullified document and it is SetID that links all versions together.) | Must |
| CR115.1 | It **MUST** be possible to add the entire contents of the SectionChoice Act (which will contain the entire text narrative of the CDA Document in formatted text format) to the patient record as a complete single entity and in doing so the system **SHOULD** retain all text markup such that the presentation format is preserved when subsequently viewed or printed. | Must |
| CR115.2 | The system **MUST** provide suitable facilities to enable a user to select which parts of a CDA Document to add to the patient record and which parts not to add. Any text formatting **SHOULD** be preserved wherever possible. | Must |
| CR115.3 | It **MUST** be possible to associate this text with a clinical code selected from the native coding scheme by the user. | Must |
| CR115.4 | The system **MUST NOT** restrict the number of entries within the patient record that can be ‘linked’ to a CDA document | Must |
| CR115.5 | The system **MUST** allow a new entry created as a result of information contained in a CDA Document to be linked to that document. | Must |
| CR115.6 | The system **MUST** allow any existing entry updated as a result of information contained in a CDA Document to be linked to that document. (Note that this may result in tow or more CDA Documents being related to the same record entity (e.g. a Problem Heading) | Must |
| CR115.7 | Within this context, it **MUST** also be possible for a user to make changes to the patient record (e.g. change existing problems/diagnosis, amalgamate existing problems) whilst ‘processing’ a CDA document without creating any links to the CDA Document being processed. | Must |
| **CR116** | When the system is displaying the whole CDA Document it **MUST** display the document according to the rendering requirements in the ‘CDA Document Technical Requirements’. | Must |
| CR116.1 | If part of a CDA Document that is filed (e.g. the SectionChoice Act) retains its CDA formatting, any subsequent display of this data **SHOULD** also be according to the rendering requirements contained in the ‘CDA Document Technical Requirements’. | Should |
| CR116.2 | If part of a CDA Document is filed (e.g. the Header information) without its original CDA formatting, any subsequent display of this data **SHOULD** also be according to the display requirements contained in the ‘CDA Document Technical Requirements’ (e.g. use appropriate heading names). | Should |
| **CR117** | As with any other changes made to a patient record, the system **MUST** record the clinical user who approved the change to the patient record together with the identity of the user making the change and the timestamp of the event. Where the user has selected to link the data to a source CDA Document the appropriate document ID/SetID must also be recorded. | Must |
| CR117.1 | When displaying part of a patient record linked to a CDA Document the user **MUST** be able to display the CDA Document (subject to their access rights) | Must |
| **CR118** | The system **MUST** retain the whole CDA Document for full clinical reference (and for Audit Trail purposes) so that the document can be recalled and displayed by all users with appropriate access rights at any time. | Must |
| CR118.1 | It **MUST** not be possible to edit or change in anyway, the original CDA Document | Must |

### Handling ‘CodedEntry’ and ‘CRETypeListChoice’ Acts

MIM 7 CDA Documents will only contain SNOMED CT codes whilst DMS variants may contain the native clinical code from the source system together with a mapped/translated SNOMED CT code where one exists.

**Note that there are currently outstanding clinical safety risks associated with the use of ‘CodedEntry’ and ‘CREType’ and suppliers must ensure that any functionality within the system designed to process this data is subject to robust clinical safety assurance.**

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR125** | The system **MUST**, for each CodedEntry Act containing a SNOMED CT code (as the native code or the mapped code), obtain the CREType by using the reference information contained in the CRETypeListChoice Act. | Must |
| **CR126** | The system **MUST** when displaying a CDA Document keep the text data from the SectionChoice Act separate from the CodedEntry and CRETypeListChoice Acts. CodedEntry and CRETypeListChoice data MAY be hidden from normal display but if this is supported, it **MUST** be clear to the user that this data exists and they **MUST** be able to select it for display. | Must |
| **CR127** | When the system displays a CodedEntry it **MUST** clearly indicate the following:* Any native clinical code, it’s term (description) and it’s coding scheme and any associated attributes
* Any mapped/translated code, its term (description) and its coding scheme (this can only be SNOMED CT) and any associated attributes
* Any associated CREType
 | Must |
| **CR128** | The system **SHOULD** provide functionality to assist a user manually adding a copy of a CodedEntry into the local patient record where the user is in full control and can see exactly how the new entry will appear in the system.  | Should |
| **CR129** | The system **MAY** provide facilities to map a received clinical code to that of the native coding system ONLY if (1) Authority approved mapping or translation tables are used and (2) this is used to assist the user in manually adding an entry to the local patient record. | May |
| **CR130** | When processing a *Medication* Act it **SHOULD** be possible to record medication issued by another organisation. | Should |
| **CR131** | When processing an *Allergies and Sensitivities* Act it **SHOULD** be possible to record the new allergies and sensitivities.  | Should |

### Handling Attachments

Embedded binary objects (files) can be included in a DMS CDA Document. When present the system must be able to detect them, inform the user of their presence, display them on demand and add them to the patient record if a user elects to do so.

The system must also check received attachments against the Authority published ‘White List’ of allowed file types and the ‘Black List’ of banned file types and others on neither list. These must be dealt with appropriately, e.g. user warnings if file is on neither list, removal if on black list.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR140** | The system **MUST** detect the presence of a NonXMLBody Act and **MUST** make users aware of this when listing the CDA Document in the “list” and when displaying the CDA Document.  | Must |
| CR140.1 | When identifying a NonXMLBody on screen, the system **MUST** display the filename and MIME type and **MUST** provide the user with the option to ‘display’ or ‘view’ the file. If selected, the system **MUST** attempt to display the file using appropriate operating system or proprietary rendering facilities. If it is not possible to display the file the system **MUST** provide a suitable error message to the user. | Must |
| **CR141** | The system **MUST** detect the presence of an embedded binary object (file) within a template with a CodedEntry Act and **MUST** make users aware of this when listing the CDA Document in the “list” and when displaying the CDA Document.  | Must |
| CR141.1 | When identifying an embedded object on screen, the system **MUST** display the filename (if available) and MIME type and **MUST** provide the user with the option to ‘display’ or ‘view’ the file. If selected, the system **MUST** attempt to display the file using appropriate operating system or proprietary rendering facilities. If it is not possible to display the file the system **MUST** provide a suitable error message to the user. | Must |
| **CR142** | It **MUST** be possible to copy an embedded object (file) to the patient record as though it was just another part of the CDA document, i.e. a link back to the CDA document **MUST** be preserved; a clinical code can be associated with it, etc. | Must |
| **CR143** | If the system receives an attachment whose MIME / file type is not on the Approved List and the reciver is unable to render the file, the system **MUST** send a negative Application/Business Acknowledgement back to the sending system with a ‘warning’ error message indicating ‘Attachment file type invalid’ (see ‘Point to Point Error Codes’ document) | Must |
| CR143.1 | The system **MUST NOT** allow an attachment with a MIME / file type to be viewed that does not follow the principles as detailed in the "Messaging - Attachment Types" document. The system **MUST** EITHER (1) prevent the entire message and attachment from reaching the system or user “list” OR (2) remove the attachment from the message and just place the message itself in the “list”.In either case the system **MUST** ensure that appropriate users are informed, e.g. by notifying an administrator, by indicating on the system that the attachment has been removed or the entire message has been removed. | Must |
| CR143.2 | It **SHOULD** be possible for an authorised user to view details about the attachment and message, e.g. sender details / authror, MIME / file type, size, etc | Should |
| **CR144** | If the file type of a received attachment is not on the ‘Approved List’ **SHOULD** be passed through to the “list” with a warning.  | Should |
| CR144.1 | When displaying the message or trying to open the attachment the system **MUST** provide an on-screen warning indicating the unrecognised file type and require a positive acknowledgement from the user before allowing a user to either open or save the attachment to the patient record. | Must |
| CR144.2 | Systems **MAY** quarantine such messages for later resolution by authorised users and/or supplier support staff. | May |

### Handling Replacements

**If the system supports Replacements it MUST support the requirements in this section. If the system does not support Replacement Documents it must support the requirements in Appendix A.**

A sender may occasionally send a replacement document to replace a previously sent document. It is a valid situation for the previous document not to exist on the local system and it is also a valid situation for replacements to be received out or order (e.g. to receive v5 before v4). The system must detect these inconsistencies and should provide facilities to ‘repair’ them where this is possible.

Where users have processed the contents of a previous document it is possible that several associated entries have been made in the local system. Some of these may still be valid and others may not. It is beyond the scope of the system to detect such differences but it is not unreasonable for the system to identify any entries in the patient record associated with a previously received document (e.g. by use of links to the original DocumentID)

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR150** | If a Replacement CDA document is received for one that has already been processed by the system, the system **MUST**:* Indicate in the Inbox list view that this is a Replacement document
* Include in the Header/Administrative Data the ID of the document it is replacing
 | Must |
| **CR151** | When a Replacement CDA document is displayed the system **MUST** clearly indicate the ID and version of the document it is replacing.  | Must |
| CR151.1 | It **MUST** be possible to easily access the replaced CDA document (e.g. by clicking on hyperlinks to ‘replaced document’) | Must |
| CR151.2 | Once the replacement document has been clinically accepted, the replaced document **MUST** be marked as ‘replaced’ in the system | Must |
| **CR152** | The system **SHOULD** process a replacement document automatically upon clinical acceptance, i.e. replacing any internal references such that the new version of the document is included.Note: It is recognised that this may be a complex task and may have to involve users modifying previous record entries which will require manual processing. | Should |
| CR152.1 | It **MUST** be possible to search for any data in the patient record linked to the replaced document. Note: Filing requirements require the source CDA Document SetID to be linked to filed data. | Must |
| **CR153** | If the system does not automatically replace a received document with its replacement, it **MUST** be possible for a user to replace any previously filed data with new data from the new document. If changes are made, the system **MUST** update the linked Document reference to the new Document reference and **MUST** record all changes in the system audit trail.If changes are not made, e.g. because the data is unchanged, the system **SHOULD** still update ALL document references to refer to the new document.(Note: The act of replacing filed data **MAY** be done manually and **MAY** be performed as an ‘update’ action or as ‘delete’ and ‘add’ actions. If the system relies on manual processing it **MUST** provide a printed report listing all filed data from the previous document to assist with making manual changes.) | Must |
| **CR154** | If it is possible to list or display a replaced document (e.g. when accessing the audit trail or browsing the ‘completed’ items list, the system **MUST** indicate that the document has been replaced and **MUST** allow the user to ‘go to’ or ‘view’ the replacement document. | Must |
| **CR155** | If a replacement CDA Document has been flagged as ‘replaced document not found in system’ (see Replacement and Nullification Validation above), the system **MUST** indicate this to the user. | Must |
| **CR156** | The system **SHOULD** also indicate whether any previous version(s) of the document are within the system (i.e. with the same SetID) | Should |
| CR156.1 | If multiple replacement documents are received for the same document set, but are received out of order, the system **SHOULD** attempt to resolve this automatically. | Should |
| **CR157** | When viewing (or printing) a CDA Document the system **MUST** clearly indicate whether any other documents from the same Set (i.e. same SetID) exist and **MUST** indicate whether the document selected is the latest or not.  | Must |

### Handing Nullifications

**If the system supports Nullify Documents it MUST support the requirements in this section. If the system does not support Nullify Documents it must support the requirements in Appendix A.**

A document withdrawal marks the end of a set of documents, i.e. it withdraws the original and any replacement documents contained in the ‘set’, i.e. it does not nullify the last document in a set and make the previously ‘active’ document in the set available.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR160** | If a Nullification CDA document is received for one that has already been processed by the system, the system **MUST**:* Indicate in the Inbox list view that this is a Nullification document
* Include in the Header/Administrative Data the ID of the document set it is nullifying (deleting)
 | Must |
| **CR161** | When a Nullification CDA document is displayed the system **MUST** clearly indicate:* the Set ID of the document(s) it is nullifying
* the reason for the nullification

It **MUST** be possible to easily access the nullified CDA document(s) (e.g. by clicking on hyperlinks to ‘nullified document’) | Must |
| **CR162** | It **MUST** be possible to search for any data in the patient record linked to the nullified document. Note: Filing requirements require the source CDA Document Set.ID to be linked to filed data. | Must |
| **CR163** | It **MUST** be possible for a user to (logically) delete any previously filed data from the nullified document. This **MUST** be recorded in the system audit trail.(Note: The act of (logically) deleting filed data **MAY** be done manually. If the system relies on manual processing it **MUST** provide a printed report listing all filed data from the previous document to assist with making manual deletions.) | Must |
| **CR164** | All withdrawn documents in a set **SHOULD** be retained by the system, along with their related *Nullify* document, and marked as ‘withdrawn’. Systems **SHOULD** allow a user to display the Nullifying document and the original documents that have been nullified. Whenever any of these documents are displayed the system **MUST** clearly indicate that the document has been ‘withdrawn’ and the reason why **SHOULD** be accessible (see Nullify document). | Should |
| **CR165** | If a nullify CDA Document has been flagged as ‘nullified document set not found in system’ (see Replacement and Nullification Validation above), the system **MUST** indicate this to the user. | Must |
| **CR166** | Once the nullify document has been processed, the nullified documents (i.e. all documents with the same Set.ID) MUST be marked as ‘withdrawn’ in the system | Must |

## Patient Record

CDA Documents must be available from the patient’s clinical record and the system must indicate the status of the document clearly, e.g. awaiting clinical review.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR170** | It **MUST** be possible from the patient clinical record view to see CDA documents that have been matched to the patient record together with their status, i.e. reviewed, filed, completed. When selecting a document to view the system **MUST** clearly display the document status. | Must |
| **CR171** | It **MUST** be possible to print a CDA document, or the filed contents of a CDA document, from the patient clinical record. | Must |
| **CR172** | Within the context of a single patient record, it **SHOULD** be possible to list all clinical correspondence, including CDA Documents, chronologically. | Should |
| CR172.1 | It **MUST** be possible to filter this list by:* Document type – specialty (e.g. Cardiology)
* Document type – service (e.g. Referral, Discharge)
* Sender Organisation

 (Note: At the time of publication, the two axis of ‘Document Type’ are being developed as SNOMED CT subsets and the post-coordinated expression specification for inclusion in the ‘CV’ document type attribute is being developed.) | Must |
| CR172.2 | It **SHOULD** be possible to filter this list by:* Sub-organisation unit/sending person(author)
 | Should |
| **CR173** | The system **SHOULD** provide facilities to enter the equivalent of a CDA document contents to the system manually (e.g. by allowing selection of the Document Type HL7 Vocabulary terms to classify documents, using META data and document from the file system) | Should |

## System Reporting

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR180** | Within the standard reporting functions of the system, it **MUST** be possible to search for a CDA Document by Document ID. | Must |
| **CR181** | The system **SHOULD** provide reporting facilities to report on aggregated data, e.g. document type by sender by time period. | Should |
| **CR182** | The system **MUST** meet the requirements contained in the ‘CDA Interoperability – Management Information’ which requires systems to routinely send aggregated reports to the Authority. These reports MUST also be available to local users of the system with the appropriate access rights. | Must |

## Audit Requirements

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR190** | When information from CDA documents has been retrieved or is processed, the local Audit trail **MUST** include entries for the following events:and the information stored in the audit record **MUST** include:* timestamp
* Patient NHS Number
* User Identifier and current role identifier
* Clinical data/document identifier
 | Must |

1. Replacement and Nullification Addendum

**If the system does not support Nullification or Replacement the requirements in this section MUST be met.**

If the system does not support replacement or nullification it will have to respond to any messages received. Whilst it is possible to not register the nullify versions of interactions in SDS and thus any attempt to send a nullify message to a system would get rejected by TMS, it is not possible to prevent replacement reports being sent over TMS and it is not possible to prevent any messages being sent over DTS or using ITK we service messaging, hence the system has to send an appropriate response.

| **Req ID** | **Requirement Text** | **Status** |
| --- | --- | --- |
| **CR200** | If the system does not support the receipt of replacement CDA documents it **MUST** send a negative Application/Business Acknowledgement back to the sender indicating ‘no support for replacement CDA documents’ (see Point to Point Error Codes). | Must |
| CR200.1 | The system **MUST** log receipt of such messages | Must |
| CR200.2 | The system **MAY** keep such messages and make them available for viewing. When displaying such a document the user **MUST** be informed that the document has been rejected back to the sender. | May |
| **CR201** | If the system does not support the receipt of nullification/withdrawal CDA documents it **MUST** send a negative Application/Business Acknowledgement back to the sender indicating ‘no support for nullification CDA documents’ (see Point to Point Error Codes). | Must |
| CR201.1 | The system **MUST** log receipt of such messages | Must |
| CR201.2 | The system **MAY** keep such messages and make them available for viewing. When displaying such a document the user **MUST** be informed that the document has been rejected back to the sender. | May |

1. Note that in a social care setting this may not be a clinician but an equivalent social care professional. [↑](#footnote-ref-1)
2. As per previous footnote – may not be a ‘clinical’ review. [↑](#footnote-ref-2)
3. Or equivalent in social care settings [↑](#footnote-ref-3)
4. Documents sent to GP systems should always be for registered patients. Referrals sent to Providers would not necessarily be expected to be present. [↑](#footnote-ref-4)
5. As above. [↑](#footnote-ref-5)
6. Or equivalent in the social care setting, e.g. sensitive personal information. [↑](#footnote-ref-6)
7. Or equivalent in the social care setting. [↑](#footnote-ref-7)
8. Or equivalent access controls in the social care setting. [↑](#footnote-ref-8)
9. Note that all CDA Documents are by their definition ‘clinical documents’ – other items in the Inbox not documented here may be administrative only. [↑](#footnote-ref-9)