



eRAD RIS

# 2024 TEST PLAN FOR CURES REAL WORLD TESTING

For eRAD RIS Version 4

UPDATED OCTOBER 31, 2023

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# Publication History

Revision	Author	Description
20231026	Kevin Brooks	▪ Copied from 2023 Test Plan and updated for 2024.
20231031	Kevin Brooks	▪ Submitted to Drummond.

# SUMMARY

## Objective

Complete the requirements for annual certification of the ERAD RIS VERSION 4 Enterprise Radiology Solution with the ONC Health IT Certification Program as outlined in the ONC 21st Century Cures Act Final Rule.

Key activities:

- Planning Phase:
  - Prepare this test plan and submit to our ONC-ACB, first for a completeness review and then for posting to the Certified Health IT Product List (CHPL).
  - Prepare test scripts and procedures for internal use.
- Testing Phase:
  - Conduct testing throughout the test period.
  - Report any non-conformities.
- Reporting Phase:
  - Compile results and submit a Results Report.

## Overview

Real World Testing (RWT) is one of seven conditions of certification for Health IT Developers participating in the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program as outlined in the ONC 21st Century Cures Act Final Rule (CURES).

This certification provides assurance to purchasers and other users that a system meets the technological capability, functionality, and security requirements adopted by the Department of Health and Human Services (HHS).

This Test Plan describes how the Real World Testing for the ERAD RIS VERSION 4 Enterprise Radiology Solution (RIS) will be conducted. Specifically, it includes:

*Descriptions of how the developer will test and demonstrate conformance to all requirements of the criterion using all versions of the adopted standard to which each Health IT Module was certified as of August 31 of the year in which the plan is due, including for any standards and implementation specifications that the developer has chosen to certify to National Coordinator-approved new versions of the adopted standard;*

## Background

Under the ONC Health IT Certification Program, health IT developers are required to conduct Real World Testing of their certified health IT (45 CFR 170.405) in the type of setting in which such Health IT Module(s) would be/is marketed.

Furthermore, health IT developers must submit to its ONC-ACB an annual real world testing plan addressing for each certified Health IT Module that enables the ONC-ACB to publish a publicly available hyperlink to the plan on CHPL no later than December 15 of each calendar year.

## What is Real World Testing?

Real World Testing is a process by which Health IT Developers demonstrate interoperability and functionality of their Certified Health IT in real world settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL). Real World Testing verifies that deployed Certified Health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange. These observations are described in a public and transparent way through Real World Testing plans and reported as Real World Testing results.

In order to maintain their certification(s), ongoing Maintenance of Certification requirements specify that Health IT Developers must develop a plan and submit a results report for these same criteria on an annual cycle for each of the setting types in which their Certified Health IT Module(s) are marketed.

## General Information

Plan Report ID Number:	[For ONC-Authorized Certification Body use only]
Developer Name:	eRAD Inc.
Product Name(s):	eRAD RIS
Version Number(s):	Version 4
Product List (CHPL) ID(s):	15.04.04.2603.eRAD.04.01.1.221218
Developer Real World Testing Page URL:	<a href="https://erad.com/meaningful-use-certification-adherence-details">https://erad.com/meaningful-use-certification-adherence-details</a>

## Schedule of Key Milestones


The following milestones have been identified for this iteration of the annual certification test planning and execution.

Note that the Real World Testing plan for calendar year 2024 is due in 2023, but testing occurs in 2024, with results reported in 2025.

Key Milestone	Care Setting	Complete By
Submit Test Plan to Drummond Group for upload to CHPL	Ambulatory Radiology	November 1, 2023
Prepare test scripts and procedures (not a deliverable)	Ambulatory Radiology	January 1, 2024
Begin collection of information as laid out by the plan.	Ambulatory Radiology	February 1, 2024
Data collection and review. Workflow simulations, following identified use cases Analysis of workflow outputs, gathered from production and test environments	Ambulatory Radiology	Quarterly, 2024
End of Real World Testing period/final collection of all data for analysis.	Ambulatory Radiology	December 31, 2024
Submit Real World Testing Report and Results	Ambulatory Radiology	February 1, 2025

## Attestation

This Real World Testing plan is complete with all required elements, including measures that address all certification criteria and care settings. All information in this plan is up to date and fully addresses the health IT developer's Real World Testing requirements.

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Date:	October 31, 2023

# SCOPE

## Testing Scope

Testing is to be performed for each **module** identified on the Certified Health IT Product List (CHPL), in each **care setting** in which it is used, and will address all **test plan elements** as defined by the final rule. Test outcomes must include (among other results) a **measurement/metric** that addresses each **applicable certification criterion** in the Health IT Module's scope of certification.

Note that it is not necessary to examine all modules, components, integrations, or configurations of the eRAD RIS VERSION 4 Enterprise Radiology Solution in order to satisfy the test objectives in this plan.

## Test Target

The eRAD RIS VERSION 4 Enterprise Radiology Solution is certified as a single item in the Certified Health IT Product Listing (CHPL). This Test Plan encompasses the full scope of testing of our solution in a single setting of care which is "Ambulatory Radiology".

Note that while test scope includes all available functionality that is marketed to this care setting, at this time a significant portion of this functionality is not currently in use by customers.

The RIS solution includes client-side, server-side, and web enabled modules and components (notably the Provider Portal and Patient Portal modules). The subset of application functionality under test is dictated by the Applicable Criteria identified in this Test Plan.

## Test Plan Elements

Per the final rule specification, the following elements have been addressed in this test plan:

- The **testing method(s)/methodology(ies)** that will be used to demonstrate real world interoperability, including a mandatory focus on scenario- and use case-focused testing;
- The **care and practice setting(s)** that will be tested for real world interoperability, including conformance to the full scope of the certification criteria requirements, and an explanation for the health IT developer's choice of care setting(s) to test;
- The timeline and plans for **voluntary updates to standards and implementation specifications** that ONC has approved (further discussed below);
- A schedule of key real world testing **milestones**;
- A description of the **expected outcomes** of real world testing;
- At least one **measurement/metric** associated with the Real World Testing for each certification in scope; and
- A **justification** for the Health IT Developer's Real World Testing approach.

## Applicable Criteria

The following criteria are in scope for this iteration of Real World Testing for eRAD RIS VERSION 4:

- 170.315(b) Care Coordination Criteria
- 170.315 (c) Clinical Quality Measures
- 170.315 (e) View, Download, and Transmit
- 170.315(g) Application Programming Interface

Specifically:

- 170.315 (b)(1): Transitions of Care
- 170.315 (b)(2): Clinical Information Reconciliation and Incorporation
- 170.315 (b)(6): Data Export
- 170.315 (c)(1): Clinical Quality Measures - Record and Export

- 170.315 (c)(2): Clinical Quality Measures - Import and Calculate
- 170.315 (c)(3): Clinical Quality Measures - Report
- 170.315 (e)(1): View, Download, and Transmit to 3rd Party
- 170.315 (g)(7): Application Access - Patient Selection
- 170.315 (g)(8): Application Access - Data Category Request
- 170.315 (g)(9): Application Access - All Data Request
- 170.315 (g)(10): Standardized API for patient and population services

See also the related documents:

- ERAD RIS RWT CRITERIA TRACKER

## Care Settings to be Tested

Each CHPL listing requires a Test Plan with corresponding test results derived from testing performed in a representative "Setting of Care" for which the product is marketed (intended for use).

As the ERAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use as an Ambulatory Radiology solution and is listed as a single module in the Certified Health IT Product Listing (CHPL). This single Test Plan encompasses the full scope of testing of our solution in a single setting of care which is "Ambulatory Radiology".

## Standards Updates

### Standards Updates (SVAP and USCDI)

Setting	Default
Standard (and version)	All standards versions are those specified in C-CDA
Date of ONC-ACB notification (SVAP or USCDI)	Not applicable
Date of customer notification (SVAP only)	Not applicable
USCDI-updated criteria	None

# TEST APPROACH

## Testing Methods / Methodologies

### Test Methods

Testing will be conducted in cooperation with the RadNet (customer) QA team, with assistance from the eRAD QE Team and support from the eRAD Development Team in the following manners:

- Workflow simulations, following identified use cases and using manufactured data and non-production or simulated testing interface services.
- Analysis of workflow outputs, such as reporting and log analysis.

### Test Procedures

#### Business Scenarios and Use Cases

To demonstrate real world interoperability and conformance to the full scope of the certification Real World Testing requirements, a variety of "business scenarios" will be identified that describe specific "use cases". The expected outcomes of these use cases will correspond to the measures selected that demonstrate conformance.

Scenarios describe objectives as user stories in general terms, while use cases will more specifically describe the step-by-step process specific actors will conduct to complete tasks.

#### Analysis of Workflow Outputs

For identified measures, supporting results will be compiled from a review of production and non-production data.

Data may be accessed via the application UI, application reporting, and queries against the application database and logs.

#### Out of Scope

Note that this test approach differs from our routine development lifecycle testing that includes other forms of testing that are out of scope for this test plan, including:

- Unit testing - with the objective of testing of all possible combinations.
- Usability testing - including user experience and training.
- Performance testing - measuring response times, scalability.
- Negative testing - attempting to simulate failures.

See also the related document ERAD RIS CRITERIA TRACEABILITY FOR CURES RWT for traceability from criteria through test scenarios and results.

### Test Tools

Generally, testing will utilize actual production systems and workflows and manual review of outcomes. However, testing tools and platforms will also be utilized when necessary to evaluate conformance.

Test tools may include internal tools, tools from 3<sup>rd</sup> party vendors, and ONC Health IT Certification tools (e.g., NIST HL7 V2 Resource Portal). The use of custom tools specific to our product will be avoided if possible.

#### Third-party software utilized

- (b.1) Transition of Care: Secure Exchange Solutions HISP

### Test Data

When possible, testing will utilize actual production data, either in a production environment or in a clone of a production environment.

In some cases, the dataset required to validate a particular transaction will not exist because the transactions / activities are either not in use by customers or are an uncommon workflow.



When necessary, synthetic data may be generated by either manually stepping through the workflow under test (e.g., registering a patient), or may be manufactured (e.g., using a test harness to simulate a scheduling event or via test automation scripting).

## Test Environments

Testing will be conducted in the following environments.

- Production Environment - Verification of outputs of production workflows, such as reporting and log analysis (i.e., not introducing test data into production).
- Test Environment - Execution of workflows in a clone of production environment using a subset of production data (e.g., for workflows for product features that are not utilized in production).
- Development Environment - Execution of workflows that require use of manufactured data, test harnesses, or simulated or non-production connections to third-party systems/services (e.g., simulating billing).

In some cases, connectivity from the test environment to third-party services is required. When this is not feasible (e.g., no equivalent non-production test system is available) or practical (e.g. user permissions or network security prevent connectivity), a simulator / test stub may be utilized.

## Justification for Real World Testing Approach

Where the ERAD RIS VERSION 4 Enterprise Radiology Solution is marketed as an Ambulatory Radiology solution, and thus is certified via a single Certified Health IT Product Listing (CHPL), this single Test Plan encompasses the full scope of testing our solution in a single setting of care which is "Ambulatory Radiology" in order to complete the requirements for annual certification with the ONC Health IT Certification Program as outlined in the ONC 21st Century Cures Act Final Rule.

To create this test plan to execute Real World Testing, the following elements have been considered:

- The overall complexity of the workflows and use cases within the care settings to in which the product is marketed (what to test).
- The test measures that provide the most appropriate transparency of interoperability capabilities within the care settings and workflows (what to measure).
- How we will work with customers to observe our Health IT Module's functionality in a production environment (where to test).

## Test Approach

Framing Real World Testing in the context of "use cases" and "scenarios" provides sufficient direction for the testing team to reference known work processes and existing test scripts to complete the prescribed testing activities. Compiling or authoring detailed "test scripts" is outside the intent and scope of this exercise.

The objective of each scenario is to capture one or more at least one measurement/metric that has been defined that demonstrate conformance to criteria.

While executing these test scenarios, the traceability from applicable certification criterion (objective) to the test scenarios (test) and their corresponding measurement/metric (outcome) will demonstrate that conformance has been fully documented.

## Test Data

When possible, testing will utilize actual production data. When not feasible or practical, synthetic data will be generated or manufactured.

In particular, exercising some features of our software would require manipulation of Real World Testing data and that is not the intent of this exercise.

Factors that may require the use of synthetic data to obtain the required measures:

- When data does not exist because the transactions / activities under test are not configured or not in use by customers.
- When the data required to validate a particular transaction does not exist, because required dataset arises from an uncommon workflow or error condition.
- The test environment is incapable of generating the required dataset, for example:
  - Connectivity to required interfaces is not available from the test environment.

- Access to required services or accounts is not available from the test environment.
- Testing requires modification of system configuration to complete the workflow.
- When testing results in modification to production data.

## Test Environments

When possible, testing will utilize actual production environments. When not feasible or practical, non-production (test or development) environments will be utilized.

In particular, enabling some features of our software would require manipulation of Real World Testing environments and that is not the intent of this exercise.

Factors that may require the use of a non-production environment to obtain the required measures:

- The functions under test are not configured or not in use by customers.
- The test requires reproducing an uncommon workflow or error condition.
- The test environment is incapable of generating the required dataset, for example:
  - Connectivity to required interfaces is not available from the test environment.
  - Access to required services or accounts is not available from the test environment.
- Testing requires modification of system configuration to complete the workflow.
- The volume of production data makes testing impractical, such as report generation.

## Variances

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### Deviations From the Test Plan

As updates to the Test Plan are discouraged once submitted, any deviations or adjustments to the approaches in this document made will be reflected in the REAL WORLD TESTING RESULTS REPORT.

The results report will include a description of any changes made, the reasons for them, and how intended outcomes were more efficiently met as a result.

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### Non-Conformities

If any non-conformities are identified, they are required to be reported within 30 days.

#### Tracking

Test failures will be logged in the Redmine defect tracking system. These features and defects should be identified via a "#CURES" tag for tracking purposes.

#### Reporting

If in the course of conducting real world testing one or more non-conformities with the full scope of any certification criterion under the Program are identified, that non-conformity shall be reported to the Drummond Group, our ONC-ACB, within 30 days.

#### Outcome

An action plan for any test failures or non-conformities will be developed in consultation with the Drummond Group.

## Exit Criteria

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### Deliverables

#### Planning Phase

- ERAD RIS TEST PLAN FOR CURES RWT (this document).
- ERAD RIS RWT CRITERIA TRACKER

## Testing Phase

- Test Results and Data
  - Evidence confirming expected outcomes corresponding to each metric that will be delivered. This is likely to include
    - Test logs
    - Workflows
    - Screen captures
    - Audit logs
- Test Summary (internal use)
  - Summary of Test Results
  - Assessment of Measures

## Reporting Phase

- ERAD RIS RWT RESULTS REPORT, with necessary supporting documentation:
  - Deviations from the Test Plan as required.
  - Non-conformities and related action plan as required.
- ERAD RIS CRITERIA TRACEABILITY FOR CURES RWT, demonstrating traceability from required criteria to test scenarios to measures.
  - Supporting Test Results Data as required.

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## Expected Outcomes

As a whole, successful Real World Testing means:

- Certified Health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary codes sets;
- Certified Health IT is exchanging EHI in the care and practice settings for which it is marketed for use; and
- EHI is received by and used in the Certified Health IT.

This will be demonstrated in the Real World Testing Results Report, which will include traceability from the Clinical Quality Measures

# BUSINESS SCENARIOS AND USE CASES

## Scenario - Care Coordination Workflow

This scenario is intended to demonstrate eRAD RIS support for C-CDA documents, including display, send, receive, and export capabilities.

### Use Cases

#### Use Case - Receive, validate, and display C-CDA documents

A third party sends a C-CDA document to eRAD RIS. The eRAD RIS receives and validates the document and incorporates those values into the patient record.

This scenario will confirm:

- The ability of eRAD RIS to receive an electronic (C-CDA) file by direct message or file.
- The ability of eRAD RIS to incorporate the problems, medications, and allergies from a received C-CDA document into the patient record.
- The ability of eRAD RIS to manually display a C-CDA within the application in human readable format.

#### Use Case - Create and send C-CDA documents

An eRAD RIS user views a patient's C-CDA document and sends it to them.

This scenario will confirm:

- The ability of eRAD RIS to create (and display) a correctly formatted C-CDA document.
- The ability of eRAD RIS to transmit a C-CDA document.

#### Use Case - C-CDA Data Export via API

An eRAD RIS user performs an export of C-CDA documents for a set of patients (e.g. all signed by a particular Doctor in the past week) and a scheduled an export (e.g. of one patient to occur on the following day) via the RIS API interface.

This scenario will confirm:

- The ability of permissioned users to perform a Data Export to include C-CDAs for a single patient, a set of patients, or all patients meeting a variety of parameters.
- The ability to initiate the export on demand or create a scheduled event.

## Scenario - Clinical Quality Measures Workflow

This scenario is intended to demonstrate eRAD RIS support for QRDA results. This includes the ability provide a file of QRDA results for patients, and the ability to export QRDA results to a file.

### Use Cases

#### Use Case - QRDA Record and Export

An eRAD RIS user captures a QRDA value and exports a .zip (compressed) file of QRDA results that includes the new value.

This scenario will confirm:

- QRDA values are captured within the RIS.
- Export will compile values for all patients matching the filter criteria entered by the user.
- Export supports either QRDA Category I format or QRDA Category III format.

#### Use Case - Import and Calculate

An eRAD RIS user imports a Clinical Quality Measures datafile.

This scenario will confirm:

- The ability to import values.
- Support for calculations on the imported data.

## Scenario - Patient Engagement Workflow

This scenario is intended to demonstrate the ability of a patient (or their authorized representative) to access their C-CDA health information via the internet.

### Use Cases

#### Use Case - View, Download, and Transmit to 3rd Party

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A patient accesses their C-CDA via the eRAD RIS Patient Portal.

This scenario will confirm:

- The ability of a patient (or their authorized representative) to view, download, and transmit their health information to a 3rd party.

## Scenario - API Access Workflow

This scenario is intended to demonstrate the ability of a third party to query and retrieve data from eRAD RIS via an API request per supplied documentation.

### Use Cases

#### Use Case - Configure API requests

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A third party accesses the online documentation for the eRAD RIS API.

This scenario will confirm:

- The API documentation provides the necessary details to configure API interactions.
- The API documentation is accessible via hyperlink.

#### Use Case - Search for Patient and retrieve data

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A third party uses the eRAD RIS API to locate a patient by name+DOB+phone and retrieves their C-CDA for the past year.

This scenario is intended to demonstrate the ability of a third party to access data via this API, specifically via functions for:

- Obtaining an access token.
- Searching for a patient using a number of criteria, including name, date of birth, MRN and phone number.
- Retrieving an entire C-CDA for a specified patient.
- Retrieving desired sections of a C-CDA for a specified date or date range.

#### Use Case - EHI Export for Enrolled Patients

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A patient enrolls their email address to accesses their EHI data.

This scenario will confirm:

- A patient can provide their email address to initiate enrollment for the EHI export service, provided via Darena's BlueButtonPRO.
- Enrolled patients will receive a C-CDA for each completed exam, provided via Darena's BlueButtonPRO.
- A patient can revoke their enrollment for the EHI export service by removing their email.

# CLINICAL QUALITY MEASURES

The following measurements and metrics have been identified to demonstrate how testing meets the intent and purpose of Real World Testing.

Specifics of each measurement/metric, including its context and traceability, is detailed via the following elements:

- Description of the measurement/metric.
- Associated certification criteria.
- Care setting(s) that is addressed.
- Justification for selected measurement/metric.
- Expected outcomes.

## Metrics for Scenario - Care Coordination Workflow

### Receive, validate, and display C-CDA documents

#### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of eRAD RIS to receive an electronic (C-CDA) file.
  - b. Conformance to the edge protocol.
  - c. The ability of eRAD RIS to validate the structure of received files.
  - d. The ability of eRAD RIS to incorporate the problems, medications and allergies from the C-CDA document into the patient record.
  - e. The ability of eRAD RIS to display the contents of the file within the application in human readable format to the user.
2. Transaction volumes:
  - a. Count of received C-CDA documents:
    - i. Received successfully.
    - ii. Received but rejected.

#### Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(b)(1) Transitions of care	(i) Send and receive via edge protocol	▪ Receive, validate, and display C-CDA documents
315(b)(1) Transitions of care	(ii) Validate and display	▪ Receive, validate, and display C-CDA documents
315(b)(2) Clinical information reconciliation and incorporation	(i) General requirements	▪ Receive, validate, and display C-CDA documents
315(b)(2) Clinical information reconciliation and incorporation	(ii) Correct patient	▪ Receive, validate, and display C-CDA documents
315(b)(2) Clinical information reconciliation and incorporation	(iii) Reconciliation	▪ Receive, validate, and display C-CDA documents
315(b)(2) Clinical information reconciliation and incorporation	(iv) System verification	▪ Receive, validate, and display C-CDA documents

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the ERAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows that receive, validate, and display C-CDA documents.

## Expected Outcomes

- Application capability:
  - A review of logs from a received C-CDA file and the values displayed when viewing the file is expected to confirm that all expected values were correctly received and incorporated into the patient's record.
  - Transmitting an invalid C-CDA file is expected fail and be noted in logs.
- Transaction volumes:
  - A count of transaction volumes in production is expected to be zero as this functionality is not in use by customers at this time.

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## Create and send C-CDA documents

### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of eRAD RIS to create an electronic (C-CDA) file.
  - b. The ability of eRAD RIS to send an electronic (C-CDA) file.
2. Transaction volumes:
  - a. Count of sent C-CDA documents.
    - i. Sent successfully.
    - ii. Failed to send.

### Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(b)(1) Transitions of care	(i) Send and receive via edge protocol	▪ Create and send C-CDA documents
315(b)(1) Transitions of care	(iii) Create	▪ Receive, validate, and display C-CDA documents

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the ERAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows that receive, validate, and display C-CDA documents.

## Expected Outcomes

- Application capability:
  - A review of logs from a received C-CDA file and the values displayed when viewing the file is expected to confirm that all expected values were correctly received and incorporated into the patient's record.
  - Transmitting an invalid C-CDA file is expected fail and be noted in logs.

- Transaction volumes:
  - A count of transaction volumes in production is expected to be low as this functionality is not in wide use by customers.

## C-CDA Data Export via API

### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of eRAD RIS to export a C-CDA to a specified location.
  - b. The ability of eRAD RIS to export a C-CDA for a set of patients according to a variety of parameters.
  - c. The ability of eRAD RIS to schedule the export of a C-CDA.
2. Transaction volumes:
  - a. Count of exported sent C-CDA documents.

### Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(b)(6) Data export	(i) General requirements for export summary configuration	▪ Create and send C-CDA documents
315(b)(6) Data export	(ii) Creation	▪ Create and send C-CDA documents
315(b)(6) Data export	(iii) Timeframe configuration	▪ Create and send C-CDA documents
315(b)(6) Data export	(iv) Location configuration	▪ Create and send C-CDA documents

### Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

### Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows for exporting C-CDA documents.

### Expected Outcomes

- Application capability:
  - A review of exported documents is expected to confirm that a valid C-CDA file was created as expected.
- Transaction volumes:
  - A count of transaction volumes in production is expected to be low as this functionality is not in wide use by customers.

## Metrics for Scenario - Clinical Quality Measures Workflow

### QRDA Record and Export

#### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of eRAD RIS to capture all of the data necessary to calculate required CQM datasets.



- b. The ability of eRAD RIS to calculate required clinical quality measures.
  - c. The ability of eRAD RIS to export QRDA results in the format of choice.
  - d. The completeness and accuracy of the QRDA results.
2. Transaction volumes:
- a. Count of exported QRDA reports.

## Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(c)(1) Clinical quality measures - record and export	(i) Record	▪ Export of QRDA results
315(c)(1) Clinical quality measures - record and export	(ii) Export	▪ Export of QRDA results
315(c)(2) Clinical quality measures - import and calculate	(ii) Calculate each and every clinical quality measure for which it is presented for certification	▪ Export of QRDA results
315(c)(3) Clinical quality measures - report	(i) In accordance with the applicable implementation specifications specified by the CMS implementation guides for Quality Reporting Document Architecture (QRDA), category I, for inpatient measures in § 170	▪ Export of QRDA results
315(c)(3) Clinical quality measures - report	(ii) In accordance with the standards specified in § 170	▪ Export of QRDA results



*Some criteria elements, such as 315(e)(1)(i)(A)(5) which applies to an Inpatient setting only, are out of scope.*

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows for capturing and exporting QRDA results in this care setting.

## Expected Outcomes

- Application capability:
  - The completeness and accuracy of the QRDA results.
  - Adherence to the QRDA Category I format or QRDA Category III format.
- Transaction volumes:
  - A count of transaction volumes in production is expected to be zero as this functionality is not in use by customers at this time.

## QRDA Import and Calculate

### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of eRAD RIS to import QRDA results in the format of choice.

- b. The ability of eRAD RIS to calculate required clinical quality measures.
2. Transaction volumes:
  - a. Count of CQM patient records imported.

## Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(c)(2) Clinical quality measures - import and calculate	(i) Import	<ul style="list-style-type: none"> <li>▪ Import of QRDA results</li> </ul>
315(c)(2) Clinical quality measures - import and calculate	(ii) Calculate each and every clinical quality measure for which it is presented for certification	<ul style="list-style-type: none"> <li>▪ Import of QRDA results</li> </ul>



*Some criteria elements, such as 315(e)(1)(i)(A)(5) which applies to an Inpatient setting only, are out of scope.*

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows for importing and processing QRDA values in this care setting.

## Expected Outcomes

- Application capability:
  - Accuracy of calculated clinical quality measures.
- Transaction volumes:
  - A count of transaction volumes in production is expected to be zero as this functionality is not in use by customers at this time.

# Metrics for Scenario - Patient Engagement Workflow

## Patient Access to C-CDA

### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of a patient to access and view their entire C-CDA via the Patient Portal.
  - b. The integrity of the access security process.
  - c. The ability of a patient to download their C-CDA in the format of choice.
  - d. Equivalent abilities for authorized representatives.
  - e. The completeness of the Activity History Log
2. Transaction volumes:
  - a. Count of C-CDAs viewed.
  - b. Count of C-CDAs downloaded.

## Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(e)(1) View, download, and transmit to 3rd party	All	<ul style="list-style-type: none"> <li>▪ Patient Access to C-CDA</li> </ul>



*Some criteria elements, such as 315(e)(1)(i)(A)(5) which applies to an Inpatient setting only, are out of scope.*

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows for patient and authorized representative access to their C-CDA in this care setting.

## Expected Outcomes

- Application capability:
  - The user workflow supports patient access to authorized values.
  - Unauthorized access attempts are logged.
  - A review of returned values is expected to confirm:
    - All expected values were returned according to the standard.
    - All returned values were accurate and complete.
  - A review of log files is expected to confirm:
    - Transactions completed without error, or errors were appropriately logged.
- Transaction volumes:
  - A count of transaction volumes in production is expected to be low as this functionality is not in wide use by customers.

## Metrics for Scenario - API Access Workflow

### Completeness of API Response

#### Description of Measurement/Metric

The eRAD RIS supports requests via an external Web API that include searching and retrieving patient data.

This measure will confirm the completeness of the eRAD RIS response to these API requests including:

1. Application capability:
  - a. The ability of a third-party application to search for a patient using a number of criteria, including name, date of birth, MRN, and phone number.
  - b. The ability of eRAD RIS to provide an entire C-CDA or desired sections of the C-CDA for a specified date or date range via API.
  - c. Confirming the integrity of the access security process.
  - d. Confirming the completeness of the response and conformance to the JSON messaging standard.
  - e. Confirming the accuracy of the response values.
2. Transaction volumes:
  - a. Count of patient search requests.
  - b. Count of C-CDA requests returned (either entire C-CDA or sections).

## Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
315(g)(7) Application access - patient selection	(i) Functional requirement	▪ Completeness of API Response
315(g)(8) Application access - data category request	(i) Functional requirements	▪ Completeness of API Response
315(g)(9) Application access - all data request	(i) Functional requirements	▪ Completeness of API Response

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows for locating and retrieving data via the API in this care setting and confirms the accuracy and completeness of the returned values.

## Expected Outcomes

- Application capability:
  - A review of values returned by the API request is expected to confirm:
    - All expected values were returned according to the standard.
    - All returned values were accurate and complete.
  - A review of log files generated by the API request is expected to confirm:
    - Transactions completed without error, or errors were appropriately logged.
- Transaction volumes:
  - A count of transaction volumes in production is expected to be zero as this functionality is not in use by customers at this time.

## Completeness of API Documentation

### Description of Measurement/Metric

Documentation for eRAD RIS is available online.

This measure will test:

1. Application capability:
  - a. The completeness of required sections of the API documentation according to the requirement, including syntax and configuration details.
  - b. That the documentation is publicly accessible via hyperlink.

## Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure
315(g)(7) Application access - patient selection	(ii) Documentation	▪ Completeness of API Documentation
315(g)(8) Application access - data category request	(ii) Documentation	▪ Completeness of API Documentation
315(g)(9) Application access - all data request	(ii) Documentation	▪ Completeness of API Documentation

## Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

## Justification for Selected Measurement/Metric

This review is sufficient to demonstrate that the API documentation is both available and publicly accessible.

## Expected Outcomes

- Application capability:
  - A review of documentation is expected to confirm it is both complete and accessible.

## Patient Access to C-CDA

### Description of Measurement/Metric

This measure will test:

1. Application capability:
  - a. The ability of a patient to enroll for the EHI export service, provided via Darena's BlueButtonPRO.
  - b. The ability of an enrolled patient to access and view their entire C-CDA via Darena's BlueButtonPRO Patient Portal.
2. Transaction volumes:
  - a. Count of patient enrollments.
  - b. Count of C-CDAs transmitted to the EHI export service provided via Darena's BlueButtonPRO.

### Associated Certification Criteria

These measures have been identified to demonstrate conformance to the following certification criterion in the **Ambulatory Radiology** care setting:

Certification Criteria	Requirement	Measure(s)
170.315 (g)(10): Standardized API for patient and population services	Data response.	▪ Patient Access to C-CDA
170.315 (g)(10): Standardized API for patient and population services	Supported search operations.	▪ Patient Access to C-CDA
170.315 (g)(10): Standardized API for patient and population services	Application registration.	▪ Patient enrollment for the EHI export service
170.315 (g)(10): Standardized API for patient and population services	Secure connection.	▪ Patient enrollment for the EHI export service
170.315 (g)(10): Standardized API for patient and population services	Authentication and authorization.	▪ Patient enrollment for the EHI export service
170.315 (g)(10): Standardized API for patient and population services	Patient authorization revocation.	▪ Patient enrollment for the EHI export service
170.315 (g)(10): Standardized API for patient and population services	Token introspection.	▪ Patient enrollment for the EHI export service
170.315 (g)(10): Standardized API for patient and population services	Documentation.	▪ Completeness of Documentation

### Care Setting(s)

This measure/metric will be captured in an **Ambulatory Radiology** setting of care, representing the sole setting of care for which the eRAD RIS VERSION 4 Enterprise Radiology Solution is marketed for use.

### Justification for Selected Measurement/Metric

This metric confirms the ability to complete typical workflows for patient and authorized representative access to their C-CDA in this care setting.

## Expected Outcomes

- Application capability:
  - The user workflow supports patient access to authorized values.
- Transaction volumes:
  - A count of enrollments in production is expected to be low as this functionality is not in wide use by customers.