

# **Department of Veterans Affairs**

## **Clinical Case Registries (CCRe)**

**ROR\*1.5\*26**

**(Registry Enhancements Base Period)**

**Requirements Specification Document**






**February 2015**

**Version 1.2**

## Revision History

Note: The revision history cycle begins once changes or enhancements are requested after the Requirements Specification Document has been baselined.

Date	Version	Description	Author
02/12/15	1.2	Updated RSD with comments from the VA. Updated section 2.6.1.1 with new SVR selection panel and report header mockups. Updated section 2.6.1.2 with new Liver Score selection panel and report header mockups.	
12/18/14	1.1	Updated RSD with comments from the VA. Changed "ROR*1.5*<Pacth # TBD>" to "ROR*1.5*26". Updated the Table of Contents, List of Figures, and List of Tables. Update section 1.2 and inserted "Table 1 – Out of Scope Requirements". Removed Functional Specifications in Section 2.6 that were implemented in previous ROR*1.5*x patchs. See Table 1. Corrected minor grammatical issues. Update the last paragraph in section 2.6.3. Removed old section 2.6.4.4 Do Not Update National Database. Removed old section 2.6.4.8 Include the number of Reports Run in Nightly HL7 Message.	
12/09/14	1.0	First draft of CCR patch for Enhancements Increment 1. Updated section 2.3 and 2.6.	

## Artifact Rationale

The Requirements Specification Document (RSD) records the results of the specification gathering processes carried out during the Requirements phase. The RSD is generally written by the functional analyst(s) and should provide the bulk of the information used to create the test plan and test scripts. It should be updated for each increment.

The level of detail contained in this RSD should be consistent with the size and scope of the project. It is not necessary to fill out any sections of this document that do not apply to the project. The resources necessary to create and maintain this document during the life cycle of a large project should be acknowledged and clearly reflected in project schedules. Do not duplicate data that is already defined in another document or a section in this document; note in the section where the information can be found.

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# 1. Introduction

## 1.1. Purpose

This Requirements Specification Document (RSD) will describe the modifications to the Clinical Case Registries (CCR) software that will be implemented with Patch ROR\*1.5\*26. These modifications are identified as Development/Modernization/Enhancement (DME) modifications, since they enhance the CCR software package, under the Registry Enhancements contract.

The audience for this RSD includes the CCR Stakeholders; Project Management Team; Functional Analyst(s), MUMPS (M) Developer(s), Delphi Graphical User Interface (GUI) Developer(s), SQA Analyst(s), and any Documentation Specialist(s) that may work on this project.

## 1.2. Scope

The software that shall be modified includes: existing Delphi GUI screens, along with the relevant Remote Procedure Call (RPC) protocols; M programs in the ROR namespace; and Data Dictionaries necessary to achieve the specified functional requirements in Section 2.6 Functional Specifications.

The software currently resides in the CCR environment and the ROR namespace in the VistA applications. This enhancement work will modify the CCR software system, so that it more accurately meets the needs of the Clinical Case Registries User Community by providing the necessary functionality. These modifications shall benefit the users by providing more reporting control and options, and by permitting more detailed analysis of local registry data that is collected throughout the VA.

The following business requirements have been deprecated through meetings and discussions with VA stakeholders. They represent functionalities that have been implemented in previous ROR patches and are out of scope (not intended as part of this round of enhancements).

*Table 1 – Out of Scope Requirements*

Business Requirement #	Business Requirement Document Description
F 1.1	Need to be able to characterize a Veteran's virologic response to antiviral medication (e.g. null response, partial response, relapse, sustained virologic response) and the specific antiviral medication regimen the Veteran received. Implemented in patch ROR*1.5*24.

F 2.1	A new Selection Panel on each report to allow the user to limit the report to patients with a diagnosis of interest -- based on the International Classification of Diseases -- in a user-specified time period of interest. Implemented in patch ROR*1.5*21.
F 2.3	Update the existing Potential Direct Acting Antiviral (DAA) Candidate report to include all HCV genotypes. <b><i>Changed the Business Requirement to read:</i></b> Update the existing Potential Direct Acting Antiviral (DAA) Candidate report. All HCV Genotypes was implemented in patch ROR*1.5*24.

## 1.3. References

- Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d). Section 508 Compliance requirements are listed on the VA Section 508 Office website at [REDACTED]
- VA Directive 6500 Information Security Program, located at: [REDACTED]
- Office of Management and Budget (OMB) Circular A-130, Appendix III, Security of Federal Automated Information Resources, located at: [REDACTED]
- VA Handbook 6500.3, Certification and Accreditation of VA Information Systems, located at: [REDACTED]

## 2. Overall Description

Patch ROR\*1.5\*26 contains modifications that require assessment of the Accessibility Specifications, Documentation Specifications, Functional Specifications, Multi-divisional Specifications, and Usability Specifications below.

### 2.1. Accessibility Specifications

The CCR registry enhancements shall be developed in compliance with the VA requirements for Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d). Section 508 requirements are listed on the VA Section 508 Office website at [REDACTED]

### 2.2. Business Rules Specification

ROR\*1.5\*26 introduces no new or additional business rules.

## **2.3. Design Constraints Specification**

ROR\*1.5\*26 introduces no new or additional design constraints.

## **2.4. Disaster Recovery Specification**

ROR\*1.5\*26 introduces no new or additional disaster recovery requirements.

## **2.5. Documentation Specifications**

Applicable CCR documentation, including the user manual, technical manual, release notes, and installation guide, shall be updated to include details regarding CCR Patch ROR\*1.5\*26.

## **2.6. Functional Specifications**

CCR Patch ROR\*1.5\*26 shall contain the following Development/Modernization/Enhancement (DME) modifications:

### **2.6.1. Enhance reporting functionality**

**2.6.1.1.** A new Selection Panel on each report to allow the user to limit the report to Veterans based on the two categories of No SVR and SVR as determined in requirement 2.6.1.

- Patch ROR\*1.5\*24 contains the code logic for SVR and Non-SVR.
- Create new SVR filter panel in the Hepatitis C Registry. The panel will have 3 radio buttons, “All Patients”, “SVR Only”, and “No SVR Only”. The default will be “All Patients”. See *Figure 1* for the panel mockup.

**Hepatitis C Registry Reports**

**List of Reports**

- BMI by Range
- Clinic Follow Up
- Combined Meds and Labs
- Current Inpatient List
- DAA Lab Monitoring
- Diagnoses
- General Utilization and Demograph...
- Inpatient Utilization
- Lab Utilization
- List of Registry Patients
- Liver Score by Range
- Outpatient Utilization
- Patient Medication History
- Pharmacy Prescription Utilization
- Potential DAA Candidates
- Procedures
- Radiology Utilization
- Registry Lab Tests by Range
- Registry Medications
- Renal Function by Range
- Sustained Virologic Response

**BMI by Range**

**Scheduled to Run on**  
 Day: 2/18/2015 at 17:27:05 Repeat: [dropdown]  
 Comment: [text area]

**Include patients confirmed in the registry**  
☒ Before the date range ☒ During the date range ☒ After the date range

**Sex**  
☒ Both ☐ Female only ☐ Male only

**OEF/OIF**  
☒ All periods of service ☐ Include only OEF/OIF ☐ Exclude OEF/OIF

**SVR**  
☒ All Patients ☐ SVR Only ☐ No SVR Only

**Additional Identifier**  
☐ Include patient ICN in the report

**Report Type**  
☒ Complete ☐ Summary

**BMI Date Range**  
☒ Most recent BMI ☐ BMI as of: 1/31/2003

**Result Ranges**

Select	BMI Range	Low	High
<input type="checkbox"/>	BMI		

Do not add the new SVR Selection panel to the Sustained Virologic Response

Figure 1 - SVR Selection Panel

- The SVR panel shall be placed below the OEF/OIF selection panel and above the Additional Identifier panel. See **Figure 1** above for the panel mockup.
- On the Current Inpatient List report, the SVR panel shall be placed below the OEF/OIF selection panel and above the Other Diagnoses panel. See **Figure 2** for the panel mockup.

**Hepatitis C Registry Reports**

**List of Reports**

- BMI by Range
- Clinic Follow Up
- Combined Meds and Labs
- Current Inpatient List
- DAA Lab Monitoring
- Diagnoses
- General Utilization and Demograph...
- Inpatient Utilization
- Lab Utilization
- List of Registry Patients
- Liver Score by Range
- Outpatient Utilization
- Patient Medication History
- Pharmacy Prescription Utilization
- Potential DAA Candidates
- Procedures
- Radiology Utilization
- Registry Lab Tests by Range

**Current Inpatient List**

**Scheduled to Run on**  
 Day: 2/18/2015 at 17:28:11 Repeat: [dropdown]  
 Comment: [text area]

**Sex**  
☒ Both ☐ Female only ☐ Male only

**OEF/OIF**  
☒ All periods of service ☐ Include only OEF/OIF ☐ Exclude OEF/OIF

**SVR**  
☒ All Patients ☐ SVR Only ☐ No SVR Only

**Other Diagnoses**  
☒ Ignore  
☐ Include Codes  
☐ Exclude Codes

Template Type: [dropdown]

Name	Code	Descr...	Code :
Diagnoses			

Figure 2 –SVR Selection Panel for Current Inpatient List report

- The report headers shall contain the label “SVR:” and the user selected value. See **Figure 3** for the report header mockup.



## BMI by Range

Registry: VA HEPC  
 Utilization Date Range: 01/31/2013 - 02/19/2015  
 Clinics: ALL  
 Divisions: ALL  
 Patients: Added on any date  
 OEF/OIF: Exclude  
 Sex: Female only  
 SVR: All Patients  
 Options:  
 Lab Test Date: Most Recent  
 Other Diagnoses: All

Report Created: 02/19/2015@10:36  
 Task Number: 407491  
 Last Registry Update: 05/01/2013  
 Last Data Extraction: 05/01/2013

All report headers shall contain the SVR: label with the selected value.

\*For this report, height values that are <36 inches or >96 inches are assumed to be erroneous and are ignored.

BMI Categories	BMI Values	Number of Patients
Underweight	<18.5	0
Normal weight	18.5-24.9	0
Overweight	25.0-29.99	0
Class I Obesity	30.0-34.9	0
Class II Obesity	35-39.9	0
Class III Obesity	>=40	0

Figure 3 - SVR Report Header label

- The SustainedVirologic Response report should not have the new SVR selection panel and shall maintain the current functionality.

### 2.6.1.2. Update the existing Potential Direct Acting Antiviral (DAA) Candidate report.

- Add a filter based on FIB4 score (which is an option in the Liver Score by Range report)
  - Shall include new filter by Liver Score by Range. This will include Liver Score Date Range and Result Ranges. The “Most recent Liver score” shall be the default radio button.
  - The new panel shall be placed after the Treatment History panel and before the Utilization Date Range panel. See **Figure 4** for the panel mockup.

**Hepatitis C Registry Report**

**Potential DAA Candidates**

**Scheduled to Run on**  
Day: 2/11/2015 at 17:28:19 Repeat:   
Comment:

**Include patients confirmed in the registry**  
☒ Before the date range ☒ During the date range ☒ After the date range

**Sex**  
☒ Both ☐ Female only ☐ Male only

**OEF/OIF**  
☒ All periods of service ☐ Include only OEF/OIF ☐ Exclude OEF/OIF

**Additional Identifier**  
☐ Include patient ICN in the report

**Treatment History**  
☐ HepC antiviral treatment naive ☐ HepC antiviral treatment experienced ☐ Exclude patients on treatment i.e. with HCV antiviral treatment within   
days

**Warning:** This report will only work if there are informative results in the result field for HCV RNA so that patients with detectable HCV RNA can be identified (e.g., patients with results of "comment" with the value only appearing in the comment field will not be identified).

**Liver Score Date Range**  
☒ Most recent Liver score ☐ Liver Score as of 1/31/2003

**Result Ranges**

Select	Liver Score Range /	Low	High
<input checked="" type="checkbox"/>	FIB-4		

Lab tests used in calculations are identified by LOINC code. If the values shown for test results appear unusual, contact your local Lab ADPAC to verify that LOINC codes are set up correctly.

**Utilization Date Range**  
Type: Year ☐ Fiscal ☐

**Divisions**  
☒ Include All ☐ Selected only  
Search:   
Include only those patients who had utilization in the selected division(s)  
All Divisions

**Clinics**  
☒ Include All ☐ Selected only  
Search:

☐ Show Report List

Figure 4 – New Selection Panel Placement

- The new filter panel shall be formatted as follows. See **Figure 5** for the panel mockup.

**Liver Score Date Range**  
☒ Most recent Liver score ☐ Liver Score as of 1/31/2003

**Result Ranges**

Select	Liver Score Range /	Low	High
<input checked="" type="checkbox"/>	FIB-4		

Lab tests used in calculations are identified by LOINC code. If the values shown for test results appear unusual, contact your local Lab ADPAC to verify that LOINC codes are set up correctly.

Figure 5 - Liver Range Selection Panel

- The report header shall display the label “**RESULTS:**” with the user selected value from the selection panel.
  - The report header values shall be displayed the same as follows. See **Figure 6:**

**Potential DAA Candidates**

Registry: VA HEPIC

Utilization Date Range: 01/31/2003 - 02/12/2015

Treatment History: Naive

Clinics: ALL

Divisions: ALL

Patients: Treated only, Added on any date

Sex: Both

Other Diagnoses: All

**Results:** FIB-4 - numeric results not less than 0 and not greater than 3.25

Report Created: 02/12/2015@09:59

Task Number: 406552

Last Registry Update: 05/01/2013

Last Data Extraction: 05/01/2013

The **Results:** title shall be displayed using the same functionality used in the Liver Score by Range report.

This report contains confidential patient information and must be handled in accordance with established policies.

#	Patient Name	SSN	Treatment Status	Most Recent HCV RNA Date	Most Recent HCV RNA	Most Recent GT	Most Recent Fill Date	Most Recent HCV Medication Fill
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*Figure 6 – Potential DAA Candidates Report Header*

- Remove the requirement to exclude patients who have received boceprevir or telaprevir.

**2.6.1.3.** Update the existing save as functionality so that when a user saves a report as a csv file that the information for all Veterans appears in one worksheet.

- This should be available for all reports.
- Update the Report “Save As” functionality for Comma-Separated Values file format (\*.csv) so it is saved as a single file.
- The following reports save multiple .CSV files.
  - BMI by Range
  - Combined Meds and Labs
  - Diagnoses
  - General Utilization and Demographics
  - Inpatient Utilization
  - Lab Utilization
  - Outpatient Utilization
  - Patient Medication History
  - Pharmacy Prescription Utilization
  - Procedures
  - Radiology Utilization
  - Renal Function by Range
  - VERA Reimbursement
- There are no changes to HTML and XML file formats.

**NOTE:** Currently, reports that contain multiple tables based upon the selected report parameters will be saved in separate .CSV files. The number of separate files for each

saved report will depend on the report that is generated and the report parameters selected. A sequential number will be appended to the names of the additional files. See **Figure 7**.

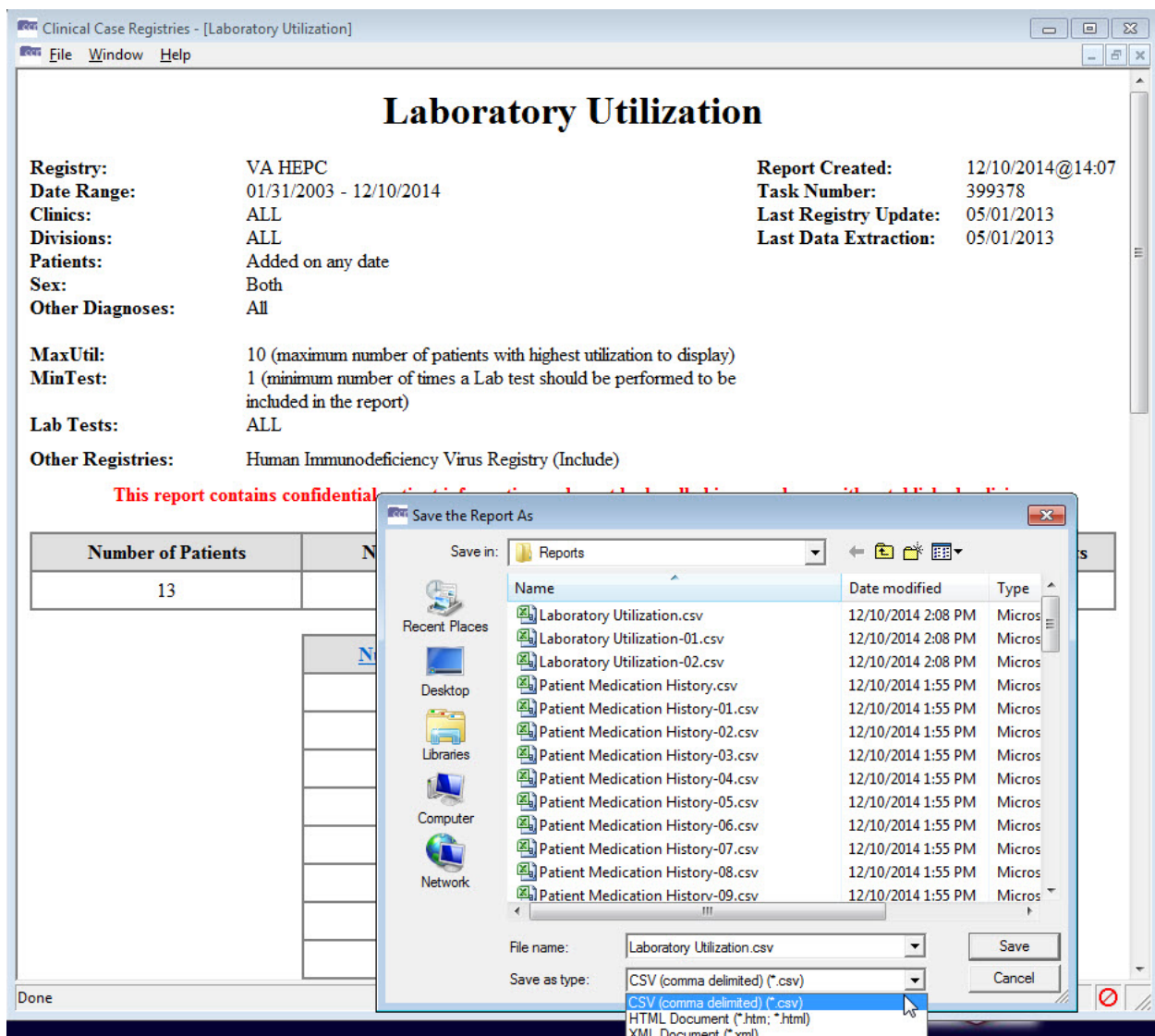


Figure 7 - .csv files

## 2.6.2. Create New Diagnosis Group for inclusion in Common Templates

### 2.6.2.1. Create a new diagnosis group for LIVER TRANSPLANTATION and add it to the Common Templates.

The new diagnosis group for Liver Transplants will be created using the listed ICD-9 and ICD-10 codes:

Table 2 – ICD Codes

ICD-9 Codes	ICD-10 Codes
V42.7, 996.82	T86.4%, Z48.23%, Z94.4

### 2.6.3. Create Additional Local Registries

Functional specifications 2.6.3.1 through 2.6.3.4 are designed to allow the CCR reporting tools to be used with the local registries, which will be built based on either ICD-9 codes, ICD-10 codes, CPT codes, and/or laboratory test results identified by LOINC codes. The ICD-9, ICD-10, CPT, and LOINC codes, as determined by the Population Health Group, within the Office of Public Health, will be specified within the patch. These registries are hereafter referred to as the “new registries” in distinction to the existing local registries and the national CCR Hepatitis C and HIV registries.

Because these new registries are not national registries, the national database will not be updated with patient data from the new registries, and data extraction and HL7 messages for the Hepatitis C and HIV registries will continue without change. All new registries will be controlled by the existing ADMIN and USER security keys. Individual keys will not exist for each new registry. The separate keys for the Hepatitis C and HIV registries will continue to exist with unchanged functionality. In addition, the nightly HL7 message which includes the number of reports that were run in the Hepatitis C and HIV national registries as well as the local registries will automatically include the reports run in the new registries as well.

#### 2.6.3.1. Create Initial Build of New Registry Patient List

After the patch is installed, the installer will schedule the initial build of the new registries using the option ROR INITIALIZE. This option allows the user to schedule the task that will populate the new registries added in ROR\*1.5\*26. The status of each new record added to the ROR REGISTRY RECORD (#798) file will be automatically confirmed. The software will search back to 01/01/1985 to identify patients with the qualifying ICD-9, ICD-10, LOINC, and CPT codes. Patients with a qualifying ICD-9, ICD-10, CPT code, or laboratory result will be automatically confirmed into the local registry for the condition of interest. The confirmation date will be set to be the earliest date of the qualifying ICD-9 or ICD-10 code or CPT Code or the qualifying laboratory result.

The following new registries will be created using the listed ICD-9, ICD-10, and CPT codes:

*Table 3– ICD & CPT Codes*

<b>Registry</b>	<b>Abbreviation</b>	<b>ICD-9 Codes</b>	<b>ICD-10 Codes</b>	<b>CPT Codes</b>
Total Knee Replacement	VA TOTAL KNEE	00.80, 00.81, 00.82, 00.83, 00.84, 81.54, 81.55	0SRC%, 0SRD%, 0SRT0, 0SRU0, 0SRV0, 0SRW0	27447
Total Hip Replacement	VA TOTAL HIP	00.70, 00.71, 00.72, 00.73, 00.74, 00.75, 00.76, 00.77, 81.51, 81.52, 81.53	0SR9%, 0SRB%, 0SRA0, 0SRE0	27130, 27132

#### **2.6.3.2. Add New Patients to New Registry Patient List**

The nightly ROR job, ROR TASK, will search for new instances of qualifying ICD-9, ICD-10, or CPT codes. Patients with a new qualifying ICD-9, ICD-10, or CPT code will be automatically added to the registry patient list with a confirmation date set to the date of the earliest qualifying ICD-9, ICD-10, or CPT code. If a patient has been deleted from a registry for one instance of a qualifying ICD-9, ICD-10, or CPT code but has an additional or new instance of a qualifying ICD-9, ICD-10, or CPT code, the patient will again be added to the new registry. When a user deletes a patient from a registry, the patient is immediately deleted from the ROR REGISTRY RECORD file and the deletion is logged.

#### **2.6.3.3. Include Report Functionality for New Registries**

In the new registries, all selection panels for the following reports will function as intended for the Hepatitis C and HIV registries, without change.

- BMI by Range Report
- Clinic Follow Up Report
- Combined Meds and Labs Report
- Current Inpatient List Report
- Diagnosis Report
- General Utilization and Demographics Report
- Inpatient Utilization Report
- Lab Utilization Report
- Liver Score by Range Report
- Outpatient Utilization Report

- Patient Medication History Report
- Pharmacy Prescription Utilization Report
- Procedures Report
- Radiology Utilization Report
- Renal Function by Range Report

#### **2.6.3.4. Exclude Report Functionality for New Registries**

All local reports currently available in CCR will be available to the new registries, excluding the following:

- Registry Lab Tests by Range Report
- DAA Lab Monitoring Report
- Potential DAA Candidates Report
- VERA Reimbursement Report
- Registry Medications Report
- Sustained Virologic Response Report

#### **2.6.4. Modifications to the Custom Controls within the CCR GUI to Ensure Complete Section 508 Certification**

No current requirements exist to make 508 compliance changes based on previous 508 testing. Any modifications to CCR under the direction of this RSD will be 508 compliant.

#### **2.6.5. Update M Version Check**

The routine RORUTL11 shall be updated to reflect the associated M version for Patch ROR\*1.5\*26 to ensure that the M version matches the GUI version.

### **2.7. Graphical User Interface (GUI) Specifications**

CCR Enhancements introduced with ROR\*1.5\*26 shall include CCR GUI changes to ensure compliance with Section 508 Conformance requirements.

### **2.8. Multi-divisional Specifications**

Multi-divisional capability, a fundamental core of the One-VA approach, can be defined as appropriate health care capable of being delivered to the treatment requestor based on his or her eligibility parameters and the capabilities of the care-providing facility, recognizing that organizational hierarchies in VHA are subject to change. The CCR application operates in a multi-divisional capacity.

## **2.9. Performance Specifications**

ROR\*1.5\*26 introduces no new or additional performance requirements.

## **2.10. Quality Attributes Specification**

ROR\*1.5\*26 introduces no new or additional quality attributes.

## **2.11. Reliability Specifications**

ROR\*1.5\*26 introduces no new or additional reliability requirements.

## **2.12. Scope Integration**

ROR\*1.5\*26 will not add any new dependencies. CCR relies on the current standard VA releases of the following:

- FileMan
- HL7
- ICD
- Kernel
- Labs
- Patient Treatment File (PTF)
- Pharmacy

## **2.13. Security Specifications**

ROR\*1.5\*26 introduces no new or additional security requirements.

## **2.14. System Features**

ROR\*1.5\*26 introduces no new or additional system features, apart from the functional changes described in Section 2.6 Functional Specifications.

## **2.15. Usability Specifications**



CCR Enhancements introduced with ROR\*1.5\*26 shall include CCR GUI changes to ensure compliance with Section 508 Conformance requirements, as specified in Section 3 Applicable Standards.

No new or additional usability specifications shall be introduced with ROR\*1.5\*26.

### **3. Applicable Standards**

ROR\*1.5\*26 will implement all Product Development (PD) programming standards and conventions, including the following:

- 3.1 CCR Enhancements shall be developed in compliance with VA requirements for Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d). Section 508 requirements are listed on the VA Section 508 Office website at [REDACTED]
- 3.2 CCR Enhancements shall be developed in compliance with VA Directive 6500, Information Security Program. VA Directive 6500 may be found in its entirety at: [REDACTED]
- 3.3 CCR Enhancements shall be developed in compliance with the Office of Management and Budget (OMB) Circular A-130, Appendix III, Security of Federal Automated Information Resources. Circular A-130 may be found in its entirety at: [REDACTED]
- 3.4 CCR Enhancements shall be developed in compliance with VA Handbook 6500.3, Certification and Accreditation of VA Information Systems. VA Handbook 6500.3 may be found in its entirety at: [REDACTED]

### **4. Interfaces**

ROR\*1.5\*26 introduces no new or additional interfaces, including communications interfaces, hardware interfaces, software interfaces and user interfaces.

#### **4.1. Communications Interfaces**

ROR\*1.5\*26 introduces no new or additional communications interfaces.

#### **4.2. Hardware Interfaces**

ROR\*1.5\*26 introduces no new or additional hardware interfaces.

### **4.3. Software Interfaces**

ROR\*1.5\*26 introduces no new or additional software interfaces.

### **4.4. User Interfaces**

ROR\*1.5\*26 introduces no new or additional user interfaces.

## **5. Legal, Copyright, and Other Notices**

ROR\*1.5\*26 introduces no new or additional legal, copyright, or other notices.

## **6. Purchased Components**

ROR\*1.5\*26 introduces no new or additional purchased components.

### **6.1. Defect Source (TOP 5)**

The Defect Source (TOP 5) is described in the Defect/Fix Status Report.

## **7. User Class Characteristics**

ROR\*1.5\*26 introduces no new or additional user class characteristics.

## **8. Estimation**

The Function Point Estimation approach for these CCR enhancements will not be used for Patch <TBD>, but overall project estimation is described in the Integrated Master Schedule (IMS) and the Performance Work Statement (PWS) for MSSR & Registry Enhancements.

## 9. Approval Signatures

REVIEW DATE: <PMO, please enter the last approval date here>

SCRIBE: PMO Support for CCR Enhancements


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 , Business Sponsor	Date
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 , IT Program Manager	Date
--	------

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 , Project Manager	Date
Contracting Officer Representative	