

Department of Veterans Affairs

Multiple Sclerosis Surveillance Registry (MSSR) (Increment 2)

Requirements Specification Document



**May 2014
Version 2.0**

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
05/14/2014	2.0	<ul style="list-style-type: none"> Updated for Increment 2 	[REDACTED]
12/13/2013	1.1	<ul style="list-style-type: none"> Organized and finalized requirements. Added unique RRC artifact ID numbers to each requirement. 	[REDACTED]
12/10/2013	1.0	<ul style="list-style-type: none"> Removed comments and accepted approved changes only. 	[REDACTED]
11/26/2013	0.4	<ul style="list-style-type: none"> Corrected version numbering to reflect draft versioning. Updated section 2.2 Business Rules based on PWS and BRD business requirements. Updated section 2.3 Design Constraints to include more design constraints. Updated section 2.4 to reflect no applicable Disaster Recovery requirements. Per Stakeholders and PMO, updated section 2.5 with a list of the applicable CLIN deliverables. Updated sections 2.6.1.1-2.6.1.4, 2.13 per Stakeholders input. 	[REDACTED]
11/25/2013	0.3	Business Stakeholder input	[REDACTED]
11/8/2013	0.2	Re-formatted to current VA PMAS/ProPath template.	[REDACTED]
10/31/2013	0.1	Initial Baseline Draft submitted for CLIN 0002AA acceptance	[REDACTED]

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

In response to Congressional legislation, the VHA established two Multiple Sclerosis Centers of Excellence (MSCoE) in 2003. These Centers (East and West) were subsequently made permanent by “The Veteran’s Benefits, Healthcare and Information Technology Act of 2006”. The MSCoEs were mandated to report on the epidemiology, healthcare use, and costs of the Veteran Multiple Sclerosis (MS) population. Current tools to date have failed to fulfill this mandate that is critical to all MSCoE functions. A VHA Handbook entitled Multiple Sclerosis System of Care Procedures 1011.06, was released to the field on December 7, 2009. This approved Handbook (which includes reference to the Congressional Mandate for the MSCoE) established policy and procedure for healthcare services for patients with MS and requires ongoing surveillance of this patient population.

The goal of this procurement is to create a surveillance system for the entire MS patient population within VHA. This objective will be met through the collection of clinical utilization, demographic, and epidemiologic data. The scope entails the creation of a front end portal within the Computerized Patient Record System (CPRS) for the entry of data by clinicians, as well as a back end data storage capability. The portal tool will be triggered annually for any patient with an MS diagnosis and will provide a user interface for data entry into the database. The tool will prompt providers to enter standard demographic and clinical variables important for clinical, quality improvement, and research activities mandated by VHA (which can be found in Appendix C of the VHA Handbook, Multiple Sclerosis System of Care Procedures 1011.06). Data shall be stored centrally at the enterprise level.

VA also requires development of a new registry system leveraging VA’s existing Converged Registries Solution (CRS) to provide clinical data surveillance tools and a back end registry database for surveillance of the entire MS population within VHA, along with software enhancements to the following existing systems: Converged Registries Solution, Traumatic Brain Injury Registry, Oncology Registry, and Clinical Case Registry. Both MSCoE (East and West) require real-time access to this data, so to provide up-to-date surveillance data on the MS patient population. Relevant clinical and administrative data from other VHA databases, such as VistA, (made available to the MS Registry) shall be aggregated and reported as required to allow for systematic evaluation and analysis. This effort is intended to provide VHA with a population- focused perspective for the MS patient population.

1.1. Purpose

The purpose of this Requirements Specification Document (RSD) is to present decomposed requirements from the Multiple Sclerosis Surveillance Registry (MSSR) Business Requirements Document (BRD) and requirements gathering sessions for MSSR development. The decomposed requirements consist of the functional, non-functional, and technical specifications described in [Section 2](#) Overall Description.

This RSD enlists all necessary requirements that are required for registry development of Increment 2. To derive the requirements, we need to have a clear and thorough understanding of the products to be developed, which is determined after detailed communications with key stakeholders from the Multiple Sclerosis Center of Excellence (MSCoE) and the Northwest Innovation Center.

This document is directed at a broad audience of stakeholders, external and internal to the project team. These stakeholders include, but are not limited to, the Multiple Sclerosis Center of Excellence (MSCoE) and Northwest Innovation Center, Business Owners, Project Managers, and the Project Team (see Table 1 below).

Table 1. Internal and External Stakeholders for MSSR Increment 2

Stakeholder	Purpose
Multiple Sclerosis Center of Excellence (MSCoE) and Northwest Innovation Center	Key stakeholders who provide guidance relative to the development of the MSSR.
Business Owners	Provide oversight for and business knowledge to the project team.
Project Managers	Oversee the management and direction of the TBI Registry Enhancements quality, schedule, and cost.
Project Team	Provide analysis, design, development, testing, configuration management, system integration, and deployment of the new registry.

1.2. Scope

The MS Registry will provide the Program Office with the ability to create new policies, programs, and plans and support the needs of the Department of Veterans Affairs (VA) MS population. The mission of the MSCoEs is to support and maintain the health, independence, quality of life, and productivity of Veterans with MS through clinical care, education, and research. The MS Regional Programs are responsible for ensuring the MS patients in their region are evaluated at least annually either at MS support programs (spoke facilities) or at the Regional Center site. This request directly supports the mission of the MSCoEs as well as meeting the intent of the legislation: ‘Veterans Benefits, Healthcare, and Information Technology Act of 2006’. S.3421, Title II, Sec 209, ‘(G).

The goal of this effort is to create a surveillance system for the entire MS patient population within VHA. This objective will be met through the collection of clinical utilization, demographic, and epidemiologic data.

The scope of this RSD is specific to the MSSR development project, and involves the creation of a front end portal within the Computerized Patient Record System (CPRS) for the entry of data by clinicians, as well as a back end data storage capability. The portal tool will be triggered annually for any patient with an MS diagnosis. This portal tool will provide a user interface for data entry into the database. The tool will prompt providers to enter standard demographic and clinical variables important for clinical, quality improvement, and research activities mandated by VHA, which can be found in Appendix C of the VHA Handbook, MULTIPLE SCLEROSIS SYSTEM OF CARE PROCEDURES 1011.06.

1.3. References

- 1.3.1. Multiple Sclerosis Surveillance Business Requirements Document (BRD), Work Effort Unique Identifying Number 20100105; March 2010, Attachment 001
[REDACTED]
- 1.3.2. Task Order No. TAC-13-09129, *Multiple Sclerosis Surveillance Registry and Registries Enhancements Performance Work Statement (PWS)*, August 28, 2013, Contract No. VA118-11-D-1003, Order No. VA118-1003-0052, which may be found in its entirety at:
[REDACTED]

- 1.3.3. VHA Handbook 1011.06, *Multiple Sclerosis System Of Care Procedures*, December 7, 2009, which can be found in its entirety at: [REDACTED]
- 1.3.4. VA Directive 6500, *Information Security Program*, located at: [REDACTED]
- 1.3.5. VA Handbook 6500.3, *Certification and Accreditation of VA Information Systems*, located at: [REDACTED]
- 1.3.6. VA Handbook 6500.6, *VA Information And Information System Security/Privacy Language*, Appendix C, March 12, 2010, Attachment 002, which can be found in its entirety at: [REDACTED]
- 1.3.7. *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]
- 1.3.8. Office of Management and Budget (OMB) Circular A-130, *Appendix III, Security of Federal Automated Information Resources*, located at: [REDACTED]

2. Overall Description

Data would be stored centrally at the enterprise level. MSCoE business owners require real-time access to these data. The MSCoE data store will provide up-to-date surveillance data for the MS patient population. Relevant clinical and administrative data from other VHA databases, such as VistA, would also be made available to the MS Registry. Data will be aggregated and reported as required to allow for systematic evaluation and analysis. This effort is not intended to replicate individual patient records, but to provide VHA with a population-focused perspective for the MS patient population.

The new MS Surveillance Registry shall be developed by leveraging VA's existing Converged Registries Solution (CRS) to provide clinical data surveillance tools and back end registry database for surveillance of the entire MS population within VHA. In accordance with the Multiple Sclerosis Surveillance BRD, the MS Surveillance Registry shall include a front end portal within the Computerized Patient Record System (CPRS) that supports entry of data by Providers, as well as a back end data storage capability.

2.1. Accessibility Specifications

The MSSR 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

Per the MSSR Performance Work Statement (PWS) and Business Requirements Document (BRD), the business rules for Increment 2 are described as follows:

Business Need 2: Provide tools and utilities to retrieve, extract, analyze, and report data from the MS Registry

- Tools will be provided to retrieve, analyze, and display data within a user interface.
- The reporting tools will provide capability to generate standard and ad hoc individual and aggregated reports.

Business Need 3: The MS system must be able to display data from VistA.

- The MS Registry must be able to display clinical and administrative data.
- The MS Registry will have storage capacity from other relevant VHA data sources.

2.3. Design Constraints Specification

The design constraints for this development effort are as follows:

- Enterprise IT architecture, infrastructure, and resources
- 508 compliance restrictions
- SQL Server 2008R2 (v10.5) for back end development
- Visual Studio 2008 for RTC compatibility and 2010 for code development
- .Net programming language and framework for front end development
- Any other design constraints directly or indirectly imposed by the following:
 - Existing or enhanced Converged Registries Solution (CRS) architectural framework
 - Future bug fixes or defects resolved by the Registries Support team
 - Austin Information Technology Center (AITC), due to capacity or access limitations

2.4. Disaster Recovery Specification

The MSSR shall follow the disaster recovery specifications, as defined in the Converged Registries Solution (CRS) architectural framework.

2.5. Documentation Specifications

Per the VA PMAS/ProPath methodology, the documentation specifications are as follows:

- Contractor Project Management Plan (CPMP) (CLIN 0001AA), which includes the Communication Plan (CLIN 0001AD), Risk Management Plan (CLIN 0001AK), and Configuration Management Plan (CLIN 0002AF) – Per the Project Management Body of Knowledge (PMBOK), the CPMP or PMP is "a formal, approved document used to guide both project execution and project control. The primary uses of the project plan are to document planning assumptions and decisions, facilitate communication among stakeholders, and document approved scope, cost, and schedule baselines. A project plan may be summarized or detailed.
- Project Risk Registry (CLIN 0001AL) – a Risk Management tool commonly used in Project Management and organizational risk assessments. It acts as a central repository for all risks identified by the project or organization and, for each risk, includes information such as risk probability, impact, counter-measures, risk owner and so on. It can sometimes be referred to as a Risk Log.

- Integrated Master Schedule (IMS) (CLIN 0001AJ) – a Program Management tool that provides assistance in the planning and scheduling of work efforts and accomplishments necessary to complete the work and tie each accomplishment to a key program event. It is time-based to produce a networked and multi-layered schedule showing all detailed tasks required to accomplish the work effort contained in the CPMP.
- Requirements Specification Document (RSD) (CLIN 0002AA) – a complete description of the behavior of the system to be developed, and may include a set of use cases that describe interactions the users will have with the software. In addition, it contains the business requirements and technical requirements (functional and non-functional), and enlists all necessary requirements that are required for successful project development. Requirements are derived and prepared, after detailed communications with the business stakeholder and project team.
- Requirements Traceability Matrix (RTM) (CLIN 0002AB) – a document, usually in the form of a table, that correlates any two baselined documents that require a many-to-many relationship to determine the completeness of the relationship. It aligns the business requirements, technical requirements (functional and non-functional) with the correlating test cases. It will be generated in using Rational Team Concert (RTM).
- Software/System Design Document (SDD) (CLIN 0002AC) - a written description of a system to provide overall architectural guidance. An SDD usually accompanies an architecture diagram with pointers to detailed feature specifications of smaller pieces of the design.
- Interface Control Document (ICD) (CLIN 0002AD) - describes the interface or interfaces between subsystems or to a system or subsystem.
- Operations Acceptance Plan (OAP) (CLIN 0002AE) – a plan used to conduct operational readiness (pre-release) of a system as part of a quality management system. The plan focuses on the operational readiness of the system to be supported, or which is to become the production environment.
- MSSR Release Package (CLIN 0002AG) – per the Austin Information Technology Center (AITC), a software release package includes the software code, a detailed Installation Guide, detailed and tested Back-Out Plan, Installation files and/or scripts staged in an agreed to location, updated and current requirements and design documentation (e.g., RSD and SDD).
- Test Readiness Review (TRR) Package (CLIN 0002AM) - a review of the plan and procedures status, procedure deviations, known problems, requirements and performance metrics, test schedule, and other information relevant to beginning of testing phase
- Master Test Plan (MTP) (CLIN 0002AN) - a document detailing a systematic approach to testing the system. It documents items to be tested, test strategy, test criteria, test deliverables, test schedule, test environments and locations, test data, staffing needs, risks and constraints, and test metrics .
- Software Code (CLIN 0002BT) –a single, comprehensive “product” which shall include the final tested code, free of all application defects, and a final comprehensive set of documentation that addresses all application capabilities
- Defect Resolution Plan (CLIN 0002BY) – a plan detailing how defects are prioritized, scheduled, fixed, and reported. It also includes a timeline for resolution and impacts to both the Software Code and documentation.
- Defect/Fix Status Report (CLIN 0002BZ) – a report detailing the status of any defects found and fixed

- Implementation and Operations Plan (CLIN 0002CC) – a plan that defines: all technical and physical requirements for hosting, housing, operating and maintaining the Registry hardware and software, all requirements associated with initial installation/implementation, any security processes and procedures to ensure compliance with security requirements defined herein, and maintenance and upgrade timelines.
- Knowledge Transfer Materials (CLIN 0002CD) – material and a 4-hour knowledge transfer virtual session to familiarize the project team with the Registry’s functional and technical features, and maintenance considerations so to minimize VA missteps in the management, administration and operational support of the MS Surveillance Registry and all Registry enhancements.

2.6. Functional Specifications

The functional specifications for MSSR in Increment 2 are as follows:

NOTE: Detailed technical requirements may be found in the MSSR Scratchpad.

- 2.6.1. The MSSR shall provide the ability to retrieve, extract, analyze, and report clinical and administrative data as a web registry application within the Converged Registries Solution (CRS) architectural framework.
- 2.6.2. The MSSR shall provide a user-friendly and seamless user interface to retrieve, analyze, and display clinical and administrative data that is within the confines of the Converged Registries Solution (CRS) UI guidelines.
- 2.6.3. The MSSR shall provide standard reports for the end user and ad hoc reporting capability via cube reporting.
- 2.6.4. The MSSR shall include appropriate extract, transform, and load (ETL) scripting, so as to ensure data interfaces with CDW.
- 2.6.5. The MSAT shall provide the end user the ability to enter MS assessments via the web registry application within the Converged Registries Solution (CRS) architectural framework
- 2.6.6. The MSAT shall utilize appropriate middleware for secure web messaging, so as to ensure health factors and progress notes are transferred to VistA.
- 2.6.7. Within the Converged Registries Solution (CRS) relational database framework, the MSSR shall have storage capacity for the health factors and progress notes that are collected through MSAT.

2.7. Graphical User Interface (GUI) Specifications

The MSSR in Increment 2 shall adhere to any and all applicable graphical user interface (GUI) specifications, as defined by the Converged Registries Solution (CRS) architectural framework.

2.8. Multi-divisional Specifications

The multi-divisional specifications for MSSR in Increment 2 shall comply with the Converged Registries Solution (CRS) Requirements Specification Document (RSD).

2.9. Performance Specifications

The MSSR does not include specific performance specifications for Increment 2, outside of those specified in the Converged Registries Solution (CRS) Requirements Specification Document (RSD).

2.10. Quality Attributes Specification

The quality attributes for the MSSR in Increment 2 shall comply with the MSSR Master Test Plan (MTP).

2.11. Reliability Specifications

The reliability specifications for the MSSR in Increment 2 shall comply with the MSSR Performance Work Statement (PWS).

2.12. Scope Integration

The scope integration for MSSR in Increment 2 shall comply with the MSSR Software Design Document (SDD) and the MSSR Interface Control Document (ICD).

2.13. Security Specifications

The MSSR in Increment 2 shall conform to applicable Enterprise Security requirements and Certification and Accreditation (C&A) requirements, including but not limited to, user authentication through MS Active Directory services, Health Insurance Portability Accountability Act (HIPAA), Privacy Act of 1974, VA Information Security standards, and Protected Health Information (PHI). In conformance with the Converged Registries Solution (CRS) framework, the security specifications for MSSR in Increment 2 shall provide three layers of access as follows:

- **Enterprise Access:** To be granted to users requiring reports and information on an enterprise level. Enterprise access will also include access to VISN level and Local level functionalities.
- **VISN Access:** To be granted to users requiring reports and information on a VISN specific level. The access will be restricted to reports and information from that user's assigned VISN. VISN level access will also include Local level functionality for sites within the VISN.
- **Local Level:** To be granted to users requiring reports and information on a Local level. Users with Local Access will be restricted to reports and information for their assigned location. Local users will not have access to VISN or Enterprise reports or information. Local level will be the most restrictive level of access.

2.14. System Features

The system features for MSSR in Increment 2 shall include the new features as specified in section 2.6 Functional Specifications.

2.15. Usability Specifications

The MSSR does not include specific performance specifications for Increment 2, outside of those specified in the Converged Registries Solution (CRS) Requirements Specification Document (RSD).

3. Applicable Standards

The applicable standards for MSSR in Increment 2 are as follows:

- VHA Handbook 1011.06, *Multiple Sclerosis System Of Care Procedures*, December 7, 2009, which can be found in its entirety at: [REDACTED]
- VA Directive 6500, *Information Security Program*, located at: [REDACTED]
- VA Handbook 6500.3, *Certification and Accreditation of VA Information Systems*, located at: [REDACTED].
- VA Handbook 6500.6, *VA Information And Information System Security/Privacy Language*, Appendix C, March 12, 2010, Attachment 002, which can be found in its entirety at: [REDACTED]
- *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]
- Office of Management and Budget (OMB) Circular A-130, *Appendix III, Security of Federal Automated Information Resources*, located [REDACTED]

4. Interfaces

4.1. Communications Interfaces

The MSSR in Increment 2 has no communication interfaces identified for this RSD.

4.2. Hardware Interfaces

The MSSR in Increment 2 has no hardware interfaces identified for this RSD.

4.3. Software Interfaces

The MSSR software interfaces for Increment 2 shall include the following:

- Interface with relevant existing VHA clinical & administrative databases, for clinical and demographic information.

- **Converged Registries Solution (CRS):** provides a common registries platform/architecture and back end relational database framework, along with common tools for retrieving, analyzing, and reporting registry data.
- **CPRS/VistA:** identification of patient with MS diagnosis from the CPRS Problem List, VistA (such as Patient Treatment File – PTF and Patient Care Encounter File – PCE).
- **Medical Domain Web Services (MDWS):** writes “notes” to VistA

4.4. User Interfaces

The user interfaces for MSSR Increment 2 shall consist of the Multiple Sclerosis Assessment Tool (MSAT) developed as a web component of the new Multiple Sclerosis Surveillance Registry (MSSR) web application within the confines of the Converged Registries Solution (CRS) relational database framework and architectural platform.

5. Legal, Copyright, and Other Notices

The legal, copyright, and other notices for MSSR in Increment 2 shall comply with the MSSR Performance Work Statement (PWS).

6. Purchased Components

The MSSR for Increment 2 requires no purchased components.

6.1. Defect Source (TOP 5)

The defect source (top 5) for MSSR in Increment 2 is described in the MSSR Defect/Fix Status Report.

7. User Class Characteristics

The intended users of MSSR in Increment 2 are described in Table 2 below.

Table 2. Intended User General Characteristics

Intended User(s)	System Proficiency	Background / Experience	Technical Support / Maint Expertise	Access Privileges
MSCoE Directors	High	High	Low	Full
NW Innovation Center	High	High	Low	Full
Clinicians	Varies	Varies	Low	Varies
MSSR Administrators	High	High	High	Full

8. Estimation

The estimation for MSSR in Increment 2 is described in the MSSR Integrated Master Schedule (IMS).

9. Approval Signatures

REVIEW DATE: June 6, 2014

SCRIBE: PMO Support Services

Signed:

_____, Business Sponsor Date

_____, Business Sponsor Date

_____, IT Program Manager/IPT Chair (VA) Date

_____, Project Manager (VA) Date

_____, 05/14/2014
_____, Program Manager (7Delta) Date

_____, 05/14/2014
_____, Project Manager (7Delta) Date