**Lab Enhancements - Autoverification, Microbiology Enhancements & Anatomic Pathology (AP) Order Dialogs**

**Microbiology Enhancements**

**System Design Document**



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**Revision History**

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**Artifact Rationale**

The System Design Document (SDD) is a dual-use document that provides the conceptual design as well as the as-built design. This document will be updated as the product is built, to reflect

the as-built product.

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**1. Introduction**

The purpose of this System Design Document (SDD) is to convey the overall design required to support the Veterans Health Information Systems Technology Architecture (VistA) Evolution (VE) Pathology and Laboratory Enhancements for Microbiology. The Microbiology enhancements include the following:

• Carbapenem Resistant Enterobacteriaceae (CRE) Naming Conventions

• Electronic Interfacing of Automated Identification and Susceptibility Testing Instruments

• Tracking Multi-Drug Resistant Organisms – NSR #20140801

**1.1. Scope**

The scope of this effort includes three primary enhancements covering the standardization of Naming Conventions, Instrument Interfacing, and Tracking Multi-Drug Resistant Organisms (MDRO).

**1. Carbapenem Resistant Enterobacteriaceae (CRE) Naming 1.2.1.Conventions - NSR**

**#20131213**

The scope for this request includes the necessary microbiology enhancements to allow Department of Veterans Affairs (VA) labs the ability to document and utilize standard data in VistA/Computerized Patient Record System (CPRS) for CRE and other MDROs. In addition, it includes the ability to nationally distribute these microbiology enhancements and other MDRO standardized reporting etiologies without requiring each individual lab to update its own local files manually.

**2. Electronic Interfacing of Automated Identification and Susceptibility 1.2.2.Testing**

**Instruments - NSR #20131213**

The scope for this request includes the ability to electronically transfer organism identification and drug susceptibility testing results (generated by an automated instrument) to VistA. The primary need is for VistA fields/databases to be built so that middleware can transfer the results from those systems into VistA.

**3. Tracking Multi-Drug Resistant Organisms - NSR #20140801 1.2.3.**

The scope of NSR #20140801 (Tracking Drug-Resistant Organisms) includes requests and other enhancements covered by one other NSR (#20140804 Clostridium difficile Program Tools). The scope encompasses the need for the following: Timely Identification; Automated Data Collection; and Enhanced Reporting.

Please refer to the VE Microbiology Business Requirements Document is located at:

**1.2. User Profiles**

The core intended user base of the Microbiology enhancement includes doctors, nurses, laboratory staff, medical facility leadership, and health department partners.

The user community of doctors, nurses, laboratory staff, medical facility leadership, and health department partners are highly proficient in clinical laboratory medicine procedures, particularly Microbiology and MDRO Management, and are also highly proficient in the use of CPRS and legacy VistA Laboratory. The user group staffs the majority of the VA’s 300 labs 24 hours a day, 7 days a week.

The technical community of the CPRS project team, VistA Lab business and technical teams, VistA Laboratory Electronic Data Interchange (LEDI) project team Microbiology, and the Laboratory System Re-Engineering Project (LSRP) team all have a broad depth of knowledge and expertise in the support and maintenance required of this solution.

**2. Background**

**2.1. Overview of the System**

The VistA Evolution (VE) Pathology and Laboratory Enhancements for Microbiology will provide enhancements that establish CRE Naming Conventions, allow for Electronic Interfacing of Automated Identification and Susceptibility Testing Instruments, and allow for the Tracking Multi-Drug Resistant Organisms (NSR #20140801).

Overall the Microbiology enhancements will provide an expanded ability to track multi drug- resistant (MDR), difficult to treat, and clinically significant microorganisms (e.g., C. difficile) and utilize an automated data extraction tool to collect information on MDR, difficult to treat,

and clinically significant microorganisms (e.g. MDR-MRSA, C. difficile). This functionality will also enable expanded capabilities for national reporting of drug-resistant organisms.

This work effort includes the development of bi-directional interfacing for microbiology automated instrumentation used in VA laboratory facilities. The current environment for performing microbial organism identification and antibiotic susceptibility testing using automated instruments is not standard across VA’s microbiology laboratories. The current lack of this capability within VISTA/CPRS is a patient safety issue for VA patients and additional effort is required by VA resources.

Adopting and implementing standard interfacing between automated microbiology instruments and VistA will improve efficiency and enhance patient safety for those laboratories lacking such interfaces today. It will also enhance the process for sites with local interfaces by lowering total cost of ownership from a nationally-supported standard and ensuring results are captured in ways that can support overall interoperability.

**2.2. Overview of the Business Process**

The new business process will allow for the following enhancements to the Microbiology package:

1. Carbapenem Resistant Enterobacteriaceae (CRE) Naming Conventions

2. Electronic Interfacing of Automated Identification and Susceptibility Testing Instruments

3. Tracking Multi-Drug Resistant Organisms – NSR #20140801

**2.3. Overview of the Significant Requirements**

All significant requirements have been outlined in detail within the RSD and BRD

documentation. Please refer to the BRD and RSD at:

**3. Conceptual Design**

Untreatable and hard-to-treat infections from CRE are on the rise among patients in US medical facilities. These bacteria are resistant to all or nearly all the antibiotics available to clinicians today. The mortality from these infections can be as high as 50%.

Currently, the incidence and prevalence of CRE in Veterans Health Administration (VHA)

facilities is unknown which is the main driving force behind this effort.

Microbiology enhancements are required to enable VA labs to document and utilize standard data in VistA/Computerized Patient Record System (CPRS) for Carbapenem Resistant Enterobacteriaceae (CRE) and other Multidrug-Resistant Organisms (MDRO) and to nationally distribute these and other MDRO standardized reporting etiologies without requiring each individual lab to update its own local files manually.

The following enhancements will be made to the Microbiology portion of the Laboratory package:

• Carbapenem Resistant Enterobacteriaceae (CRE) Naming Conventions

• Electronic Interfacing of Automated Identification and Susceptibility Testing Instruments

• Tracking Multi-Drug Resistant Organisms – NSR #20140801

**3.1. Conceptual Application Design**

This work effort includes the development of bi-directional interfacing for microbiology automated instrumentation used in VA laboratory facilities. The current environment for performing microbial organism identification and antibiotic susceptibility testing using

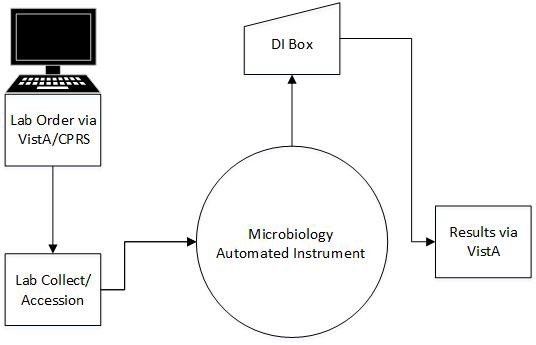
automated instruments is not standard across VA’s microbiology laboratories. Most sites have no ability to interface with such instruments, requiring manually inputting test information, retrieving printouts, and manually entering results into VistA. Private-sector Laboratory Information Systems (LIS) almost universally provide support for microbiology interfacing.

Some VA microbiology laboratories do have locally-developed (i.e., Class III) interfaces in place, typically through some type of middleware to go between VistA and the instruments. Those interfaces are inefficient in terms of having multiple local resources providing varying degrees of support. They have also proven difficult to be widely implemented. Locally- developed interfaces can introduce variation in how the test results are captured and annotated in VistA, particularly when interfacing with different instrument/middleware products. Such variation could impede the interoperability of the result information within VA and with health care partners.

The system shall provide an electronic interface between automated Microbiology Instrumentation and the VistA Laboratory application. This will be done by the IRM after the patch has been installed. Instructions will be provided.

**3.1.1. Application Context**

The figure below illustrates the connection between the instrument and DI box and then from the DI box to VistA. This is in accordance with the requirement to electronically transfer organism identification and drug susceptibility testing results, generated by an automated instrument, to VistA. The connection cannot be done programmatically and the recommendation is to include the instructions for setting this up in the patch description.



**Figure 1: Application Context Diagram**

**3.1.2. High-Level Application Design**

Table 2 below provides a breakdown of the objects in the high level application design.

**Table 1: Objects / Components to be Built or Modified**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ID** | **Name** | **Description** | **Interface**  **Name** | **Interface**  **System** |
| Enhanced  reporting | Lab Data  file, (#63) | Expanded reporting and report data  functionality of the Methicillin- Resistant Staphylococcus aureus Program Tools (MRSA-PT). |  | M code |

Table 2 provides a breakdown of the internal data stores.

**Table 2: Internal Data Stores**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ID** | **Name** | **Data Stored** | **Steward** | **Access** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ID** | **Name** | **Data Stored** | **Steward** | **Access** |
| Results storage | Lab  Data file,  (#63) | File that holds the microbiology results sent  from the auto instrument. |  | M code/FileMan |

**3.1.3. Application Locations**

There are no application location changes identified at this time.

**3.2. Conceptual Data Design**

**3.2.1. Project Conceptual Data Model**

No changes to the Conceptual Data Model are anticipated as a part of this project.

**3.2.2. Database Information**

Table 3 provides an overview of the database inventory.

**Table 3: Database Inventory**

|  |  |  |  |
| --- | --- | --- | --- |
| **Database Name** | **Description** | **Type** | **Steward** |
| Vista Laboratory | Legacy Laboratory  Module used for performing and reporting laboratory tests/results | Modify | Microbiology and  laboratory services |

**3.2.3. User Interface Data Mapping**

This section describes and defines the format and information that will be available for users of the product to be able to enter data into the database or to retrieve information from the database if applicable.

**3.2.3.1. Application Screen Interface**

No changes are anticipated to the application screen interface.

**3.2.3.2. Application Report Interface**

The Veterans Health Administration (VHA) Patient Care Services (PCS), Pathology & Laboratory Medicine (P&LMS) National Program Office and the National Infectious Diseases Service (NIDS) support enhancing functionality of the Methicillin-Resistant Staphylococcus Aureus (MRSA) Program Tools (MRSA-PT) to be renamed MDRO program tools which will include Clostridium Difficile (C. difficile) and other pathogens to be identified. The following reports will be renamed to MDRO and will be slightly modified.

**3.2.3.2.1. Print Isolation Report**

Select MRSA Tools Reports Menu Option: 2 Print Isolation Report

Do you want to select all locations? NO// YES

This report is designed for a 176 column format (landscape).

DEVICE: HOME// SSH VIRTUAL TERMINAL Right Margin: 80// CENSUS LIST AND MDRO HISTORY

Geographical Location: 202

Report printed on: Sep 22, 2015@14:36:58 PAGE: 1

LAST MRSA POS LAST CRB-R POS LAST ESBL POS LAST VRE POS

LAST CDF POS

PATIENT SSN IN 365 DAYS IN 365 DAYS IN 365 DAYS IN 365 DAYS

IN 365 DAYS

-----------------------------------------------------------

**Figure 2: Print Isolation Report**

**3.2.3.2.2. Print Nares Screen Compliance List**

Print Nares Screen Compliance List

Do you want to select all locations? NO// YES

This report is designed for a 132 column format (compressed).

DEVICE: HOME// SSH VIRTUAL TERMINAL Right Margin: 80// NARES SWAB ORDER LIST

Geographical Location: 202

Report printed on: Sep 22, 2015@14:39:15 PAGE: 1

DATE MRSA IN NARES LAB

PATIENT SSN ENTERED WARD ADT PAST YEAR ORDERED ORDER DATE

**Figure 3: Print Nares Screen Compliance List**

**3.2.3.2.3. MDRO Inpatient Evaluation Center (IPEC) Admission Report**

Select MRSA Tools Reports Menu Option: 1 Print MRSA IPEC Report

Select one of the following: A Admission Report

D Discharge/Transmission Report

Run (A)dmission Or (D)ischarge/Transmission Report: Admission Report

Begin with ward admission date: T-100 (JUN 14, 2015) End with ward admission date: T (SEP 22, 2015)

Do you want to select all locations? NO// Select Geographical Location:

**Figure 4: MDRO IPEC Admission Report**

**3.2.3.2.4. MDRO IPEC Discharge/Transmission Report**

Select MRSA Tools Reports Menu Option: 1 Print MRSA IPEC Report

Select one of the following: A Admission Report

D Discharge/Transmission Report

Run (A)dmission Or (D)ischarge/Transmission Report: d Discharge/Transmission Re port

Begin with ward discharge date: T-100 (JUN 14, 2015) End with ward discharge date: T (SEP 22, 2015)

Do you want to select all locations? NO// Select Geographical Location:

**Figure 5: MDRO IPEC Discharge/Transmission Report**

**3.2.3.2.5. Patients Transferred to a Particular Ward**

CHOOSE 1-5: 3 ZZMRSA MAS MENU MRSA Mas Menu

IMM PCE Immunization Tracking Menu ...

ISO Print the wristband ISOLATION ward listing

PAW Patients Admitted to Ward

PTF Inquire PTF Record

PTW Patients Transferred to a Particular Ward

ZZM Clinic Max # of Days in Future

You've got PRIORITY mail!

Select MRSA Mas Menu Option: PTW Patients Transferred to a Particular Ward

\* Previous selection: WARD LOCATION equals PRRTP START WITH WARD LOCATION: PRRTP//

GO TO WARD LOCATION: PRRTP//

\* Previous selection: DATE/TIME from Jan 1,2015 to Jul 15,2015@24:00

START WITH DATE/TIME: Jan 1,2015// (JAN 01, 2015) GO TO DATE/TIME: Jul 15,2015// (JUL 15, 2015)

DEVICE:

**Figure 6: Patient Transferred to a Particular Ward Report**

**3.2.3.2.6. Generic Report Description**

Table 4 provides a description of the Generic Report and the linkage to each data source.

**Table 4: Generic Report Description**

|  |  |
| --- | --- |
| **Report Column** | **Data Source** |
| Demographic Data | 200 - several fields |
| Date/Time Specimen  Taken | 63.05-.01 |
| Date/Time Report  Completed | 63.05-.03 |
| Site/Specimen | 63.05-.05 |
| Micro Accession | 63.05-.06 |
| Requesting Physician | 63.05-.07 |
| Ward | 63.05-.08 |
| Amended Report | 63.05-.09 |
| Preliminary Bact Report  Status | 63.05-11.5 |
| Organism | 63.05-12 --> ISOLATE 63.3-.01 --> ORGANISM 61.2-.01 (CRE or  MDRO) |
| SNOMED Code | 61.2 -.02 |

|  |  |
| --- | --- |
| **Report Column** | **Data Source** |
| Patient 405 .03 | 405-.03 |
| Date/Time 405 .01 | 405-.01 |
| Transaction 405. .02 | 405-.02 |
| Ward Location 405 .06 | 405-.06 |

**3.2.3.3. Unmapped Data Element**

There are no Unmapped Data Elements identified at this time.

**3.3. Conceptual Infrastructure Design**

**3.3.1. System Criticality and High Availability**

This VHA project will inherit the Disaster Recovery procedures of the VA hosting environment supporting the application. The Laboratory module is part of VistA and will be covered under the current VistA Disaster Recovery Plan.

**3.3.2. Special Technology**

No special technology has been identified as required for this project.

**3.3.3. Technology Locations**

There is no special technology identified, therefore location identity is not required.

**3.3.4. Conceptual Infrastructure Diagram**

**3.3.4.1. Location of Environments and External Interfaces**

There are no changes to the location of environments and/or external interfaces.

**3.3.4.2. Conceptual Production String Diagram**

There are no Production String additions anticipated for this project.

**4. System Architecture**

This section describes the system and/or subsystem(s) architecture for the project.

**4.1. Hardware Architecture**

There will be no changes to the hardware architecture.

**4.2. Software Architecture**

VistA Legacy Laboratory is a module within the VistA system. It also includes a universal interface that will connect to laboratory instrumentation and/or middleware for the purpose of sending orders to the instruments and receiving results from the instruments. This interface between the instrument and VistA will need new configurations in order to have the ability to recognize and send results found for MDRO or CRE to Vista.

**4.3. Network Architecture**

There will be no changes to the existing VistA network architecture.

**4.4. Service Oriented Architecture / ESS**

This project provides processing changes to the existing VistA Laboratory system. No new services or changes to services are planned. The VistA Laboratory still provides clinical laboratory results to the VA enterprise and consumes requests for laboratory tests (i.e. lab orders).

**4.5. Enterprise Architecture**

The VistA Microbiology capability is an enhancement to the VistA Legacy system and all tools used in development are approved on the VA Technical Reference Model (TRM)/ Standards Profile (SP).

The current TRM/SP is located VA Enterprise Architecture (EA) v2.1 at

**5. Data Design**

No changes are anticipated to the data design for the Micro Enhancement at this time.

**5.1. DBMS Files**

This section describes the proposed Micro Enhancement design.

**5.2. Non-DBMS Files**

There are no Non-DBMS files associated with this project. All file references will be native to the existing VistA (legacy) database.

**5.3. Data View**

There is no change to the Data View with this project. The logical data model of the system will remain the same.

**6. Detailed Design**

This section describes the proposed design in detail.

**6.1. Hardware Detailed Design**

No additional hardware to support the Micro Enhancement is anticipated.

**6.2. Software Detailed Design**

This section provides conceptual and final detailed information associated with the design of the software being delivered.

**6.2.1. Conceptual Design**

This section introduces the conceptual information that establishes the basis for how the software will be built.

**6.2.1.1. Product Perspective**

See Section 3.

**6.2.1.1.1. User Interfaces**

The VistA Legacy Lab application and CPRS will be the viewers for these requirements

**6.2.1.1.2. Hardware Interfaces**

The auto instrument interfaces will interface with VistA via HL7. The main automated Microbiology testing instruments in use at VA labs are: Biomerieux VITEK, VITEK2, VITEK- MS, BD-Phoenix, Brucker Biotyper, and Siemens Microscan.

**6.2.1.1.3. Software Interfaces**

No changes are anticipated to software interfaces at this time for the Micro Enhancement

**6.2.1.1.4. Communications Interfaces**

The interface between VistA and each participating system is established through a persistent or a transient (non-persistent) TCP/IP connection. Two TCP sockets provide bi-directional communications between each participating system. (Reference: LEDI IVHL7 Interface Specification ([http://www.va.gov/vdl/documents/Clinical/Lab-Electr\_Data\_Intrchg\_](http://www.domain/vdl/documents/Clinical/Lab-Electr_Data_Intrchg_) (LEDI)/la\_52\_74\_la\_52\_80\_hl7\_interface\_spec.pdf ))

**6.2.1.1.5. Memory Constraints**

No memory constraints are identified at this time for the Micro enhancement.

**6.2.1.1.6. Special Operations**

No special operations are identified at this time for the Micro enhancement.

**6.2.1.2. Product Features**

See section 3.0

**6.2.1.3. User Characteristics**

LR users will encompass VA healthcare professionals including medical technologists (MT), Laboratory Information Managers (LIM), clinicians, nurses, and clerks.

**6.2.1.4. Dependencies and Constraints**

• Comply with 508 standards

• Comply with VistA Legacy Order Entry/Results Reporting to Laboratory communication schema.

• Use VistA Legacy Laboratory module

**6.2.2. Specific Requirements**

**6.2.2.1. Database Repository**

The Micro Enhancement will leverage the current VistA Laboratory Modules and Order

Entry/Result Reporting Databases.

**6.2.2.2. System Features**

Carbapenem Resistant Enterobacteriaceae (CRE) Naming 1.2.1.Conventions - NSR #20131213

• The system shall provide the ability to identify and report standardized CRE information, enabling the prevention and control of CRE infections within Veterans Health Administration (VHA) medical facilities.

• The system shall provide the ability for Microbiology Staff to report organism names with CRE modifying language to alert the clinician that their patient has a Multidrug Resistant Organism (MDRO) and requires contact isolation.

• The system will present an organism field for the user to identify and track each occurrence of CREs and other MDROs to ensure better care.

• The system shall provide access for clinicians outside the laboratory (Infection Control staff) to view CRE organism information.

• The system shall provide access for designated users, such as a LIM, to create new organism etiology entries that are repeatable, accurate, and easily implemented so that data entry for the related organisms is standardized and organism names appear consistent in all related reports and extracts.

• The system shall allow the ability to aggregate CRE and other MDRO information to provide a national level view to VA Central Office (VACO) leaders of how CRE is affecting the VA.

• The system shall provide access for designated users such as the Director of the National Pathology and Laboratory Service Line, the ability to rapidly deploy new entries to the etiology field file, so that new organism names can be updated nationally in a standardized manner.

• The system shall provide designated users a mechanism to provide approved and standardized organism names so that they can be added to the etiology field file. (This can be similar to the process used for updating the National Drug File.)

Electronic Interfacing of Automated Identification and Susceptibility 1.2.2.Testing Instruments - NSR #20131213

• The system shall provide the ability for organism identification and susceptibility test results to be electronically transmitted to VistA.

• The system shall provide an electronic interface between automated Microbiology

Instrumentation and the VistA Laboratory application.

• The system shall provide an electronic interface to enable the VistA acceptance of Minimum Inhibitory Concentration (MIC) results from automated Microbiology instrumentation.

• The system shall provide an electronic interface to enable the VistA acceptance of Susceptible, Intermediate, Resistant, and Susceptible Dose Dependent (S, I, R, & SDD) results from automated Microbiology instrumentation.

• The system shall provide electronic interface to enable VistA to accept the NTE HL7 segment from automated Microbiology instrumentation.

• The system shall provide the ability to have a bi-directional interface to send and receive the following patient and specimen data to the testing instrument: patient demographics, accession number, collection type/date, specimen type, patient ward/ location and

ordering provider so that microbiology data can be used effectively for patient care, epidemiology, infection control, and antibiotic stewardship purposes.

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• The system shall provide designated users the ability to analyze and track data trends (for statistical analysis) regarding health care associated infections and transmissions

collected at Veterans Health Administration (VHA) facilities so that the user can improve the quality of patient care outcomes, develop policies, and make recommendations for improvement throughout VHA.

• The system shall provide designated users the ability to generate reports (e.g., on a monthly basis and as needed) on MDROs, difficult to treat, or clinically significant microorganisms documented on site to provide accurate data on health care associated infections and transmissions to VHA leadership.

• The system shall provide designated users the ability to generate reports (e.g., on a monthly basis and as needed) on MDROs, difficult to treat, or clinically significant microorganisms documented on site to provide accurate data on health care associated infections and transmissions to VHA leadership.

• The system shall provide designated users, the ability to utilize information on MDROs , difficult to treat, or clinically significant microorganisms (e.g., Methicillin-Resistant Staphylococcus Aureus [MRSA], Clostridium Difficile [C. difficile]) on site, to determine proper steps are taken to ensure diseases are not transmitted to others

• The system shall provide designated users the ability to know when any collected specimen has been released with a positive microorganism result so they can determine next steps for clinical management of a patient.

• A report can be generated that contains information for patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include:

o Patient admission date and time associated with a given specimen collection

• The system shall provide designated users the ability to view the patient's location at the time of specimen collection so that the user can determine whether the specimen was collected while inpatient or outpatient to determine the next step of clinical care (isolation

precautions).

• The system shall provide designated users the ability to view the date and time of a patient's most recent discharge from your inpatient facility, (if within 28 days), prior to the positive specimen collection so that so that the user can determine if the infection or colonization is healthcare associated.

• A report can be generated that contains information for patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include the date and time of the patient’s most recent discharge from a specified inpatient facility. The report must contain only those patients whose discharge date was within 28 days

prior to the collection date of the specimen that tested positive.

• The system shall provide designated users the ability to notify nursing staff of patients with positive C.difficile tests that have also tested positive for NAP1 so that appropriate isolation procedures for the patient are followed ensuring against the spread of infection.

• The system shall provide designated users the ability to notify housekeeping staff of patients with positive C. difficile tests that have also tested positive for NAP1 so that appropriate measures can be taken to eliminate C. difficile spores in the environment.

• The system shall provide designated users the ability to know the date and time of other MDROs, difficult to treat, or clinically significant microorganism specimens collected (e.g., MRSA, Carbapenem Resistant Enterobacteriaceae [CRE] tests) to determine if the infection or colonization is healthcare associated.

• The system shall provide designated users the ability to view (in a report format) information for inpatients to determine if a patient had clinical symptoms at the time of specimen collection (e.g., diarrhea) to know if the hospital onset case is clinically confirmed.

• The system shall provide designated users (assigned at the facility) the ability to configure and modify tools (e.g., MRSA-Program Tools [MRSA-PT]) used for reporting and tracking MDROs, difficult to treat, or clinically significant microorganisms, so the user can ensure data collected is compliant with standard guidelines and necessary updates.

• The system shall provide designated users (assigned at the facility) the ability to verify if the program (tools used for reporting MDROs, difficult to treat, or clinically significant microorganisms) set up correctly so that the users can get in the system and use the setup.

• The system shall provide designated users Tools for MDROs, difficult to treat, or clinically significant microorganism assigned at the facility, the ability to make updates to new or existing locations (facility units) where specimens are collected to ensure accurate data collection or extraction.

• The system shall provide designated users Tools for MDROs, difficult to treat, or clinically significant microorganisms assigned at the facility, the ability to make changes to program tool parameters (e.g., observation status period) to ensure data collection or extraction is compliant with current departmental policies and guidelines.

**6.2.2.3. Design Element Tables**

**6.2.2.3.1. Routines (Entry Points)**

The identification routines related to this project are still under development by the team. Once the analysis is completed this section will be updated.

**Table 5: MMRSISL Routine (Instructions)**

|  |  |
| --- | --- |
| **Routines** | **Instructions** |
| **Routine Name** | MMRSISL |
| **Enhancement**  **Category** | Modify |
| **RTM** | 2.6.3.2 of RSD/ 3.2.3.2.1 of SDD |
| **Related Options** | List options that directly call or are called by the routine. |
| **Related Routines** | List routines that directly call or are called by the routine. |
| **Data Dictionary (DD) References** | 104; 104.2; 104.3;42;44;DPT(“CN”);100 |
| **Related Protocols** | N/A |

|  |  |
| --- | --- |
| **Routines** | **Instructions** |
| **Related Integration Control Registrations (ICRs)** | N/A |
| **Data Passing** | NONE |
| **Input Attribute Name and Definition** | NONE |
| **Output Attribute**  **Name and Definition** | TASKED |
| **Current Logic** | Define the current logic in the routine that the design will modify. If this is  new code, enter “N/A”. |
| **Modified Logic (Changes are in bold)** | Define the logic in the routine that the design will implement. |

**Table 6: MMRSORD Routine (Instructions)**

|  |  |
| --- | --- |
| **Routines** | **Instructions** |
| **Routine Name** | MMRSORD |
| **Enhancement**  **Category** | Modify |
| **RTM** | 2.6.3.2 of RSD/ 3.2.3.2.2 of SDD |
| **Related Options** | List options that directly call or are called by the routine. |
| **Related Routines** | List routines that directly call or are called by the routine. |
| **Data Dictionary (DD) References** | 104; 104.2; 104.3;42;44;DPT(“CN”);100 |
| **Related Protocols** | N/A |
| **Related Integration Control Registrations (ICRs)** | N/A |
| **Data Passing** | NONE |
| **Input Attribute Name and Definition** | NONE |
| **Output Attribute**  **Name and Definition** | TASKED |
| **Current Logic** | Define the current logic in the routine that the design will modify. If this is  new code, enter “N/A”. |
| **Modified Logic (Changes are in bold)** | Define the logic in the routine that the design will implement. |

**Table 7: MMRSIPC Routine (Instructions)**

|  |  |
| --- | --- |
| **Routines** | **Instructions** |
| **Routine Name** | MMRSIPC |
| **Enhancement**  **Category** | Modify |
| **RTM** | 2.6.3.2 of RSD/ 3.2.3.2.3 of SDD |
| **Related Options** | NA |
| **Related Routines** | NA |
| **Data Dictionary (DD) References** | 104; 104.2; 104.3;42;44;DPT(“CN”);100 |
| **Related Protocols** | N/A |
| **Related Integration Control Registrations (ICRs)** | N/A |
| **Data Passing** | NONE |
| **Input Attribute Name and Definition** | NONE |
| **Output Attribute**  **Name and Definition** | TASKED |
| **Current Logic** | Define the current logic in the routine that the design will modify. If this is  new code, enter “N/A”. |
| **Modified Logic (Changes are in bold)** | Define the logic in the routine that the design will implement. |

**Table 8: MMRSISL Routine (Instructions)**

|  |  |
| --- | --- |
| **Routines** | **Instructions** |
| **Routine Name** | MMRSISL |
| **Enhancement**  **Category** | Modify |
| **RTM** | 2.6.3.2 of RSD/ 3.2.3.2.1 of SDD |
| **Related Options** | List options that directly call or are called by the routine. |
| **Related Routines** | List routines that directly call or are called by the routine. |
| **Data Dictionary (DD) References** | 104; 104.2; 104.3;42;44;DPT(“CN”);100 |
| **Related Protocols** | N/A |

|  |  |
| --- | --- |
| **Routines** | **Instructions** |
| **Related Integration Control Registrations (ICRs)** | N/A |
| **Data Passing** | NONE |
| **Input Attribute Name and Definition** | NONE |
| **Output Attribute**  **Name and Definition** | TASKED |
| **Current Logic** | Define the current logic in the routine that the design will modify. If this is  new code, enter “N/A”. |
| **Modified Logic (Changes are in bold)** | Define the logic in the routine that the design will implement. |

**6.2.2.3.2. Templates**

No planned additions or modifications to Templates identified at this time for the Micro enhancement.

**6.2.2.3.3. Bulletins**

No planned additions or modifications to bulletins identified at this time for the Micro enhancement.

**6.2.2.3.4. Data Entries Affected by the Design**

No data entries are expected to be affected by the Micro Enhancement design.

**6.2.2.3.5. Unique Record(s)**

No changes to unique Record IDs identified for the Micro Enhancement.

**6.2.2.3.6. File or Global Size Changes**

No significant change to the global is anticipated with the Micro Enhancement.

**6.2.2.3.7. Mail Groups**

No planned additions or modifications to mail groups identified at this time for the Micro enhancement.

**6.2.2.3.8. Security Keys**

No security keys added or modified to support the Micro Enhancement are anticipated at this time.

**6.2.2.3.9. Options**

The system should provide an option for the IP to review and approve the MDRO data for release for National Reporting and results that are left unapproved or with no action should send an alert or message to all authorized MDRO users (at that facility) that outstanding results require attention.

The system should also provide an option for the IP to search for data based on patient location or date/time of admission so it is possible to monitor trends or trouble spots (RSD 2.6.3.6.1. Acceptance Criteria).

**Table 9: MRSA IPEC Auto-Extract Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA IPEC AUTO-EXTRACT (TASKED) |
| **Enhancement Category** | Modify |
| **Associated Menu Options that will invoke this reference** | N/A |
| **Data Passing** | No change |
| **Menu Text Description** | MDRO IPEC AUTO-EXTRACT (TASKED) |
| **Option Type** | Run Routine |
| **Option Definition** | This option will auto-extract MRSA data for entry into the Inpatient  Evaluation Center (IPEC) for the previous month's MRSA prevalence and transmission measures, via a MailMan message. This option should  be scheduled to run once a month. This option should not be run  interactively; it should only be tasked to run via TaskMan. |
| **Current Entry Action**  **Logic** | D TASK^MMRSIPC5 |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | N/A |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | N/A |

**Table 10: MRSA IPEC Auto-Extract Option**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA IPEC AUTO-EXTRACT (TASKED) MMRS MRSA IPEC AUTO- EXTRACT |
| **Enhancement**  **Category** | New Modify Delete No Change |

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Associated Menu Options that will invoke this reference** | N/A |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** | MMRS MRSA IPEC AUTO-EXTRACT |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** | MMRISL |
| **Option Definition** | DESCRIPTION: This option will auto-extract MRSA data for entry into the Inpatient Evaluation Center (IPEC) for the previous month's MRSA prevalence and transmission measures, via a MailMan message. This option should be scheduled to run once a month. This option should not be run interactively; it should only be tasked to run via TaskMan. |

**Current Entry Action Logic**

D TASK^MMRSIPC5

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Current Exit Action Logic**

N/A

**Modified Exit Action Logic (Changes are in bold)**

N/A

**Table 11: MRSA LAB Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA LAB OPTIONS ZZMRSA LAB MENU |
| **Enhancement Category** | Modify. Change name. |
| **Associated Menu Options that will invoke this reference** | Free standing option |
| **Data Passing** | N/A |

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Menu Text Description** | ZZMRSA LAB MENU |
| **Option Type** | Menu |
| **Option Definition** | Currently not defined. |
| **Current Entry Action**  **Logic** | No change |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | N/A |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | N/A |

**Table 12: MRSA LAB Option**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA LAB OPTIONS ZZMRSA LAB MENU |
| **Enhancement**  **Category** | New Modify Delete No Change |
| **Associated Menu Options that will invoke this reference** |  |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** |  |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** | N/A |
| **Option Definition** | No current definition at the menu level. |

**Current Entry Action Logic**

Direct menu access from the Laboratory DHCP main menu.

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Current Exit Action Logic**

N/A

**Modified Exit Action Logic (Changes are in bold)**

N/A

**Table 13: MRSA MAS Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA MAS MENU |
| **Enhancement Category** | Change routine name |
| **Associated Menu Options that will invoke this reference** | Found as a self contained menu option in the Laboratory DHCP main  menu |
| **Data Passing** | N/A |
| **Menu Text Description** | MRSA Mas Menu |
| **Option Type** | Run routine |
| **Option Definition** | No definition at the menu level |
| **Current Entry Action**  **Logic** | No change |
| **Modified Entry Action Logic (Changes are in bold)** | No change |
| **Current Exit Action**  **Logic** | No change |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | No change |

**Table 14: MRSA MAS Option**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA MAS MENU |
| **Enhancement**  **Category** | New Modify Delete No Change |

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Associated Menu Options that will invoke this reference** | Found in Laboratory DHCP main menu |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** | No description at this time. |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** | N/A |
| **Option Definition** | No definition in option |

**Current Entry Action Logic**

Direct menu access from the Laboratory DHCP menu

**Modified Entry Action Logic (Changes are in bold)**

Name changed to MDRO MAS MENU

**Current Exit Action Logic**

N/A

**Modified Exit Action Logic (Changes are in bold)**

N/A

**Table 15: MRSA Tools Lab Parameter Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA Tools Lab Parameter Setup |
| **Enhancement Category** | Modify. Change name |
| **Associated Menu Options that will invoke this reference** | Laboratory DHCP menu |
| **Data Passing** | N/A |
| **Menu Text Description** | This option allows the user to define parameters for the multi-drug  resistant organism (MDRO) that is to be searched for. This information is used to obtain prior history of MRSA and to display precaution measures for the selected organism(s). |
| **Option Type** | Run routine |

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Definition** | This option allows the user to define parameters for the multi-drug  resistant organism (MDRO) that is to be searched for. This information is used to obtain prior history of MRSA and to display precaution  measures for the selected organism(s). |
| **Current Entry Action**  **Logic** | LAB^MMRSIPCP |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | N/A |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | N/A |

**Table 16: MRSA Tools Lab Parameter Options**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA TOOLS LAB PARAMETER SETUP |
| **Enhancement**  **Category** | New Modify Delete No Change |
| **Associated Menu Options that will invoke this reference** | Called directly from the Laboratory DHCP menu |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** | This option allows the user to define parameters for the multi-drug resistant organism (MDRO) that is to be searched for. This information is used to obtain prior history of MRSA and to display precaution measures for the selected organism(s). |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** | MMRSIPCP |
| **Option Definition** | This option allows the user to define parameters for the multi-drug resistant organism (MDRO) that is to be searched for. This information is used to obtain prior history of MRSA and to display precaution measures for the selected organism(s). |

**Current Entry Action Logic**

**Current Entry Action Logic**

LAB^MMRSIPCP

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Current Exit Action Logic**

D LAB^MMRSIPCP

**Modified Exit Action Logic (Changes are in bold)**

Q

**Table 17: MRSA Tools Parameter Setup Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA TOOLS PARAMETER SETUP |
| **Enhancement Category** | Change name |
| **Associated Menu Options that will invoke this reference** | Access it directly from the LABORATORY DHCP menu |
| **Data Passing** | N/A |
| **Menu Text Description** | MA MMRS MRSA PARAMETER SETUP |
| **Option Type** | Run Routine |
| **Option Definition** | This option is used to add/edit the parameters which will modify the  operation of the MRSA Program Tools application. This option defines the division(s) and business rules for MRSA nares screening. |
| **Current Entry Action**  **Logic** | D DIV^MMRSIPCP |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | Q |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | Q |

**Table 18: MRSA Tools Parameter Setup Option**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA TOOLS PARAMETER SETUP |
| **Enhancement**  **Category** | New Modify Delete No Change |
| **Associated Menu Options that will invoke this reference** |  |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** |  |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** | MMRSIPCP |
| **Option Definition** | This option is used to add/edit the parameters which will modify the operation of the MRSA Program Tools application. This option defines the  division(s) and business rules for MRSA nares screening. |

**Current Entry Action Logic**

D DIV^MMRSIPCP

**Modified Entry Action Logic (Changes are in bold)**

No change

**Current Exit Action Logic**

No change

**Modified Exit Action Logic (Changes are in bold)**

No change

**Table 19: MRSA Tools Reports Menu Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA Tools Reports Menu |
| **Enhancement Category** | Change name of option |

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Associated Menu Options that will invoke this reference** | This is a menu option accessible from the Laboratory DHCP menu |
| **Data Passing** | N/A |
| **Menu Text Description** | No description found at menu level. |
| **Option Type** | Menu |
| **Option Definition** | No option definition at menu level. |
| **Current Entry Action**  **Logic** | N/A |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | N/A |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | N/A |

**Table 20: MRSA Tools Reports Menu Option**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA TOOLS REPORTS MENU |
| **Enhancement**  **Category** | New Modify Delete No Change |
| **Associated Menu Options that will invoke this reference** | Menu option found in the Laboratory DHCP menu and is a direct link |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** | No description at the menu level |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** |  |
| **Option Definition** |  |

**Current Entry Action Logic**

**Current Entry Action Logic**

N/A

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Current Exit Action Logic**

N/A

**Modified Exit Action Logic (Changes are in bold)**

N/A

**Table 21: MRSA Tools Reports Menu Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA Tools Reports Menu |
| **Enhancement Category** | Change the routine name |
| **Associated Menu Options that will invoke this reference** | Laboratory DHCP menu |
| **Data Passing** | N/A |
| **Menu Text Description** | MRSA Tools Reports Menu |
| **Option Type** | Menu |
| **Option Definition** | No definition at the menu level |
| **Current Entry Action**  **Logic** | N/A |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | N/A |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | N/A |

**Table 22: MRSA Tools Setup Menu Option**

**Options Activities**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA TOOLS SETUP MENU |
| **Enhancement**  **Category** | New Modify Delete No Change |
| **Associated Menu Options that will invoke this reference** |  |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** | No description found at menu level. |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** | N/A |
| **Option Definition** | No description found at menu level. |

**Current Entry Action Logic**

N/A

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Current Exit Action Logic**

N/A

**Modified Exit Action Logic (Changes are in bold)**

N/A

**Table 23: MRSA Tools Ward Mapping Setup Option (Instructions)**

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Name**  **(MENU TEXT field)** | MRSA Tools Ward Mapping Setup |
| **Enhancement Category** | Change name of option |
| **Associated Menu Options that will invoke this reference** | Self contained within the Laboratory DHCP menu. |
| **Data Passing** | N/A |
| **Menu Text Description** | MRSA Tools Ward Mapping Setup |

|  |  |
| --- | --- |
| **Options** | **Instructions** |
| **Option Type** | MENU |
| **Option Definition** | No definition at menu level. |
| **Current Entry Action**  **Logic** | N/A |
| **Modified Entry Action Logic (Changes are in bold)** | N/A |
| **Current Exit Action**  **Logic** | N/A |
| **Modified Exit Action**  **Logic**  **(Changes are in bold)** | N/A. |

**Table 24: MRSA Tools Ward Mapping Setup Option**

|  |  |
| --- | --- |
| **Options** | **Activities** |
| **Option Name** | MRSA TOOLS WARD MAPPING SETUP |
| **Enhancement**  **Category** | New Modify Delete No Change |
| **Associated Menu Options that will invoke this reference** | Runs directly from the Laboratory DHCP menu option |
| **Data Passing** | Input Output Both Global Reference Local Reference |
| **Menu Text**  **Description** | No definition at menu level |
| **Option Type** | Edit Print Menu Inquire  Action Run Routine Other |
| **Associated Routine** |  |
| **Option Definition** | No definition at menu level. |

**Current Entry Action Logic**

N/A

**Modified Entry Action Logic (Changes are in bold)**

N/A

**Current Exit Action Logic**

N/A

**Modified Exit Action Logic (Changes are in bold)**

N/A

**6.2.2.3.10. Protocols**

No new protocols are anticipated to be delivered during the Microbiology Enhancement.

**6.2.2.3.11. Remote Procedure Call (RPC)**

No new RPC’s are anticipated to be delivered during the Microbiology Enhancement.

**6.2.2.3.12. Variables Defined in Interface**

No interface variables have been identified at this time.

**6.2.2.3.13. Types Defined in Interface**

No types have been identified at this time.

**6.2.2.3.14. GUI**

No changes will be made to the GUI. The VistA Legacy Lab application and CPRS will be the viewers for these requirements.

**6.3. Network Detailed Design**

No new network infrastructure is required to support the Microbiology Enhancement.

**6.4. Security and Privacy**

**6.4.1. Security**

Any individually identifiable information needs to be transmitted/retrieved in a manner that meets all VA Handbook 6500 requirements.

**6.4.2. Privacy**

The proposed solution ensures to meet all Veterans Health Administration (VHA) Security, Privacy, and Identity Management requirements including VA Handbook 6500 (see the Enterprise Requirements section of the RTM).

**6.5. Service Oriented Architecture / ESS Detailed Design**

The Microbiology Enhancement does not add to provided and/or consumed services.

**6.5.1. Dependencies**

This work effort includes the development of bi-directional interfacing for microbiology automated instrumentation used in VA laboratory facilities. The current environment for performing microbial organism identification and antibiotic susceptibility testing using

automated instruments is not standard across VA’s microbiology laboratories. Most sites have no ability to interface with such instruments, requiring manually inputting test information, retrieving printouts, and manually entering results into VistA. Private-sector laboratory information systems (LIS) almost universally provide support for microbiology interfacing; the lack of this capability within VISTA/CPRS endangers VA patients and wastes VA resources.

Some VA microbiology laboratories do have locally-developed (i.e., Class III) interfaces in place, typically through some type of middleware to go between VistA and the instruments. Those interfaces are inefficient in terms of having multiple local resources providing varying degrees of support. They have also proven difficult to implement widely. Locally-developed interfaces can introduce variation in how the test results are captured and annotated in VistA, particularly when interfacing with different instrument/middleware products. Such variation could impede the interoperability of the result information within VA and with health care partners.

The system shall provide an electronic interface between automated Microbiology Instrumentation and the VistA Laboratory application. This will be done by the IRM after the patch has been installed. Instructions will be provided.

**7. External System Interface Design**

There will not be an External System or Interface Design for the Micro Enhancement capability.

**8. Human-Machine Interface**

There are no additional human-machine interfaces for the Micro enhancement. The current functionality of VistA Legacy Laboratory module and Health Level 7 module are leveraged. The enhancements are to use background processing and changes to the dialog of the interface.

**9. Attachment A – Approval Signatures**

This section is used to document the approval of the System Design Document. The review should be conducted face to face where signatures can be obtained ‘live’ during the review. If unable to conduct a face-to-face meeting then it should be held via LiveMeeting and concurrence captured during the meeting. The Scribe should add /es/name by each position cited. Example provided below.

X

Business Sponsor

X

VA Project Manager