**VistA Evolution Anatomic Pathology Order Dialog**

**Requirements Specification Document**



**Department of Veterans Affairs**

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**1. Introduction**

**1.1. Purpose**

The purpose of this Requirements Specification Document (RSD) is to convey the analysis and requirements associated to the delivery of enhancements to the Veterans Health Information Systems and Technology Architecture (VistA) Anatomic Pathology (AP) Laboratory Module. The AP Laboratory service needs a mechanism for clinicians to provide required patient-specific, procedure-specific and specimen- specific information to facilitate specimen processing by pathologists. This mechanism must be in place for use by the specimen labeling application in order to generate a primary specimen label that positively identifies the specimen and accurately associates it with the patient. In addition, this request is a dependency

for a national project, Bar Code Expansion – Positive Patient Identification (BCE- PPI), which will not be able to proceed with interface development if the AP Order Dialog is not in place.

**1.2.Scope**

The requested AP Order Dialog will improve ordering clinicians’ ability to provide required patient-specific, procedure-specific and specimen-specific information to facilitate specimen processing by pathologists. The AP Order Dialog will provide ordering clinicians with the ability to:

 Electronically create, view, update and edit an AP Order anytime during the

AP Order process

 Use electronic order entry to properly and accurately process AP Orders

 Use standardized and specialized templates to enter procedure and specimen-specific lab request information that can be used by the AP lab to process and evaluate associated AP Order lab specimen submissions

 Electronically match the AP Order lab specimen request to the patient and specimen at the time of collection and at time of labeling

 *Future Requirement once BCE Project Re-started:* Provide required patient and preliminary AP Order lab specimen information to the Point of Care Specimen Collection System that can be used for AP specimen collection

**1.3.Stakeholders**

The following groups were consulted in the elaboration of the requirements for VE AP Order Dialog:

• Computer Patient Record System (CPRS) project team

• VistA Lab business and technical teams

• VistA Laboratory Electronic Data Interchange (LEDI) project team

• Laboratory System Re-Engineering Project (LSRP) team

• Bar Code Expansion (BCE) – Patient Positive Identification (PPI) team

The intended audience for the RSD includes, but is not limited to, the VistA Lab Working Group members including:

• Project Managers

• Functional Analysts

• Developers

• SQA Analysts

• Technical Writers

• Business Users

• Affected Stakeholders

**1.4.References**

 VE AP Order Dialog Business Requirements Document

 VE AP Order Dialog Requirements Traceability Matrix

 VA Handbook 6500 – Information Security Program

 VistA Evolution Program Charter

 Vista Evolution Program Plan

 CPRS GUI:

 CPRS Technical Manual:

 LEDI User Manual:

 LSRP:

 Information Model Summary Report (IMSR):

**2. Overall Description**

**2.1. Accessibility Specifications**

The user interface for the Veterans Health Information Systems and Technology Architecture (VistA) Laboratory application uses roll-and-scroll screens developed in MUMPS (M). A section 508 compliance review will be conducted in accordance with Program Management Accountability System (PMAS) standards.

 NOTE: The VistA Lab Product Roadmap references eHMP Services that encompasses Order Management Services which includes CPRS. The recommended long term target solution will align the project with the OneVA EA and Enterprise Shared Services architecture and infrastructure. It will leverage enterprise solutions such as the eMI, eHMP as a replacement for CPRS and use of VistA service Assembler (VSA) generated services for integration with VistA.

.

**2.2.Business Rules Specification**

The AP Order Dialog Business Requirements Document (BRD) can be found in TSPR at:

**2.3.Design Constraints Specification**

Design constraints will be documented in the System Design Document (SDD).

**2.4.Disaster Recovery Specification**

This VHA project will inherit the DR 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.

**2.5.Documentation Specifications**

The AP Dialog Requirements Specification Document (RSD) will document functional and non-functional requirements.

The AP Dialog System Design Document (SDD) will document the design constraints related to functional requirements.

The AP Dialog Traceability Matrix will track requirements traceability.

**2.6.Functional Specifications**

2.6.1.

442691 – AP Order Dialog

The need to provide required patient-specific, procedure-specific and specimen- specific information to create an electronic AP Order (e.g., Computerized Patient

Record System [CPRS]) that interfaces with the Department of Veterans Affairs (VA) Anatomic Pathology system (e.g., Veterans Health Information Systems Technology Architecture [VistA]) so that Pathologists can process AP specimens accurately.

2.6.2.

442692 – Business Requirement

The system shall enable an ordering clinician, to view routinely captured pre- populated Patient Demographics in the AP Order, eliminating the need to manually retype information that is automatically captured as a part of all service orders.

**2.6.2.1.** 470572 – User Story: Patient Demographics

As an ordering clinician, I want to validate the patient-specific demographic information pre-populated to the AP Order (e.g., CPRS), so that I can enter the order for the correct patient.

**2.6.2.2.** 470799 - Acceptance Criteria

The system shall display pre-populated patient-specific demographics when the clinician creates an AP Order. Clinician opens order and can view patient specific demographic information.

o Name

o Patient ID

o Gender

o Provider

o Date of Birth

2.6.3.

470573 - Business Requirement

The system shall present the clinician with the required data prompts in CPRS/eHMP needed when ordering an AP test to enable proper processing and evaluation of associated Anatomic Pathology (e.g., VistA) specimen submissions.

**2.6.3.1.** 490100 - User Story: General Order Information

As an ordering clinician, I need to communicate general ordering information, so that the health care team and laboratory can act on the request appropriately.

**2.6.3.2.** 490101 - Acceptance Criteria

The system shall display the following data fields at the time of order entry:

• Anatomic Pathology Procedure (Standardized List)

• Clinical History (Free Text)

• Pre-Operative Diagnosis (Free Text)

• Operative Findings (Free Text)

• Post-Operative Findings (Free Text)

• Specimen Type (Standardized List)

• Site/Specimen (Source) (Standardized List)

• Submission Type (Standardized List)

• Urgency (Standardized List)

• Order Date/Time (Default)

• Expected Collection Date/Time (Default)

• How Often? (Number)

• How Long? (Hours/days/weeks)

• Special Stains/Studies (Standardized List/Locally Defined)

• Order Comment (Free Text)

• Ordering Provider

• Surgeon - if Surgeon not Ordering Provider

• Order Placer

• Electronic Signature

Note: specific rules for each AP procedure (i.e. Bone Marrow, Bronchial, etc.) are provided in subsequent use cases/acceptance criteria.

**2.6.3.3.** 470574 **–** User Story: Order Date/Time

As an ordering clinician, I need the ordering date and time pre-populated on the AP Order so that traceability is provided.

**2.6.3.4.** 470800 **–** Acceptance Criteria

The system shall pre-populate the following when the user creates the AP Order. Order date/order time (default current date/time stamp). Clinician opens completed order and sees order date and time.

**2.6.3.5.** 470579 – User Story: Expected Collection Date

As an ordering clinician, I need to modify the expected collection date and time on an AP order so the AP orders can be used for planning and collection activities.

**2.6.3.6.** 470801 - Acceptance Criteria

The system shall make the fields for expected collection date and expected collection time default to "Today" or "Now", and it can be edited by the clinician. Clinician opens order and enters and either accepts default expected date and time of collection or changes expected date and time of collection.

2.6.4.

442693 **–** Business Requirement

The System shall allow the creation of an AP Order using and specialized templates (with guided entry prompts) that are designed according to source specialty with procedure and specimen specific information that can be used by the AP Lab to process and evaluate associated AP specimen submissions.

**2.6.4.1.** 474205 – User Story: Bone Marrow

As an ordering clinician, I need to capture information in the AP Order Template for

Bone Marrow so that a provider can render a diagnosis of the specimen.

**2.6.4.2.** 474206 – Acceptance Criteria

The system shall present to the user a source/specialty template for Bone Marrow specimen with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Bone Marrow (Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

o Aspirate

o Core Biopsy

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Sternum

o Right Posterior Iliac Crest

o Left Posterior Iliac Crest

o Right Anterior Iliac Crest

o Left Anterior Iliac Crest

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Bone Marrow specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall not prompt the user to enter the following fields for a Bone Marrow procedure:

 Operative Findings – Do not display

 Post-operative Findings - Do not display

 Submission Type – Do Not display

2.6.5.

474207 - User Story: Bronchial

As an ordering clinician, I need to capture information in the AP Order Template for

Bronchial so that a provider can render a diagnosis of the specimen.

2.6.6.

474208 - Acceptance Criteria

The system shall present to the user a source/specialty template for Bronchial specimen with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Bronchial (Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

o Washing

o Brushing

o Wang Needle

o Sputum

o Bronchial-Alveolar Lavage (BAL)

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

 Laterality (optional)

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Bronchial specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall not prompt the user to enter the following fields for a Bronchial procedure:

 Operative Findings – Do not display

 Post-operative Findings - Do not display

 Submission Type – Do Not display

2.6.7.

474209 - User Story: Bronchial Biopsy

As an ordering clinician, I need to capture information in the AP Order Template for

Bronchial Biopsy so that a provider can render a diagnosis of the specimen

2.6.8.

474210 - Acceptance Criteria

The system shall present to the user a source/specialty template for Bronchial Biopsy with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Bronchial Biopsy(Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

o Endobronchial Biopsy

o Transbronchial Biopsy

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Laterality

 Submission Type – (Optional/Multiple/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Bronchial

Biopsy specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall allow options to the user to enter the following fields for a Bronchial

Biopsy procedure:

 Operative Findings – Optional

 Post-operative Findings - Optional

2.6.9.

474211 - User Story: Dermatology

As an ordering clinician, I need to capture information in the AP Order Template for

Dermatology so that a provider can render a diagnosis of the specimen.

2.6.10.

474212 - Acceptance Criteria

The system shall present to the user a source/specialty template for Dermatology with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Dermatology(Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Operative Findings (Optional/Multiple/Limited Choices)

 Post-operative Findings (Optional/Multiple/Limited Choices)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

o Excision

o Shave ED&C

o Punch Biopsy

 Size of Punch

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Laterality

 Left

 Right

 Midline

 Submission Type - (Optional/ 1 per Specimen Type/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Dermatology specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

2.6.11.

474213 - User Story: Fine Needle Aspirate

As an ordering clinician, I need to capture information in the AP Order Template for Fine

Needle Aspirate so that a provider can render a diagnosis of the specimen.

2.6.12.

474214 - Acceptance Criteria

The system shall present to the user a source/specialty template for Fine Needle

Aspirate with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Fine Needle

Aspirate(Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Laterality

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Fine Needle

Aspirate:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall not prompt the user to enter the following fields for a Fine Needle

Aspirate:

 Operative Findings – Do not display

 Post-operative Findings - Do not display

 Submission Type – Do Not display

2.6.13.

474215 - User Story: General Fluid

As an ordering clinician, I need to capture information in the AP Order Template for

General Fluid so that a provider can render a diagnosis of the specimen.

2.6.14.

474216 - Acceptance Criteria

The system shall present to the user a source/specialty template for General Fluid with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = General Fluid (Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Specimen Type (Standardized List/Required/Multiple/Limited Choices)

o CSF

o Pericardial Fluid

o Peritoneal Fluid

o Pleural Fluid

o Synovial Fluid

o Other

 Site/Specimen (source) – (Auto Text)

o CSF

o Pericardial Fluid

o Peritoneal Fluid

o Pleural Fluid-Right

o Pleural Fluid-Left

o Synovial Fluid- For Synovial Fluid- list common joints, including Right

and Left for Laterality

 Right Knee

 Left Knee

 Other, Free Text

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for General Fluid:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall not prompt the user to enter the following fields for a General Fluid:

 Operative Findings – Do not display

 Post-operative Findings - Do not display

 Submission Type – Do Not display

2.6.15.

474217 - User Story: General Surgery

As an ordering clinician, I need to capture information in the AP Order Template for

General Surgery so that a provider can render a diagnosis of the specimen.

2.6.16.

474218 - Acceptance Criteria

The system shall present to the user a source/specialty template for General Surgery with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = General Surgery (Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Operative Findings (Optional/Multiple/Limited Choices)

 Post-operative Findings (Optional/Multiple/Limited Choices)

 Specimen Type - Display “Enter Procedure or Operation” (Standardized

List/Optional/Multiple/Limited Choices)

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Laterality (Optional)

 Left

 Right

 Midline

 Free Text

 Not Applicable

 Submission Type – (Optional/Multiple/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for General

Surgery specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

2.6.17.

478550 - User Story: Gastro-Intestinal (GI), Upper GI

As an ordering clinician, I need to capture information in the AP Order Template for Gastro-Intestinal (GI), Upper GI so that a provider can render a diagnosis of the specimen.

2.6.18.

478551 - Acceptance Criteria

The system shall present to the user a source/specialty template for Gastro-Intestinal

(GI), Upper GI with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Gastro-Intestinal (GI), Upper

GI (Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Operative Findings (Optional/Multiple/Limited Choices)

o Normal Mucosa

o Polyp

o Ulcer

o Mass

o Other (Free Text entry)

 Post-operative Findings (Optional/Multiple/Limited Choices)

 Specimen Type - Display “Enter Procedure or Operation” (Standardized

List/Optional/Multiple/Limited Choices)

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Laterality (Optional)

 Not Applicable

 Free Text

 Submission Type – (Optional/Multiple/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Gastro- Intestinal (GI), Upper GI specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

2.6.19.

478548 – User story: Gastro-Intestinal, Lower GI

As an ordering clinician, I need to capture information in the AP Order Template for

Gastro-Intestinal, Lower GI so that a provider can render a diagnosis of the specimen.

2.6.20.

478549 – Acceptance Criteria

The system shall present to the user a source/specialty template for Gastro-Intestinal

(GI), Lower GI with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Gastro-Intestinal (GI), Lower GI (Required)

 Clinical History (Required/Free Text)

 Pre-Operative Diagnosis (Required/Free Text)

 Operative Findings (Optional/Multiple/Limited Choices)

o Normal Mucosa

o Polyp

o Ulcer

o Mass

o Other (Free Text entry)

 Post-operative Findings (Optional/Multiple/Limited Choices)

 Specimen Type - Display “Enter Procedure or Operation” (Standardized

List/Optional/Multiple/Limited Choices)

 Site/Specimen (source) – (Required/Free Text)

 Submission Type – (Optional/Multiple/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Gastro- Intestinal (GI), Lower GI specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

2.6.21.

478552 - User Story: Gynecology (PAP)

As an ordering clinician, I need to capture information in the AP Order Template for

Gynecology (PAP) so that a provider can render a diagnosis of the specimen.

2.6.22.

478553 – Acceptance Criteria

The system shall present to the user a source/specialty template for Gynecology (PAP)

specimen with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Gynecology (PAP) (Required)

 Clinical History (Required/Multiple)

o Choices to include (multiple selections possible):

 Annual

 Follow-up to Abnormal PAP

 Hysterectomy

 Birth Control Pills

 Radiation/Chemotherapy

 Abnormal Bleeding

 IUD

 Post Partum

 Other

o Menstrual Status (choose one, mandatory):

 Menstrual LMP: indicate date

 Post-menopausal

o Hormone Therapy (choose one, mandatory):

 No Hormone Therapy

 HRT

 Vaginal Cream (Hormonal)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

o Thin Prep

o Conventional

 Site/Specimen (source) – (Optional/ 1 per Specimen Type/Limited Choices)

o Select from

 Vaginal

 Cervical

 Endocervical

o Laterality – Do not display

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Gynecology

(PAP) specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall not prompt the user to enter the following fields for a Gynecology

(PAP) procedure:

 Pre-Operative Diagnosis - Do not display

 Operative Findings – Do not display

 Post-operative Findings - Do not display

 Submission Type – Do Not display

2.6.23.

478554 – User Story: Urine

As an ordering clinician, I need to capture information in the AP Order Template for Urine (including Urinary Tract procedures producing washings) so that a provider can render a diagnosis of the specimen.

2.6.24.

478555 – Acceptance Criteria

The system shall present to the user a source/specialty template for Urine (including

Urinary Tract procedures producing washings) specimen with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Urine (Required)

 Clinical History (Required/Free Text)

o Additional section with choices, optional selection, multiple selections possible

 Instrumentation 72 hours prior to collection: Yes/No

 Cystoscopy: Yes/No, If Yes:

 Cystoscopic Findings- Free Text

 Pre-Operative Diagnosis (Required/Free Text)

 Specimen Type (Standardized List/Optional/Multiple/Limited Choices)

o Voided

o Bladder Wash

o Catheterized Urine

o Ileal Conduit

o Right Ureter

o Left Ureter

o Other (Free Text)

 Site/Specimen (source) – (Auto)

o Laterality- do not display; laterality is indicated in Specimen type if applicable

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Urine specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

The system shall not prompt the user to enter the following fields for a Urine procedure:

 Operative Findings – Do not display

 Post-operative Findings - Do not display

 Submission Type – Do Not display

2.6.25.

478556 – User Story: Urology, Prostate

As an ordering clinician, I need to capture information in the AP Order Template for

Urology, Prostate so that a provider can render a diagnosis of the specimen.

2.6.26.

478557 – Acceptance Criteria

The system shall present to the user a source/specialty template for Urology, Prostate with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Urology, Prostate

(Required)

 Clinical History (Required/Free Text)

o Choices

 Increased PSA

 Abnormal DRE

 Prostate Cancer

 Other (Free Text)

o Display/pull in current Free PSA result, including date done

 Pre-Operative Diagnosis (Required/Free Text)

 Operative Findings (Optional/Multiple/Limited Choices)

 Post-operative Findings (Optional/Multiple/Limited Choices)

 Specimen Type - (Standardized List/Optional/Multiple/Limited Choices)

o Prostate Needle Biopsy

o TURP

 Site/Specimen (source) – (Required/Free Text)

o Laterality- mandatory for Needle Biopsy, Not Applicable for TURP

 Submission Type – (Optional/Multiple/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Urology, Prostate specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

2.6.27.

478558 – User Story: Urology, Bladder/Ureter

As an ordering clinician, I need to capture information in the AP Order Template for

Urology, Bladder/Ureter so that a provider can render a diagnosis of the specimen.

2.6.28.

478559 – Acceptance Criteria

The system shall present to the user a source/specialty template for Urology, Bladder/Ureter with the listed data elements:

 Anatomic Pathology Procedure (Standardized List) = Urology, Bladder/Ureter

(Required)

 Clinical History (Required/Free Text)

o Free text

o Cystoscopy Findings-Free Text

 Pre-Operative Diagnosis (Required/Free Text)

 Operative Findings (Optional/Multiple/Limited Choices)

 Post-operative Findings (Optional/Multiple/Limited Choices)

 Specimen Type - (Standardized List/Optional/Multiple/Limited Choices)

o Bladder Biopsy

o TURBT

o Ureter

 Site/Specimen (source) – (Auto)

o Laterality - Required for Bladder and Ureter, Not Applicable for TURBT

 Submission Type – (Optional/Multiple/Limited Choices)

o Fresh

o Fixed

o Intra-Op Consult

 Urgency (Standardized List/Required)

 Expected Collection Date/Time (Default/Required)

 How Often? (Default to 1Time/Required)

 How Long? (Required if How Often >1)

 Special Stains/Studies (Standardized List/Locally Defined/Optional/Multiple)

 Order Comment (Optional/Free Text)

 Ordering Provider (Required/Default to Provider Entering Order if they have

Ordering Privileges (e.g. ORES Key)

 Surgeon if Surgeon not Ordering Provider (Optional)

 Electronic Signature (Required)

The system shall capture the following information in the background for Urology, Bladder/Ureter specimen:

 Order Date/Time (Default/Required)

 Order Placer (Required)

2.6.29.

478560 - Business Requirement

The system shall present to the ordering clinician the applicable stain or study(ies) to select when opening an existing order.

**2.6.29.1.** 478560 – User Story: Select Stains/Studies

As an ordering clinician, I need the ability to select a specific stain or study(ies) to render accurate diagnosis of the specimen.

**2.6.29.2.** 478561 – Acceptance Criteria

Clinician opens order and selects the specific stain and study(ies) required.

2.6.30.

442694 – Business Requirement

The system shall capture required information when a clinician is placing an order so that the information can be used for subsequent specimen processing and report functions (to include collection and labeling).

As an ordering clinician, I want information captured in an AP Lab Order available to Veterans Health Administration (VHA) Systems (e.g., VA Anatomic Pathology, Point of Care Specimen Collection System) so that the information can be used for subsequent specimen processing and report functions (to include collection and labeling).

**2.6.30.1.** 470583 – User Story: Patient Specific Information

As an ordering clinician, I need the patient-specific information captured in the AP Order Dialog to be available in the VA Anatomic Pathology System (e.g., Vista) to ensure accurate specimen processing.

**2.6.30.2.** 470802 – Acceptance Criteria

Clinician opens order and views name, unique ID, DOB, Provider, sex. The system shall populate the VistA system with patient-specific information from the AP Order.

o Name

o patient ID

o Date of Birth

o Provider

o Gender

2.6.31.

470584 – Business Requirement

The system shall populate the VistA system with expected date and time of collection information from the AP Order.

**2.6.31.1.** 470584 – User Story: Expected Date/Time of Collection

As an ordering clinician, I need expected date and time of collection to be captured in the AP Order Dialog to be available in the VA Anatomic Pathology System (e.g., VistA) for use in management tracking reports and to ensure traceability.

**2.6.31.2.** 470803 – Acceptance Criteria

Clinician is able to view expected date and time of collection using applicable menu options within the VA AP System.

2.6.32.

470592 – Business Requirement

The system shall capture the Clinical History information entered by the clinician in the AP Order Dialog and it shall be viewable to laboratory Providers using the VISTA VA Anatomic Pathology Application. The Clinical History shall be presented for all source specialties.

**2.6.32.1.** 470592- User Story: Clinical History Information Captured

As an ordering clinician, I need the Clinical History information captured in the AP Order Dialog to be viewable to Providers using the VA Anatomic Pathology System (e.g., VistA) so they can render accurate diagnosis of the specimen.

**2.6.32.2.** 470804 – Acceptance Criteria

Clinical History can be viewed in the AP System for Bone Marrow, Bronchial, Bronchial Biopsy, Dermatology, Fine Needle Aspirate, General Fluid, General Surgery, Gastro- Intestinal, Upper GI, Gastro-Intestinal, Lower GI, Gynecology, Urine, Urology, Prostate, Urology, Bladder/Ureter.

2.6.33.

470593 – Business Requirement

The system shall capture the Pre-operative Diagnosis information entered by the clinician in the AP Order Dialog and it shall be viewable to laboratory Providers using the VistA VA Anatomic Pathology Application. The Pre-operative Diagnosis shall be presented for all source specialties.

**2.6.33.1.** 470593 – User Story: Pre-Operative Diagnosis

As an ordering clinician, I need the Pre-operative Diagnosis information captured in the AP Order Dialog to be viewable to Providers using the VA Anatomic Pathology System so that they can render accurate diagnosis of the specimen.

**2.6.33.2.** 470805 – Acceptance Criteria

Pre-operative Diagnosis information can be viewed in the AP System for Bone Marrow, Bronchial, Bronchial Biopsy, Dermatology, Fine Needle Aspirate, General Fluid, General Surgery, Gastro-Intestinal, Upper GI, Gastro-Intestinal, Lower GI, Urine, Urology, Prostate, Urology, Bladder/Ureter.

2.6.34.

470597 – Business Requirement

The system shall capture the Operative Findings information entered by the clinician in the AP Order Dialog and it shall be viewable/editable in the VistA VA Anatomic Pathology System Application. The Operative Findings shall be presented for the following source specialties: Dermatology, General Surgery, Gastro-Intestinal, Upper GI, Gastro-Intestinal, Lower GI, Urology, Prostate and Urology, Bladder/Ureter.

**2.6.34.1.** 470597 – User Story: Operative Findings

As an ordering clinician, I need the Operative Findings field information captured in the AP Order Dialog to be available in the VA Anatomic Pathology System (e.g., Vista) for rendering patient-specific diagnosis.

**2.6.34.2.** 470806 – Acceptance Criteria

Clinician will enter, view, and modify data for Operative Findings.

Operative Findings information can be viewed in AP System for Dermatology, General Surgery, Gastro-Intestinal, Upper GI, Gastro-Intestinal, Lower GI, Urology, Prostate, Urology, and Bladder/Ureter.

2.6.35.

470599/470807 – Post-Operative Findings

The system shall capture the Post-operative Findings information entered by the clinician in the AP Order Dialog to be viewable/editable in the VistA VA Anatomic Pathology Application. The Post-operative Findings shall be presented for the following source specialties: Dermatology, General Surgery, Gastro-Intestinal, Upper GI, Gastro- Intestinal, Lower GI, Urology, Prostate and Urology, Bladder/Ureter.

2.6.36.

470600/470808 – Specimen Type

The system shall capture the Specimen Type information entered by the clinician in the AP Order Dialog and it shall be viewable/editable in the VistA VA Anatomic Pathology Application. The Specimen Type shall be presented for all source specialties.

2.6.37.

470601/470809 – Site/Specimen

The system shall capture the Site/Specimen (source); including Laterality field information entered by the clinician in the AP Order Dialog and it shall be viewable/editable in the VistA VA Anatomic Pathology Application. The Site/Specimen (source), including Laterality shall be presented for all source specialties.

2.6.38.

470602/470810 – Submission Type

The system shall capture the Submission Type information entered by the clinician in the AP Order Dialog and it shall be viewable/editable in the VistA VA Anatomic Pathology Application. The Submission Type shall be presented for the following source specialties: Bronchial Biopsy, Dermatology, General Surgery, Gastro-Intestinal, Upper GI, Gastro-Intestinal, Lower GI, Urology, Prostate and Urology, Bladder/Ureter.

2.6.39.

470605/470812 – Special Stains/Studies

The system shall capture the Special Stains/Studies information entered by the clinician in the AP Order Dialog to be viewable/editable in the VistA VA Anatomic Pathology Application. The Special Stains/Studies information shall be presented for all source specialties.

2.6.40.

442695 – AP Order Information

The system shall ensure that the AP order information is available to support matching the patient and specimen during specimen collection so that patient-specimen misidentification is avoided and errors associated with patient-specimen misidentification are prevented.

2.6.41.

478562/478563 – Match Patient to AP Order

The system shall provide the ability to match patient to AP Order. (E.g. patient wristband data to patient identification information on AP Order) (Process/procedure requirement, not system)

2.6.42.

478564/478565 – Match Patient to Specimen

The system shall provide the ability to match patient to specimen collected. (E.g. patient wristband data to bar code data on label) (Process/procedure requirement, not system)

2.6.43.

442696 – Edit Specimen Information

The system shall provide the ordering clinician the ability to update/edit specimen- specific information any time during the AP Order process so that errors or omissions can be corrected before specimen collection.

2.6.44.

478556/478567 - Edit Bone Marrow Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Bone Marrow specimen collection.

2.6.45.

478568/478569 – Edit Bronchial Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Bronchial specimen collection.

2.6.46.

478570/478571 – Edit Bronchial Biopsy Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Bronchial Biopsy specimen collection.

2.6.47.

478572/478573 – Edit Dermatology Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Dermatology specimen collection.

2.6.48.

478574/478575 – Edit Fine Needle Aspirate Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Fine Needle Aspirate specimen collection.

2.6.49.

478576/478592 – Edit General Fluid Specimen

The system shall provide the ability to update/edit all specimen-specific information for

General Fluid specimen collection.

2.6.50.

478578/478579 – Edit General Surgery Specimen

The system shall provide the ability to update/edit all specimen-specific information for

General Surgery specimen collection.

2.6.51.

478580/478581 – Edit Gastro-Intestinal, Lower GI Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Gastro-Intestinal, Lower GI specimen collection.

2.6.52.

478582/478583 – Edit Gastro-Intestinal, Upper GI Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Gastro-Intestinal, Upper GI specimen collection.

2.6.53.

478584/478585 – Edit Gynecology Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Gynecology specimen collection.

2.6.54.

478586/478587 – Edit Urine Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Urine specimen collection.

2.6.55.

478588/478589 – Edit Urology, Prostate Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Urology, Prostate specimen collection.

2.6.56.

478590/478591 – Edit Urology, Bladder/Ureter Specimen

The system shall provide the ability to update/edit all specimen-specific information for

Urology, Bladder/Ureter specimen collection.

2.6.57.

470606 – Write & Amend Orders

The system shall provide the Anatomic Pathology Staff the ability to write and amend orders within the scope of practice, organizational policy/or jurisdictional law so that AP specimens can be processed accurately.

2.6.58.

470616/470814 – Update all Specimen Specific Information

The system shall provide the ability to update all specimen-specific information at any time during the AP Order (e.g., CPRS) process.

2.6.59.

470618 - Labels

The system shall provide the specimen specific information entered by the clinician in the AP Order (e.g., CPRS) to interface with the specimen labeling application, so that specimen labels created at the time of collection are accurately and easily matched to the specimen and corresponding patients .

If specimen collection system not available, and as an alternative, the system shall produce general labels and a printed order requisition capability for the purpose of labeling specimen at the time of collection.

2.6.60.

470619/470815 - Label for Single Specimen Collection

The system shall generate a unique label for a single AP Order with a single specimen collected.

2.6.61.

470619/470815.1 – Labels for Multiple Specimens Collection

The system shall generate a unique label for each individual specimen for a single AP Order with multiple specimens collected,

2.6.62.

470620 - Parent Specimen

The system shall provide AP Lab staff the ability within the VistA AP application to generate labels that can be positively linked to a single specimen (parent) when the specimen must be divided (children) for testing purposes so they can be linked to the parent specimen.

2.6.63.

470628/470818 – Unique Label for each independently tested specimen

The system shall create a unique label for each independently tested specimen. (Example: Specimen is collected and is to be sent off for three independent/separate tests. Three individual labels will be created for each test linking back to the specimen collected.)

2.6.64.

442697 – Display group for AP Service Orders

The system shall create a new display group for service orders called Anatomic

Pathology so that the ordering clinician can filter and view all AP Orders.

2.6.65.

470629/470819 **– Filter**/Display AP Orders Only

The system shall provide the ability to filter the displayed order information. Filter criteria: AP Orders only

2.6.66.

470630/470820 – Sort by AP Orders

The system shall provide the ability to sort the displayed order information so AP Orders are grouped together.

2.6.67.

442698 – Add Patient Location & Submitting Provider

The system shall provide the ability for the specimen collector to add actual patient geographical location and submitting provider information at the time of specimen collection as separate data elements so this information can be captured in the original AP Order, as it may be different from when the AP order was placed.

2.6.68.

470632/470821 – Patient Location

The system shall provide the ability to update patient geographical location at the time of specimen collection. (Role: Specimen Collector)

2.6.69.

470634/470822 – Submitting Provider

The system shall provide the ability to update submitting provider at the time of specimen collection. (Role: Specimen Collector)

2.6.70.

442699 – Additional Provider

The system shall provide the ability to indicate additional provider contacts on the AP Order so that designated care providers can view report findings and alerts.

2.6.71.

470679/470823 – Add Providers at Ordering

The system shall provide the ability, at the time of AP Order creation to add additional providers to receive report findings and alerts. (Role: Ordering Clinician)

2.6.72.

470680/470624 **–** Add Providers at Specimen Testing

The system shall provide the ability, during the specimen testing process to add additional providers to receive report findings and alerts. (Role: Anatomic Pathology Staff)

2.6.73.

442701 – View Guidelines

The system shall provide the ability to for the ordering clinician to view guidelines or restrictions on the AP Order to ensure subsequent order processing will be compliant with local Anatomic Pathology guidelines or restrictions.

2.6.74.

470683/470825 – View Guidelines for Specimen Collection

The system shall provide the ability, to view the local/national guideline for proper specimen collection. (Role: Ordering Clinician or Specimen Collector)

2.6.75.

470684/470827 – View Guidelines for Specimen Handling

The system shall provide the ability, to view the local/national guidelines for specimen handling procedures. (Role: Ordering Clinician or Specimen Collector)

2.6.76.

470681 – View Existing AP Lab Orders

The system shall provide the ability for the ordering clinician to view existing AP lab orders for a specific patient to ensure duplicate orders are not created.

2.6.77.

470682/470828 – Verify No Duplicates

The system shall provide the ability to view a patient’s existing AP lab orders to verify no

duplicate orders exist.

2.6.78.

470682/470828.1 – Delete Duplicate Orders

The system shall provide the ability to delete duplicate orders.

2.6.79.

478593 – Ordering Clinician Signature

The system shall provide the ability for the ordering clinician to authenticate or sign an AP Order (e.g., CPRS) according to local policy and/or jurisdictional law so the AP order can be processed.

2.6.80.

478594/478595 – Ordering Clinician Electronic Signature

The system shall provide the ability to authenticate or sign an AP order (e.g., CPRS).

2.6.81.

478596 – CPRS Cover Sheet

The system shall provide the ability for the ordering clinician to view AP Orders in the

Lab Order Display box on the Cover sheet so that I can see recent AP Orders.

2.6.82.

478597/478598 – View AP Orders in Lab Order Display on Cover Sheet

The system shall provide the ability to view AP Orders in the Lab Order Display box on the Cover sheet.

2.6.83.

485633 – Patient Preparation Instructions

The system shall provide the ability to view patient preparation and specimen collection instructions during the ordering and collection processes to ensure the order complies with local and standard operating procedures.

2.6.84.

485633/485644 – View Local Patient Preparation Instructions

The system shall provide the ability to view the local patient preparation and collection instructions for the source specialty specimen collected.

2.6.85.

485665/485666 – View Instructions for Special Stains and Studies

The system shall provide the ability to view the local patient preparation and collection instructions for the source specialty specimen special stains and studies.

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

CPRS enhancements will be required to support the AP Order Dialog requirements. CPRS will use the current VistA RPC interfaces to retrieve and transmit Lab Order and Results data to/from VistA. LEDI will be used to transmit Lab Orders and Results to VA, DoD and Commercial Labs.

**2.8. Multi-divisional Specifications**

There are no explicit multi-divisional specifications stated for this project.

**2.9. Performance Specifications**

 There shall be no negative impact on performance or response rates.

 VA user population is estimated to 130,000 plus clinical users.

**2.10. Quality Attributes Specification**

 In accordance with the Office of the National Coordinator for Health Information Technology’s Meaningful Use Stage 2 final ruling, employ and industry recognized User Centered Design (UCD) process. The methods for UCD are well defined in documents and requirements such as ISO 9241-11, ISO 13407, ISO 16982, National Institute of Standards and Technology Interagency Report 7741, ISO/International Electrochemical Commission

62366 and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD process will not be prescribed.

 Adhere to an industry recognized User Interface (UI) Best Practices Guideline or Style Guide. Follow the UI guidelines for the defined development platform and if not available, adhere to VA’s Best Practices Guidelines/Style Guide.

 The MUMPS (M) code developed for this project will be compliant to all VA MUMPS Coding Standards and Conventions.

**2.11. Reliability Specifications**

 The AP Order Dialog must be available 24 hours a day, 7 days a week.

Consistent with VistA uptime at 99.9%.

 The system shall be available for order entry/input during periods of CPRS/EHR down time. Data stored on terminals shall be synchronized with CPRS/EHR when connectivity is reestablished.

 Scheduled down time for routine maintenance must not exceed 3 hours per week and unscheduled down time must not exceed 3 hours per month.

**2.12. Scope Integration**

The AP Order Dialog must be interoperable with other software systems including:

 Computerized Patient Record System (CPRS)

o The Computerized Patient Record System (CPRS) is a VistA computer application. CPRS enables you to enter, review, and continuously update all the information connected with any patient. With CPRS, you can order lab tests, medications, diets, radiology tests and procedures, record a patient’s allergies or adverse reactions to medications, request and track consults, enter progress notes, diagnoses, and treatments for each encounter, and enter discharge summaries. In addition, CPRS supports clinical decision-making and enables you to review and analyze patient data.

 VistA Laboratory (Lab) Package Server Software and Fileman

o The VistA packages include of VistA Lab Service and OERR packages and VistA RPC APIs that support Lab Order and Results workflow and functionality. VistA Fileman is the underlying database and file structure where the Lab data is stored. VistA Messaging provides Health Level 7 (HL7) messaging capabilities.

 VistA Order Entry Results and Reporting Package (OE/RR)

o The VistA OE/RR package handles the transmission of lab order data and results between CPRS and other VistA packages.

 VistA Laboratory Electronic Data Interchange (LEDI)

o VistA Laboratory Electronic Data Interchange (LEDI) software application provides secure and encrypted electronic messaging functionality for lab test ordering and result reporting between VA Health Care Facilities (host and collection), DoD (host and collection) and commercial laboratories (collection only). This electronic messaging functionality is based on the Health Level Seven (HL7) Version 2.3 and VistA Health Level Seven (HL7) Version 1.6 Standard Specifications. These specifications are used as the basis for defining VistA

Laboratory Universal Interface (UI) and LEDI HL7 Interface Standard

Specification Version 1.2.

 Laboratory System Re-Engineering Project (LSRP)

o The LSRP system is a Laboratory Information Management System (LIMS) for the VA Pathology and Laboratory Medicine Service (PLMS). It was developed as a replacement for the current VistA Lab system but was only deployed at one site

- the Huntington VAMC. The system uses Cerner Millennium PathNet, a

Commercial Off-The-Shelf (COTS) LIMS. The Cerner Millennium PathNet is interfaced with VistA to maintain system integration with the more than 40

applications currently receiving and/or providing information from VistA.

 COTS Specimen Labeling Application (Bar Code Expansion (BCE) – Patient

Positive Identification (PPI))

o BCE-PPI is a national project developing a COTS specimen labeling application.

**2.13. Security Specifications**

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

**2.14. System Features**

The system features introduced by this project are detailed in Section 1.2.

**2.15. Usability Specifications**

 This project shall adhere to with the Office of the National Coordinator for Health Information Technology’s Meaningful Use Stage 2 final ruling, employ and industry recognized User Centered Design (UCD) process. The methods for UCD are well defined in documents and requirements such as ISO 9241-

11, ISO 13407, ISO 16982, National Institute of Standards and Technology

Interagency Report 7741, ISO/International Electrochemical Commission

62366 and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD process will not be prescribed.

 Adhere to an industry recognized User Interface (UI) Best Practices Guideline or Style Guide. Follow the UI guidelines for the defined development platform and if not available, adhere to VA’s Best Practices Guidelines/Style Guide.

Where applicable, the following table details Usability/User Interface Requirements:

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| **Identifier** | **Usability/User Interface Requirements** |
| NONF2661 | Left align content in table cells to facilitate quick visual scan. |
| NONF2662 | Left align text for column headers to facilitate visual scan and make columns and content appear more organized. |

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| **Identifier** | **Usability/User Interface Requirements** |
| NONF2663 | Use mixed case instead of all caps whenever possible (e.g., dropdown list items, table data, table headers, hyperlinks, tab names). Limit the use of “all caps” throughout the application. |
| NONF2664 | Simplify button labels. Re-label buttons to reflect standard terminology that is common in web interfaces and other applications (e.g., “Cancel”). Emphasize the action being performed in the most succinct way possible. Minimize redundancy in text/terminology that is used to convey the same action. |
| NONF2665 | Left align page/section titles to anchor titles in consistent locations regardless of window sizing. |
| NONF2666 | Labels for fields should be left aligned to facilitate quick visual scan and make forms and field groupings appear more organized. |
| NONF2667 | Avoid using acronyms or abbreviations unless (a) they are widely understood/well known or (b) there is very limited space to display the full meaning. This supports naïve user understanding. If limited space results in using a non-common acronym/abbreviation, ensure it is specified within “Help” and/or as a tooltip. |
| NONF2668 | Use colors such as red and green only for status driven content. Avoid using red for text/content, links, button labels, etc. This will reduce risk for user error, improve link discoverability, and facilitate understanding of differences in navigation/actions/content. It will also help users to isolate important status information (using red, green, etc.) from other less important information when viewing and processing information provided to them on a page. |
| NONF2669 | Provide visual separation between the navigation space and the main content area. |
| NONF2670 | Add field level validation and notification of missing information on the  same page without launching a new window or navigating to another page. |
| NONF2671 | Make all text hyperlinks appear consistent in style. |
| NONF2672 | Make drop-down selection box widths appropriate for content and visual appeal. |
| NONF2673 | Use standard and always visible radio buttons for “Yes/No” options instead of requiring the user to click in a drop down box and then click to select the “Yes” or “No” option. |
| NONF2674 | Use standard date and time selection widgets. Where date and time are selected/picked from a standard widget, also provide direct data entry to support keyboard navigation. Enable field level validation immediately upon entry. Include instructional format text within the field entry box. |
| NONF2675 | Provide standard sort behavior and visual indications on columns in all tables. |
| NONF2676 | Define and adhere to a standard model for use and design of controls, buttons, hyperlinks, and navigation elements. |

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| **Identifier** | **Usability/User Interface Requirements** |
| NONF2677 | Ensure that text is sized to be readable (for example, by using the 007 Rule to assure text size is readable for users with 20/40 vision. The formula:  Text height = .007 \* distance between eyes and screen). |
| NONF2678 | Place common navigation elements in consistent locations. |
| NONF2679 | Place critical information “above the fold” (i.e., in the top portion of the  screen that is immediately viewable). |
| NONF2680 | Use consistent screen flow models, elements, and terms to support similar workflows. |
| NONF2681 | Use consistently named buttons when actions are the same (e.g., Add vs. Save vs. Submit). |
| NONF2682 | Enable users to print views from where they are in the interface. Avoid requiring the user to “run a report” in order to print something that is viewable on the screen. |
| NONF2683 | Provide field entry tool tips at the field location. Ensure consistency across the application in field labels, formats, location of tooltips, and tool tip text. |
| NONF2684 | Provide visual indication of required fields. |
| NONF2685 | Display field labels in close proximity to entry elements. |
| NONF2686 | Use consistent elements to filter data. |
| NONF2687 | Use consistent elements to sort data. |
| NONF2688 | Use a consistent model for display, layout, and grouping of data entry fields. |
| NONF2689 | Provide alternate row shading in lengthy tables of data, form elements, etc. |
| NONF2690 | Ensure that icons are recognized by users. |
| NONF2691 | Provide some “white space” between status icons in report views, white  board views, etc. |
| NONF2692 | Auto-populate default values in entry/selection fields when possible and appropriate. |
| NONF2693 | Visually differentiate status icons from clickable icons, when appropriate. |
| NONF2694 | Define and support the appropriate user tab sequence through fields in forms in order to support keyboard navigation when entering data in forms. |
| NONF2695 | Define and adhere to standard action button placement on screens, forms, etc. |
| NONF2696 | Visually distinguish the primary action button on a page. |
| NONF2697 | Consistently use screen elements, action elements, workflow sequences within/across screens, language, etc. |
| NONF2698 | Provide error messages in user-centric language with specific instructions on the meaning of the error and how to recover from it. Use error messages and method of display consistently across the interface. |

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| **Identifier** | **Usability/User Interface Requirements** |
| NONF2699 | Provide context-specific Help. |
| NONF2700 | Do not use the term “sex” or any like abbreviations of that to represent gender. |

**2.16. Additional Non-Functional Requirements**

2.16.1.

**General Non-Functional Requirements**

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| **Identifier** | **Non-Functional Requirements (NONF) Category** |
| **System Performance Reporting Requirements**  (Note: Each system developed by the VA Office of Information and Technology (OI&T) must comply with the following mandatory requirements.) | |
| NONF-  391899 | Include instrumentation to measure all performance metrics specified in the Non-  Functional Requirements section of the Requirements Traceability Matrix (RTM). At a minimum, systems will have the ability to measure reporting requirements for Responsiveness, Capacity, and Availability as defined in the non-functional requirements section of the RTM. |
| NONF-  463749 | Make the performance measurements available to the Information Technology (IT)  Performance Dashboard to enable display of “actual” system metrics to customers and  IT staff. |
| **Operational Environment Requirements** | |
| NONF-  429605 | System response times and page load times shall be the same or better than the current  Veterans Health Information Systems Technology Architecture (VistA) system. |
| NONF-  429606 | Maintenance, including maintenance of externally developed software incorporated into the application(s), shall be scheduled during off peak hours or in conjunction with  relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance. |
| NONF-  390684 | Information about response time degradation resulting from unscheduled system  outages and other events that degrade system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence. The  notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OIT to provide accurate data in the service impact notice of the ANR. |
| NONF-  390673 | Provide a real-time monitoring solution to report agreed/identified critical system  performance parameters. |
| NONF-  391896 | Critical business performance parameters shall be identified e.g., transaction speed,  response time for screen display/refresh, data retrieval, etc. in a manner that data capture can occur to support metric reporting and support the OI&T performance dashboard display. If no such performance metrics are required or provided there will be no program specific Service Level Agreements (SLA) created, nor shall there be any active/real time monitoring through OI&T Performance Dashboard to provide the business owners any performance metrics. |

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| **Identifier** | **Non-Functional Requirements (NONF) Category** |
| NONF-  390678 | Notification of scheduled maintenance periods that require the service to be offline or  that may degrade system performance shall be disseminated to the business user community a minimum of 48 hours prior to the scheduled event. |
| **Documentation Requirements** | |
| NONF-  429609 | The training curriculum provided by the applicable Program Office shall state the  expected training and task completions time(s) for primary users and secondary users to become proficient at using any IT application or system that is enhanced or created as a result of this New Service Request (NSR). |
| NONF-  429610 | All training curricula, user manuals, and other training tools, shall be developed and/or  updated by the applicable Program Office(s) and delivered to all levels of users prior to release of any IT application or system that is enhanced or created as a result of this NSR. The curricula shall also reflect necessary updates to business processes and procedures that are changed as a result of this NSR. |
| NONF-  392051 | IT will provide the level of documentation required to support the system and maintain  operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management office for sustained operations, maintenance, and support  ([http://vaww.eie.va.gov/lifecycle/default.aspx)](http://vaww.eie.domain/lifecycle/default.aspx)) prior to approval by any VA change control board and release into production. |
| **Implementation Requirements** | |
| NONF-  429612 | Technical Help Desk support for the application shall be provided for users to obtain  assistance. |
| NONF-  390674 | The IT solution shall be designed to comply with the applicable approved Enterprise  SLA. |
| NONF-  429613 | The implementation must be completed by timeframes agreed upon by both the  Business Owner and OI&T. |
| **Data Protection/Back-up/Archive Requirements** | |
| NONF-  392156 | Based upon the criticality of the system, provide a back-up and data recovery process  for when the system is brought off-line for maintenance or technical issues/problems. |
| NONF-  431707 | Data protection measures, such as back-up intervals and redundancy shall be  consistent with systems categorized as mission critical (12 hour restoration). |
| NONF-  490900 | Provide ability to Purge AP Orders consistent with the current functionality to purge  Clinical Laboratory Orders in VistA. |
| **Data Quality/Assurance Requirements** | |
| NONF-  391305 | A monitoring process shall be provided to ensure that data is accurate and up-to-date  and provides accurate alerts for malfunctions while minimizing false alarms. |
| **User Access/Security Requirements** | |
| NONF-  390698 | Ensure the proposed solution meets all VHA Security, Privacy, and Identity Management  requirements including VA Handbook 6500 (see the Enterprise Requirements section of the RTM). |
| **Usability/User Interface Requirements** | |
| NONF-  392110 | Adhere to good User Interface/User Centered Design (UI/UCD) principles as outlined in  the User Interface/User Centered Design Principles Appendix of the BRD. |

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| **Identifier** | **Non-Functional Requirements (NONF) Category** |
| **VistA Evolution (VE): Conceptual Integrity** | |
| NONF-  392052 | Provide standards based messaging and middleware infrastructure needed to support  both Legacy Veterans Health Information Systems Technology Architecture (VistA) and future VistA 4 deployments. |
| **VE: Availability** | |
| NONF-  392024 | Maintenance window, including maintenance of externally developed software  incorporated into the VistA 4 application(s), will be by mutual agreement between OI&T and the VHA Point of Contact (POC) for the affected facility(ies). VHA will provide POCs for each facility. |
| NONF-  392338 | VistA application unavailability due to an unplanned outage or planned outages that exceed the defined maintenance window will not exceed 8.76 hours per year and will not  exceed 43.8 minutes per month (99.9% availability). |
| NONF-  392336 | The application shall be available 24 hours a day, seven days a week, with an uptime of  99.9%. |
| NONF-  392335 | All system updates and scheduled maintenance should occur between the hours of  1800 and 0600 (per local time), when clinical usage would be lightest. |
| **VE: Interoperability** | |
| NONF-  392343 | The system shall support all recognized health system standards i.e., Health Level 7  (HL7), Fast Healthcare Interoperability Resources  ([http://www.hl7.org/implement/standards/fhir/overview.html).](http://www.hl7.org/implement/standards/fhir/overview.html)) |
| NONF-  392346 | Systems must be heterogeneous and agnostic for operating systems and code bases. |
| NONF-  392345 | Provide the ability to securely transfer large files (of 4-8 gigabyte) from an external  source to VA systems. |
| NONF-  392350 | Provide access to the system over a remote access solution, maintaining normal  baseline performance. |
| **VE: Manageability** | |
| NONF-  392352 | Provide Service Desk/Incident and Problem Management tracking related to  maintenance events of patient care systems with priority over non-patient care systems. |
| NONF-  392344 | Provide data related to maintenance events, both routine and exceptional, including key  metadata:  • Predicted routine work  • Occurrences where maintenance is completed, including restart from down time  • Identity of the organization performing maintenance  • User performing maintenance (if available)  • Identity of the system  • Date/time, physical location  • Systems impacted  • Does it affect patient care  • Non-urgent or emergent |
| NONF-  392355 | Provide audit capabilities for system access and usage with settings that are configurable to support internal and external audits based on federal and VHA  mandates. |
| NONF-  490901 | Provide audit capabilities for any changes to an AP Order Dialog once it is initially  entered. |

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| **Identifier** | **Non-Functional Requirements (NONF) Category** |
| NONF-  392362 | The system must comply with VA Directive 6300 Records and Information Management  and with VHA Records Control Schedule (RCS) 10-1, in general and specifically with Electronic Final Version of Health Record: Destroy/Delete 75 years after last episode of patient care, or longer (if specified). |
| **VE: Performance** | |
| NONF-  392347 | Provide an Infobutton Query Responder on all platforms with a response time of less  than .5 seconds. |
| NONF-  392351 | The system shall recognize, report, and retransmit data lost, with less than 0-1% chance  of incomplete patient records. |
| NONF-  392348 | Provide patient data (for data within the system) transactions (e.g., capture, search,  request for data) within .5 seconds. |
| NONF-  392349 | Mouse or key-based UI controls, e.g., menus, checkboxes shall provide instantaneous responsiveness (<90ms). |
| NONF-  392342 | Part-screen refreshes after user action shall complete within a pro-rated interval between 200 ms and 1200 ms times a percentage of the screen area being refreshed.  For example, a component 10% of the screen area would refresh in (1200 – 200) \* 0.10  + 200 = 300 ms. |
| **VE: Reliability** | |
| NONF-  392353 | Provide system reliability:  • Threshold = 99.9%  • Objective = 99.99% system and application |
| NONF-  392354 | Provide system reliability:  • Level 1 severity =<1 failure per month  • Level 2 severity =<2 failures per month  • Level 3 severity =<3 failures per month |
| **VE: Security** | |
| NONF-  392360 | Provide management of electronic attestation of information including the retention of  the signature of attestation (or certificate of authenticity) associated with incoming or outgoing information. |
| **VE: Supportability** | |
| NONF-  392363 | Provide alerts (that extend beyond system messages to external systems like mobile  devices) for malfunctions, while preventing false alarms for local, regional, and national evaluations in real time. |
| NONF-  436333 | Provide national, regional and local reports on performance metrics as specified in the  VistA 4 Effectiveness and Value / Benefits Framework [(http://go.va.gov/6rs9)](http://go.domain/6rs9)) on a bi- weekly basis. |
| NONF-  392356 | Provide performance metrics (from request for information to receipt of information on  the screen) monitored by the system and system administrators so they know what the user experience is like without users having to call them and tell them the system is running very slow. |
| NONF-  392357 | Provide the ability for VHA and IT staff to create standard and ad-hoc reports of usage, bandwidth, response time, login time, and other variables with a verification process for  measuring the capabilities of the system. |
| NONF-  392359 | Provide end-user training on how to generate the various system performance reports  (e.g., in standard file formats such as Comma Separated Values [CSV], Portable  Document Format [PDF], or Excel) depending on the user's needs. |

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| **Identifier** | **Non-Functional Requirements (NONF) Category** |
| NONF-  392364 | Provide the ability to view system statistics (e.g., information on the specific network  environment) and identify areas that are having issues or are beyond capacity, in near- real-time (to be quantified at a later time). |
| NONF-  392365 | Technical Help Desk support for the application via instant message, on-line, phone, and  remote desktop access support, shall be provided for users to obtain assistance 24/7. |
| NONF-  392366 | The IT solution shall be designed to comply with the applicable approved Enterprise  SLAs. |
| NONF-  392367 | Data protection measures, such as back-up intervals and redundancy shall be  consistent with systems categorized as mission critical (1hr restoration, 2hrs backup recovery). Impact of system failure must be monitored on a near real time basis. |
| NONF-  392386 | Provide the ability to set thresholds and notification type (e.g., email or text alerts) when  alerting the user about response time degradation and unscheduled outages. |
| NONF-  392388 | Disaster Recovery Plans (DRP) and Continuity of Operations Plan (COOP) will be  updated and tested semi-annually to address the VistA 4 product (see National Security and Homeland Security Presidential Directive: National Continuity Policy. NSPD-  51/HSPD-20, May 9, 2007 <http://www.fas.org/irp/offdocs/nspd/nspd-51.htm)> |
| **VE: Usability** | |
| NONF-  392379 | Provide viewability/usability of VistA 4 applications on mobile devices. |
| NONF-  392368 | User prompts and screen help shall be embedded into the system to guide use of the  solution. |
| **VE: Documentation** | |
| NONF-  392387 | The training curriculum shall be provided in two hours or more of training time for  primary users and secondary users to become proficient at using the VistA 4 application(s). |
| NONF-  392375 | All training curricula, user manuals and other training tools shall be developed/updated  by the VE Program Office and delivered to all levels of users 4 weeks in advance of the release of the enhancement through mediums that will best support the sharing of information to all affected staff. |
| NONF-  392382 | Provide follow-up training classes tailored to VHA workflow 4 weeks after the users have  begun to use the system. |

2.16.2.

**Enterprise Requirements**

**Identifier Requirement**

**Type**

**Description**

NONF-

413868

508

Compliance

(Standard)

All Section 508 requirements will be adhered to. Compliance with Section 508 will be determined by fully meeting the applicable requirements as set forth in the VHA Section 508 checklists (1194.21,

1194.22, 1194.24, 1194.31 and 1194.41) located at: [http://www.ehealth.va.gov/508/resources\_508.html](http://www.ehealth.domain/508/resources_508.html) or as otherwise specified. Checkpoints will be established to ensure that accessibility is incorporated from the earliest possible design or acquisition phase and successfully implemented throughout the project.

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| **Identifier** | **Requirement**  **Type** | **Description** |
| NONF-  411349 | Business  Intelligence / Analytics | The system requires the capability to generate aggregate reports as  needed (e.g., Meaningful Use Quality Measures, quality monitoring, performance accountability, research initiatives, etc.), with the ability to strip personally identifying information. Structured clinical data will be collected according to recognized standards within Meaningful Use (SNOMED, LOINC, RxNorm, etc). The system requires a variety of reporting tools (e.g., patient-centric, facility-centric, region/service- centric, enterprise-level, and population-based, etc.). These reporting tools shall be relevant, adaptable and easily used by the end-user. The reports generated and their associated data shall also be easily exportable. The system requires the capability to identify, track, and report aggregate performance stratified by key patient characteristics such as gender, race/ethnicity, Benefit Category, diagnostic categories (e.g., mental illness diagnoses, etc.) and other factors, in order to track health disparities and address the needs of vulnerable populations. System tools may include predictive modeling. It is imperative that impact on workflow (both system performance and healthcare team  processes and outcomes) is tracked when modifications are made to the system. |
| NONF-  411350 | Cognitive  Support / Knowledge Management / Clinical Decision Support (for CDS requests only) | The system shall provide ready access to cognitive support, knowledge  management, and clinical decision support (CDS) tools that will prompt the user in context-sensitive ways that are appropriate for the patient, provider, and healthcare setting. CDS tools will leverage such resources as VA-DoD evidence based practice guidelines, appropriateness criteria, treatment algorithms and clinical protocol/pathways, drug and disease reference information sources, risk and similar mathematical calculators, and other tools and resources that will be defined in the future. CDS systems will support clinical practice that is concordant with evidence- based guidelines where appropriate, while capturing exceptions within the individualized patient care plan. CDS systems should be designed  with workflow, patient safety, and patient-centered care in mind. CDS will be utilized in a manner consistent with usability criteria in section 8.3.9 and provide CDS at key points within the clinical workflow without  causing hindrance. Cognitive support for health care professionals and patients will be model-driven and will help end-users place the data into context in ways that make clinical sense for that patient and support shared decision-making between patient and clinician. CDS tools will build on model-driven cognitive support to integrate patient-specific data and evidence-based practice guidelines and research results into daily practice. Cognitive support shall provide relevant information to prevent defined clinical errors and function to address patient safety, improved quality, improve efficiencies and enable cost reductions. The system  shall facilitate the users’ ability to do what is “right” and make it difficult to make errors in the provision of best practice healthcare. To that end, the system shall rely on Guidance-Based methods and provide recommendations based on Clinical Practice Guidelines (CPGs)/Diagnosis/Standard treatment options, but avoid interfering with patient treatment decisions. The system shall provide guidance tailored  to be as specific as possible to the patient being treated utilizing patient- specific data (e.g., relevant labs, the problem list, relevant medications, antimicrobial profiles, and context-specific diagnostic and treatment recommendations). The CDS system will allow multiple capabilities to access the same CDS widgets. Each CDS widget will access a |

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| **Identifier** | **Requirement**  **Type** | **Description** |
| centralized CDS database. It is important that there is flexibility in the  CDS capability in order to stimulate innovation and include emerging capabilities (e.g., predictive modeling, text mining, population and public health considerations, and mobile tools for remote activity monitoring) and data integration. | | |
| NONF-  411345 | EHR  Certification / Meaningful Use | The Electronic Health Record (EHR) shall be certified and be compliant  with the standards, specifications, and certification criteria issued by HHS and maintain that certification throughout its lifecycle. EHR Certification includes Meaningful Use requirements. The EHR shall adhere to all Meaningful Use Objectives and Standards for Eligible Providers and Eligible Hospitals (42 CFR 495.6(d)-(g)) as published or modified through the Office of National Coordinator from the Health Information Technology Policy and HIT Standards Committees, as well as Certification Criteria (45 CFR 170.302, 170.304, &170.306) and Standards (45 CFR 170.205, 170.207, & 170.210). |
| NONF-  413836 | Executive  Order  (Standard) | All executive order requirements will be adhered to. |
| NONF-  413850 | Identity  Management  (Standard) | All Enterprise Identity Management requirements will be adhered to.  These requirements are applicable to any application that adds, updates, or performs lookups on persons. |
| NONF-  411347 | Interoperability | The system shall be compliant with the interoperability standards, specifications, and certification criteria issued by the U.S. Department of  Health and Human Services (HHS). |
| NONF-  411348 | Patient Driven  Care and Care  Coordination | The system shall have the capability of incorporating patient self-entered  data in order to provide context-specific care. This may include results of home monitoring and patient-reported functional outcomes (e.g., Veterans RAND 12-Item Health Survey, Functional Independence Measurement, Patient Health Questionnaire-9, Patient Reported Outcomes Measurement Information System, etc.) provided as  structured documents that use structured encoded data elements. The system shall support self-entered data by authenticated patients and clearly identify this as patient-entered data so that providers may  consider this in their review and interpretation. Authenticated and labeled self-entered data will be available across applications. The system must capture in standard format (e.g., Health Level 7 Clinical Document Architecture) the plan of care (including individualized treatment considerations and goals) which will be shared with the patient and members of the treatment team. The system shall generate a summary record that meets Meaningful Use standards. The system shall have the capability to generate, at all user-defined levels, a list and summary of all patients meeting defined criteria (e.g., diagnosis of diabetes), for purposes of panel management and care coordination. The system shall be compliant with and support the criteria of the National Committee for Quality Assurance (NCQA) for Patient Centered Medical Home, Level 3 recognition program. |
| NONF-  413859 | Privacy  (Standard) | All VA Privacy requirements will be adhered to. Efforts that involve the collection and maintenance of individually identifiable information must  be covered by a Privacy Act system of records notice. |

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| **Identifier** | **Requirement**  **Type** | **Description** |
| NONF-  413863 | Security | All VA security requirements will be adhered to. Based on Federal  Information Processing Standard 199 and National Institute of Standards and Technology (NIST) SP 800-60, recommended Security Categorization is High.  The Security Categorization will drive the initial set of minimal security controls required for the information system. Minimum security control requirements are addressed in NIST SP 800-53 and VA Handbook 6500, Appendix D. |
| NONF-  430024 | Terminology  Services | Utilize nationally standardized terminology for all terms used in the  solution. |
| NONF-  413871 | Terminology  Services  (Standard) | Application/services shall reference Standard Data Services as the authoritative source to access non-clinical reference terminology. |
| NONF-  413874 | Terminology  Services  (Standard) | Application/Services shall use VA Enterprise Terminology Services as  the authoritative source to access clinical reference terminology. |
| NONF-  413873 | Terminology  Services  (Standard) | Applications recording the assessments and care delivered in response  to an Emergency Department visit shall conform to standards defined by the VHA-endorsed version of C 28 – Health Information Technology Standards Panel (HITSP) Emergency Care Summary Document Using Integrating the Healthcare Enterprise (IHE) Emergency Department Encounter Summary (EDES) Component. |
| NONF-  413875 | Terminology  Services  (Standard) | Applications exchanging data summarizing a patient’s medical status  shall conform to standards defined by the VHA-endorsed version of C 32  – HITSP Summary Documents Using HL7 Continuity of Care Document  (CCD) Component. |
| NONF-  411313 | Terminology  Services  (Standard) | Provide the ability to express all content using nationally recognized reference and authoritative terminology standards (e.g., Logical  Observation Identifiers, Names, and Codes [LOINC] and Systematized  Nomenclature of Medicine Clinical Terms [SNOMED CT], etc.). |
| NONF-  413870 | Terminology  Services  (Standard) | Provide the ability to record observations using standardized terms. |
| NONF-  413872 | Terminology  Services  (Standard) | Provide the ability for users to submit a request to Standards and  Terminology Services for new standardized terms (e.g., via New Term  Rapid Turnaround process). |
| NONF-  411351 | VE: HIPAA | Computer systems shall track accounting of disclosure information when the system is accessed by a non-VA user. |
| NONF-  411346 | VE: HIPAA | Computer systems shall allow for the correction or amendment of any  piece of individually identifiable information. |

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| **Identifier** | **Requirement**  **Type** | **Description** |
| NONF-  413848 | VE: Identity  and Access  Management | All Enterprise Identity and Access Control requirements will be followed.  These requirements are applicable to any application that uses or manages identity information, and/or requires control of user access at any level.For specific guidance refer to the Enterprise Identity and Access Management BRD (https://vaww.portal2.va.gov/sites/infosecurity/projects/Identity%20And%  20Access%20Management/SignedOfficial%20Documents/Forms/AllItem s.aspx). Adherence to the guidance provided in these documents ensures compliance with NIST Access management policies as well as FICAM Guidance. |
| NONF-  413843 | VE: Identity  Services | All Enterprise Identity Management requirements will be followed. These  requirements are applicable to any application that adds, updates, or performs lookups on persons.  For specific guidance refer to the Identity Services BRD [http://tspr.vista.med.va.gov/warboard/anotebk.asp?proj=1385&Type=Acti](http://your_srver.domain.ext/warboard/anotebk.asp?proj=1385&amp;Type=Acti) ve  Adherence to the guidance provided in these documents ensures compliance with NIST Access management policies as well as Federal Identity, Credential, and Access Management (FICAM) Guidance. |
| NONF-  413869 | VE: Security  and Privacy | All VA security requirements as defined in VA Handbook 6500 shall be  followed. To assist BRD development, the Security Requirements Steering Committee (SRSC) has made available an authoritative extract of those requirements. |
| NONF-  413867 | VE: Security  and Privacy | All NIST SP 800-53 security control family requirements shall be  followed. An extract of VA cross-cutting enterprise security and privacy requirements (categorized by current NIST SP 800-53 security control families) is available from the VA SRSC. |
| NONF-  432211 | VE: Security and Privacy | Relevant Health Insurance Portability and Accountability Act (HIPAA)  security and privacy requirements shall be followed. An extract of HIPAA requirements is available from the VA SRSC. An extract of HIPAA security requirements to be implemented in health care-related projects is available from VHA Health Care Security Requirements. |
| NONF-  413839 | VE: Security and Privacy | Provide data sensitivity and segmentation support for HL7 Version 3  Standard: Privacy, Access and Security Service; Release 1, Section  6.1.1, table 5: Data Segmentation Business Requirements. |

2.16.3.

**HIPAA Security Requirements**

The following HIPAA Security Requirements are standardized.

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| **Identifier Description** |
| 411316 Information system shall implement reasonable and appropriate security  164.308 (a)(1)(ii)(B).1 measures to reduce risk. |
| 411318 Information system shall implement reasonable and appropriate security  164.308 (a)(1)(ii)(B).2 measures to minimize vulnerabilities. |
| 411319 Information systems shall validate a user's right of access (authorization) to  164.308 (a)(4)(ii)(B).2 electronic Personal Health Information (ePHI). |
| 411320 Information system shall monitor user log-in attempts.  164.308 (a)(5)(ii)(C).2 |

411334

164.308 (a)(5)(ii)(C).3

411332

164.308 (a)(5)(ii)(C).4

411330

164.308 (a)(5)(ii)(C).5

411336

164.308 (a)(5)(ii)(D).1

411322

164.308 (a)(5)(ii)(D).2

411325

164.308 (a)(5)(ii)(D).3

411323

164.312 (a)(1).1

411321

164.312 (a)(2)(i).1

411337

164.312 (a)(2)(i).2

411339

164.312 (a)(2)(ii).2

411333

164.312 (a)(2)(iii).1

411326

164.312 (a)(2)(iv).1

411327

164.312 (b).1

Information system shall notify user of invalid log-in attempts.

Information systems shall enforce a limit to the number of consecutive invalid user log-in attempts during a specified time period.

Information systems shall log user log-in attempts.

Information system shall provide capability to create passwords. Information system shall provide capability to change passwords. Information system shall safeguard passwords.

Information system shall implement an electronic mechanism that allows only authorized entities access to ePHI.

Information system shall assign a unique name and/or number to identify a user.

Information system shall use a unique name and/or number to track a user.

Information system shall implement a process to allow access to necessary ePHI during an emergency.

Information system shall implement electronic mechanism to terminate an electronic session after a predetermined time of inactivity.

Information system shall implement mechanism to encrypt and decrypt ePHI.

Information system shall record activity in information systems that contain or use ePHI.

411324164.312 (b).2 Information system shall examine activity in information systems that contain or use ePHI.

411338

164.312 (c)(1).1

411335

164.312 (c)(1).2

411331

164.312 (c)(2).1

411329

164.312 (c)(2).2

411328

164.312 (d).1

411342

164.312 (e)(1).1

411341

164.312 (e)(2)(i).1

Information system shall implement an electronic mechanism to protect ePHI

from improper alteration.

Information system shall implement an electronic mechanism to protect ePHI

from improper destruction.

Information system shall implement electronic mechanism to verify that ePHI

has not been altered in an unauthorized manner.

Information system shall implement electronic mechanism to verify that ePHI

has not been destroyed in an unauthorized manner.

Information system shall implement electronic mechanisms to authenticate a user.

Information system shall implement mechanisms to guard against unauthorized access to ePHI during transmission.

Information system shall implement mechanisms to verify that electronically transmitted ePHI is not improperly modified during transmission.

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| 411340  164.312 (e)(2)(ii).1 | Information system shall implement mechanisms to encrypt ePHI during  transmission. |
| 411344  164.312 (d).2 | Information system shall implement electronic mechanisms to authenticate an  interfacing system or other entity. |
| 411343  164.312 (e)(2)(ii).2 | Information system shall implement mechanisms to encrypt ePHI at rest on mobile devices or removable electronic media. |

**3. Applicable Standards**

This project will adhere to the existing Department of Veterans Affairs (VA) legacy development standards and requirements described in the Enterprise Level Requirements maintained by the Veterans Health Administration (VHA) Health Information Technology, Software Engineering and Integration, Enterprise (SEIE) Requirements Management.

Open Source Electronic Health Record Agent (OSEHRA) Gold Disc Certification. VA Enterprise VistA is the standard version adopted by the Department of Veterans Affairs for executable Class 1 code at all 133 VA Medical Center (VAMC) VistA instances. The Enterprise version is known as the “FOIA Release” of VistA. It can be accessed via the OSEHRA website.

**4. Interfaces**

The AP Order Dialog will interface with the following systems:

 Computerized Patient Record System (CPRS)

 VistA Laboratory (Lab) Package Server Software and Fileman

 VistA Order Entry Results and Reporting Package (OE/RR)

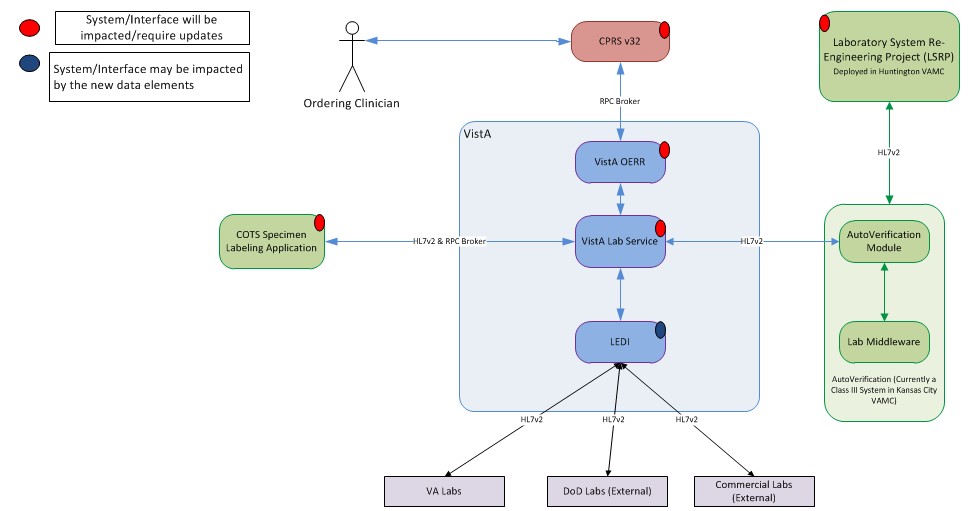
 VistA Laboratory Electronic Data Interchange (LEDI)

 Laboratory System Re-Engineering Project (LSRP)

 COTS Specimen Labeling Application part of national project, Bar Code

Expansion (BCE) – Patient Positive Identification (PPI)

The Diagram below depicts the AP Order Dialog interfaces.



**4.1. 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

**4.2. Hardware Interfaces**

 Bar Code Expansion (BCE) – Patient Positive Identification (PPI)

o Printer/device used to generate the label(s)

o Barcode scanner/reader

**Note**: Based upon input from the business analysts, this release of AP Order

Dialog will be deployed before the BCE PPI project is ready

**4.3. Software Interfaces**

Computerized Patient Record System (CPRS)

 CPRS will require enhancements to support the AP Order Dialog requirements. The CPRS team is in the process of gathering requirements for CPRS v32 which has a deployment date around September 2015. The VistA Lab team will need to work with the CPRS team to ensure AP Order dialog requirements can be incorporated into the CPRS v32 requirements in time to meet the CPRS v32 schedule.

VistA Laboratory Server Software and FileMan

 It is not clear at the present time if the new data elements being captured as part of AP Order Dialog will require changes to the VistA Lab server software and the FileMan data

structures and APIs. These requirements need to be further reviewed with the VistA Lab and FileMan teams to determine impact.

VistA Laboratory Electronic Data Interchange (LEDI)

 This electronic messaging functionality is based upon the Health Level Seven (HL7) Version 2.3 and VistA Health Level Seven (HL7) Version 1.6 Standard Specification.

 Laboratory orders are transmitted via VA VistA systems using LEDI for VA facilities and Laboratory Data Sharing and Interoperability (LDSI) software via DoD Composite Health Care System (CHCS) systems for DoD facilities using the HL7 messaging protocol over a TCP/IP connection utilizing a secure Virtual Private Network (VPN)/firewall.

 A VPN connection will be established on an isolated tunnel from the VA national gateway to DoD medical treatment facilities.

 Inbound traffic will contain released data from DoD HOST Laboratory as noted in diagram. (See documentation referenced in section 4.1)

 HL7 messages will be generated from CHCS sites, transported securely over DoD-VA VPN, and then routed to VAMCs where requests will be processed by LEDI software.

Laboratory System Re-Engineering Project (LSRP)

 The system uses Cerner Millennium PathNet, a Commercial Off-The-Shelf

(COTS) LIMS.

COTS Specimen Labeling Application – (Bar Code Expansion – Patient Positive

Identification (BCE-PPI))

**4.4. Data Requirements**

New data elements will be captured as part of the AP Order Dialog enhancements. The required data elements are documented in the following documents/links:

 **VE\_Lab\_AP\_Order\_Dialog IMSR\_V0\_1:** The Information Model Summary Report

 **VHA\_BIA\_NDO\_Analysis\_AP\_Order\_Dialog:** The mapping of Process Model Data Objects (DOs) to Normalized Data Objects (NDOs)

 **VHABA\_AP\_Order\_Dialog\_DD:** The Information Model Data Dictionary

**4.5. User Interfaces**

CPRS is the graphical user interface (GUI) for VistA lab functionality.

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

There are no changes to legal, copyright and other notices.

**6. Purchased Components**

No additional purchased components are required to execute the functionality outlined within this Requirements Specification Document (RSD).

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

N/A

**7. User Class Characteristics**

There will be no changes to user class characteristics

**8. Estimation**

N/A

1 **Project Software Functional Size and Size-Based Effort and Duration**

2 **Estimate**

3 **Application**

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| **Item** | **A** | **B** | **C** | **D** | **E** | **Total** |
| **Counted Function**  **Points** |  |  |  |  |  |  |
| **Estimated Scope**  **Growth** |  |  |  |  |  |  |
| **Estimated Size at**  **Release** |  |  |  |  |  |  |

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| **Size-Based Effort Estimates** | **Labor Hours** | **Probability** |
| **Low-Effort Estimate – With indicated probability, project will consume no more than:** |  |  |
| **High-Effort Estimate – With indicated probability, project will consume no more than:** |  |  |

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| **Size-Based Duration Estimates** | **Work Days** | **Probability** |
| **Low-Duration Estimate – With indicated probability, project will consume no more than:** |  |  |
| **High-Duration Estimate -- With indicated probability, project will consume no more than:** |  |  |

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7 **Figure 1: Cumulative Probability (“S-curve”) Chart**

**9. Approval Signatures**

REVIEW DATE: *<date>*

SCRIBE: *<name>*

Signed:

Integrated Project Team (IPT) Chair Date

Business Sponsor Date

IT Program Manager Date

Project Manager Date

**A. Acronym List and Glossary**

**Glossary**

|  |  |
| --- | --- |
| **Term** | **Meaning** |
| AP | Anatomic Pathology |
| BCE-PPI | Bar Code Expansion – Positive Patient Identification |
| BCRO | Bar Code Resource Office |
| COTS | Commercial-Off-The-Shelf |
| CPRS | Computerized Patient Record System |
| EHR | Electronic Health Record |
| HIPAA | Health Insurance Portability and Accountability Act |
| ISO | International Organization for Standardization |
| LEDI | Laboratory Electronic Data Interchange |
| LIMS |  |
| LSRP | Laboratory System Re-Engineering Project |
| MTRS |  |
| OE/RR |  |
| OI&T | Office of Information and Technology |
| PHI | Protected Health Information |
| PLMS |  |
| PII | Personally Identifiable Information |
| RCA | Root Cause Analysis |
| MUMPS (M) | Massachusetts General Hospital Utility Multi-Programming System. It is the original medical system and computer language upon which VistA was based and enhanced. |
| OERR | Order Entry Results Reporting |
| RSD | Requirements Specification Document |
| SF | Standard Form |
| SNOMED | Systemized Nomenclature of Medicine |
| SRS | Software Requirements Specification |
| STS | Standards and Terminology Services |
| VE | VistA Evolution |
| VHA | Veterans Health Administration |
| VISTA | Veterans Health Information Systems and Technology  Architecture |

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| --- | --- |
| **Term** | **Meaning** |
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VLE Anatomic Pathology Order Dialog

Requirements Specification Document 49 June 2015