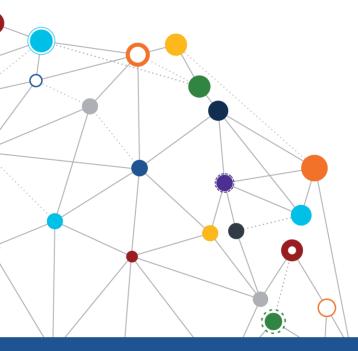
3D Printing Enterprise Design Pattern

Cloud-based 3D Printing Services July 2019 | Enterprise Program Management Office





U.S. Department of Veterans Affairs

Office of Information and Technology



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Table 1: Change Matrix

Version	Date	Description of Updates
1.0	3/2019	3D Printing Segment 2: Cloud-based 3D Printing Services
2.0	6/2019	Updated to include solutions for the immediate, interim, and future state; adjudication of stakeholder comments.



1 Context

A key application for three-dimensional (3D) printing at the Department of Veterans Affairs (VA) is 3D printed models. 3D printed models are produced from images acquired from advanced imaging procedures, such as computerized tomography (CT), magnetic resonance imaging (MRI), ultrasound (US), and 3D surface scans. Most of these images are stored in the Digital Imaging and Communications in Medicine (DICOM) format to transmit, store, retrieve, print, process, and display medical imaging information.

At VA, DICOM files currently reside on the Veterans Information Systems and Technology Architecture (VistA) Imaging System. The VistA Imaging System integrates the DICOM files with clinical images derived from endoscopy, pathology, dermatology, cardiology, and radiology procedures within each VA Medical Center (VAMC) and within health facilities external to VA.¹ The VistA Imaging System does not have a single data repository; rather, each site supports its own single storage repository for storing images. This will change as VA continues its transition to the Cerner system, where all images will migrate to Cerner's CareAware MultiMedia (CAMM) Archive. The CAMM is designed to manage all forms of multimedia and integrate multimedia with Veteran electronic health records (EHRs).²

2 Problem

VA hospitals without a 3D printer need to rely on those VA hospitals and facilities that are equipped with the 3D printer resources that are necessary to produce 3D printed models. Since the existing VA 3D printers are not connected to the VA network, their accessibility is limited. In addition, the current workflow uses locally installed software (SW) that requires license agreements; this limits the users who can access the necessary SW. As the use of 3D printing becomes more prevalent at VA, these issues have resulted in an inefficient workflow that is not scalable. The design and use of cloud-based 3D printing services will help address these issues.

Figure 1 illustrates three key pillars for establishing an agile architecture that can advance the current 3D printing technology landscape at VA, supporting future growth, as the number of 3D printers increase in quantity at VA hospitals and facilities. Each pillar is addressed in a separate *3D Printing* Enterprise Design Pattern (EDP) segment document.³ This EDP document focuses on the area that is highlighted in red.

¹ Department of Defense (DoD) facilities are external to VA.

² For additional information on CAMM, refer to https://www.cerner.com/solutions/imaging.

³ Refer to the *3D Printing* EDPs at https://www.oit.va.gov/library/recurring/edp/index.cfm.

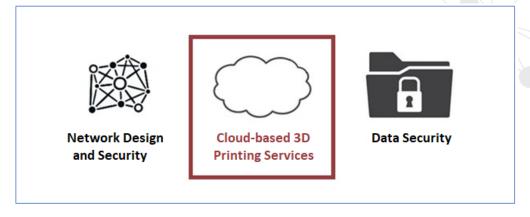


Figure 1: VA 3D Printing Pillars⁴

3 Approach

This section addresses solutions for the immediate, interim, and future state of 3D printing at VA.

3.1 Cloud-based 3D Printing Services

3.1.1 Cloud Repository

Capability for the Interim State

Since the Cerner rollout to full operational capability is not expected to be completed until 2027, there needs to be implementation of an interim central image repository for 3D printing and research. The establishment of a central internal image repository will enhance collaboration through the discovery and iterative design of existing models by implementing the following actions:



⁴ Source: Figure 1 was created by the VA Office of Information and Technology (OIT) Architecture and Engineering Service (AES) Enterprise Design Pattern (EDP) Team from information obtained from VA Subject Matter Experts (SMEs).

- Doctors, radiologists, and technicians must ensure that all 3D print files, e.g., stereolithography (STL) files⁵ and object (OBJ) files,⁶ are stored within the enterprise image repository that is located on the VA Enterprise Cloud (VAEC).⁷
 - Stored STL files must be encapsulated into DICOM files once implementation of the new DICOM standard is made available.⁸
- When a new 3D model (STL) or image file (DICOM, x-ray, etc.) is saved to the image repository, a copy of that file must be saved to the EHR for the patient.
 - The 3D printing systems architect should ensure that the 3D print file and/or model contains an identifier that can link the model to a patient. The reference or identifier should be obtained through tokenization,⁹ where the token becomes the identifier.
 - \circ $\;$ The identifier should become embedded into the 3D model.
 - \circ $\,$ If the 3D print file cannot store the identifier, the identifier should be included in the file name.

• The 3D printing system architect must ensure implementation of a file system to support the storage of metadata within the image repository.

- The minimum data required for metadata should include:
 - The name of the creator or author of the 3D print file
 - The identification of the specific printer used
 - A description of how the 3D object was made (e.g., material, etc.)
 - The file version
 - Iteration information
- Developers should create application programming interfaces (APIs) for the image repository to provide services (e.g. upload, save files) for SW modeling tools that are hosted on the VAEC.

Capability for the Future State

• Doctors, radiologists, and technicians must ensure that all 3D print files, e.g., stereolithography (STL) files and object (OBJ) files, are stored within the CAMM.

⁵ STL is a commonly used file format in 3D printing describing the surface geometry of a 3D object without any representation of color or texture. For more information, refer to https://3dprintingforbeginners.com/stl-and-obj-files-101/.

⁶ OBJ is a geometry definition file format from 3D modeling programs that is commonly used in 3D printing. It can represent texture, color and other CAD attributes of the three-dimensional object. .OBJ is also easily exported from most CAD tools and is supported by 3D printers. For more information, refer to https://3dprintingforbeginners.com/stl-and-obj-files-101/.

⁷ Refer to the VAEC SharePoint site at https://vaww.portal.va.gov/sites/ECS/SitePages/Home.aspx.

⁸ DICOM encapsulated STL Service-Object Pair (SOP) Class was added to the 2019b standard in April 2019.

⁹ For more information on tokenization, refer to https://searchsecurity.techtarget.com/definition/tokenization.

3.1.2 Hosted Software

Capability for the Interim and Future State

A move to migrate locally installed 3D printing SW modeling tools to the VAEC¹⁰ will enable a requesting party to more easily process DICOM files into 3D printer readable files. Migration plans should include the following:

- The 3D Printing Advisory Committee must approve the 3D printing SW modeling tools prior to submitting the request for VA Technical Reference Model (TRM)¹¹ assessment.
- Project teams must ensure that the 3D Printing SW modeling tools approved by the VA TRM (or approved "with constraints") are hosted on the VAEC.
- In collaboration with the Enterprise Cloud Solutions Office (ECSO), the 3D printing system architect must ensure that the 3D printing SW modeling tools that are part of a medical system are hosted on the Federal Risk and Authorization Management Program (FedRAMP)¹² high enclave of the VAEC.¹³
- Project teams must ensure that the 3D printing segmentation SW that is acquired will support DICOM Query/Retrieve (Q/R), or storage provider capabilities. These capabilities allow DICOM images residing in the image repository to be accessed. (CAMM will be the future state image repository).
- Project teams should ensure the 3D printing segmentation SW compression of DICOM files.

Capability for the Immediate State

There is an immediate need to improve the existing workflow for 3D printing before the interim solution is implemented. To accomplish this, the existing Compass Router¹⁴ will be utilized.

- Each VAMC must configure their Compass Router to connect directly with a predetermined location for the computer that will perform the segmentation on the image.
- Once an image is acquired through a specific modality (e.g., MRI, CT), the image must be routed directly to the computer that is hosting the segmentation SW tool.



¹⁰ Refer to the VAEC SharePoint Site at https://vaww.portal.va.gov/sites/ECS/SitePages/Home.aspx.

¹¹ Refer to the TRM to identify approved applications and standards on the internal VA network at http://trm.oit.va.gov/. External vendors may utilize a less comprehensive site at

https://www.oit.va.gov/services/trm/.

¹² Refer to FedRAMP at https://www.fedramp.gov/.

¹³ Refer to FIPS PUB 199, *Standards for Security Categorization of Federal Information and Information Systems*, at https://csrc.nist.gov/csrc/media/publications/fips/199/final/documents/fips-pub-199-final.pdf.

¹⁴ The Compass Router is a medical image workflow solution that permits the user to route, replicate, monitor, and alter DICOM store jobs that are based on content or schedule. (Source: http://www.laurelbridge.com/new-version-of-compass-dicom-image-router-released).

3.1.3 3D Print Job Management System

Capability for the Interim and Future State

As the use of 3D printing grows at VA, an enterprise print job management system can help (1) ensure that segmentation and/or print requests are routed to the proper locations, with the resources to handle the request; and (2) spread the workloads in a manner that maximizes the available resources. The intended users for this system include doctors, radiologists, and technicians.

The following guidance should be used to implement a print job managing system:

- Doctors, radiologists, and technicians must ensure that all 3D print job requests are sent to the enterprise print job management system hosted on the VAEC.
- Developers must design the print job management system to prioritize and route requests that are based on factors that include:
 - Required printer type and materials necessary to print the 3D model
 - Specific 3D print facility chosen by the requestor (if desired)
 - Number of print jobs in the queue for the requested printer
- Developers should design the print job management system to receive and analyze dashboard information and to aid in routing print job requests.
- Developers must design the print job management system to allow users to track/update individual segmentation/print job requests.
- Developers must design the print job management system to send notifications to users (e.g., print job requesters and 3D print facility technicians).

Compliance with these standards applies to the following scenarios:

- Accessing 3D printing SW modeling tools
- Printing a 3D model
- Accessing a 3D model file for discovery and iterative design

4 Use Cases

The following use cases illustrate how a user can print a 3D model by utilizing the 3D cloudbased services that are described in this document.

4.1 Patient-Specific Models – Immediate Solution

Assumptions

• The surgeon requests an MRI scan with the intention of creating a 3D model; the radiologist is notified to perform the scan and requests the 3D print model.

- The location of the segmentation and printing has been determined before the radiologist performs the MRI scan.
- The segmentation and printing will be performed at the same VA hospital/facility.
- The Compass Router has been configured to connect to the computer hosting the segmentation SW tool.

Use Case Description

- 1. After the radiologist performs an MRI scan, the scan is routed to the VistA Imaging System and the computer hosting the segmentation SW tool.
- 2. The radiologist specifies the information for the 3D model (e.g., type of print, cutting guide, anatomical model, prosthetic, etc.) by email to the technician who will perform the segmentation. The information includes the model description, material, DICOM file ID, and finish/post processing instructions.
- 3. The technician generates a 3D model that is suitable for printing, using the SW modeling tool.¹⁵ The ordering physician and radiologist approve the model.
- 4. The technician uploads the STL file to the 3D printer's print preparation SW, which is installed on a local machine and connected to the 3D printer.
- 5. The technician prepares the 3D printer and prints the 3D model.
- 6. The technician prepares the model for shipping to the requested VA hospital location. A confirmation notification is sent to the requesting radiologist.

Figure 2 illustrates the use case described for the immediate solution to printing a 3D model. The numbered actions in the preceding use case are represented by corresponding numbered labels in the graphic.

¹⁵ Currently, the Compass Router cannot accept STL files, so the STL file cannot be transferred to VistA Imaging to be stored as part of the Veteran's EHR. The physician can add a note to the Veteran's EHR indicating that a 3D model was printed, but not stored with the Veteran's EHR.

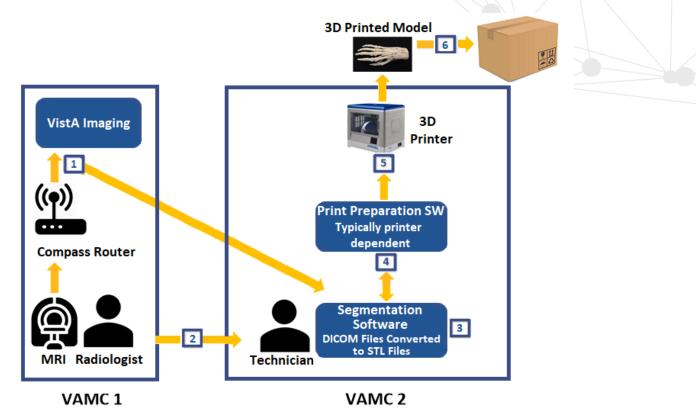


Figure 2: 3D Printing Workflow – Immediate Solution

4.2 Patient-Specific Models – Interim Solution

Assumptions

- The segmentation and printing will be performed at the same VA hospital/facility.
- The radiologist and technician are part of the 3D printing user group and have proper role-based access control (RBAC) permissions to access 3D printing SW tools (i.e., segmentation SW and 3D Print Job Management System).
- The surgeon requests an MRI scan with the intention of creating a 3D model; the radiologist is notified to perform the scan and requests the 3D print model.

Use Case Description

- 1. After the radiologist performs an MRI scan, the scan is routed to the VistA Imaging System and the image repository.
- 2. The radiologist logs in to the 3D Print Job Management System that is hosted on the VAEC to request a 3D print model.
- 3. The radiologist specifies the information for the 3D model (e.g., type of print, cutting guide, anatomical model, prosthetic, etc.), including model description, material, DICOM



file ID, and finish/post processing instructions. The 3D Print Job Management System determines which 3D printer to use, based on the information provided by the radiologist.

- 4. The 3D Print Job Management System sends a notification to the VA hospital/facility with the identification of the proper 3D printer to print the model.
- 5. A technician at this VA hospital/facility receives the request and logs in to the segmentation SW tool that is hosted on the VAEC.
- 6. The technician utilizes the SW tool's DICOM Q/R capability to retrieve the DICOM file from the image repository. The technician generates a 3D model that is suitable for printing, using the SW modeling tools hosted on the VAEC.
- 7. The 3D model and associated native files, such as STL, computer-aided design (CAD), etc., are stored in the:
 - a. Image repository
 - b. Vista Imaging (to maintain a copy with the patient's EHR)
- 8. The ordering physician and radiologist approves the model. The technician downloads the STL file to the 3D printer's print preparation SW, which is installed on a local machine and connected to the 3D printer.
- 9. The technician prepares the 3D printer and prints the 3D model.
- 10. The technician updates the status of the print request on the 3D Print Job Management System.
- 11. The technician prepares the model for shipping to the requested VA hospital location. A confirmation notification is sent to the requesting radiologist.

Figure 3 illustrates the use case described for the interim solution to printing a 3D model, utilizing the cloud-based 3D printing services from a DICOM file. The numbered actions in the preceding use case are represented by corresponding numbered labels in the graphic.

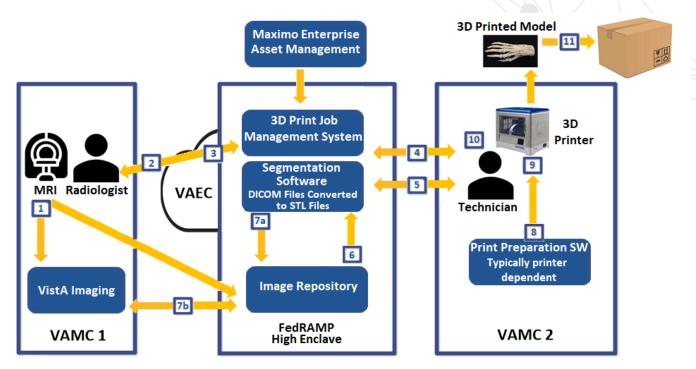


Figure 3: 3D Printing Workflow – Interim Solution¹⁶

4.3 Patient-Specific Models – Future Solution

Assumptions

- The segmentation and printing will be performed at the same VA hospital/facility.
- The radiologist and technician are part of the 3D printing user group and have proper RBAC permissions to access 3D printing SW tools (i.e., segmentation SW and 3D Print Job Management System).
- The surgeon requests an MRI scan with the intention of creating a 3D model; the radiologist is notified to perform the scan and requests the 3D print model.

Use Case Description

1. After the radiologist performs an MRI scan, the scan is routed to the CAMM.

¹⁶ Source: Figure 3 was created by the VA Office of Information and Technology (OIT) Architecture and Engineering Service (AES) Enterprise Design Pattern (EDP) Team from information obtained from VA Subject Matter Experts (SMEs).

- 2. The radiologist logs in to the 3D Print Job Management System that is hosted on the VAEC to request a 3D print model.
- 3. The radiologist specifies the information for the 3D model (e.g. type of print, cutting guide, anatomical model, prosthetic, etc.), including model description, material, DICOM file ID, and finish/post processing instructions. The 3D Print Job Management System determines which 3D printer to use, based on the information provided by the radiologist.
- 4. The 3D Print Job Management System sends a notification to the VA hospital/facility, with the proper 3D printer to print the model.
- 5. A technician at this VA hospital/facility receives the request and logs in to the segmentation SW tool that is hosted on the VAEC.
- 6. The technician utilizes the SW tool's DICOM Q/R capability to retrieve the DICOM file from the CAMM. The technician generates a 3D model that is suitable for printing, using the SW modeling tools hosted on the VAEC.
- 7. The 3D model and associated native files, such as STL, computer-aided design (CAD), etc., is stored in the CAMM.
- 8. The ordering physician and radiologist approves the model. The technician downloads the STL file to the 3D printer's print preparation SW, which is installed on a local machine and connected to the 3D printer.
- 9. The technician prepares the 3D printer and prints the 3D model.
- 10. The technician updates the status of the print request on the 3D Print Job Management System.
- 11. The technician prepares the model for shipping to the requested VA hospital location. A confirmation notification is sent to the requesting radiologist.

Figure 4 illustrates the use case described for the future solution to printing a 3D model, utilizing the cloud-based 3D printing-services from a DICOM file. The numbered actions in the preceding use case are represented by corresponding numbered labels in the graphic.

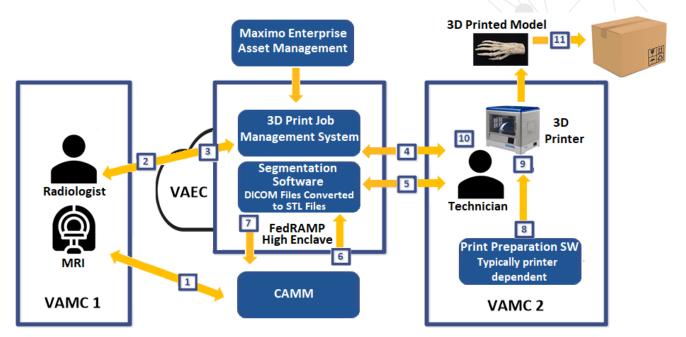


Figure 4: 3D Printing Workflow – Future Solution

5 Impacts

If project teams do not adhere to cloud-based 3D printing services guidelines, the following negative impacts may be realized:

- Inefficient workflow for 3D printing that is not scalable
- Inefficient use of SW licenses
- Ability to search for existing 3D models and perform iterative design
- Inefficient use of existing 3D printing resources
- Difficulty in sharing DICOM files



Appendix A: References

• NIST 800-53 Security and Privacy Controls for Federal Information Systems and Organizations:

https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf

- VA Directive 6550:
- https://www.va.gov/vapubs/viewPublication.asp?Pub_ID=790&FType=2
- VA Directive 6551: https://www.va.gov/vapubs/viewPublication.asp?Pub_ID=829&FType=2_
- VA EDPs: <u>https://www.oit.va.gov/library/recurring/edp/</u>
- VA DEA User Stories: <u>https://vaww.portal2.va.gov/sites/asd/TechStrat/IPTS/External%20Documents/DEA%20</u> <u>User%20Stories%20v2.3%20(ACTIVE).doc</u>
- VA TRM: <u>http://trm.oit.va.gov/</u> and <u>https://www.oit.va.gov/services/trm/</u>
- VIP Guide: <u>https://vaww.vaco.portal.va.gov/sites/OIT/epmo/vip/Policy%20%20Guidance/VIP%20G</u> <u>uide%203.2.pdf</u>



Appendix B: Description of Complex Figures

Figure 1: The VA 3D Printing Pillars graphic shows three pillar images of agile architecture for 3D printing at VA. The first is titled Network Design and Security, with an image of interconnected lines and points. The second image is titled Cloud-based 3D Printing Services, with an image of a cloud. A red border surrounds the image to denote that it is the subject of this segment. The third image is titled Data Security, with an image of a lock on a file folder.

Figure 2: Figure 2 illustrates the use case described for the immediate solution to printing a 3D model. The 3D Printing Workflow - Immediate Solution graphic is described in detail in the use case in Section 4.1. The graphic displays a corresponding numbered label for each numbered action that is described under the heading, Use Case Description.

The graphic shows two text boxes displayed horizontally: VAMC 1 and VAMC 2. An MRI icon and a radiologist icon are displayed horizontally at the bottom of the VAMC 1 text box. An adjacent arrow points upward to a Compass Router icon in the VAMC 1 text box. The Compass Router points upward to a VistA Imaging label in the VAMC 1 text box. An arrow extends from the VistA Imaging label in the VAMC 1 text box. An arrow extends from the VistA Imaging label in the VAMC 1 text box. The radiologist icon in the VAMC 1 text box points to the Technician icon in the VAMC 2 text box. The radiologist icon in the VAMC 1 text box points to the Technician icon in the VAMC 2 text box. The Segmentation Software label in the VAMC 2 text box points upward to the Print Preparation Software label (which includes the words, typically printer dependent). The Print Preparation Software points upward to the 3D Printer icon, which points upward to a 3D Printed Model icon points to the shipping box icon, which is also displayed above the VAMC 2 text box.

Figure 3: Figure 3 illustrates the use case described for the interim solution to printing a 3D model, utilizing the cloud-based 3D printing services from a DICOM file. The 3D Printing Workflow - Interim Solution graphic is described in detail in the use case in Section 4.3. The graphic displays a corresponding numbered label for each numbered action that is described under the heading, Use Case Description.

The graphic displays three text boxes horizontally: the VAMC 1; the FedRAMP High Enclave, shown as part of the VAEC by overlapping a VAEC icon; and the VAMC 2. The VAMC 1 text box displays an MRI icon and a radiologist icon horizontally at the top of the text box. An adjacent arrow points downward to a VistA Imaging label near the bottom of the VAMC 1 text box. An arrow extends from the VistA Imaging label in the VAMC 1 text box to an Image Repository label at the bottom of the FedRAMP High Enclave text box. The Image Repository label uses two arrows to point to and from the Segmentation Software label (that includes the words, DICOM files converted to STL files) above it in the FedRAMP High Enclave text box. A 3D Print Job Management System label in the FedRAMP High Enclave text box is situated above the Segmentation Software label. The Maximo Enterprise Asset Management label is above the FedRAMP High Enclave text box and points downward to the 3D Print Job Management System label that is inside the FedRAMP High Enclave text box. Two arrows point from the 3D Print Job Management System label and the Segmentation Software label in the FedRAMP High Enclave text box to the technician icon in the VAMC 2 text box. A Print Preparation Software label in the VAMC 2 text box points upward to a 3D Printer icon in the VAMC 2 text box, which points to a 3D Printer Model icon above the VAMC 2 text box. The 3D Printer Model icon points to the shipping box icon that is also above the VAMC 2 text box.



Figure 4: Figure 4 illustrates the use case described for the future solution to printing a 3D model, utilizing the cloud-based 3D printing-services from a DICOM file. The 3D Printing Workflow - Future Solution graphic is described in detail in the use case in Section 4.4. The graphic displays a corresponding numbered label for each numbered action that is described under the heading, Use Case Description.

The graphic displays three text boxes horizontally: The VAMC 1; the FedRAMP High Enclave, shown as part of the VAEC by overlapping a VAEC icon; and the VAMC 2. An MRI icon and a radiologist icon are displayed vertically in the VAMC 1 text box. The FedRAMP High Enclave text box vertically displays a Segmentation Software label (that includes the words, DICOM files converted to STL files) and above it, a 3D Print Job Management System label (which includes the words, typically printer dependent). A Maximo Enterprise Asset Management label situated above the FedRAMP High Enclave text box, points to the 3D Print Job Management System label in the FedRAMP High Enclave text box. The radiologist icon in the VAMC 1 text box points to the Print Job Management System label in the FedRAMP High Enclave text box. The radiologist icon in the VAMC 1 text box. The MRI icon in the VAMC 1 text box points to a CAMM label that is situated below the FedRAMP High Enclave text box. In the FedRAMP High Enclave text box, the 3D Print Job Management System label use two arrows to point to the technician icon in the VAMC 2 text box. The Print Preparation Software label in the VAMC 2 text box points to the 3D Printer icon above it. The 3D Printer icon in the VAMC 2 text box points to the 3D Printer icon, which is also above the VAMC 2 text box.



Appendix C: Additional Use Cases

C.1 Orthotics

Assumptions

- The image repository will contain all imaging files from all instances of VistA Imaging Systems.
- Whenever a new image is stored to the VistA Imaging System, a copy will be sent to the Image Repository.
- The segmentation and printing will be performed at the same VA hospital/facility.
- The orthotist and technician are part of the 3D printing user group and have proper RBAC permissions to access 3D printing SW tools (i.e. segmentation SW and 3D Print Job Management System).

Use Case Description

- An orthotist¹⁷ performs a 3D surface scan.
- The orthotist sends the surface scan to the Vista Imaging system.
- The orthotist logs in to the 3D print job management system that is hosted on the VAEC and requests a 3D printed model.
- The orthotist specifies the information for the 3D model; e.g. type of print ("hand brace"), model description ("surface scan, left hand"), material ("SLS Nylon"), surface scan file name, and finish/post processing instructions.
- The 3D Print Job Management System determines which 3D printer to use, based on the information provided by the orthotist.
- The 3D Print Job Management System sends a notification to the VA facility with the selected 3D printer.
- A technician at the VA facility receives the request.
- The technician utilizes the SW tool's DICOM Q/R capability to retrieve the DICOM file from the Image Repository.
- The technician creates an STL from the orthotic model using software on the VAEC and saves the file to the image repository.
- The requestor approves the model.
- The technician downloads the STL file to the 3D printer's print preparation SW that is installed on a local machine and connected to the 3D printer.
- The technician prints the 3D model.

¹⁷ An orthotist specializes in orthotics, a medical specialty that focuses on the design and application of orthoses. An orthosis is an externally applied device used to modify the structural and functional characteristics of the neuromuscular and skeletal system.

- The VAEC Job Management System monitors the print, delivering real time status, and notifies the requestor when the print is complete.
- The technician post processes the printed model and delivers the model to the requestor.

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