VA Medical Equipment Pre-Procurement Assessment

(*Indicates field is completed by Biomedical Engineering)

*Equipment Category (VA-MDNS):	*Vendor:
*Requesting Service:	*Model:
*Requestor:	Vendor Contact:
*Installation Location: (Room-Bldg-Division):	If server based, specify rack space and power requirements:
*Biomedical Engineering Point of Contact:	*MDIA VLAN Number for Installation:
*Equipment Description (i.e., layman's description of equipment function and systems it communicates with):	
*If Biomedical Engineering is NOT the Primary System Manager for system management and maintenance, please note the responsible department below. Other	

Medical Device /System Configuration

What OS and version/Service Pack does the system utilize (e.g., Win7- SP1, Win Svr 2008, Linux)?		
Does the system use a database application to operate?	Yes	No
If yes, specify which application/version:		
Membership in the facility's Windows Domain is: Required Recommended Not Recommended N/A		
Is a desktop web browser required to access the medical system/application?	Yes	No
If yes, specify which browsers and versions are supported: If yes, does it require the use of https: and the VA SSL certificates – explain below:		
If a browser is required, does it require a specific version of Java?	Yes	No
If yes, specify the version:		
Is ActiveX required for client operation?	Yes	No
If yes, specify configuration requirements:		
If Windows based, can the system use the National Medical Device Update Server for OS patches?	Yes	No
If no, specify how OS patching will be accomplished:		
Can critical and routine OS and system security patches be applied as they become available without prior vendor approval?	Yes	No
If no, specify how approval notification to VA will be accomplished:		

Can the device support the use of McAfee Anti-Virus (AV) software?	Yes	No
If no, what AV packages and versions are supported and describe the mechanism to provide updates.		
Can USB ports be disabled on the device without compromising operation?	Yes	No
Can auto run be disabled for portable media?	Yes	No
Can VA install host-based security components such as a firewall, host intrusion prevention system (HIPS), anti-malware software, and/or any other security suite software required to operate on the VA production network?	Yes	No

If "No" is the response to any of the above questions regardiung updates and anti-virus software, please explain further for each item in the space below.

Authentication and User Account

Is an administrator or power user account required to operate the device?	Yes	No
Can the device be made to require individual user authentication?	Yes	No
Does the device support password aging and strong user password accounts?	Yes	No
Does the device support auto logoff or/and session lock?	Yes	No
Does the system support the use of Active Directory for user authentication?	Yes	No
If yes, specify configuration requirements, LDAP etc.:		
Does the system support the use of PIV/Smart Card only authentication?	Yes	No

Data Handling

Specify which Electronic Protected Health Information ePHI data elements are stored on the device (e.g., last name, SSN, DOB):		
How many records with sensitive information can be stored on the device?		
How long will they be retained on the device?		
Is ePHI encrypted prior to transmission?	Yes	No
If yes, what is the encryption mechanism(s)?		
What is the media used for long term storage?		
How is data transmitted to the storage repository (e.g. LAN, DVD, USB, etc.)?		
Is ePHI stored only on a drive partition or a separate drive to assist with end-of-life media sanitization?	Yes	No
Will the medical device require data backups?	Yes	No
If yes, specify how the system and data are backed up and what media is used: Describe backup process: (data centers are lights out so this needs to be known up front)		
*Where will backups be stored and secured?		
Does the device have the ability to assign unique ID numbers (accession numbers) instead of using patient identifying information (e.g., Social Security Number)?	Yes	No
If yes, how is it generated?		
Does the device utilize a laptop for system operation?	Yes	No
If so, can the laptop be encrypted without impacting clinical functionality?	Yes	No
If yes, what encryption software can be used?		

Networking

What are the LAN bandwidth requirements for full connectivity/performance?		
What are the WAN bandwidth requirements for full connectivity/performance?		
Provide a comprehensive list of all TCP and UDP ports that are required for operation: **Note: If more space is needed, please attach the comprehensive list of ports required for operation to this document. Attach a network diagram showing all communication requirements.**		
How many fixed IP addresses does the device require?		
Is the device compatible with IP V6?	Yes	No
Vendors' products should be designed such that only ports required for the intended operation of the device are active. Are unused ports closed or disabled?	Yes	No
Can this be accomplished without impacting system operation?	Yes	No
Vendors' products should be designed such that only services required for the intended operation of the device are active. Are unused services (e.g., Telnet, IIS, etc.) disabled?	Yes	No
Can this be accomplished without impacting system operation?	Yes	No
Provide a comprehensive list of all services that are required for system operation:		
Can the device be serviced remotely?	Yes	No
Does the vendor have an existing Site to Site (S2S) VPN tunnel or individual user VPN account(s)?	Yes	No
What remote access software does the system utilize (e.g., Dameware, PC Anywhere, etc.)?		
Does the device require connection to the Internet to operate?	Yes	No
If yes, please justify and provide connection info (IP, port, protocol and traffic direction):		

Wireless

Does the device utilize wireless communication?	Yes	No
• If yes, what protocols are used?		
The encryption module must have FIPS 140-2 certification. Provide certificate number:		
Are any ePHI data elements transmitted via the wireless link?	Yes	No
• If yes, list each element (e.g. last name, DOB, SSN).		

Integration with VA Healthcare Information Systems (if applicable)

*Has the device been validated with VA's Clinical Procedures package?	Yes	No
*Has the device been validated with VA's Vista Imaging?	Yes	No
*Does the device have bi-directional HL7 interface?	Yes	No
List all other systems that the device will communicate with in order to operate properly, e.g. VistA, domain controllers, vendor's support network, etc.:		

Signature Page

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Chief, Biomedical Engineering   Date
Concur/Non-Concur

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Chief Information Officer   Date
Concur/Non-Concur

_____

Information Security Officer   Date
Concur/Non-Concur