

**Medical Equipment Pre-Procurement Assessment**  
(to be completed by potential vendors)

**Equipment Description:**

**Vendor/Model:**

**Vendor Contact:**

**Requesting Clinical Service:**

**Medical Equipment Configuration**

- |   |                              |                             |
|---|------------------------------|-----------------------------|
| <input type="checkbox"/> What OS does the system utilize?   |                              |                             |
| <input type="checkbox"/> Can critical security patches be installed without prior vendor approval?                        | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does the device incorporate a switch or hub into its design?                                     | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Is the switch or hub required as part of the system configuration?                               | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Which Anti-virus software is approved by the device manufacturer?                                |                              |                             |
| <input type="checkbox"/> If server based, does the system require a specific version of Java for proper client operation? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If server based, does the system utilize an ActiveX control for client interaction?              | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If yes, specify configuration requirements.  |                              |                             |

**Authentication and User Accounts**

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| <input type="checkbox"/> Is an administrator or power user account required to operate the device? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Is an administrator account required for service?                         | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the device be made to require user authentication?                    | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does user authentication support Strong Passwords?                        | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does user authentication support password aging?                          | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the device be part of the facility's Windows domain?                  | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

**Data Handling**

- |   |                              |                             |
|---|------------------------------|-----------------------------|
| <input type="checkbox"/> Will the medical device require data backups?  | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Is ePHI stored only on a drive partition to assist with end of service media sanitization? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> What ePHI data elements are stored on the device?  |                              |                             |
| <input type="checkbox"/> Can ePHI be stored directly to a network drive, rather than local (machine) storage?       | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

**Networking**

- |   |                              |                             |
|---|------------------------------|-----------------------------|
| <input type="checkbox"/> What are the LAN/WAN bandwidth requirements for full connectivity/performance? |                              |                             |
| <input type="checkbox"/> What ports in the TCP/IP stack are utilized for network communication?         |                              |                             |
| <input type="checkbox"/> Can unutilized ports be closed without negatively impacting device operation?  | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the device support DHCP for network address configuration?                 | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> How many IP addresses does the device require?                                 |                              |                             |
| <input type="checkbox"/> Can the device operate properly without connection to the Internet?            | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the target system be addressed via a fully qualified domain name (FQDN)?   | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

**Wireless**

- |  |                              |                             |
|--|------------------------------|-----------------------------|
| <input type="checkbox"/> Does the device utilize wireless communication?   | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If so, what protocols are used?   |                              |                             |
| <input type="checkbox"/> Is any ePHI transmitted via the wireless link?  | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does the device support installation of FIPS 140-2 certified wireless security clients? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If so, which ones?  |                              |                             |

**Integration with VA Health Care Information Systems**

- ☐ Has the device been validated with VA's Clinical Procedures package?
- ☐ Has the device been validated with VA's Vista Imaging?
- ☐ Does the device have a bi-directional HL7 interface?
- ☐ Provide a DICOM conformance statement.

- |                              |                             |
|------------------------------|-----------------------------|
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |

*(to be converted to a VA form)*

**Medical Equipment Pre-Implementation Worksheet**

**Equipment Description:**

**Vendor/Model:**

**Vendor Contact:**

**Requesting Clinical Service:**

**Contact Information & Sign-Off**

**Clinical Service POC:**

Phone:

**Biomedical Engineering POC:**

Phone:

**ISO:**

Phone:

**IT POC:**

Phone:

**Medical Equipment Documentation Review**

- ☐ Manufacturer Disclosure Statement for Medical Device Security (MDS<sup>2</sup>)
- ☐ Existing Site-to-Site or One-VA VPN Agreement
- ☐ Purchase documents and associated equipment quotations
- ☐ Business Associate Agreement
- ☐ Equipment description, information flow, and network connectivity requirements
- ☐ Documentation of network configuration and installation requirements
- ☐ Clinical Procedures integration documentation provided with VA contacts, if applicable
- ☐ DICOM conformance statement provide, if applicable

**Security Precautions**

- ☐ Does the equipment support Anti-virus protection with updates via McAfee ePolicy Orchestrator? ☐ YES ☐ NO
- ☐ Does the equipment support automated OS critical patch installation? ☐ YES ☐ NO
- ☐ Will the medical equipment be configured for Device Authentication using Active Directory? ☐ YES ☐ NO
- ☐ Will the medical equipment be configured for User Authentication using Active Directory? ☐ YES ☐ NO
- ☐ Who will provide and manage: Disaster Recovery?
- ☐ Will vendor require Remote Access via VPN? ☐ YES ☐ NO
- ☐ Will vendor provide a network device (switch, router)? Needs risk assessment. ☐ YES ☐ NO
- ☐ Will vendor provide any wireless devices? Needs risk assessment. ☐ YES ☐ NO

**Network Design and Constraints**

- ☐ Notification to network administrator to configure medical VLAN Medical VLAN:
- ☐ Medical equipment installation location(s)
- ☐ Network administrator reviews risk assessment for any network or wireless devices.
- ☐ List all target systems that the device will communicate with
- ☐ Network administrator configures the ACL with input from Biomedical Engineering, verifies connectivity, and documents configuration.

**Post Installation Support Strategy**

- ☐ Post implementation support strategy developed.
- ☐ Post implementation secure use strategy developed.(i.e. frequency of removal of ePHI from device, physical security of device, etc.)

*(to be converted to a VA form)*