Implementation Considerations for Digital Pathology

Kent Rarick - Senior Manager Product Services, Aperio

Stefan Tunev - Senior Scientific Program Manager, Medtronic

Overview

- Medtronic Overview – Current and Future plans
- Needs Assessment – System Components
- Infrastructure – Work Surface, Scanner Room, DSR Room
- IT Considerations – Connectivity, Bandwidth, Storage
- External Collaboration – SecondSlide, Internal Portal
- Compliance Validation – Tailored Life Sciences Services
- Tips & Tricks – Automation, Preparation, Maintenance
- Questions

Medtronic – Current Organization

- Medtronic Clients:
  - 2 onsite pathologists (CA)
  - 3 onsite pathology scientists (CA)
  - 5 remote pathologists located within another business division (MN)
  - 2 independent contract pathologists - remote (MN, CA)
  - 4 contract pathology CROs with 8 pathologists total (MN, MD, MA, Quebec)
  - Project managers (US, EU, Japan)

Medtronic Growth Proposal

Process Improvements

1. Expand Scanning capacity throughout organization
2. Enable collaboration between pathologists on all projects
3. Faster turn around times for consultants
4. Maintain GLP Validation

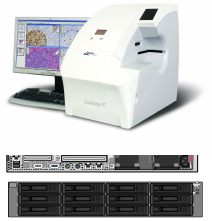
Aperio Solutions

1. Evaluate Scanning Needs per site.
2. Implemented a Multi-Site with Centralized Spectrum & Image Analysis
3. Utilize existing “Cloud” solutions and/or Implement Internal Portal
4. Maintain GLP Compliance Module (*e*sig & audit trails) & GLP Validation for each site

Medtronic Phased Multi-Site

Santa Rosa, CA

2 Onsite Pathologists
3 Onsite Pathology Scientists



Spectrum Server

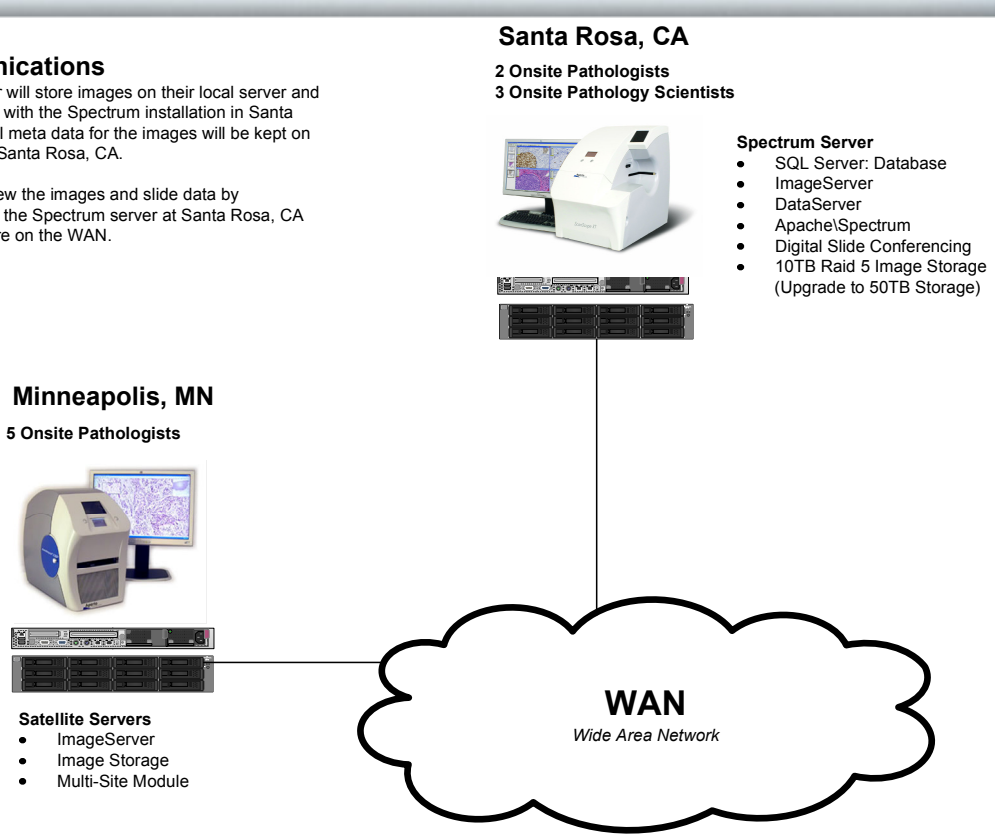
- SQL Server: Database
- ImageServer
- DataServer
- Apache\Spectrum
- Digital Slide Conferencing
- 10TB Raid 5 Image Storage (Upgrade to 50TB Storage)

Medtronic Phase I – Additional Scanner(s)

Communications

Each scanner will store images on their local server and communicate with the Spectrum installation in Santa Rosa, CA. All meta data for the images will be kept on the server in Santa Rosa, CA.

Clients will view the images and slide data by connecting to the Spectrum server at Santa Rosa, CA from anywhere on the WAN.



Medtronic Phase II – Remote Access

Communications

Each scanner will store images on their local server and communicate with the Spectrum installation in Santa Rosa, CA. All meta data for the images will be kept on the server in Santa Rosa, CA.

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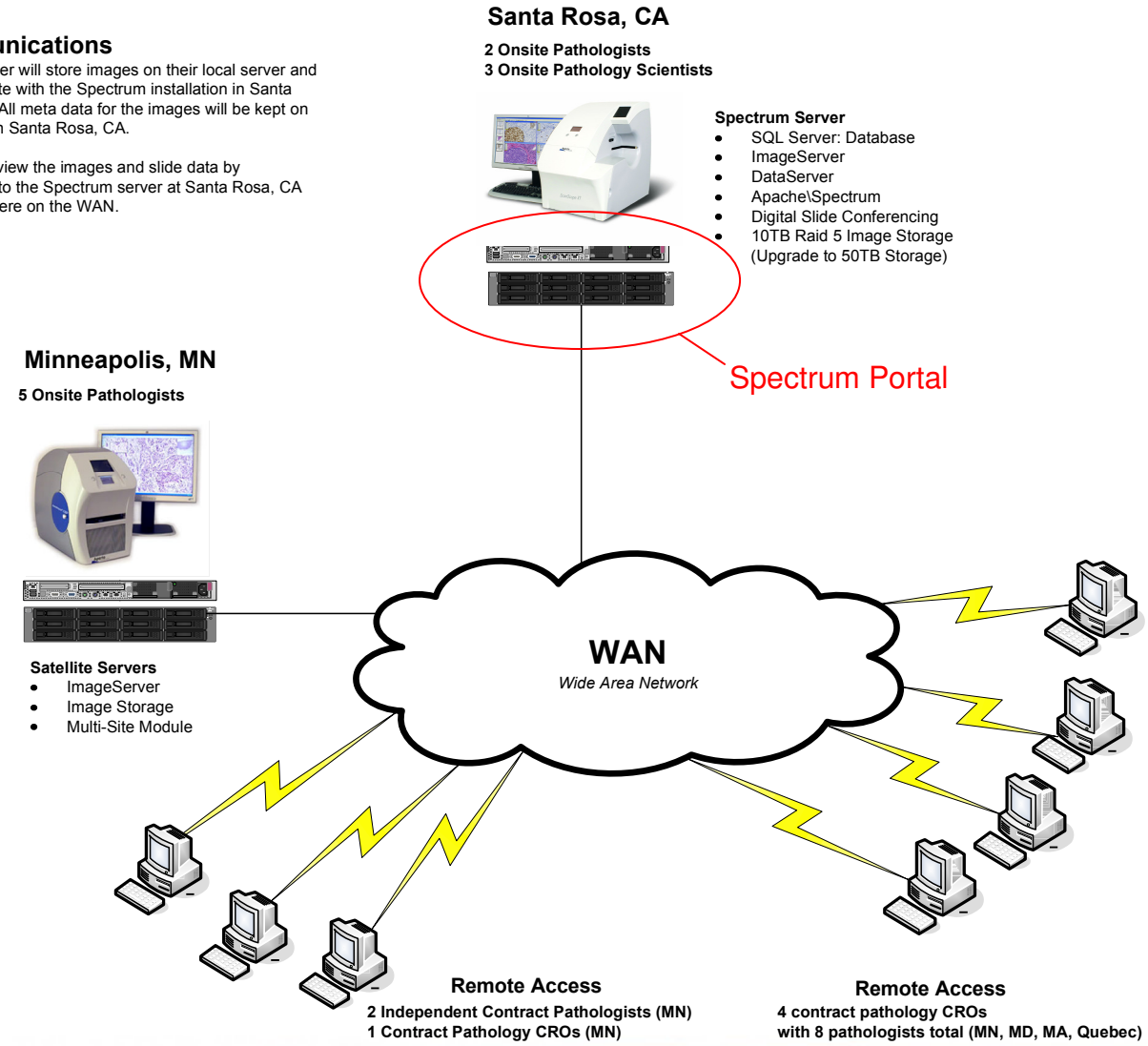


Needs Assessment

- Pathology peer-review, consultations
- Morphometric measurements, manual
  - Image Scope
  - Third party software
- Automated tissue analysis
  - Genie + Image Analysis Toolbox
  - Definiens Tissue Studio™
- Slide archiving

Needs Assessment

- Infrastructure
- Staffing
- Scanning Throughput
  - 1 ScanScope XT + 1 FTE = 5000 slides/month=2TB
- Number of Users
- Digital Storage Solutions: Long Term

Needs Assessment - What to buy?

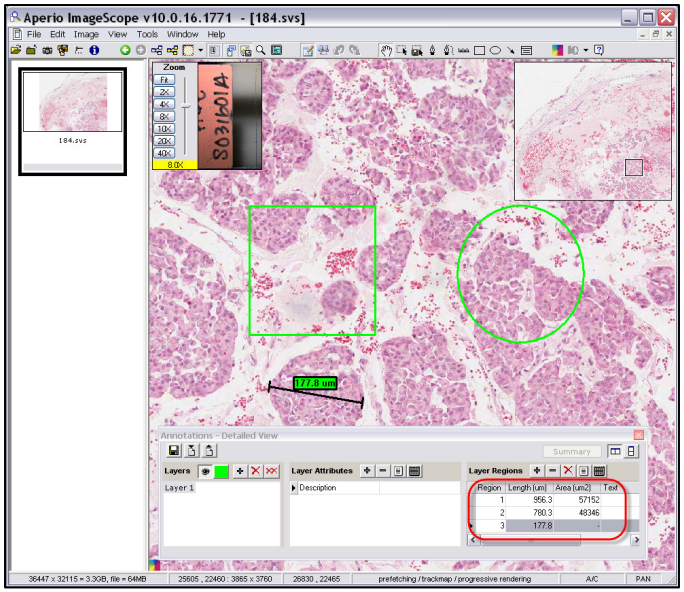
- Scanner (model), PC & Installation
- DSR (Size?)
- Service Contract

- Barcode Package
- Validation Package
- GLP Package

- Genie and Image Analysis Toolbox

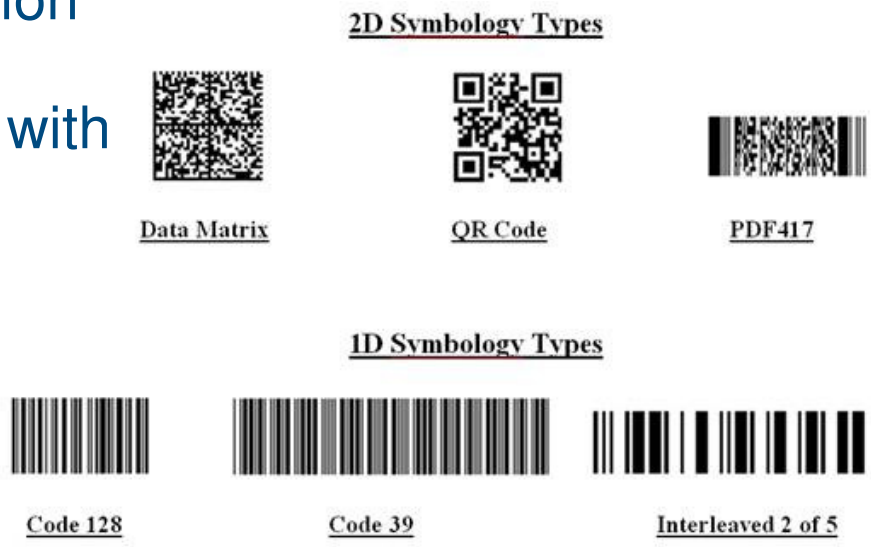
Needs Assessment - Scanner & Storage

- Slide Scanner
- Digital Slide Repository (DSR)
- Spectrum Plus
- Workstation
- Image Scope



Needs Assessment – Backup & Barcodes

- DSR Back-up
- Surge Protection
  - Electrical
  - Intranet
  - Firewall and port protection
    - Teleconferencing
  - Automated Slide Printer with 2D Matrix barcode



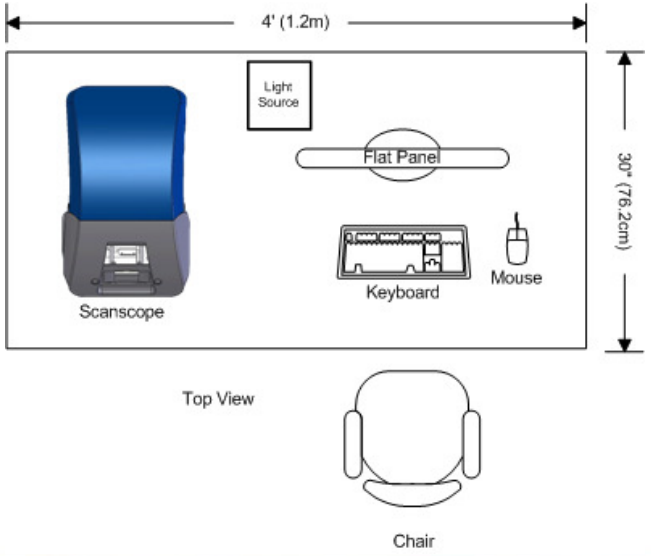
Needs Assessment - Staffing

- Digital Pathology Specialist
  - Laptop with Remote Access
  - SOPs
- IT support
  - Validation Support
  - Back-up scanner operators

Infrastructure – Work Surface

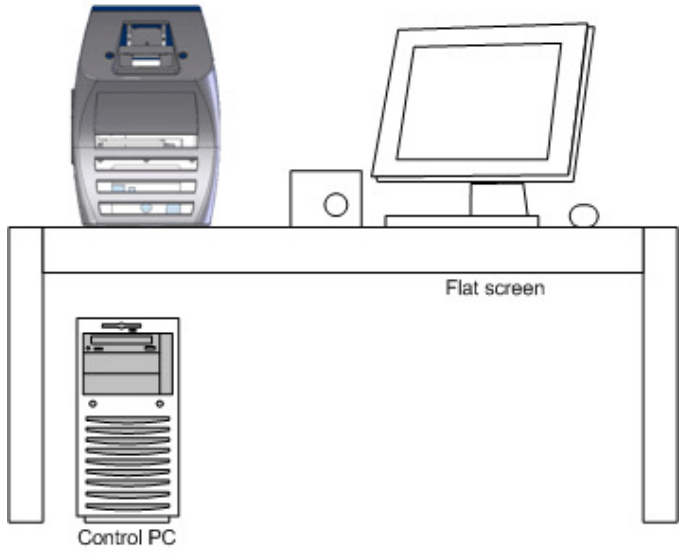
- ScanScope work area
  - good lighting
  - Clean and cool (at or below 70°F, 21°C)
  - Relative humidity not to exceed 70 percent
  - must be level to within 1° with minimum dimensions of 6 feet (1.8 meters) long by 30 inches (76.2 centimeters) deep.

- The work surface should be
  - Of standard desk or workbench height
  - Heavy duty and very stable
  - able to easily support 125 pounds



Infrastructure – Work Surface

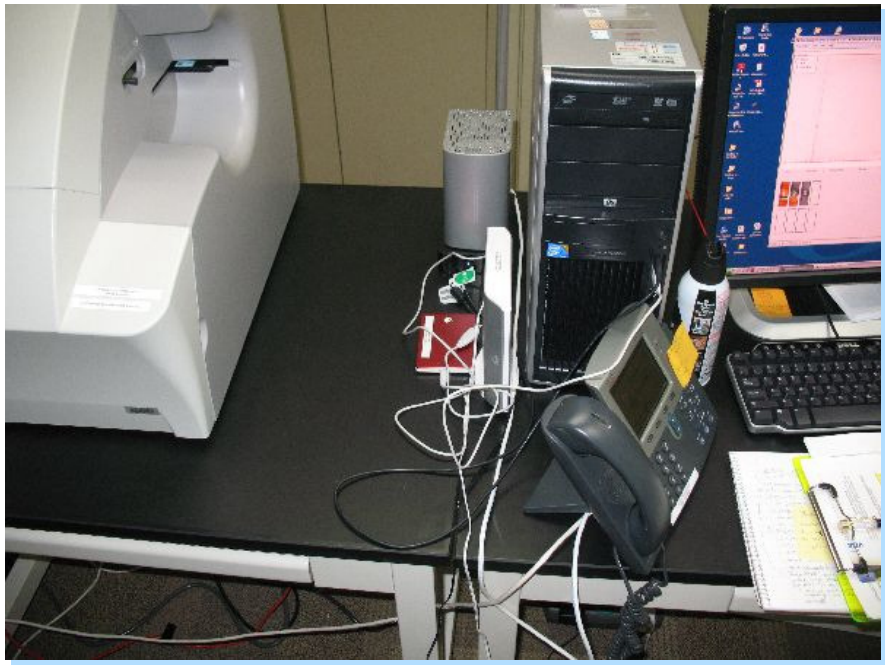
- Do not locate the Scanner
  - where it may be subjected to direct sunlight
  - where it may be subjected to large temperature variations such as near a heating or air conditioning vent.
  - next to an instrument that vibrates during operation (such as a centrifuge or stainer)



Front View

Infrastructure – Work Surface

- VWR Contour Laboratory Tables
  - If vibrations are present: VWR Balance Table

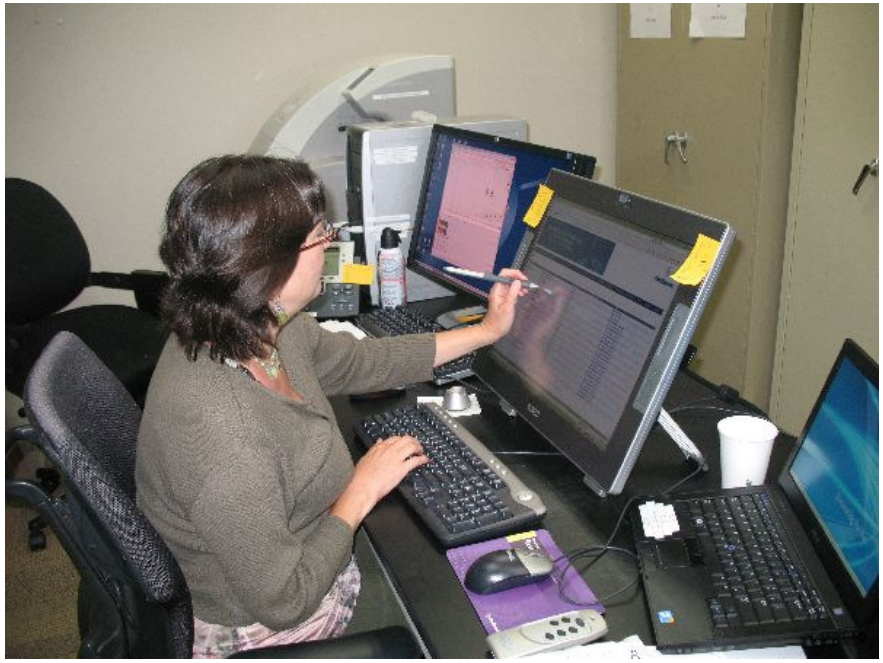


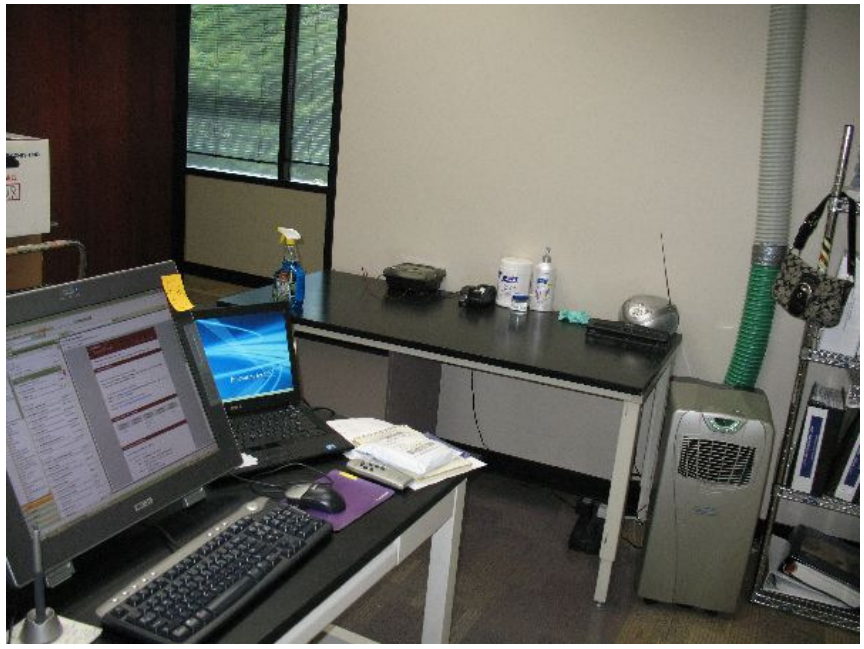
Infrastructure - Scanner Room

- Internet Connection
- Direct Scanner PC to DSR connection (Gigabit)
- Telephone with wireless headset
- UPS - APC Smart-UPS 1000VA USB & Serial 120V

Infrastructure - Scanner Room

- Secure space
  - space for additional work bench/table and chairs





Infrastructure - Scanner Room

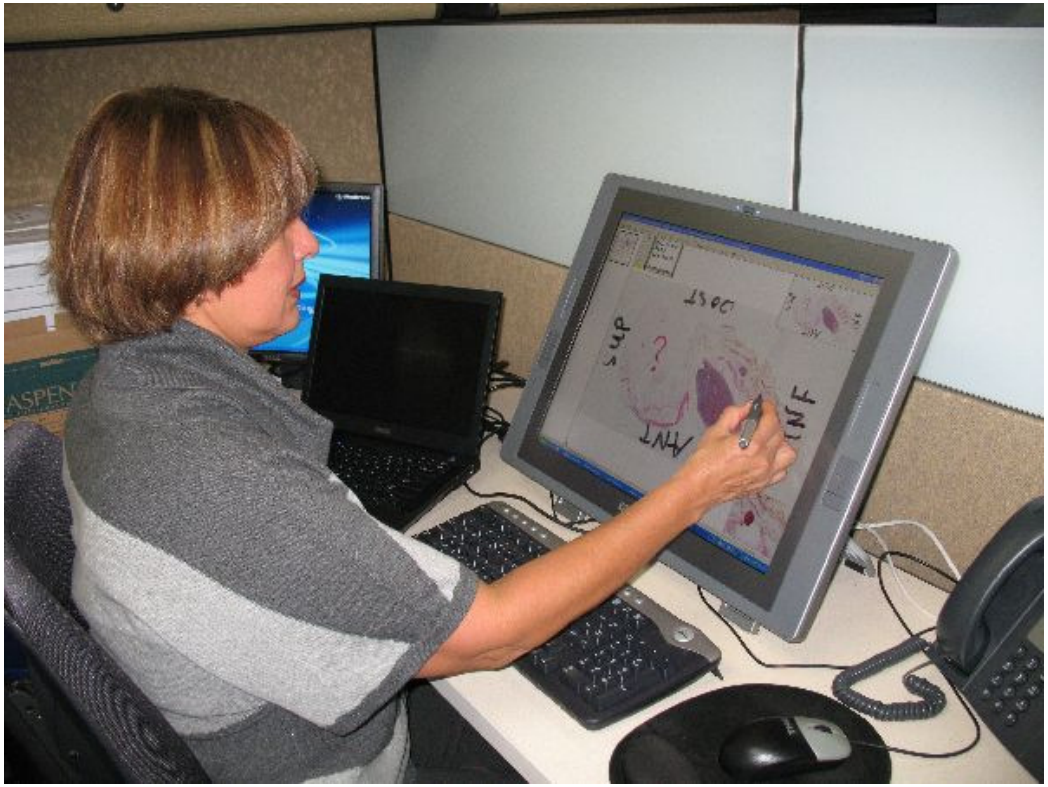
- AC and Temperature monitored
- Air Quality
  - Active air filtration
  - Reduce dust sources

Infrastructure - DSR Room

- Secure space
- AC and Temperature monitored
- Air Quality
- Space to grow

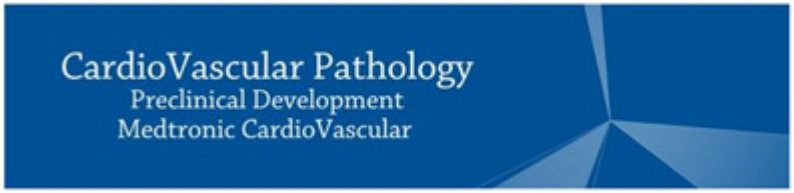
Infrastructure - User Stations

- Separate space(s)
- Internet, telephone, bench space
- Cintiq 21UX by Wacom



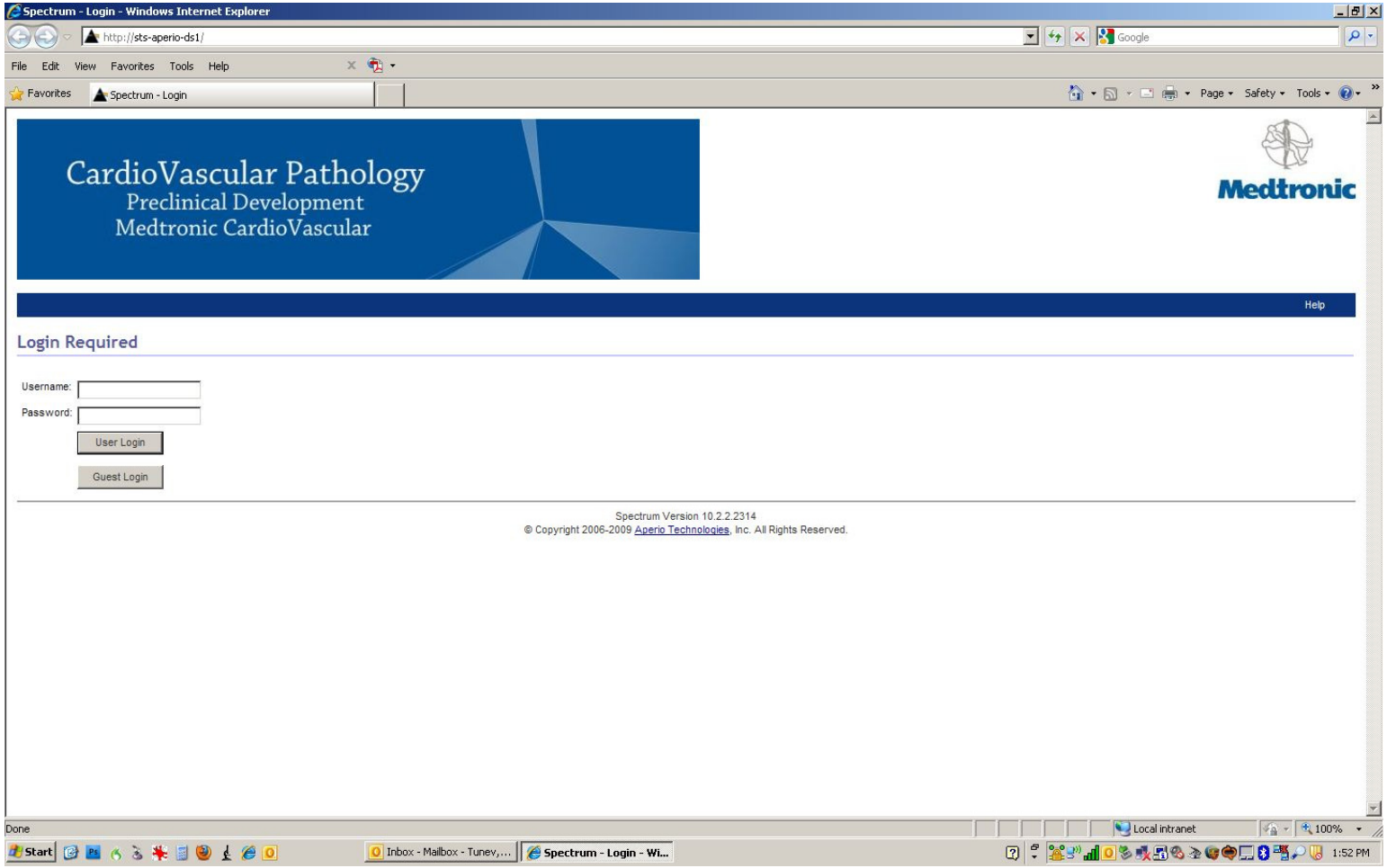
Collaboration

- Working with contractors
  - Use Second Slide
  - Mail external hard drive with images
  - Personal login in Spectrum Plus
  - Build your own portal



Collaboration - Spectrum

- Spectrum Plus: Customize it!



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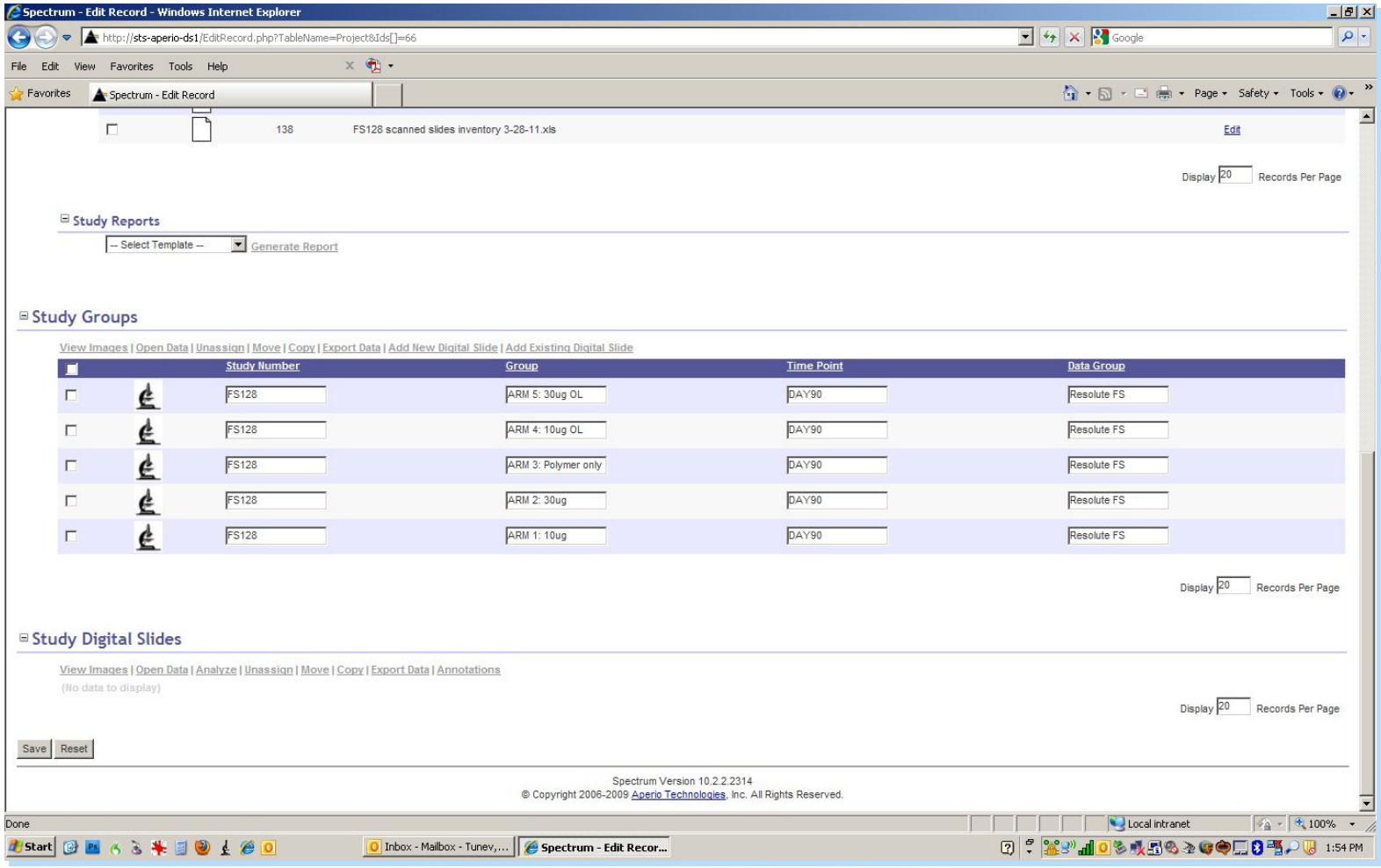
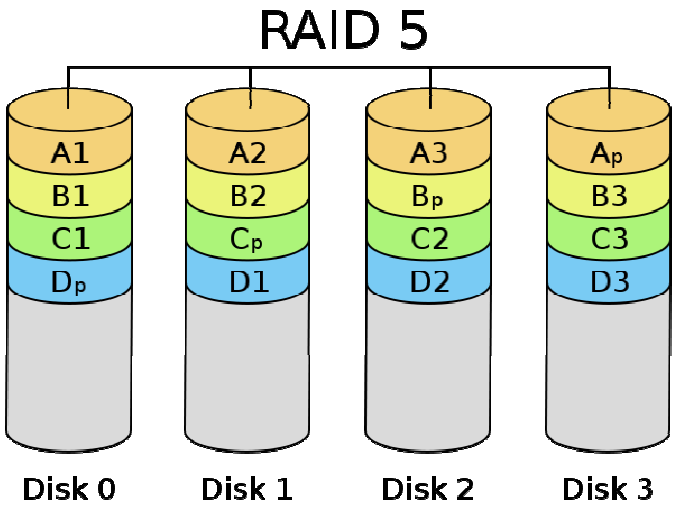


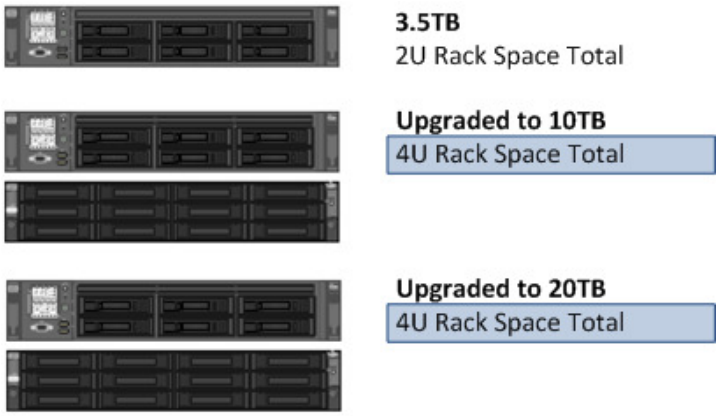
IT Considerations - Long Term Storage

- External Hard Drive Libraries
  - Cheap, but need manual back up for each volume (time!)
  - Least liked solution by IT
- RAID 5 and above rated servers (DSR)
  - Local, More expensive, Secure, Need IT management
- Cloud Storage
  - Netflix
  - Apple
  - Amazon

IT Considerations - Long Term Storage

- DSR: Understand Digital Space
  - Raid 5
  - 4TB DSR= 2TB effective space





http://en.wikipedia.org/wiki/Standard_RAID_levels

IT Considerations – Bandwidth & Speed

- Digital Slide **Capturing** Bandwidth

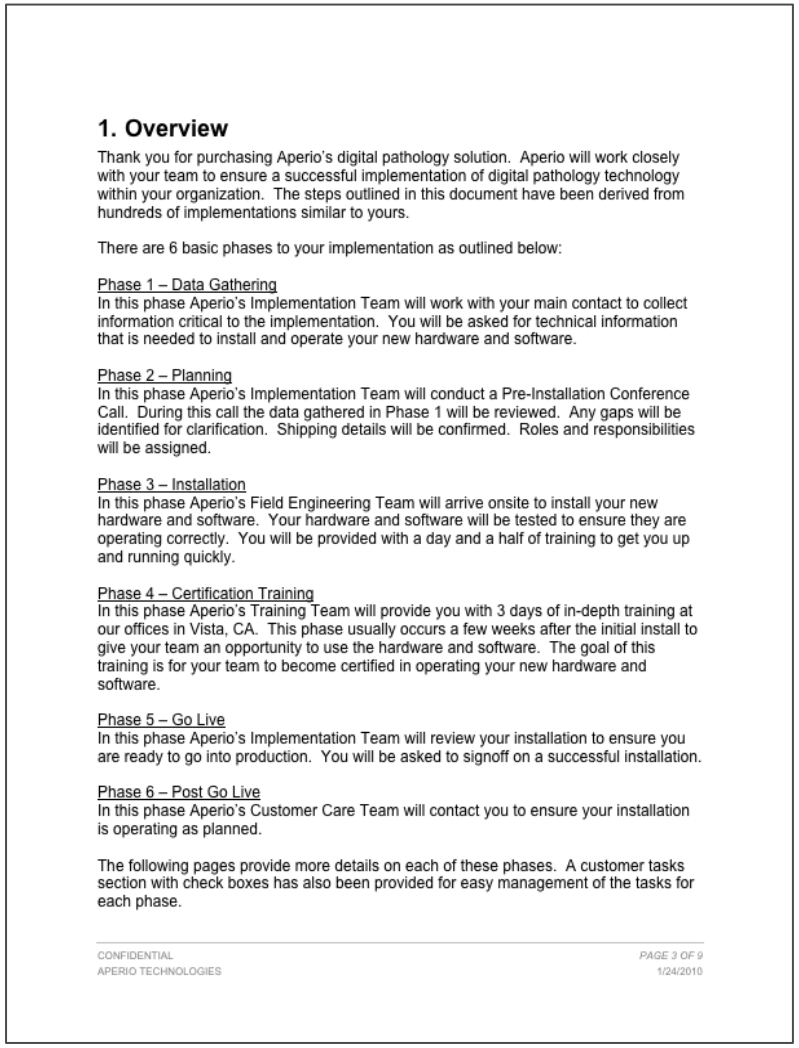
  Bandwidth required for background slide transfer between the ScanScope Control PC and the DSR.
  - approximately 20MB of continuous bandwidth per slide.

- Digital Slide **Viewing** Bandwidth

  Bandwidth required between the viewing station and the DSR
  - Varies with the type of slide, viewing habits of the Pathologist, tissue area, nature of each case, and many other factors.
  - Aperio “streams” the image from the DSR to the viewing station at a a rate of about 40KB/s

IT Considerations - Phased Implementations

- Aperio's 6 phased approach
  - Data Gathering
  - Planning
  - Installation
  - Certification Training
  - Go Live
  - Ongoing Support



1. Overview

Thank you for purchasing Aperio's digital pathology solution. Aperio will work closely with your team to ensure a successful implementation of digital pathology technology within your organization. The steps outlined in this document have been derived from hundreds of implementations similar to yours.

There are 6 basic phases to your implementation as outlined below:

Phase 1 – Data Gathering
In this phase Aperio's Implementation Team will work with your main contact to collect information critical to the implementation. You will be asked for technical information that is needed to install and operate your new hardware and software.

Phase 2 – Planning
In this phase Aperio's Implementation Team will conduct a Pre-Installation Conference Call. During this call the data gathered in Phase 1 will be reviewed. Any gaps will be identified for clarification. Shipping details will be confirmed. Roles and responsibilities will be assigned.

Phase 3 – Installation
In this phase Aperio's Field Engineering Team will arrive onsite to install your new hardware and software. Your hardware and software will be tested to ensure they are operating correctly. You will be provided with a day and a half of training to get you up and running quickly.

Phase 4 – Certification Training
In this phase Aperio's Training Team will provide you with 3 days of in-depth training at our offices in Vista, CA. This phase usually occurs a few weeks after the initial install to give your team an opportunity to use the hardware and software. The goal of this training is for your team to become certified in operating your new hardware and software.

Phase 5 – Go Live
In this phase Aperio's Implementation Team will review your installation to ensure you are ready to go into production. You will be asked to signoff on a successful installation.

Phase 6 – Post Go Live
In this phase Aperio's Customer Care Team will contact you to ensure your installation is operating as planned.

The following pages provide more details on each of these phases. A customer tasks section with check boxes has also been provided for easy management of the tasks for each phase.

CONFIDENTIAL PAGE 3 OF 9
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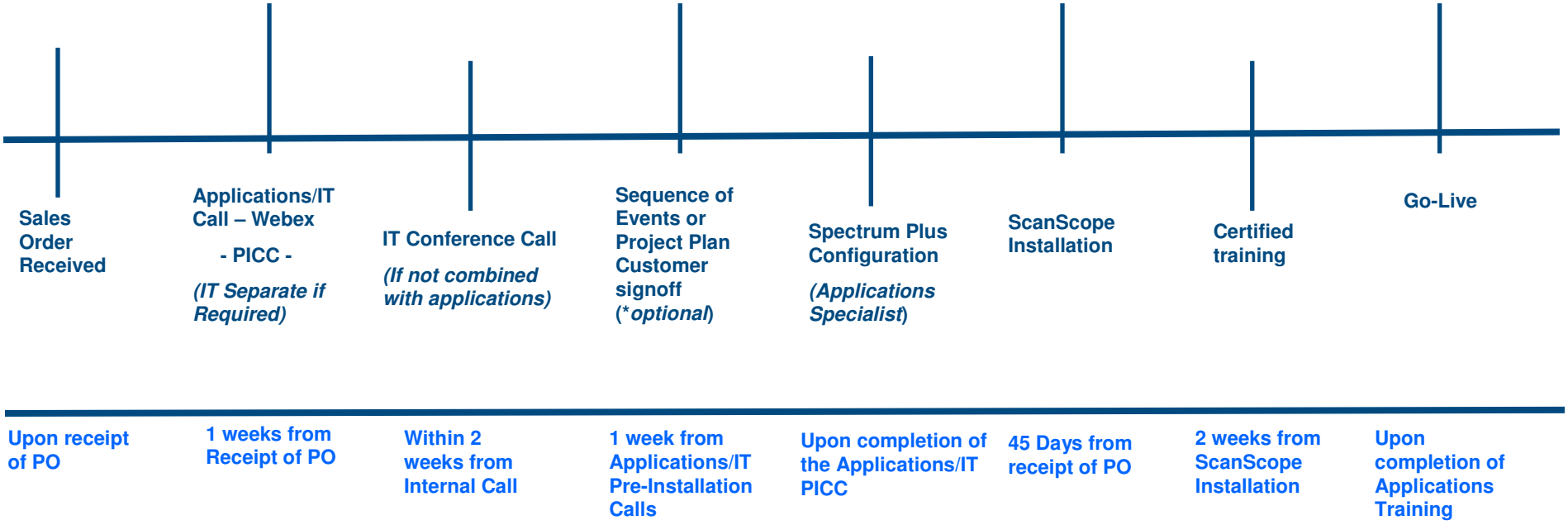
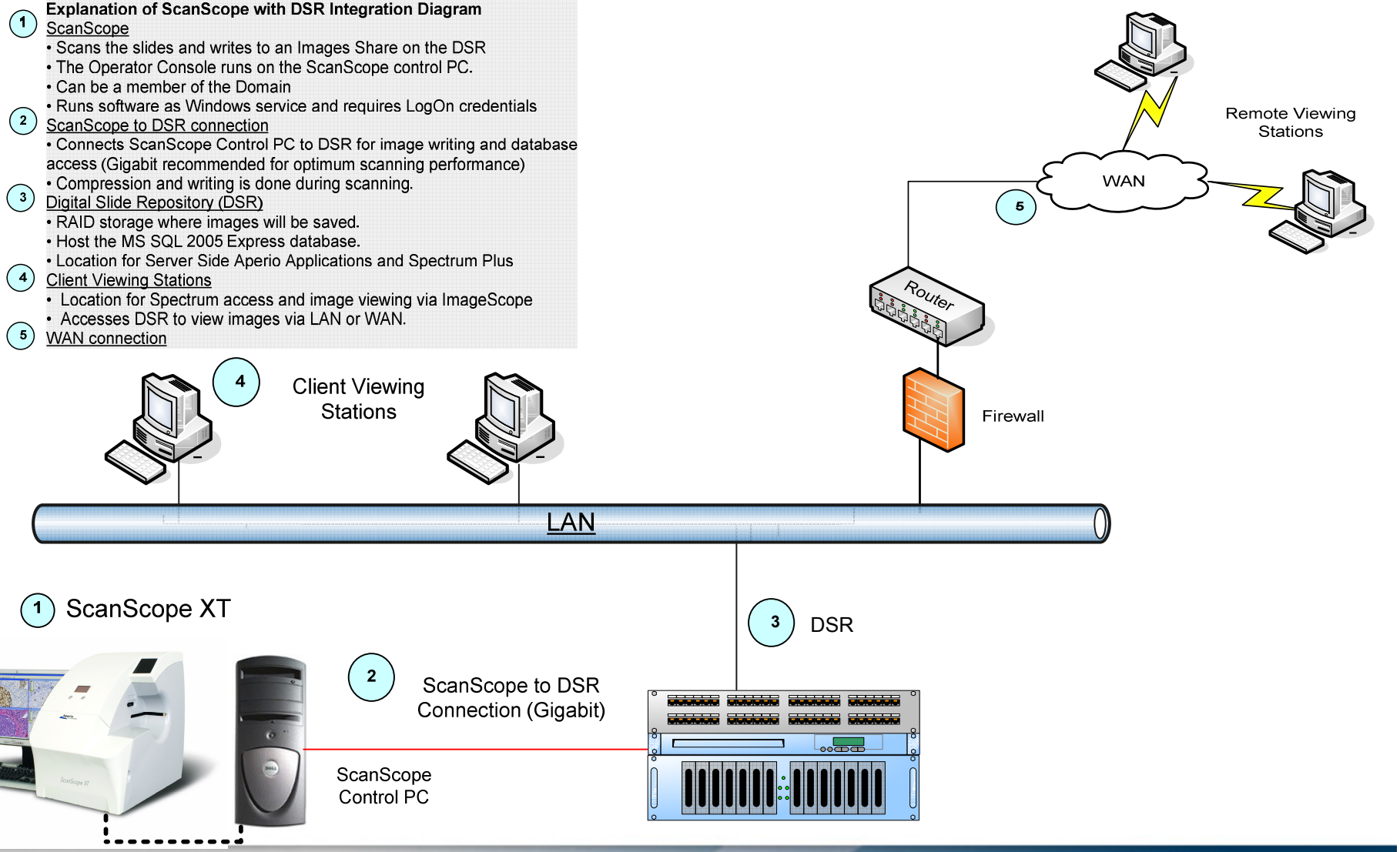
IT Considerations - Implementations Timeline



IT Considerations – Aperio System Connections

Explanation of ScanScope with DSR Integration Diagram

1. ScanScope
   - Scans the slides and writes to an Images Share on the DSR
   - The Operator Console runs on the ScanScope control PC.
   - Can be a member of the Domain
   - Runs software as Windows service and requires LogOn credentials
2. ScanScope to DSR connection
   - Connects ScanScope Control PC to DSR for image writing and database access (Gigabit recommended for optimum scanning performance)
   - Compression and writing is done during scanning.
3. Digital Slide Repository (DSR)
   - RAID storage where images will be saved.
   - Host the MS SQL 2005 Express database.
   - Location for Server Side Aperio Applications and Spectrum Plus
4. Client Viewing Stations
   - Location for Spectrum access and image viewing via ImageScope
   - Accesses DSR to view images via LAN or WAN.
5. WAN connection

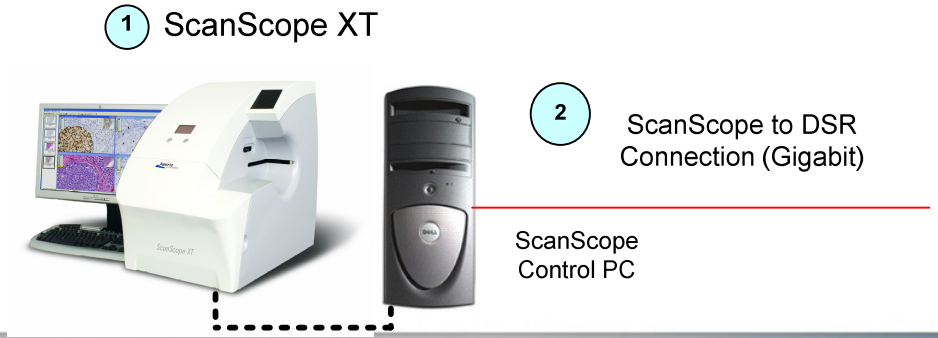


IT Considerations – ScanScope with Control PC

- ScanScope is delivered with everything:
  - (Monitor, Keyboard, Mouse)
- Dotted line designates proprietary connection
- Control PC is not to be used as a workstation
- ScanScope processor is the Control PC

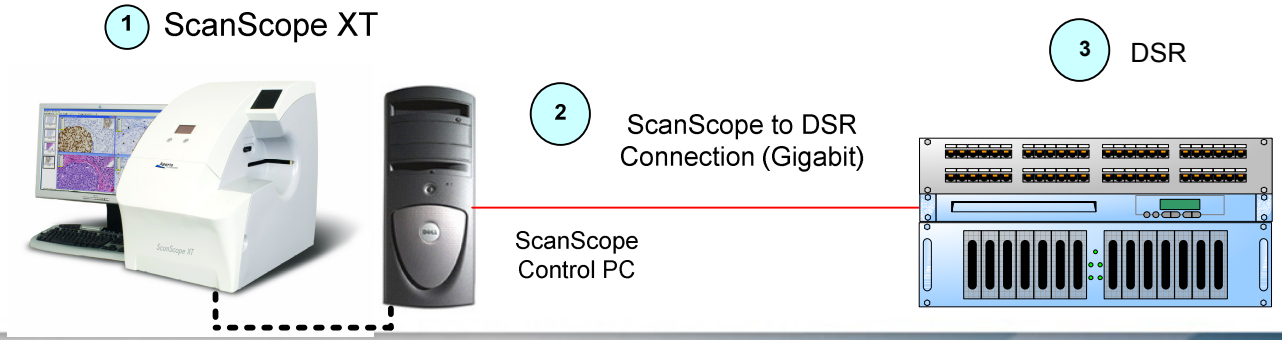
IT Considerations – ScanScope to DSR Connection

- High Speed Connection
  - Preferably Gigabit Direct Connection
- As Aperio Scans the slide it writes and compresses the image at the Server
- Aperio can take up to 20mb of bandwidth when scanning
- Options do exist if a direct connect is not available



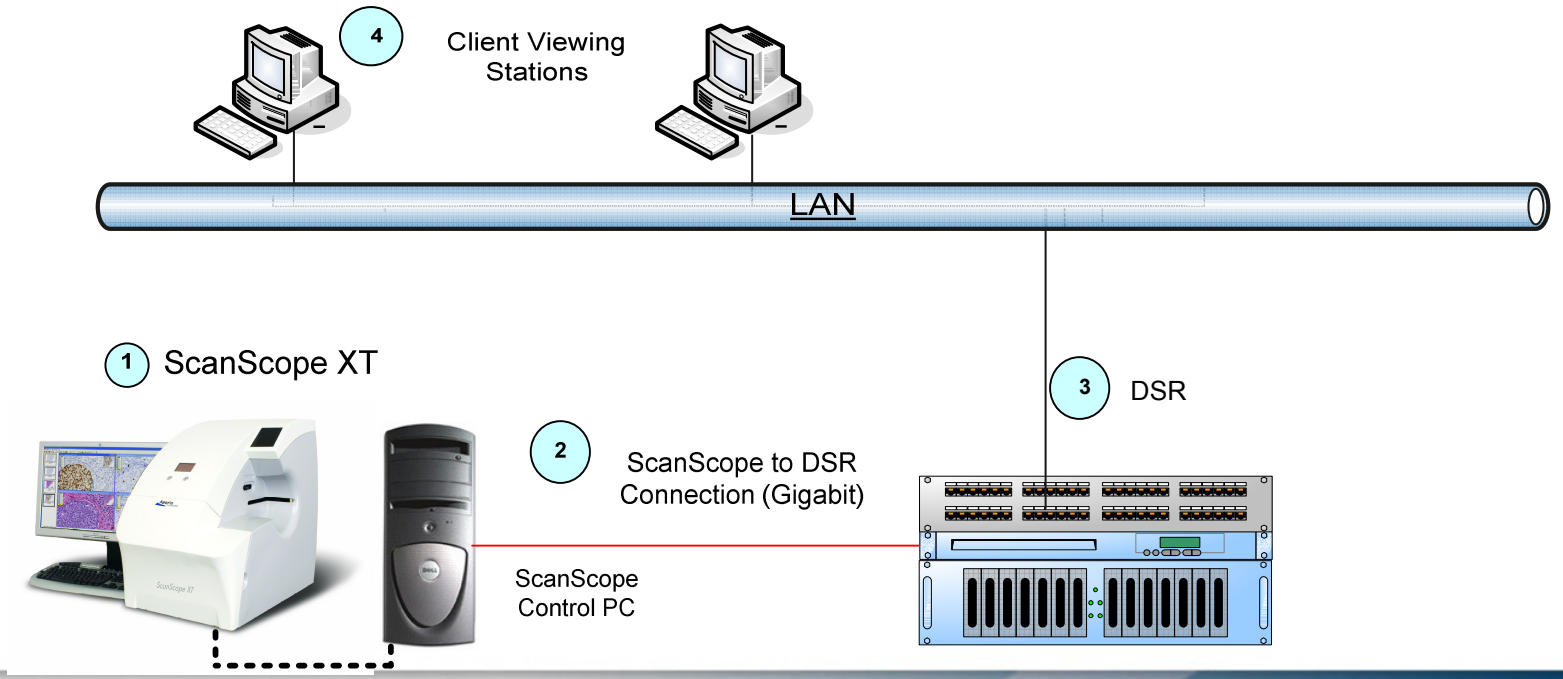
IT Considerations – Digital Slide Repository (DSR)

- Digital Slide Repository (DSR)
  - Where the Images are stored
  - Typically where Aperio applications are installed
  - Can be a virtual server
    - Must meet Aperio minimum Specifications



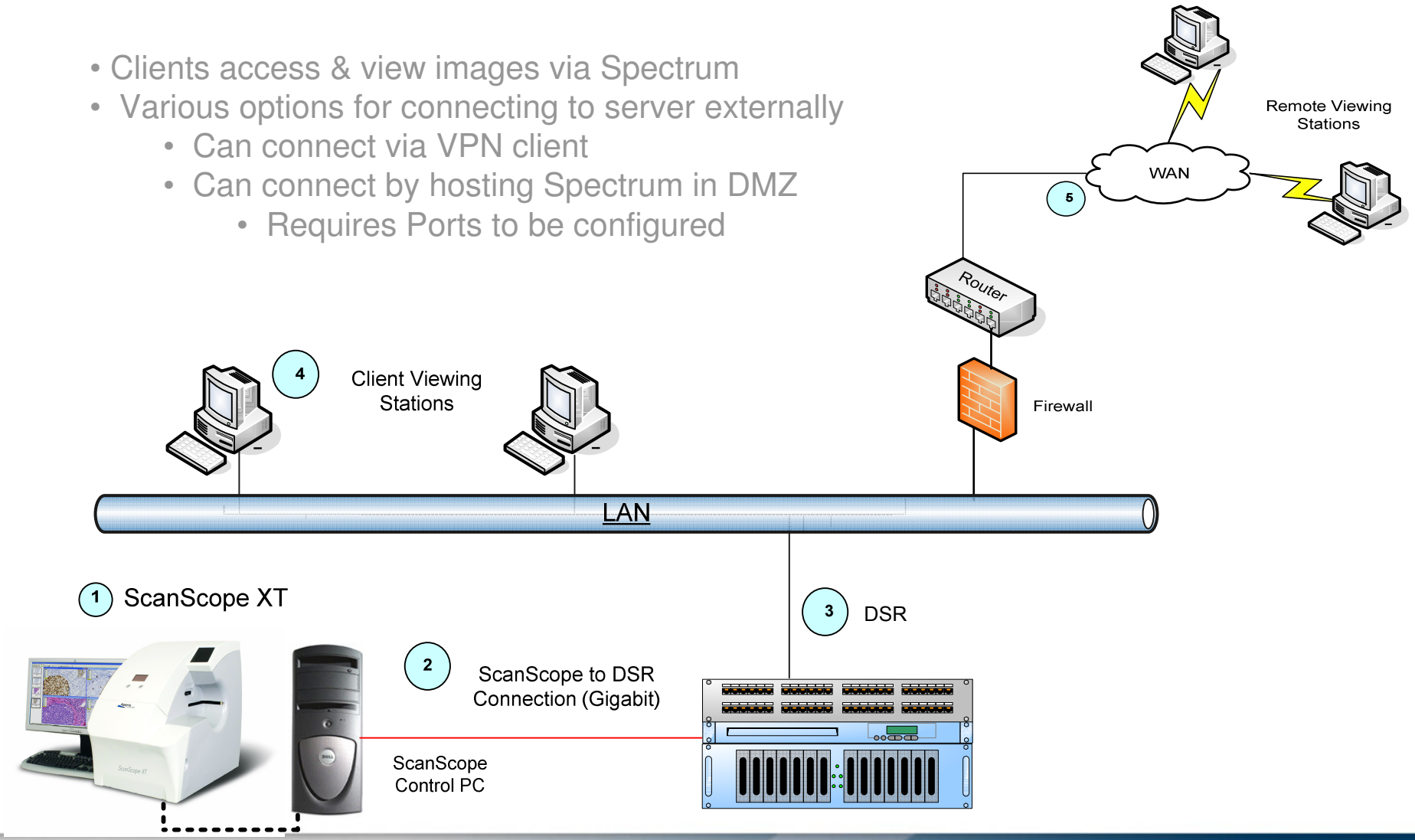
IT Considerations – Client Viewing Stations

- Clients connect to Spectrum via a WEB browser
- ImageServer streams the image to the client
- ImageScope is the client application to view images
    - Requires Local Admin Rights to install but not to use
- If ImageScope is not installed, the client can use WebScope



IT Considerations – Remote Viewing

- Clients access & view images via Spectrum
- Various options for connecting to server externally
  - Can connect via VPN client
  - Can connect by hosting Spectrum in DMZ
    - Requires Ports to be configured



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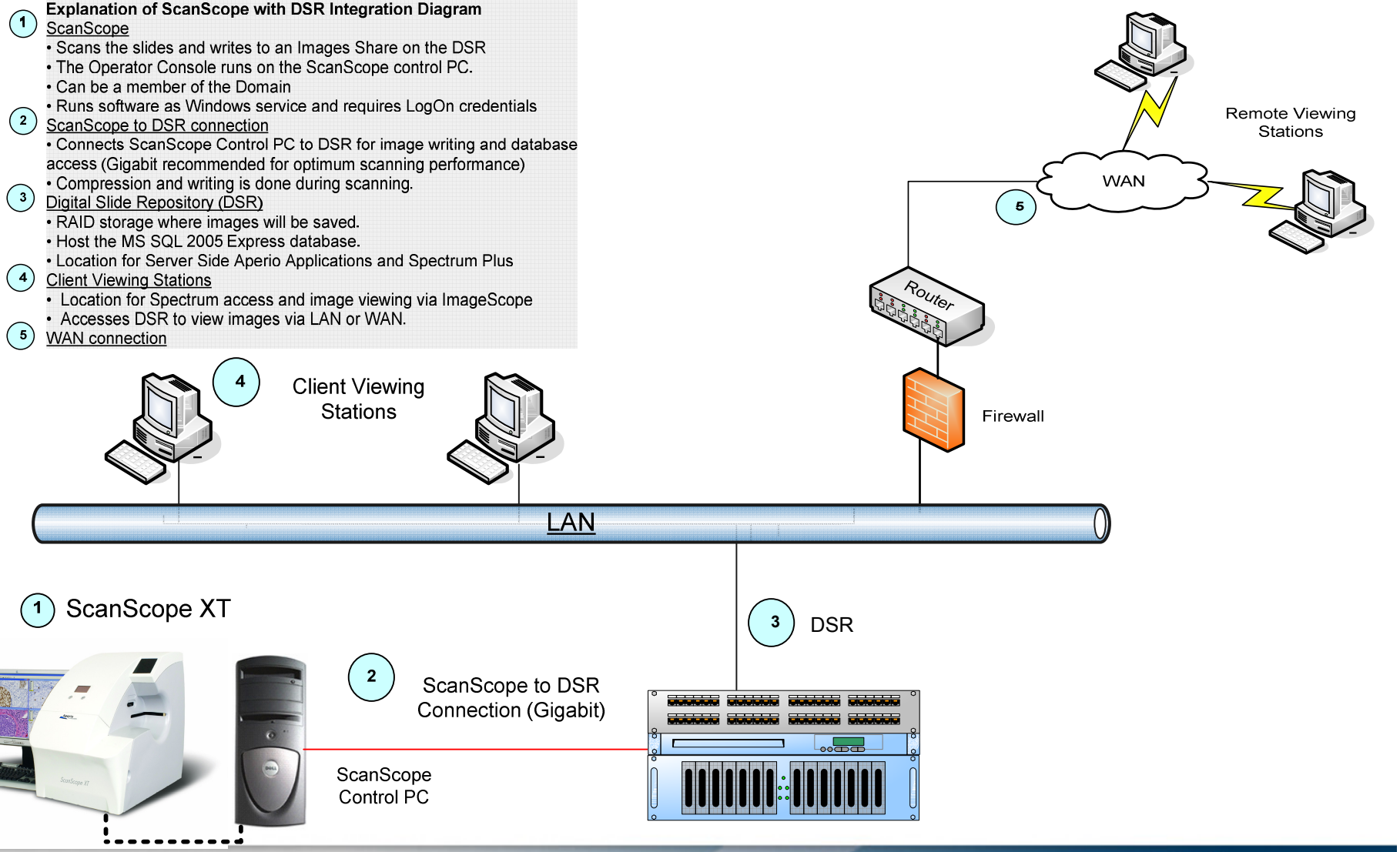
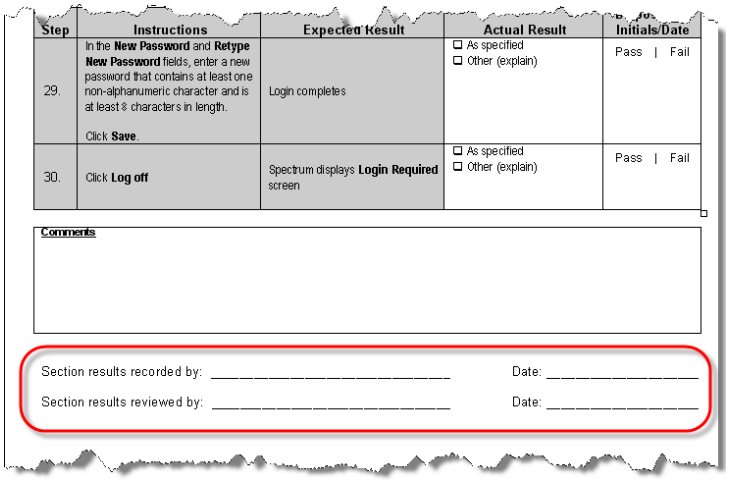


Aperio Validation Services

- Advantages of using Aperio
  - Customized Compliance Modules for Life Sciences & Healthcare
  - Protocols obtained through the development of the specifications
  - Vendor's existing work saves time and cost vs. developing in-house

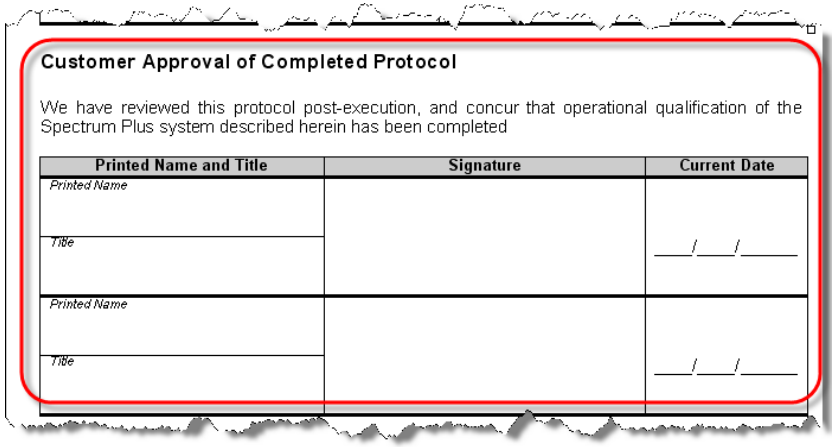


Step	Instructions	Expected Result	Actual Result	Initials/Date
29.	In the **New Password** and **Retype New Password** fields, enter a new password that contains at least one non-alphanumeric character and is at least 8 characters in length. Click **Save**.	Login completes	☐ As specified ☐ Other (explain)	Pass | Fail
30.	Click **Log off**	Spectrum displays **Login Required** screen	☐ As specified ☐ Other (explain)	Pass | Fail

Comments

Section results recorded by: _____ Date: _____

Section results reviewed by: _____ Date: _____



Customer Approval of Completed Protocol

We have reviewed this protocol post-execution, and concur that operational qualification of the Spectrum Plus system described herein has been completed

Printed Name and Title	Signature	Current Date
Printed Name *Title*		___/___/_____
Printed Name *Title*		___/___/_____

Aperio IQ/OQ/PQ Validation

Installation Qualifications (IQ):

ScanScope and Control PC IQ	One IQ per ScanScope
Spectrum Plus / DSR IQ	One per overall installation

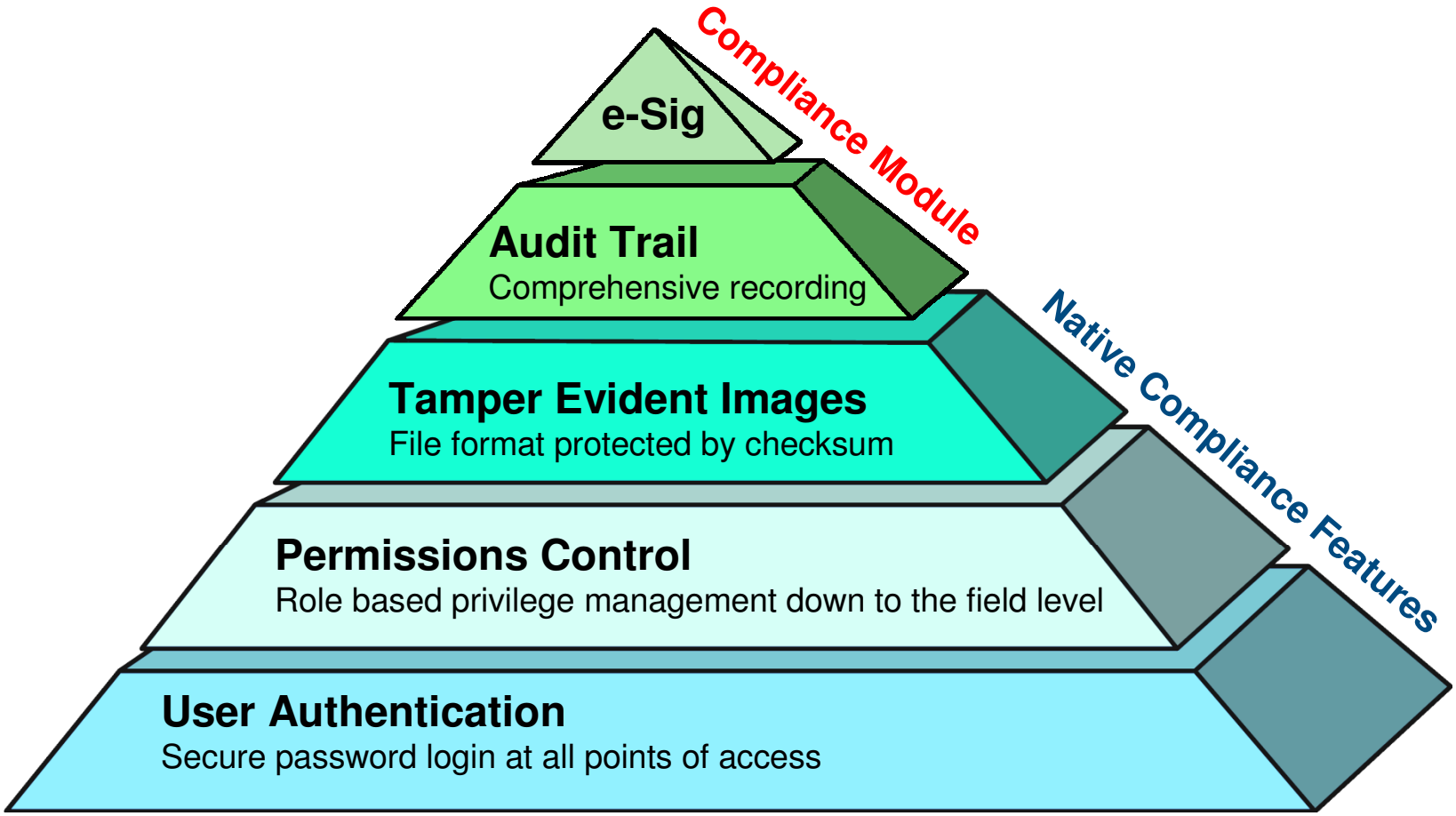
Operational Qualifications (OQ):

ScanScope and Control PC OQ	One OQ per ScanScope
Spectrum Plus OQ	One per overall installation (covers ImageScope and related software functionality as well)

Performance Qualifications (PQ):

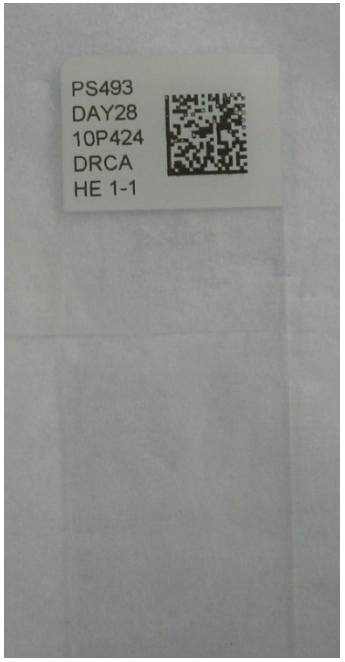
Generalized Workflow PQ	Option for customers with a standard installation
Custom Workflow PQ	Aperio provides framework for customer to develop own PQ (or Aperio can develop it)
System Load Test PQ	For multiple ScanScope implementations

Aperio Spectrum Compliance Features



Few Tips on Slide Scanning

- Automated Slide Printers (2) with 2D Matrix barcode capability



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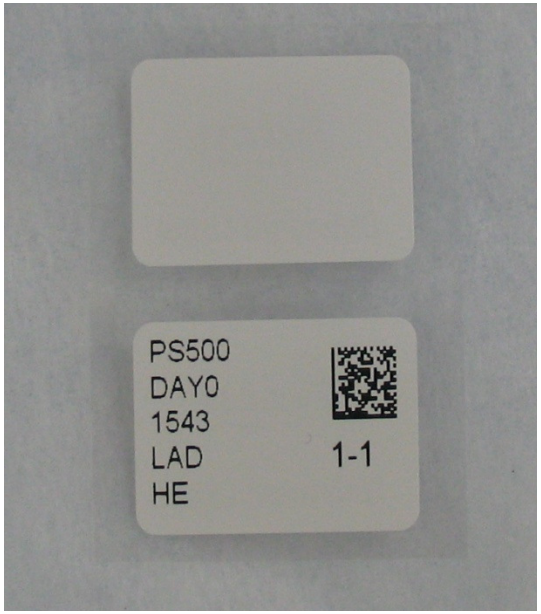


Few Tips on Slide Scanning

- 2D Matrix Barcode

View Images | Open Data | Analyze | Unassign | Move | Copy | Export Data | Annotations

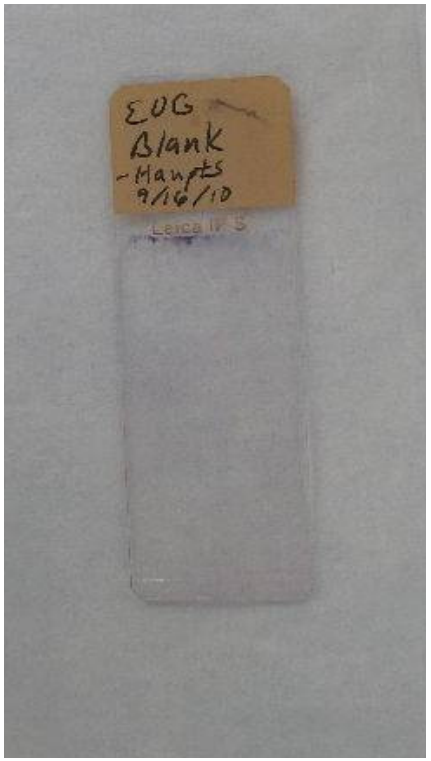
Label	Thumbnail	Report	Study Number	Arms	Time Point	Animal Number	Tissue	Section	Stain	Slide ID	Bar
			PS493	Arm 4	DAY28	11P025	MLCX	1-1	H&E	14427	
			PS493	Arm 4	DAY28	11P025	MLCX	1-1	EVG	14428	
			PS493	Arm 4	DAY28	10P498	MLAD	1-1	EVG	14392	PS4
			PS493	Arm 4	DAY28	10P498	DLAD	1-1	EVG	14394	PS4

Few Tips on Slide Scanning

- No Barcode: Use Groups

Few Tips on Slide Scanning

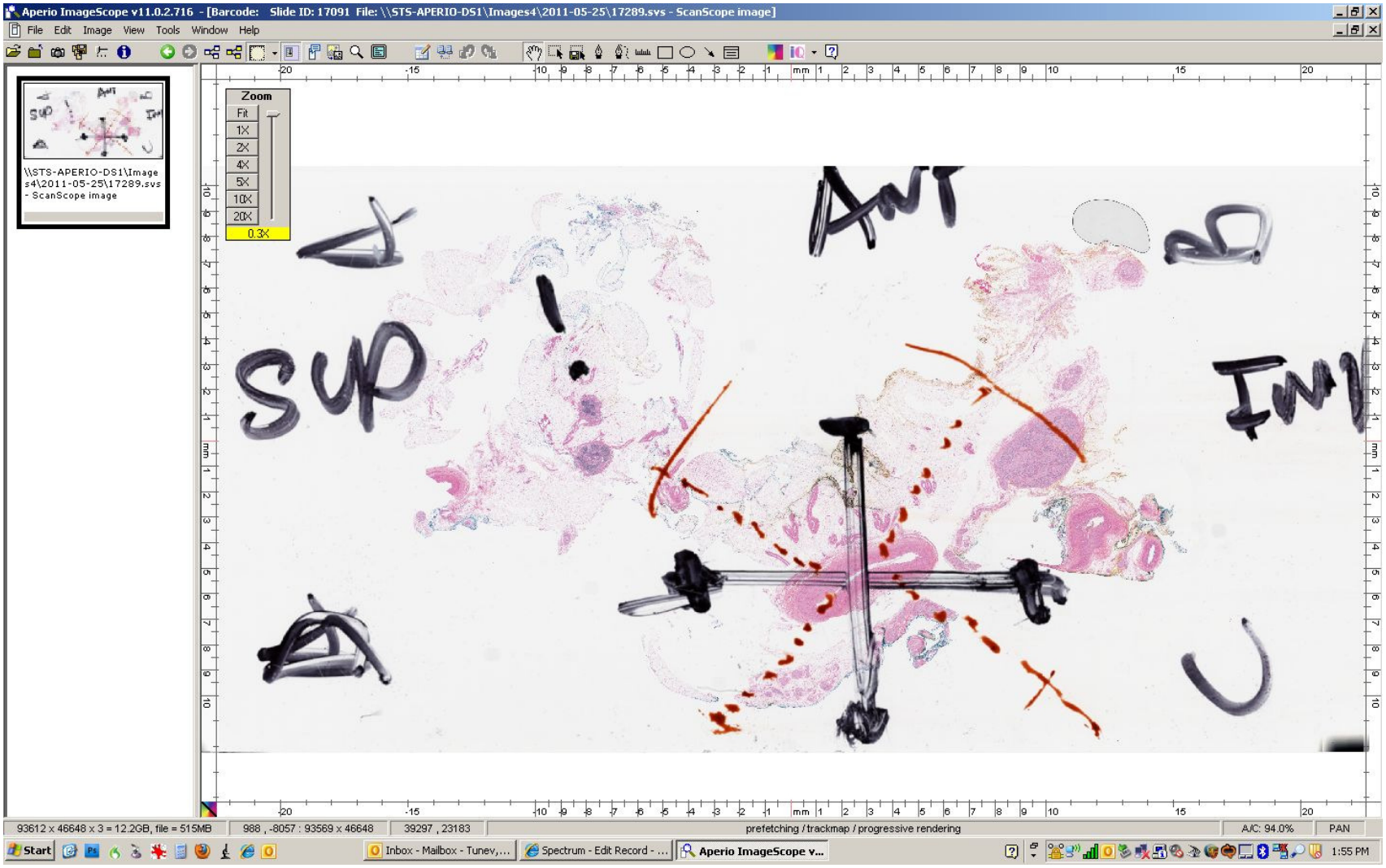
- Blank Background Slides



Few Tips on Slide Scanning

- Slide Cleaning

Few Tips on Slide Scanning



Questions