DICOM
Digital Imaging and Communications in Medicine

FDA

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DICOM STANDARDIZATION OF WSI DATA

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PIXELMED PUBLISHING, LLC

Disclosures

- Editor of the DICOM Standard (NEMA contract)
- Owner of PixelMed Publishing, LLC
- Consulting for Algotec (Philips), Bioclinica, BKMedical, Medigate, Mayo
- Subcontractor to BWH on NCI Imaging Data Commons (IDC) project
- Subcontractor to Leeds (UK NHS) on Northern Pathology Imaging Co-operative (NPIC) project

Overview

- What is DICOM?
- Why DICOM? Interoperability
- DICOM for WSI in detail
- Regulatory implications of interoperability
- Which aspects of DICOM can assuage regulatory concerns?
- Use cases for mathematically identical pixels in DICOM vs. proprietary
- DICOM solutions for proprietary compression sources
- Color management
- Computational Pathology (AI/ML) and DICOM
- Regulatory issues of AI/ML – annotations for truthing

What is DICOM

- A protocol for exchanging images and image-related information
- Between different implementations (vendors) of image producers and consumers
- I.e., interoperability of images

- Sending ("storing") images ("instances")
- Finding them ("query/retrieve")
- Various other services (e.g., workflow management)

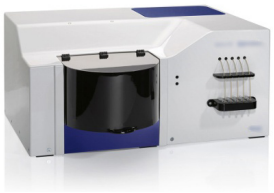
- Protocols, messages and operations
- An information model – common stuff (Patient/Study/Series/Image), Specimen
- A data dictionary ("elements", "attributes")
- Information object definition ("IOD") – modality/specialty specific
- Objects pairs with services ("Service Object Pair" (SOP) Classes)
- File format – record a DICOM message in a file (on media)

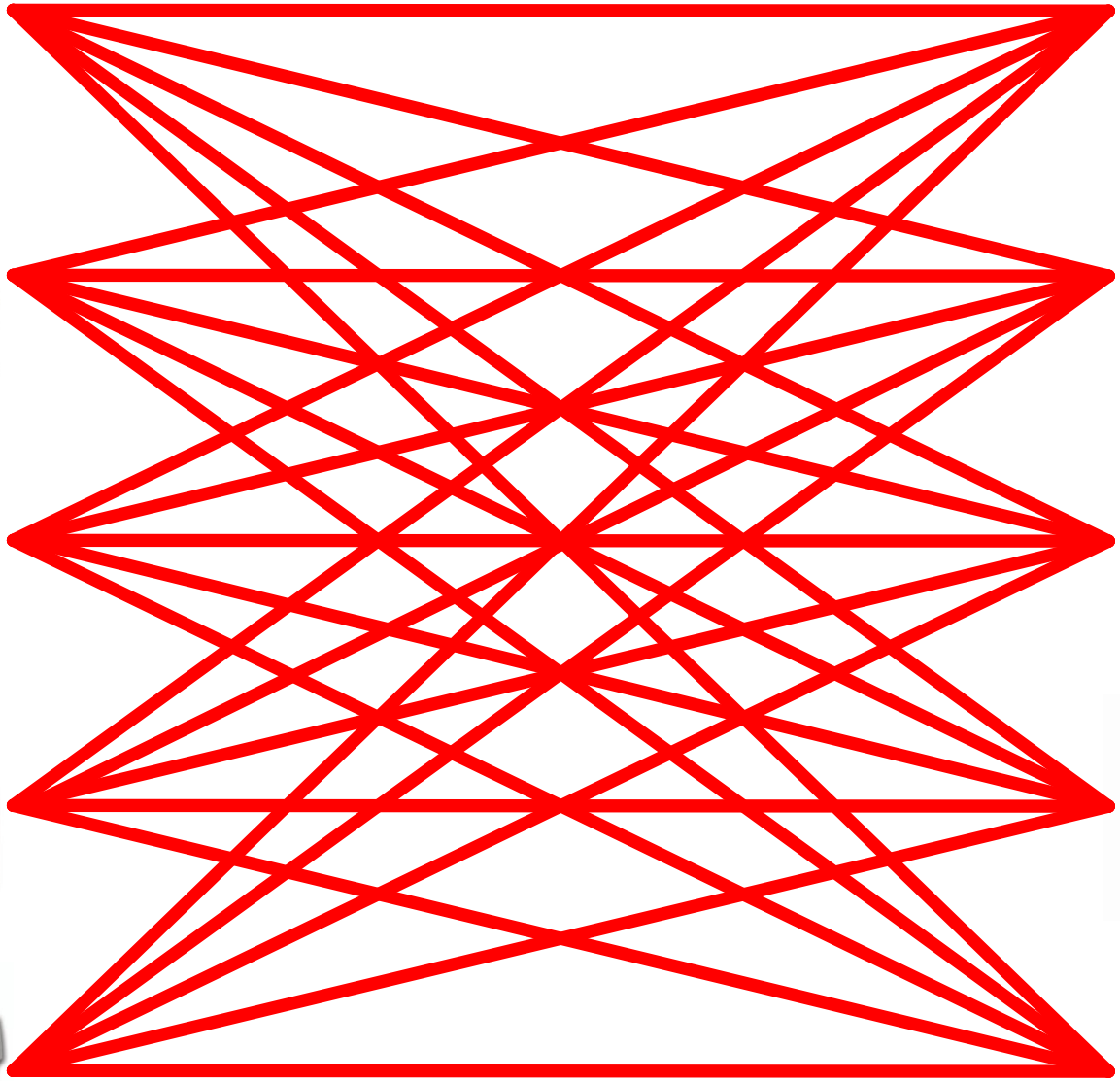
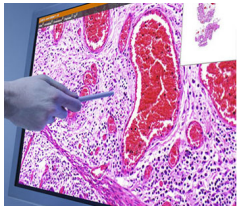
Interoperability

*"the ability of two or more systems or components to **exchange** information and to **use** the information that has been exchanged"*

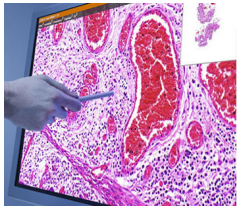
IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries. 1990

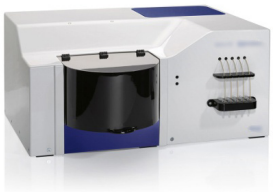










Why Interoperability?

- A single vendor is rarely expert in everything (acquisition, processing, storage, viewing, analysis)
- A single vendor can rarely devote resources to everything
- E.g., one vendor makes great scanner (fast, few errors, easy to load, sharp images)
- Another vendor makes great viewer (efficient navigation, better tools)
- Yet another makes a dedicated analysis tool (whether H&E or IHC or whatever)
- Another vendor makes a dedicated cytology, hematology or microbiology scanner

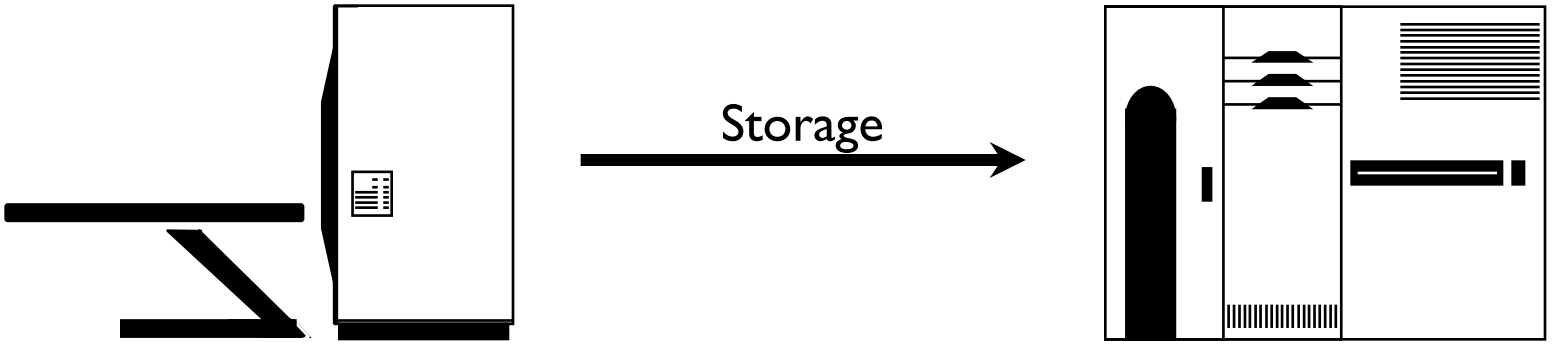
- Users want "best of breed": "mix and match" "plug and play interoperability"
- Users with multiple scanners want to see everything in the one viewer they routinely use (and are trained and validated on)

- Lesson from radiology: seamless mixture of all sorts of different brands, models, versions of different types of scanner, independent of archive, mixture of different general purpose ("universal") and specialty-specific viewing, analysis and planning tools

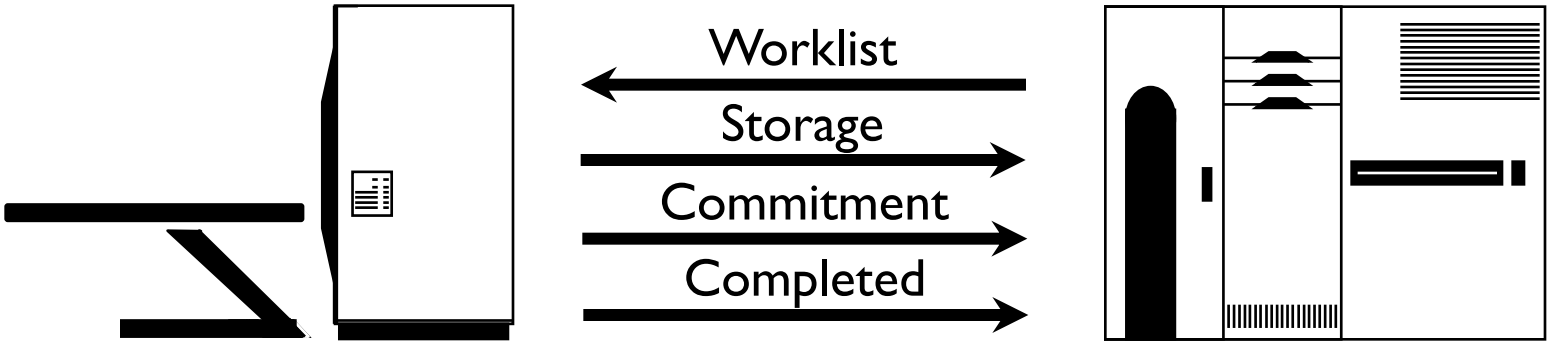
Why DICOM?

- Enormous experience in radiology and cardiology
- 35 years since ACR-NEMA PS3 Standard (1985), which became DICOM
- A consensus of user and industry representatives. later adopted by ISO as ISO 12052
- 80 million CT studies per year in US (CBS News, 2015) – all DICOM
- Huge supporting infra-structure – for both DICOM file format, protocol and services
- All manner of products essentially commoditized: scanners, archives, workstations, viewers, PACS, toolkits for products, testing, analysis, research
- Both commercial and free, closed and open source tools
- Conformance and interoperability testing venues (e.g., IHE Connectathons)
- Modality agnostic – e.g., XR, MR, NM also Visible Light, esp. Ophthalmology, Endoscopy
- Application agnostic – human, veterinary, small animal research, non-destructive testing (esp. aerospace and nuclear power), security (esp. baggage scanning)
- Emphasis on reliable, consistent, standard metadata (common data elements, value sets)

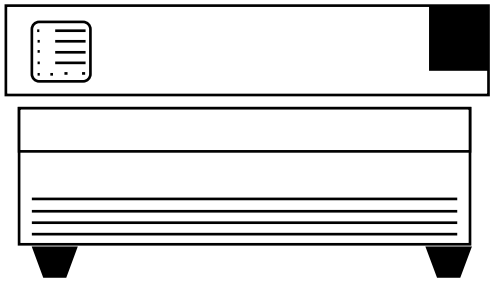
DICOM and Radiology Modality



DICOM and Radiology Modality

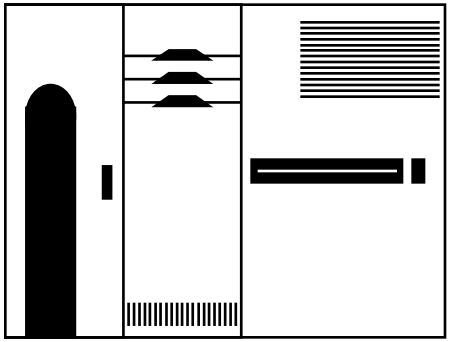


DICOM and Slide Scanner



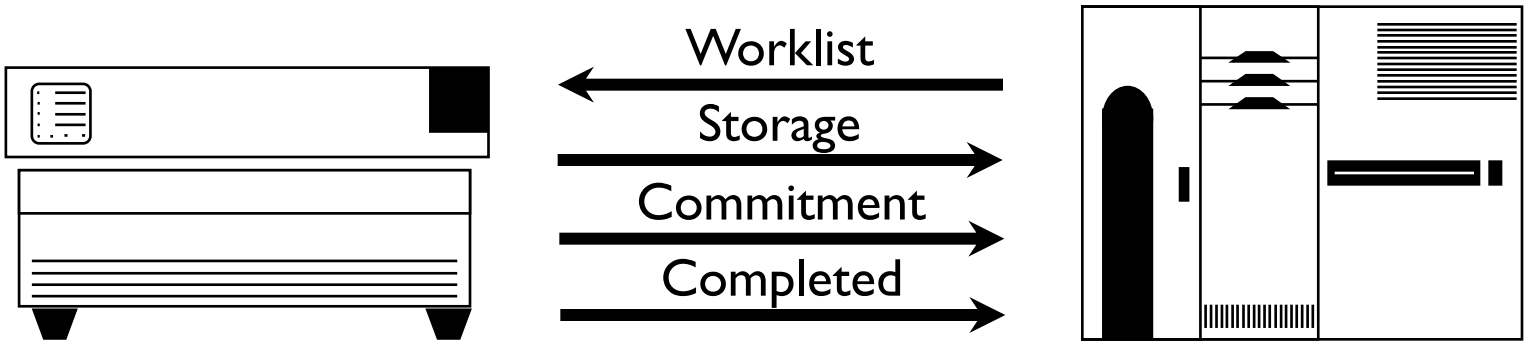
Slide Scanner

Storage

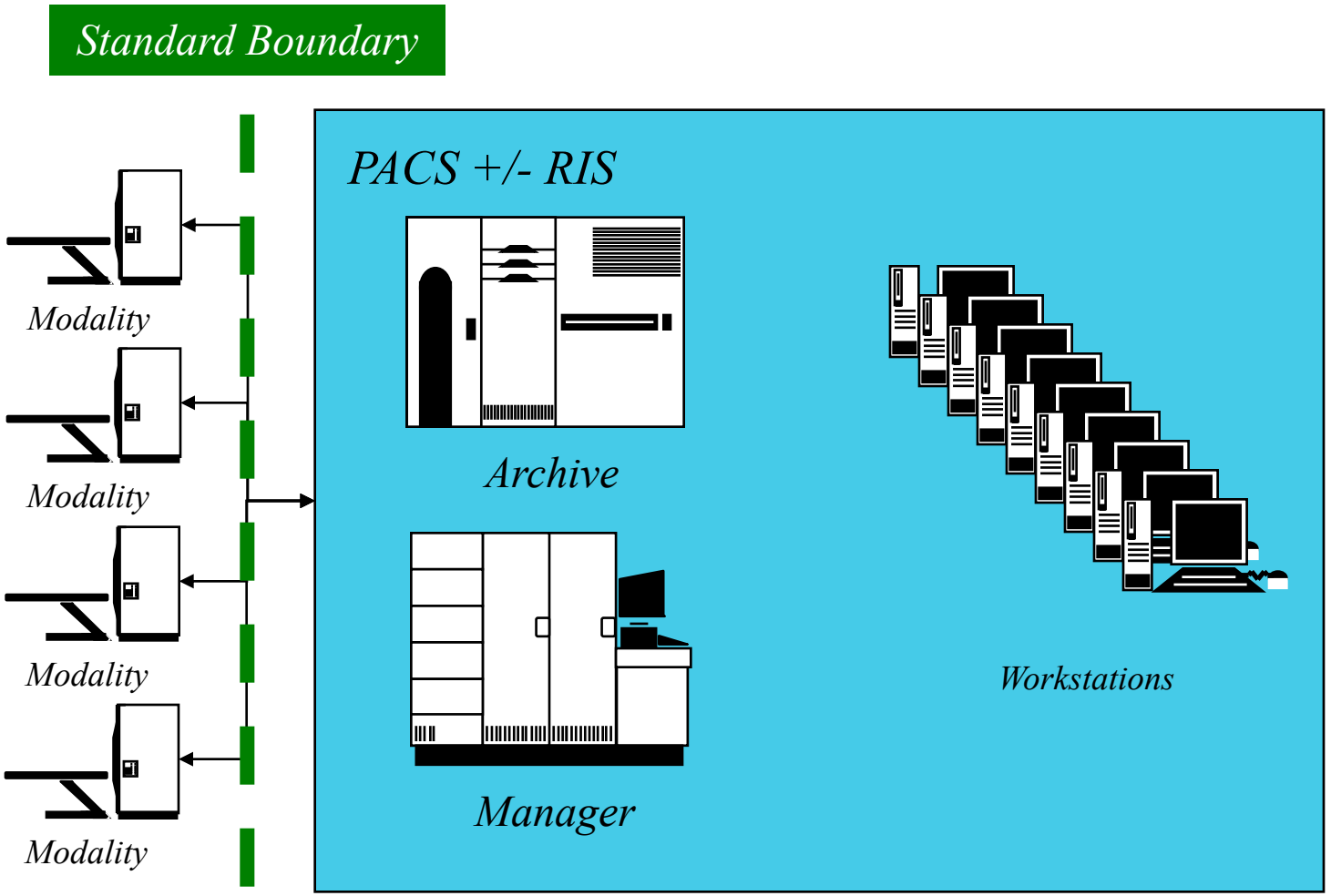


PACS

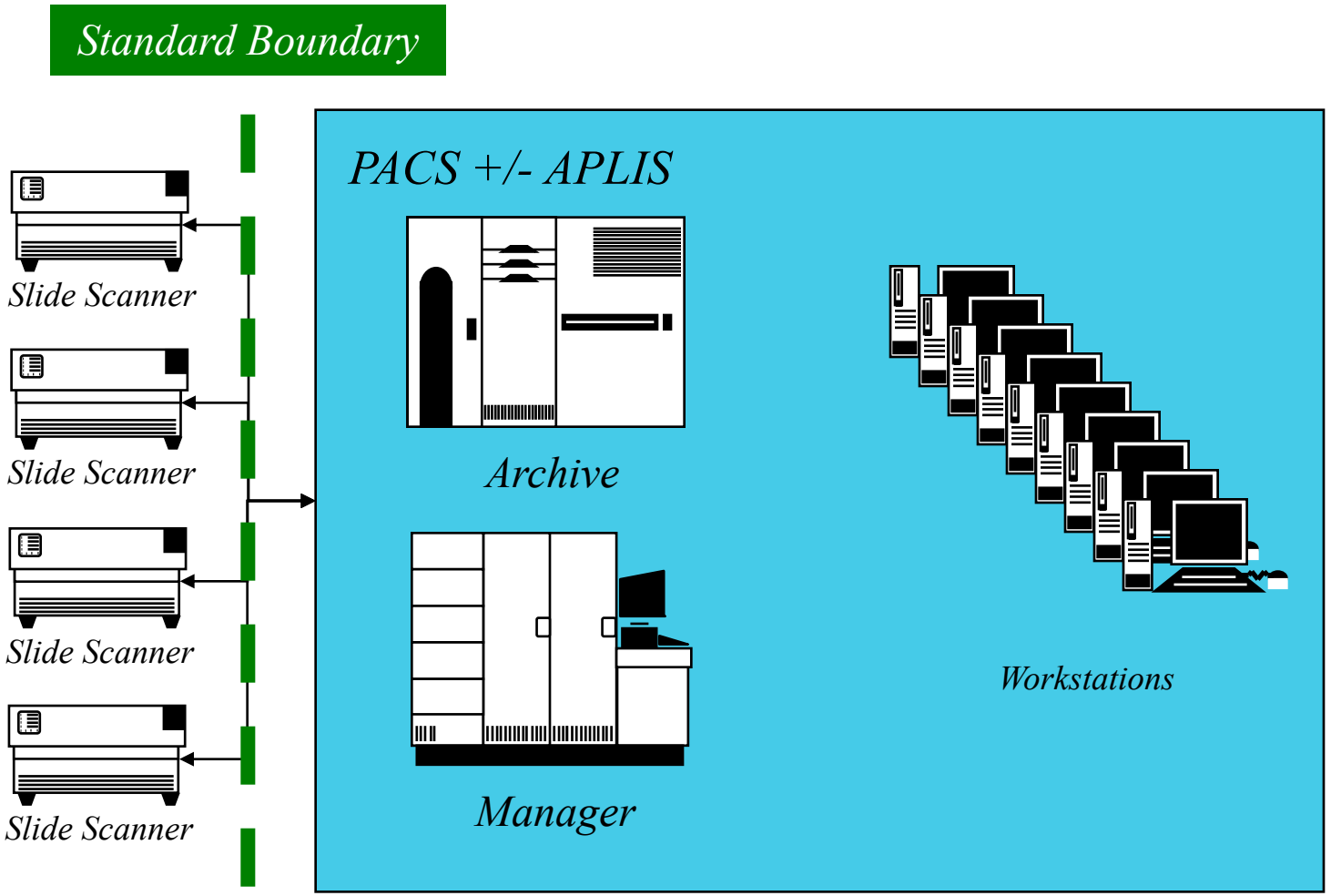
DICOM and Slide Scanner



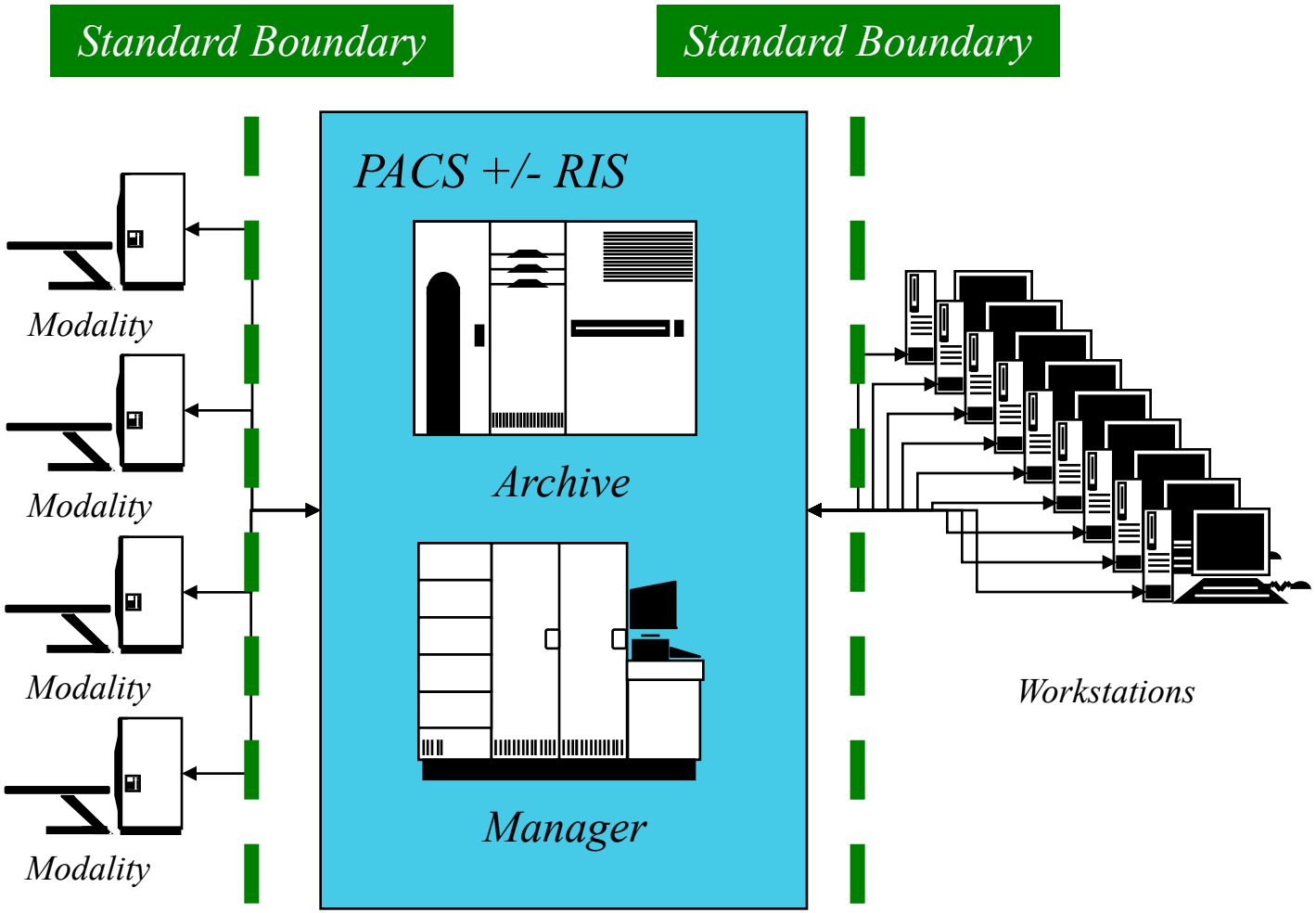
DICOM Modality to PACS



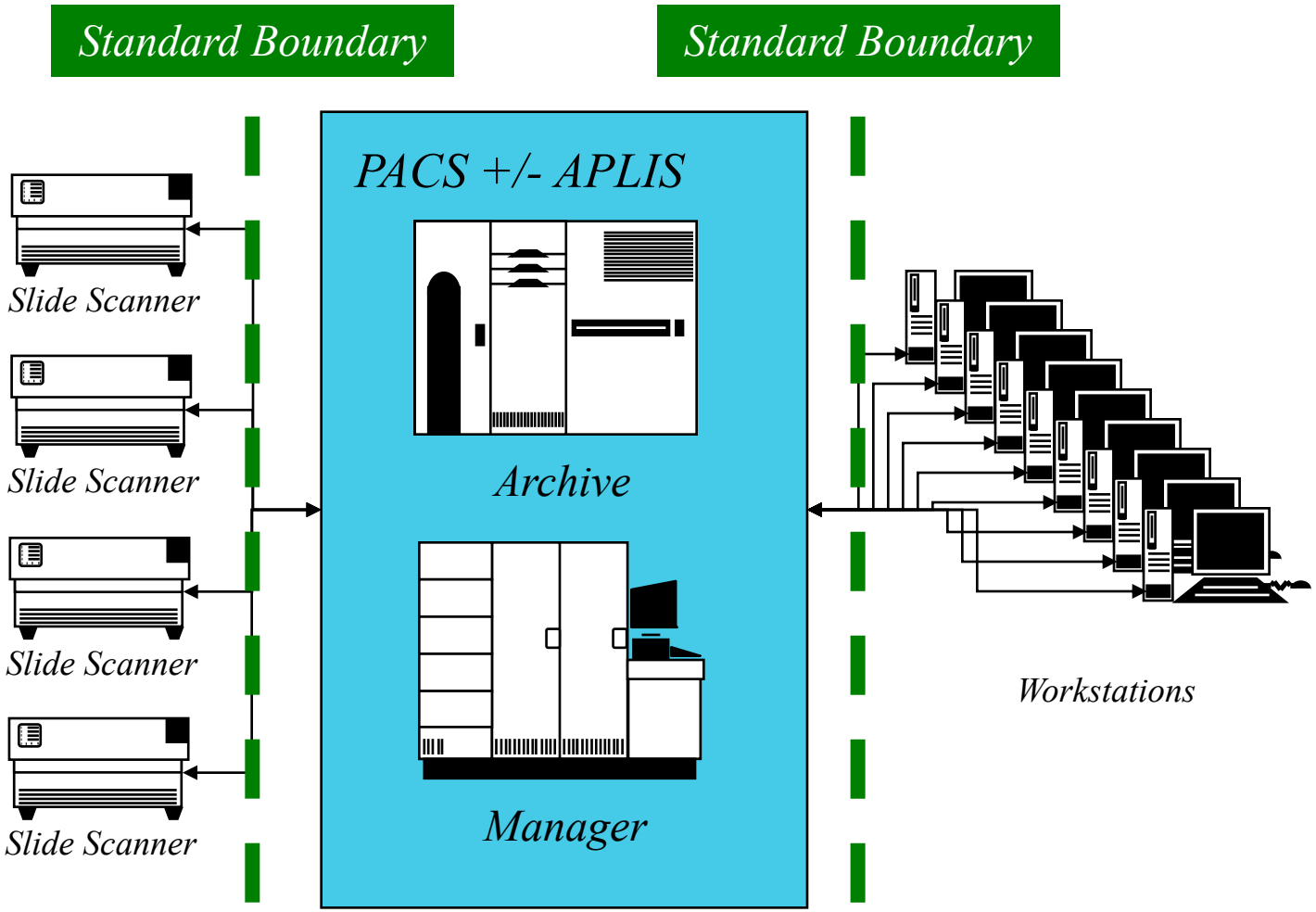
DICOM WSI to PACS



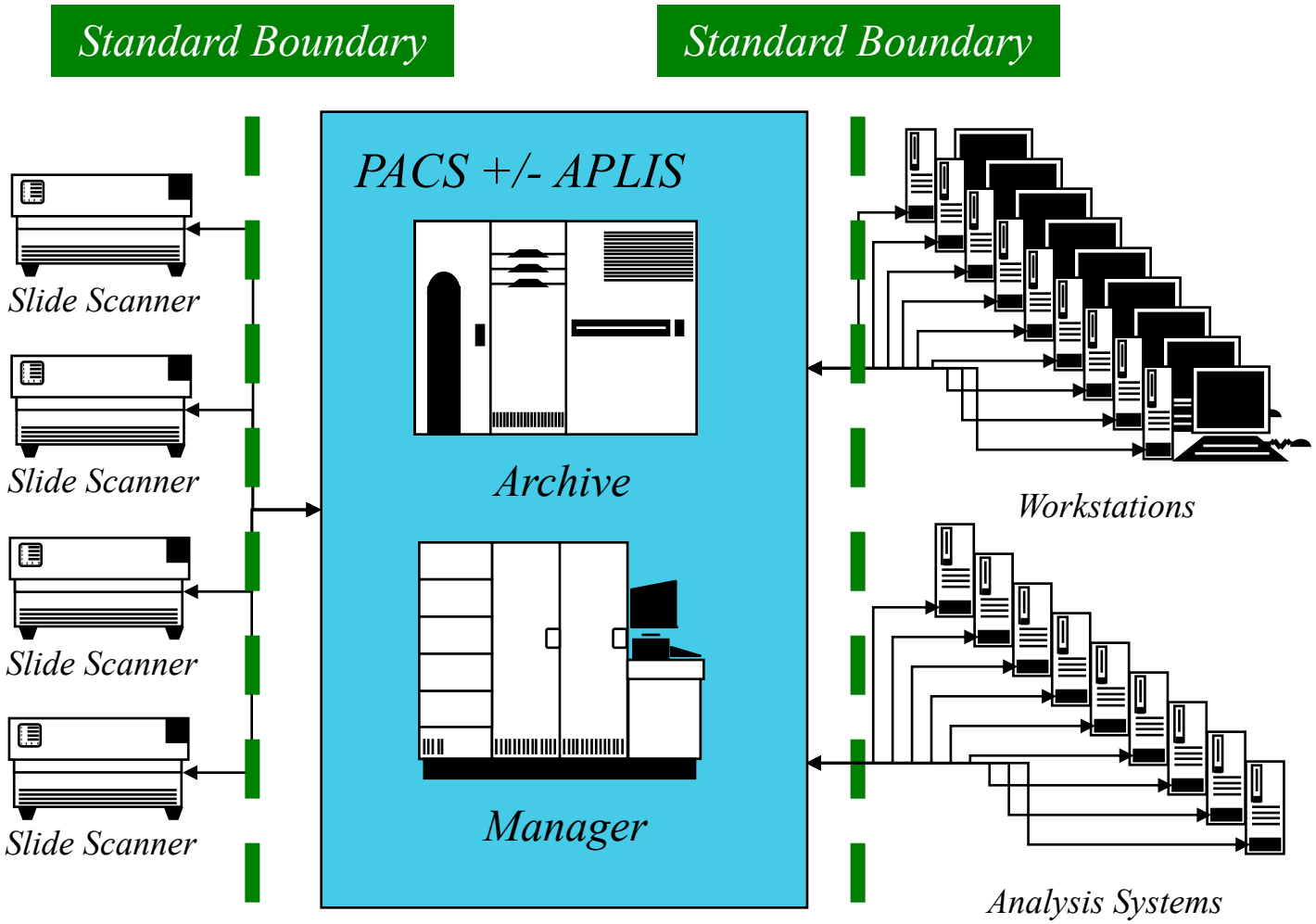
DICOM – Radiology Workstation



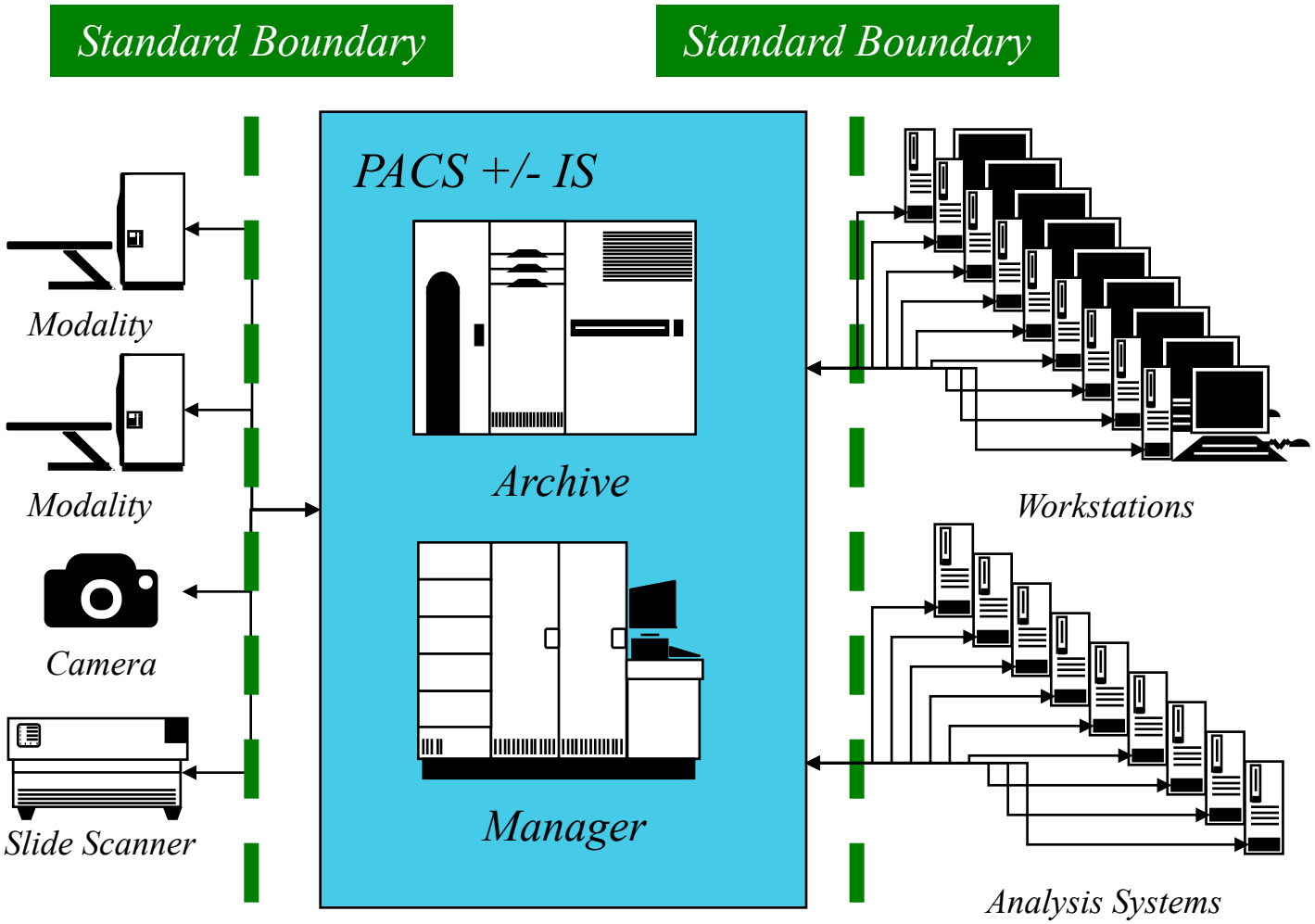
DICOM – Pathology Workstation



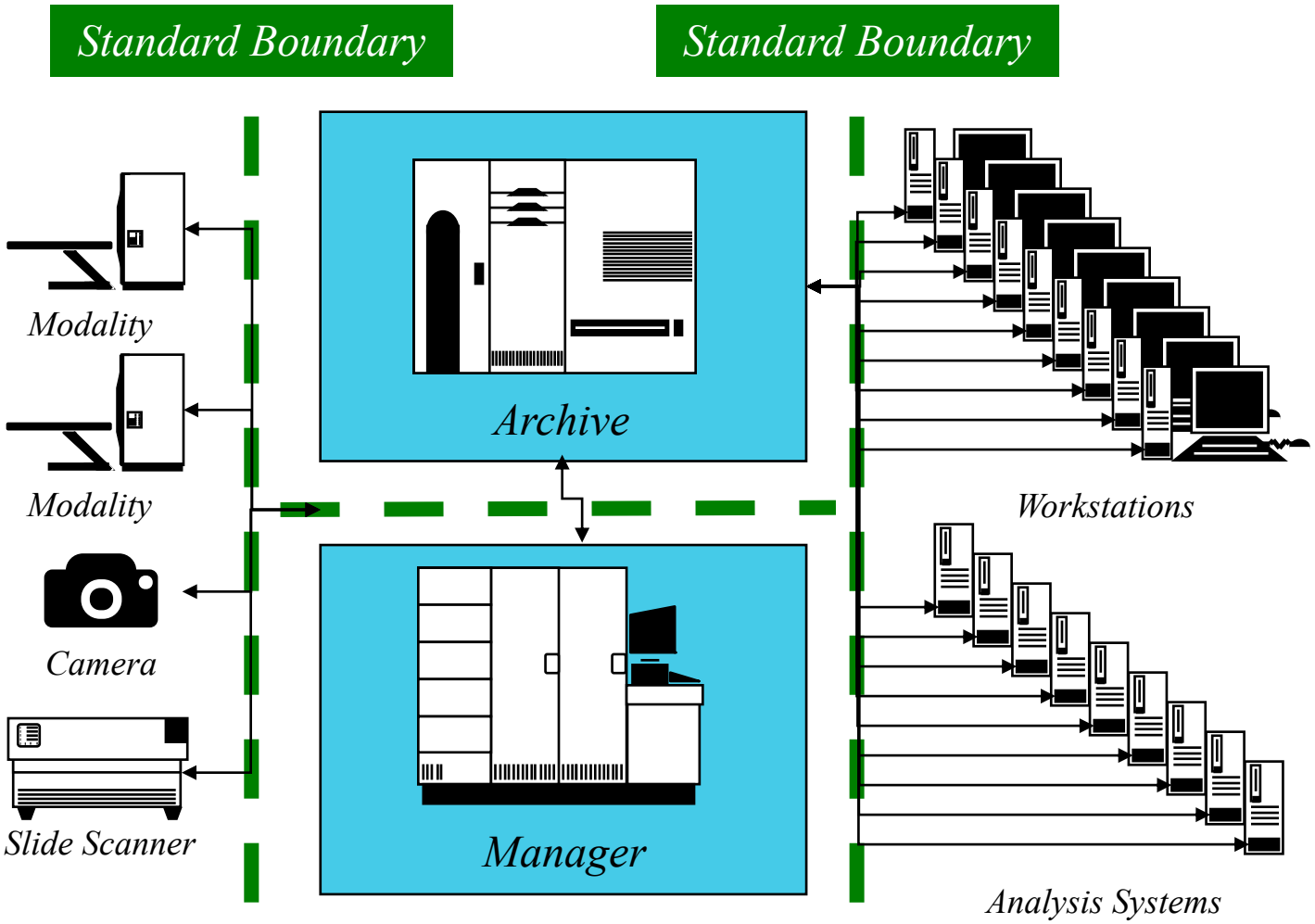
DICOM – Analysis Systems



DICOM – Enterprise Imaging



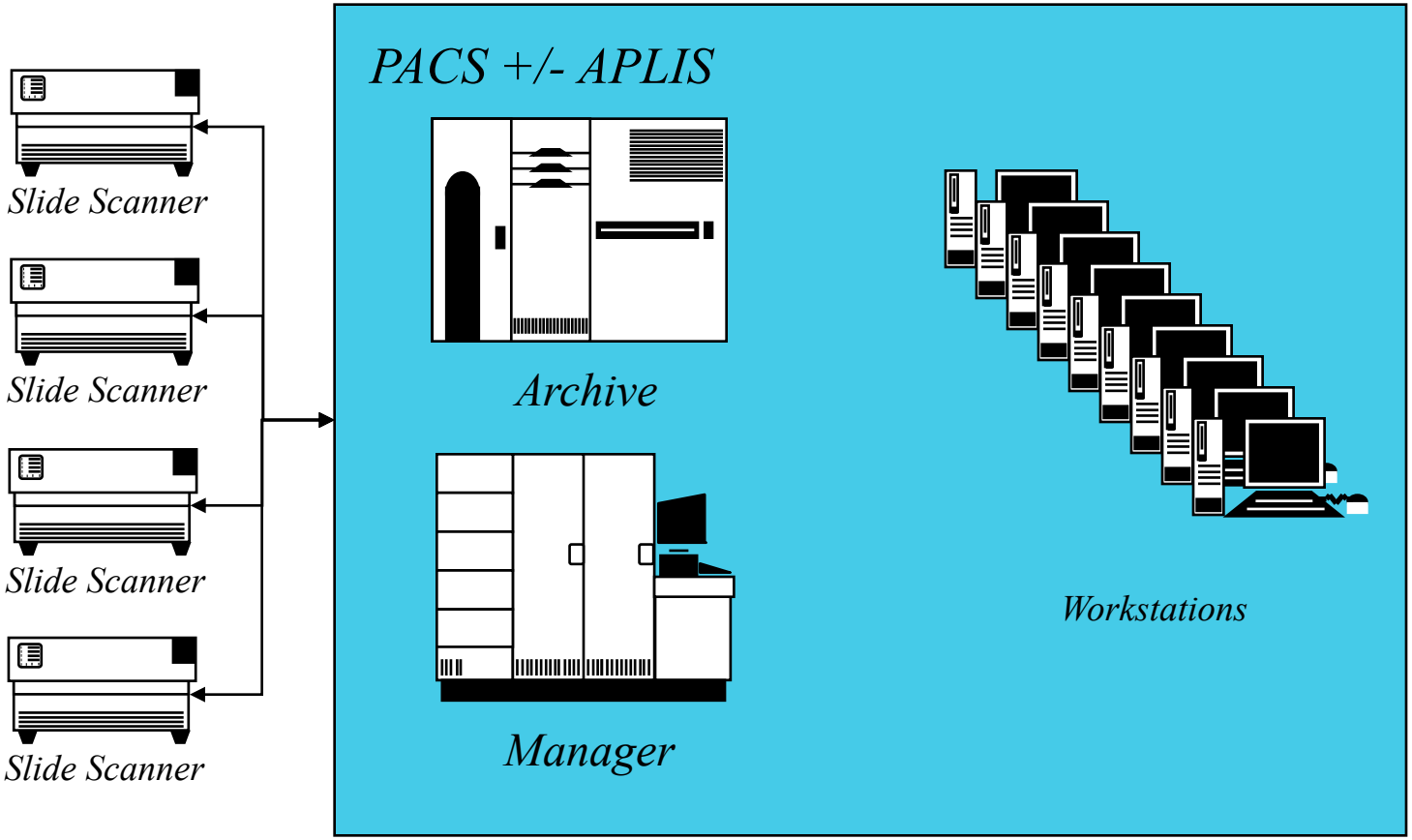
DICOM – Deconstructed PACS



FDA “entire pixel pathway”

Single Vendor Black Box
Philips, Leica Aperio AT2 510(k)s

Leica Aperio AT2 to Sectra 510(k)



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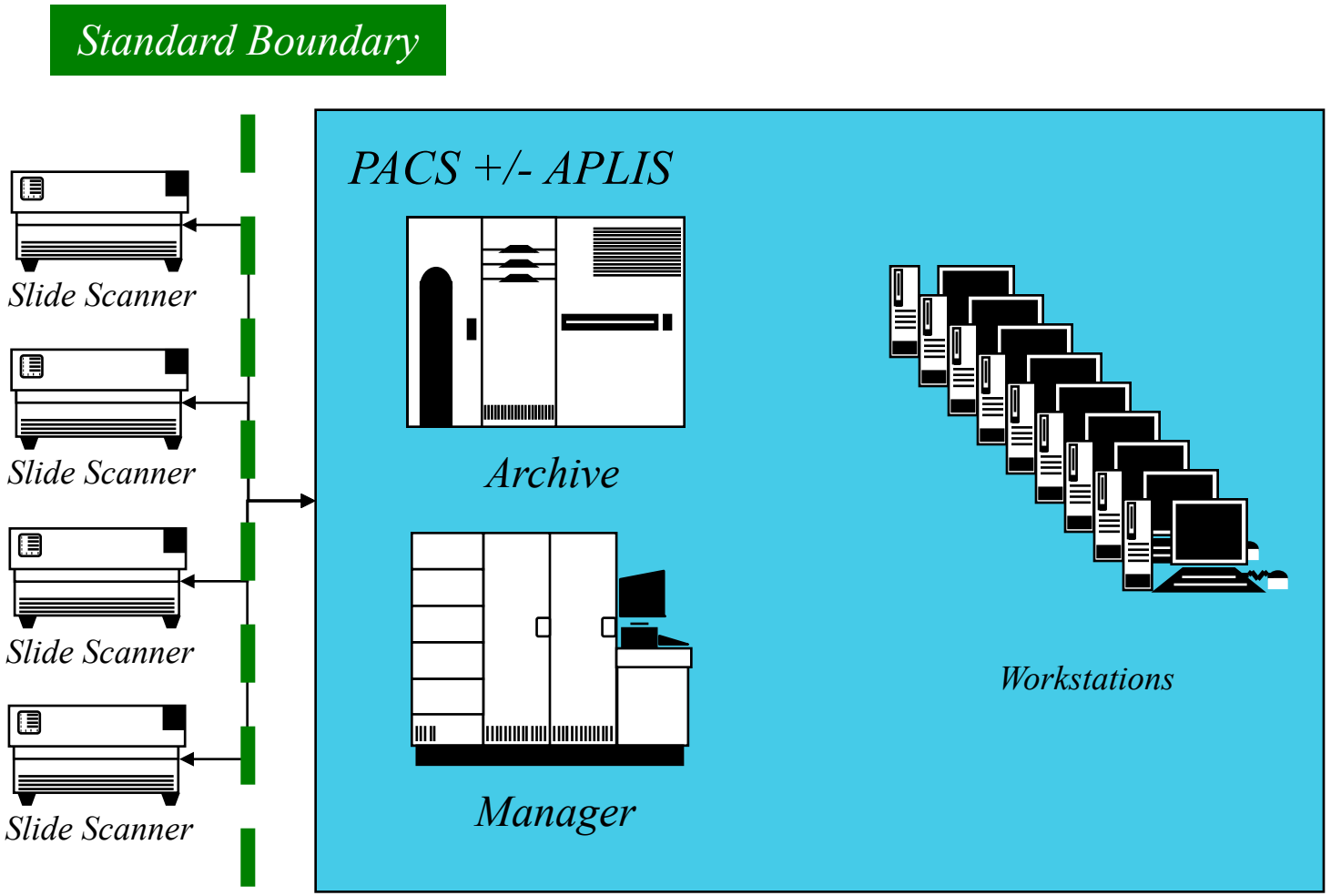
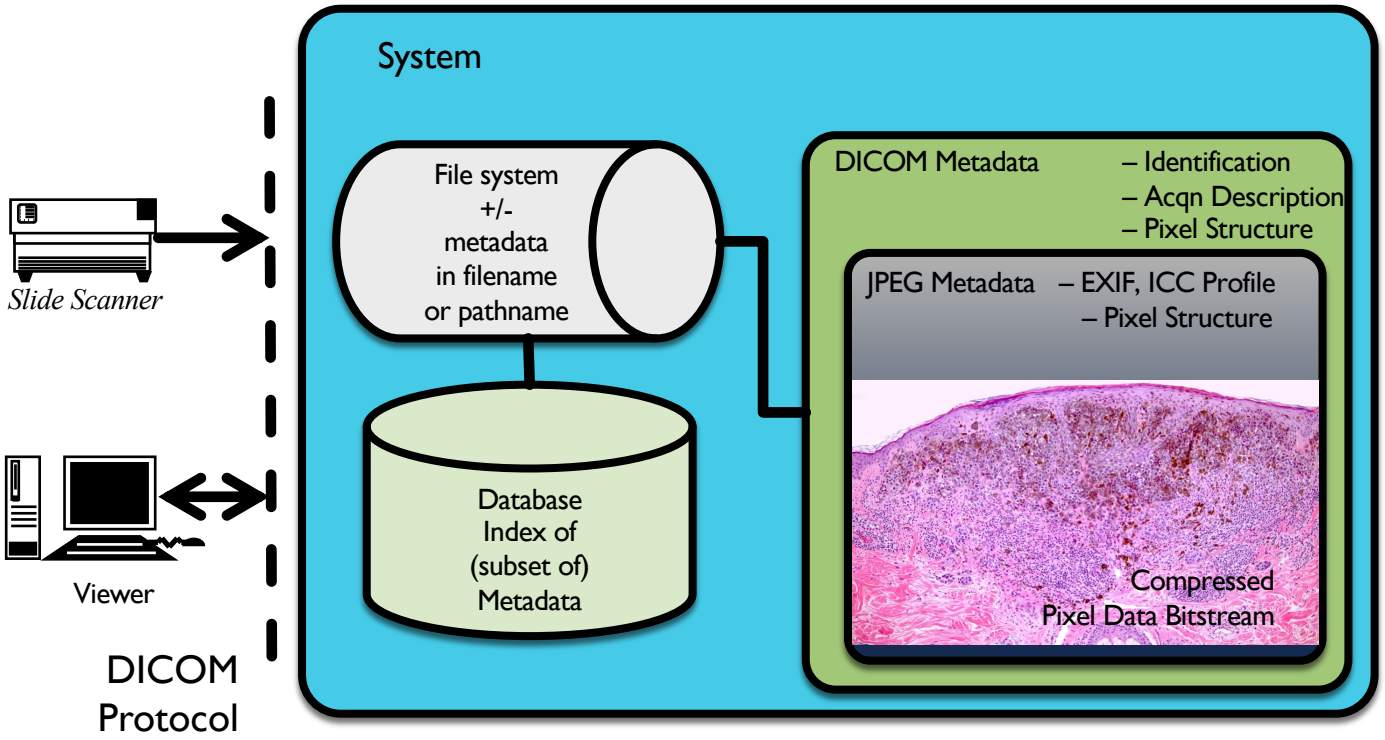


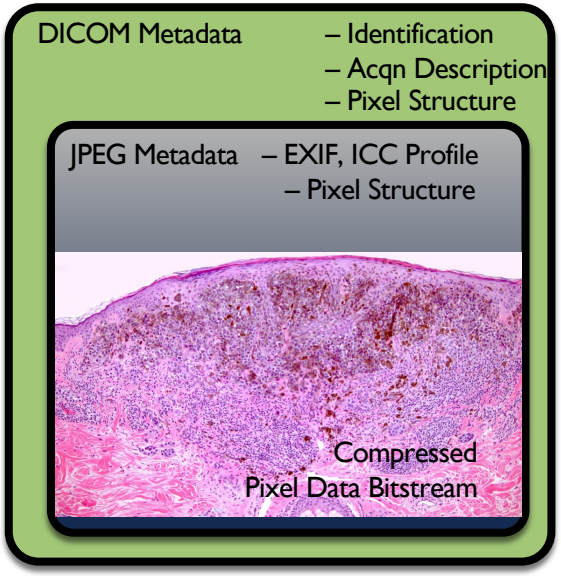
DICOM WSI – What and How

- File format for:
  - whole slide images (tiled pyramid)
  - single fields – slide microscopy
  - gross microscopy
- File contains:
  - compressed pixels (JPEG or JPEG 2000)
  - metadata – identifying AND descriptive
- Protocol for sending and receiving, etc.
- Other stuff like workflow, annotation, segmentation, structured reports, …

DICOM System and Metadata



DICOM File – Metadata included



Metadata – Standard Information Model

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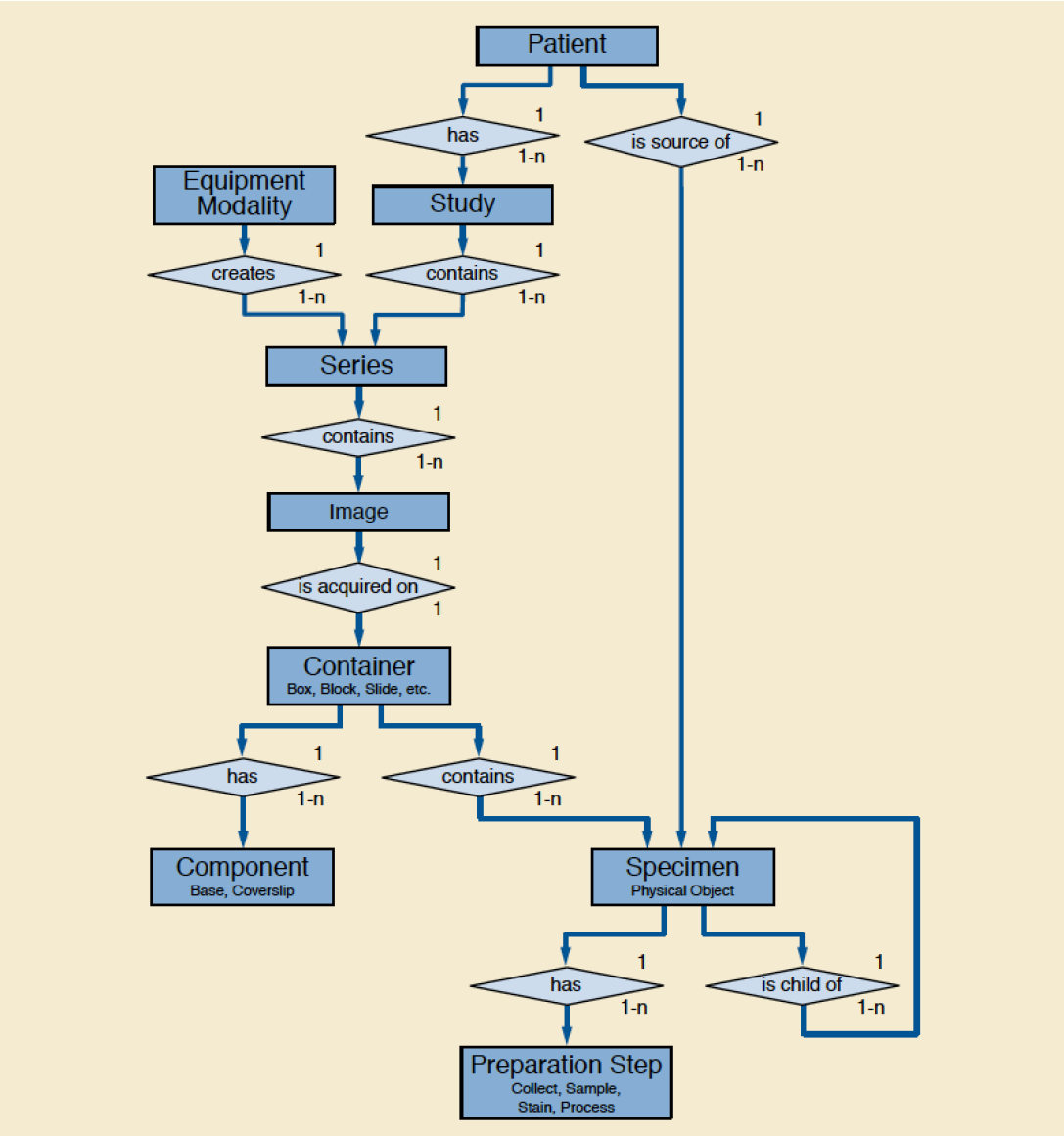

DICOM Modality-Specific Metadata

- Common base, but different (mandatory/optional) features for different applications
- For example,
  - MR Image
    - single frame, 12-16 bit grayscale image
    - MR acquisition - pulse sequence parameters
    - 3D patient relative co-ordinate/vector position
  - X-Ray Angiography Image
    - multi-frame, 8-10 bit grayscale image
    - XA acquisition - radiation/collimation/motion
    - dynamic C-arm/table relative positioning
  - Whole Slide Microscopy Image
    - tiled multi-frame, 8-16 bit per channel true color or grayscale image
    - specimen and container identification
    - specimen processing description – collection, fixation, embedding, staining

DICOM Common Metadata Attributes

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(0x0008,0x0005) CS Specific Character Set        VR=<CS>   VL=<0x000a>  <ISO_IR 192>
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(0x0008,0x0018) UI SOP Instance UID      VR=<UI>   VL=<0x002c>  <2.25.303027567746224774473319543698839323449>
(0x0008,0x0020) DA Study Date    VR=<DA>   VL=<0x0008>  <20190105>
(0x0008,0x0023) DA Content Date          VR=<DA>   VL=<0x0008>  <20190605>
(0x0008,0x002a) DT Acquisition DateTime          VR=<DT>   VL=<0x0014>  <20190403134345+0200 >
(0x0008,0x0030) TM Study Time    VR=<TM>   VL=<0x000e>  <170000.000000 >
(0x0008,0x0033) TM Content Time          VR=<TM>   VL=<0x000e>  <153114.151937 >
(0x0008,0x0050) SH Accession Number      VR=<SH>   VL=<0x0008>  <D19-1002>
(0x0008,0x0060) CS Modality      VR=<CS>   VL=<0x0002>  <SM>
(0x0008,0x0070) LO Manufacturer          VR=<LO>   VL=<0x000e>  <3DHISTECH Kft.>
(0x0008,0x0090) PN Referring Physician's Name    VR=<PN>   VL=<0x0014>  <Beckwith^Bruce^^^MD >
(0x0008,0x0201) SH Timezone Offset From UTC      VR=<SH>   VL=<0x0006>  <+0200 >
(0x0008,0x1030) LO Study Description     VR=<LO>   VL=<0x0008>  <Placenta>
(0x0008,0x1090) LO Manufacturer's Model Name     VR=<LO>   VL=<0x0002>  <? >
(0x0008,0x9206) CS Volumetric Properties         VR=<CS>   VL=<0x0006>  <VOLUME>
(0x0010,0x0010) PN Patient's Name        VR=<PN>   VL=<0x0010>  <Histech^Theresa >
(0x0010,0x0020) LO Patient ID    VR=<LO>   VL=<0x0008>  <1473843 >
(0x0010,0x0021) LO Issuer of Patient ID          VR=<LO>   VL=<0x0012>  <XYZ Medical Center>
(0x0010,0x0030) DA Patient's Birth Date          VR=<DA>   VL=<0x0008>  <19920915>
(0x0010,0x0040) CS Patient's Sex         VR=<CS>   VL=<0x0002>  <F >
(0x0018,0x1000) LO Device Serial Number          VR=<LO>   VL=<0x0002>  <? >
(0x0018,0x1020) LO Software Versions     VR=<LO>   VL=<0x0034>  <2.0.0.98298\2.3.0.32188\DicomObjects.NET v8.40.110.2>
(0x0018,0x9073) FD Acquisition Duration          VR=<FD>   VL=<0x0008>  {62}
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(0x0020,0x0011) IS Series Number         VR=<IS>   VL=<0x0000>  <>
(0x0020,0x0013) IS Instance Number       VR=<IS>   VL=<0x0002>  <2 >
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(0x0020,0x0052) UI Frame of Reference UID        VR=<UI>   VL=<0x002c>  <2.25.312720432849011477406910130848517432703>
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DICOM Specimen Metadata Attributes

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    > (0x0040,0x0554) UI Specimen UID    VR=<UI>   VL=<0x002c>  <1.25.273676883697851244691030743452742612l4>
    > (0x0040,0x0562) SQ Issuer of the Specimen Identifier Sequence      VR=<SQ>   VL=<0xffffffff>
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    > (0x0040,0x0031) UT Local Namespace Entity ID       VR=<UT>   VL=<0x0012>  <XYZ Medical Center>

    > (0x0040,0x0610) SQ Specimen Preparation Sequence   VR=<SQ>   VL=<0xffffffff>
  ----:
    > (0x0040,0x0612) SQ Specimen Preparation Step Content Item Sequence         VR=<SQ>   VL=<0xffffffff>
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    > (0x0040,0xa040) CS Value Type      VR=<CS>   VL=<0x0004>  <TEXT>
    > (0x0040,0xa043) SQ Concept Name Code Sequence      VR=<SQ>   VL=<0xffffffff>
  ----:
    > (0x0008,0x0100) SH Code Value      VR=<SH>   VL=<0x0006>  <121041>
    > (0x0008,0x0102) SH Coding Scheme Designator        VR=<SH>   VL=<0x0004>  <DCM >
    > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x0014>  <Specimen Identifier >

    > (0x0040,0xa160) UT Text Value      VR=<UT>   VL=<0x000c>  <D19-1002 A-1>
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    > (0x0008,0x0102) SH Coding Scheme Designator        VR=<SH>   VL=<0x0004>  <DCM >
    > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x0010>  <Processing type >

    > (0x0040,0xa168) SQ Concept Code Sequence   VR=<SQ>   VL=<0xffffffff>
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    > (0x0008,0x0102) SH Coding Scheme Designator        VR=<SH>   VL=<0x0004>  <SRT >
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DICOM Specimen Metadata Attributes

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  > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x0008>  <Staining>

----:
  > (0x0040,0xa040) CS Value Type      VR=<CS>   VL=<0x0004>  <CODE>
  > (0x0040,0xa043) SQ Concept Name Code Sequence      VR=<SQ>   VL=<0xffffffff>
----:
  > (0x0008,0x0100) SH Code Value      VR=<SH>   VL=<0x0006>  <G-C350>
  > (0x0008,0x0102) SH Coding Scheme Designator        VR=<SH>   VL=<0x0004>  <SRT >
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  > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x0012>  <hematoxylin stain >

----:
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  > (0x0040,0xa043) SQ Concept Name Code Sequence      VR=<SQ>   VL=<0xffffffff>
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  > (0x0008,0x0100) SH Code Value      VR=<SH>   VL=<0x0006>  <G-C350>
  > (0x0008,0x0102) SH Coding Scheme Designator        VR=<SH>   VL=<0x0004>  <SRT >
  > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x0010>  <Using substance >

  > (0x0040,0xa168) SQ Concept Code Sequence   VR=<SQ>   VL=<0xffffffff>
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  > (0x0008,0x0102) SH Coding Scheme Designator        VR=<SH>   VL=<0x0004>  <SRT >
  > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x001a>  <water soluble eosin stain >
```

Metadata – Standard Coded Terminology

- Lens, e.g., (445621001, SCT, "High power non-immersion lens")
- Sensor sensitivity, e.g., (414298005, SCT, "Full Spectrum")
- Illumination color, e.g., (415770004, SCT, "Ultraviolet")
- Illumination method, e.g., (111744, DCM, "Brightfield illumination")
- Illumination type, e.g., (445679001, SRT, "Tungsten halogen lamp")
- Filters, e.g., (445465004, SCT, "Green optical filter")

- Use of codes results in consistency between vendors & sites
- Not buried in proprietary metadata, structured or free text, or file name convention
- Primarily SNOMED but can use other specialty-specific schemes

DICOM Slide Metadata Attributes

```
(0x0048,0x0001) FL Imaged Volume Width   VR=<FL>   VL=<0x0004>  {18.9371}
(0x0048,0x0002) FL Imaged Volume Height          VR=<FL>   VL=<0x0004>  {32.736}
(0x0048,0x0003) FL Imaged Volume Depth   VR=<FL>   VL=<0x0004>  {0.6}
(0x0048,0x0006) UL Total Pixel Matrix Columns    VR=<UL>   VL=<0x0004>  [0x000006fa]
(0x0048,0x0007) UL Total Pixel Matrix Rows       VR=<UL>   VL=<0x0004>  [0x00000571]
(0x0048,0x0008) SQ Total Pixel Matrix Origin Sequence    VR=<SQ>   VL=<0xffffffff>
  ----:
    > (0x0040,0x072a) DS X Offset in Slide Coordinate System     VR=<DS>   VL=<0x0002>  <25>
    > (0x0040,0x073a) DS Y Offset in Slide Coordinate System     VR=<DS>   VL=<0x0002>  <50>

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(0x0048,0x0011) CS Focus Method          VR=<CS>   VL=<0x0004>  <AUTO>
(0x0048,0x0012) CS Extended Depth of Field       VR=<CS>   VL=<0x0002>  <NO>
(0x0048,0x0102) DS Image Orientation (Slide)     VR=<DS>   VL=<0x000e>  <-1\0\0\0\-1\0 >
(0x0048,0x0105) SQ Optical Path Sequence         VR=<SQ>   VL=<0xffffffff>
  ----:
    > (0x0022,0x0016) SQ Illumination Type Code Sequence         VR=<SQ>   VL=<0xffffffff>
  ----:
    > (0x0008,0x0100) SH Code Value      VR=<SH>   VL=<0x0006>  <111744>
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    > (0x0008,0x0104) LO Code Meaning    VR=<LO>   VL=<0x0018>  <Brightfield illumination>

    > (0x0028,0x2000) OB ICC Profile     VR=<OB>   VL=<0xf9b8>  [0x00,0x00,0xf9,0xb8,0x00,0x00,0x00,0x00,
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        0x07,0xda,0x00,0x0b,0x00,0x12,0x00,0x14,0x00,0x1e,0x00,0x0f,0x61,0x63,0x73,0x70,
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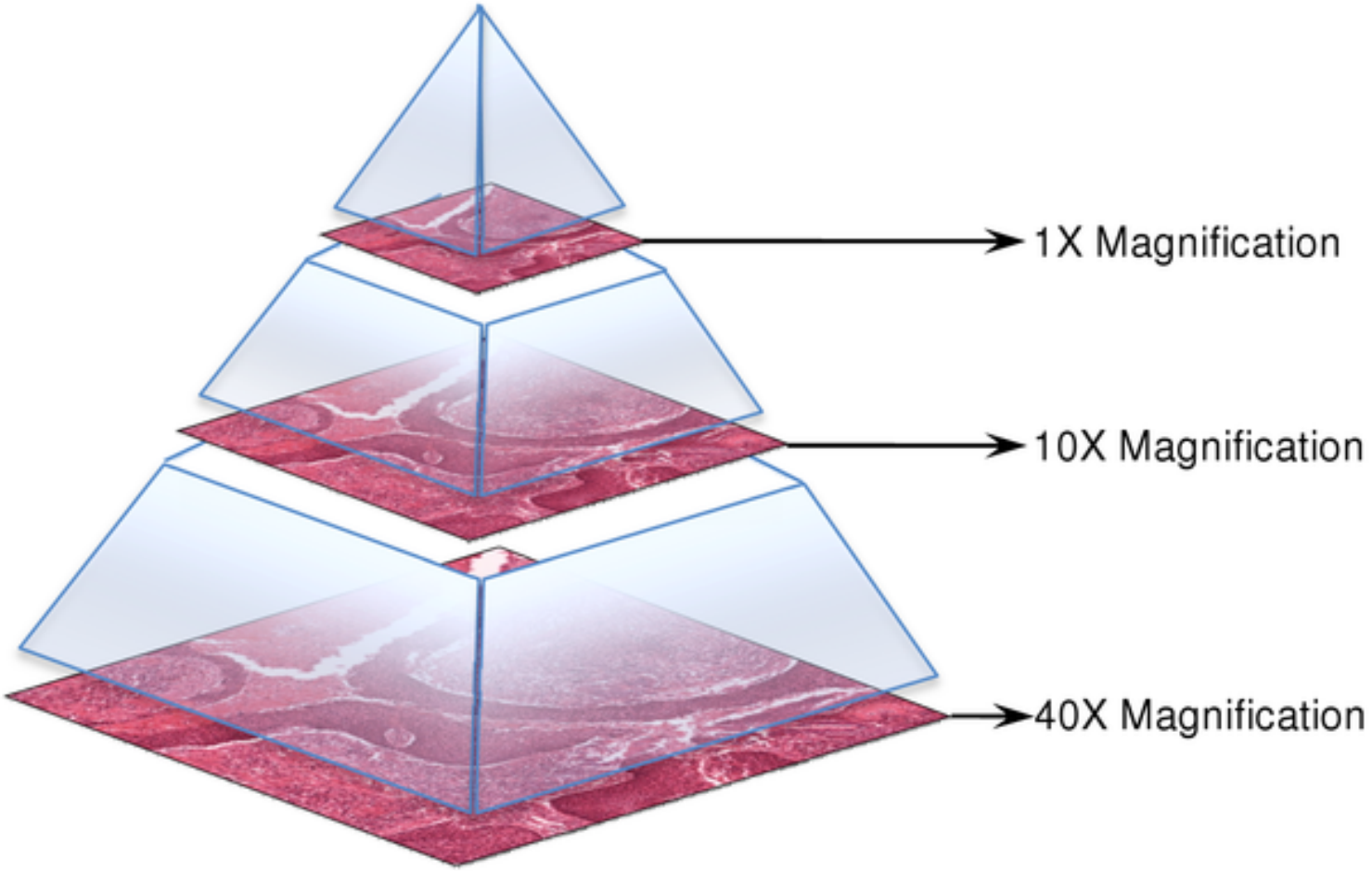
```

DICOM Pixel Data Encoding

- Needs to be (lossy) compressed
  - to be tractable size to store/transmit
  - user experience suggests modest compression does not affect diagnostic task
- Use an industry standard compression scheme – JPEG, JPEG 2000
- Having been lossy compressed on scanner, do not want to recompress
  - causes further unnecessary loss (blurring, artifacts)
  - corollary – if lossy compressed with proprietary scheme, want lossless re-encoding
- Base (highest resolution) of slide tissue area at 40x is very big
  - tissue area 25mm x 15mm @ 0.25µm = 100,000 x 60,000 pixels
  - virtual microscopy (pan/zoom) experience requires pre-computed down-sampled layers
- Originally two competing approaches for DICOM encoding
  - store multiple layers of pyramid, chop each layer into tiles, compressing each separately
  - store entire base layer as JPEG 2000, wavelet transform inherently multi-resolution
  - tiled pyramid approach was selected, can still use JPEG 2000 for each tile separately

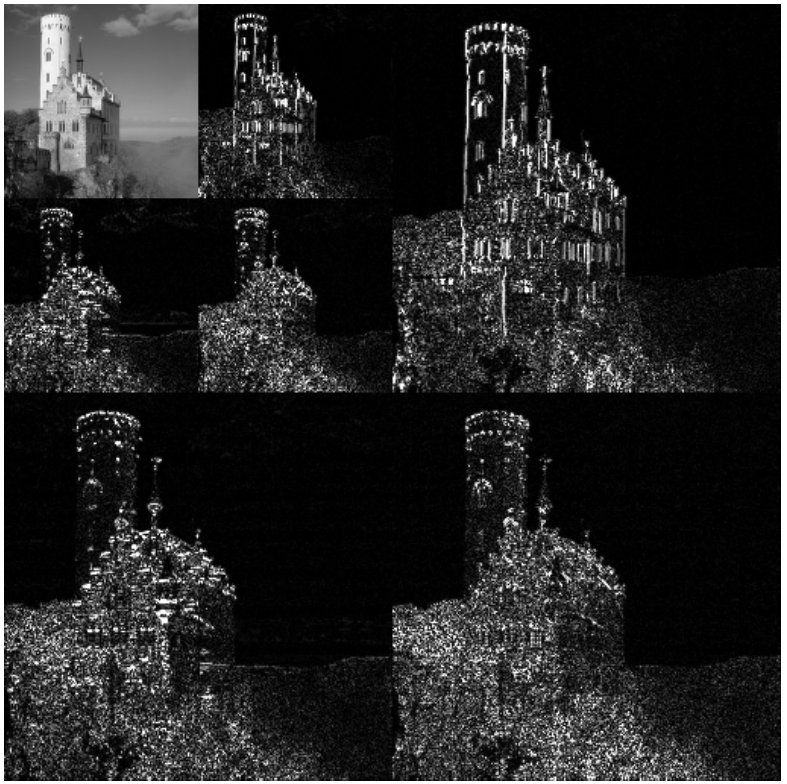
How digital slides are stored in a pyramid structure.



Wang Y, Williamson KE, Kelly PJ, James JA, Hamilton PW (2012) SurfaceSlide: A Multitouch Digital Pathology Platform. PLOS ONE 7(1): e30783. https://doi.org/10.1371/journal.pone.0030783
http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0030783

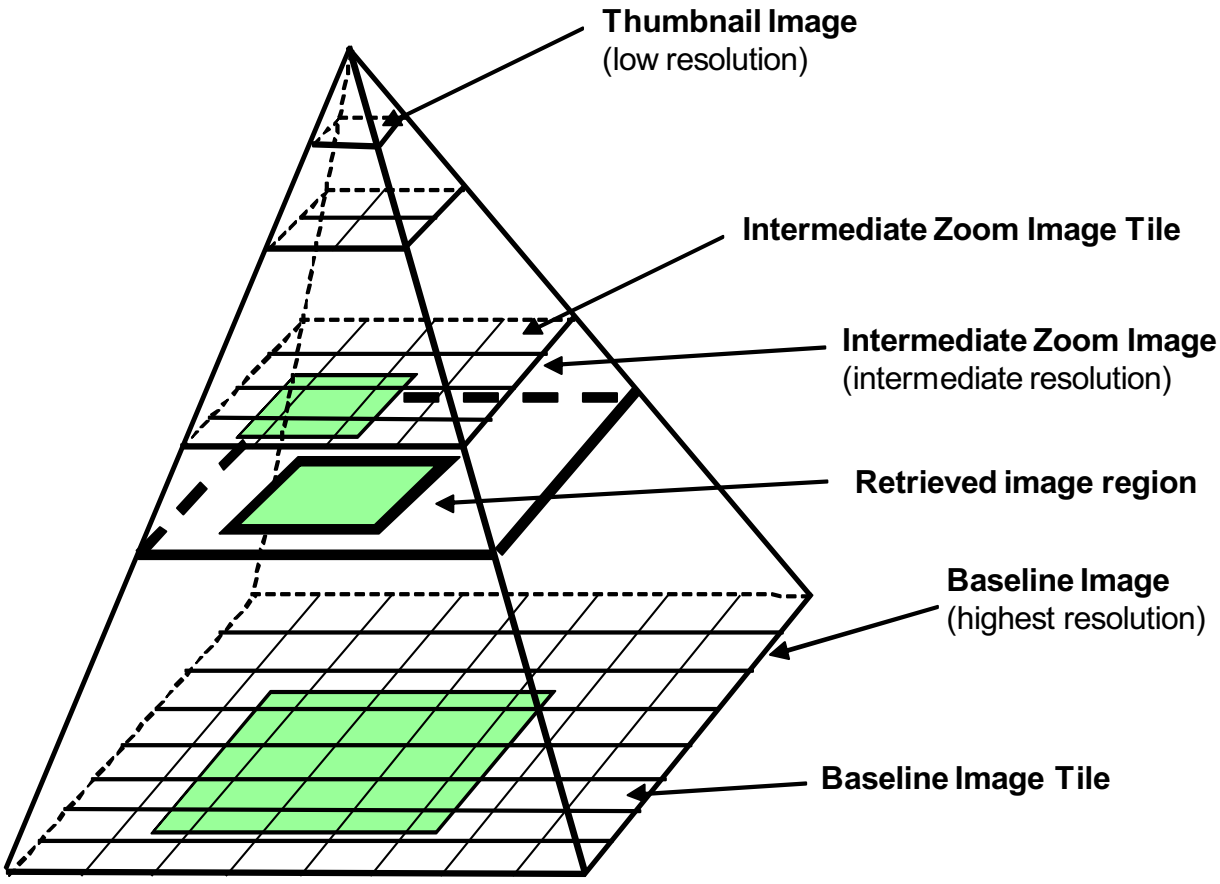
Wavelet Multi-resolution

LL level 2	*LH* level 2	*LH* level 1
HL level 2	*HH* level 2	
HL level 1		*HH* level 1

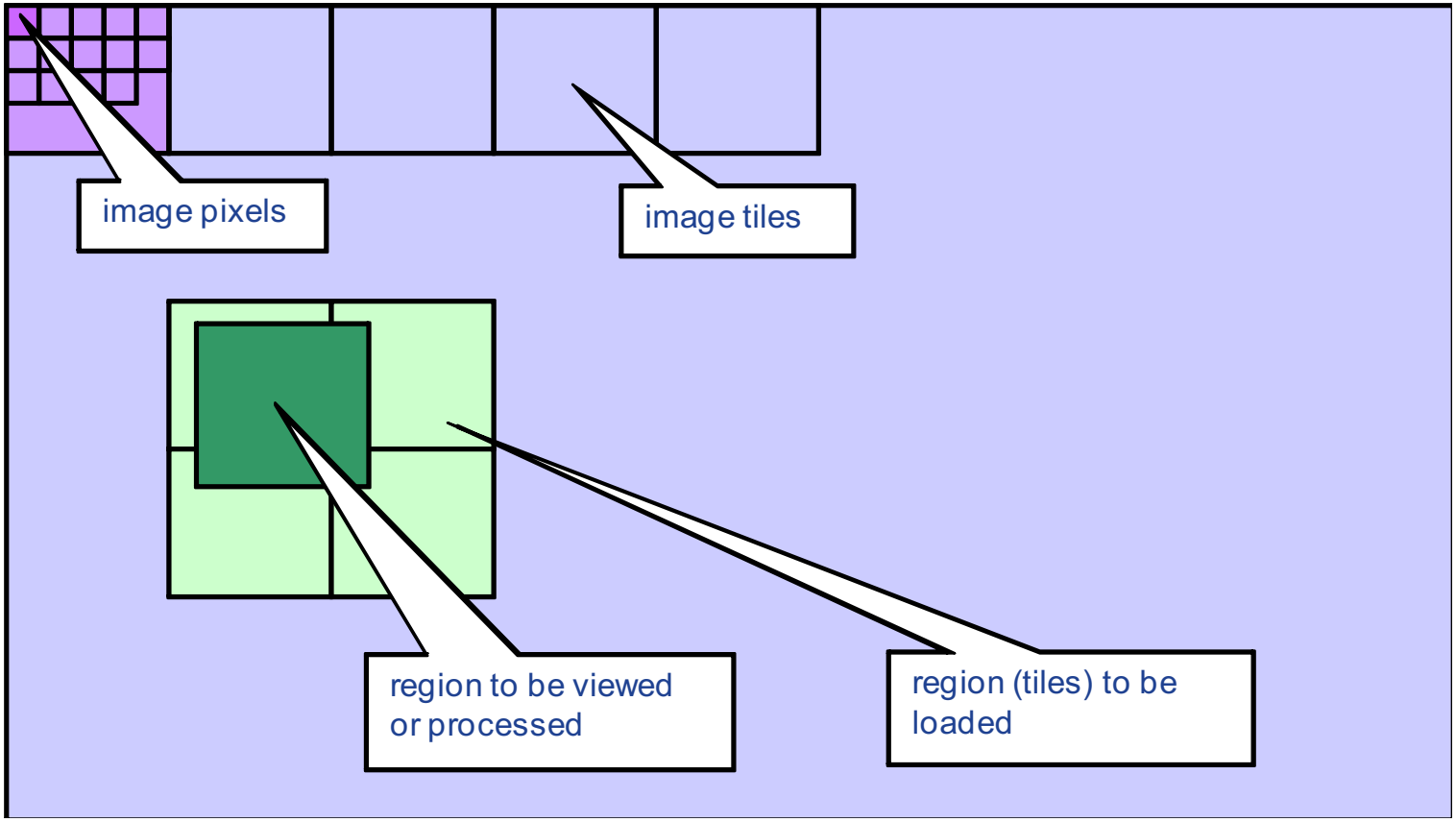


https://www.researchgate.net/publication/258384778_Soccer_Ball_Detection_by_Comparing_Different_Feature_Extraction_Methodologies/figures
https://commons.wikimedia.org/wiki/File:Jpeg2000_2-level_wavelet_transform-lichtenstein.png

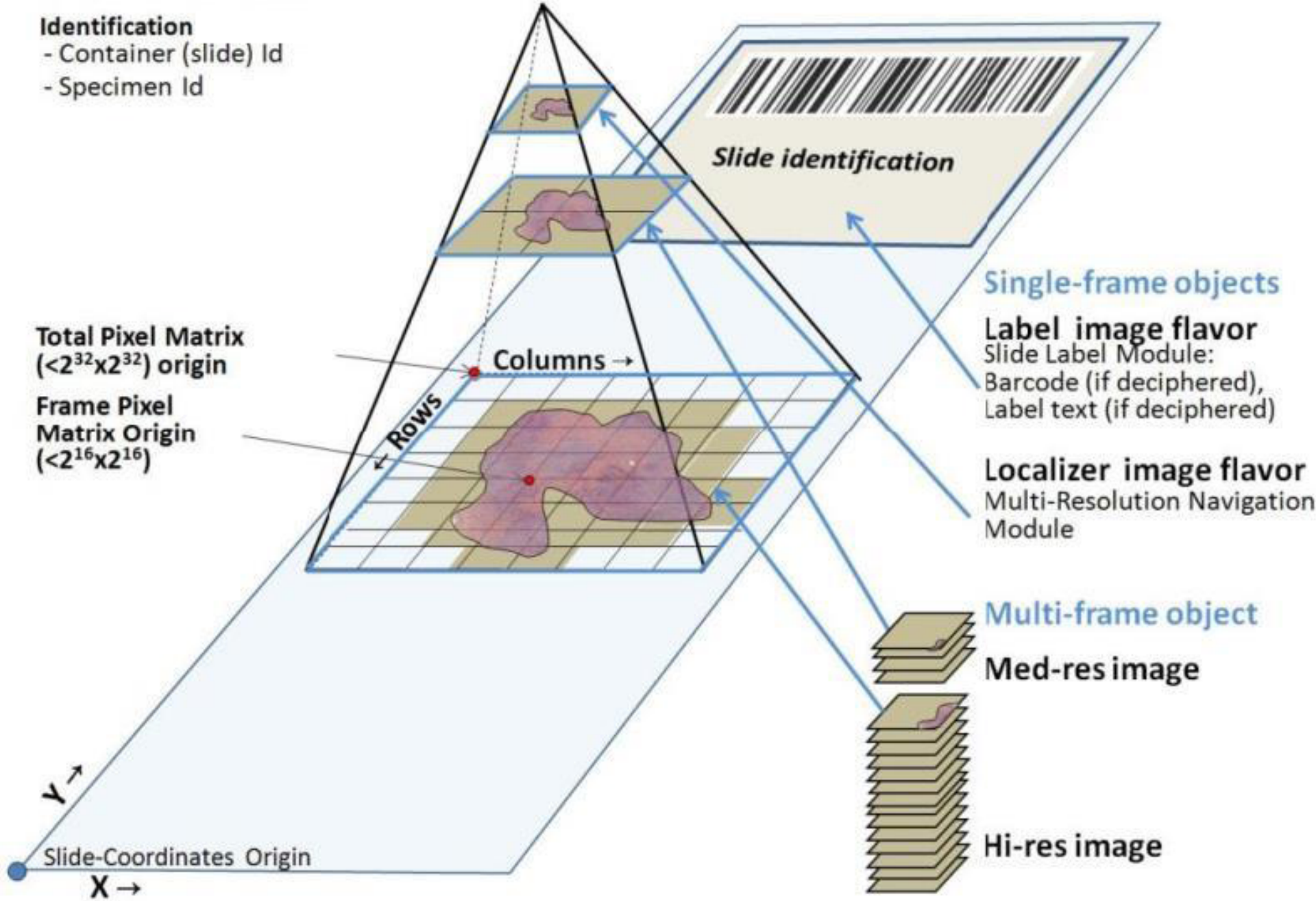
Tiled Pyramid Approach



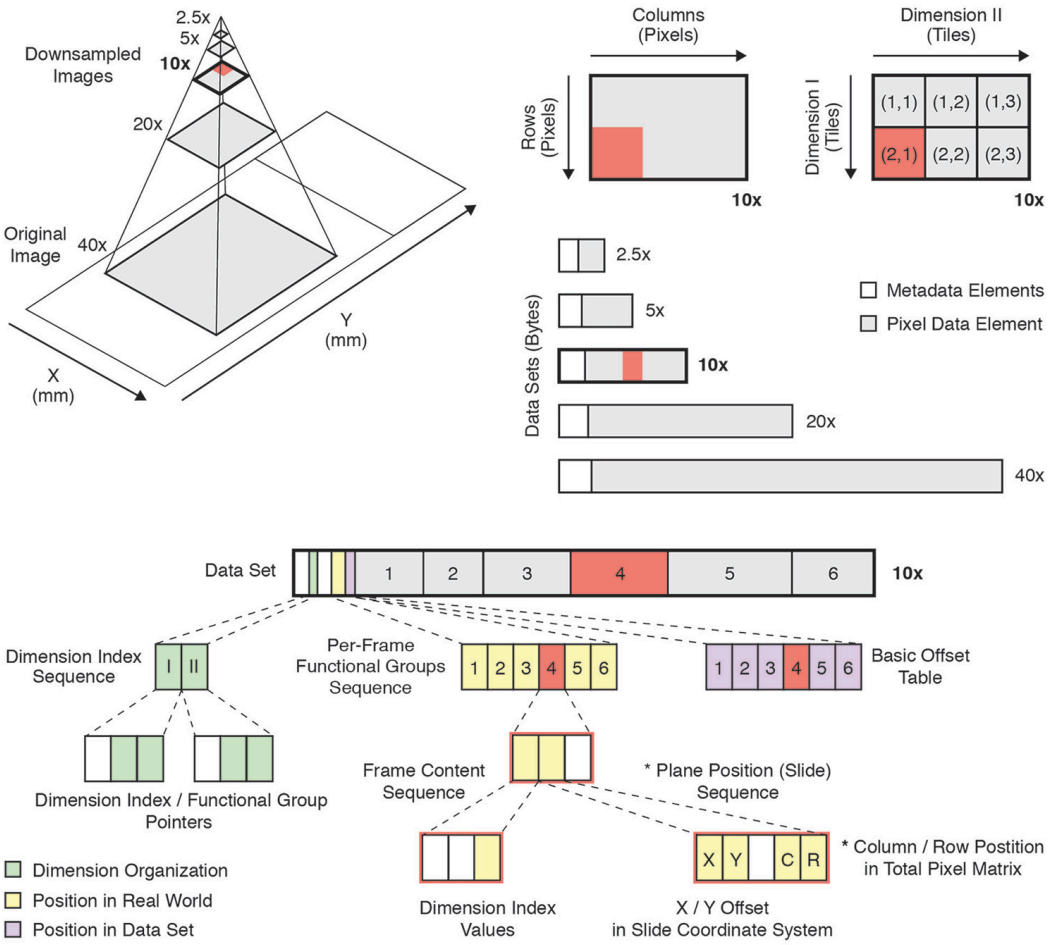
Tiled Pyramid Approach



Garcia-Rojo et al. 2016

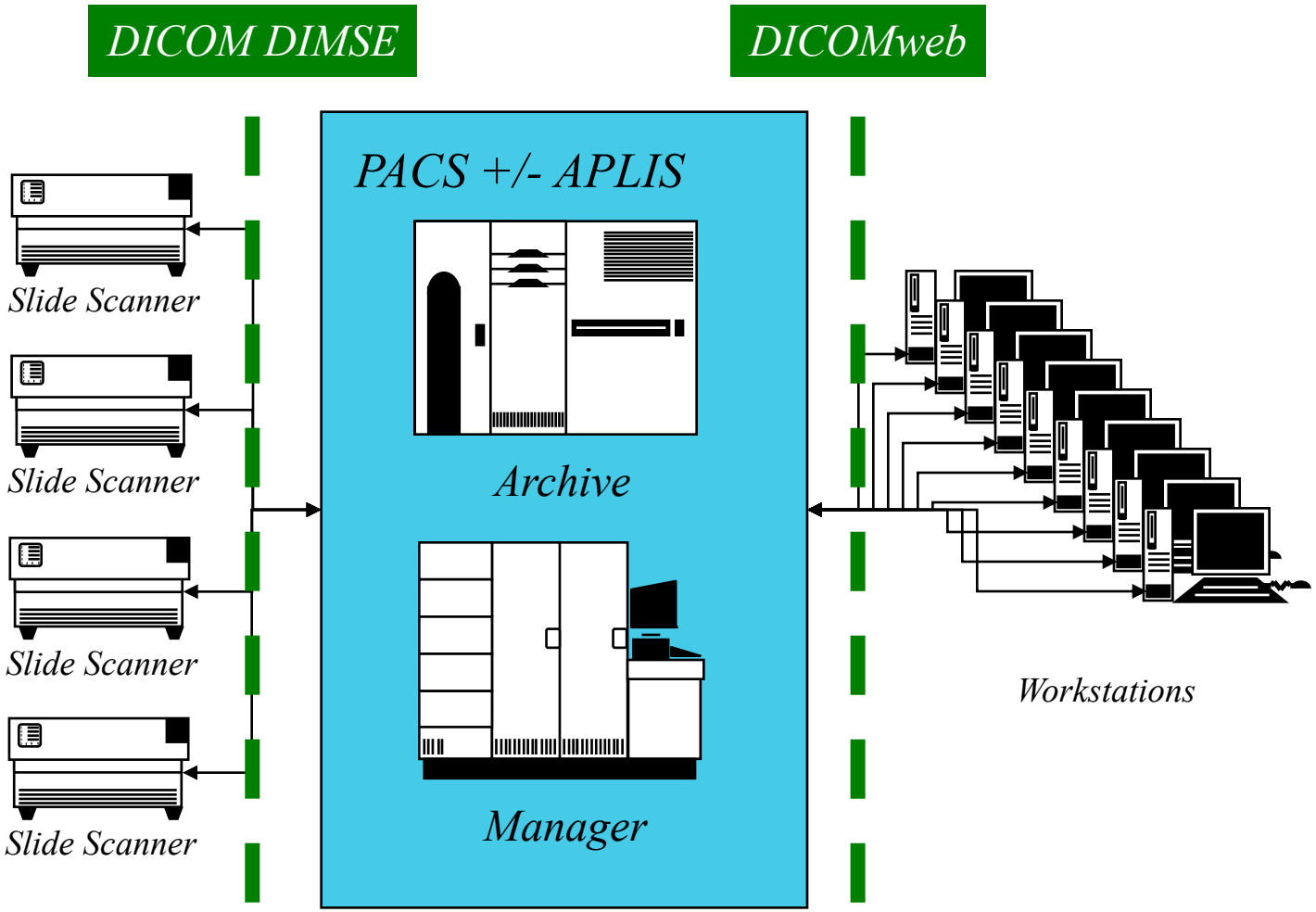


DICOM Whole Slide Images – Tiled Multi-frame Pyramidal Representation

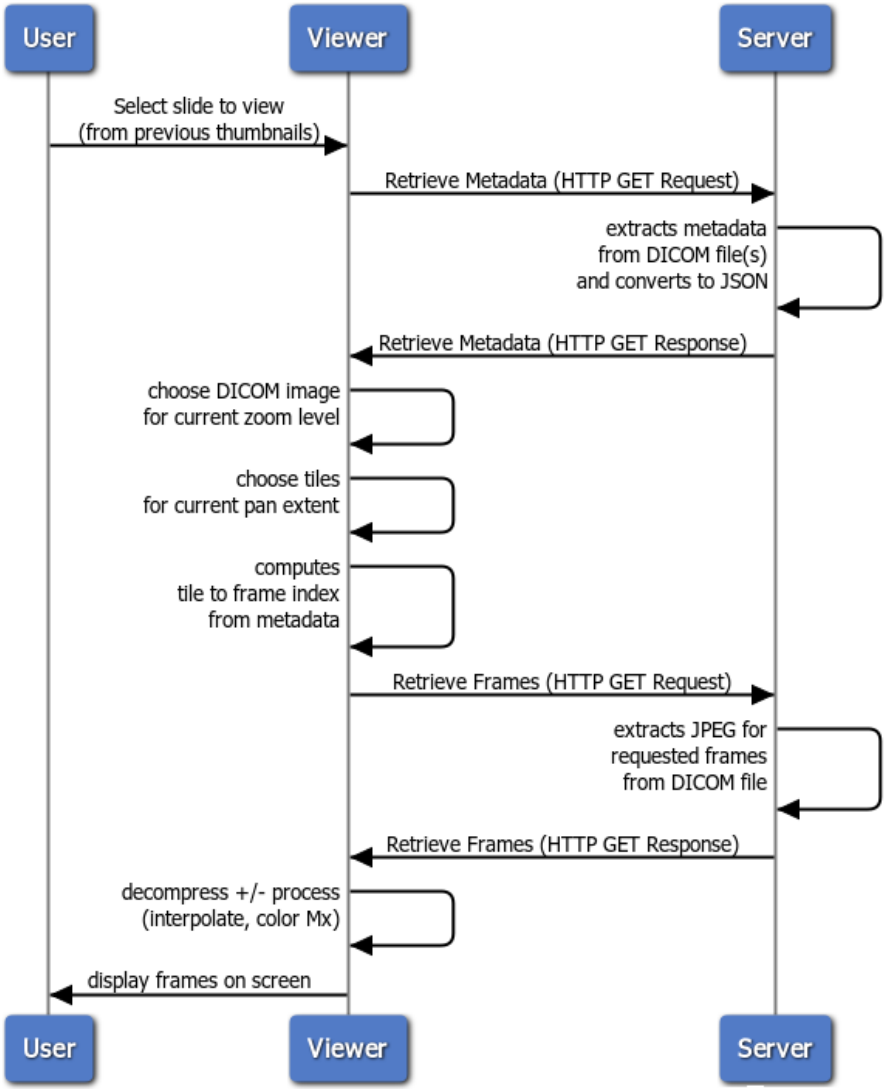


Herrmann MD et al. Implementing the DICOM Standard for Digital Pathology. J Pathol Inform. 2018;9(1):37.

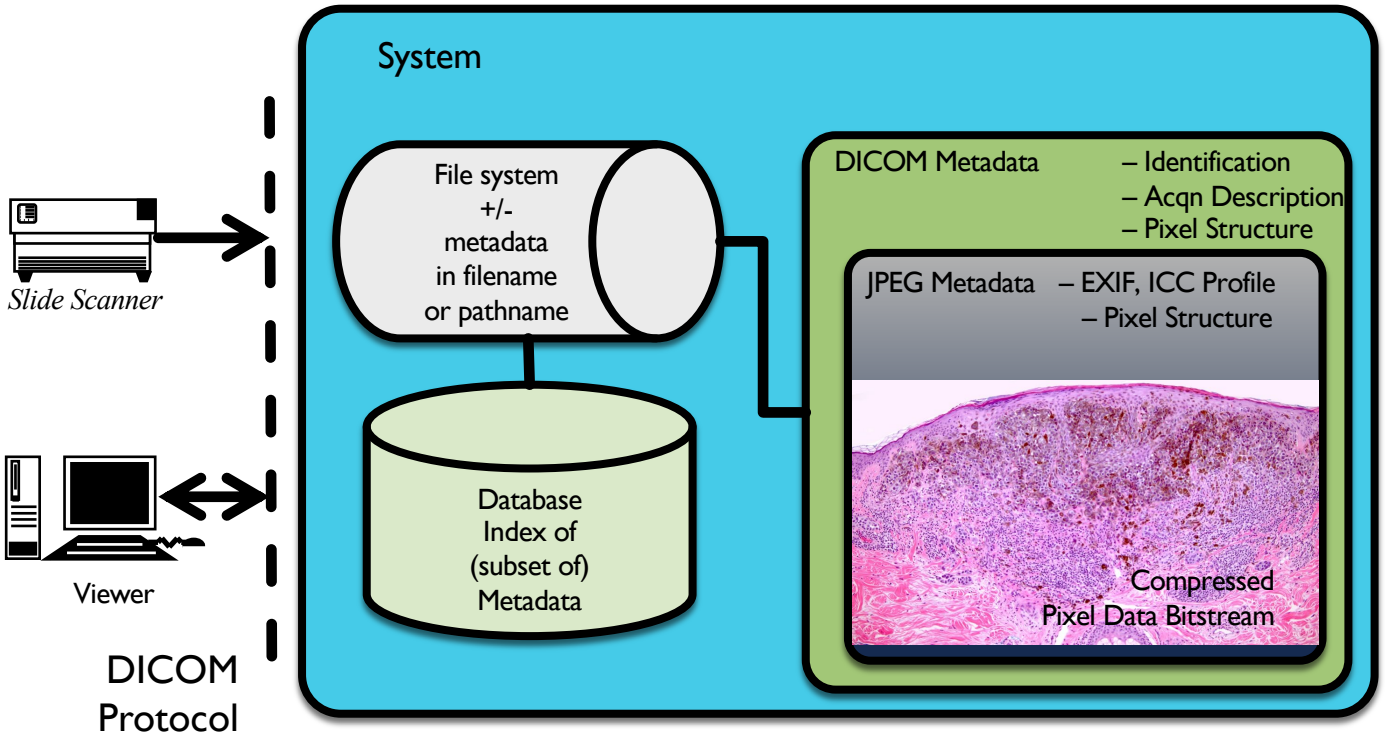
DICOM – Pathology Workstation



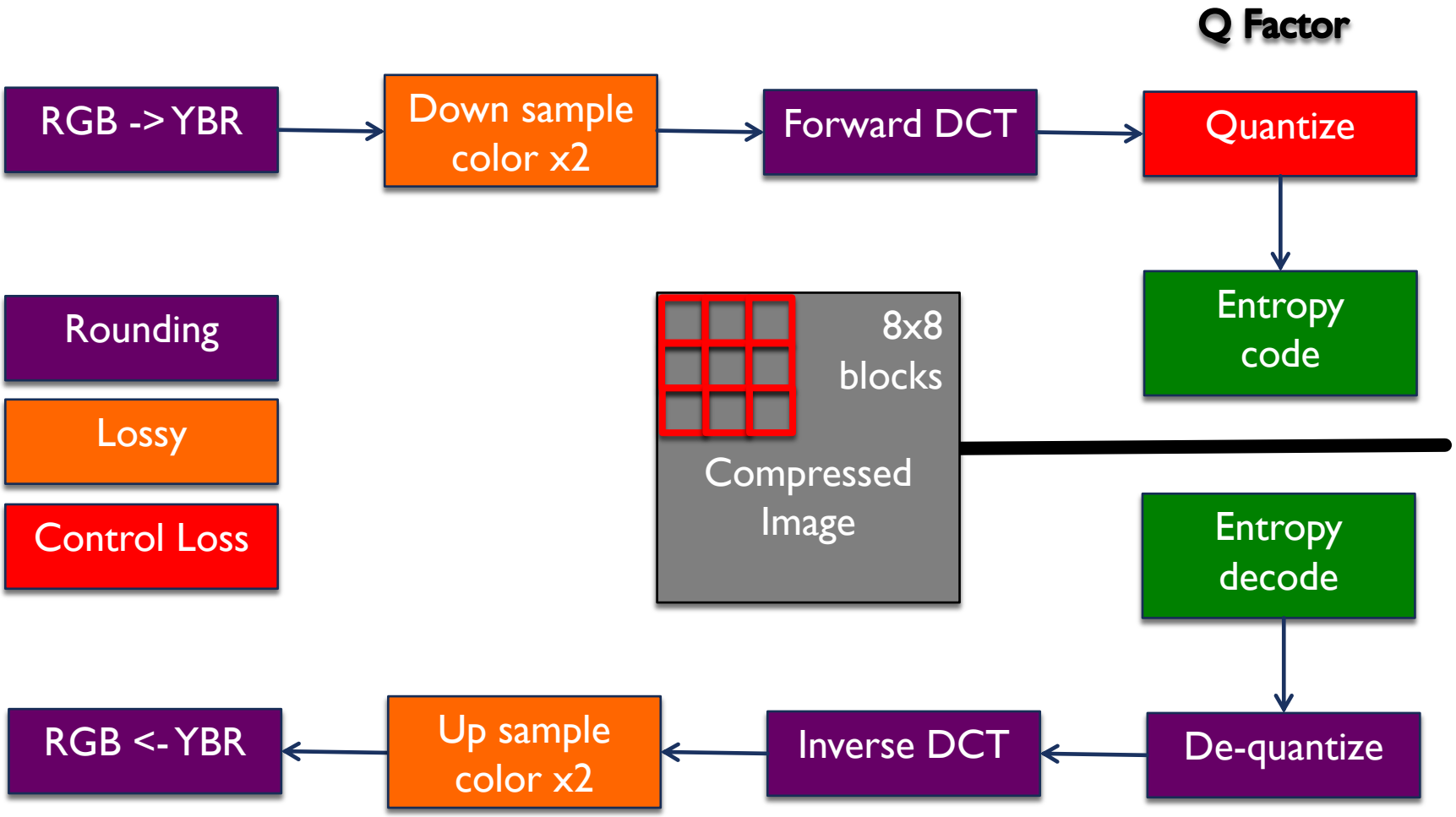
DICOMweb (WADO-RS)
Virtual Microscopy Viewer Transactions



DICOM Encapsulated Compressed (JPEG, JPEG 2000) Pixel Data



How JPEG (Baseline) works



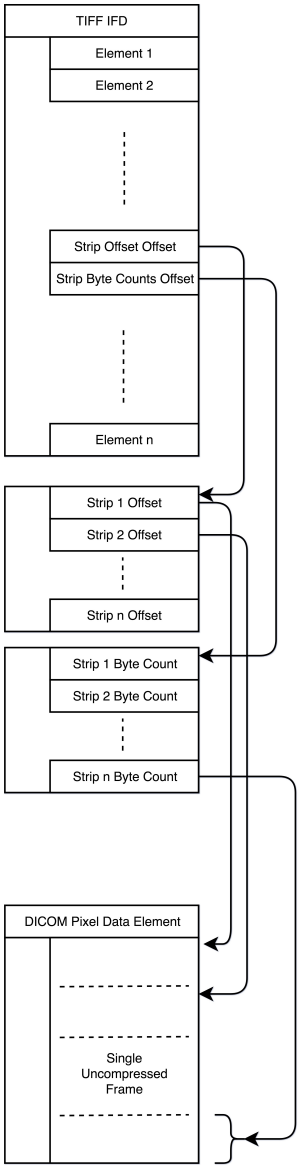
Mathematically Identical Pixels when converting proprietary to DICOM

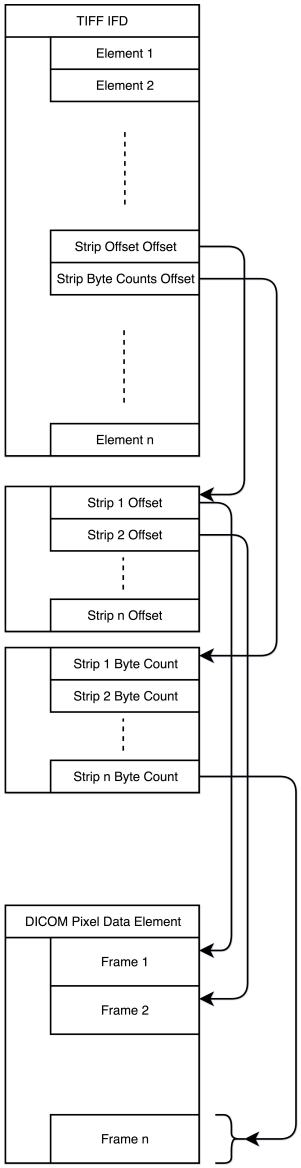
- IFF scanner already provides tiled JPEG pyramid
  - can be re-encoded in DICOM ***without changing*** the compressed coefficients
  - no further lossy color space conversion (no YCbCr or J2K ICT)
  - no further chrominance channel re-sampling
  - no further lossy transformation (DCT or floating point wavelet)
  - could losslessly (reversibly) change entropy coding, but don't need to
  - can mess with marker segments (e.g., insert Quantization and Huffman tables in every frame)
  - can add or remove ICC profile if sent separately (in separate DICOM attribute)
- Use Case: Leica Aperio YCbCr JPEG SVS file (as used for AT2 DX 510(k))
  - several pyramid layers encoded same way that DICOM does, just in BigTIFF format
  - extract each pyramid level and create one DICOM image per pyramid level
  - for each pyramid level, copy JPEG bitstream, inserting Q and H marker segments
  - re-use existing pyramids, so no new interpolated pyramid layers
  - result contains mathematically identical pixels for each source layer
  - can even co-exist in one file – dual-personality DICOM-TIFF file

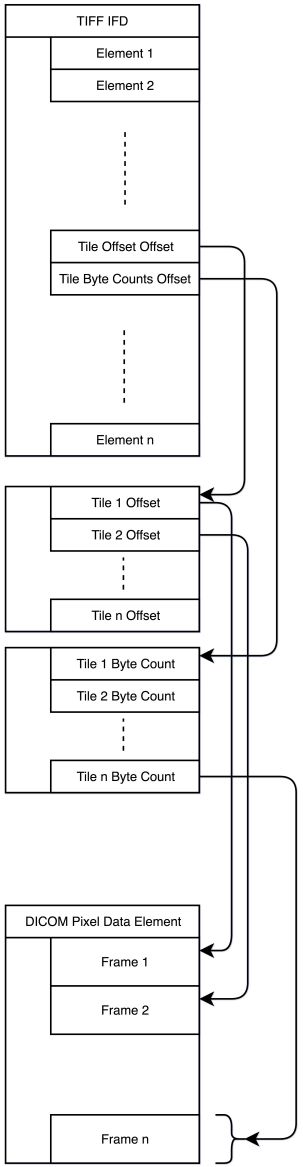
Dual Personality DICOM-TIFF

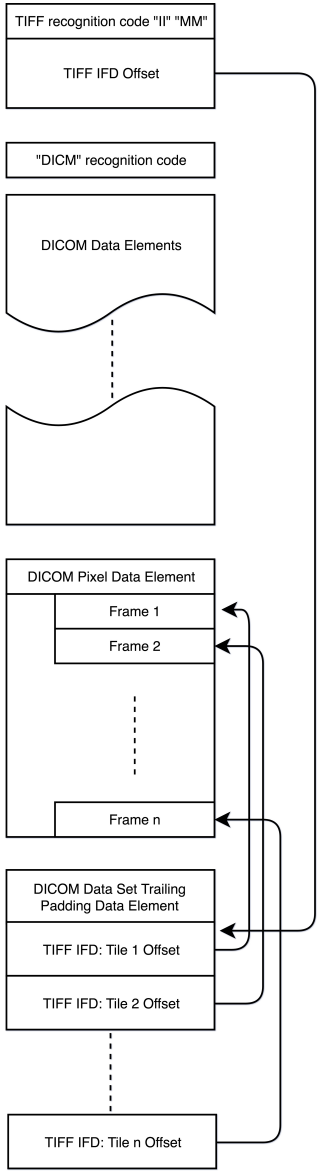
- DICOM file format was designed to coexist with a second format
- Bulk data (compressed pixels) shared between both formats
- E.g., a single stored file can be both DICOM and (Big)TIFF

- Mechanism is use of 128 preamble to contain TIFF Image File Directory (IFD) that points to Dataset Trailing Padding after DICOM content, which points back to payload of DICOM Pixel Data element
- Both DICOM and TIFF use sufficiently similar JPEG encoding of pyramidal tiles to make this work for WSI


TIFF IFD
Element 1
Element 2
Strip Offset Offset
Strip Byte Counts Offset
Element n
Strip 1 Offset
Strip 2 Offset
Strip n Offset
Strip 1 Byte Count
Strip 2 Byte Count
Strip n Byte Count
DICOM Pixel Data Element
Single Uncompressed Frame


TIFF IFD
Element 1
Element 2
Strip Offset Offset
Strip Byte Counts Offset
Element n
Strip 1 Offset
Strip 2 Offset
Strip n Offset
Strip 1 Byte Count
Strip 2 Byte Count
Strip n Byte Count
DICOM Pixel Data Element
Frame 1
Frame 2
Frame n


TIFF IFD
Element 1
Element 2
Tile Offset Offset
Tile Byte Counts Offset
Element n
Tile 1 Offset
Tile 2 Offset
Tile n Offset
Tile 1 Byte Count
Tile 2 Byte Count
Tile n Byte Count
DICOM Pixel Data Element
Frame 1
Frame 2
Frame n


TIFF recognition code "II" "MM"
TIFF IFD Offset
"DICM" recognition code
DICOM Data Elements
DICOM Pixel Data Element
Frame 1
Frame 2
Frame n
DICOM Data Set Trailing Padding Data Element
TIFF IFD: Tile 1 Offset
TIFF IFD: Tile 2 Offset
TIFF IFD: Tile n Offset

Mathematically Identical Pixels when converting proprietary to DICOM

The conversion from tiled pyramidal JPEG proprietary format to DICOM has no effect on the encoded pixel data quality

It is mathematically lossless (reversible)

But …

- What if compression scheme is proprietary and/or not tiled?
  - if full frame compression, needs to be decompressed, tiled and recompressed
  - may be able to do this losslessly
    - IFF decompression adds no further loss
    - IFF recompression adds no further loss (but pixel data size may increase, significantly)
- What if more pyramid layers are required?
  - e.g., if only the base (highest resolution) layer is supplied
  - resampling and interpolation create different data in new layers
    - which may appear different from what the scanner vendor originally encoded, e.g., LL bands in a wavelet multi-resolution decomposition
- Use case: Philips proprietary iSyntax full image wavelet compression (510(k))
  - can export as DICOM reversible J2K tiled full image (base layer only)
    - used same reversible color transformation
    - used same integer 5,3 wavelet
    - no loss on conversion to DICOM but up to 10x larger pixel data size
  - needs additional pyramid layers to be synthesized, which may differ from original
  - often needs to be converted to JPEG (lossy) or PNG (lossless but big) to display in viewer
  - DICOMweb WADO-RS RetrieveRendered transaction specifies what client accepts, server converts

Regulatory == Image Quality Issues

- What does the scanner provide (is what was approved/cleared)?
  - ideally would be DICOM when clinicals for submission done
- What changes occur during format conversion for storage (ideally, none)?
  - conversion to DICOM can be lossless for per-frame JPEG and per-frame J2K
  - from full image J2K or proprietary wavelet may be lossless but big
- What changes occur during frame retrieval (ideally none, if any, preferably reversible, if fast enough)?
  - if JPEG, just extract the frame +/- apply server-side color management
  - if J2K and client supports J2K, extract the frame, else convert to lossless PNG
- What changes occur during lossy decompression (ideally imperceptible)?
  - not all decoders behave identically (e.g., difference in JPEG codecs)

Regulatory == Image Quality Issues

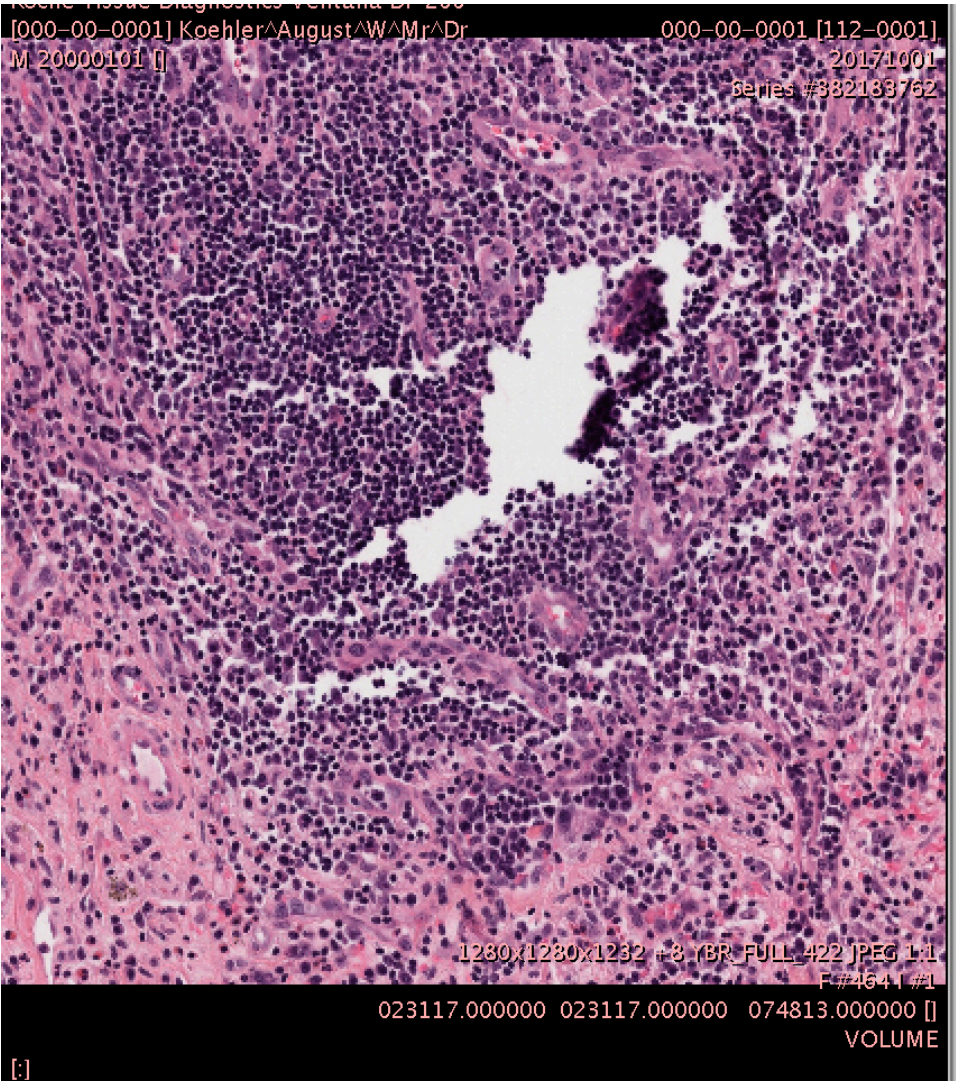
- What changes occur during color management?
  - different ICC profiles from scanner (if any; may just nominate color space e.g., sRGB)
  - color management application is inherently lossy and platforms differ (putting aside viewing environment and human perception issues)
  - DICOMweb supports application of profile by client, by client browser is running in, or by server
  - how to measure?
    - DeltaE? <1.0 JND OK?
    - what actual matters to observer performance?
- What changes occur during other processing for display?
  - interpolation and resampling for intermediate levels of zoom
- What changes occur with display monitor?
- What is the relative contribution of these effects when combined?
- Is interoperability "safe"?
  - clinical validation of safety of quantifiable effects vs. validate all combinations (infeasible)?

DICOM & Quality Issues

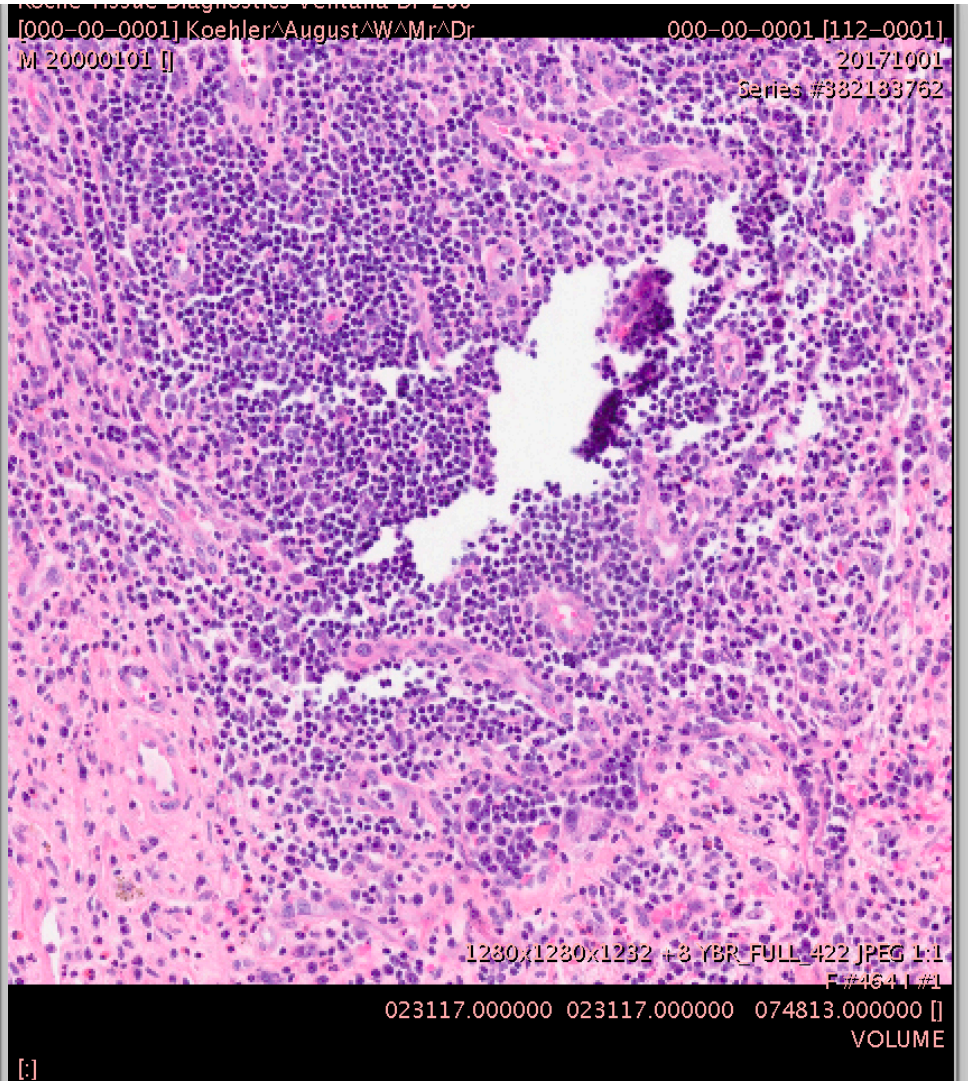
- DICOM enables interoperability with same image quality
  - if implemented and deployed correctly
- Same pixels (ideally)
  - as stored and retrieved, can be mathematically proven
  - as displayed, depends on display software behavior (mitigate: pre-stored pyramid layers)
  - demonstrably similar pixels (quantify, test with observer detect difference or clinical performance) if compression change, pyramids different, display software different
- Same colors, IFF:
  - calibrated scanner
  - ICC profiles supplied by scanner vendor
  - applied by server/client combination (various permutations possible)
  - calibrated monitor
  - similar viewing environment
  - one has faith in sufficiency of color management based on ICC
- Use case: Roche ICC Profile

Color Consistency in WSI
DICOM use of ICC Profiles

- Color calibration, normalization
  - vendor calibrates scanner
  - site-specific staining, etc. – how this is done is out of scope
- Color consistency (once truth established)
  - ICC profiles – generic non-medical industry standard
  - supports calibrated scanners and displays
  - consider choice of ICC method (LUT, TRC, matrix) , rendering intent
- DICOM WSI object
  - requires ICC profile (perceptual rendering intent)
- Services for application of ICC profiles
  - DICOMweb – apply server or client side, +/- in JPEG
- Applicable to all color imaging, not just pathology



No ICC Profile Applied

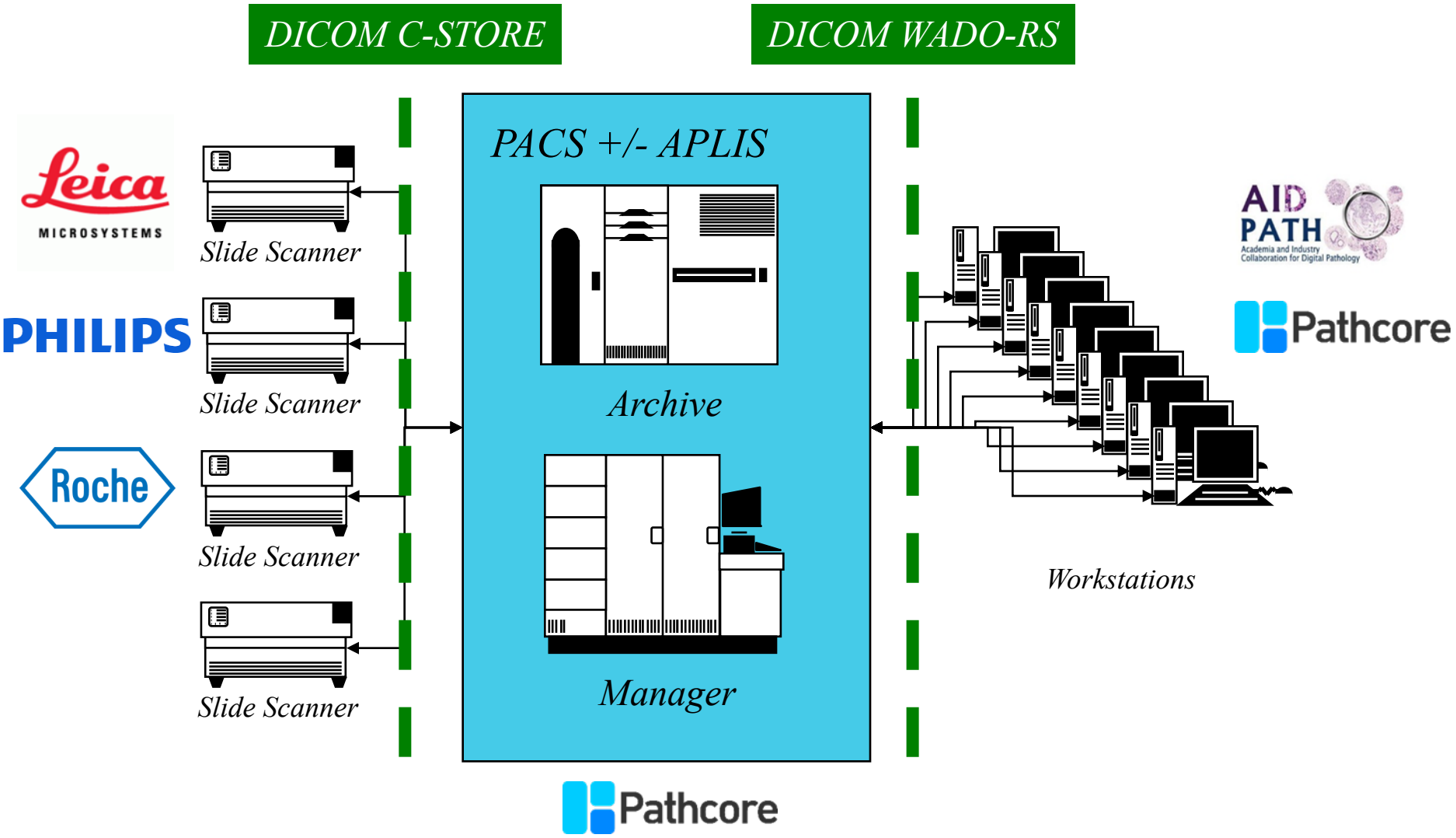


With ICC Profile Applied

Overcoming regulatory barriers

- Radiology examples
  - digital mammography – 1st approved printed to film!
  - then vendor provided displays (monitors)
  - then any 5MP display
  - now any PACS, any (cleared) workstation software, DICOM-based interoperability
  - repeated for digital breast tomosynthesis (DBT)
- Digital pathology
  - one vendor – entire pixel pathway
  - another vendor based on predicate
  - now paired scanner + archive/viewer vendors – technical data only
  - well on the way to fully open interoperability – needs DICOM

PV 2017 Connectathon



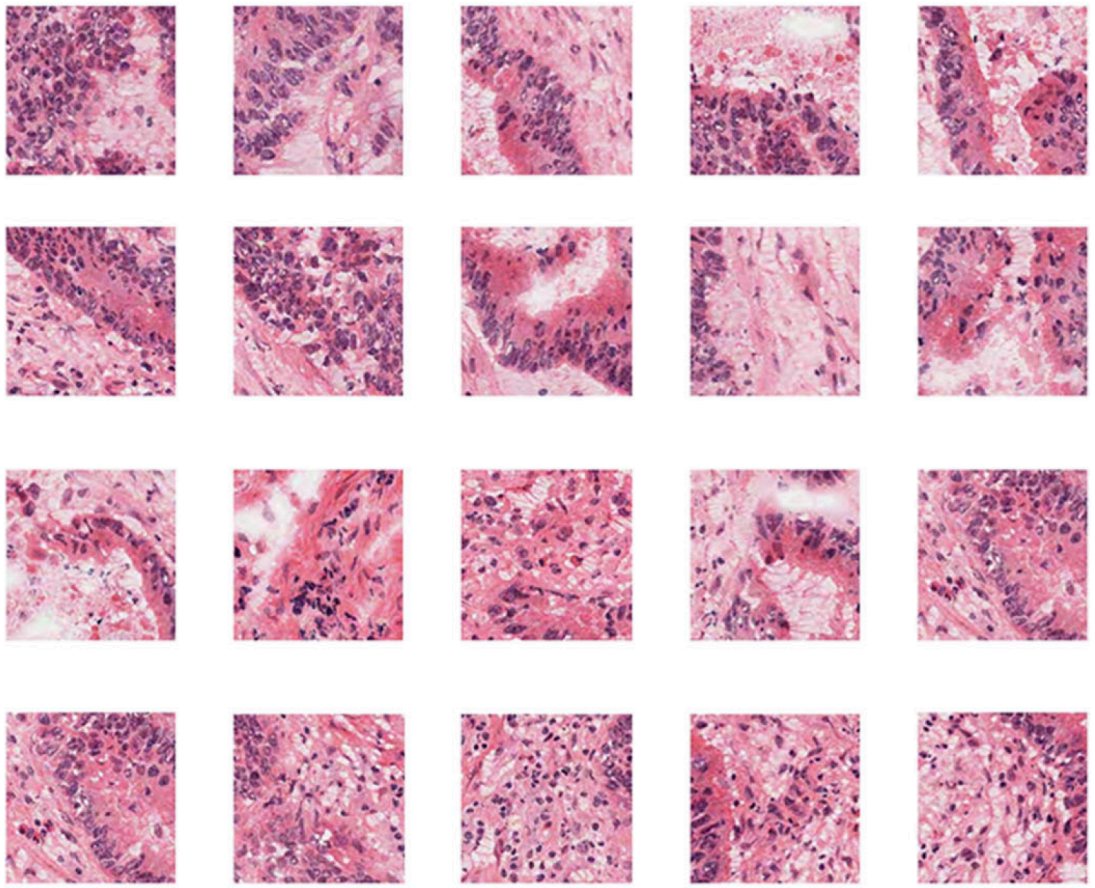
DICOM WG 26 WSI Connectathons
Participation to date

	PV'17	PI'18	ECDP'18	PV'18	ECDP'19	PV'19
AidPath	View		Archive, View			
Corista		Analyze, View				View
Gestalt				Archive, View		
Infinitt						Archive
Neagen				Archive, View	Archive, View	Archive, View
PathCore	Archive, View	Archive, View		Archive, View		Archive, View
Sectra		View	View	View		View
3DHistech					Scan	Scan
Hamamatsu		Scan	Scan		Scan	Scan
Huron						Scan
Leica	Scan	Scan		Scan		
Motic				Scan		Scan
Philips	Scan		Scan	Scan	Scan	Scan
Roche Ventana	Scan	Scan	Scan	Scan	Scan	Scan

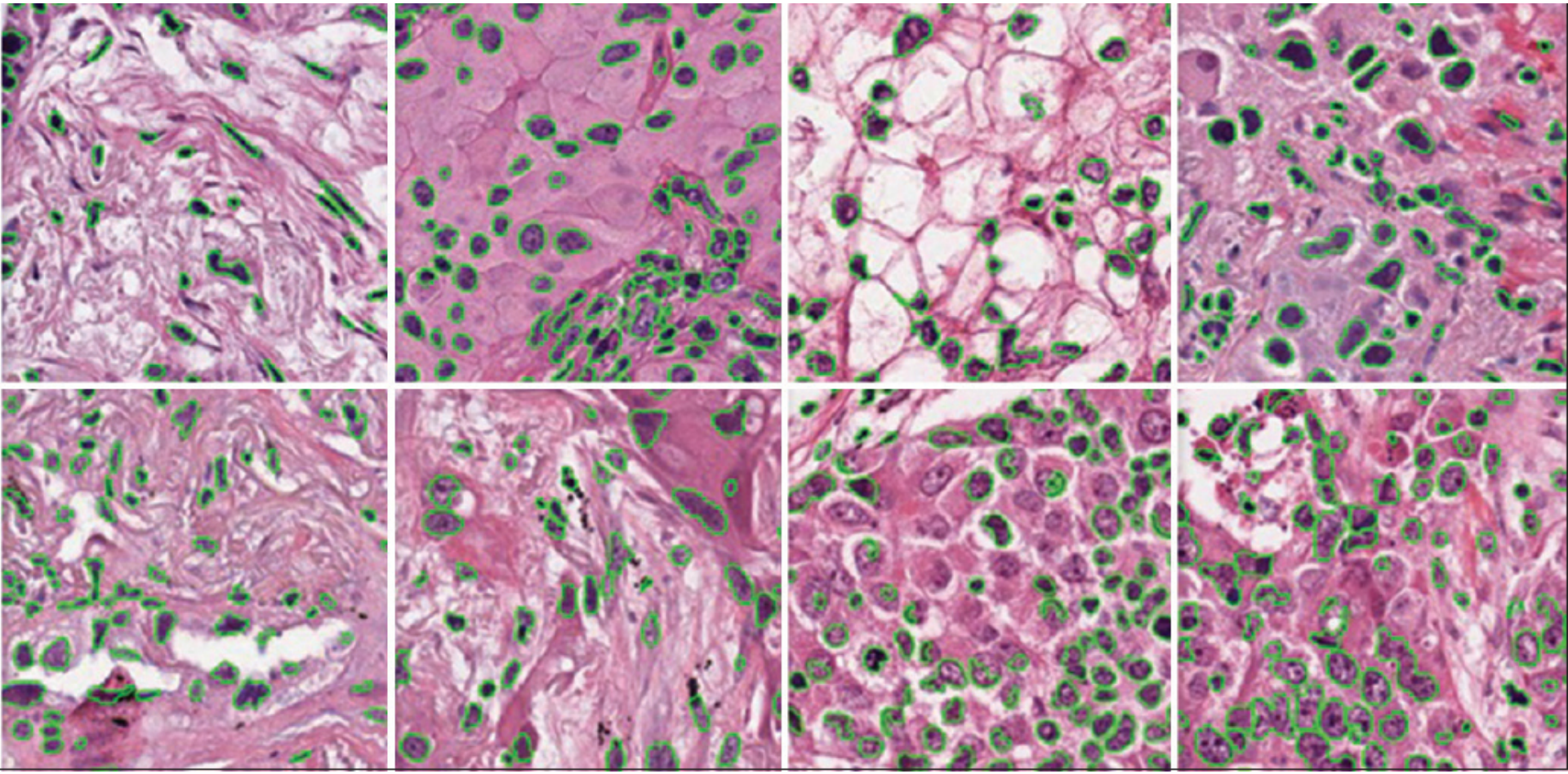
DICOM Role in Computational Pathology (AI/ML)

DICOM
Digital Imaging and Communications in Medicine

- Annotations
  - input ("hot spots")
  - output from analysis algorithms (per field, all pixels on WSI, overall scores)
  - DICOM Segmentations – per pixel classification
  - DICOM Structured Reports – outlines, measurements, categories, scores
  - something new in DICOM that scales to millions of nuclei, membranes, etc.
  - DICOM Parametric Maps (e.g., scores, saliency, other "heat maps")
- Critical to make interoperable for
  - gathering of truth for training & test data (e.g., from human pathologists)
  - operational deployment (displayable in any viewer)
  - monitoring of performance in the field (for degradation, lack of generalizability)
  - feedback into updated models (re-training, locked or continuous learning)



Yoon et al. Tumor Identification in Colorectal Histology Images Using a Convolutional Neural Network. J Digit Imaging. 2018 Jul 31;1–10.



Wen et al. A methodology for texture feature-based quality assessment in nucleus segmentation of histopathology image. JPI. 2017.

Semantic Annotations

- Annotations must be meaningful to an algorithm without the need for human interpretation
  - not just vector graphics or text
  - coded labels coupled with entity, image locations and regions of interest
  - numeric measurements with coded concepts and unit
- I.e., DICOM Structured Reports NOT Presentation States or PDF or SC
  - regions coded as contours (in DICOM SR or RTSS) or as pixels (in DICOM SEG)
- Anti-lesson from radiology
  - radiologists rarely annotate in clinical routine – do pathologists?
  - CP (AI/ML) changes the game – interoperable semantic annotations now valuable

Summary

- What is DICOM?
- Why DICOM? Interoperability
- DICOM for WSI in detail
- Regulatory implications of interoperability
- Which aspects of DICOM can assuage regulatory concerns?
- Use cases for mathematically identical pixels in DICOM vs. proprietary
- DICOM solutions for proprietary compression sources
- Color management
- Computational Pathology (AI/ML) and DICOM
- Regulatory issues of AI/ML – annotations for truthing