

# ITC Status Report

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# ITC Status Report

- ITC / WUCON Network Re-configuration
- Credentialing Events Database
- ITC Data Security Policy / 21CFR11 Compliance
- MINERVA/PEREGRINE

## ITC / WUCON Network Re-configuration

- Re-configuration is necessitated by changes in Internet connectivity at ITC.
- ITC to be integrated into WU Radiation Oncology secure network (part of WU Clinical Operations Network).
- Network security policy at WU (and submitting institutions) requires secure upload of patient data.

# ITC Internet Functions

1. Email (itc@castor.wustl.edu)
2. Public WWW Servers (ATC, ITC)
3. Digital Data Upload to ITC
4. Secure Data Review (Remote Review Tool)
5. Secure online forms (DDSI, Facility Quest., etc.)
6. Digital Data Download (HTTPS)
7. CMS/FOCAL Broadband Data Review
8. WebSys / Rapid Image Viewer

# Secure Digital Data Upload to ITC

- ITC plans to migrate from FTP to SFTP for data submission (SFTP is *not* the same as FTPS).
- SFTP uses SSH server with restricted accounts:
  - Non-interactive login with restricted command set
  - Limited file access (user locked into chroot “jail”)
- Broadly available clients
  - Windows: Filezilla, WinSCP, WSFTP (recent versions)
  - Linux: sftp, gftp

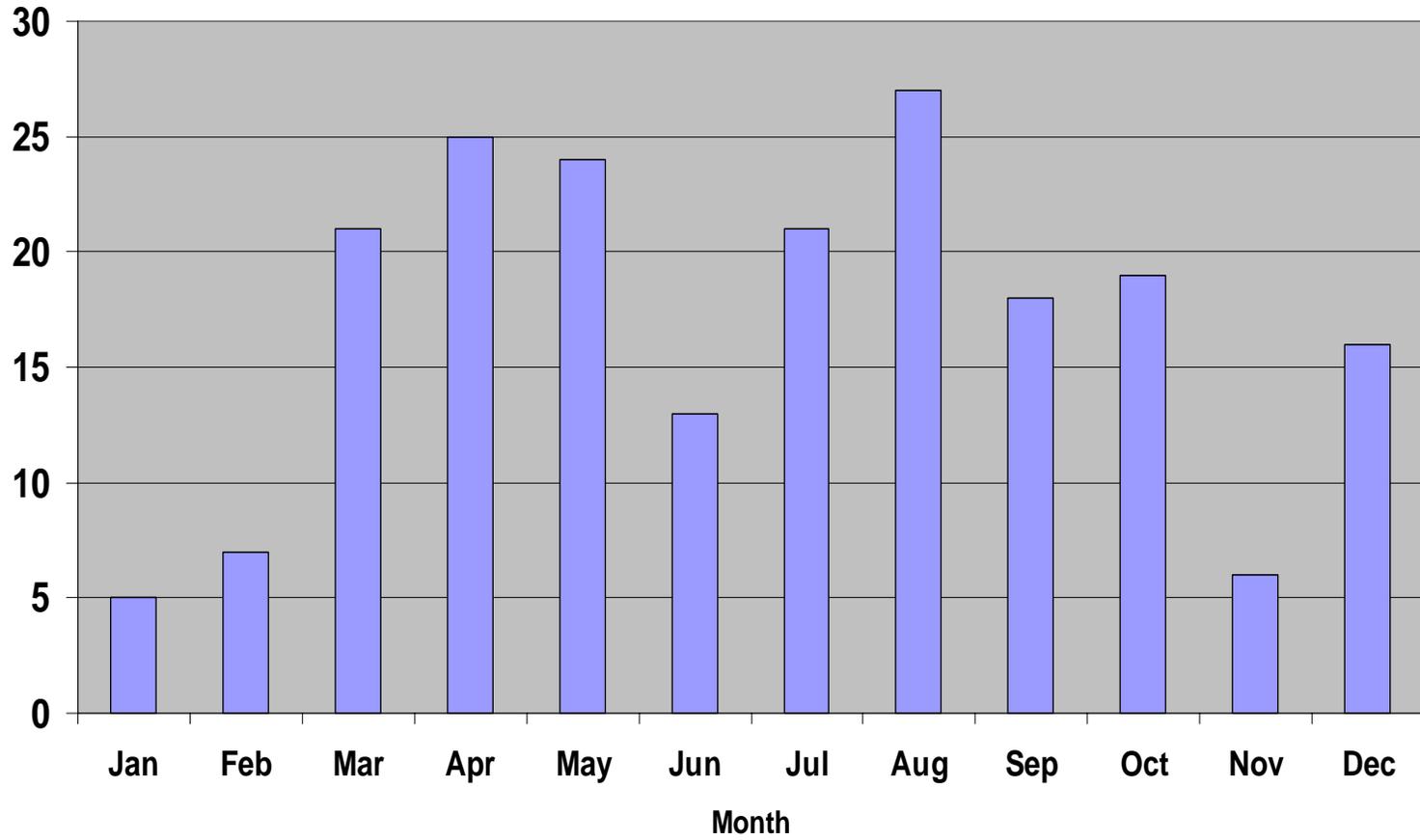
# Migrating from FTP to SFTP

- Advantages
  - Secure transmission of both passwords and data.
  - Firewall-friendly: single, outbound connection (TCP port 22)
  - Procedure is the same as for FTP for most users.
  - No change needed to existing accounts/passwords.
  - Many institutions already use clients that will work with SFTP: Filezilla, WSFTP (recent versions)
- Concerns
  - Integrated FTP submission mechanism in some TPS (e.g., XiO) – an alternative submission mechanism for affected users is in preparation.

# SFTP Migration Plan

- Test server has been implemented
- Testing with institutional volunteers – Feb 2006
  - “Reality check” on submission procedures, firewall policies, technical support issues.
  - Eight candidate institutions have been identified, representing a variety of institutions and TPS.
- Finalize updated submission procedures and notify all institutions of change – March 2006
- SFTP server ready to receive data – May 2006
- Existing FTP server de-commissioned – July 2006

### New FTP Accounts Created in 2005 (202 Total)





# RRT Access Via Citrix

- Internet access to the Remote Review Tool will be through the WU Radiation Oncology Citrix server.
- Requires download of free Citrix Presentation Server Client (available for Windows, Mac OS X, Linux, etc.)
- RRT runs on web browser on Citrix server at WU.
- Behavior (and responsiveness) of the tool under Citrix is essentially the same as with a local browser.
- Printing images, DVHs requires access to reviewer's local printer (currently in testing).

# CMS/FOCAL Access Via Citrix

- Review Features
  - Multi-modality image fusion (PET/CT, MR/CT, etc.)
  - 3D Plan review
- Data Import
  - DICOM RT / RTOG Data Exchange treatment planning data imported via ITC software
  - DICOM images files (CT, MR, PET) imported directly into FOCAL
- Reviewer Access
  - ITC Citrix Server gives ITC users access to FOCAL tools.
  - Internet access to selected users via WU Rad Onc Citrix Server is a work in progress.

# ITC QA Events Database

- Track dates and status of QA process steps performed at ITC
- In use since Jan 2005.

ITC QA Events Version 04122701

**QA Events**

Image-Guided Therapy Center An Advanced Technology Clinical Trials QA and Support Center

<b>Sponsor</b>	RTOG	Data_Inventory_Complete	5/20/2004	Done
		Sent_for_OARTV_Review	6/9/2005	Sent
<b>Protocol</b>	0126	OARTV_Review_Complete		
		Sent_for_DVA_Review		
<b>Case</b>	220	DVA_Review_Complete		
<b>Institution</b>	TORSB			
<b>Event</b>	Data_Inventory_Complete			
<b>Reviewer</b>	rjh			
<b>Requested by</b>	rjh			
<b>Comment</b>				
<b>Modified by</b>	haynes			
<b>Modified date</b>	1/7/2005 1:25:16 PM			

# Credentialing Events Report

Example:  
 QA Events  
 Report for  
 RTOG 0413

## Event Tracking by Case for 0413 Cases & Dry Runs

Case	Institution	Registration	Data Rcv'd	DVA Sent	DVA Done	PI Sent	PI Done	DVA Pending	PI Pending	DVA days	PI days
2	WMBH	3/23/2005	3/29/2005	3/29/2005	3/29/2005	3/29/2005	3/29/2005	-	-	0	0
3	UCOLHS	4/7/2005	4/11/2005	4/11/2005	4/11/2005	4/11/2005	4/11/2005	-	-	0	0
5	WMBH-Tr	4/18/2005	4/19/2005	4/19/2005	4/20/2005	4/20/2005	4/20/2005	-	-	1	0
7	WMBH	4/25/2005	4/29/2005	4/29/2005	4/29/2005	4/29/2005	4/29/2005	-	-	0	0
9	AOS	4/27/2005	5/5/2005	5/5/2005	5/6/2005	5/6/2005	5/6/2005	-	-	1	0
13	WMBH	5/3/2005	5/12/2005	5/16/2005	5/16/2005	5/16/2005	5/16/2005	-	-	0	0
16	WMBH	5/6/2005	5/12/2005	5/16/2005	5/25/2005		5/25/2005	-	-	9	-
18	AOS	5/10/2005	5/17/2005	5/17/2005	5/18/2005	5/17/2005	5/18/2005	-	-	1	1
20	CONHNH	5/12/2005	5/17/2005	5/17/2005	5/19/2005	5/19/2005	5/19/2005	-	-	2	0
21	WMBH	5/13/2005	5/20/2005	5/23/2005	5/23/2005	5/23/2005	5/23/2005	-	-	0	0
22	WMBH	5/16/2005	6/2/2005	5/25/2005	5/25/2005	6/2/2005	6/2/2005	-	-	0	0
25	WMBH	5/17/2005	5/20/2005	5/23/2005	5/23/2005	5/23/2005	5/23/2005	-	-	0	0
29	DMCSPC	5/17/2005	5/27/2005	6/1/2005	6/1/2005	5/31/2005	6/1/2005	-	-	0	1
30	WMBH	5/18/2005	5/20/2005	6/16/2005	8/24/2005	6/16/2005	8/24/2005	-	-	69	69
33	MKDOGD	5/25/2005	5/25/2005	5/25/2005	5/27/2005	5/26/2005	5/27/2005	-	-	2	1
34	WMBH	5/26/2005	6/10/2005	6/10/2005	6/13/2005	6/10/2005	6/13/2005	-	-	3	3
35	STNFRD	5/31/2005	6/3/2005	6/6/2005	6/6/2005	6/6/2005	6/6/2005	-	-	0	0
38	WMBH	6/3/2005	6/10/2005	6/10/2005	8/24/2005	8/24/2005	8/24/2005	-	-	75	0
39	ERLANG	6/3/2005									
40	HOACNY	6/3/2005	6/7/2005	6/7/2005	6/8/2005	6/8/2005	6/8/2005	-	-	1	0
42	CCSTAG	6/6/2005	6/10/2005	6/10/2005	6/10/2005	6/10/2005	6/10/2005	-	-	0	0
43	UAB	6/7/2005	6/8/2005	6/8/2005	6/8/2005	6/8/2005	6/8/2005	-	-	0	0
44	BRYNPA	6/8/2005	6/14/2005	6/15/2005	6/15/2005	6/15/2005	6/15/2005	-	-	0	0
45	WBI	6/8/2005									
46	ROSPRK	6/9/2005									

# ITC Credentialing Events Database

- Sequence of credentialing steps per protocol (e.g., for NSABP B-39/ RTOG 0413)
  1. Start
  2. Digital data submitted
  3. DDSI submitted
  4. Color isodoses submitted
  5. All data received
  6. Digital data review ITC
  7. Sent to RPC for review
  8. ITC process complete
  9. Finished
- Status (success/failure)
- Date
- Comment

**Credentialing Events** Version 05.12.23.03

Sponsor: RTOG  
 Protocol: 0413  
 Institution: WUSTL (Washington University)  
 Attempt: 1

Start	1/5/2005	began
Digital Data Submitted	12/5/2005	pass
DDSI submitted	12/8/2005	pass
Color isodoses submitted	12/8/2005	pass
All Data Received	12/8/2005	done
Digital Data review ITC	12/9/2005	pass
Sent for Review RPC		
ITC process complete		
Finished		

Quit

# ITC Data Security Policy

- Standard Operating Procedures
  - Processing of protocol case and credentialing data
  - Computer system management
- Software Validation
  - Test data sets
  - Test plan, execution, results
- Auditing (work in progress)
- Risk Assessment
  - Backup, network security, disaster recovery

# ITC Standard Operating Procedures

- Data Processing Draft Procedures
  - Processing incoming FTP data
  - Moving FTP data to working directory
  - Copying data from submitted CD
  - Copying data from submitted tape cartridge
  - Extracting RTOG/DICOM TP data
  - Calculating DVHs
  - Chart setup for new protocol/credentialing case
  - New case registration in QA database
  - Creating backup CD for submitted data archive

## ITC Standard Operating Procedures (2)

- Computer System Management Procedures
  - Work in Progress
    - Creating new FTP account
    - Changing FTP account password
    - Creating RRT account
    - Changing RRT account password, review permissions
    - Rotating backup tape cartridges
    - Performing full backup of ITC software and data
    - Restoring data from backup tape cartridges



# ITC Software Validation

- Digital Data Import Software
  - Test suite (format specific)
    - Historic data (compare data imported by existing and new software versions)
    - Problem data (demonstrate correct import with new software version)
  - Formal report identifying changes in software, data used for testing, signed by developer and IT director.

# ITC Software Validation (2)

Promotion Report  
for read\_dicom  
software (imports  
DICOM TP data  
into CMS format for  
RRT review)  
version 1.100 –  
12/9/2005

Software Promotion Report

read\_dicom (read\_process.c)

Report on the promotion of Version 1.100 of **read\_dicom** (read\_process.c, the program that imports DICOM datasets submitted to ITC into ITC's internal FOCUS 3.1 format patient database).

The version in use for processing at ITC as of 7/26/05 is 1.94; the changes made from v1.94 to v1.100 are:

1. Corrected incorrect sense of wedge orientation angle, DICOM is CCW, RTOG Data exchange is CW
2. Continue processing after error report if 3rd value of "IMAGE TYPE" is missing from CT (seen from JCOG and BrachyVision)
3. Added trap to existing DMLC shape extracting code that exits the shape extracting code for motorized wedge
4. Continue after error report if Referenced SOP Instance UID (0008,1155) is missing or NULL within Referenced Structure Set Sequence (300C,0060) in RT Plan
5. Correct format in an error message re *skincnt* (%s changed to %d; *skincnt* is int)
6. One message formerly sent to "stderr" now done with *aapm\_status()*
7. The level of 12 messages raised from INFO to STATUS (this causes the message to be echoed on the processor's display as well as being logged)

This is considered a minor change promotion. The following testing was done:

1. **rtog\_mskcc** data rtog0413\_test.zip received 11/23/05 was extracted with both v1.94 and v1.100. The wedges extracted with v1.94 were incorrectly oriented (first observed by MSKCC personnel). The wedges extracted with v1.100 were correctly oriented (as observed and confirmed by MSKCC personnel). A recursive **diff** on the two patient trees revealed only four flag value differences in the **telplan** files corresponding to the four beams in the plan. All other differences were non-meaningful, i.e., timestamps, patient IDs.
2. **rtog\_penros** data 0413c0467resub received 12/6/05 was extracted with both v1.94 and v1.100. v1.94 aborted processing at the 1<sup>st</sup> CT file. v1.100 issued an error message at every CT file but continued processing.
3. **rtog\_ucdav** data ucdnasbp0413 received 10/24/05 was extracted with both v1.94 and v1.100. v1.94 aborted at the 1<sup>st</sup> beam containing a motorized wedge. v1.100 issued a message at each motorized wedge and continued processing.
4. This item was tested with the data that showed the problem when the fix was introduced in the test environment between 7/27/05. The modified code continued processing after issuing an error message.
5. This item was tested with the data that showed the problem when the fix was introduced in the test environment between 11/10/05 and 12/6/05. The modified code correctly sent the error message while v1.94 core dumped.
6. This item was tested with the CMS test data having the problem when the fix was introduced in the test environment on 7/27/05. The modified code sent the error message to the screen and the log; v1.94 only sent the error to the screen.
7. These messages are seen on screen while processing with v1.100 but not with v1.94.

Approved W. Bosch

Date 12-9-05 JW

# ITC Risk Assessment – Currently in Review

- Digital Data Backup
  - RAID file storage
  - Disk-to-disk backup
  - Incremental tape backup
  - Complete backup of software and data
- Network Security
  - Currently in review as part of WU Clinical Operations Network re-configuration
- Disaster Recovery
  - Off-site storage of backup media
  - Off-site backup server(s) – work in progress

# Preliminary Timeline for Documenting ITC Data Security

- 4/30/2006 – Completed draft documents
  - Standard Operating Procedures
  - Software Validation
- 6/30/2006 – Risk Assessment draft document complete
- 10/31/2006 – Audit draft document complete
- 12/31/2006 – Data Security Plan in place