

Submitting Product Certification Data via Web-Based Collaboration Sites

Teamcenter submittal-in-place
regulatory compliance

Premium Partners:



Microsoft

Abstract

- Teamcenter Community and Regulatory Submittals of Technical Data

Eclipse Aviation invented the very light jet (VLJ) and it just might have re-invented how technical data gets locked, submitted, and reviewed in regulatory processes. It's a first in more than 40 years, the first startup jet airplane company to sell thousands of units (remember Bill Lear?), Eclipse is making good on regulators need to see and analyze test data with the storage cost of conventional evidence management. The Eclipse Model 500 is in the thick of aircraft-type certification. Eclipse is betting on Teamcenter Community to put its design-anywhere-build-anywhere strategy into certify-where for world-wide access to analysis. This presentation looks at how Eclipse is achieving submit-in-place regulatory compliance with artifact release, discussion and routings as structured, activity-based regulatory review. Teamcenter Community (TcC) manages $\frac{3}{4}$ terabyte in the first administrative law submittal of stress analysis permitting FAA to effectively review Eclipse methods of calculation and margins-of-safety-schedules (MOSS) making the Model 500 the most analyzed general aviation aircraft in history. TcC may make the most responsive regulatory information pipeline ever. Not only will this process make the Eclipse Model 5XX? lean, incidents with the coming Model 500 investigations can move at the speed of access. Eclipse moves TcC beyond Microsoft's SharePoint and Office that TcC is built over and UGS datasets to new analytic and simulation files. Eclipse bets on TcC global

Who's here

- Manufacturers?
- Regulators?
- Lawyers?
- Collaboration hosts?

The Regulatory Product Data Problem Statement Restated (Management)

Submitting and evaluating technical data necessary for product certification is so complex that it needs is closed environment which includes tools for managing

- Documents
- Visualization
- Discussions and tasks
- Meetings

Such an environment used to be called a courtroom – but manufacturers and regulators are so distributed that its just collab'

Special Issues in Product Cert'

- Structuring data (e.g. bills-of-material (BOM), master document lists (MDL))
- Change management of the data (e.g. Evidence in litigation is single-pass; regulator data is multi-pass)
- Record making
- Security

The Regulatory Product Data Problem Statement Restated (Geek)

Regulatory product certification is an exercise in content and event management

**so we thought,
"Why not try Teamcenter Community"?**

Eclipse Aviation

- Less than \$1.4M purchase price
- Jet speeds, safety, comfort
- Operating costs significantly lower than current options
- 6 occupants
- Can operate out of over 10,000 U.S. airports
- Advanced all-glass



Eclipse 500 Jet Performance



Takeoff Distance Sea level, ISA to 50 ft @ MGTOW	2,155 ft
Landing Distance Sea level, ISA @ 4,600-lb landing weight	2,040 ft
Rate of Climb - 2 engines	2,990 ft/min
Rate of Climb - 1 engine	888 ft/min
Time to Climb - 35,000 ft	19 min
Takeoff at 5,000 ft at 68°F (1,524 m at ISA +15)	3,350 ft
Single Engine Takeoff Climb at 5,000 ft at 68°F (1,524 m at ISA + 15)	293 ft/min
Single Engine Service Ceiling	25,000 ft
Cruise Speed	375 kt
V_{so}	67 kt
V_{mo}/M_{mo}	285 kt /0.64 Mn
Max. Altitude	41,000 ft
Range, 4 occupants NBAA IFR, 100 nm alternate, 200-lb Pilot, three 170-lb passengers	1,280 nm
Range, 4 occupants IFR 45-minute reserve	1,395 nm

Loaded with Standard Features for Safety and Comfort

- Twin turbofan engines
- Automotive-quality appointments
 - Leather upholstery
 - Semi-club and six-seat configurations
- Comprehensive avionics suite standard to maximize safety
- Dual-zone air conditioning and heating to assure pilot and



The Eclipse Team



200 people dedicated to Eclipse 500

About the Eclipse certification strategy

- Eclipse is an all-digital engineering company.
- Electronic submittal was agreed on from day #1, but
 - CDs?
 - CDs with electronic watermarks??
 - Websites???
 - Collaboration sites????

Product Regulation

Scope of this issue

Premium Partners:



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Regulators – You've got some

Partner Certifiers →  **UGS**
Transforming the
process of innovation

Industry Associations →



Insurers →



Governments →



Treaty Groups →



**All of these
can lead to litigation**

Regulatory Product Technical Data

Evidence submitted to prove compliance with requirements of a regulation or a regulator's finding.

Regulatory Technical Data

Evidence submitted to prove compliance with requirements of a regulation or a regulator's finding.

Types:

- Documents: Specifications, drawings, models
- Data: Measurements, logs
- Analysis: Calculations, reports

Regulatory Technical Data are Not

- Application forms
- Attachments to forms
- Findings on forms
- Meeting minutes forms about forms
- Transmittal forms

These taken together in their cumulative entirety are called **Red Tape**
Think medical records, auto accidents, taxes

Top players here include [FileMaker](#) and [OpenText/LiveLink](#)

Oops, products people, this stuff is just metadata to us:

- FAA Form 8110
- DOD Form 1423
 - FDA Form
- USPTO Form

Regulatory Technical Data from a Document Management System (DMS) (Geek) View is:

- Bulky: e.g. Eclipse data runs in terabits per topic
- Complex to present
- Complex to structure, e.g. Master Document Lists
- Mind crushing to revise
- Relating any discussion to artifacts is a source of the great suspicion about regulatory processes
- Very complex organization

Regulators claim interest in new electronic technical data submittal

- They get buried in evidence - [IBM Antitrust Suit Records 1950-1982](#)
- They want to save money
- Somebody passed a law
 - ➔ ...That is spawning an industry
 - ➔ ...the retarded can talk about electronic security
- **THEY NEED TO GET INTEGRITY INTO PRODUCT CERTIFICATION PROCESSES AT A TIME WHEN PUBLIC PRESSURE AND PRODUCT COMPLEXITY ARE GROWING**

...and finally, your government is trying to help

- Paper reduction regulation
- Electronic signature and contracting law and technology is in place
- Upgraded compliance
 - Product supervision growing
 - Financial people can now get it, e.g. Sarbox
 - Product data requirements are being clarified

Product Certification is the Entirety of all the artifacts generated in the process

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Product Certification Process models: The Examiner

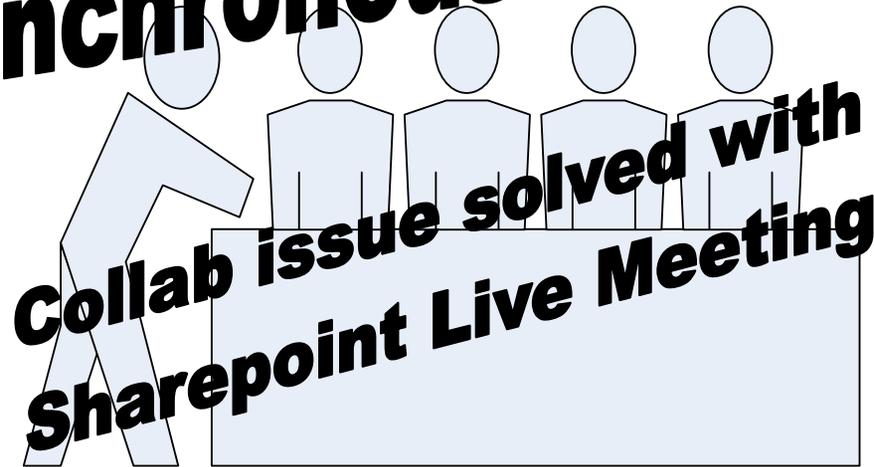


Issues are solved via document management

Standard:

Regulatory Examiner receive the application, and issues a finding
to the client. Responds with justification to grant

Synchronous findings



Project Panel (FAA Aircraft Certification Office (ACO))

Standard:

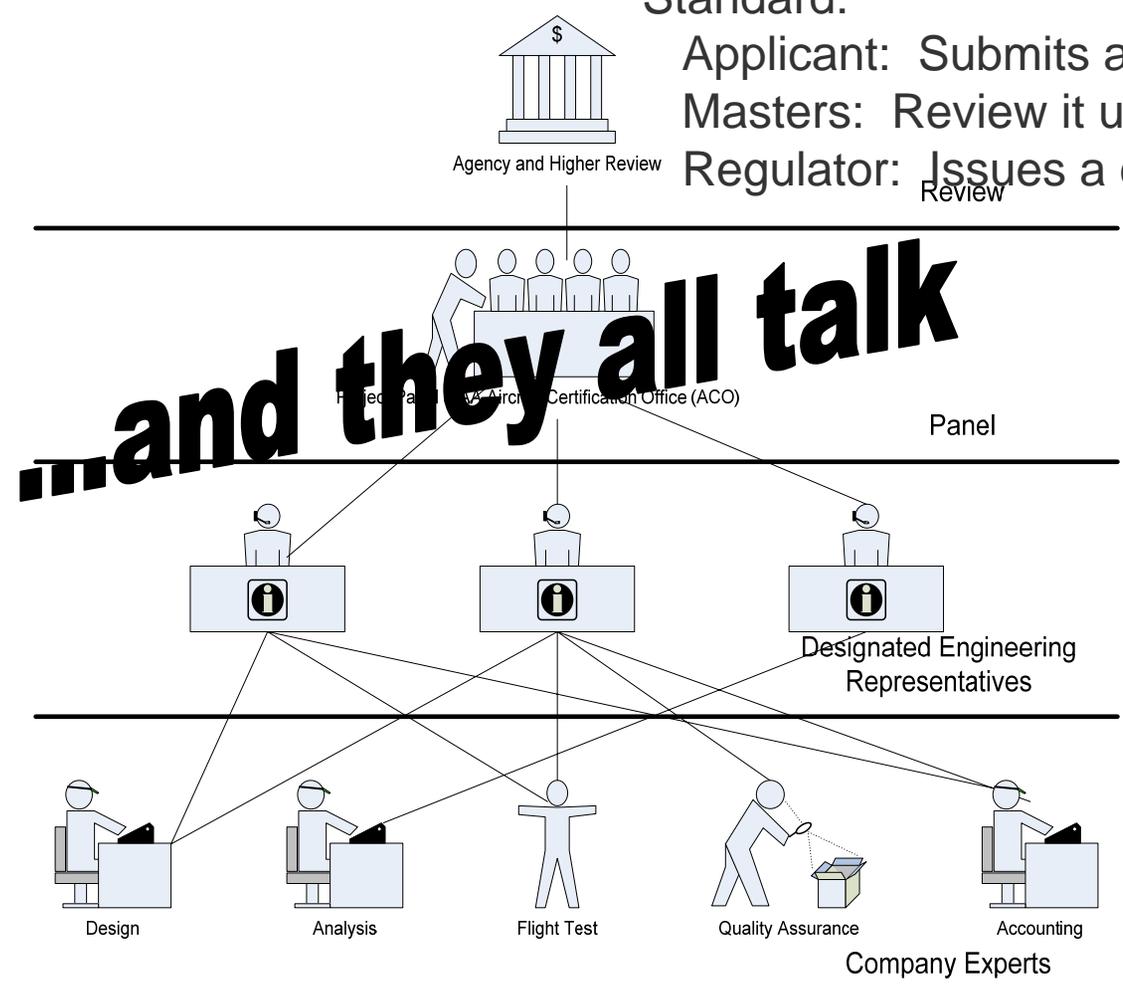
Applicant: Presents a case with supporting data

Regulator(s): Vote and issue opinions

The Process Layers (Traps) Very complex organization. Some models: The Examiner with delegations

Standard:

- Applicant: Submits a data package
- Masters: Review it until satisfactory
- Regulator: Issues a certificate



The Risks

- The evidence
 - if only!
 - Events
 - Notes, discussions
 - Meetings
 - Approvals (Votes)
- Access
 - Control
 - Membership
 - Organization
 - Documents
 - Procedural Metadata
 - Membership

Where Eclipse is

- Rollups of data and approvals
- Certification support
 - Remove all limitations
 - Extend cert'd
 - Product changes

TcC as a Regulatory Site

The state of the product as a
regulatory enabler

Premium Partners:



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Components

- DMS
 - Vault
 - History
 - Classification
 - Status
 - type
- Messaging
 - Alerts
 - Tasks
- Annotation

Components

- Change mgt
- Signature and watermark
- Security
- Data integrity
- Collect all data, including metadata

Hosting from the Applicants

- Confidentiality and trade secrets
 - Liability to the reg –
 - the mailroom effect
 - Keeping lists up to date as content changes
- Packaging and delivery
- Depth of content
- Communication
 - Meetings
 - Events
 - Routing
 - Alerts

Templates as part of compliance

- Meetings
 - Agenda
 - Documents
 - Attendees
 - Minutes
- Forms
 - InfoPath
- Routings and signatures
- Version

Rules

- Store-in-one-place
- Duration of storage
 - Backups into bonded site
- Admin
 - Who
 - Audit

TcC Regulatory Features

The screenshot shows a Microsoft Internet Explorer browser window displaying the Teamcenter Community website. The address bar shows <http://tcc.eacint.com/55gsa/default.aspx>. The page content includes:

- Announcements:** A section titled "Getting Started with Teamcenter Community!" dated 12/2/2005 1:28 PM by Charles Kraft. It includes a link to "Add new announcement".
- Eclipse Structural Analysis Navigator:** A section with links to "Eclipse Model 500 Gallery", "Summary of critical Margins of Safety", "Overall Life Summary of Fatigue and Damage Tolerance Analysis", "Summary of critical Margins of Safety FAA", and "Overall Life Summary of Fatigue and Damage Tolerance Analysis FAA". It includes a link to "Add new link".
- Teamcenter Links:** A section with a link to "Teamcenter Engineering".
- Image Web Part:** A section displaying a 3D model of an aircraft with callouts for "Links to Teamcenter Engineering" and "Routing".
- Routing Slip Task List - Teamcenter Community:** A table with columns for Subject, Due Date, Status, and Role.

Subject	Due Date	Status	Role
FSW Release Process	Wednesday, February 15, 2006	Initiated	Reviewer

Callouts on the right side of the page point to specific features:

- "Links to other tools" points to the "Teamcenter Engineering" link.
- "Links to Teamcenter Engineering" points to the "Teamcenter Engineering" link.
- "Routing" points to the "Routing Slip Task List" table.

The bottom of the browser window shows the Windows taskbar with several open applications, including "Schematic Int...", "Regulatory Da...", "eac-ppt-templ...", and "Versions - Micr...". The system tray shows the date and time as 5:29 PM.

TcC Regulatory Features

The screenshot shows a Microsoft Internet Explorer browser window displaying a routing slip form. The browser title is "Routing Slip Task - Microsoft Internet Explorer". The address bar shows the URL: http://tcc.eacint.com/55gsa/_layouts/tcc/wfDispForm.aspx?wid=cab9de28-12ea-48ab-8cce-af8f4387f739&src=http%3a%2f%2ftcc.eacint.com%2f55gsa%2fdefault.aspx. The page title is "STRUCTURAL ANALYSIS AND MATERIALS Routing Slip Content: FSW Release Process".

The form includes a "Site Map" on the left with a search box and a "Refresh" button. The main content area has a "Name" field with the value "FSW Release Process" and a "Description" field with the value "design criteria for workflow". Other fields include "Coordinator" (Ray Arambula), "Status" (Initiated), and "Due Date" (2/15/2006 12:00:00 AM). There is a "Comment" field with a text area.

Below the form, there is a table of "Reviewers" with columns for "Name", "Order", and "Response".

Name	Order	Response
Brent Christner		Optional
Charles Kraft		Optional
James Lehto		Optional
John McCoury		Optional
Sampath Vadla		Optional

An orange box labeled "Signature" is positioned above the reviewers table, with a diagonal line extending from it towards the "Mgt.FSW.ppt" entry in the "Other Links" section.

The "Other Links" section contains a link for "Instant Visual Conference". Below this is a "Routing Slip History" table:

Date	Modified by	Action	Comment
2/14/2006 3:15:41 PM	Ray Arambula	Initiate	Routing slip created.

The browser's status bar at the bottom shows "Done" and "Trusted sites".

TcC Regulatory Features

Documents and Lists - Microsoft Internet Explorer

Address: http://tcc.eacint.com/55gsa/_layouts/1033/viewlists.aspx

Home Documents and Lists Create Site Settings Logout Help Up to Teamcenter Community

STRUCTURAL ANALYSIS AND MATERIALS Documents and Lists

Site Map

This page shows all the libraries, lists, discussion boards, and surveys in this Web site. Click the name of a library or list to view its contents. To create a new library or list, click Create.

Search for site: [] Refresh

- Teamcenter Community
 - Site Content
 - 9-tutorial_assembly
 - Analysis
 - Avionics and Electrical Eng
 - Certification
 - Corporate
 - Designated Engineering Re
 - EAC Supplier Site Templat
 - Eclipse Model 500 Training
 - ECM
 - EDM Department
 - EDM Development
 - EDM Supplier
 - EDM TcC Dvl
 - EDM UG Projects
 - Facilities
 - Gear Assy
 - Human Resources
 - kanooter_valve
 - Mfg Datamart
 - Mfg Operations
 - Quality
 - Reliability, Maintainability

Document Libraries

	Description	Items	Last Modified
PDM Enhanced Library	Create an enhanced document library that supports cut/copy/paste capabilities and integration with Teamcenter Visualization tools.	34474	3 months ago
Shared Documents	Share a document with the team by adding it to this document library.	4770	2 months ago

Picture Libraries

There are no picture libraries. To create one, click **Create** above.

Lists

Announcements	Use the Announcements list to post messages on the home page of your site.	2	4 months ago
Capture Manager	Create and manage knowledge capture sessions and their associated links	0	4 months ago
Eclipse Structural Analysis Navigator	This provides an entry point to calculation sheets by assembly.	5	2 months ago
Eclipse Structural Analysis Navigator - V13	This Site contains MathCAD V 13 files.	1	4 months ago
Events	Use the Events list to keep informed of upcoming meetings, deadlines, and other important events.	0	5 months ago
FAA Stress Mgt	Issues relating to TcC as a channel for submittal-in-place of type data for stress.	43	3 months ago
Tasks	Use the Tasks list to keep track of work that you or your team needs to complete.	0	5 months ago
Visual Issues	Use the Visual Issues list to manage issues created with Teamcenter Visualization tools.	0	5 months ago

Discussion Boards

There are no discussion boards. To create one, click **Create** above.

Surveys

There are no surveys. To create one, click **Create** above.

Site Map

- Actions & Views
- User Preferences
- Site Settings
- Create
- Advanced Search
- Software Downloads

Done

Trusted sites

start Microsoft ... C:\Documents... Schematic Int... Regulatory Da... Regulatory Da... eac-ppt-templ... Versions - Micr... Documents an... 60% 5:30 PM

TcC Regulatory Features

The screenshot shows a Microsoft Internet Explorer browser window displaying a web application titled "Shared Documents". The browser's address bar shows the URL: <http://tcc.eacint.com/55gsa/Shared%20Documents/Forms/AllItems.aspx>. The page header includes navigation links: Home, Documents and Lists, Create, Site Settings, Logout, Help, and Up to Teamcenter Community. The main content area features a "Site Map" on the left and a document list on the right. The document list is titled "Share a document with the team by adding it to this document library." and contains the following table:

Type	Name	Launch	Modified	Modified By	Checked Out To
	Config. Mgt.FSW.ppt		2/14/2006 2:07 PM	Ray Arambula	
	Cutaway.jpeg	Open Insert	1/5/2006 2:38 PM	Ram Meda	
	L_eclipse.gif	Open Insert	12/6/2005 6:10 PM	Ram Meda	
	PRI_SPT.gif	Open Insert	12/7/2005 9:40 AM	Ram Meda	
	Recycle Bin		1/5/2006 2:59 PM	Ram Meda	

A callout box labeled "Document Content" is positioned to the right of the table, with a line pointing to the "Cutaway.jpeg" document entry. The browser's taskbar at the bottom shows several open applications, including "Schematic Int...", "Regulatory Da...", and "Shared Docum...". The system tray indicates the time is 5:31 PM and the battery level is at 60%.

TcC Regulatory Features

Home - mtg - Microsoft Internet Explorer

Address: <http://tcc.eacint.com/5465E5/mttg2/default.aspx>

Home Logout Help Up to EDM Development

mtg

Home Workspace Documents Visual Issues Knowledge Capture Routing Slips Other

Modify This Workspace

Site Map

Search for site: Refresh

- Teamcenter Community
 - Site Content
 - tutorial_assembly
 - Analysis
 - Avionics and Electrical Eng
 - Certification
 - Corporate
 - Designated Engineering Re
 - EAC Supplier Site Templat
 - Eclipse Model 500 Training
 - ECM
 - EDM Department
 - EDM Development
 - Site Content
 - Happy-Happier
 - Happy-Happier1
 - meeting
 - mtg
 - Site Content
 - EDM Supplier
 - EDM TcC Dvl
 - EDM UG Projects
 - Facilities

Conference Agenda

Title	Presenter	Duration	Status	Capture
There are no items to show in this view of the "Conference Agenda" list. To create a new item, click "Add new item" below.				
Add new item				
Change Order				
Send Conference Links				

Conference Attendees

Name	Edit Response
Charles Kraft	Accepted
Ram Meda	Accepted
Sampath Vadla	None

Manage attendees

Confencing Tools - Teamcenter Community

The confencing server has not been properly configured. Please contact your Teamcenter Community system administrator for assistance. Index was out of range. Must be non-negative and less than the size of the collection. Parameter name: index

Current Conference Server: [Dropdown]

Application Sharing Conference

Sharing your desktop or any specified application.

Conference Code:

Startup Options:

- List host's name in the public conference directory
- Show conference title with host's name

Visual Conference

Confencing on visualization data from "Workspace Documents".

- Manage Conference Data
- Pre-Download Data
- Show All Users' Download Status

NX Collaborate Conference

Confencing between NX applications.

Objectives

There are no items to show in this view of the "Objectives" list. To create a new item, click "Add new item" below.

Add new item

Discussions & Notes

Subject	Replies	Posted By
There are no items to show in this view of the "Discussions & Notes" discussion board. To create a new item, click "Add new discussion" below.		
Add new discussion		

Tasks

Title Assigned To

There are no items to show in this view of the "Tasks" list. To create a new item, click "Add new item" below.

Add new item

Decisions

Decision	Contact	Status
There are no items to show in this view of the "Decisions" list. To create a new item, click "Add new item" below.		
Add new item		

Regulatory record making

Discussions

Done

start Microsoft ... C:\Documents... Schematic Int... Regulatory Da... Regulatory Da... eac-ppt-templ... Versions - Micr... Home - mtg - ... 61% 5:31 PM

Eclipse Wins with TcC

- Diverse projects
 - Certification data developers
 - Presentation developer
 - Thoubleshooters doing last-minute analysis
 - DERs and consultants
 - Suppliers doing customer content development
- TcC handles very big data package $\frac{3}{4}$ terabyte in one project
- Saved EDI (we didn't have to make the CDs)
- Saved travel

Wins for TcC

- Document permissions
- Wide searching
- Change Mgt
 - Routing
 - TcE
- Meeting Templates
- Viewers

Suggestions

- Get buy-in for using TcC from the agency
- The collaboration site is exclusive
 - The only place to discuss the project
 - Use a need-to-know criteria for viewing and membership
- Turn-on versioning
- Use change management

Where TcC needs to go to be a regulatory collaboration tool

Premium Partners:



Microsoft

UGS-PLM needs to support TcC as a regulatory enabler

- UGS-PLM customer base is dominated by safety-critical, regulated products
- USG-PLM needs a clearer position on good electronic records management (GERM)
- USG-PLM participation in GERM to get explicit approvals by agencies
- USG-PLM needs signature plug-ins
- TcC is not missing any elements for certification processes – some upgrade

Where collaboration needs to go with regulation

- Third-party
 - Hosting
 - Storage
- ACLs which prevent deletion of any data
- Linking structures (e.g. BOM, MDL) into TcC from TcE
- Links to non-UGS-PLM best-in-class
 - Rational
 - Matlab
 - MathCAD

Thanks, and good regulating

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