

# *Digitizing Data Deliverables*

US EPA Regions 5, Laboratory Services & Applied  
Sciences Division, Analytical Services Branch

August 5, 2019

Presenter: Michelle Kerr





# Disclaimer

Information in this report is derived from a variety of references, some of which have been peer-reviewed. Mention of trade names or commercial products or firms does not constitute endorsement or recommendation for use.

The views expressed are those of the author/editor/speaker only and do not necessarily represent those of the United States or the US EPA.

# Electronic Data Implementation Team (eDIT) Members

- ▶ Sylvia Griffin (Data Coordination, Records)
- ▶ Michelle Kerr (MS, GC, ESAT)
- ▶ Danielle Kleinmaier (Organic Methods)
- ▶ Anna Knobel (Analytical & Inorganics)
- ▶ Rob Thompson (Lead, LIMS)
- ▶ Amanda Wroble (Metals)
- ▶ Angela Ockrassa-Davis (Quality Assurance)
- ▶ Other contributors: David Hoff (Records), Marcus Caruthers (Information Management Branch), Ashley Fisseha (SharePoint, SFD)
- ▶ Managers: George Schupp, Dennis Wesolowski





# Purpose & Objectives

## Procedure – Process - People

- ▶ Prepare an SOP and develop a training program for electronic data packages
- ▶ *EPA Strategic Plan 2018-2022. Improve efficiency and effectiveness (Objective 3.5)*
- ▶ *EPA Strategic Plan 2018-2022. Streamline the process of accepting analog records (Objective 3.2).*
- ▶ **Objective:** electronic laboratory data packages as the original record of final data
- ▶ Streamline the data reporting and review process
- ▶ Reduce paper and ink usage





# Report Terminology

Report Type	Definition
Level I Report	LIMS report that excludes batch QC (i.e. only sample results)
Level II Report	LIMS report that includes samples results AND batch QC.
Level III Report	Not currently used at ASB. It is the same as a level II report, but also includes instrument QC summaries.
Level IV Report	.PDF compiled by the chemist of reports & all underlying documentation

# Considerations



Accreditation  
requirements

Guidance  
documents and  
Agency directives,  
Regional  
procedures

Electronic work  
flows,  
precedents

Network  
resources



Software  
compatibility

LIMS, Crystal  
Report, Qualtrax,  
Adobe

Meets Agency  
legal  
requirements

Integration of  
automated  
processes

Software and  
training needs

Staff input



## Considerations (con't)

- ▶ ANAB, 2011. Accreditation Requirement: Control and Use of Accreditation Symbol.
- ▶ EPA, 2009. Guidance for Labeling Externally Validated Data for Superfund Use. *Office of Solid Waste and Emergency Response*.
- ▶ EPA, 2015. EPA Information Standards: *Document Digitization Scanning Standards*. EPA Classification No. CIO 2155-S-01.0. Approval Date: August 4.
- ▶ EPA (2017). DRAFT Information Directive Guidance: *Electronic Signature Guidance*. IT Operations Workgroup (ITOWG) Electronic Signature.
- ▶ Adobe® (2017). *Electronic and digital signatures in Adobe Sign for government. A white paper*.



# Electronic Data Implementation Team Tasks

## ► Determine:

- Software needs
- Training needs
- Working drive / server compatibility
- Data reporting workflow
- Existing models

## ► Modify (processes):

- SOPs (e.g. GEN 013, 018, data verification SOPs)
- The Quality Mgmt Plan
- Work Instructions (005, 005A)

## ► Develop:

- SOP, workflow
- Training
- Recommendations for future steps

**August 29, 2017 –  
April 1, 2018**

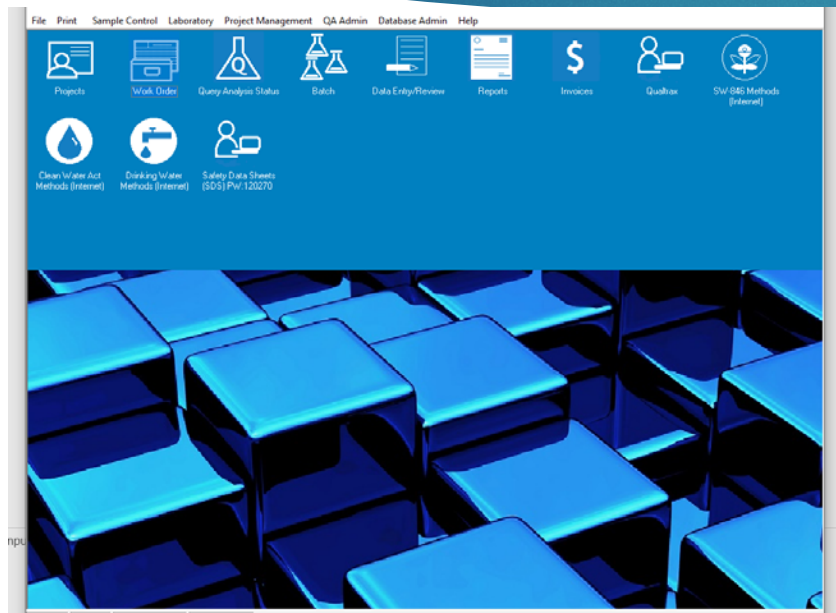


# Summary of SOP: Electronic Data Packages (eLDPs)

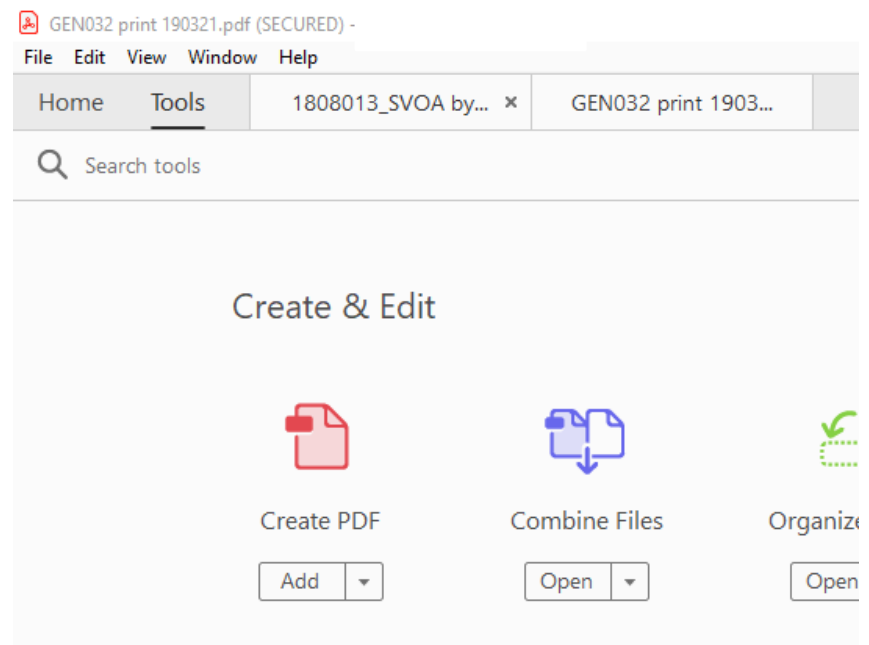
- ▶ Includes the required components, organization and nomenclature
- ▶ Includes group specific components and organization
- ▶ Provides guidance on associated tasks such:
  - ▶ Document digitization
  - ▶ Adobe® organization tools
  - ▶ Electronic and digital signatures
  - ▶ Network filing
  - ▶ Data reporting Qualtrax workflow



# Basis of Electronic Data Packages (eLDPs)



Login Name:

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Title	SOP GEN032 Electronic Data Packages	CRL Document #	Version # 1
Effective Date	3/29/2018 11:37:37 AM	Status Published	Page 5 of 18

### 5.1 General Required Components of Electronic Laboratory Data Packages (eLDPs)

The table below summarizes the required content included in eLDPs.

Row	Data Package Item	Brief Description
1	Cover Page with Digital Signature	A cover page with the template provided in attachment 1. This cover page should be filled out and signed electronically by the analyst.
2	Section Dividers	It is recommended that all eLDPs include the primary section dividers detailed in <a href="#">Section 5.3</a> . The dividers can exist in two forms: bookmarks alone or page inserts that are bookmarked.
3	LIMS Final Level I / II Report and the Case Narrative	The standard final LIMS electronic data report that is generated. The report is automatically signed in LIMS.
4	Data Verification Checklist	All eLDPs must include a completed data verification checklist. The checklist should include electronic signatures (See <a href="#">Section 5.4.4</a> ) of both the analyst and second reviewer.
5	Verified Work Order Login Form	The verified work order login form that is signed electronically by the WO login reviewer. This can be retrieved from the designated network location and/or LIMS .PDF icon for "other documents" in the LIMS work order login screen. All eLDPs must include this form and it is used to confirm preservation (e.g. pH, cooler temperatures etc.).
6	Temporary Electronic Pathway For Data Verification Purposes	Data verification checklists or memos to file documents must contain a reference to the data's electronic pathway. The 'R5CRL Vol1' drive shall be the working data repository and include any instrument results and method parameter files.
7	Supporting Data	Supporting data refers to all the data generated to support reported sample results. This includes but is not limited to LIMS bench sheets, LIMS sequence sheets, instrumental analysis data (including samples, QC, and calibration data), spreadsheets, notebook/logbook entries of original observation, unreported project data (e.g. instrument blanks, unused dilutions and/or re-runs).
8	Pen and Ink updates to the SOP(s), Client Contacts, CAs, and NCRs	Any relevant .PDFs of client contacts, corrective action (CAs) and nonconformance reports (NCRs) associated with data.

### 5.2 ANAB Logo Policy

The LIMS-generated level I / level II report portion of the full data package must adhere to the ANAB logo policy.

# User-Friendly Tips for eLDPs

- ▶ Consistent order of components and sections
- ▶ Section dividers
- ▶ Bookmarks (**tiered**)
- ▶ Cumulative page numbers
- ▶ Stamping and other versions of Adobe® electronic signatures.

*Robert Thompson*

Date: 2017.06.12 16:26:27  
-05'00'

**REVIEWED**

By Robert Thompson at 4:55 pm, Feb 27, 2018

*Robert Thompson*

Digitally signed by ROBERT  
THOMPSON  
DN: c=US, o=U.S. Government,  
ou=USEPA, ou=Staff, cn=ROBERT  
THOMPSON,  
dnQualifier=0000081142  
Date: 2018.02.27 16:48:58 -06'00'


# User-Friendly Tips for eLDPs

## Document Digitization

- ▶ Scan paper originals
  - ▶ Ensure appropriate **image quality**
    - ▶ Legible (e.g., contrast and brightness)?
    - ▶ Were all pages scanned?
    - ▶ Proper alignment (Agency recommendation is skew < 3°)?
    - ▶ Minimum resolution applied (Agency recommendation is 300 pixels per inch)?
- ▶ Paper originals go through reviewer
- ▶ Once the Level IV eLDP is reported, hardcopies can be recycled.
- ▶ Return COC to client







# Workflows - Processes

## Transmittals to Client

- ▶ Procedure is mostly the same as before
- ▶ Send D.C. an email with ASB deliverables (Standard Excel EDD and Level I/II report)
- ▶ If client requests a level IV data package, D.C. shares on ASB Sharepoint site

## Data Reporting Workflow

- ▶ An extension of the case narrative workflow
- ▶ Place the final .PDF in the "Data for Transfer to EDMS" folder on the network I:Drive.
- ▶ Used to notify the D.C. when the level IV eLDP is ready for transfer to EDMS
- ▶ Includes Qualtrax auto-notifications

# Workflows - Processes

The screenshot displays a SharePoint interface for the 'Chicago Regional Laboratory US EPA Region 5' site. The left sidebar shows navigation options like 'Document Subsite...', 'Lab Certification Pr...', 'WA 2-55 Workgroup', 'Home', 'About', 'Members', 'Announcements', 'Documents' (highlighted), 'CRL Customer Satis...', 'Calendar', 'Discussions', 'Accessibility', 'Site Contents', 'Subsites', 'Pages', and 'Recycle bin'. The main content area shows a list of documents under the 'Data' folder. The table includes columns for 'Name', 'Modified', and 'Modified By'. A large blue arrow icon points towards the document list.

Name	Modified	Modified By
Buckeye Reclamation Landfill	July 23, 2018	Kerr, Michelle
Charlevoix	February 14, 2018	Kerr, Michelle
Chem Central	May 24, 2018	Kerr, Michelle
Chemical Solvents	July 14, 2017	Griffin, Sylvia
Fremont	June 12, 2018	Kerr, Michelle
GLNPO Long Term Bio Monitori...	October 2, 2017	Kerr, Michelle
Hancock Manufacturing	September 14, 2018	Kerr, Michelle
McLouth PFAS	August 9, 2018	Thompson, Robert A.
PFAS POE Treatability Project	November 1, 2017	Griffin, Sylvia
R9 PFC Project	May 15, 2018	Thompson, Robert A.
RACER Buick City Site	May 1, 2018	Snyder, Robert

# Workflows - Processes

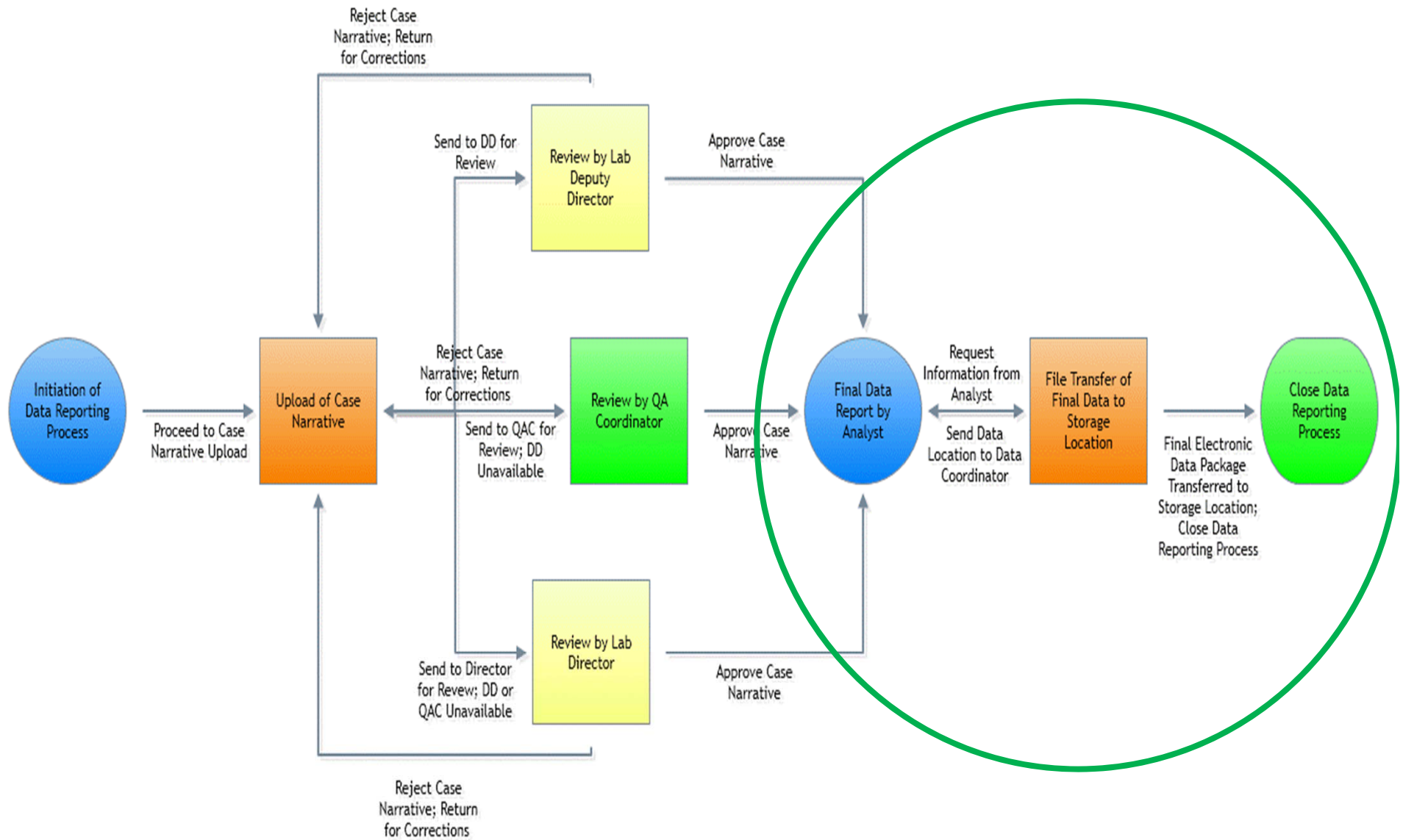
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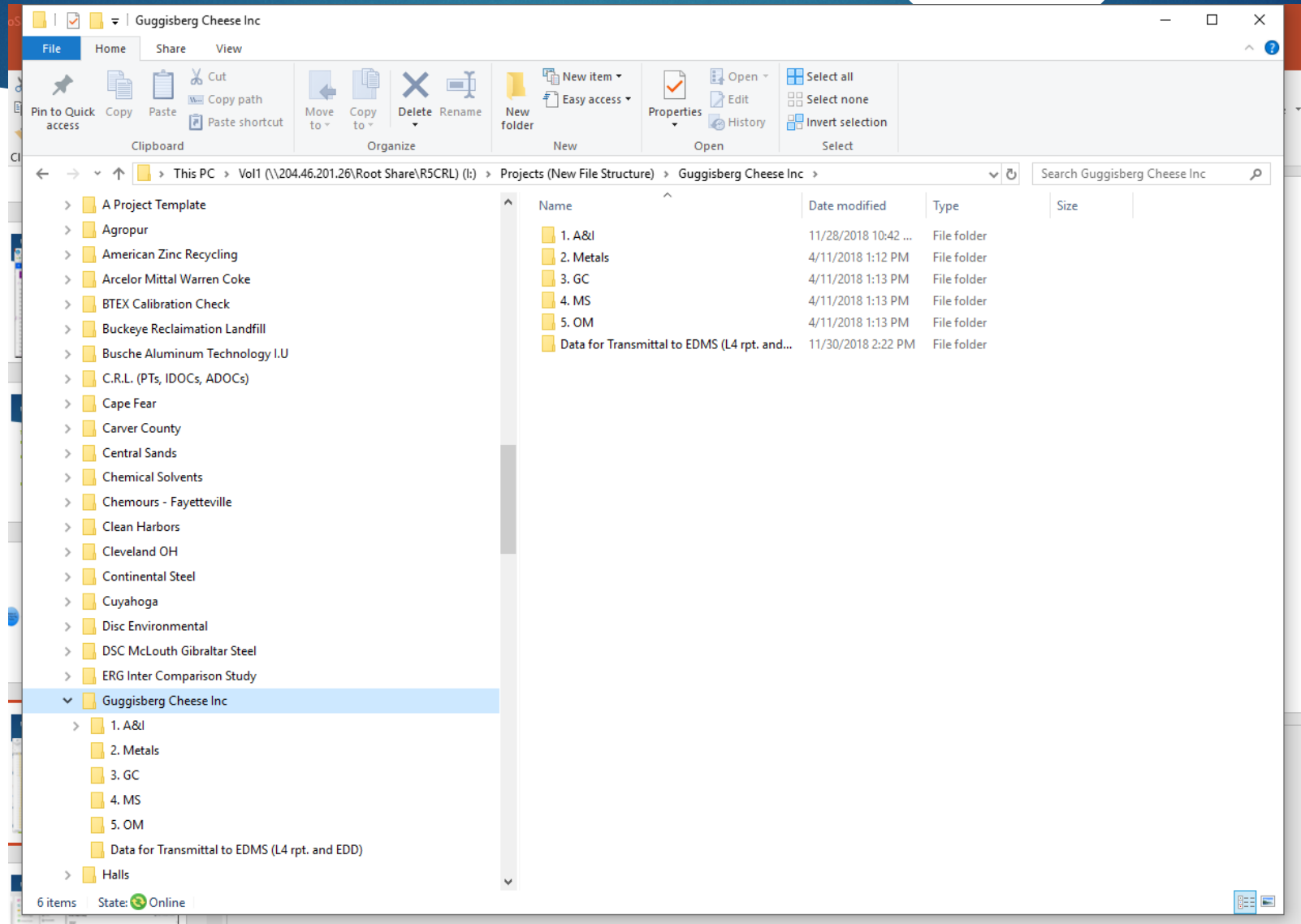
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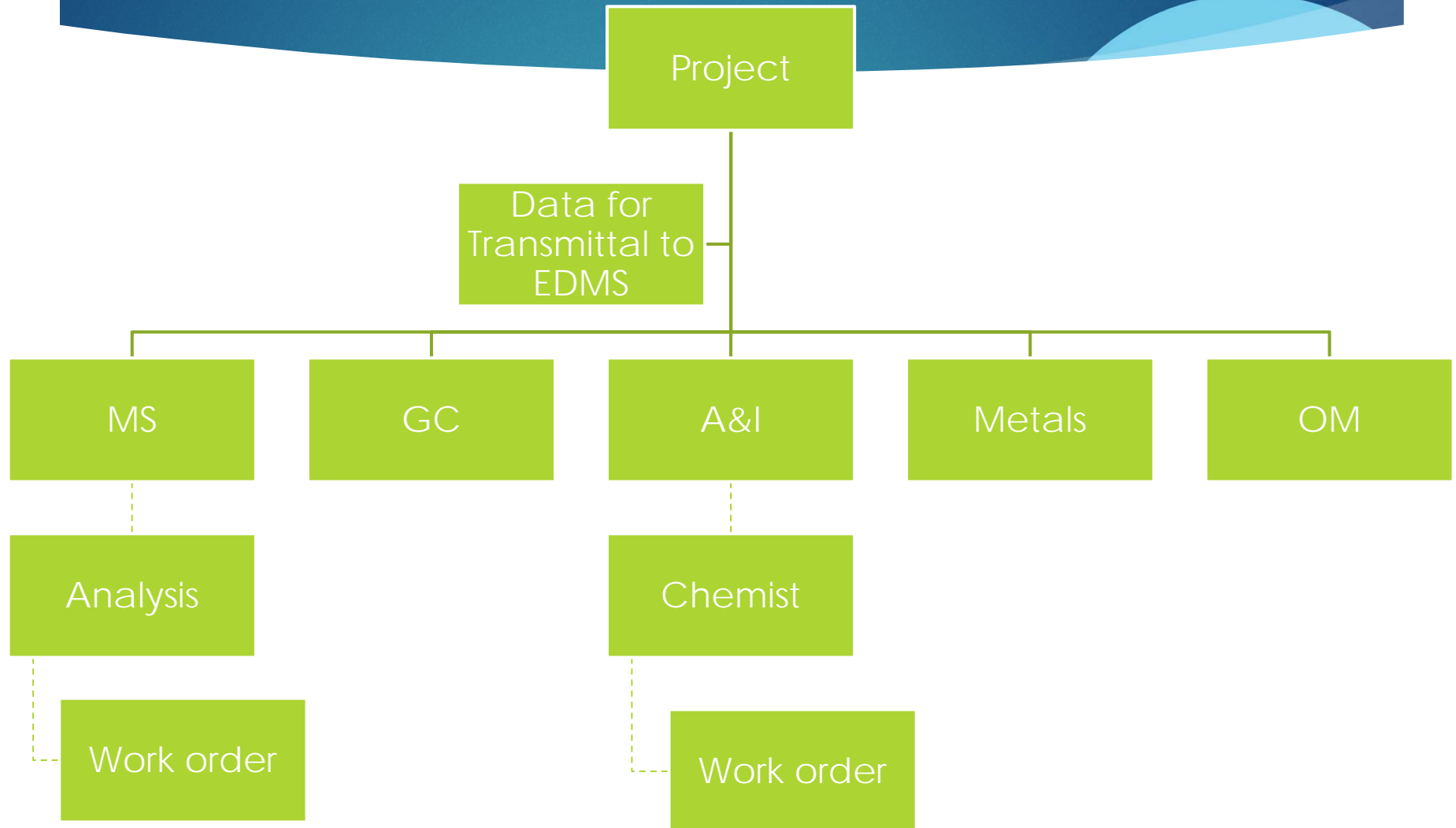




# Workflows - Processes



# Filing Structure Update



# Workflows - Processes

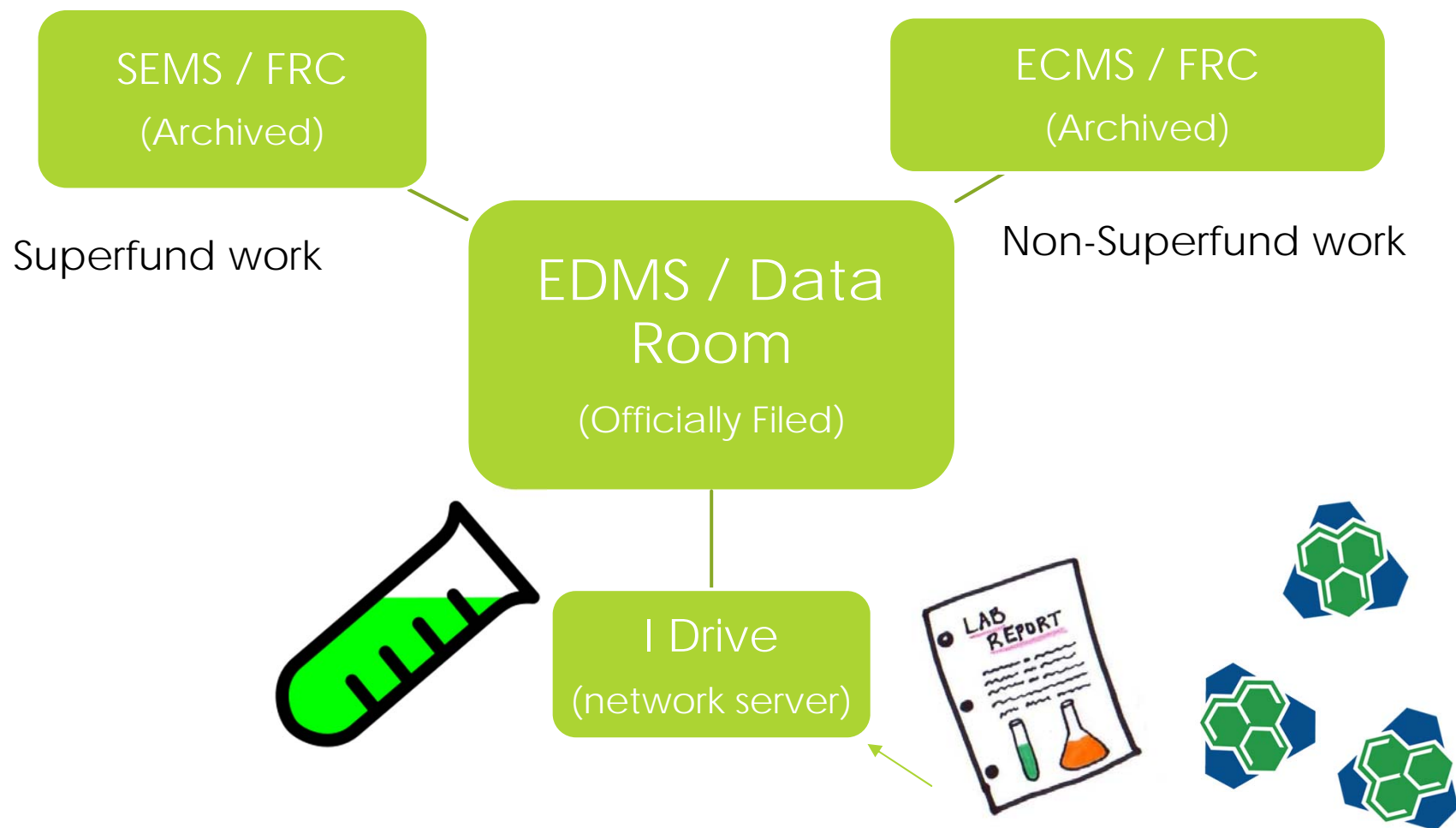
The screenshot displays the Qualtrax web application interface. On the left is a sidebar with various tool icons and labels: Edit PDF, Export PDF, Comment, Organize Pages, Enhance Scans, Protect, Fill & Sign, Prepare Form, Compare Files, Combine Files, and Certificates. The main content area is titled "Data Reporting" and includes a search bar, a user profile "Kerr Michelle", and a "View Printable Version" link. The workflow steps are listed in a table-like format:

Step	Description
Analysis	Volatiles
Case Narrative - Does the associated LIMS report contain descriptive qualifiers?	No - The routine case narrative attachment is sufficient
Case Narrative Attachment	17436 case narrative 18120031.docx <a href="#">View</a>
Case Narrative - Analyst Comment	Targeting today for transmittal to client, ShoreMet/ Jamie Paulin/RCRA.
Case Narrative - Approval Comment (DD)	Approve ShoreMet VOA case narrative
Case Narrative - Return Comment (DD)	
Case Narrative - Approval Comment (QAC)	
Case Narrative - Return Comment (QAC)	
Case Narrative - Approval Comment (LD)	
Case Narrative - Return Comment (LD)	
Data Reporting - Is a Level IV final data package requested by the client?	No
Data Reporting - Location of Final Electronic Data Package	I:\Projects (New File Structure)\ShoreMet\Data for Transmittal to EDMS (L4 rpt. and EDD)
Data Reporting - Analyst Comment	

The bottom of the screen shows a Windows taskbar with various application icons and a system clock indicating 12:40.



# Archiving Records



# EDMS

## Electronic Data Management System

RMD EDMS R5 EDMS Home RMD Intranet

Search this site

RMD EDMS

R5 EDMS Home

RMD Subsite Home

AAB

CB

**CRL**

ESB

HRB

IMB-ISS

IMB

FO

Libraries

Recent

Pages

**+ New** **↑ Upload** **↻ Sync** **↻ Share** **More**

**CRL EDMS** **All Documents** **Internal** **Find a file**

Project or Site Name	Division	Project Completion Date	Work Order Number	Statute Law	Retention Period	Litigation Hold Case	Modified By	Modified	Edit	Item Child Count	Analysis_Matrix
Agropur	WD		TBD	CWA	Non-Superfund=10yr	None	Thompson, Robert A.	August 22	0		Not Applicable
BTEX Calibration Check	ARD		1803009	CAA	Non-Superfund=10yr	None	Thompson, Robert A.	May 23	2		VOCs_air
Buckeye reclamation Landfill	SFD		1807009, 1807010	CERCLA	Superfund=75yr	None	Thompson, Robert A.	July 27	3		PFCs_water
Cape Fear	ORD		TBD	Not Applicable	Non-Superfund=10yr	None	Thompson, Robert A.	June 12	2		PFCs_water
Carver County	LCD		1805011, 1805014	RCRA	Non-Superfund=10yr	None	Thompson, Robert A.	June 5	14		Not Applicable
Central Sands	WD		1805005, 1805007	RCRA	Non-Superfund=10yr	None	Thompson, Robert A.	May 31	14		Not Applicable
Charlevoix	SFD		TBD	CERCLA	Superfund=75yr	None	Griffin, Sylvia	June 13	0		Not Applicable
CRL QA Data Packages	RMD		NA	Not Applicable	Non-Superfund=10yr	None	Thompson, Robert A.	May 18	65		Not Applicable
Disc Environmental	LCD		1807014	TSCA	Non-Superfund=10yr	None	Griffin, Sylvia	August 22	2		PCBs_Oil

# Training

Date	Topics
3/6/2018 10:00am	<b>Module 1 (optional)</b>
	Printing to PDF
	Assembling a PDF from multiple files
	Organizing pages (insert, delete, re-order)
	Scanning to PDF, resolution settings
3/8/2018 10:00am	Document Digitization
	Verification
	<b>Module 2 (optional)</b>
	Basic annotation of a PDF (e.g. add text, highlight)
	Adding stamps, shapes, strike-through and additional comment tools
	Split screen viewing
	Bookmarks and pagination

Date	Topics
3/13/2018 10:00am	<b>Module 3a (optional)</b>
	LIMS signature
	Setting up your LIMS and adobe signatures
	Digital signatures vs. electronic signatures
	Using stamps as an electronic signature version (e.g. reviewer checklists)
	<b>Module 3b (optional)</b>
	Qualtrax workflow
	Saving files and network structure update
	Amended data requests
	<b>Module 3c (optional)</b>
	Portfolio Demonstration

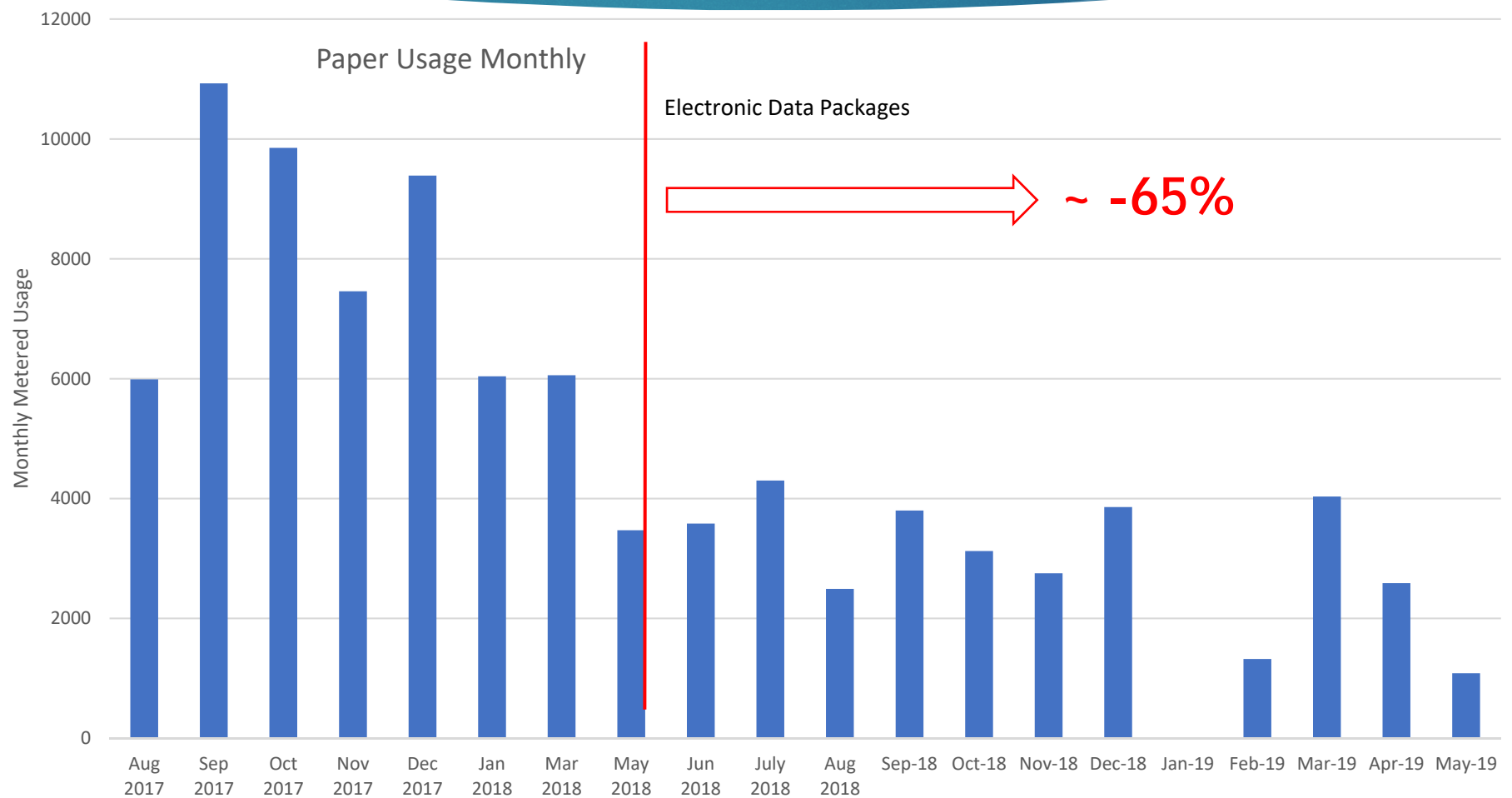
# How does Region 5 compare?




Region	QC Documents	Data Packages	COCs
1	Hardcopy	Hardcopy	Hardcopy
2	<b>Electronic</b>	<b>Electronic</b>	Working on it
3	Hardcopy	Hardcopy	Hardcopy
4	Hardcopy	Hardcopy	Hardcopy
5	<b>Electronic</b>	<b>Electronic</b>	Working on it
6	Hardcopy	Hardcopy	Hardcopy
7	<b>Electronic</b>	Hardcopy	Hardcopy
8	Hardcopy	Hardcopy	Hardcopy
9	<b>Electronic</b>	<b>Electronic</b>	Hardcopy
10	Hardcopy	Hardcopy	Hardcopy



# Results





# Results

- ▶ Standardized process for all analysts to follow when creating data package
  - ▶ Reduction of errors and missing information
  - ▶ Reduction in time processing, reviewing data
  - ▶ Increase consistency
  - ▶ Increase time available for sample analysis
- ▶ Meeting NARA upcoming requirement for electronic records by 2022
- ▶ Modernize
  - ▶ Streamline preparation, archiving of data packages
  - ▶ Reduced need for printing devices
- ▶ Increase transparency
  - ▶ Faster FOIA response
- ▶ Improve customer service
  - ▶ Faster access to data

## On the Horizon

- ▶ Using LIMS to compile data packages
- ▶ Using LIMS and or SharePoint to send client deliverables/notifications
- ▶ SOP Version 2
- ▶ Electronic COCs, cloud-based client surveys

# Digitizing Data Deliverables



**Thank You!**