Digitizing Data Deliverables

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

August 5, 2019

Presenter: Michelle Kerr

Disclaimer

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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. No accepting analog records 2022.

   ▶ **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
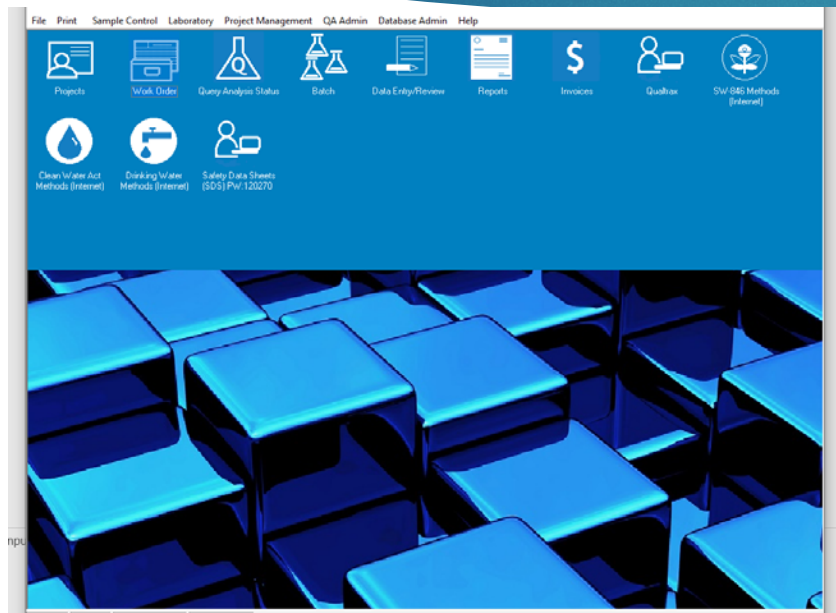 - Recommendations for future steps

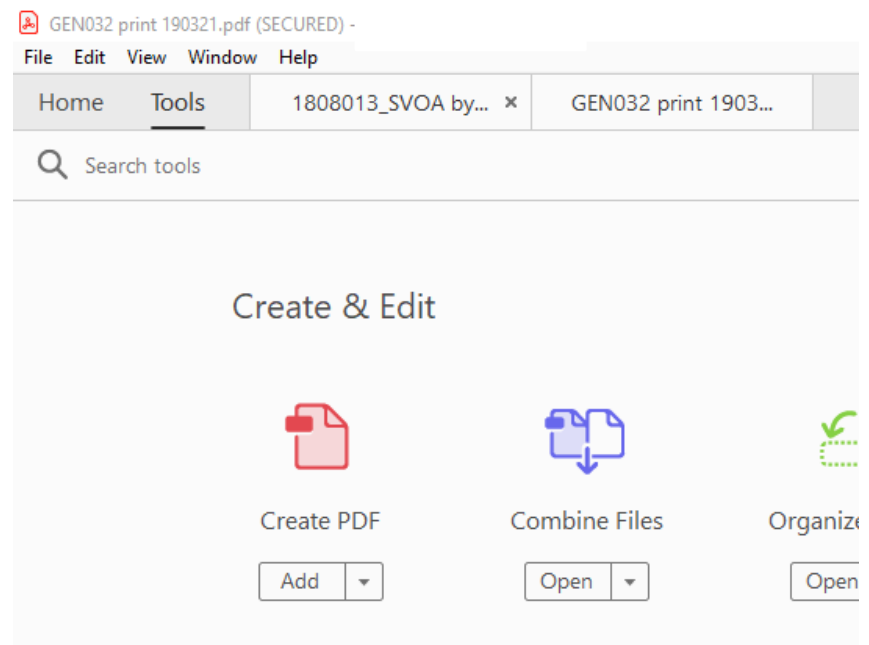## August 29, 2017 – April 1, 2018

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)

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 Section 5.3. 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 Section 5.4.4) 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.
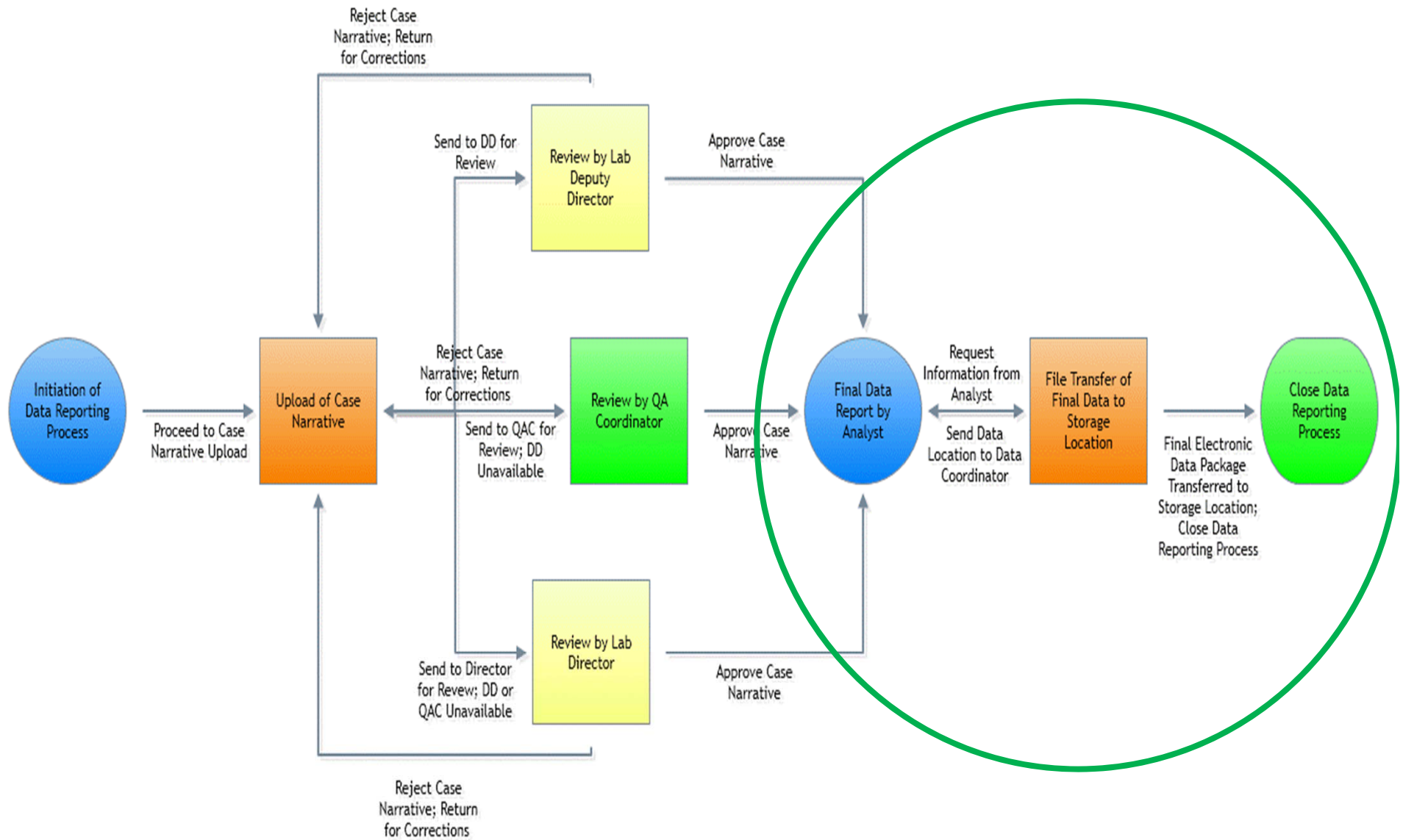
▶ Return COC to client

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)

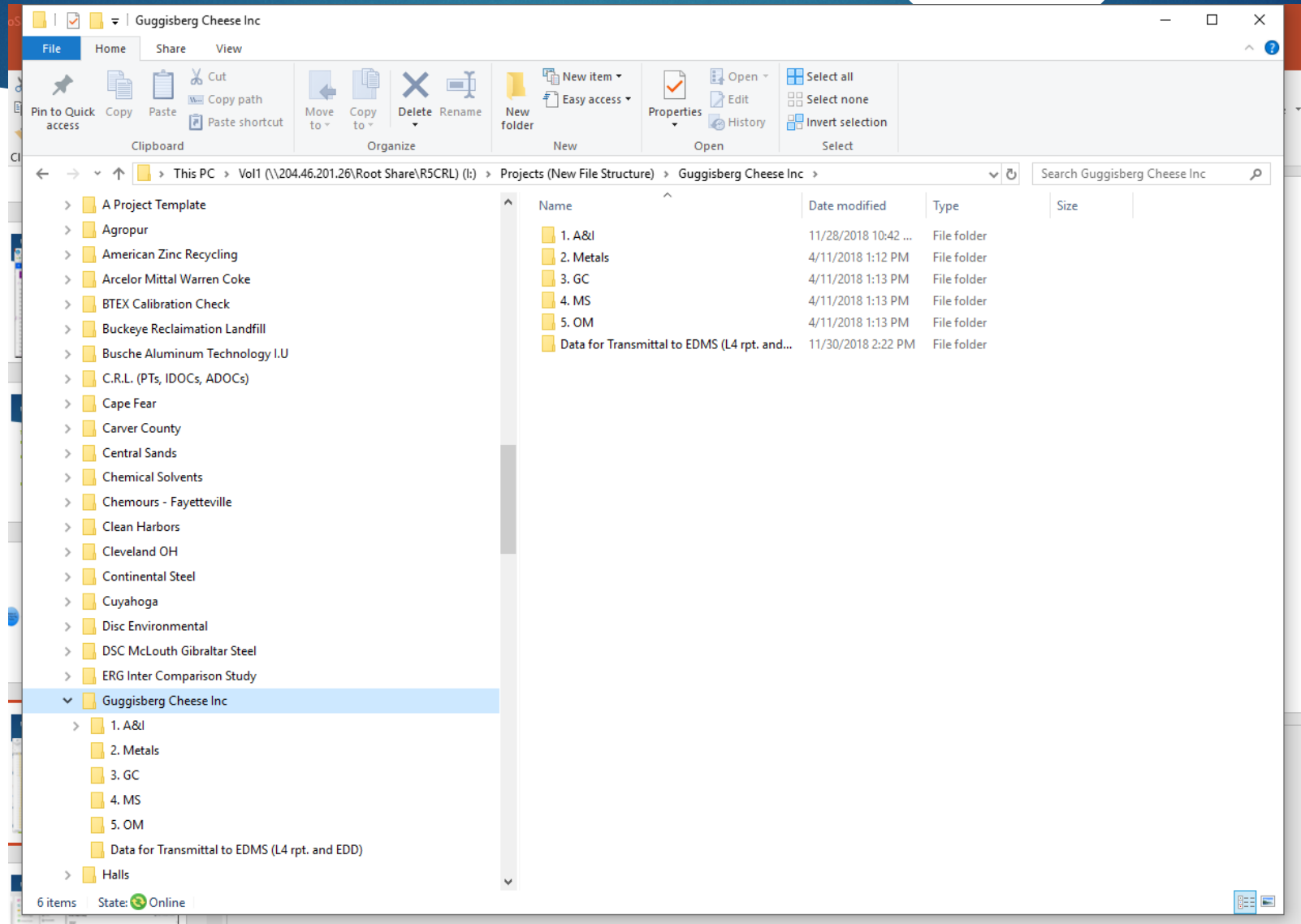- If client requests a level IV data package, D.C. shares on ASB Sharepoint site

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
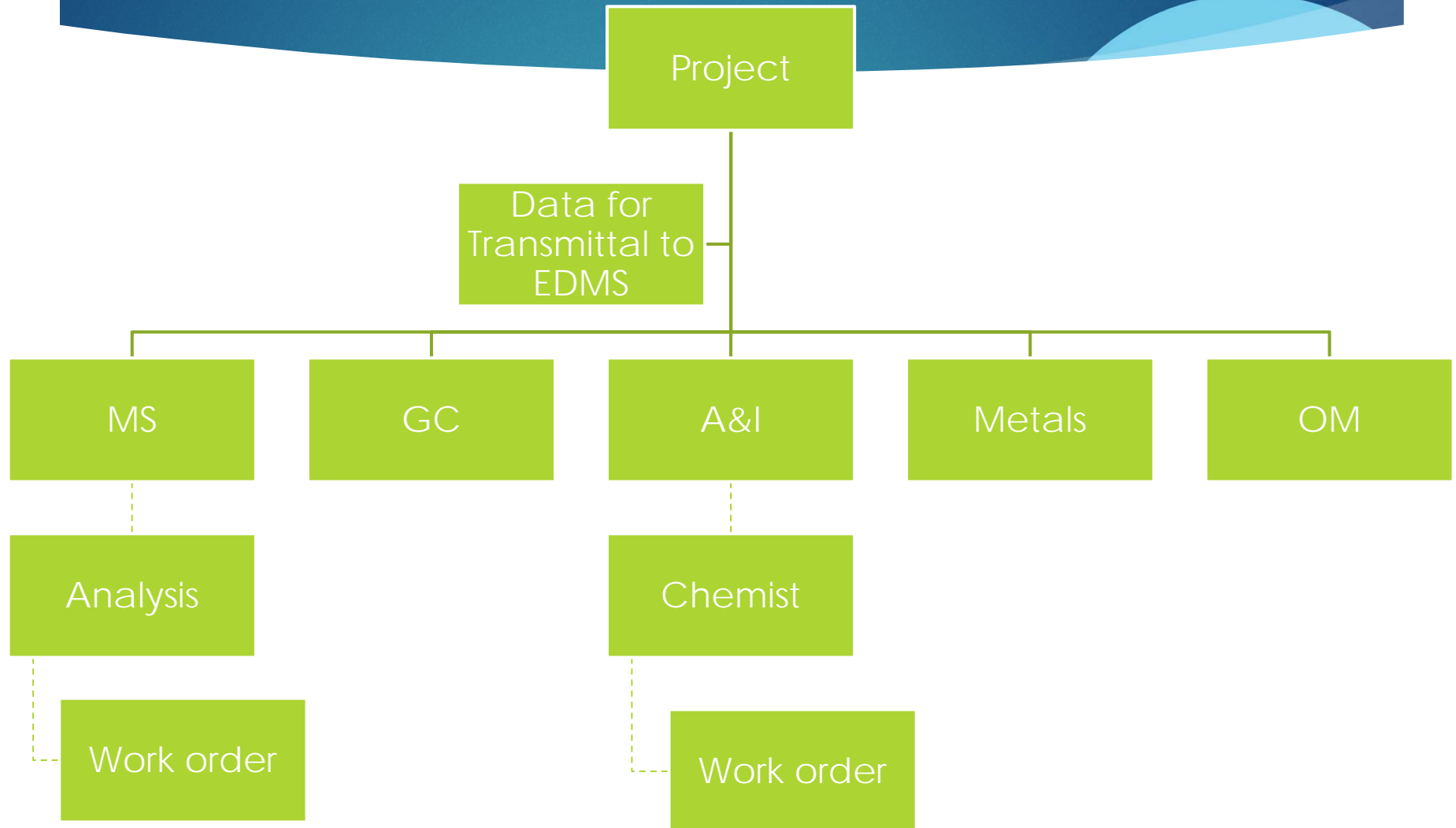
- Includes Qualtrax auto-notifications

Workflows - Processes

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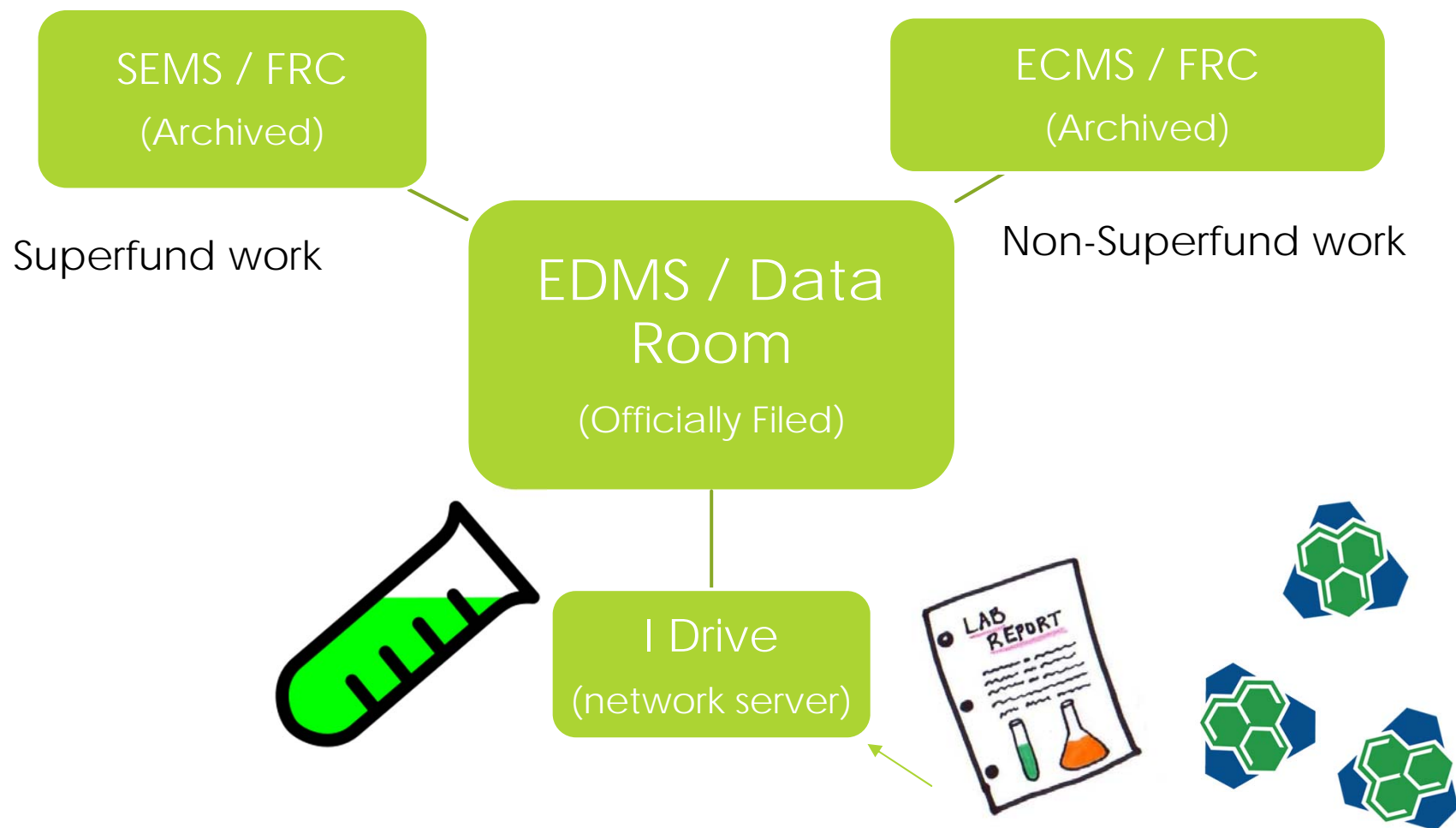
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Reject Case Narrative; Return for Corrections

Send to DD for Review

Review by Lab Deputy Director

Approve Case Narrative

Initiation of Data Reporting Process

Proceed to Case Narrative Upload

Upload of Case Narrative

Reject Case Narrative; Return for Corrections

Review by QA Coordinator

Send to QAC for Review; DD Unavailable

Approve Case Narrative

Request Information from Analyst

Final Data Report by Analyst

Send Data Location to Data Coordinator

File Transfer of Final Data to Storage Location

Final Electronic Data Package Transferred to Storage Location; Close Data Reporting Process

Close Data Reporting Process

Send to Director for Revew; DD or QAC Unavailable

Review by Lab Director

Approve Case Narrative

Reject Case Narrative; Return for Corrections

Workflows - Processes

Filing Structure Update

Workflows - Processes

Archiving Records

SEM S / FRC
(Archived)

ECMS / FRC
(Archived)

Superfund work

Non-Superfund work

EDMS / Data Room

(Officially Filed)

I Drive
(network server)

EDMS
Electronic Data Management System

Training

Date	Topics
3/6/2018 10:00am	**Module 1 (optional)**
	Printing to PDF
	Assembling a PDF from multiple files
	Organizing pages (insert, delete, re-order)
	Scanning to PDF, resolution settings Document Digitization Verification
3/8/2018 10:00am	**Module 2 (optional)**
	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	**Module 3a (optional)**
	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)
	Module 3b (optional)
	Qualtrax workflow
	Saving files and network structure update
	Amended data requests
	Module 3c (optional)
	Portfolio Demonstration

How does Region 5 compare?

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

Results
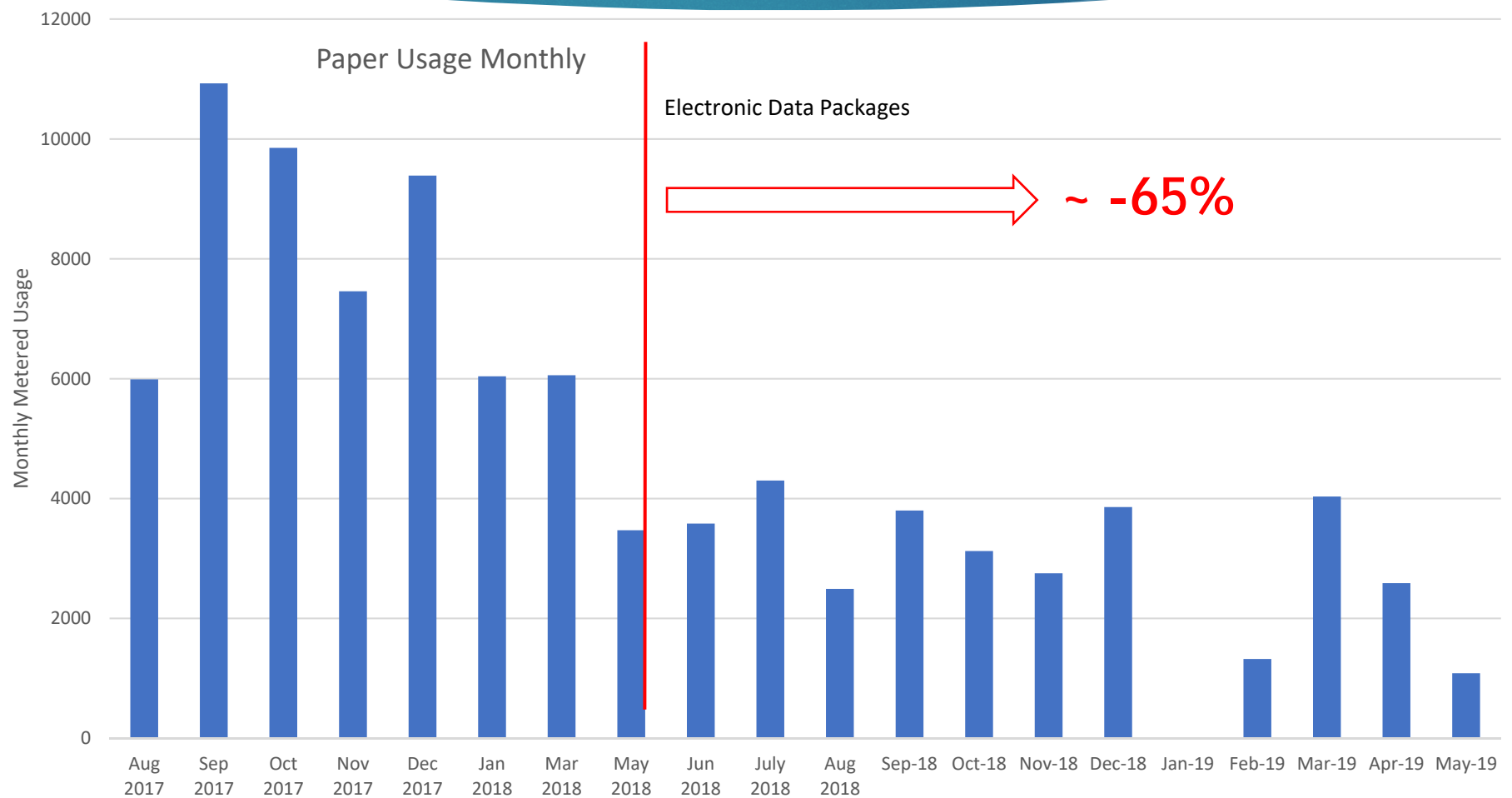
Results

- 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!