Electronic Data Exchange and Evaluation System

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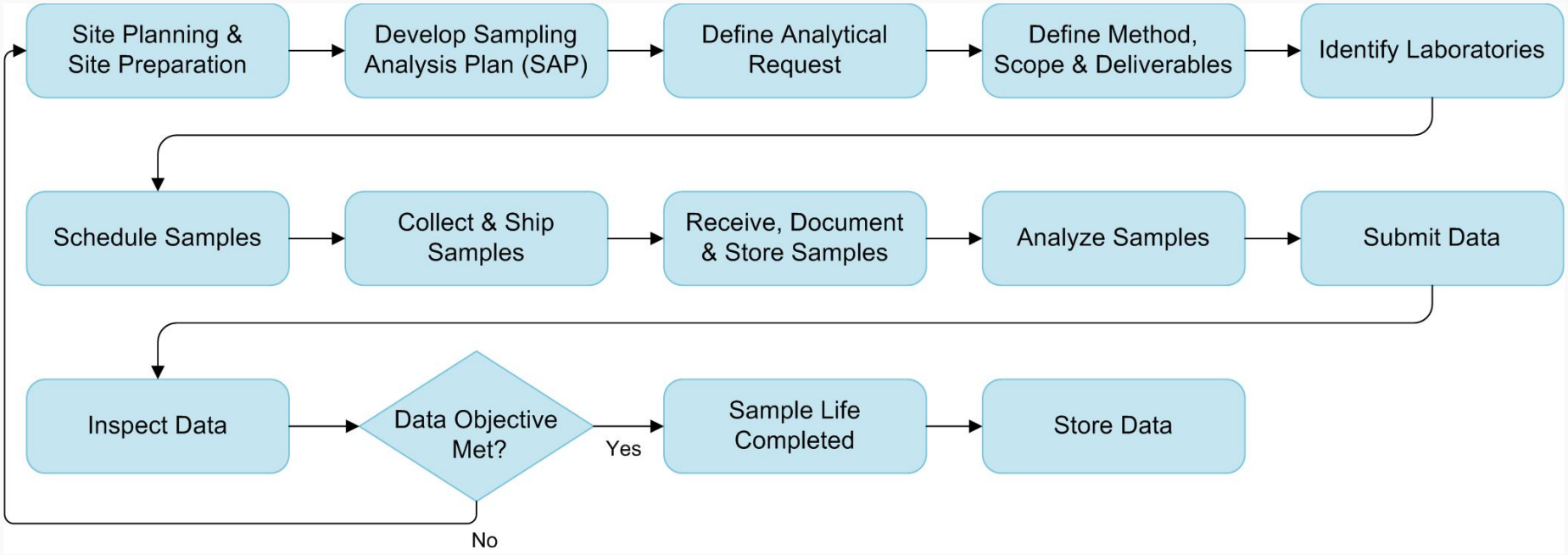
Life of a Sample



Note: The sample can be an environmental sample collected from a Superfund site or a sample collected in support of FDA, NIH, DOD, etc.

What Challenges Data Users Are Currently Facing

- Reduction of available funding to continuously develop, update and maintain an electronic/automated review tool
- Program and Project Mangers are required to answer the same pressing questions with shrinking resources and funding pools
- Environmental and human health decisions must be made based on credible data
- The wrong review tool is used
  - Does not allow users the ability to define project quality objectives upfront; forcing them to use set requirements
  - Can only process specific Electronic Data Deliverables (EDDs)
  - Only set up for limited methods
- Incorrect implementation of automated review processes
  - No planning
  - No training for laboratory and data user

Electronic / Automated Data Review Tools

- Automated/electronic data review tools currently on the market:
  - Accept a limited set of EDD formats (one or two)
  - Perform data review based on existing methods only and/or specifications – can only pick one of the listed methods
  - The tests/checks performed are hardcoded/set – making changes costly and time consuming
  - Limited scalability
  - If any of the above requirements change, the tool will need major updates or a complete redo
- What is missing/needed:
  - Format neutral data review tool
  - Provide data users with the ability to modify review spec based on their needs
  - User friendly web User Interfaces (UI) to set up requirements and customize on an as-needed basis – real time – no development delay
  - Ability to recalculate/verify results
  - Scalable and configurable

Better Data; Better Preparedness; Lower Cost

- Applies to any large monitoring program that involves laboratory analysis of samples — food, clinical, environmental, agricultural, or forensic
- Scalable processes for managing sample or specimen collection and laboratory analysis through a centralized system
- Leverage technology to reduce costs and improve quality
- Minimizes cost while simultaneously maximizing data quality and ensuring legal defensibility
  - **Better data:** ASB's Electronic data eXchange and Evaluation System (EXES) provides independent assessment and validation of laboratory data
  - **Lower costs:** During the past 15 years, EXES has saved EPA *more than $60 million* through automation

What Sets our Tool Apart from Others on the Market

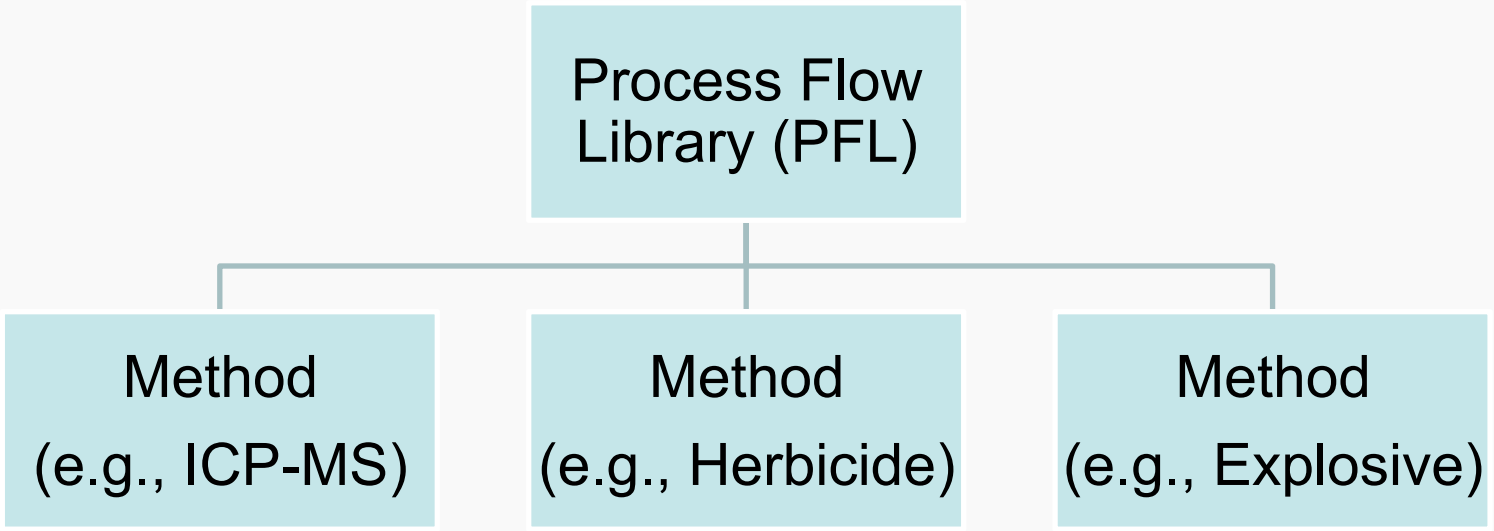
- Efficiently evaluates analytical data **regardless of the format of the data deliverable** that is submitted.
- Provides users with advanced customization capabilities to **review, edit, and add evaluation parameters, tests, Method Quality Objectives (MQOs)**, and Quality Assurance Project Plan (QAPP) requirements.
- The EXES is comprised of **a dynamic test creation core** working in tandem with an expandable reference data set that is not limited to specific analytical processes and procedures.

How Does It Work?

- A Web-based data assessment/validation and management tool that can evaluate analytical data. It uses:
  - Format neutral domain and data model
  - Re-usable Process Flow Libraries (PFL)
  - Method Evaluation Libraries (MELs)
  - Method Evaluation Procedures (MEPs)
  - UI for custom test creation
- It is capable of supporting federal, state and commercial laboratory data assessment needs.

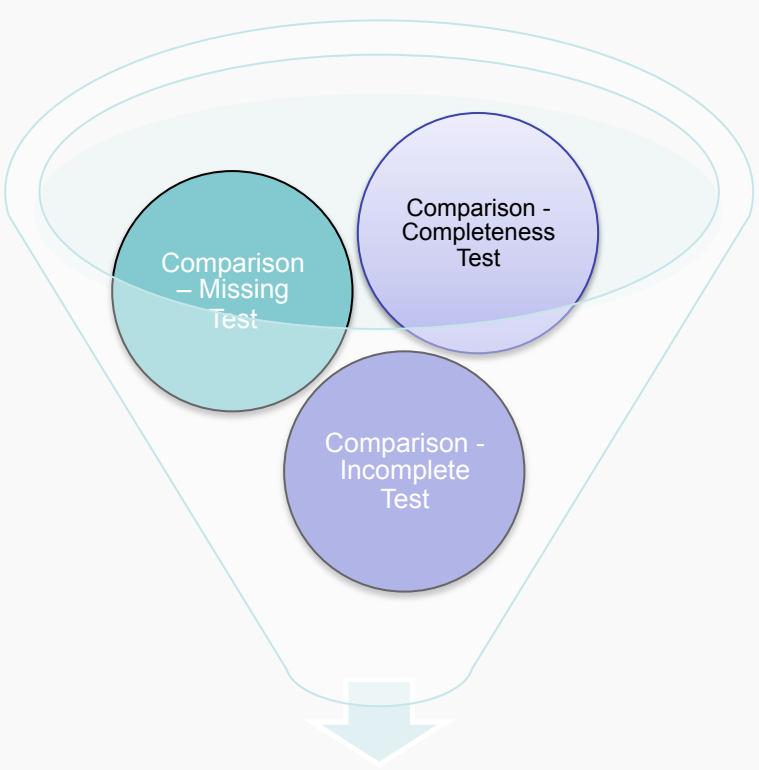
What is a Process Flow Library?

- What analytical methods will I be using?
- What type of data deliverables?
  - Hardcopy, EDD, PDF of hardcopy.
  - What type of electronic deliverables (XML, Excel, CSV, etc.)
- What services will be performed on the submitted data?
  - Method compliance review
  - Data validation assessment

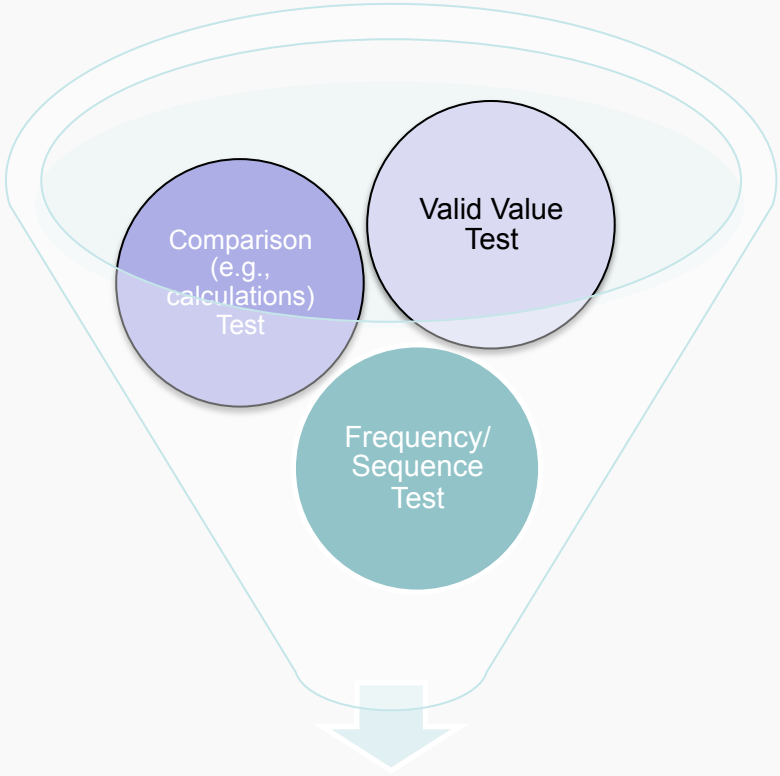


Method Evaluation Procedure (MEP)

- How do I want to assess my methods?
- MEPs are containers of tests that would be applied against the method data.
- One method will have one or more associated MEPs based on the type and level of review requested/needed



Method compliance Assessment MEP



Data Usability/Validation Assessment MEP

Tests

- Tests are assessment criteria applied to the EDD based on the associated MEP.
- A test is dynamically created through a sophisticated User Interface (UI).
- A test can be reused across Methods.
- Tests may reference method quality objectives stored in the Method Evaluation Libraries (MELs).

Test Types

Comparison:

Calculation

Reported vs. Calculated

Reported vs. MQOs/MELs

Valid Value:

Is the reported value a valid value acceptable by the method and/or to the client?

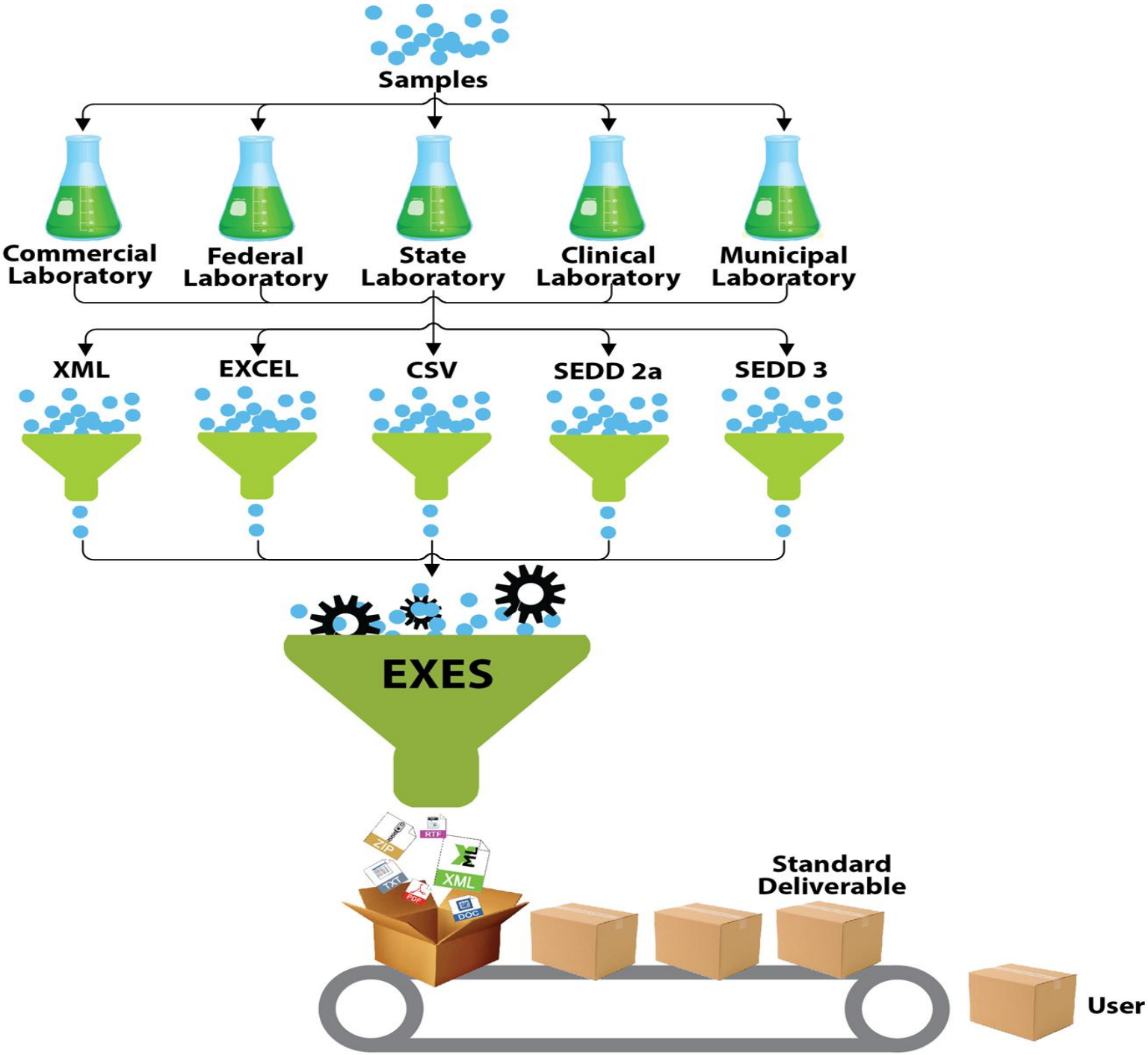
Four General Test Types

Frequency :

Do we have the correct number of initial/blank/QC performed? Is the frequency as outlined in method?

Sequence:

Do we have the correct sequence of analysis as outlined in the method?


Samples
Commercial Laboratory
Federal Laboratory
State Laboratory
Clinical Laboratory
Municipal Laboratory
XML
EXCEL
CSV
SEDD 2a
SEDD 3
EXES
ZIP
RTF
XML
TXT
PDF
DOC
Standard Deliverable
User

EXES Benefits/New Features – You Are in Control

- **Flexible** - user interfaces that enable you to create test rules, data review criteria and reports dynamically; **select and create your desired level of assessments.**
- **Reusable** - features allow users the ability to create new libraries or search and modify existing libraries; saving time and effort, and resulting in cost savings.
- **Consistent** - reproducible and independent electronic review improves overall project transparency.
- **Customizable** - tailored deliverable process flow to meet your specific analytical evaluation needs. **Capability to support multiple programs with different program needs.**

The Key Architectural Principles

- **Modern and Simple to Use** - Allows users to specify desired data assessment outputs in terms of reports and assessment results that can be standardized or customized according to the user's needs.
- **Easily Extendable Component -** Data driven and modular approach allows for rapid expansion in response to new program/client needs with minimum to no development effort and cost.
- **Format Neutral –** Accepts all types of EDDs – XML, EXCEL, CSV, etc.)
- **Data Manager–** The only automated data review tool with a data management component serving as a Web-based secure data & report repository – completely paperless

What is EXES Data Manager (EDM)?

- EDM provides a Web-based/centralized data management tool:
  - Stores all laboratory deliverables
  - Data assessment/validation reports available within minutes of data upload
  - Spreadsheets and outputs include both field and analytical data ready for upload to databases and mapping tools
  - Provides results based on data user's assessment criteria
  - Allows users to edit and regenerate all dynamic reports
  - Provides an audit tracking log of all changes made by user name and date/time
  - Who can have access to what portion of data or reports in EDM can be set based on data user's request

EPA Superfund
Contract Laboratory Program
Use of Electronic Data Review

U.S. Environmental Protection Agency

Analytical Services Branch

Goal

- To provide customers with timely and consistent planning, implementation, analysis, review, and deliverables for analytical data.
- To support a diverse spectrum of legally defensible environmental data collection projects across Superfund and other EPA programs.

CLP Use of EXES

- The Contract Laboratory Program has used EXES to provide automated data review to CLP customers for over 15 years
  - EXES has saved EPA well over ***60 Million*** in manual data review costs
- "Enhanced" EXES is no longer CLP-specific
- The Analytical Services Branch is piloting projects across EPA to provide consistent and cost-effective data review to EPA customers

EXES Pilot Projects

EXES and EDM Pilots:

- EPA Region 3 laboratory
- EPA Region 10 laboratory
- Great Lake National Program Office
- US Army Corps of Engineers
- EPA Region 9 laboratory
- EPA Region 2 laboratory

Lessons Learned

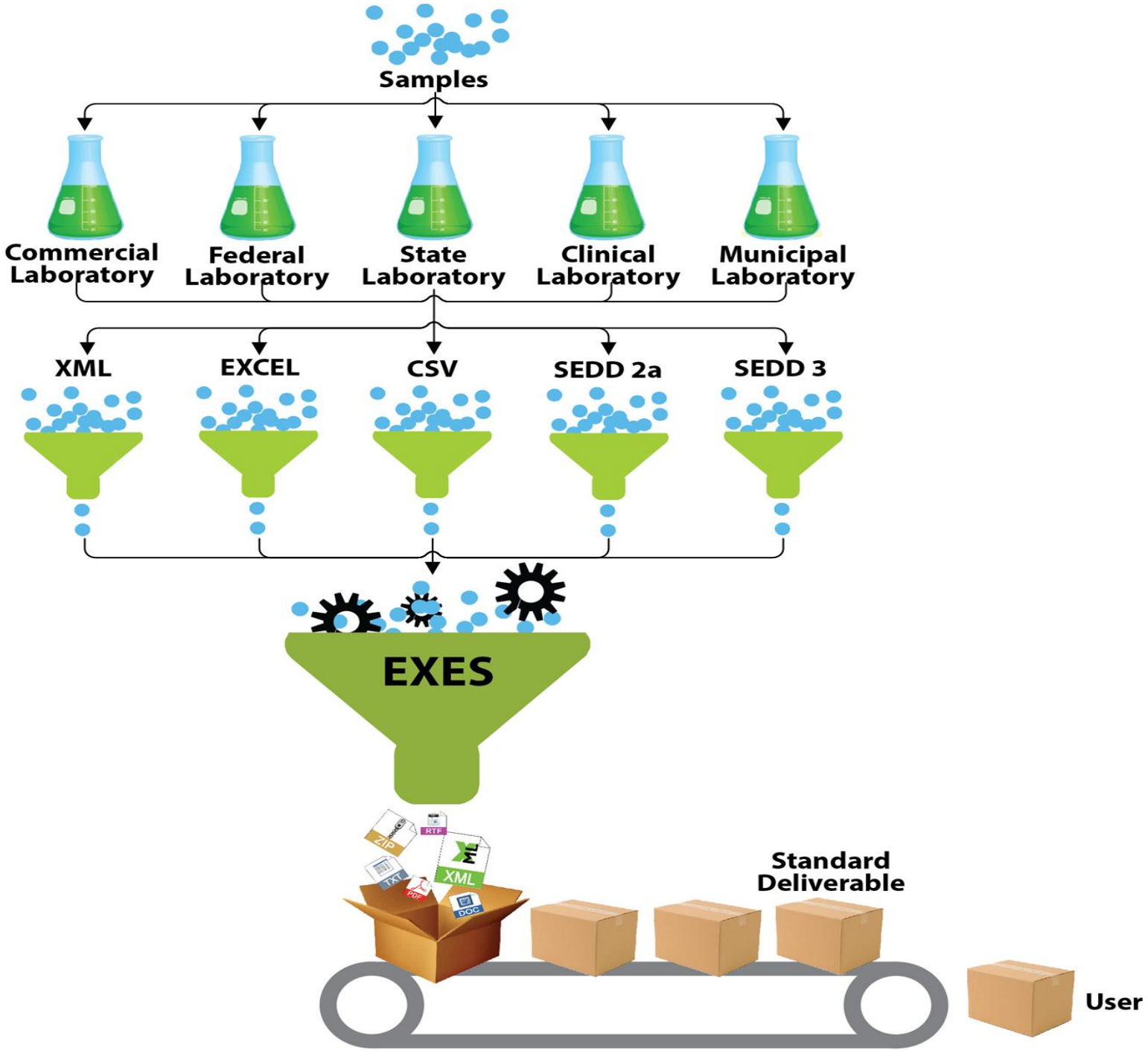
- EXES can be applied to a wide range of analytical methods –not just CLP methods
- There is a huge need for consistent, automated data review throughout EPA and other programs
- Demand for a consistent reporting format, such as SEDD/Universal Data Deliverable, is increasing
- Budget pressures are pushing EPA and labs to find more efficient/automated ways for data review

Lessons Learned

- EXES can accept any electronic format (xml, csv, etc) but the Staged Electronic Data Deliverable (SEDD) is best for consistency and formatting
- SEDD is still catching on
- Flexibility is key

What is Our Goal?

- EPA Superfund data users are currently getting data from many different labs/sources
- Data should go through same evaluation process (EXES)
- Data should end up in the same place (EDM)


Samples
Commercial Laboratory
Federal Laboratory
State Laboratory
Clinical Laboratory
Municipal Laboratory
XML
EXCEL
CSV
SEDD 2a
SEDD 3
EXES
ZIP
RTF
XML
TXT
PDF
DOC
Standard Deliverable
User

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