



Air Toxics LTD

Laboratory Services Since 1989

Commercial Laboratory Perspective on Automated Analytical Data Validation

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Obsolete



- **Main Entry:**
 - 1ob·so·lete
- **Function:**
 - *adjective*
- **Etymology:**
 - Latin *obsoletus*, from past participle of *obsolescere* to grow old, become disused, perhaps from *ob-* toward + *solēre* to be accustomed
- **1 a:** no longer in use or no longer useful **<an *obsolete* word>** **b:** of a kind or style no longer current : **old-fashioned** **<an *obsolete* technology>**



Cause



- Aging analytical data systems
- Limited database structures
 - Laboratory Information Management System (LIMS)
 - Environmental Information Management System (EIMS)
- Proprietary EDDs
- Hardcopy data validation
- Resistance to change

...prevents maximum efficiency and effectiveness

Why Review Data?



- Assure quality and data usability
- Agency requirement
- Assume human error
- Perceived data fraud



Industry Norm



- Considerable resources are used to manually validate laboratory analytical data
- Guidelines vary from program to program
- Unavailable data
- Difficult to share data
- Inconsistency of manual review

Laboratory Norm



- 100s of electronic formats
- No standardization of deliverables
- Industry lacks common approach to data
- Limited client acceptance of new technology
- Dated LIMS

Manual Review Steps



- Data Verification: evaluating the completeness, correctness, consistency, and compliance of a data package
- Data Validation: assessment in accordance with EPA regional or national functional guidelines or project-specific guidelines
(typically recalculation in addition to verification)
- Data Usability Review: determining whether the quality of the data produced meets the intended use of the data

Is Manual Review Effective?



- With manual resources, how much data is actually reviewed?
- What is the cost?
- What is the time required to determine usability?

"Data validation has been used to detect fraud, but it should be noted that the nature of fraudulent reporting is to make hard copy data packages appear compliant and, therefore, data manipulation in most cases will not be detected by this tool."

*1997, California Military Environmental Coordination Committee
in association with Chemical Data Quality/Cost Reduction Process Action Team*

Staged Electronic Data Deliverable (SEDD)



- Non-proprietary standard (XML)
- Portable
- Long-term storage
- Agency and program neutral

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SEDD Benefits

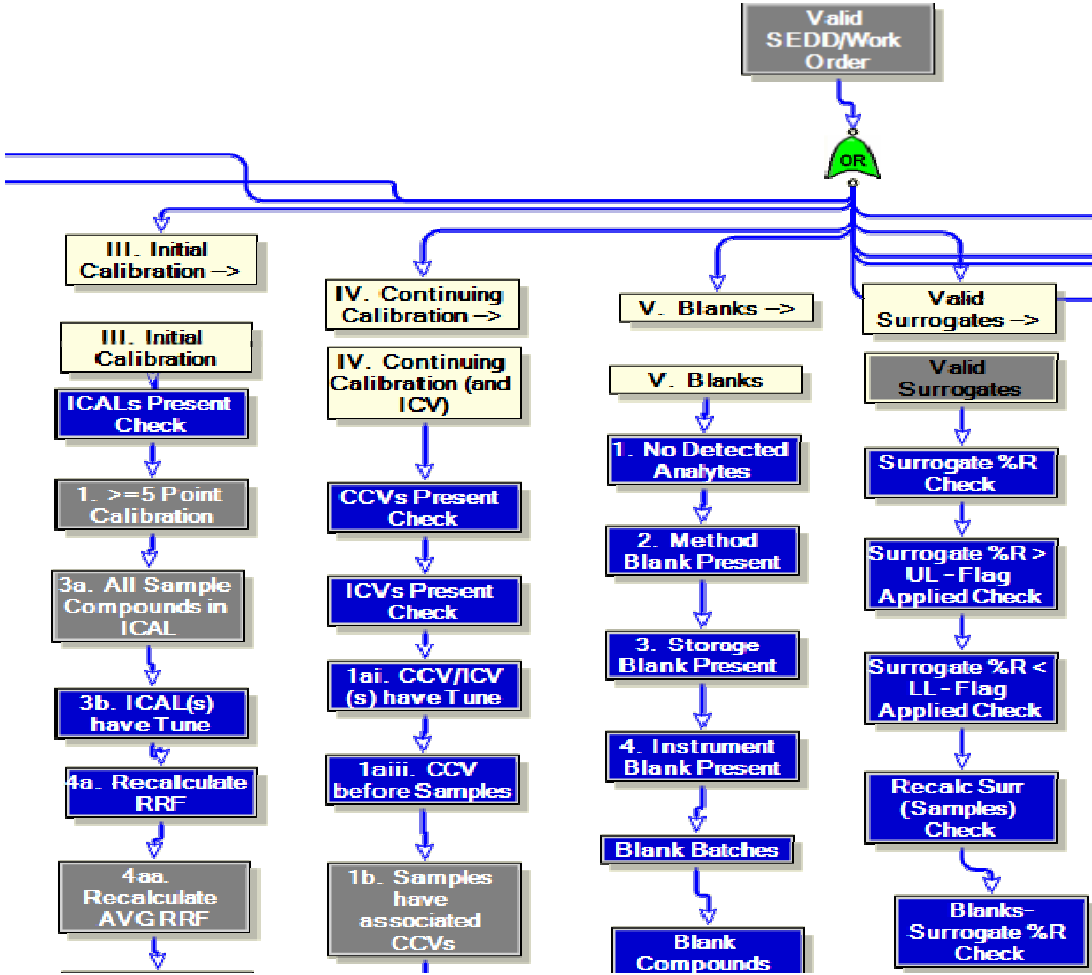


- Complete raw analytical data
- Enables full recalculation
- Standardized data sharing and delivery
- All databases can be populated with SEDD
- Automate data verification/validation

“Use of electronic data deliverables and electronic data validation, wherever possible, will promote objectivity, substantially reduce costs, and facilitate data exchange.”

*1997, California Military Environmental Coordination Committee
in association with Chemical Data Quality/Cost Reduction Process Action Team*

Software



Example Rules



- Manual integrations?
 - Standards?
 - Samples?
 - Check compounds?
- Multiple analysis of standards?
 - Tune checks?
 - Initial calibrations?
 - Ongoing calibration checks?
- Initial calibration after sample analysis?
- Aborted run time?
- Clock-time discrepancy?
- Removal of a detection or negative proof present?

Laboratory Validation

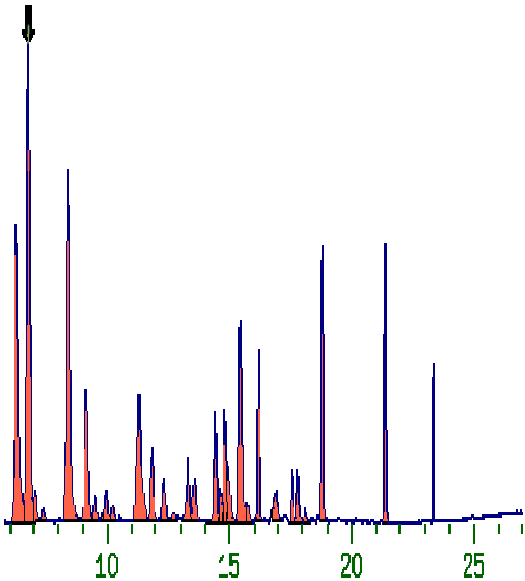


- 100% Automated Data Review
- Bench level
- Errors are corrected before SDG is released
- Eliminates **95%** of manual review time
- Integrates within laboratory processes

Does it Work?



- Vapor Intrusion Investigation
 - Inside homes
 - >6000 TO-15 analyses, 800 SDGs
 - Laboratory performed automated validation
 - Client performed full manual Level IV review for all SDGs



Comparison	Manual	Computer
Hours	2400	27
Cost	\$70,000	electricity
Result	<i>No Findings</i>	<i>No Findings</i>

Reality of Manual Review



- It's a feel good thing
 - Expensive
 - Perceived value
 - Minimal benefit

Roadblocks



- “I’ll lose my job” – *Data Validator*
- “Labs can’t do Stage 3, don’t ask” – *EPA*
- “You need human judgment” – *Project Chemist*
- “I like it the way it is” – *Varied*
- “We’ve tried before, it never worked” – *Consulting Firms*
- “It reduces billable hours” - *Consulting Firms*

Required Change



- Laboratories must innovate
 - Embrace SEDD
- SEDD must become the standard
 - Remove reliance on proprietary EDDs
- Improve efficiency of data flow
 - Upgrade Data Systems
- Focus on usability
 - Automate verification/validation

Future Benefits



- Enhanced confidence in data usability
- Consistent sharing of data
- Continued automation
- Mutual benefit to all parties
- Rapid decision making

Contact Information



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