Automated Audit Software for Streamlining On-site Laboratory Audits and Monitoring Laboratory Performance

Richard M. Amano, Principal Chemist
Tim Fitzpatrick, Senior Scientist
Laboratory Data Consultants, Inc.
7750 El Camino Real, Ste 2L
Carlsbad, CA 92009

Introduction

- Laboratory audits are routinely conducted by the regulatory community and commercial entities to assure data of known quality can be generated using acceptable procedures and adequate QA systems
- Three common issues:
  - High effort/cost of doing on-site audits
  - Inconsistent audits and documentation of findings
  - Inadequate tracking of past audits, PEs, correspondence, and corrective action

Development Process

- Identified the need to improve the audit process
- Reviewed current issues with the auditing process
- Determined what processes handled manually now could be effectively integrated with some automation
- Used the NELAP documents and checklists as a starting point
- Focused on audit consistency, electronic retrieval of technical audit references, and improve assessor efficiency

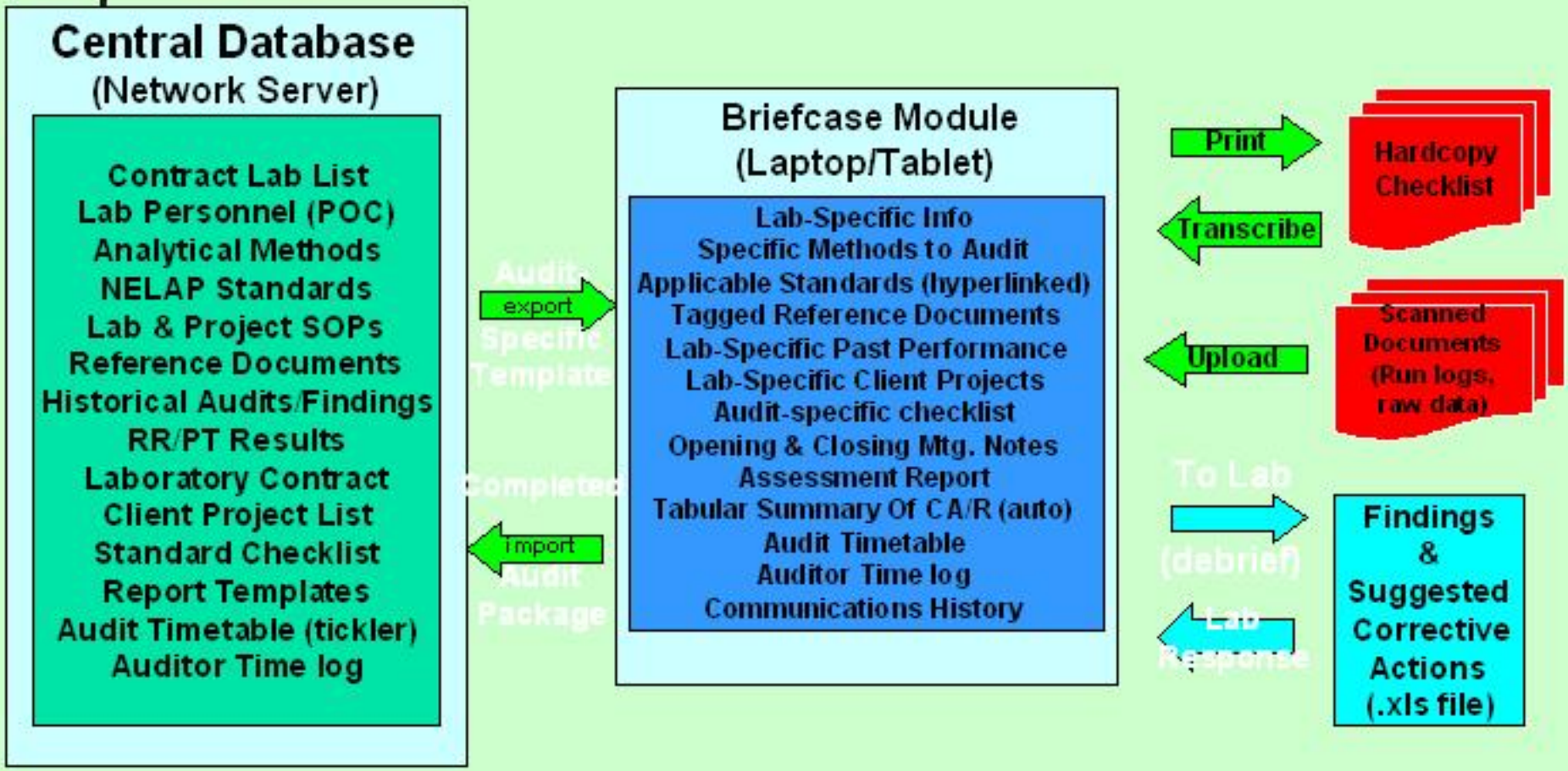
Product

- Built on a Microsoft ACCESS platform
- Developed for Internal and External Laboratory audits
- Uses NELAP-type checklist which can be customized
- Ability to reference and retrieve past documents such as past audits, PE results, NELAP audits, and hyperlinks to technical references
- Generates final audit report
- Provides centralized storage of audit records

Primary Components

- Central Audit Database
- Briefcase Module

Audit Process Overview



Central Database

- Contract lab list
- Audit/Lab Personnel
- Analytical methods
- NELAP standards (i.e., checklists)
- QAPPs/Lab SOPs
- Reference documents (i.e., DOD QSM, AFCEE QAPP, Navy IR, etc)
- Historical audits/findings
- PE/Round-robin results
- Report templates
- Audit schedule (e-mail ticklers)
- Audit time log

Summary

- Standardization of the audit process and audit reporting through automation
- Use of NELAP and other agency or project specific checklists and requirements
- Centralized storage of audit records for review by the audit team
- Allows for improved tracking of past deficiencies, PE results, and corrective action
- Real time retrieval of audit reference documents with hyperlinks
- Generation of clear, concise, and technically sound reports for the laboratory and data users
- Reduced time and effort with expedited reporting

Briefcase Module

- Specific methods for audit
- Hyperlink to reference documents
- Past PE/round-robin results
- Project specific questions
- Audit specific checklist
- Opening/closing meeting notes
- Audit report
- Tabular summary of findings (automated in Excel format)
- Audit schedule
- Audit time log
- Communication history
- Audit specific e-documents

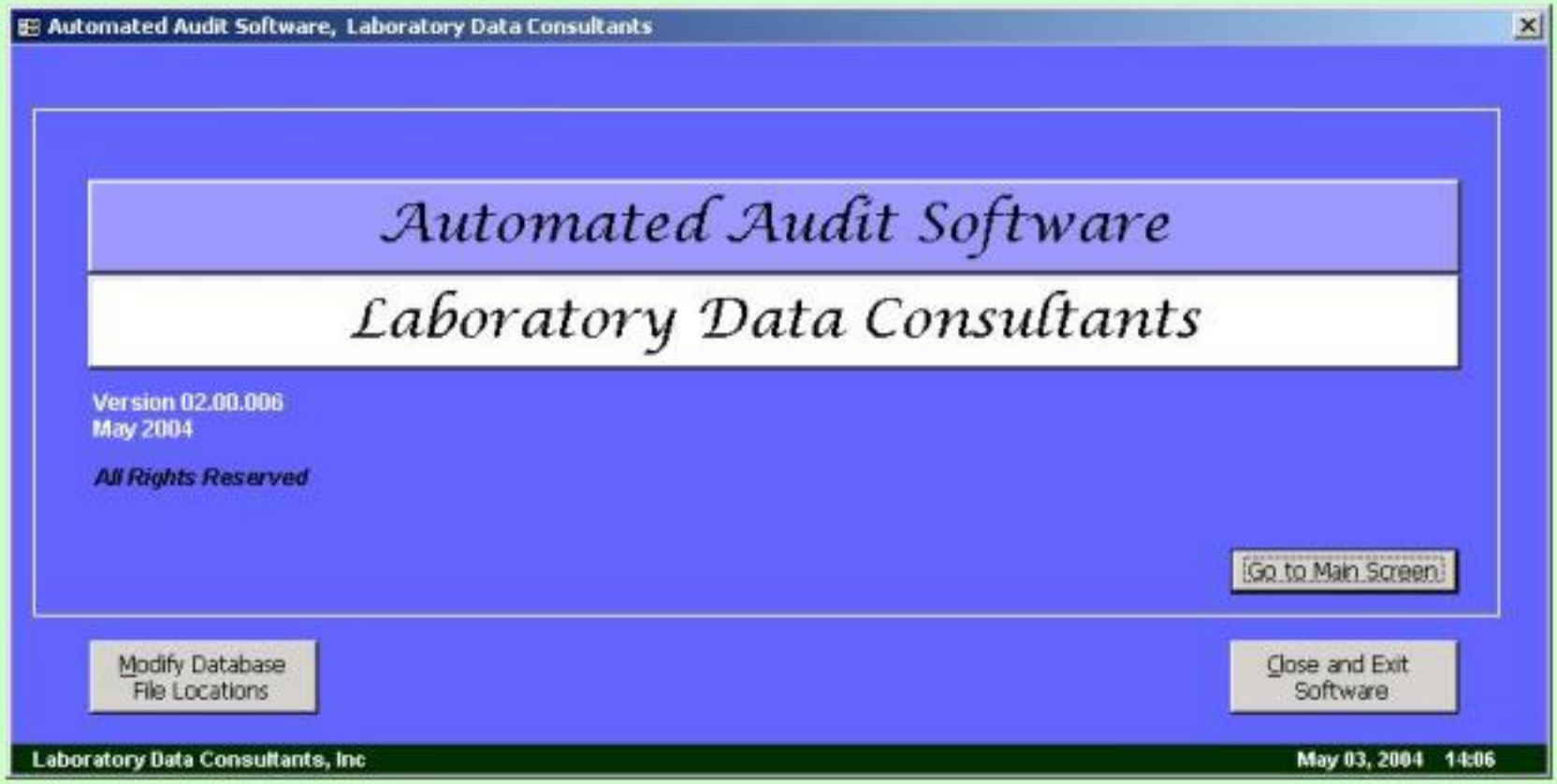
Contacts

- Laboratory Data Consultants, Inc.

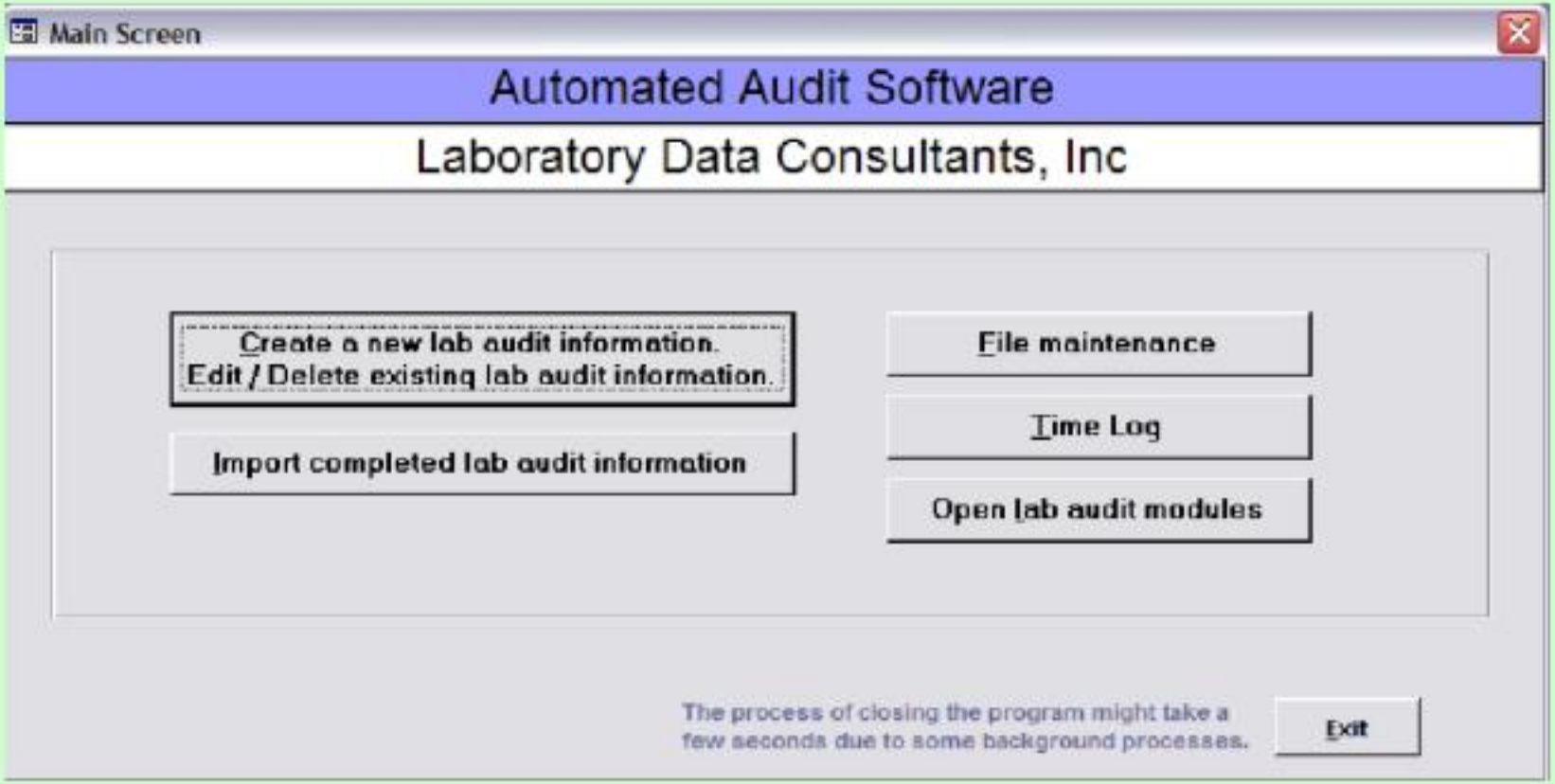
Richard Amano: ramano@lab-data.com, 760-634-0437

Tim Fitzpatrick: tfitzpatrick@lab-data.com, 760-634-0437

AAS Software



AAS Opening Screen



Lab List

Create New Field Audit

EDIT existing lab audit

Tim Test 01 — Test Audit for Demo Day
E31640 — FL DEP - Satellite Lab

Step 3. Highlight a laboratory to audit.

E87412	Columbia Analytical Services - Kelso WA	Kelso	WA
E82502	Columbia Analytical Services, Inc. - FL	Jacksonville	FL
E83330	DB Environmental Laboratories, Inc.	Rockledge	FL
E83079	ELAB, Inc.	Ormond Beach	FL
E86048	Everglades Laboratories, Inc.	West Palm Beach	FL
E31780	FL DEP - Central Laboratory	Tallahassee	FL
E31640	FL DEP - Satellite Lab	Tallahassee	FL
E87575	Frontier Geosciences, Inc.	Seattle	WA
E45049	Lee County Environmental Laboratory	Fort Meyers	FL
E56731	Metro Dade Environmental Resources Management	Miami	FL
E43155	Orange County Environmental Protection Division - Laborat	Orlando	FL
E43639	Orange County Environmental Protection Division - Laborat	Orlando	FL
E82001	PPB Environmental Laboratories, Inc.	Gainsville	FL
E86006	Spectrum Laboratories, Inc. - FL	Ft. Lauderdale	FL
E42206	St. Johns River Water Management District	Miami	FL
TBD	To Be Determined		
TVA001	TVA Environmental Chemistry Laboratory	Chattanooga	TN
E63507	U.S. Geological Survey, WRD, OWQRL	Ocala	FL
E86240	US Biosystems, Inc.	Boca Raton	FL
VCL001	Vizcaya Chemical Laboratories, Inc.	Miami	FL
E86678	XENCO Laboratories - Miami	Miami Lakes	FL

Add new laboratory | View / Edit laboratory information

Close | < Back | Next > | Time Log | Open Checklist

Audit Schedule/Tracking

Create New Field Audit

EDIT existing lab audit

Tim Test 01 — Test Audit for Demo Day
E31640 — FL DEP - Satellite Lab

Step 4. Enter audit schedule information

Lab ID: E31640 — Lab Name: FL DEP - Satellite Lab

Date of Last Audit: 01/22/2003 (mm/dd/yyyy)
Date of Next Audit*: 01/15/2004
* Date of Last Audit + 12 months

Date Lab was Notified: 12/05/2003
Method of Notification: phone call and email
Person Notified: Tim Fitzpatrick
Title of Person Notified: Head Honcho

Date of On-Site Visit: 01/15/2004
Date Audit Report Sent to Lab: 01/15/2004
Date Lab Response Due: 02/11/2004 — Date Audit Report Sent to Lab + 30 days. Auto filled-in only if blank
Date Lab Response Received: 02/15/2004
Date Evaluation of Response Due: 02/22/2004 — Date Lab Response Received + 7 days. Auto filled-in only if blank
Date Evaluation of Response Sent: 02/25/2004
Date of Lab Response to Evaluation: 03/05/2004
Date of Followup Audit: 04/01/2004
Comments: just a test for Time Test 01

Close | < Back | Next > | Time Log | Open Checklist

Past Audits

Create New Field Audit

EDIT existing lab audit

Tim Test 01 — Test Audit for Demo Day
E31640 — FL DEP - Satellite Lab

Step 5. Build audit content

FDOH Historical Audits | SFWMD Historical | Internal Audit | RR / PT Results
Analytical Methods | Prep Types | Projects | Miscellaneous

SFWMD Historical Audits

Click to View Document	Tag	Lab ID	Lab Name	Document ID	Doc Date	Document Description
SFWMD Audits	☑	E31640	FL DEP - Satellite Lab	Audit-05-14-2003.p	07/14/2003	
SFWMD Audits	☑	E31640	FL DEP - Satellite Lab	Audit-Reply-05-14-	05/14/2003	
SFWMD Audits	☐	E31640	FL DEP - Satellite Lab	Audit-Resp-05-14-;	08/26/2003	

Past PE/Round Robin Studies

Create New Field Audit

EDIT existing lab audit

Tim Test 01 — Test Audit for Demo Day
E31640 — FL DEP - Satellite Lab

Step 5. Build audit content

FDOH Historical Audits | SFWMD Historical Audits | Internal Audit | RR / PT Results
Analytical Methods | Prep Types | Projects | Miscellaneous

RR / PT Results ,

Click to View Document	Tag	Lab ID	Lab Name	Document ID	Doc Date	Document Description
RR-PTE31640	☑	E31640	FL DEP - Satellite Lab	DEP-RTC-2002.pdf	07/25/2003	
RR-PTE31640	☐	E31640	FL DEP - Satellite Lab	DEP-USGS-2002.pc	07/18/2002	
RR-PTE31640	☑	E31640	FL DEP - Satellite Lab	DEPWP-92-96-RTC.	11/14/2002	

Audit Checklist

Audit Worksheet

Lab Audit Worksheet - IV. Analytical Method

I / II Laboratory and Sample | III. Gen Info, A to C | III. Gen Info, D to I | IV. Analytical Method | V. Sample Preparation | VI. Supplemental for Hg and Meltg

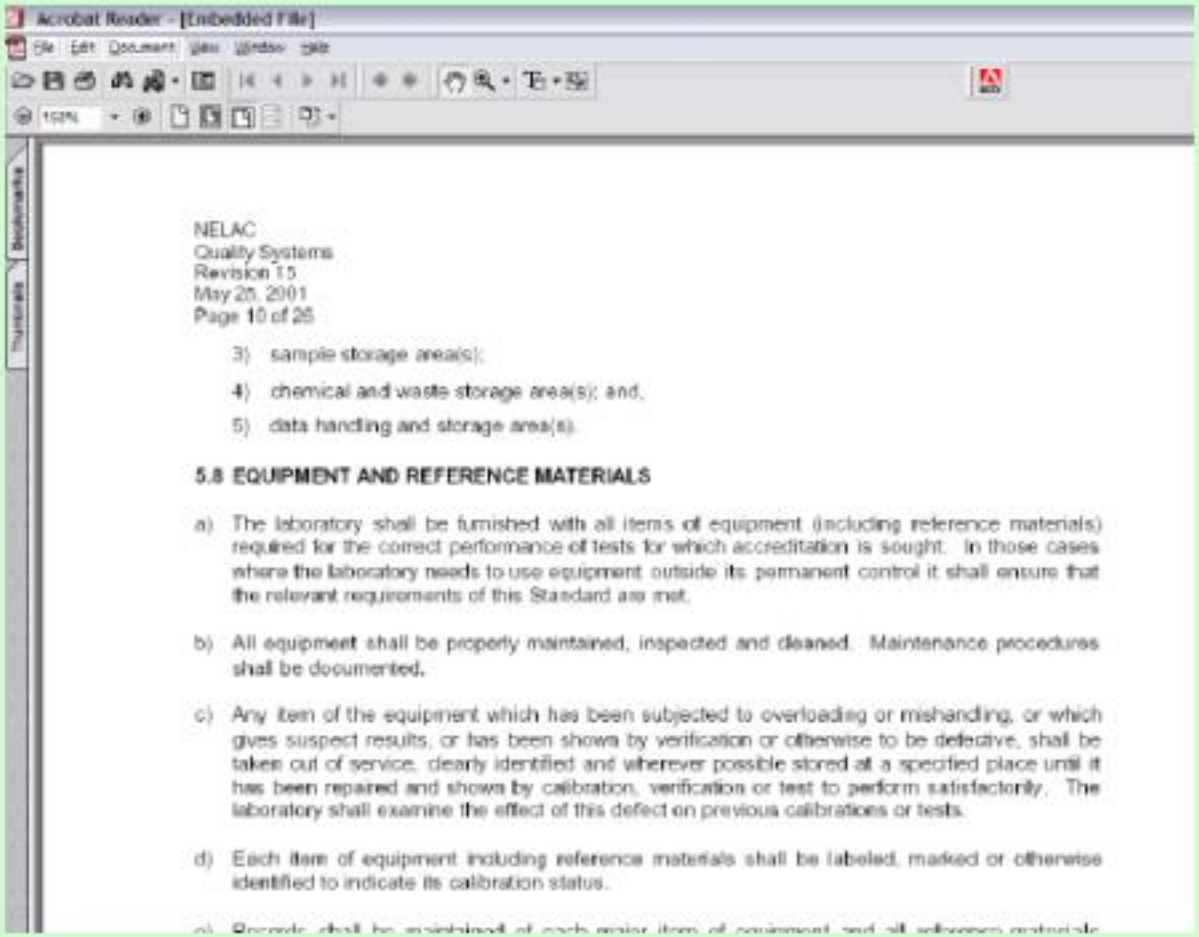
Additional Questions | VII. FDOH | VIII. SFWMD | IX. RR / PT | X. Internal Audits | XI. Miscellaneous

IV. Analytical Method Worksheet

FILTER Analytical Method EPA 200.7 (Use * as a wild card character)

Method			Applicable STD	Link to Docs	Compliance	Findings / Observations
EPA 200.7	1.	What make and model of instrumentation is used for the analysis?	5.8 (a)	.\ReferenceFiles\5-8.pdf	CA	Perkin-Elmer ICP is in poor working order, is not acceptable for routine analysis.
EPA 200.7	2.	Which analytical method was used to analyze the samples?	WMD Contract			EPA 200.7
EPA 200.7	3.	Is this a method specified in the lab contract?	WMD Contract			Yes
EPA 200.7	4.	Did the reported MDL comply with contract specifications?	WMD Contract			Yes
EPA 200.7			5.9.4.2.1 (h)	.\ReferenceFiles\5-9-4-2.pdf		
EPA 200.7	5.	Does the lab have SOPs for all methods being reviewed?	5.10.1.1	.\ReferenceFiles\5-10-1-1.pdf		Yes
EPA 200.7	6.	Are the SOPs readily accessible?	5.10.1.1 (c)	.\ReferenceFiles\5-10-1-1.pdf		Yes

Specific PDF Hyperlink



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NELAC
Quality Systems
Revision 15
May 25, 2001
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3) sample storage area(s);

4) chemical and waste storage area(s); and,

5) data handling and storage area(s).

5.8 EQUIPMENT AND REFERENCE MATERIALS

a) The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests for which accreditation is sought. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Standard are met.

b) All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented.

c) Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

d) Each item of equipment including reference materials shall be labeled, marked or otherwise identified to indicate its calibration status.

Audit Checklist-Print Format

Basic Audit Worksheet

I. Lab Information

Lab ID / Name : E31640 FL DEP - Satellite Lab
Date : 01/15/2004
Auditors : Teich, Larry Hernandez, Yvette Hernandez, Yvette Manzano, Juan

II. Sample Information

Project Code :
Date : Field ID : Test Project01, Test Project02

III. General Information

		Applicable Standard	Any Findings	Comments
A.	**Sample Containers and Train Decontamination and Prep**			
1.	Is decontamination procedure acceptable?	FC1000	CA	Sample containers are washed in DI water. Does not comply with FC1000 procedure.
2.	Is sample equipment storage procedure acceptable?	FC1000		procedure is acceptable
3.	Is there an existing QC check on bottles and sampling equipment?	N/A		Yes
4.	Are containers and preservatives kept separate?	IMD Contract		Yes
B.	**Sample Handling**			
1.	Is log-in procedure adequate?			Yes
2.	Is COC adequate?	5.11.3 (d)		Yes
3.	When were samples submitted to lab?	Project Validation		Samples submitted 8/12/2003
4.	When were samples logged into LIMS?	Project Validation		Logged 8/12/2003
5.	Check sample COC for completeness and accuracy	Project Validation		No discrepancies
6.	Do LIMS #s match the corresponding field #s?	Project Validation		Yes
7.	What % of samples is lost due to defective containers?	Project Validation		5%
8.	What % of samples is lost due to misidentification?	Project Validation		<1%
9.	Was storage refrigerator temperature monitored daily?	5.11.4 (e)	CA	Sample refrigerator monitoring is sporadic
10.	Were contents of coolers verified vs COC?	IMD Contract		Yes
11.	Was sample temperature checked upon receipt?	5.11.2 (e)(1)		Yes, with spec

Additional Audit Questions

Audit Worksheet

Lab Audit Worksheet – VII. FDOH

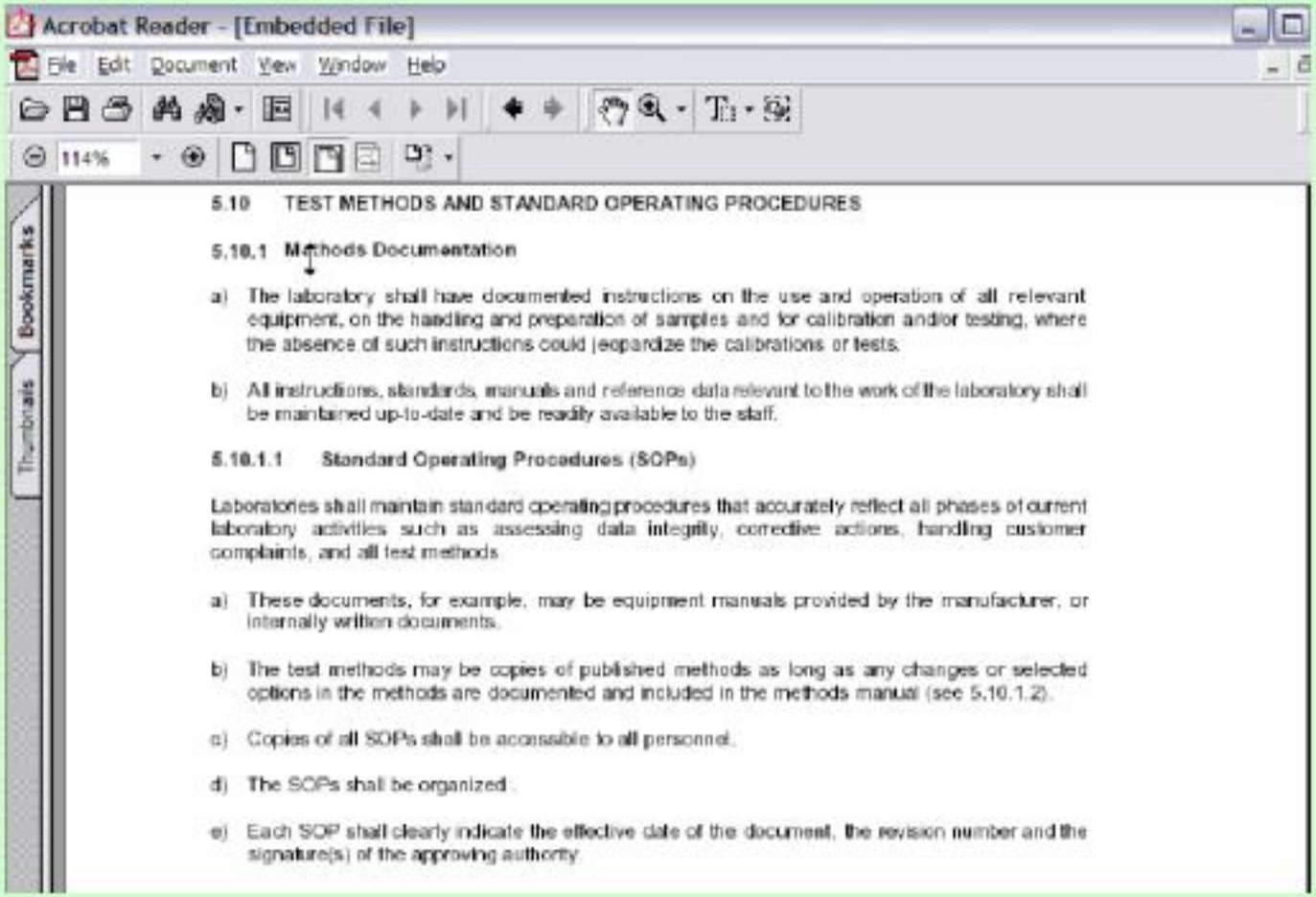
I / II Laboratory and Sample | III. Gen Info, A to C | III. Gen Info, D to I | IV. Analytical Method | V. Sample Preparation | VI. Supplemental for Hg and MeHg

Additional Questions | VII. FDOH | VIII. SFWMD | IX. RR / PT | X. Internal Audits | XI. Miscellaneous

VII. FDOH Historical Audit Additional Questions

		Applicable STD	Link to Docs	Compliance	Findings / Observations
1	Did the lab resolve the matter of Hg contamination monitoring?	5.10.1.1	.\ReferenceFiles\5-10-1-1.pdf	CA	Persistent Hg contamination problem not aqequately addressed, needs immediate attention

Specific PDF Hyperlink



5.10 TEST METHODS AND STANDARD OPERATING PROCEDURES

5.10.1 Methods Documentation

a) The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of samples and for calibration and/or testing, where the absence of such instructions could jeopardize the calibrations or tests.

b) All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

5.10.1.1 Standard Operating Procedures (SOPs)

Laboratories shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities such as assessing data integrity, corrective actions, handling customer complaints, and all test methods.

a) These documents, for example, may be equipment manuals provided by the manufacturer, or internally written documents.

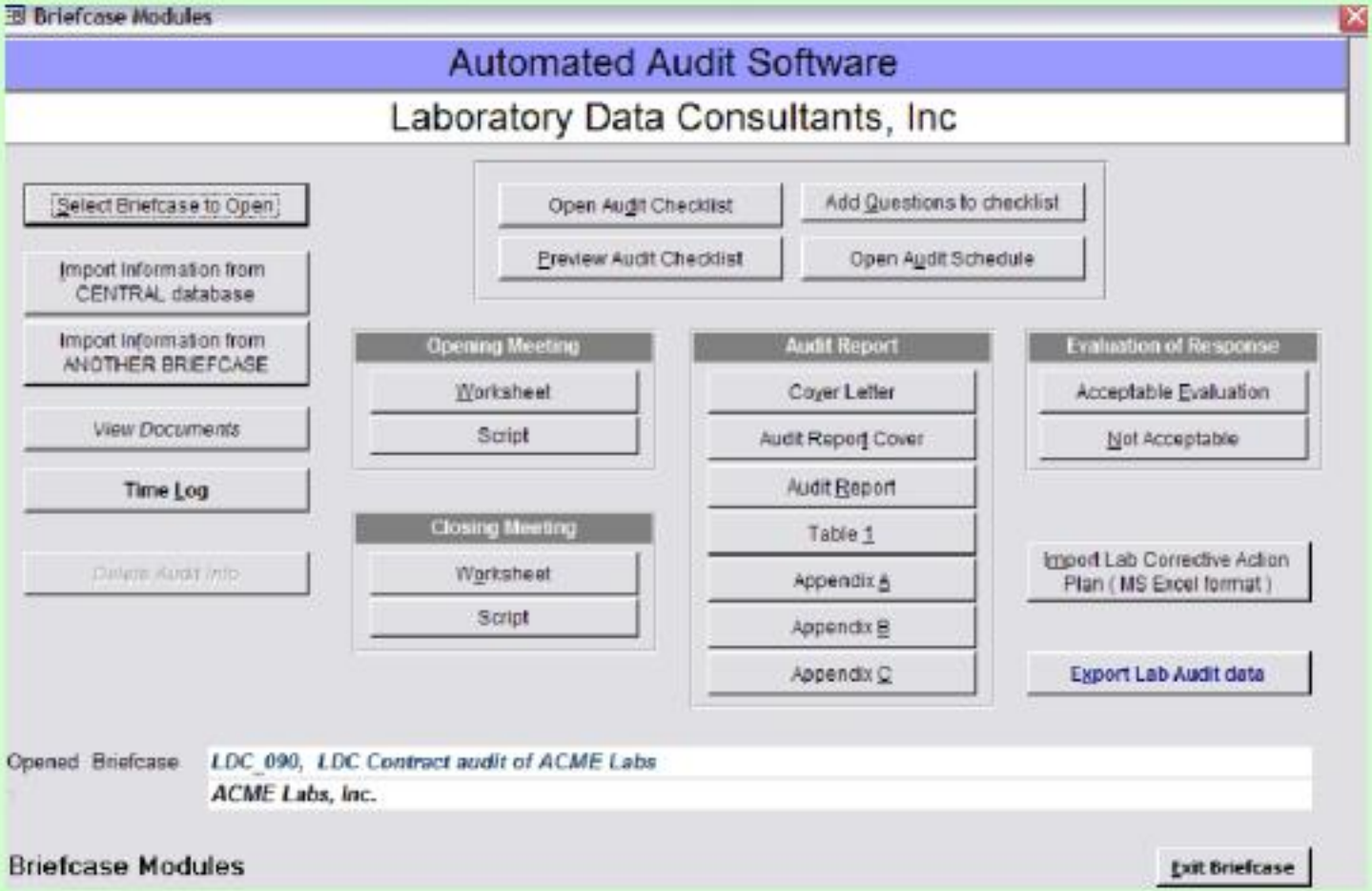
b) The test methods may be copies of published methods as long as any changes or selected options in the methods are documented and included in the methods manual (see 5.10.1.2).

c) Copies of all SOPs shall be accessible to all personnel.

d) The SOPs shall be organized.

e) Each SOP shall clearly indicate the effective date of the document, the revision number and the signature(s) of the approving authority.

Briefcase Module



Audit Report Template

Assessment Report

Assessment Report

1.0 Introduction

FL DEP - Satellite Lab currently provides Analytical Testing and Sampling Servic for the South Florida Water Management District (District) under contract C5131. The following District projects were audited:

Test Project01, Test Project02. Water Quality parameters audited include: EPA 200.7, EPA 245.1, EPA 353.2 (Nitrate (N)), EPA 353.2 (Nitrate-Nitrite (N)), EPA 353.2 (Nitrate-Nitrite (N))-unpreserved, EPA 353.2 (Nitrite (N)), EPA 365.1 (Orthophosphate), EPA 365.1

The District last audited the laboratory on 1/22/2003. The audit process includes four primary phases: 1) Review of laboratory preliminary documentation; 2) Proficiency Testing (PT) and previous audit findings review; 3) On-site audit; and 4) Corrective action.

2.0 General Information

The audit was conducted by the District as part of the on-going contract between the District and FL DEP - Satellite Lab. Larry Teich, Yvette Hernandez were the assigned auditors for the District. Larry Teichserved as lead auditor. The audit was structured as a general evaluation of laboratory capabilities to support District projects and to assess laboratory compliance with District contract requirements, NELAC standards and the laboratory's own QA manual and SOPs.

FL DEP - Satellite Lab occupies 0 building(s), totaling 45000 SQ FT. The laboratory currently operates with approximately full and part-time personnel, which includes approximately 0 technical staff.

3.0 Laboratory Preliminary Documentation Review

A review of laboratory supplied documentation was conducted prior to the onsite audit and as part of the on-site audit. Documentation included the laboratory's quality assurance (QA) manual, selected standard operating procedures (SOPs), list of major analytical instrumentation, historical proficiency testing and round-robin (PT/RR) information for the past year and historical findings from previous FDOH and SFWMD audits. Deficiencies remaining open from the initial document review are found in Table 1 as referenced in Section 6.0 of this report.

3.1 QA Manual and SOPs

The laboratory QA manual was reviewed for compliance with NELAC standards for Quality systems. Lab SOPs were reviewed for compliance with methodology requirements and overall technical merit. Any non-conformances are documented as findings in Table 1.

Audit Findings

Table 1

Table 1

Finding No.	Findings / Observations	Comp-liance	Rule	Checklist Section	District Suggested Corrective Action	Laboratory Proposal Corrective Action Plan	Accep-ted ?
1	Sample containers are washed in DI water. Does not comply with FC1000 procedure.	CA	FC1000	III. A.			☐
2	Sample refrigerator monitoring is sporadic	CA	5.11.4 (a)	III. B.			☐
3	QA manual is 3 years old, needs to be updated	CA	5.5.1 (e)	III. C.			☐
4	MDL generation is spotty, should be done yearly	R	5.5.4 (a)(4)	III. C.			☐
5	No, recommend more training for analysts on equipment.	R	5.6.2 (c)(2)	III. C.			☐

Audit Closure Letter Template

Acceptable Evaluation

(Template Response Letter when all responses are Acceptable)

2051 E. Paul Dirac Dr.

Tallahassee FL 32310

Subject: Audit Response Evaluation

We have received your response dated regarding the District's report for a laboratory audit conducted on 01/20/2003 - 01/22/2004 . Your response to all deficiencies is satisfactory.

Staff from our QA unit will be visiting your again in to verify that corrective actions have been implemented.

Please do not hesitate to contact (lead auditor's name) Larry Teich lteich@sfwmd.gov or my supervisor, Della Ivanoff divanoff@sfwmd.gov if you want further clarification about the audit. Please copy (contract manager's name and email) in every communication you send to us.

Thank you.

Sincerely,