

# QC Program/QCS Update to Lab Advisory Committee

Steven Sievert and Jay Mattison  
Quality Certification Services, Inc.  
Minneapolis, MN  
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## Topics to highlight

1. **Changes in Guidelines approved in April**
  - Certification status and audit definitions
  - Service Provider responsibilities
2. **Changes in audit schedule**
3. **Updated features on Samples Unknown Certification Report**
4. **Updates to QCS website**



## Changes in Auditing Guidelines

- **Approved by Audit Review Committee**
- **Approved CDCB in April 2007**
- **Effective May 1, 2007**
  - **Definition of Certification Status**
  - **Definition of Audit Type**
  - **Notification Requirement**
  - **Publishing of Certification Status**



## Certification Status Definitions



## Certification Status Definitions

- **Certified**

A “certified” provider is one that in compliance with the CDCB guidelines and the Uniform Operating Procedures (UOP) for its service area.

- Provisional
- Conditional
- Decertified
- In Review



## Certification Status Definitions

- Certified

- **Provisional**

A provider is not in compliance with one or more aspects of the CDCB guidelines and/or the UOP will be deemed as “provisional.” Upon coming into compliance and review by the auditor, the provider may be:

- restored to full certification,
- designated conditional until an audit is conducted,
- designated provisional for an addition period of review, or
- decertified.

- Conditional
- Decertified
- In Review



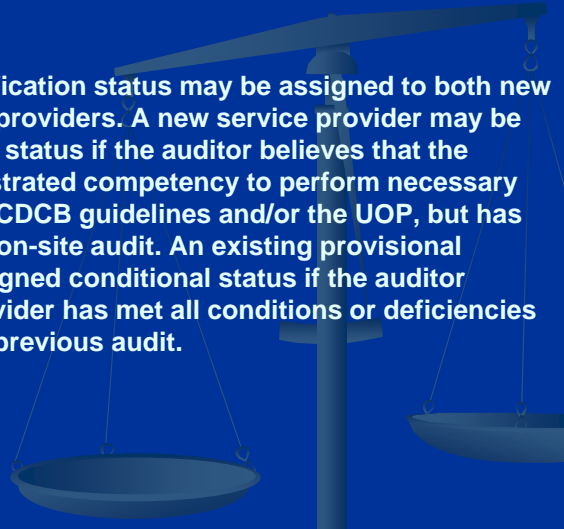
## Certification Status Definitions

- Certified
- Provisional

- **Conditional**

A “conditional” certification status may be assigned to both new and existing service providers. A new service provider may be assigned conditional status if the auditor believes that the provider has demonstrated competency to perform necessary procedures meeting CDCB guidelines and/or the UOP, but has not undergone a full on-site audit. An existing provisional provider may be assigned conditional status if the auditor believes that the provider has met all conditions or deficiencies outlined as part of a previous audit.

- Decertified
- In Review



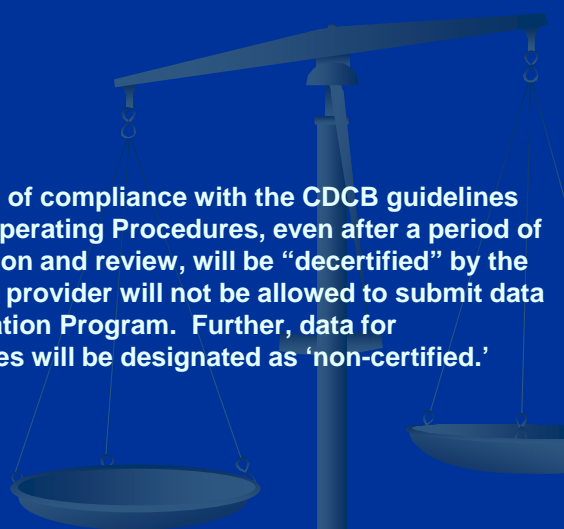
## Certification Status Definitions

- Certified
- Provisional
- Conditional

- **Decertified**

A provider that is out of compliance with the CDCB guidelines and/or the Uniform Operating Procedures, even after a period of provisional certification and review, will be “decertified” by the auditor. A decertified provider will not be allowed to submit data to the Genetic Evaluation Program. Further, data for management purposes will be designated as ‘non-certified.’

- In Review



## Certification Status Definitions

- Certified
- Provisional
- Conditional
- Decertified

### In Review

A provider may be listed as 'in review' on the website. This is not an official certification status, but simply a temporary designation used while the audit is being conducted and data evaluated. During this review period, the auditor may request additional documentation from the provider. The length of the review process is not an indicator of certification status and should not be construed as such.



## Audit Definitions



## Audit Definitions

- Off-Site
- On-Site
  - **Mandatory**
    - Regularly scheduled audit conducted during the centering month
  - Discretionary



## Audit Definitions

- Off-Site
- On-Site
  - Mandatory
  - **Discretionary**
    - Deemed necessary by either the auditor or provider when:
      1. Changes in facilities, equipment, or staffing have occurred,
      2. Certain aspects of the provider's performance are out of compliance with CDCB guidelines and/or the UOP,
      3. Provider wishes to attain full certification from a conditional status,
      4. Provider wishes to regain full certification from a provisional status, or
      5. Provider wishes to regain provisional certification from a decertified status



## Service Provider Responsibilities

- Approved by Audit Review Committee and CDCB in April 2007

### Service Provider Responsibilities

- To notify the auditor of changes in ownership, location address, billing address, list of customers and/or affiliates, equipment or meter technicians within 30 days.
- To pay the fees charged by the auditing organization prior to issuance of certification. For those providers certified biennially, but billed in annual installments, certification will be issued on an annual basis with a renewal on receipt of the second installment payment.



## On-Site Audit Schedule



## New On-Site Lab Audit Schedule

- Old Audit Schedule was unbalanced
  - 29 labs in even years, 18 in odd years
- QCS management met with auditor in April and created a balanced schedule
  - 24 in even years, 22 in odd years
  - Two labs consolidated into one this year
- Schedule is available on-line at [www.quality-certification.com](http://www.quality-certification.com)



## Samples Unknown Website Changes





## Additions to Samples Unknown Certification Report

- QCS and auditor worked together to identify charts that would be useful to lab personnel – the result...
  - *Ability to record instrument history*
  - *Reports now have historical instrument data charted*
  - *Comparison charts with individual lab compared to all labs each month*
  - *Will be adding MUN results in near future*



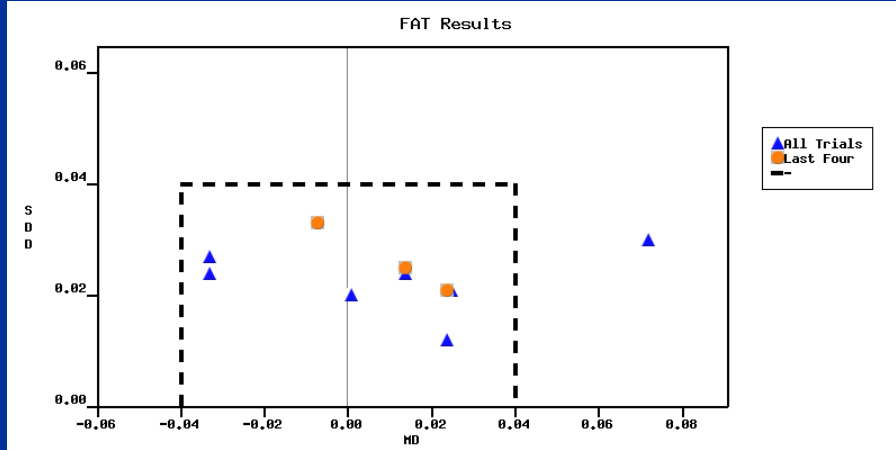
## Instrument History Function

- Lab can enter general notes and instrument maintenance history monthly when entering results from unknown samples

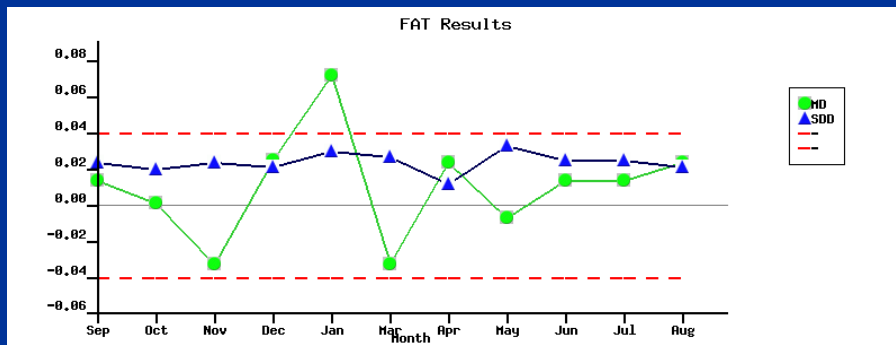
Station 3 bentley 2000				Machine History
Month	FAT Results			
	MD	SDD	RMD	
Sep	0.014	0.024-0.014		
Oct	0.001	0.020-0.011		
Nov	-0.033	0.024-0.006		
Dec	0.025	0.021-0.001		
Jan	0.072	0.030 0.015		Samples Arrived Frozen
Mar	-0.033	0.027 0.008		Betty was out for this run. Alternate Tech ran samples.
Apr	0.024	0.012 0.009		Batch 114 went perfect
May	-0.007	0.033 0.008		Machine Down 2 days
Jun	0.014	0.025 0.016		
Jul	0.014	0.025 0.014		
Aug	0.024	0.021 0.006		Samples 1 & 4 were spilled.



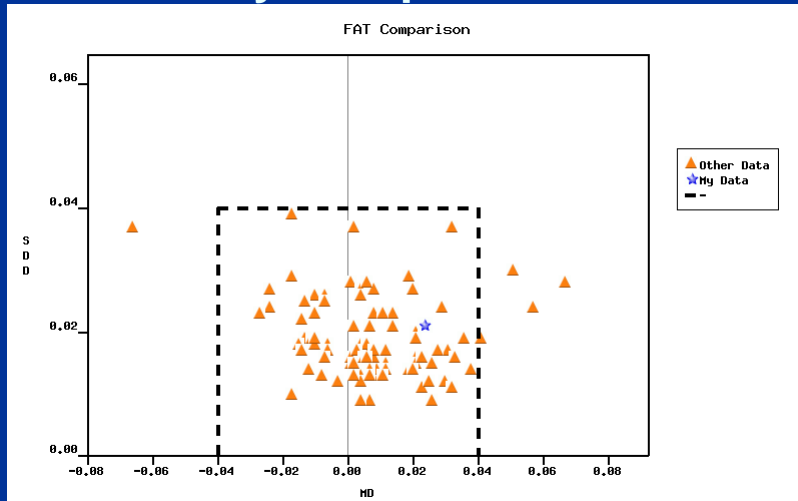
# Historical Instrument Performance



# Historical Instrument Performance



## Monthly Comparison Chart



## Improvements to QCS Website

- Updated Information for all Providers
  - Contact Information
  - Certification Status
  - Expiration Dates
- Email changes (contact numbers, email addresses, web links) to Steve ([jsievert@dhia.org](mailto:jsievert@dhia.org))
- Updated regularly when audits are complete
- Visit [www.quality-certification.com](http://www.quality-certification.com) to learn more...



**The QCS team thanks your for your  
support and cooperation**

***Steve Sievert, QC Program Manager***

***Paul Sauve, On-Site Lab Auditor***

***David Harrison, Programmer***

***Rod Knutson, Accountant***

***Jay Mattison, Administrator***

