PFT Laboratory Accreditation Readiness
Part I
“The On-site Visit”

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AARC Diagnostic Chair
Conflict of Interest

I have no real or perceived conflict of interest that relates to this presentation. Any use of brand names is not in any way meant to be an endorsement of a specific product, but to merely illustrate a point of emphasis.
Objectives

Learning objectives for this presentation:

- Describe the drivers for a quality assurance program
- Review the current accreditation models
- Define the path of workflow in performing a site visit of a PFT laboratory.
Drivers of Accreditation in Lung Function Testing

- *Spirometry in Primary Care Practice*
  - 30 primary care clinics, 15 trained group / 15 usual group
  - 3.4% in usual group and 13.5% in trained group met ATS acceptability and reproducibility criteria
  - 1,012 pt. tests, 2,928 blows (2.89)
Drivers of Accreditation in Lung Function Testing

- Improving the Quality of Bedside Spirometry
  - Audit of testing outside the PF lab - Cleveland Clinic
  - 15% - ATS acceptability/reproducibility criteria
  - CI Project - 63.5% acceptability/reproducibility
Drivers of Accreditation in Lung Function Testing

Certification of DLCO Measurements for Clinical Trials

- Results of the initial DLCO simulation tests from 125 pulmonary laboratories
  - 94 (75.2%) Passed with coaching; no hardware
  - 24 (19.2%) Failed. Passed after servicing
  - 6 (4.8%) Failed. Passed with new equipment
  - 1 (0.8%) Site dropped

Drivers of Accreditation in Lung Function Testing
Our decision to have all 16 of our centers achieve accreditation with The Joint Commission was not just a business decision, but also a commitment to achieve the highest possible quality of care for our patients.

Joann Zimmerman, R.N. M.S.
Chief Operating Officer
Surgery Center Partners
Los Altos, Calif.

Katrina Hynes MHA RRT RPFT
AARC’s Alternate representative to TJC Laboratory section
PFL Accreditation Programs

- Self-assessment questionnaire
- Submission of the application forms, along with the laboratory procedure and policy manuals
- Site visit by the accreditation assessment panel
PFL Accreditation Programs

Accreditation involves:

1. Completion of a pre-assessment data verification form;
2. An on-site assessment to:
   - assess laboratory appearance
   - observe testing procedures
   - assess quality assurance procedures and documentation
   - review manuals
   - assess equipment
   - assess laboratory safety

Pulmonary Function Testing Standards
- PFT Standards

Blood Gases
- Blood Gas Proficiency Testing

Applications
- Apply for Physician Approval
- Register a New Facility

Accredited Facilities
- Notify Us of Changes to a Facility
- List of Accredited Pulmonary Function Testing Facilities
PFL Accreditation Programs

- American Thoracic Society
  - Appointed an Expert Panel to plan and implement a US PFL accreditation.

ATS Pulmonary Function Laboratory Accreditation Program

Planning Committee Members:

David Kaminsky, MD, University of Vermont
Allan Coates, MD, Hospital for Sick Children, Toronto, Canada
Patricia Clark, RPFT, University of Washington
Bruce Culver, MD, University of Washington
Allen Dozor, MD, New York Medical College
Paul Enright, MD, University of Arizona
Carl Mottram, RRT, RPFT, FAARC, Mayo Clinic
Timothy Myers, MBA, RRT, FAARC
Margaret Rosenfeld, MD, Children’s Hospital Regional Med. Ctr, Univ. of Washington
Gregg Ruppel, MEd, RRT, RPFT, FAARC, St. Louis University
Daniel Weiner, MD, Children’s Hospital of Pittsburgh

Steven Crane, MD, ATS
Barbara Horner, ATS
ATS PFL Accreditation Program

- ATS PFL Management and Procedure Manual
  - 2016 3rd Edition
Mayo Clinic

- Mayo Clinic
- Rochester, MN
- Arizona
- Florida
- Mayo Clinic Health System (60 communities)
Mayo Clinic’s PFL Quality Assurance Program

Strategic Goals

- Unnecessary repeat testing due to lack of training, education, and undefined expectations
- Variability in equipment used and testing methodology
- Awareness of national recommendations and guidelines for quality outcomes
- Quality metrics and integrative practices for pulmonary function testing across the enterprise
Mayo Clinic’s PFL
Quality Assurance Program

Program Components

- On-site inspection
- BioQC program review
- Mechanical model demos
- Reporting process
Mayo Clinic’s PFL Quality Assurance Program

- On-site inspection
Mayo Clinic’s PFL Quality Assurance Program

- Onsite inspections were conducted by Mr. Mottram and Ms. Hynes
  - Checklist – Modeled after ATS accreditation
Quality Management Systems in the Pulmonary Function Laboratories

- Clinical and Laboratory Standards Institute “Quality Systems and Laboratory Practice Committee”
  - Professionals
  - Government – FDA, CDC, CMS
  - Industry
Quality Management Systems in the PFL

CLSI’s “Path of workflow” Model
Mayo Clinic’s PFL Quality Assurance Program

- Pre-test
  - Pre-test instructions
  - Questionnaire
- Height* and weight
- Personnel competency
- Equipment quality assurance program
Mayo Clinic’s PFL Quality Assurance Program

Personnel (corresponding to Ch. 2 ATS Manual)

<table>
<thead>
<tr>
<th>Personnel Information</th>
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<tbody>
<tr>
<td><strong>Employee Position/Title</strong></td>
<td><strong>Employee Name:</strong></td>
</tr>
<tr>
<td>Medical Director</td>
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<tr>
<td>Technical Director/Manager</td>
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<tr>
<td>Lead Technologist</td>
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<tr>
<td>Additional Personnel</td>
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<td>Additional Personnel</td>
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</table>

(Online version of this form will allow for accruing lines of information)

Technologist Training and Continuing Education

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<thead>
<tr>
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<th>No</th>
<th>Comments/Actions</th>
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<tbody>
<tr>
<td>✗</td>
<td></td>
<td>Orientation to Lab</td>
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<tr>
<td>✗</td>
<td></td>
<td>Competency Assessment</td>
</tr>
<tr>
<td>✗</td>
<td></td>
<td>Periodic Review</td>
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<tr>
<td>✗</td>
<td></td>
<td>Continuing Education</td>
</tr>
</tbody>
</table>

* indicates required activities.
Mayo Clinic’s PFL Quality Assurance Program

- Educational/training requirement
- Basic requirement: Completion NIOSH spirometry course
- CRT/RRT with 6 months PFT experience
- CPFT/RPFT
Mayo Clinic’s PFL Quality Assurance Program

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Brand</th>
<th>Model/Serial Number</th>
<th>Software Version</th>
<th>Purchase Year</th>
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<tr>
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List all of the laboratory’s PFT equipment, including all measuring devices, e.g., stadiometers.
Mayo Clinic’s PFL Quality Assurance Program

### Quality Control (corresponding to Ch. 5 ATS Manual)

<table>
<thead>
<tr>
<th>Instrument Maintenance</th>
<th>Comments/Actions</th>
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<tbody>
<tr>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
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<tr>
<td>Preventive maintenance (PM) schedule available*</td>
<td></td>
</tr>
<tr>
<td>Corrective maintenance records*</td>
<td></td>
</tr>
<tr>
<td>Corrective actions taken recorded*</td>
<td></td>
</tr>
<tr>
<td>New instrument validation and verification process available and documentation available for each new instrument*</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Installation Manual</th>
<th>Comments/Actions</th>
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<tr>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
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<tr>
<td>New equipment installation manual available*</td>
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<tr>
<td>Vendor/purchase contract maintained*</td>
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<tr>
<td>Equipment installation records available</td>
<td></td>
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<tr>
<td>Instrument calibration data available from manufacturer*</td>
<td></td>
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<tr>
<td>Instrument calibration data available from user*</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Measurement Precision &amp; Linearity</th>
<th>Comments/Actions</th>
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<tr>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
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<tr>
<td>Spirometry linearity testing*</td>
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</tr>
<tr>
<td>Precision established for each pulmonary function test performed (e.g., spirometry, DLCO, lung volumes)*</td>
<td></td>
</tr>
<tr>
<td>Precision established for mechanics controls (known-volume syringe, isothermal bottle)*</td>
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<tr>
<td>Precision established for biologic controls*</td>
<td></td>
</tr>
<tr>
<td>Accuracy established for each bio procedure* Please specify frequency: Bin Go, Spirometry, Lung Volumes, Gas analysis certificates available*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calibration of Calibrators</th>
<th>Comments/Actions</th>
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<tbody>
<tr>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
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<tr>
<td>Calibration syringe validation available (minimally every 2 years)*</td>
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<tr>
<td>DLCO simulator/device calibration available</td>
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<tr>
<td>Gas analysis certificates available*</td>
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<tr>
<td>Leak testing documentation available*</td>
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<table>
<thead>
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<th>Recordkeeping and Logs</th>
<th>Comments/Actions</th>
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<tr>
<td><strong>YES</strong></td>
<td><strong>NO</strong></td>
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<tr>
<td>Problem/troubleshooting log available*</td>
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<tr>
<td>Preventive maintenance log available*</td>
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<tr>
<td>Calibration log available*</td>
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<tr>
<td>Quality control log available*</td>
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<tr>
<td>Storage of logs defined (system and length)</td>
<td></td>
</tr>
</tbody>
</table>
Mayo Clinic’s PFL Quality Assurance Program

- Testing
  - Direct observation of testing performance
  - Testing sequence
  - Identify unusual testing techniques/behaviors
  - Understanding of ATS-ERS testing requirements
    - Acceptability/repeatability criteria
Mayo Clinic’s PFL Quality Assurance Program

- Issues outside the ATS-ERS acceptability/repeatability
  - Spirometry
    - BD delivery and consistent waiting time
  - Diffusing Capacity
    - < 4 minute wait period or inert gas cut-point criteria prior to repeat maneuvers
  - Lung volumes
    - < 1 minute thermo-equilibration period prior to testing
    - Pre-panting prior to shutter closure
    - Inappropriate panting rates secondary to linked TVG-Raw
    - Not performing “linked” VC maneuvers
Mayo Clinic’s PFL Quality Assurance Program

Post-test process
Questions?