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# Spirometry Quality Control Grading and Escalation Criteria

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**Introduction**

Spirometry accreditation follows a different path from other Diagnostic Accreditation Program (DAP) accreditation programs. In all other cases, the accreditation award is granted by the DAP Committee based on review of the report generated from an on-site assessment. In pulmonary function level 3 (PF3) hospitals where spirometry is performed, spirometry is assessed as part of the PF3 **on-site** assessment for accreditation.

By contrast, pulmonary function level 2 (PF2) facilities conducting only spirometry testing are not assessed on their premises, but rather assessed using a quality control (QC) program (also referred to as a desktop audit). Successful QC performance will lead to the issuing of an accreditation award every four years for these testing sites. Where unsuccessful QC performance is observed, it will be escalated to the DAP Committee for decision.

This introduction is intended to define the conditions under which a PF2 facilities' QC performance will be escalated to the DAP Committee for action.

**Spirometry Performance Review: QC Report Grading and Escalation**

Spirometry results are reviewed by the pulmonary function consultants each cycle. There are two cycles per year—January to June and July to December.

From the data submitted by each facility, three components are reviewed:

- medical interpretation of patient results by the physician
- technical performance of the spirometry test
- quality control, including biologic normal results, and verification of spirometry system linearity with a calibration syringe

The following tables describe how spirometry QC is graded by pulmonary function experts. When unsuccessful QC performance is escalated, the DAP Committee would then determine follow-up actions for the facility in order to maintain their accreditation award.

Performance criteria for the medical interpretation and technical components were developed in conjunction with the Pulmonary Function Advisory Group and the pulmonary function consultants.

**Note:** Failure to submit spirometry QC data will results in automatic escalation to the DAP Committee for decision regarding status of accreditation award.

**Table A – Medical interpretation grade**

| DAP grade | Definition | Potential risks | Escalation criteria | Escalation action |
|---|---|---|---|---|
| **A** | Complete agreement with interpretation | None | N/A | N/A |
| **B** | Slight variation, unlikely to affect patient care | None | N/A | N/A |
| **C** | Interpretation varies, slight effect on patient care | Reporting a lesser or greater degree of abnormality than is warranted by the data | N/A | N/A |
| **D** | Significant variation with immediate effect on patient care | • Reporting a patient as normal who is abnormal and vice versa<br>• Interpretation as obstructive when restrictive and vice versa<br>• Use of inappropriate parameters or criteria to form a diagnosis<br>• This could potentially lead to incorrect treatment or unnecessary follow-up | Two in one survey cycle<br>**or**<br>one in each of two consecutive survey cycles | 1. Request next **five** patients and resubmit to pulmonary function consultants<br>2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps<br>3. Prepare a briefing note with the outcome to the DAP Committee* |

* If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

**Table B – Technical Interpretation Grade**

| DAP grade | Definition | Potential risks | Escalation criteria | Escalation action |
|---|---|---|---|---|
| **A** | ≥90% of test sessions (patient reports) are acceptable | None | N/A | N/A |
| **B** | 80% of test sessions (patient reports) are acceptable | None | N/A | N/A |
| **C** | 60% to 70% of test sessions (patient reports) are acceptable | Inconsistent results with potential impact on patient results | Two consecutive survey cycles | 1. Request next **five** patients and resubmit to pulmonary function consultants<br>2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps<br>3. Prepare a briefing note with the outcome to the DAP Committee* |
| **D** | ≥50% of test sessions (patient reports) are **unacceptable** | Severe inconsistency with strong potential for impact on patient results | One survey cycle | |

| **Test performance (technical criteria)** | |
|---|---|
| **Acceptable** | None of the criteria listed below are observed |
| **Unacceptable** | Any or all of the following criteria are observed:<br><br>**Unacceptable Maneuvers**<br>• Cough or artifact in the first second<br>• Excessive back extrapolated volume – slow start<br>• End of test criteria not met<br>• Poor effort<br><br>**Post-bronchodilator Administration**<br>• Inadequate wait time for post-testing<br><br>**Unacceptable test session**<br>• Poor FVC repeatability<br>• Poor FEV1 repeatability<br>• Only one or two acceptable maneuvers<br>• No acceptable maneuvers |

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**Table C – Biological QC performance grading**

| DAP grade | Definition | Potential risks | Escalation criteria | Escalation |
|---|---|---|---|---|
| **A** | Six of six months demonstrate ≤3% CV for FVC and FEV1 | None | N/A | No |
| **B** | Any of six months demonstrate >3% and <5% CV for FVC and/or FEV1 | | N/A | No |
| **C1** | Three or fewer months reported, all demonstrate FVC and FEV1 ≤3% CV** | Compromised oversight of facility with potential impact on patient results | One survey cycle** | No |
| **C2** | Any of six months demonstrate ≥5 and <10% CV for FVC and/or FEV1 | Inconsistent results with potential impact on patient results | One survey cycle | 1. Request the facility submit **five** replicates of this test within one month accompanied by a written **action plan**<br>2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps<br>3. Prepare a briefing note with the outcome to the DAP Committee* |
| **D1** | Any of six months demonstrate ≥10% CV for FVC and/or FEV1 | Severe inconsistency with strong potential for impact on patient results | One survey cycle | |
| **D2** | Three or fewer months reported for second consecutive cycle | Compromised oversight of facility with potential impact on patient results | Two consecutive survey cycles | Prepare a briefing note to the DAP Committee for decision regarding status of accreditation award |

* If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

** Not applicable to new facilities joining partway through a survey cycle.

**Table D – Linearity performance grading**

| DAP grade | Definition | Potential risks | Escalation criteria | Escalation |
|---|---|---|---|---|
| **A** | Six of six months demonstrate all data within target range | None | N/A | No |
| **B** | One of six months demonstrate data outside target range | None | N/A | No |
| **C1** | Two or three of six months demonstrate data outside target range | Inconsistent results with potential impact on patient results | One survey cycle** | No |
| **C2** | Three or fewer months reported, all demonstrate data within target range** | Compromised oversight of facility with potential impact on patient results | One survey cycle** | 1. Request the facility submit **five** replicates of this test within one month accompanied by a written **action plan**<br>2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps<br>3. Prepare a briefing note with the outcome to the DAP Committee* |
| **C3** | Three or fewer months reported, any demonstrate data outside target range** | Compromised oversight of facility and inconsistent results with potential impact on patient results | One survey cycle** | |
| **C4** | Calibration syringe validation past due (expired) | Failure to comply with revalidation may result in incorrectly measured volumes and potentially incorrect diagnosis | One survey cycle | Request the facility submit **evidence** of syringe validation prior to next QC cycle |

* If reports correlate and problem has resolved, the DAP Committee briefing note is for information only. If quality assurance concern persists, the briefing note is submitted to the DAP Committee for decision regarding status of accreditation award.

** Not applicable to new facilities joining partway through a survey cycle.

**Table D – Linearity performance grading (continued)**

| DAP grade | Definition | Potential risks | Escalation criteria | Escalation |
|---|---|---|---|---|
| **D1** | Four or more of six months demonstrate data outside target range | Severe inconsistency with strong potential for impact on patient results | One survey cycle | 1. Request the facility submit **five** replicates of this test within one month accompanied by a written **action plan**<br>2. If data is still unacceptable, forward to consulting respirologist for risk assessment and next steps<br>3. Prepare a briefing note with the outcome to the DAP Committee* |
| **D2** | Two or three of six months demonstrate data outside target range for second consecutive cycle | Inconsistent results with potential impact on patient results | Two consecutive survey cycles | |
| **D3** | Three or fewer months reported, any demonstrate data outside target range for second consecutive cycle | Compromised oversight of facility and inconsistent results with potential impact on patient results | Two consecutive survey cycles | |
| **D4** | Calibration syringe validation past due (expired) for second consecutive cycle | Failure to comply with revalidation may result in incorrectly measured volumes and potentially incorrect diagnosis | Two consecutive survey cycles | Prepare a briefing note to the DAP Committee for decision regarding status of accreditation award |

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