

# CRITICAL DETAILS OF Arterial Blood Gas LABORATORY CERTIFICATION

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We began managing the respiratory care department at Johnson Memorial Hospital, a 165-bed rural hospital near Indianapolis, in summer of 1999. Unfortunately, we both had to become quickly acclimated to the department. Within the first week, we discovered serious problems with previous state inspections of the arterial blood gas (ABG) laboratory. Though neither of us had extensive experience in laboratory accreditation, we realized we would have to quickly overcome the learning curve.

The ABG laboratory had serious problems with regulatory compliance for several years, earning the

institution numerous Type I violations from the state inspector two surveys in a row. A Type I violation is the most urgent, serious inspection result a laboratory can receive. Most of the problems identified in the first problematic survey had gone unaddressed through the second, and still had not been addressed. Our next inspection was scheduled to be performed within four months; without immediate strict adherence to details of laboratory regulations, not only would patient care continue to be endangered, the loss of ABG laboratory state licensure was almost guaranteed. Upon researching the reason for this long-standing deficiency, we found that the department consists of 12 full-time therapists; and, like most small hospitals, only one person handled all the details of ABG laboratory certification.

A common problem of small institutions happens when a sole person is responsible for handling certification details and then leaves employment. Upon resignation, the details go unattended; and certification is in danger. This was precisely the problem found at our hospital, except the problem was com-

## Take-Home Notes

- An ABG laboratory out of compliance risks loss of laboratory accreditation and closure, which can negatively affect a hospital's service and financial operations.
- Small hospital department managers who also run an ABG laboratory can follow this step-by-step guide for bringing the lab under compliance with state and national regulations.

pounded by the fact that the individual responsible for the details of ABG certification/licensure was expected to be fluently knowledgeable about the details of certification/licensure with no training and no support from upper management. The person was also expected to address all needs of the laboratory while at the same

ever reason, it had passed inspection. However, with another inspection looming, corrections needed to happen immediately. The hospital would most likely have its license to perform and analyze arterial blood gases suspended if we could not show documented improvement on these outstanding issues. Although the ABG laboratory is only one small

pitals. Employees of small hospitals often have expanded scope of practice far beyond counterparts in larger institutions.

Management of personnel in small and large hospitals also differs. Typically, clinical managers of smaller hospitals come from staff or supervisory positions found in larger hospitals. Smaller hospital management is often filled with experienced clinical personnel who can greatly help the advancement of clinical practice in smaller institutions but have limited experience with the broader scope of hospital operations. The ABG laboratory is a prime example of this; in larger hospitals, ABG analysis may be performed by a department wholly dedicated to just ABGs. Even if the respiratory care department handles the drawing and analysis of the ABGs, a laboratory will typically handle routine quality control (QC) performance and maintenance. As a result, the respiratory supervisor advancing to manager would have little, if any, knowledge about the subject.

Also, smaller hospitals have smaller education budgets; thus, the new manager may have little support for overcoming the learning curve of regulatory compliance, and the possibility of failure becomes more likely.

Our previous two state inspections consistently showed the deficiencies listed below, all of which classify as Type I deficiencies (violations):

- Missing policies and procedures pertaining to the performance and analysis of arterial blood gases.
- No ABG competencies had ever been performed beyond the

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time carrying a full workload of respiratory therapy treatments, providing full-time accountability for respiratory staffing, acting as a resource for solving all equipment problems, and performing all department managerial duties.

In addition, this person was supposed to have begun a sleep laboratory and create programs for outpatient pulmonary rehabilitation and asthma education, as well as serve on numerous other hospital-wide committees. In a nutshell, the job had become untenable.

Upon this person's resignation, attention to ABG laboratory licensure seemed fairly inconsequential in comparison to the other responsibilities of the position. In light of the previous surveys, the state inspectors had been quite forgiving.

State inspections happen every two years. The inspector had to know that the laboratory's violations were occurring over a four-year period of time, and possibly longer; but, for what-

part of total hospital operations, an inability to perform ABGs would mean the hospital may not be able to admit mechanically ventilated patients, perform inpatient and outpatient surgeries, or admit patients with any serious form of pulmonary or cardiac disease.

Administration could arrange ABG coverage through a licensed contract service while regulatory issues were rectified, but hospital workflow would be severely hampered; and, ultimately, some patients would have to be transferred to more capable institutions for care. Loss of the ABG laboratory would have also negatively affected financial stability and reputation of the hospital.

Interestingly, we discovered after speaking with peers in our area that our situation was not unique because smaller institutions face a much higher risk of noncompliance and have a disproportionate amount of regulatory trouble because of the very nature of staffing in smaller hos-

general department employee orientation.

- No documented followup could be located when QC tests analyzed as deficient.
- No log of ABG machine deficiencies was being kept.
- No medical director review of ABG machine QC was in place.
- No performance improvement plan was in place; quality assurance was not monitored.

All of these inspection deficiencies add up to the most detrimental inspection result a laboratory can receive: Type I violations. These violations can result in delays or loss of accreditation and can ultimately trigger a costly followup inspection survey. Faced with the loss of ABG laboratory accreditation, we pulled together a plan that would guarantee regulatory compliance. The process of creating our plan led us to chart the confusing but necessary steps of gaining ABG machine certification and laboratory licensure.

**Step one**

Our first step was to learn all necessary steps in gaining certification and/or licensure. While a number of organizations are involved with certification, they all have common goals: ensuring the hospital is correctly drawing and analyzing ABGs and ensuring the test information is accurate. The following lists all the organizations needed to obtain licensure.

*CLIA (Clinical Laboratory Improvement Amendments)*— In 1967, Congress passed the Clinical Laboratory Improvement Amendments, which established quality standards for all laboratory testing. These standards were updated in 1988. By law, CLIA certification must be obtained before a laboratory

may operate. Steps to obtaining a CLIA certificate include:

- Applying for a CLIA certificate
- Providing proof of participation in a CLIA-approved external proficiency testing program
- Passing an inspection performed by a CLIA laboratory inspector
- Becoming accredited through a CLIA-approved accrediting agency.

**External proficiency testing**

ABG analyzers must have quality control tests run once every eight hours to assure analyzer accuracy. In addition to this routine QC testing, the laboratory must pay an external organization to review the accuracy of the analyzer and the proficiency of the analyzer operator once a quarter. Typically, the department will perform a special QC test once every three months using QC controls sent to the hospital by the external organization.

Once the control tests are performed, the results are recorded and sent to the external organization for grading. Problems with test results can be either the result of a bad analyzer or poor testing technique on the operator's behalf.

These results are kept near the ABG analyzer and reviewed during inspections. Failure to comply with participation in an external proficiency testing program will result in suspension/revocation of state licensure. Our hospital chose the College of American Pathology Proficiency Testing Program.

As mentioned earlier, CLIA regulations require the laboratory to be accredited through a CLIA-approved accrediting

agency, meaning you'll be paying another agency for another inspection similar to that of the CLIA inspector. Our hospital chose the Joint Commission on Accreditation of Hospitals for our ABG laboratory, as our larger Laboratory department was already using the Joint Commission as its accrediting agency. This information is also available on the CLIA web site: [www.hcfa.gov/medicaid/clia/cliahome.htm](http://www.hcfa.gov/medicaid/clia/cliahome.htm).

**Obtain state licensure**

Next, an application is made to the State Department of Health; and the medical lab surveyor will schedule another inspection of the laboratory to assure all requirements are being met. If all certifications are in place (in our case, CLIA and Joint Commission, as well as CAP Proficiency Testing), then a state license will be granted for a one-year period. Surveys are conducted once a year.

**Step two**

Once we learned specifically how to obtain licensure, we reviewed the inadequacies of our current operation to discover specifically how the Type I violations were occurring so we could formulate a plan to pull the laboratory into compliance. We thoroughly reviewed the inspector's comments and the regulations with which we were noncompliant; however, most of the changes put into place were the result of common-sense deduction about how one would assure that:

- Staff can competently obtain an ABG.
- Staff can competently operate the ABG analyzer.
- Staff can ensure the analyzer is

(continued on page 49)

# Checklist for CLIA Compliance

## I. General Administrative & Personnel

- 1 Has a CLIA certificate been obtained? If not, has an application been submitted?
- 1 Have all personnel (director, clinical consultant, technical consultant [general/technical supervisor, if high complexity] and testing personnel) been listed on the CLIA application form?
- 1 Are all personnel qualified by CLIA regulations for the duties they perform in the laboratory?
- 1 Is documentation available for education, experience, and special training for all positions covered by the regulations as listed above?
- 1 Is there a written job description detailing the responsibilities of all personnel in the laboratory?
- 1 Are there sufficient appropriate personnel to perform the testing workload?
- 1 Is a system in place and a written procedure available for initial and continued evaluation of the competence of laboratory personnel?
- 1 Are the director and medical director available as required for consultation?

## II. Facility and Safety

- 1 Is there an "Exposure Control Plan for Bloodborne Pathogens" for the laboratory?
- 1 Is it readily available to employees, and have they been familiarized with its contents?
- 1 Are universal precautions used in the laboratory?
- 1 Is appropriate personal protective equipment readily available?
- 1 Have the staff been trained in their application and use?
- 1 Is there a "Chemical Hygiene Plan" for hazardous materials, if needed?
- 1 Is it readily available to employees and have they been familiarized with its contents?
- 1 Are Material Safety Data Sheets available for all hazardous materials used in the laboratory?
- 1 Are all hazardous materials stored appropriately (e.g., flammables cabinets, acids and alkali stored separately, etc.) and labeled properly?
- 1 Are all disposable sharps discarded in an appropriate sharps container?
- 1 Are "red-bag" containers and sharps containers readily available?
- 1 Is eating, drinking, smoking, application of cosmetics and handling of contact lenses strictly forbidden in laboratory areas?
- 1 Are refrigerators used for food separate and apart from those used for specimens (i.e., no storage of food in laboratory refrigerators or laboratory areas)?
- 1 Are all electrical equipment or appliances up to generally accepted standards of electrical safety?
- 1 Are fire extinguishers available and in proper working order?
- 1 Do staff personnel know how to use them?
- 1 Are laboratory personnel familiar with alternate routes of escape?

## III. Patient Test Management

- 1 Are all tests requested in writing?
- 1 If a test is ordered orally, is it followed with a written request within 30 days?

### Does the written requisition contain:

- 1 The patient's name and/or other unique identifier?
- 1 The name or other identifier of the person requesting the test?
- 1 The test to be performed?
- 1 The date (and time, if appropriate) of specimen collection?
- 1 Any additional information to assure accurate and timely testing and reporting of results?

### Does the laboratory have and follow written procedures for:

- 1 Preparation of the patient?
- 1 Collection of the specimen?
- 1 Labeling of the specimen?
- 1 Preservation and/or transportation of the specimen?
- 1 Processing of the specimen?

### Do laboratory records show:

- 1 Patient's name or other unique identifier through all phases of testing?
- 1 Date and time specimen was received in the laboratory?
- 1 Condition of unacceptable specimen and disposition thereof?
- 1 Date that all testing was performed?
- 1 Identity of all personnel performing testing?

### Are the results of laboratory testing:

- 1 Released only to authorized persons?
- 1 Reported in timely fashion?

### Does the laboratory report contain:

- 1 The name and address of the laboratory?
- 1 The test performed?
- 1 The result?
- 1 The unit of measurement?
- 1 The pertinent "normal range" for the test?
- 1 Does the laboratory have and follow written procedures for reporting imminently life-threatening results?
- 1 Does laboratory policy prohibit reporting results that exceed the reportable range for the instrument or system?
- 1 Are test reports maintained in a manner that permits ready identification and timely accessibility?
- 1 Does the laboratory notify the appropriate person of any errors?
- 1 Is a corrected report issued?

### Are the following records maintained for two years:

- 1 Test requisitions?
- 1 Test reports, including instrument printouts and worksheets, and reports from reference laboratories?
- 1 Corrected reports?
- 1 Documentation of all quality control activities?
- 1 Documentation of all quality assurance activities?

## IV. Proficiency Testing

- 1 Is the laboratory registered with an approved PT provider?
- 1 Are PT results reviewed by the director?
- 1 Are deficiencies investigated and remediation instituted if indicated based on this review?

## V. Instrument Maintenance

- 1 Is an instrument log maintained for each instrument used in the laboratory?

### Is the following recorded in the instrument log:

- 1 Daily and periodic maintenance: procedure and log?
- 1 Scheduled and unscheduled manufacturer's preventive maintenance?
- 1 Instrument problems and attempts to rectify recorded in maintenance log?

## VI. Procedure Manual

- 1 Does the laboratory have a "Procedure Manual"?
- 1 Does it contain all procedures performed in the laboratory?
- 1 Is it accessible and understandable to testing personnel?
- 1 Do procedures accurately reflect actual laboratory practice?
- 1 Is the "Procedure Manual" reviewed and signed by the director?
- 1 Are all new procedures or changes in procedure signed by the director?

### Does each procedure contain

- 1 Procedure for obtaining specimens for the test?
- 1 Any special instructions to the patient that may be required?
- 1 Procedure for handling, preservation and storage?
- 1 Criteria for rejection of unacceptable specimens?
- 1 Directions for preparation of reagents, standards, controls, etc., for the test?
- 1 Directions for performing the test?
- 1 Normal or expected ranges for the test, panic values, etc.?
- 1 Procedure to follow if quality control is out of range?
- 1 Sample handling in the event of instrument or system malfunction?
- 1 Is each procedure reviewed and signed annually by the director?
- 1 Are discontinued procedures maintained for two years?

## VII. Quality Control

- 1 Is a quality control program maintained for the ABG laboratory?
- 1 Does it state acceptable limits and procedures to follow if limits are exceeded?
- 1 Are controls run in the same manner as patients?
- 1 Are quality control results reviewed by the director?
- 1 Are prepared controls labeled as to content, preparation date, storage requirements, and expiration date?
- 1 Are all expired materials discarded on or before the expiration date?

## VIII. Quality Assurance

- 1 Does the laboratory have a written quality assurance program?
- 1 Are the effectiveness of policies and procedures periodically evaluated?
- 1 Does the evaluation identify problems and suggest solutions?
- 1 Are the solutions monitored to ensure their effectiveness?
- 1 Are the results of the evaluations discussed with the laboratory staff?
- 1 Are breakdowns in communications between physicians and laboratory personnel recorded?
- 1 Are corrective actions taken to remedy these breakdowns?
- 1 Does the laboratory have a procedure for documenting, investigating, and correcting complaints about the laboratory?

accurate, so medical decisions based on results are sound.

- Staff can identify instances when the analyzer is not producing accurate results and can take specific actions to remedy the situation.

It is important to consult the lab director whenever you are working on certification/licensure issues. ABGs are considered moderately complex tests, which make up a small minority of the vast numbers of tests that full-scale laboratories perform. Lab directors are subjected to numerous inspections on an annual basis and thus are experts in gaining regulatory compliance. Use them as licensure consultants; their advice is invaluable.

Below is a compilation of the deficiencies that caused our ABG laboratory to receive Type I violations during their last joint commission surveys, along with our action plans enacted to bring the laboratory into compliance. Most of these deficiencies were sited in the last two inspections as well.

**Missing Policies and Procedures: Joint Commission Standard HR.1.**

*Problem:* During the course of establishing the ABG laboratory, all necessary policies and procedures were written. However, if they cannot be found in the “Policies & Procedures Manual” when the inspector looks for them, the laboratory will definitely receive a “deficiency.” A missing policy means the staff cannot reference the particular policy if a question arises; ABGs cannot be properly performed if the staff does

not know how to perform them.

*Solution:* Replace or rewrite all policies and procedures in the ABG manual.

**Competencies: Joint Commission Standard HR.3**

*Problem:* Annual competency testing had never been performed in the hospital. As Joint Commission and CLIA standards state, earning a respiratory degree and owning a license is not enough to prove a staff person’s skill level. Inspectors require hospitals to prove therapist competency annually, and documentation proving competency performance should be available upon inspection.

*Solution:* The respiratory supervisor quickly drew up competency documentation and monitored all staff as they performed ABG analysis and QC controls. The therapists also were inserviced in remedial steps to perform when QCs fell out of designated ranges, as well as what to do if the ABG analyzer needed to be serviced.

**Remedial Action for Deficient QCs: Joint Commission Standard QC 1.1.3, QC 1.4.**

*Problem:* Quality controls are performed roughly every eight hours daily. The therapists had rarely missed QC performance in our hospital; yet when QCs fell outside designated ranges (which indicate the ABG analyzer could be producing incorrect analyses), no action was taken. In one month, half of all Level II QCs obtained unacceptable values; yet no followup occurred, and the ABG analyzer continued to be used. This is a cardinal sign of absent training; the staff were performing their

duties as they were instructed and simply did not know of any followup procedures that were supposed to happen when QCs fell out of acceptable ranges and needed corrective action.

*Solution:* First, the respiratory supervisor performed and documented inservicing on all necessary steps pertaining to ABG analyzer-deficient QC remedial actions. Second, an easy-to-read list of actions was printed, laminated, and posted in plain sight near the ABG analyzer for reference when the QCs fell out of range. Third, a deficiency log was initiated, on which therapists would record instances when the ABG analyzer fell out of service or when QCs fell out of range.

**No Review of Lab Activities by the Lab Director: Joint Commission Standard QC 1.1.1.**

*Problem:* Unless the hospital’s laboratory department director is also serving as ABG lab director, the respiratory care department medical director usually serves as ABG lab director. By CLIA regulation, the lab director is responsible for all policies in place that control the activities of a department. As part of directorial duties, it is required to have all quality control and performance improvement (PI) information forwarded to the director for review. The director can then give input for improving service. Dated signatures of QC and PI departmental information show proof of routine record review by the director.

*Solution:* We initiated a logbook of all QC and PI information tracked by the ABG laboratory, and now material is presented

to the medical director on a monthly basis. The medical director signs and dates the reports after reviewing monthly statistics.

**No Performance Improvement Plan in Place: Joint Commission Standard PI.1, PI.3, PI.5**

*Problem:* All regulatory agencies require health care entities have a plan in place to continually improve the level of service provided to patients. To date, no performance improvement plan had been formulated for the ABG laboratory.

*Solution:* A PI plan was quickly

formulated and implemented. The measurements of the plan are now reported to the medical director on a monthly basis and the hospital quality council receives a report on a quarterly basis. Common PI indicators measured in the ABG laboratory include:

- Number of missed QCs
- Number of re-draws due to poor samples
- Universal precaution compliance
- Proper reporting/documentation of ABG results
- Durations of time between "STAT" orders and ABG result delivery.

**Success is sweet**

Our most recent state inspection was in April 2000, and we passed without incident. We look forward to our Joint Commission inspection in Spring 2001 with confidence. Full compliance with regulatory standards means that we can feel more comfortable about inspections, as well as more confident that we are delivering the best possible care to our patients. 🎉

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**EDITOR'S NOTE**

For a more detailed version of this feature article, including a list of CLIA-approved proficiency testing programs and other resources for lab directors, log on to the AARC web site at [www.aarc.org](http://www.aarc.org).