



Blood Gas Analysis and the Respiratory Therapist

Overview

Respiratory therapists have raised concerns recently through *AARC Connect* listservs about surveyors' review of personnel qualifications for blood gas analysis conducted in moderate and high complexity laboratories. The issues involve qualifications to assess competencies of testing personnel; whether respiratory therapy is considered a chemical, physical or biological science or medical technology; and whether bachelors' degrees with a title other than "respiratory therapy" are accepted based on review of college transcripts to determine equivalency. A survey of section members was conducted to gain additional insight into the issues.

Background

The Centers for Medicare and Medicaid Services (CMS) regulates all human laboratory testing (except research) in the US through the Clinical Laboratory Improvement Amendments (CLIA). In January 2015, CMS revised surveyor guidelines pertaining to CLIA regulations to require mandatory citations in four areas "regardless of the presence or absence of any negative outcome or potential harm." One of the four citations involves personnel qualifications. While the CLIA regulations have not changed in this area, the requirement to issue mandatory citations could be the reason some concerns are being raised at this time.

Frequently Asked Questions (FAQs)

These Frequently Asked Questions (FAQs) address skills related to blood gas analysis. They are designed to help you understand the qualification requirements of testing personnel in moderate and high complexity labs and those who are responsible for assessing competencies within this specialty.

Testing Personnel – Moderate Complexity Testing

Q. What type of degree do I need if I draw/analyze blood gases in a moderate complexity lab?

A. Respiratory therapists can qualify to do moderate complexity testing if they hold a doctoral, master's, bachelor's or associate's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution.

Q. Does a degree in respiratory therapy, regardless of whether it's an associate degree or a bachelor's degree or higher, meet the definition of a degree in a chemical, physical or biological science or medical technology?

A. Yes. According to information the AARC received from the Joint Commission, respiratory therapy degrees are considered a "biologic science."

Q. What happens if my degree isn't in "Respiratory Therapy"? Does that still count?

A. It depends. It is up to the surveyor's expertise to make the determination as to whether an individual's education and training meets the various qualification standards depending on the complexity of the testing. Recognizing that accrediting institutions vary in the title of degrees they convey for a variety of professions including respiratory therapy, surveyors may ask for documents pertaining to diplomas, certificates, degrees, continuing education, and training and experience in making their decisions. Licensure and credentials are not taken into account in making these determinations. **Note:** For CLIA **recertification** surveys, surveyors are not required to review personnel *qualification* records of individuals previously evaluated unless there have been changes in the individual's position and/or the laboratory's test menu since the last survey.

Testing Personnel – High Complexity Testing

Q. Are the qualifications for testing personnel in a high complexity lab the same as those who do blood gas testing in a moderate complexity lab?

A. No. Because the complexity of testing is greater in this setting, respiratory therapists must have at a minimum a bachelor's degree in respiratory therapy or cardiovascular technology or an associate degree related to pulmonary function. In some cases, an associate degree in a laboratory science or medical laboratory technology may also qualify. Although CMS interprets an associate degree in a laboratory science to mean a "chemical or biological science", it is most likely that having an associate degree in respiratory therapy alone may not be sufficient to meet the testing personnel qualifications for high complex testing. Keep in mind the key here is laboratory testing, not respiratory therapy. To qualify with an associate's degree requires at least 60 semester hours, or equivalent, that at a minimum includes either --

- 24 semester hours of medical laboratory technology courses; or
- 24 semester hours of science courses that include 6 semester hours of chemistry and biology each; and

- 12 semester hours of chemistry, biology or medical laboratory technology in any combination; and
- Have laboratory training that meets certain conditions outlined in regulations.

Q. For high complexity testing, will a BS in Health Science qualify?

A. It depends. The regulations state specifically a Bachelor's Degree in Respiratory Therapy. If you have a bachelor's degree or higher that is not in respiratory therapy, it is up to the surveyor to determine if you meet the qualifications based on a review of your personnel record as applicable.

Assessing Competencies of Testing Personnel

Q. I understand that laboratory testing personnel must be assessed as to their competencies. What does that include?

A. There are six competencies that must be assessed and documented to meet the CLIA regulations. They involve:

- Direct observation of routine patient testing
- Monitoring the recording and reporting of test results
- Review of immediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records
- Direct observation of performance of instrument maintenance and function checks
- Assessment of previously analyzed specimens, internal blind samples or external proficiency testing samples
- Assessment of problem solving skills

The data and information regarding the six methods used for competency assessment can be gathered by anyone with knowledge of the process. However, the assessment itself must be done by the individual with qualifications for the specific complexity of testing.

Q. Can testing personnel also assess and sign-off on competencies?

A. Only certain qualified individuals may perform the competency assessments of testing personnel. In order to assess competencies, a respiratory therapist must be acting in the capacity of a technical consultant for moderate complexity testing or as a technical supervisor if the competencies are for high complexity testing.

Q. What qualifications do I need to be a technical consultant?

A. In general, a technical consultant (moderate complexity testing) requires at a minimum a bachelor's degree in a chemical, biological, or physical science or medical technology and at least 2 years of training and/or experience in non-waived testing in the specialty, e.g., blood gas analysis, for which he/she is responsible. Duties may not be delegated to others.

Q. If I want to assess competencies in a high complexity lab, what qualifications do I need to be a technical supervisor?

A. Generally, the technical supervisor at a minimum requires a bachelor's degree in a chemical, physical or biological science or medical technology and at least 4 years training and/or experience in high complexity testing with a minimum of 6 months experience in blood gas analysis. However, the technical supervisor can delegate responsibilities in writing to the general supervisor of the laboratory.

Q. Does the general supervisor need special qualifications to assess competencies for blood gas analysis in a high complexity lab?

A. Yes. For blood gas analysis, the general supervisor must be qualified as: 1) the technical supervisor (see above); **OR** 2) the laboratory director (generally either a physician or a PhD who meets certain requirements and is certified by a board approved by the Department of Health and Human Services); **OR** 3) have earned a bachelor's degree in respiratory therapy or cardiopulmonary technology and have at least one year of training and/or experience in blood gas analysis; **OR** 4) have earned an associate degree related to pulmonary function and have at least 2 years training and/or experience in blood gas analysis.

Miscellaneous Questions

Q. I've heard that accreditation organizations such as the Joint Commission (JC) and the College of American Pathologists (CAP) can have standards that are more restrictive than CMS' regulations. Is that true?

A. Yes. Accreditation organizations have the authority to implement their own standards as long as they are not less restrictive than CMS' regulations. How your hospital is surveyed depends on which organization is conducting the survey, including state surveyors from CMS. For example, if the accreditation organization requires a general supervisor for moderate complexity blood gas testing, even though the regulations indicate others may qualify, your facility has to comply. Or, an accreditation organization may not permit

non-physicians or individuals without a doctoral degree to direct waived and moderate complexity laboratories, even though the CLIA regulations may allow it. The guidelines we present in these FAQs are based on CMS' interpretation of the regulations.

Q. To eliminate inconsistencies in the surveyor's findings, why doesn't the AARC get CMS to revise the guidelines to mandate that respiratory therapists, regardless of the title of their degree, are qualified to do blood gas testing and competencies?

A. Unfortunately, this is not a "one size fits all" situation, especially when taking into account possible variations in accreditation organizations' standards. Moreover, there are too many variations in respiratory therapists' degrees and course work to suggest that it is possible to have a definition that would eliminate inconsistencies in surveyor's findings and meet all laboratory requirements. At least 35 different degree titles were reported just in the small amount of responses to the AARC's survey. Qualifications and competency are based on the complexity of tests. The guidelines rely on the surveyor's professional judgment and they are the experts in the survey process. If a hospital has concerns about the inspection findings, it must deal directly with the accreditation organization.

Q. Is there a way that I can find out if my course work meets the CLIA regulations prior to the time a surveyor reviews my hospital's laboratory?

To determine if your course work meets the CLIA qualifications for testing, the Joint Commission recommends checking with the state CLIA office where your hospital is located. In the end, however, it is up to the surveyor to make determinations on a case-by-case basis, as applicable. The following link provides contacts for both state and regional CLIA offices:

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html

Q. If I wanted to read the actual regulations regarding CLIA personnel qualifications, where can I find them?

A. The titles, qualifications and responsibilities of CLIA lab supervisors, testing personnel and those who perform staff competencies are outlined in the Code of Federal Regulations (CFR) – Part 493 – Laboratory Requirements, Subpart M, Personnel for Nonwaived Testing. You can access them at the link below:

http://www.ecfr.gov/cgi-bin/text-idx?SID=983be5c0eb3df3015f5ce4c08df089f1&mc=true&tpl=/ecfrbrowse/Title42/42cfr493_main_02.tpl

Q. Is there a website I can access to get general information about CLIA?

A. There is a wealth of CLIA information and resources on the CMS website at the link below. You can download the CLIA Interpretive Guidelines and keep them handy if you have further questions about qualifications. In addition to the State Agency and Regional Office CLIA contacts noted above, the site offers CLIA brochures, CLIA regulations and Federal Register notices, a chart on the top 10 CLIA deficiencies as of November 2014, a list of accreditation organizations and much more.

<https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html>

Q. Is there any further action AARC plans to take to deal with the issues raised by AARC members?

A. Given the AARC survey results overall and that only two citations were mentioned, it does not appear at this time that many hospital laboratories that conduct blood gas testing are facing major problems. However, because the survey responses indicated that many of the hospitals had not yet been surveyed, the AARC will continue to monitor the situation as necessary.