Personnel Standards for Laboratory Professionals
(Policy Number 04-01)

Policy Statement

For reasons of patient safety and quality laboratory testing, the American Society for Clinical Pathology (ASCP) supports personnel standards for laboratory professionals. These standards could take the form of practice requirements, certification requirements, or licensure. These personnel standards must include the following elements: appropriate academic and clinical training for laboratory professionals; passage of a competency examination offered by an approved national certification organization; appropriate continuing competency standards; and recognition of ASCP's professional terminology.

Background and Rationale

I. Education and Professional Terminology

Technologist-level personnel should possess a baccalaureate degree and successfully complete an accredited or approved training program or specified work experience. Technician-level personnel should possess an associate degree and successfully complete an accredited or approved medical laboratory-training program. Further, in an effort to enhance the supply of laboratory personnel, ASCP supports exempting laboratory personnel from these personnel standards for a period of three years, after which these standards must be satisfied. Additionally, individuals who currently perform testing but do not meet these personnel standards shall be exempt from these standards provided they pass a national certification examination.

State and federal regulation referring to laboratory testing personnel should use the terminology recognized as the industry standard. These terms are "medical technologists" and "medical laboratory technicians."

"Medical technologists" and "medical laboratory technicians" are the terms most widely recognized by medical laboratory practitioners, employers, and national certification organizations. ASCP estimates that it has certified approximately 64 percent of the 295,000 employed as medical technologists and medical laboratory technicians in 2000.[1, 2] These terms are the ones recognized by the federal government, including the U.S. Department of Health and Human Services, U.S. Department of Labor, the U.S. Public Health Service, the National Institutes of Health, the U.S. Department of Veterans Affairs, and the U.S. Bureau of Citizenship and Immigration Services. In addition, the term "medical technologist" is the term used by the National Labor Relations Board to bestow professional status on these healthcare practitioners. The College Entrance Examination Board also uses these terms.

ASCP believes these terms are more reflective of patient understanding of laboratory personnel. ASCP is concerned that alternative terminology can cause confusion. The Society notes that "clinical scientists," who hold doctoral degrees in the natural sciences, may be confused with "clinical laboratory scientists," an alternative term for "medical technologists." This alternative terminology could confuse patients about the laboratory profession as well as individuals who may consider careers as medical laboratory practitioners.

II. Training and Competency Assessment

Discussed below are several studies pertaining to personnel standards and test performance. These studies rely on proficiency testing data, a quality control check required by the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA), of laboratories performing moderate and high complexity testing. They indicate that there is a significant positive correlation between the quality of laboratory testing and the training possessed by testing personnel or their national

certification. Given that patient diagnoses are often based on laboratory test findings, erroneous test results expose patients to a significantly higher risk of inaccurate diagnosis and improper treatment, which can result in patient injury or death.[3, 4] As a result, ASCP believes personnel standards, specifically academic and clinical training requirements coupled with national certification and continuing education, can serve as important tools for enhancing the quality of care and patient safety.

In 1998, the *Journal of the American Medical Association* published a study by Jerry Hurst et al. comparing the quality of non-waived testing in physician's office laboratories and traditional testing sites (hospital and independent clinical laboratories). For this study, the traditional testing sites relied solely on licensed medical technologists. He subdivided physician's office laboratories into those using licensed medical technologists, either as testing personnel, supervisory personnel, or laboratory consultants, and those that do not (California law allows physicians, podiatrists, nurses, physicians assistants, pharmacists, respiratory care technicians, and perfusionists to perform non-waived testing). Hurst concluded that testing by licensed medical technologists is superior to testing performed by individuals who are not licensed laboratory professionals. His data indicates that licensed personnel in traditional testing sites are more than 4 times less likely to incorrectly analyze proficiency testing specimens than alternative laboratory personnel.[5] Hurst also found that at physician office laboratories, testing performed by licensed laboratory personnel is superior to that involving individuals who are not licensed laboratory practitioners.

The *Journal of the American Medical Association* published a study by Tina M. Stull et al. in 1998. In it, she examines proficiency testing results at traditional testing sites (hospital and independent clinical laboratories) and alternative testing sites (e.g., physician office laboratories, nursing homes, blood banks, mobile health units, ambulatory surgical centers, hospice providers, community clinics, rehabilitation facilities, end-stage renal disease centers, and residential care facilities).[6] Stull uses a similar approach to Hurst, but unlike Hurst she does not rely exclusively on traditional testing sites. Like Hurst, Stull concludes that testing performed at traditional testing sites, which are more likely to employ trained laboratory practitioners than alternative testing sites, outperforms testing at alternative testing sites. She sites differences in testing personnel and their training as a reason for the differences in proficiency testing scores. Stull's data reveals that alternative testing sites are 2.19 to 7.51 times more likely to incorrectly analyze proficiency testing specimens. Unsatisfactory test event scores at alternative testing sites for glucose, hemoglobin, and bacteriology, the 3 most commonly offered tests at these sites, were particular high: 15 percent, 9.1 percent, and 7.2 percent, respectively.[7]

The *Journal of the American Medical Association* published a study in 1987 by researcher Mary E. Lunz et al. that examined the relationship between laboratory test quality and national certification of laboratory personnel. Lunz compared the proficiency testing scores of ASCP certified medical technologists and non-certified medical technologists employed at licensed medical laboratories in Illinois. Lunz found that laboratories employing ASCP certified medical technologists significantly outperformed those that do not. She found that non-ASCP certified medical technologists are 5 times more likely to unsuccessfully analyze proficiency testing specimens.[8] Lunz indicated that ASCP certification predicts more accurate performance of laboratory tests. Because national certification requires specific academic and clinical training, this study also suggests that test quality improves with increased amounts of academic education.

III. Impact of Erroneous Test Results on Patient Health

Without proper training, the likelihood of erroneous test results increases substantially.[9] With medical diagnoses highly dependent on laboratory test results, erroneous test results can have a significant impact on patient care.[10] Researcher Paul Nutting estimates that more than 25 percent of these problems affect patient care.[11] These effects include delays in receiving appropriate care and the provision of inappropriate or harmful diagnoses

Bruce Vladeck, PhD, former Administrator of the U.S. Health Care Financing Administration (now called the Center for Medicare and Medicaid Services), the federal agency charged with managing the CLIA program, said in an agency press

release "the quality of testing is very important to patient care…Erroneous test results can lead to improper diagnoses and treatment, which may ultimately cause unnecessary injuries and death. 'False positive' and 'false negative' lab results also produce higher costs, both for the patient and the health care system as a whole."[12]

References

[1] Interview with Kory Ward-Cook, American Society for Clinical Pathology Board of Registry, August 19, 2003.

[2] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook.

[3] Foubister, Vida, Bench Press: The Technologist/Technicians Shortfall is Putting the Squeeze on Laboratories Nationwide. CAP Today. September 2000. pp 84.

[4] Surveys Show Improvement in Physician Office Labs. Press Release, U.S. Health Care Financing Administration. September 7, 1995.

[5] Hurst, Jerry, Nickel, Karen, and Hilborne, Lee H. Are Physician Office Laboratory Results of Comparable Quality to Those Produced in Other Laboratory Settings. Journal of the American Medical Association. February 11, 1998. v279, n6. pp. 468.

[6] Stull, Tina M.; Hearn, Thomas L.; Hancock, John S.; Handsfield, James H., and Collins, Carlyn L. Variation in Proficiency Testing Performance by Testing Site. Journal of the American Medical Association. February 11, 1998. v279, n6. pp 463.

[7] Stull, Tina M.; Hearn, Thomas L.; Hancock, John S.; Handsfield, James H., and Collins, Carlyn L. Variation in Proficiency Testing Performance by Testing Site. Journal of the American Medical Association. February 11, 1998. v279, n6. pp 465.

[8] Lunz, Mary E.; Castleberry, Barbara M.; James, Karen; and Stahl, John. The Impact of the Quality of Laboratory Staff on the Accuracy of Laboratory Results. Journal of the American Medical Association. July 17, 1987. V258, n3 pp 361-3.

[9] Stull, Tina M.; Hearn, Thomas L.; Hancock, John S.; Handsfield, James H., and Collins, Carlyn L. Variation in Proficiency Testing Performance by Testing Site. Journal of the American Medical Association. February 11, 1998. v279, n6. pp 465.

[10] Foubister, Vida, Bench Press: The Technologist/Technicians Shortfall is Putting the Squeeze on Laboratories Nationwide. CAP Today. September 2000. pp 84.

[11] Nutting, Paul A.; Main, Deborah S.; Fischer, Paul M.; Stull, Tina M.; Pontious, Mike; Boone, D. Joe; Holcomb, Sherry. Problems in Laboratory Testing in Primary Care. The Journal of the American Medical Association, February 28, 1996. v275 n8 p638.

[12] Surveys Show Improvement in Physician Office Labs. Press Release, U.S. Health Care Financing Administration. September 7, 1995.

Additional Supporting Materials

ASCP Policy Statement on Scope of Practice for Medical Laboratory Personnel
(Appendix to Policy Number 04-01)

The ASCP believes it is important to the nation's health to maintain strict definitions of job descriptions for laboratory professionals.

Technician

A Technician has the appropriate educational background to perform laboratory procedures according to established and approved protocols that require the limited exercise of independent judgment and interpretation. These tests are performed with the technical supervision of a technologist, manager, or laboratory director. The Technician may perform laboratory procedures across the major areas of the laboratory, or concentrate activity in one area such as blood banking, chemistry, hematology, immunology, microbiology, or histology. Examples of the Technician's duties include the following:

- Follows established procedures for collecting and processing biological specimens for analysis.
- Performs chemical, microbiologic, immunologic, hematologic and immunohematologic laboratory procedures that require limited independent judgment.
- Recognizes unexpected results and instrument malfunction and takes appropriate action.
- Provides laboratory information to authorized sources.
- Demonstrates laboratory technical skills to other laboratory personnel.

Technologist

A Technologist has the appropriate educational background to perform, interpret, and correlate laboratory procedures that require the broad exercise of independent judgment and responsibility with minimal technical supervision. A Technologist maintains equipment and records; performs quality assessment activities related to test performance; and may also function as a supervisor, educator, manager, consultant or researcher within a medical laboratory setting. The term Technologist includes persons performing a broad range of laboratory procedures as well as persons concentrating their activities in an area such as blood banking, chemistry, hematology, immunology, microbiology, histology, or cytology. The Technologist has an understanding of roles and relationships of practitioners in the health related fields.

The Technologist's role subsumes all aspects of the Technician's role. In addition, examples of the scope of duties for the Medical Technologist are:

- Evaluates and solves problems related to collection and processing of biological specimens for analysis.
- Performs full range of chemical, microbiologic, immunologic, hematologic and immunohematologic laboratory procedures.
- Differentiates and resolves technical, instrument, and physiologic causes of problems or unexpected test results.
- Participates in the evaluation of new techniques and procedures in laboratory.
- Incorporates principles of educational methodology in the instruction of laboratory personnel, other health care professionals and consumers.
- Provides administrative and technical consulting services on laboratory testing.
- Gives direction and guidance to technical and support personnel.