Competency Assessment for Medical Laboratory Practitioners and Existing Rules and Regulations

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by

Dr. Rajeshree P. Parikh

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Ed.D. University of Central Florida, 1998
S.B.B. American Society of Clinical Pathologists, 1993
M.S. University of Central Florida, 1992
M.Ed. Gujarat University, 1975
B.Ed. Gujarat University, 1974
B.S. Gujarat University, 1972

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Abstract

Some of the challenges clinical laboratories faces today are the design and implementation of competency assessment programs. Section 493.1451 (b) (8) of the Clinical Laboratory Improvement Amendments of 1988 (CLIA, 1988) regulations states that technical supervisors are responsible for ensuring that staff maintain competency to perform test procedures and report results promptly, accurately, and proficiently. CLIA (1988) requires that the skills of technical personnel be assessed annually.

The purpose of this study was to compare the perceptions of certified medical laboratory personnel who worked as educators, employers, or practitioners regarding the required competencies of three levels of laboratory personnel: Medical laboratory technician (MLT), medical laboratory technologist (MT) and clinical laboratory Specialist.

Descriptive statistics, which included means, standard deviations, ranks, and Spearman Rank-Order Correlation, revealed some degree of discrepancies among the respondents. However, educator's response reflected the appropriateness of the competencies in direct relation to increasing competency level of laboratory roles, Medical Laboratory Technician (MLT), Technologists (MT) and Specialists. Employers and Practitioners, on the other hand, rated MTs and Specialists as almost equal.

Furthermore, comparison among the practitioners revealed distinct discrepancies in the perceptions of performing and evaluating laboratory tests. The greatest variation was noted among practitioners in their rating of competency level required for specialist roles.
These specific results will be useful for further development of required personnel qualifications and their relationship to competency-based performance evaluations intended to maintain quality control practices and laboratory proficiency. Result of the study will also provide guidelines for further discussing curriculum revision for practitioners training and to establish distinct levels of competencies for three different levels of medical laboratory personnel: MLTs, MTs, and Specialists.

Introduction

One of the challenges clinical laboratories have faced is the design and implementation of competency assessment programs. Section §493.1451 (b) (8) of the Clinical Laboratory Improvement Amendments of 1988 (CLIA’88) regulations stated that technical supervisors are responsible for ensuring that staff maintain competency to perform test procedures and report results promptly, accurately, and proficiently (Federal Register, 1992). CLIA’ 88 requires that the skills of technical personnel be assessed annually. The accreditation standards (1992) of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) emphasize the quality of interdepartmental functions and performance improvement (Hansen, 1996). As a result of such rules and regulations all laboratories were required to document competency assessment of their employees. Over the past twenty years there has been significant investment in the laboratory to improve and establish the roles and responsibilities for laboratory medical personnel. Despite this, however, there is very little empirical evidence to suggest that competency levels of laboratory personnel have been evaluated objectively.

During the 1990's, hospital administrators, physicians, insurance providers, and patients have expected more for their health care dollars (Berte & Nevalainen, 1996).
Health care costs have risen tremendously and the general public wants the costs reduced. Furthermore, the impact of health care reform, managed care and prospective payment systems (PPS) has led hospital management to make more concerted efforts to control costs within their institutions (Karni, 1997).

The impact of managed care and PPS along with the increase of automation and computerization has generated incentives to reduce laboratory testing and personnel. In addition, because of simplified instrumentation, fewer individuals with baccalaureate or advanced level degrees were required. On the other hand, more sophisticated procedures and analyses, the emergence of new laboratory subspecialties, and laboratory participation in test selection, utilization, and interpretation have suggested a need for more personnel trained at the baccalaureate, masters, and doctoral levels (Karni, 1997).

According to the result of an American Society of Clinical Pathologists’ Board of Registry (BOR) survey (1995), students have been facing increasing difficulties in receiving training and finding jobs. Concurrently, however, many allied health care industries have experienced personnel shortages due to the effects of restructuring, reengineering, downsizing or rightsizing. Some schools of allied health in the United States have made an effort to train multi-competent allied health professionals to meet the personnel needs of small hospitals, physicians’ offices, clinics, comprehensive health care centers, and rural areas (Bamberg & Blayney, 1984). However, the selection of curriculum for clinical laboratory technology programs has presented an ongoing problem for educators. In order to prepare students for entry-level positions and future professional competence, educators have been seeking a way to make sound decisions concerning curriculum content.
This article was prepared to provide information that would help in determining an optimal competency-based performance evaluation. The focus of this article was to identify how medical laboratory personnel view competency levels according to their education, experience, on-the-job training, orientation, and employment status. The level of congruency among various laboratory personnel levels was identified as a starting point for dialogue and curriculum planning. However, since certifying agencies have already established criteria for expected competency levels, this study was not intended to define competency according to the laboratory personnel level. The question still remains regarding the characteristics of performance levels expected of entry-level personnel of medical technology programs.

The goal of clarifying expected competencies of the various personnel levels serve a number of functions. Identification of desired competencies removes curricular discussions from discipline-specific considerations and territorial issues, which in turn facilitates a focus on desired characteristics of medical technology graduates. Results of such a study can provide information about areas of mutual agreement among diverse laboratory departments and different levels of laboratory personnel. This data may also suggest a means for the restructuring of knowledge and technical skills in medical technology education and on-the-job training. A competency-focused approach to achieve quality performance goals may be valuable for addressing the educational needs of a diverse population of students and employees. For educational leaders anticipating curricular review or revision, knowledge of employer's expectations of competency for the various levels of laboratory personnel can provide the groundwork for deliberation. Many features of the laboratory have changed in recent years, but the underlying
principles of laboratory analysis and work ethics have remained the same. Evaluation of laboratory personnel was always documented in different ways, such as performance evaluations, certifying examinations, and proficiency testing. Competency assessment is another form of evaluation for laboratory personnel that does not eliminate traditional patterns of evaluating, but instead refines these patterns to make them more objective. By comparing the perceptions of medical laboratory professionals, it is assumed that a true reflection of differences in competency levels in current medical laboratory practice can be obtained. This seems to reflect the rater's experience of the real world in terms of perception. In other words, it supports the definition of the Hutchinson Dictionary of Ideas (1994) that perception is an individual's assessment or personal ideas of the real world. People's perception of the world is necessarily based on incomplete or unreliable information. Perception affects the attitude of people and events.

Griffin supported this notion of perception in 1988: "The most remarkable capacity of the human perceptual system is that it can take in an array of ambiguous information and construct a coherent, meaningful representation of the world. But we generally do not realize how subjective this construction is. Perception seems so immediate to us that we feel as if we are taking in a copy of the true world as it exists." (5).

The BOR Research and Development Committee presented a 30-item list of laboratory tasks, representing six broad categories of competency criteria used for the performance evaluation of laboratory personnel: technical skills; judgement and analytical decision making; knowledge base; communication; teaching and training; and supervision, management, and administration. These categories are used by many
organizations to evaluate the performance of medical laboratory personnel. The majority of employers directly observe a laboratory employee performing selected tasks in assigned areas. They document participation in proficiency testing, quality control, and an external competency assessment program to gauge technical performance as well as cognitive skills (Minard, 1995).

Roles and Responsibilities Determined by the ASCP

Technically trained laboratory workers are usually categorized as technologists, technicians, or specialists, depending upon their training, education and certification. Although job descriptions and responsibilities can overlap, generally specialists have more education and greater depth of experience than technologists do, and technicians are expected to be capable of accepting greater responsibilities. Technologists, or clinical laboratory scientists, as they are designated by the certification agency, are capable of supervising and directing the technical components of even the most complex clinical laboratory. Technicians are often required to work under the direct supervision of technologists or specialists in a hospital or independent laboratory (Crowley & Tillman, 1986).

Each level represents a definition for the six competencies: technical skills, judgement and analytical decision-making, knowledge base, communication, teaching and training, and supervision and management. In evaluating responses across the six competencies, the greatest amount of overlap between MT and MLT occurs in the technically oriented categories: technical skills, knowledge base, and
judgement/analytical decision making. As responsibilities increase in complexity, autonomy, and authority, the differentiation between the MT and MLT increases as well.

The tables D1 to D6 presented in this article establishes a comparison in the ASCP Professional Levels Definitions for each of the six skills in 1982 and 1996. In these fourteen years, levels of competency requirements have changed dramatically for technicians and technologists, while expected competencies of specialists have not changed at all. Medical laboratory technicians are performing more routine testing and medical technologists are becoming increasingly involved in supervision and management. Medical technologists are performing more than expected work and has to involve in training others and getting trained as well. To achieve reliable, cost effective laboratory outcome, it is important that appropriately ordered tests are correctly done, interpreted and reported.

Due to automation manual dexterity is not as great as it was emphasized in 1960s and 1970s. It has been vicious cycle, and technologists are becoming increasingly frustrated and angry at the process (Johns, 1996). Those who are very easily frustrated by the ongoing changes may consider competency assessment as another quality fad and continue business as usual, harboring bitterness about staff and resource cutbacks and business as usual (Berte and Nevalainen, 1988).

It is no longer enough to be technically competent. In order to succeed in competitive environment updated skills, flexibility, and positive attitude is very important (Burke, and Rolen-Mark, 1996). It is important that undergraduate and professional courses are firmly rooted in the basic sciences and liberal arts with professional preparation in clinical laboratory science courses. It is essential that educators encourage
and enhance skills in communication, critical thinking, problem solving, and leadership so laboratory personnel can become confident about what they learn and apply to laboratory tasks and push their professional competency limits to the highest level.

What is Competency?

**Competency** is an outcome or demonstration of adequate ability as measured by a relatively simple, observable behavior that can be clearly identified and precisely measured as to its frequency of performance (Johnson, 1977). Competency defines the ability to carry out the total performance responsibilities of the given practitioner’s generic position (Wilson, 1976). Barrasso in 1981 defined competency as the combined knowledge and skill factors necessary to fulfill work obligations adequately. In other words, competency is the ability to carry out a specific task within given parameters of control. Formal education is, perhaps, the most efficient route to achieving competence. Continuing education ensures its maintenance. Validation of the initial achievement occurs with successful completion of a certification examination.

The ability to communicate effectively is a generally accepted indication of competency in general education. Various authorities of medical laboratory technology educators have provided lists of competencies. Six of the competencies presented by the American Society of Clinical Pathologists are technical skills, judgment and analytical decision making, knowledge base, communication, teaching and training, and supervision and management. Competency assurance is the certainty that the practitioner is able throughout a career to carry out the responsibilities of the position filled (Wilson, 1977b).
What is Competence?

The standard of Training Agency (1988) defines competence as a wide concept, which embodies the ability to transfer skills and knowledge to new situations within the occupational area. It encompasses organization and planning of work, innovation, and coping with non-routine activities. It also includes those qualities of personal effectiveness that are required in the workplace to deal with co-workers, managers, and customers. Price (1978, 1981) defines competence in relation to definition of profession. The definition of profession implies that a practitioner has certain intellectual and technical skills as well as appropriate values and attitudes, which can be defined in terms of competence (Brown, 1978). The competence required for clinical laboratory personnel reflects performance in many dimensions such as knowledge, intelligence, technical skills, problem solving abilities, interpersonal skills, and skills in oral and written expression. If any one of these components is deficient or inadequate, performance by the clinical laboratory employee may be affected. In the clinical laboratory science curriculum, theoretical knowledge, technical skills are emphasized as key elements for developing individual’s competency level. But interpersonal skills, attitudes, values, feelings, and emotions are neglected in professional education and evaluation because of the time and effort necessary to include them. In most cases effective objectives are taught by example only or left to chance (Anderson, 1986).

Competencies may be defined as identified and assessable behaviors reflective of requisite professional knowledge, performance skills, therapeutic applications and attitudes. A competency-based curriculum, then, is a purposefully provided vehicle for
ensuring that learners possess predetermined professional attributes (Broski ET al.,
1977).

**Why Competency Assessment is Necessary?**

The introduction of recent health care reforms such as the Final Rule of Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) released on February 28, 1992; the Final Rule of Occupational Exposure to Blood-Borne Pathogens released on December 6, 1991; the Final Rule of Occupational Exposure to Formaldehyde on May 27, 1992; and the 1992. The rules and regulations cited in the recent literatures are as follows (Best, 1993; George, 1996; Hansen, 1996):

Joint Commission on Accreditation of Health Care Organizations (JCAHO) standards will cause tremendous changes in the next five to ten years. Expanding areas in the clinical laboratory of the twenty-first century will require a higher level of skills, education, and training for medical laboratory personnel to perform highly sensitive and complex assays. The American Society for Medical Technology (ASMT) published a position paper in 1982 charting professional levels of laboratory skills at career entry for CLA, MLT, MT, and specialists in the medical laboratory field. This philosophical delineation of the laboratory personnel categories does not, however, describe differences in required competency levels for the performance of tasks among levels.

Recent literature represents the anticipation of implementing the regulations of the Clinical Laboratory Improvement Amendments of 1988 (CLIA'88), which will address the quality of laboratory testing and consumer safety. The ASCP noted that the statutory revisions proposed would exempt nearly one-half of the nation's laboratories from any quality standards or inspections. Laboratories not inspected under CLIA'88 would be
those that historically have been shown to benefit the most by introducing quality practices. Several issues under CLIA’88 remain to be addressed in future regulations that include personnel standards, changes within the complexity models, and proficiency testing. However, on December 6, 1994, the Health Care Financing Administration (HCFA) and the US Public Health Service did release a final rule recognizing the ASCP as a certifying agency for cytotechnologists. According to the regulation, cytotechnologists certified by the ASCP now meet the cytotechnologist personnel qualification requirements under CLIA’88. In its comments, the government stated that "the qualifications used by the ASCP to qualify an individual as a cytotechnologist include both educational and training components that are similar to or more stringent than the current CLIA requirements for cytotechnologists (Stombler, 1995, p. 104)."

1. The new accreditation standards of the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) emphasize the quality of interdepartmental functions and performance improvement.

2. The JCAHO requires assessment of a person's competency on the job as part of the organization's quality improvement plan.

3. JCAHO requires individual competency to perform tests safely and accurately and to prevent transfer of infection. The laboratory director must maintain competency of staff initially and continuously.

4. The JCAHO team confers with representatives from departments throughout the institute, reviews documentation as a proof of performance, interviews group of staff members, and visits various areas of the institute, especially where staff members directly serve patients.
5. The Clinical Laboratory Improvement Amendments of 1988 (CLIA’ 88) requires that the competency of technical personnel performing moderately complex testing be assessed semiannually during the first year of employment and annually thereafter.

6. CLIA’ 88 requires that facilities participate in proficiency testing (PT) for all regulated analytes. The legislation requires semiannual verification of unregulated analytes.

7. The American Association of Blood Banks (AABB) requires that at least annually, the employee must demonstrate their abilities to perform their duties.

8. AABB requires a quality assessment and improvement program to ensure personnel are knowledgeable and skilled in their assigned duties.

9. College of American Pathologists (CAP) requires a sufficient work force with adequate documented training and experiences to meet the needs of the laboratory with periodic evaluation process.

Thus, The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) recently developed guidelines for clinical laboratory testing requires that for a diagnostic clinical laboratory "personnel responsible for test performance and those responsible for direction/supervision of the testing activity are identified. Personnel performing tests have adequate and specific training and orientation to perform the tests and demonstrate satisfactory levels of competence." The CLIA '88 demands that almost all laboratories require certification based on the scope of testing offered. Physicians' offices will be required to perform regular laboratories that offer similar services.

Although there is no standard number of tests that a physician must perform to acquire or maintain competence, less than one procedure per month is thought to be not enough to
attain competence. For physicians in practice, it is not known with what level of competence simple laboratory procedures are performed.

On the other hand, technologists have moved from being on the bench and running tests to consulting management and troubleshooting. They are also involved in teaching, research, and development, and acting as liaisons for laboratory testing. The education and training of medical laboratory technicians must be strengthened to accommodate these increased demands. The major growth areas of testing in the 1990s will be in flow cytometry, DNA probes, molecular biology, and cytogenetics. These areas will continue to require the education, skills, and training of degree-holding medical technologists. The final impact of CLIA '88 on the clinical laboratory will be the disappearance of on-the-job trainees and certified laboratories by 1997. By 1997, all high-complexity testing laboratory personnel will be required to have associate's degrees in medical laboratory science.

Because CLIA '88 has legalized the use of less highly trained and educated personnel for most technical and administrative laboratory functions except in the cytology laboratory, hospital administrators may no longer see the need to differentiate between the duties and responsibilities of medical technologists and those of technicians. In many hospitals laboratory productivity will decrease and costs will increase as a result. The traditional bachelor's degree in medical technology and four to six years of experience required for supervisory positions may also be downgraded to an associate's degree and two years of experience as a result of CLIA '88. This level of education and training is insufficient to successfully manage a high complexity laboratory setting. Because the quality of laboratory testing is more reliant on the qualifications of the
laboratory supervisor than on any other position, quality will be most affected by the
decreased standards. However, due to risk management factors, laboratories may
continue to hire the most qualified individuals for professional and technical positions.

The important factor that relates to this study is under CLIA '88. Medical
technologists must be assessed for competency semiannually during the first year of
employment and annually thereafter. This assessment must include all of the following:
direct observation, review of intermediate results, blind testing using proficiency testing
samples or internal samples, assessment of problem-solving skills, and monitoring. It
would be the responsibility of the technical supervisor to assure that medical
technologists are competent.

A grandfather provision was also recommended, allowing an individual serving as
a general supervisor on or before the date of the published rule to continue to qualify if he
or she meets the requirements. Such requirements include earning an associate degree in
laboratory science, medical technology, or its equivalent, which is defined as a total of
sixty semester hours; achieving two years of experience as general supervisor; graduating
from high school or attaining an equivalent degree; or receiving laboratory training as
described in the CLIA '88 rule for high-complexity testing, six years of which must be
taken in a supervisory role (McN ett, 1993).

Furthermore, prevention of error is accomplished more through effective training
and continuing education than through surveillance. This system will force more
conscious attention to meeting the expectations of the many clients who must be satisfied
by laboratory services, including patients, physicians, third-party payers, and managed
care organizations.
Modern health care managers are looking for better ways to motivate their employees as well as to document and evaluate employee performance and competencies. The term productivity is familiar to most health care managers, while the term efficiency is less familiar. Productivity and efficiency are unique and valuable indicators of effective employee performance. A performance-based incentive program using an Intensive Pay Index Chart is proposed as a tool through which hospital or company managers can provide technicians or technologists with ongoing motivation to improve both their productivity and efficiency on the job (Lodge, 1991).

Training professionals must be able to respond to the needs of medical laboratory personnel accurately, quickly, and cost-effectively. The best solution is a comprehensive framework that delineates a distinct hierarchy of competencies required by the managers in an organization. The competency domain model used for the Sandwith (1993) study identifies and orders five domains of managerial competency: conceptual/creative, leadership, interpersonal, administrative, and technical.

Substantial modification in the medical technology curriculum is needed to prepare graduates for changing technological regulations, staffing requirements, and operational changes that will occur in laboratory medicine in the 20th century. The interdependent roles of laboratory technicians and technologists need to be more clearly defined. Promotion of a career-ladder should be a continuous pattern, from phlebotomist to laboratory assistant, then from laboratory assistant to technician. Curriculum reforms are also necessary to improve the products and services that laboratory educators provide to their customers (Best, 1993).
How competency is measured?

Performance appraisals have recently become the focus of legal scrutiny. Because the appraisal process may lead to salary adjustments, promotions, opportunities for development, discipline, or even termination, issues such as fairness and discrimination are raised. Snyder (1991) discussed specific constitutional and statutory laws that prohibit discrimination in performance appraisals. In addition, specific rulings from selected court cases illuminate key legal defense factors in performance appraisal. How to assess the competency of each staff member represented below was published in Technical Supervisor responsibilities, Section 493.1451 Federal Register, 1992, and literature written by Allered and Steiner, 1994; Best, 1993; Berte and Nevalainen, 1995; George, 1996; Hansen, 1996; Christian, Peddecord, Francis, and Krolak, 1997.

1. Directly observe the individual performing routine tests including patient or donor preparation, if applicable, specimen handling, processing and testing.
2. Monitor the individual recording and reporting test results.
3. Review the individual's intermediate test results or worksheets, proficiency-testing results, quality control record, and preventive maintenance records.
4. Directly observe the individual checking functions on instruments and maintaining instrumentation.
5. Provide hands on testing to assess test accuracy by requiring that the individual analyze a previously analyzed specimen, internal blind testing samples, or external proficiency-testing sample.
6. Administer written test.
7. Conduct oral test and critique oral responses to procedure queries.
8. Document performance deficiencies or critical incidents related to procedure and use to assess trouble-shooting skills.

9. Assess the individual's problem solving skills for example by case studies.

10. Assess completion of learning activities.

Benefits of Competency program

Competency assessment program would be useful to educators, employers and employees. It provides information of employee's progress, objective documentation for each task performance, and opportunity to employee to evaluate own strength and weaknesses to perform required task for promotion and merit pay increases. Increases supervisor's awareness of employee's performance level and improves communication between supervisors and employees along with job performance and employee satisfaction. Competency assessment program enhances employee understanding of what is expected of them and how they are doing to facilitate employee orientation, training and counseling. Furthermore, it identifies areas that requires training or retraining and encourages employees to read carefully and review critically policies and procedures. In addition to these benefits competency assessment criteria facilitates identification of incompetent employees and provide appropriate training program to improve their performance level. Improves ability to implement corrective action plan and self-improvement opportunities. Improves quality of results, products, and services which results in establishing image of competent staff to outside customers and assures consistency of performance with personnel and instruments. This benefit promotes confidence in peers and fosters better morale (Christian et. al., 1997).
It is essential that progression of competency assessment be documented appropriately. Use of checklists and forms for orientation, initial training checklists, form for direct observation of each test with detail steps for required skills, method of assessment of problem solving skills, and competency assurance checklist. Interactive machines or computer programs to provide feedback and training for theory and practical aspects or case studies for problem solving skills can be sued. Documentation of proficiency testing, and required training to meet the demands during all shifts that include operating new machines, quality control process, and common problem or malfunctions. Checklists or documentation of case study discussions for enhancing trouble-shooting skills demonstrate recognition of the problem and managing it by finding the solution or taking corrective action.

Characteristics of competent staff

Study of Christian et. al (1997) identified seven major characteristics of a competent staff, which are listed as follows:

1. Competent staff produces accurate results in a timely manner.
2. Recognizes problems and errors, trouble shoots, take initiatives and solves problems.
3. Makes no errors or few errors as possible.
4. Possess education, training and continuing education
5. Follows policies and procedures and correctly performs testing.
6. Knows what and why the test is needed to be done.
7. Processes good communication and interpersonal skills.

Failure to provide competent services includes three major principles (Fortune, 1976): Failure to stay current in their field; failure to make day-to-day adjustments to
practice; and failure to one or more fundamental skill areas needed for competent practice. In another words, factors that influence human performance includes but not limited to are:

1. Deficiency in desired to reach optimum performance level, for example and incentive or motivational deficiency.

2. Deficiency in skill or knowledge to understand the information and perform the task.

3. An environment or time constraints due to over work and interference from other job responsibilities.

4. A physical deficiency such as visual acuity, color blindness, physical strength and weakness, and motor dexterity.

5. Deficiency in problem solving and decision making skills.

Allred and Steiner (1994) supports the above principle stated by fortune and states that prevention of problems by adequate initial training is far less costly than subsequent detention of errors and corrective actions, which would have to include some degree of retraining. CLIA regulations require personnel to be completely trained in procedures before performing analysis.

According to Haynes (1991) there are three basic reasons for making an appraisal for employee performance: 1) To encourage good behavior or to correct and discourage substandard performance; 2) To satisfy employees' curiosity about how well they are doing; and 3) To provide a firm foundation for later evaluations in an employee's career. Such matters as pay raises, promotions, transfers, or separation can be handled more smoothly if the employee is aware of the possibilities beforehand.

Elements of performance appraisals include:
1. Competencies are derived from an assessment of the required knowledge, skills and attitudes to perform the task.

2. Competencies are stated in observable and measurable terms.

3. Achievement of competencies are compared and evaluated against performance standards.

4. Committed to write instruction modules containing competency statements, assessment of prerequisite skills, alternate learning activities, feedback and motivational statements for the corrective action.

5. Aimed to improve performance.

6. Regular, periodic scheduling that allow self-paced instruction to master each competency.

5. Prepare set of measurement criteria for each competency level.

Unfortunately, there is no standardized curriculum or certification process for the technologist or technician. There is also no licensure for them in most states, but there are agencies that offer certification based on various educational and experimental requirements. Certification requirements for technologists can range from a baccalaureate degree to on-the-job training (OJT), depending on the agency (e.g., HEW, HHS). The purpose for these examinations is to qualify technical personnel as technologists so independent laboratories can meet Medicare's personnel standards. The diversity in education and experience for persons certified at the technologist and technician levels means that the employer must rely on personal interviews, references, and observation as sources of information about a prospective employee's true capabilities.
CONCLUSIONS AND RECOMMENDATIONS

Conclusions

Some of the challenges clinical laboratories face today is the design and implementation of competency assessment programs. Section 493.1451 (b) (8) of the Clinical Laboratory Improvement Amendments of 1988 (CLIA, 1988) regulations states that technical supervisors are responsible for ensuring that staff maintain competency to perform test procedures and report results promptly, accurately, and proficiently. CLIA (1988) requires that the skills of technical personnel be assessed annually.

The purpose of this study was to compare the perceptions of certified medical laboratory personnel who worked as educators, employers, or practitioners regarding the required competencies of three levels of laboratory personnel: Medical laboratory technician (MLT), medical laboratory technologist (MT) and clinical laboratory Specialist. All respondents were certified by the American Society of Clinical Pathologists.

Descriptive statistics, which included means, standard deviations, ranks, and Spearman Rank-Order Correlation, revealed some degree of discrepancies among the respondents. However, educator's response reflected the appropriateness of the competencies in direct relation to increasing competency level of laboratory roles, Medical Laboratory Technician (MLT), Technologists (MT) and Specialists. Employers and Practitioners, on the other hand, rated MTs and Specialists as almost equal. Furthermore, comparison among the practitioners revealed distinct discrepancies in the perceptions of performing and evaluating laboratory tests. The greatest variation was
noted among practitioners in their rating of competency level required for specialist roles. No apparent differences were found according to demographic factors.

Although educators, employers, and practitioners ranked competency statements slightly differently for each section, it is apparent that all three groups were congruent in their perceptions regarding Section IX, Supervision/Management as the least important and Section I, Specimen Collection, as the most important. However, responses reflected the appropriateness of the competencies for each of the levels of clinical laboratory specialist, medical laboratory technologist and medical laboratory technician, with more competencies and complexity of competencies attributed to the higher levels of practice.

The results of this study will be useful for further investigation and development of required personnel qualifications and their relationship to competency-based performance evaluations intended to maintain quality control practices and laboratory proficiency. These results will be useful in discussing curriculum revision for practitioner training. The study will also provide guidelines for employers to establish distinct levels of competency for three different levels of practitioners in order to utilize the workforce efficiently for what educators have prepared them.

Recommendations

The clinical laboratory field is changing dramatically, and opportunities are shifting as well. It is no longer enough to be technically competent. Increasingly less qualified people are doing less-technical testing, and more experienced people are taking on supervisory roles. Rapid changes in the current health care environment raise the importance of clarifying the roles of MLTs, MTs, and Specialists in the clinical laboratory. These days it is the job of the MT to undergo the greatest change in the new
health care environment and to require technical work and communication, problem solving, management and consultation skills. The survey prepared for this research included the tasks required to be performed by MTs as well as Specialists in the first year on the job were included in the Competency survey. This notion was supported by the comments of one respondent, who described the situation at her community hospital: “The techs who work in this institution must be able to do everything…from drawing blood to being able to answer insurance and billing questions, machine maintenance, QC testing, CAP surveys, inspections by CAP and other agencies, etc.” Furthermore, her comments elaborated the current position of smaller institutes by stating that because of downsizing and budget cuts most small community hospitals are operating with "skeleton staffs" that possess knowledge and abilities in five major areas of the lab.

What is needed first is a clear understanding of the functional role of the laboratory, which includes job description, grouping of tasks involved, required skills, responsibilities and accountability required from the employee or student. Understanding of job description, performance standards, task analysis, amount of judgment and degree of responsibility required for each task permit a job evaluation or competency assessment rating that reflects hierarchical order on a career track.

It is essential that educators and employers understand the functional roles of the different levels of certified personnel to help improve existing educational standards. While educational experiences and academic competency scores should coincide with the performance requirements of an entry-level position, it is the responsibility of the employers to institute these standards.
This research has provided information regarding perceptions of competency levels for three different categories of laboratory personnel: MLT, MT and Specialist. Competency is an interaction of knowledge, intelligence, technical skills, and attitude. If any one of these skills is deficient or inadequate, performance by the clinical laboratory personnel may be affected. CLIA’ 88 and JCAHO require competency assessment documentation for all analysts performing moderately complex testing. However, the precise mechanism of the annual certification of competency is not specified in the regulations but is left up to the individual laboratory (Allred and Steiner, 1994). Many of the competency aspects depend on how training was provided in the fundamentals of laboratory science and in the practical aspects of performing analyses. Along with the results obtained for the research, comparison of the professional definitions provided by the ASCP (1982, and 1996) clearly points in the direction of curriculum reform. Since roles and responsibilities have not been changed since 1982, it is reflected in the results as MTs were almost equally rated as Specialist.

Optimal task performance of clinical laboratory personnel should be the greatest concern of present and future laboratory medicine. The result of this study indicated that, while there is a great deal of overlap in the levels of practice at career entry for MLT, MT and Specialist, perceptions for the performance of tasks are not congruent among each other. These findings were also supported by the comments of one respondent who wrote that "the expertise of the individual is the key to their ability to perform laboratory functions, not their registration level." The respondent explained by personal experience the perception of incongruency between the various levels of laboratory personnel: "I have personally seen ASCP (MT) techs that could not function as well as an MLT. It
really boils down to the individual motivation and intelligence and not what level of education or registry they have." Many respondents felt that specialist competency levels were equivalent to those of MTs. This may indicate that specialists may not have the opportunities to enhance their higher-level skills enough to distinguish their tasks from MT-level performance.

It is certain that our clinical laboratory profession requires a standardized training program. Organizations such as the Health Care Financing Administration (HCFA), the Food and Drug Administration (FDA), JCAHO, the College of American Pathologists (CAP), Commission on Office Laboratory Accreditation (COLA) and CLIA’88 have all set laboratory quality standards that require a prescribed level of employee education and training. However, training and documentation prerequisites in these standards are ambiguous (Berte & Nevalainen, 1996). The discrepancy among practitioners for the entry-level position presents a challenge to educators and to employers. Evaluating the competency level of an individual is the most variable and unknown factor in testing and is therefore the weak link in the analytical sequence.

However, Beck, Doing, and Nettles (1997) reported a comparison between technicians and technologists, resulting in the identification of distinct differences between the roles of different levels of personnel. While skills within the categories of problem-solving, supervision, management, and interpersonal relations are often overlapping between MTs and Specialists, the exclusion of these skills from the Beck, Doing, and Nettles study eliminated the possibility of comparing job similarities between the three levels of laboratory personnel.
Harmening (1995) and others asked program directors to assign a set of competencies to MLTs, MTs, both groups, or neither group. They found the greatest overlap between MLTs and MTs in the areas of technical skills, knowledge base, and analytical decision-making skills. In view of these educators, the largest distinctions between the MLT and MT levels of practice were in the communication, teaching and supervision competencies. They concluded that the program directors in this study could distinguish between the two levels of practice and that the MT has a broader scope of practice than the MLT. However, they did not include the Specialist category as part of the comparison. In addition, the survey items had more than one concept to establish appropriate congruencies for each competency statement. A unipolar question provides more reliable responses than one question containing double or triple concepts (Sudman and Bradburn, 1982, 21, 41, 132-136). Therefore roles and responsibilities should be reevaluated by developing appropriate survey instrument with one question referring to one specific concept.

To meet these challenges, the educational experiences of MLT, MT, and specialist programs and new employee training programs must change. In order to support the self-directed team approach, laboratory personnel at all levels must develop problem solving, interpersonal, and evaluative skills. Beck, Doing, and Nettles (1997) recommended that educators must devote less educational time to teaching technical skills. On the other hand employers must be willing to hire less technically proficient personnel at the entry level if they want MTs to manage the laboratory, relate to other health care workers, evaluate laboratory tests, and educate others. However, that would contradict the results of a study reported by Harmening et.al (1995), Hunter and LoSuituto’s study (1993), and
other research that conclude that performing analytical tests requiring technical skills is the most important job competency for entry-level practitioners. Employers need to acknowledge the training provided for each level and utilize it by hiring them for that purpose. For example, if MTs are trained less in technical skills and more in supervisory and teaching skills, then they should hire them to perform those tasks. Employers need to provide new orientation programs that can allow new employees to rotate through technical duties in addition to quality assurance, evaluation of results, personnel management, purchasing reagents and instruments, etc.

The incentive for this sort of change involves the employers' and educators' combined effort to build the bridge between the understanding of level of training provided by the educators and expectations of the employers for entry-level personnel. Educators must find a way to make sound decisions regarding curriculum content to prepare students for entry-level positions that meet the required expectations of employers for competency level. Educators and employers need to reengineer the laboratory work force to create appropriate distinctions between the levels of practice and to realize that educators are preparing them with distinct levels of skills. As stated by one of the respondents in this study, in order to decrease the frustration and dissatisfaction levels of employees; and to retain qualified, experienced, knowledgeable personnel who wants to recognize their skills and knowledge in the workplace expectations of educators, employers and practitioners should be unified: "I have given this survey a lot of thought and time because I think technicians are being given too much responsibility for their training and we need to unify expectations." However any person who has been trained only in one institute with higher levels of competency should not be considered a
"technologist" capable of across-the-board laboratory testing. Eventually an industrious person may acquire depth and breadth of knowledge in each discipline and then can be considered as qualified as one who acquired knowledge of each discipline in formal course work at a medical technology school (LaMotte, 1981).

Frustration exists within all three levels of laboratory personnel because the assigned duties do not always reflect certification level. Although some entry-level MLT personnel can perform tasks at specialist-level competency, opportunities for them to achieve higher levels of authority are minimal. This same principle also applies to specialists who may be qualified and trained to perform at the highest level of competency, yet find their tasks equivalent to MT-level duties. As a result, specialists often decide to change career goals in which they can perform according to their competency level. Otherwise, those who remain in the field as MTs may experience a lack of motivation to perform at the levels they are qualified for. Students of the medical technology programs and Specialist programs should also focus of a didactic curriculum that includes courses in hematology, blood banking, chemistry, and microbiology, and get exposure to specialized areas such as flow cytometry, molecular biology, supervision and management, and teaching and consulting. They should also broaden their scope with computer and financial management of the health care industry.

Thus, result of the comparison of perceptions of competence for medical laboratory personnel and provided review of the literature would be extremely valuable in developing curriculum for the medical technology programs. It is important that educational systems incorporate continuous education and clinical laboratory work experience to facilitate the completion of higher-level degrees (i.e. MLT to MT, MT to
Specialist). Computer courses would be an excellent method to promote the education of those employees who do not have the opportunity to set aside time for attending in-class courses. In addition to certification, objective competency assessment scales should be used to determine the roles and responsibilities of each of the three medical laboratory positions and to decrease frustration levels among the employees.

The comparison of ASCP Professional Levels Definitions, 1982 and 1996
<table>
<thead>
<tr>
<th>Table D-1</th>
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<tr>
<td><strong>ASCP Professional Levels Definitions, 1982 and 1996: Knowledge</strong></td>
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<table>
<thead>
<tr>
<th></th>
<th>1982</th>
<th>1996</th>
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<tbody>
<tr>
<td>Technician</td>
<td>• Has a working comprehension of the technical and procedural aspects of laboratory tests.</td>
<td>• Has a working comprehension of the technical and procedural aspects of laboratory tests.</td>
</tr>
<tr>
<td></td>
<td>• Maintains an awareness and complies with safety procedures and ethical standards of practice.</td>
<td>• Correlates laboratory tests to disease processes and understands basic physiology, recognizing appropriate test selection and abnormal test results.</td>
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</tbody>
</table>
| **Technologist** | • Understands the underlying scientific principles, as well as of the technical and procedural aspects of laboratory testing.  
• Has a general comprehension of the physiologic, biochemical, immunologic, microbiologic, and genetic factors that affect health and disease, laboratory tests, and the importance of laboratory tests to medical care.  
• Is familiar with the various services available in the hospital and has an appreciation of the roles and relationships of paramedical and other health-related fields. |
| **Specialist** | • Has knowledge of advanced scientific principles, as well as of the technical, procedural, and research aspects of laboratory testing in the specialty area and of factors that influence disease processes and laboratory tests.  
• Has knowledge of the structure and function of the organization, principles of management and education, as well as of the roles of other members of the health care team. |

• Understands the underlying scientific principles of laboratory testing as well as the technical, procedural, and problem-solving aspects.  
• Has a general comprehension of the many factors which affect health and disease, and recognizes the importance of proper test selection, the numerous causes of discrepant test results, and ethics including result confidentiality.  
• Correlates abnormal laboratory data with pathologic states, determines the validity of test results and the need for additional tests.  
• Understands and enforces safety regulations, uses statistical methods and applies business and economic data in decision-making.  
• Has an appreciation of the roles and interrelationships of paramedical and other health-related fields and follows the ethical code of conduct for the profession.  

• Has knowledge of advanced scientific principles as well as the technical, procedural, and research aspects of laboratory testing in the specialty area and of factors which influence disease processes and laboratory tests.  
• Has knowledge of the structure and function of the organization, principles of management and education, as well as the roles of other members of the health care team.
<table>
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<tr>
<th></th>
<th>1982</th>
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<tbody>
<tr>
<td><strong>Technician</strong></td>
<td>• Can read and follow directions and perform those tests in a</td>
<td>• Comprehends and follows procedural guidelines of laboratory tests to include: 1) quality control monitoring; 2) computer applications; 3) instrumentation troubleshooting; and 4) specimen collection and processing requirements.</td>
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<td>clinical laboratory that are considered to be of a straightforward</td>
<td></td>
</tr>
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<td></td>
<td>nature.</td>
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<td></td>
<td>• Has a practical understanding of quality control that is</td>
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<td>sufficient to enable him/her to determine whether or not tests are</td>
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<td>within limits and to make requisite adjustments according to</td>
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<td></td>
<td>specified procedures.</td>
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<tr>
<td></td>
<td>• Is capable of performing simple instrument maintenance.</td>
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<tr>
<td><strong>Technologist</strong></td>
<td>• Is capable of performing technically demanding tests.</td>
<td>• Can perform and interpret standard, complex, and specialized tests.</td>
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<tr>
<td></td>
<td>• Has an understanding of quality assurance sufficient to enable him/</td>
<td>• Has an understanding of quality assurance sufficient to implement and monitor quality control programs.</td>
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<tr>
<td></td>
<td>her to monitor and implement quality control programs.</td>
<td>• Can participate in the introduction and implementation of new</td>
</tr>
<tr>
<td></td>
<td>• Can participate in the introduction and implementation of new</td>
<td>procedures and in the evaluation of new instruments.</td>
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<tr>
<td></td>
<td>procedures, and in the evaluation of new instruments.</td>
<td>• Evaluates computer generated data and troubleshoots problems.</td>
</tr>
<tr>
<td></td>
<td>• Has a basic knowledge of accuracy, precision, normal ranges, and</td>
<td>• Understands and uses troubleshooting, validation, statistical,</td>
</tr>
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<td>correlation with existing methods.</td>
<td>computer, and preventative maintenance techniques to insure proper</td>
</tr>
<tr>
<td><strong>Specialist</strong></td>
<td>• Can perform all laboratory tests and appropriate equipment</td>
<td>laboratory operation.</td>
</tr>
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<td></td>
<td>maintenance in the</td>
<td></td>
</tr>
</tbody>
</table>
specialty area.

- Has the knowledge, ability, and technical skill to research, develop, implement, and evaluate new and existing methodologies, including instrumentation and quality assurance.

specialty area.

- Has the knowledge, ability, and technical skill to research, develop, implement and evaluate new and existing methodologies, including instrumentation and quality assurance.
Table D-3

ASCP Professional Levels Definitions, 1982 and 1996: Judgment and Decision-Making

<table>
<thead>
<tr>
<th></th>
<th>1982</th>
<th>1996</th>
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<tbody>
<tr>
<td>Technician</td>
<td>• Can recognize the existence of common procedural and technical problems to take corrective action according to predetermined criteria.</td>
<td>• Recognizes the existence of procedural and technical problems and takes corrective action according to predetermined criteria. • Prioritizes test requests to maintain standard patient care and maximal efficiency.</td>
</tr>
<tr>
<td></td>
<td>• Prioritizes test requests to maintain standard patient care and maximal efficiency.</td>
<td>• Prioritizes test requests to maintain standard patient care and maximal efficiency.</td>
</tr>
<tr>
<td>Technologist</td>
<td>• Can exercise initiative and independent judgment in dealing with the broad scope of procedural and technical problems. • Can participate in, and may be delegated the responsibility for decisions involving quality control programs, instrument selection, preventative maintenance, safety test procedures, and reagent purchases.</td>
<td>• Can exercise initiative and independent judgment in dealing with the broad scope of procedural and technical problems. • Can participate in, and may be delegated the responsibility for decisions involving: quality control/quality assurance programs, instrument and methodology selection, preventative maintenance, safety procedures, reagent purchases, test selection/utilization, research procedures, computer/statistical data.</td>
</tr>
<tr>
<td></td>
<td>• Can participate in, and may be delegated the responsibility for decisions involving quality control programs, instrument selection, preventative maintenance, safety test procedures, and reagent purchases.</td>
<td>• Can participate in, and may be delegated the responsibility for decisions involving quality control programs, instrument selection, preventative maintenance, safety test procedures, and reagent purchases.</td>
</tr>
<tr>
<td>Specialist</td>
<td>• Can implement and delegate decisions regarding laboratory operation and of exercising independent judgment in problem solving. • Can anticipate and respond to unique situations regarding patients and/or samples in a laboratory setting. • Can participate in policy decisions affecting laboratory performance or laboratory personnel in the specialty area.</td>
<td>• Can implement and delegate decisions regarding laboratory operation and of exercising independent judgment in problem solving. • Can anticipate and respond to unique situations regarding patients and/or samples in a laboratory setting. • Can participate in policy decisions affecting laboratory performance or laboratory personnel in the specialty area.</td>
</tr>
</tbody>
</table>
Table D-4

ASCP Professional Levels Definitions, 1982 and 1996: Communication

<table>
<thead>
<tr>
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<th>1982</th>
<th>1996</th>
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<tbody>
<tr>
<td>Technician</td>
<td>• Communicates straightforward information, e.g., reports test</td>
<td>• Communicates test results, reference ranges and specimen requirements to authorized sources.</td>
</tr>
<tr>
<td></td>
<td>results and quotes ? ranges and specimen requirements.</td>
<td>• Preparers drafts of procedures for laboratory tests according to standardized format.</td>
</tr>
<tr>
<td>Technologist</td>
<td>• Communicates technical or general information to medical, paramedical, or lay persons, including problems or matters of a scientific, technical, and/or administrative nature.</td>
<td>• Communicates pertinent technical information to medical, paramedical, or lay individuals through lectures, conferences, work group interaction, memberships, publications, legislative activities, and continuing education.</td>
</tr>
<tr>
<td>Specialist</td>
<td>• Can communicate in depth with other health care personnel on the application and validity of laboratory data, as well as on the policies and operation of the specialty area.</td>
<td>• Can communicate in depth with other health care personnel on the application and validity of laboratory data as well as the policies and operation of the specialty area.</td>
</tr>
<tr>
<td></td>
<td>• Can represent the specialty area to the community at large.</td>
<td>• Can represent the specialty area to the community at large.</td>
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</tbody>
</table>
Table D-5

ASCP Professional Levels Definitions, 1982 and 1996: Teaching and Training Responsibilities

<table>
<thead>
<tr>
<th>1982</th>
<th>1996</th>
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<tbody>
<tr>
<td>Technician</td>
<td>Technician</td>
</tr>
<tr>
<td>• Is capable of demonstrating ? technical skills.</td>
<td>• Trains new technicians and provides information to the patient and public as needed and participates in continuing education lectures and conferences for departmental personnel, and demonstrates technical laboratory skills to students and new employees.</td>
</tr>
<tr>
<td>Technologist</td>
<td>Technologist</td>
</tr>
<tr>
<td>• Can provide instruction in the basic theory, technical skills, and application of laboratory test procedures.</td>
<td>• Provides instruction in theory, technical skills, safety protocols, and application of laboratory test procedures.</td>
</tr>
<tr>
<td>• May participate in the evaluation of the effectiveness of educational programs.</td>
<td>• Provides continuing education and professional development for laboratory personnel.</td>
</tr>
<tr>
<td>• May participate in the evaluation of the effectiveness of educational programs.</td>
<td>• May participate in the evaluation of the effectiveness of educational programs.</td>
</tr>
<tr>
<td>Specialist</td>
<td>Specialist</td>
</tr>
<tr>
<td>• Can plan, implement, and evaluate effective educational programs.</td>
<td>• Can plan, implement, and evaluate effective educational programs.</td>
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Table D-6

ASCP Professional Levels Definitions, 1982 and 1996: Supervision and Management

<table>
<thead>
<tr>
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<th>1982</th>
<th>1996</th>
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<tbody>
<tr>
<td>Technologist</td>
<td>• Has a basic understanding of management theory and functions.</td>
<td>• Has an understanding of management theory, economic impact and management functions.</td>
</tr>
<tr>
<td></td>
<td>• Can participate in and develop responsibility for establishment of technical and administrative procedures.</td>
<td>• Participates in and takes responsibility for establishing technical and administrative procedures, quality control/quality assurance, standards of practice, safety and waste management procedures, information management and cost effective measures.</td>
</tr>
<tr>
<td></td>
<td>• Can supervise technicians, aides, and clerical personnel as directed.</td>
<td>• Supervises laboratory personnel.</td>
</tr>
<tr>
<td>Specialist</td>
<td>• Can perform and direct administrative functions in the overall operation of the laboratory in the specialty area.</td>
<td>• Can perform and direct administrative functions in the overall operation of the laboratory in the specialty area.</td>
</tr>
<tr>
<td></td>
<td>• Can provide direct supervision of other personnel in that discipline.</td>
<td>• Can provide direct supervision of other personnel in the discipline.</td>
</tr>
</tbody>
</table>
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