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ABSTRACT

The Bioscience Industry Skills Standards Project (BISSP) is developing national, voluntary skill standards for technical jobs in biotechnology and pharmaceutical companies and clinical laboratories in hospitals, universities, government, and independent settings. Research with employees and educators has pinpointed three issues underscoring the need for skill standards in the bioscience industry: new employees with four-year college degrees are not prepared for entry-level technical jobs; programs fail to prepare people for specific occupations because educators do not understand the skills occupations require; and college graduates dissatisfied in entry-level positions result in high turnover rates. The bioscience skills standards development process involved a number of processes: identifying a learning occupation; conducting and validating job analysis; researching current education and training programs; developing and validating skill standards; and developing performance criteria and assessment methods. Each of the 34 integrated skill standards contains these components: scenario; workplace setting; key competency areas; tasks for performing routine procedures; tasks for solving problems; skills, knowledge, and attributes; and tools and equipment. They are designed to assist employers, educators, and current and future workers. Guidelines are being developed to implement the skills standards. (Appendixes include the validation process and results, skill standards charts and matrices, and current certification processes.) (YLB)

GATEWAY TO THE FUTURE

SKILL STANDARDS FOR THE BIOSCIENCE INDUSTRY

For Technical Workers in Pharmaceutical Companies, Biotechnology Companies, and Clinical Laboratories

Education Development Center, Inc.

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SKILL STANDARDS FOR THE BIOSCIENCE INDUSTRY

For Technical Workers in Pharmaceutical Companies, Biotechnology Companies, and Clinical Laboratories

APRIL 1995 EDUCATION DEVELOPMENT CENTER, INC.
THE INSTITUTE FOR EDUCATION AND EMPLOYMENT

ACKNOWLEDGMENTS

The work of the Bioscience Industry Skill Standards Project is a broad-based, spirited collaboration of nearly 1,000 people and 300 organizations, representing all parts of the bioscience industry (technical workers, supervisors, and managers), educators (teachers and administrators), labor, and local and state government. We have included in this book the names of the people and organizations that have participated most actively—on the project's Technical Committee, as technical advisors, and as participants in one or more of the many workshops we have held to develop the skill standards. Some of the project participants, listed in Appendix D, have generously given many days of assistance. Without the combined expertise of all these people, we could not have developed these Integrated Skill Standards, which, we think, capture the true nature of the work that beginning-level technical specialists do in this complex, skill intensive industry.

There are several people and organizations that deserve special acknowledgment. Debra Nolan and Carolyn Lee, our two Project Officers in the Department of Education, have assisted us in many ways throughout the project. We also thank Betsy Brand, Assistant Secretary of Education under the Bush Administration, and Augusta Souza Kappner, Assistant Secretary under the Clinton Administration, as well as Michaela Meehan at the Department of Labor.

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We look forward to continued work with many of these people to develop education programs and systems that translate the Bioscience Integrated Skill Standards from paper to action.

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The *Oxford English Dictionary* traces the development of the term "standard" to medieval times, when soldiers quickly lost sight of their leaders. When going into battle, leaders began to carry with them "standards"—tall stakes to which a pennant was attached. During times when neither side could tell who belonged to whom, leaders planted these standards, which, by virtue of their height, stood out in the landscape, provided a direction for the soldiers, and showed what ground had been captured.

Executive Summary

The National Context

Over the past decade our nation's policymakers, employers, teachers, students, and parents have become increasingly aware of the need to raise both the academic achievement levels and the work skills of people graduating from our schools. The development of academic standards for various grade levels in science, mathematics, English, social studies, and other subject areas should help to increase academic achievement. New or revised legislation, such as the Carl D. Perkins Vocational and Applied Technology Education Act, the School-to-Work Opportunities Act, and the Goals 2000 Educate America Act are intended to raise both work and academic skills.

In 1992 and 1993, the U.S. Departments of Education and Labor funded 22 projects—including the Bioscience Industry Skill Standards Project—to develop national, voluntary skill standards for a variety of industries. These projects identify what people must know and be able to do to qualify for beginning- to middle-level occupations in various sectors of our nation's economy. This information, generated through strong collaboration between industry, educators, and labor, provides a sound starting point for the development of education and training programs that will prepare people for employment and career advancement and meet the country's need for knowledgeable, high-skilled workers.

Although industry skill standards cannot, by themselves, create more high-skilled jobs, their use by employers and educators can help ensure that more people—particularly those who have been underserved by our education system—are prepared for high-skilled, high-wage jobs.

The Bioscience Industry

The Bioscience Industry Skill Standards Project focuses on technical jobs found in biotechnology and pharmaceutical companies, and clinical laboratories in hospitals, universities, government and independent settings. The bioscience industry is at the forefront of some of the most exciting scientific innovations of our time. During the past two decades, tremendous changes have occurred in the biological sciences regarding the understanding of biological processes, the techniques available to uncover these mysteries, and the potential impact these discoveries and their applications will have on the world.

The implications of these changes for employment in bioscience laboratories are highly significant for the future of the U.S. economy. As Louis Richman states in a recent article in *Fortune*:

> *[There is a] large and rapidly growing population of technicians—a new worker elite who are transforming the American labor force and potentially every organization that employs them. As the farmhand was to the agrarian economy of a century ago and the machine operator was to the electromechanical industrial era of recent decades, the technician is becoming the core employee of the digital Information Age.*[1]

The development of national, voluntary, and industrywide skill standards provides both educators and employers with practical tools for helping people gain access to the skills and knowledge they need to enter into this growing and promising industry.

Why Are the Skill Standards Needed in the Bioscience Industry?

Our research and discussions with employees and educators across the country have pinpointed three issues underscoring the need for skill standards in the bioscience industry.

1. Many new employees with four-year college degrees in biology, chemistry, or related fields are not interested in or sometimes not prepared for the beginning-level technical jobs they enter.

Managers often state that they tend to use the four-year college degree as a "de facto" skill standard. At the same time, while college courses provide the theoretical knowledge required, graduates often lack the practical, entry-level hands-on experience needed in the workplace.

Responses to a project survey of more than 150 bioscience managers and technical workers indicated that all of the work performed by a Bioscience Technical Specialist I, as identified by experienced workers in the project's Job Analysis Workshops, can be learned in a well-planned education program during a two- to three-year period. Such a program could begin in high school and include both classroom learning and applied, work-based experience and continue on in a vocational education or two-year or four-year academic institution.

2. Many programs designed to prepare people for specific occupations sometimes fail to do so because their planners and teachers do not understand what skills the occupations require.

Employers and educators report that the most successful work preparation programs are those designed with the active participation of industry. Our process of planning and implementing education/training programs to meet the skill standards relies heavily on continuous collaboration among educators and

> *There is a well-documented need for employers and educators to speak the same language. It does a disservice to students to educate them in the name of career advancement and then not adequately prepare them to actually perform on the job. Efforts such as the Bioscience Skill Standards Project will help ensure that our students are employable upon graduation anywhere in the nation.*
>
> Leslie Snider, Ph.D.
> Professor of Biology
> MiraCosta College

industry to ensure that program graduates will meet all current and evolving industry skill requirements.

3. Many college graduates experience a high degree of dissatisfaction in entry-level positions, resulting in high turnover rates. Employers often spend large sums recruiting and training replacement workers.

The costs to employers of retraining and added recruitment, and the costs to beginning workers of misused education investment are wasteful, and should be unnecessary.

Increasingly, employers are realizing they should place value not on inputs, such as time spent in school, but on outcome-based criteria—demonstrated mastery of knowledge, skills, and behaviors required to do the job. New workers who meet these outcome-based criteria will more likely be hired for beginning-level jobs and will be better prepared to work efficiently and interact with their coworkers. Their solid grounding in the fundamentals of the industry will also make them more eligible to work in various jobs within the organization and qualify for advancement to higher-level positions.

Project Goals and Guiding Principles

The first goal of the Bioscience Industry Skill Standards Project is to create national, voluntary skill standards for a broad cluster of beginning- to middle-level technical occupations in the bioscience industry. These skill standards will be benchmarks for educational systems to prepare people with basic work skills and industry-specific, technical skills, knowledge, and behaviors required to qualify for jobs and career opportunities in this high-skilled, high-growth industry.

The second goal is to promote the acceptance and creative use of the standards by employers, educators, unions, and others. To accomplish these goals, the project has reached out to and involved all of these stakeholder groups in the development of the standards.

To help achieve these two goals, five principles have guided the process of creating and implementing the skill standards.

1. **Industry, labor, and education must work together** to ensure work-related education prepares people for requirements of real-life work.

> *This represents a first for industry and academia to partner in the development of core curricula for the pharmaceutical technologist of the future.*
>
> Kenneth A. Martlage
> Manager, Performance Improvement
> Eli Lilly and Company

2. **Experienced workers are the experts** in regard to their jobs and can identify the work performed in their occupations and required skills, knowledge, and behaviors.

3. **People should be prepared for a "Learning Occupation,"** which encompasses skills and knowledge needed for a number of related occupations throughout the industry. This opens up a broad range of work opportunities and makes people more adaptable for various jobs in an organization.

4. **"Integrated Skill Standards,"** rather than compartmentalized, task-focused skill standards, are needed to prepare people for real-life work. Integrated Skill Standards place duties and tasks, and the know-how needed to perform them, in the context of real work scenarios which require decision-making and problem solving.

5. **School- and work-based learning should begin in the elementary grades** where real-life work applications are incorporated into academic subjects and students learn in schools and in work-based settings.

The Bioscience Skill Standards Development Process

The project engaged in the following process to develop and implement the bioscience skill standards.

- **Identified a Learning Occupation.** Industry advisors helped us identify a Learning Occupation, *Bioscience Technical Specialist* I, which combines nearly 20 related occupations sharing a common core of required skills, knowledge, and behavioral attributes.

- **Conducted Job Analysis Workshops.** Beginning-level technical specialists from varied workplaces around the country participated in a series of workshops to identify the job functions and tasks performed by a Bioscience Technical Specialist I, as well as the requisite knowledge, skills, attributes, and tools and equipment.

- **Validated the job analysis.** The combined results of the job analysis process were validated by a survey of more than 150 bioscience technicians, supervisors, and managers. Respondents rated the importance of each task to the Learning Occupation, identified the amount of combined education and work experience needed to learn each task, and indicated whether the importance of each task was expected to increase or decrease in the future.

- **Researched current education and training programs.** Project staff are identifying and reviewing high school and postsecondary bioscience education and training programs currently operating. A report will be issued by May 1995.

- **Developed the skill standards.** Industry representatives and bioscience educators worked together for several months to create 34 Integrated Skill Standards, each based on a real-life work scenario that includes a routine procedure, a problem, and the tasks, skills, knowledge, and behavioral attributes required to master the scenario.

- **Validated the skill standards.** The draft skill standards were reviewed and validated by industry representatives and bioscience educators in eight workshops held around the country. Reviewers assessed the reality, clarity, and appropriateness of the scenarios for beginning-level technical workers. They also reviewed each part of the skill standards for accuracy and completeness, making revisions and additions where necessary.

- **Developed performance criteria and assessment methods.** A team of industry representatives and bioscience educators determined criteria for assessing mastery of the tasks and identified appropriate assessment methods. At present, the team is working to determine performance criteria and assessment methods for each skill standard in its entirety.

The Integrated Skill Standards Format

Each of the 34 Integrated Skill Standards contains the following components:

- **A scenario** presenting a real-life work situation and including a routine procedure and an unanticipated problem the student must master

- **The workplace setting** in which the scenario would occur—research and development, manufacturing, clinical laboratories, or generic (applicable to all settings)

- **Key competency areas** representing the Bioscience Technical Specialist I's major areas of responsibility within the context of the scenario

- **Tasks for performing routine procedures,** which must be mastered to successfully perform the scenario's routine procedure

- **Tasks for solving problems**, which must be mastered to solve the scenario's problem

- **Skills, knowledge, and attributes** (general and industry-specific) necessary to master the scenario's routine procedure and problem

- **Tools and equipment** routinely used by technical specialists in bioscience work

Who Can Use the Integrated Skill Standards?

The Integrated Skill Standards have been designed to assist employers, educators, and current and future workers.

Employers. The standards will guide employers as they interview prospective employees, assess the readiness of current employees to move to higher positions, develop (in partnership with educators) programs to prepare future employees, and conduct in-house training.

The acceptance of Integrated Skill Standards by employers will require that traditional job descriptions and evaluations shift their emphasis from time spent in school to what a person knows and can do in the work setting. This includes "connecting" skills such as problem solving, decision-making, teamwork, and resource management.

Educators. The standards will serve as benchmarks for educators to create and continuously update education/training programs and performance criteria that meet current and evolving labor market needs. This will ensure that students are prepared for skilled occupations with career opportunities and/or for advanced education and training.

Widespread adoption of Integrated Skill Standards by educators will require modification of traditional task-focused teaching and assessment to include project- and team-based learning, work experience, emphasis on problem solving, and integration of academic and work-related learning.

Current and future workers who need training or retraining. The standards will help workers understand what they must know and be able to do to enter or advance in the bioscience industry. Program graduates will receive joint certification from education and industry—portable credentials that recognize their academic and technical mastery and are acknowledged by employers throughout the country.

> *The successful high-performance, high-wage workplace draws its strength from workers' broad skills, knowledge, and judgment. A set of national skill standards helps ensure that workers will have opportunities for education and skill development that will not only develop a more productive economy, but also produce secure, well-paying jobs.*
>
> John J. Sweeney
> International President
> Service Employees International Union, AFL-CIO, CLC

Guidelines for Implementing the Skill Standards: Continuing Work and Future Products

The real significance of the Integrated Skill Standards depends on the degree to which they are used to develop innovative education and training systems—in both industry and education—that prepare people for successful work experiences. To facilitate the use of the standards by these groups, the project's Education and Training Team is developing (1) guidelines for creating locally based consortia of stakeholders to plan and implement education systems and (2) program guidelines, suggested curriculum units, and strategies for using these materials in schools, workplaces, and other learning venues.

The Education and Training Team includes specialists in secondary and postsecondary education, industry and union representatives, and people with knowledge of assessment, certification, and related topics. They come from every area of the country.

The Education and Training Team is working in six specialty areas: K–8 and high school curriculum development; postsecondary curriculum development; work-based learning; teacher, career counselor, and workplace mentor development; assessment and certification; and articulation.

Among the many materials being developed by the team are the following:

- Bioscience applications for academic subjects in elementary and middle grades
- Curricula for industry awareness, orientation, and exploration for all students in middle grades
- Examples of teaching and learning methods that emphasize integrated, active learning (e.g., project-based learning, problem-centered learning, team-based teaching and learning), rather than rote acquisition of information
- Guidelines for teacher and career counselor development to (1) learn about the bioscience industry (workshops, industry internships, partnering with industry mentors) and (2) create and use recommended methods (problem-centered, project-based, team teaching)
- Model work-based learning experiences coordinated with classroom learning
- Training methods for work-based mentors and student supervisors
- Guidelines for workers to teach concepts and procedures in schools
- Criteria for certification that dovetail with existing certifying and licensing mechanisms
- Guidelines for skill assessment, including recommendations for use of computer-based assessment tools
- Methods for crediting people for relevant work experience and training in related fields
- Recommended uses of skill standards by employers to prepare workers to move up the bioscience career "lattice"

The expertise within the Education and Training Team's work is supplemented by Education Development Center, Inc. (EDC), an international nonprofit research and development organization with extensive experience in education planning and implementation. This experience includes the efforts of EDC's Institute for Education and Employment, which has worked in communities with consortia of educators, employers, workers, and other stakeholders to develop and implement education systems to prepare people for skilled jobs and careers.

The information being developed by project staff and the Education and Training Team will be compiled into *Guidelines for Education and Training*, to be published by September 1995. Most of its recommendations, sample curricula, and school- and work-based teaching strategies will be appropriate for use in any school-to-work or industry-specific education/training system.

The project has discussed working with several consortia and plans to develop collaborative education/industry systems in various sites to realize the bioscience skill standards. The education/training systems developed by these consortia will follow the same five guiding principles that have shaped the development of the bioscience skill standards.

The National Context

- **Research, Legislation, and Policies Related to Skill Standards Development**

During the past decade in the United States, great concern has been focused on the need to raise both the academic achievement levels and the work skills of people graduating from our national education system. There have been two reasons for this concern. The first is the realization that the education system is failing to serve the majority of the population, thereby contributing to inequalities of opportunity. Specifically, an estimated 75 percent of young people who will not complete four years of college are mastering neither the academic skills nor the work-related skills required to obtain well-paying jobs with career opportunities. This situation was spotlighted most effectively by the report *The Forgotten Half: Non-College Bound Youth in America.* [2]

The second is the need to educate all of our people to participate in a changing global economy in which high quality and efficiency are necessary to compete. In a competitive global market, workers are required to have strong academic, technical, and interpersonal skills in order to outperform workers in other countries. *America's Choice: High Skills or Low Wages* [3] identified the choice the United States needs to make to regain its competitive position in the world economy. It emphasizes the need for work organizations to move toward "high performance" and for educators to prepare people for high-skilled jobs. The report *What Work Requires of Schools* [4] identified basic work-related skills, such as communication, critical thinking, resource management, and problem solving, that all people in the workforce need, regardless of occupation or industry.

The responses to these two emphases—the need to better educate underserved populations and to increase the competitive global market advantage of the workforce—have resulted in the passage of several pieces of legislation and the creation of a number of education reforms. These include the Carl D. Perkins Vocational and Applied Technology Education Act (1990), which mandated integration of academic and vocational education and funded "Tech Prep" programs; the School-to-Work Opportunities

Act (1994), which provides funding for state and local public/private planning and implementation of programs; and the Goals 2000 Educate America Act (1994), which sets eight general education goals, including that every adult be able to compete in the workforce.

Academic standards have been developed for various grade levels in science, mathematics, English, social studies, and other subject areas. Tech-prep programs, typically spanning the last two years of high school and one to four years of postsecondary school, have combined academic and work-related education to prepare people for skilled occupations.

In 1992 and 1993, the U.S. Departments of Education and Labor funded 22 projects to develop national, voluntary skill standards in a variety of critical industries. The Bioscience Industry Skill Standards Project at Education Development Center, Inc. (EDC) is one of these. The industry skill standards projects are identifying what people need to know and what they need to be able to do to qualify for beginning- to middle-level occupations in a range of industries. The information has been generated through strong collaboration between industry, labor, and educators. It provides a sound starting point for the development of education and training programs that will prepare people for employment and career advancement. The National Skill Standards Board, created by the Goals 2000 legislation, will have an important fund of information upon which to draw about processes for building industry-education partnerships and about the specific work content of occupations in various industries. This information can be coordinated with ongoing efforts to develop standards for academic content areas.

High-quality industry skill standards will foster high expectations for education and serve as guideposts for state and local development of high-quality education. Industry skill standards cannot, by themselves, create more high-skilled jobs. However, their implementation will clarify goals for students. This should help ensure that more people, particularly those who have been underserved by our education system, are prepared for the high-skilled jobs that are created. As more employers realize the need for creating high-skilled jobs, more of the workforce, as well as the country's economy, will benefit.

Bioscience: An Industry of the Future

- **Bioscience Industry: Descriptions, Economic Data**

The Bioscience Industry Defined

The bioscience industry, as defined in this project, includes biotechnology and pharmaceutical companies, as well as clinical laboratories in hospitals, universities, government, and independent settings. In each of these industry subsectors, there is a need for workers in beginning-level technical occupations in research and development, quality systems, production, clinical testing, and diagnostic work.

The project focuses only on the work of occupations in the medical applications segment of biotechnology. It does not focus on all the segments that pertain to agriculture, energy, or environment. It also does not focus on the instrumentation segment of the pharmaceutical sector. Likewise, the project does not cover technical occupations that involve direct service provision (e.g., radiology). However, many of the job functions, tasks, skills, and knowledge areas identified in this project will apply to many occupations in these related fields. This cross-applicability lends support to arguments for creating introductory, work-related education programs at the high school level that cut across traditional industry boundaries and concentrate on more generic work-related knowledge, skills, and behaviors.

The Future of Bioscience

The bioscience industry is at the forefront of some of the most exciting scientific innovations of our time. During the past two decades, tremendous changes have occurred in the biological and chemical sciences regarding the understanding of life science processes, the techniques available to uncover these mysteries, and the potential impact these discoveries and their applications will have on the world. Biotechnology, the term used to describe these techniques, has had a revolutionary effect on the bioscience industry and on clinical and research

laboratories. The extent to which this science is dramatically influencing our everyday lives will accelerate further as new research findings are applied to real-life situations. The ability to engineer the most basic components of a living cell implies changes for the way science is pursued in diverse areas, including human health care, agriculture, animal health care, the chemical and fuel industry, and environmental management.

Some of the greatest progress has been shown in medical research and applications in human health care. New understanding of the human body, coupled with innovative technologies, is responsible for vast strides in the diagnosis, treatment, and prevention of disease. Products are now available for the treatment of heart attacks, cancer, AIDS, diabetes, hemophilia, anemia, and tissue rejection. DNA probes are used to detect a variety of genetic diseases, including Huntington's disease, Duchenne muscular dystrophy, and cystic fibrosis, as well as infectious agents, including viral and bacterial infections and salmonella contamination of food. The potential of monoclonal antibodies is being realized in products that test for sexually transmitted diseases, hepatitis B, and cystic fibrosis and in home detection kits for rectal cancer, pregnancy, and ovulation. These products represent the beginning of the development of a wealth of new applications and services for human health care.

The bioscience industry represents an important economic influence in the United States. Its contributions are directly reflected in the cost of health care (drugs, therapeutics, diagnostics, vaccines, reduced time for diagnosis), agricultural and marine products (plant and animal development and health care, herbicides, pesticides, growth hormones), environmental protection programs (water pollution, sewage disposal, biodegradation of xenobiotic compounds, microbes in metal recovery and mining), and fuel and chemical production (fuel from energy crops, ethanol, hydrogen and methane production, enhanced oil recovery, chemicals from fermentation).

The implications of these changes for employment in bioscience laboratories are highly significant for the future of the U.S. economy. As Louis Richman states:

> *[There is a] large and rapidly growing population of technicians—a new worker elite who are transforming the American labor force and potentially every organization that employs them. As the farmhand was to the agrarian economy of a century ago and the machine operator was to the electromechanical industrial era of recent decades, the technician is becoming the core employee of the digital Information Age. The trend reflects what Stephen R. Barley, an ethnographer at Stanford University's school of engineering, describes as the "technization" of American labor.*[5]

The reality of these changes is reflected in the current and projected employment statistics for technical jobs in the bioscience industry. By the year 2000, the projected need for clinical laboratory technical workers is expected to increase from 268,000 people (1992 figure) to about 350,000 people.[6] In the pharmaceutical sector, although some companies have

recently downsized, companies still employ hundreds of thousands of technical workers, many of whom must be replaced in the coming years. The Bureau of Labor Statistics reported a total of 244,000 "science technicians" working in 1993,[7] a figure expected to grow by 25 percent by 2005. In the biotechnology sector, 97,000 people were employed in 1993, a 23 percent increase over 1992[8] and it is projected to increase to over 105,000 by the year 2000.[9] The demand for technical workers, particularly in manufacturing, will be increasing as more test products are approved for mass production.

The projected high employment growth in bioscience makes it an important industry for which to develop education programs based on solidly researched, comprehensive skill standards. Another reason to develop skill standards and education pathways into the industry is its relatively high pay rates. Salaries for beginning-level workers are higher in the bioscience field than in many other industries. Median annual salaries for technicians range from $22,000 to $26,000; for technologists (middle-level jobs), the median salary is about $32,000.[10]

Clearly, the bioscience industry is one of our country's industries of the future. The bioscience skill standards provide practical tools for developing education bridges for people to move into this promising future.

> *Today's modern biotechnology industry is based on the fast-moving scientific advances in cellular and molecular biology and on our growing knowledge of the human immune system. There is no doubt that biotechnology will be one of the foundations for the future.*
>
> Carl B. Feldbaum
> President
> Biotechnology Industry Organization

Why Does the Bioscience Industry Need Skill Standards?

- **Misfits Between Education and Employers'/Workers' Needs**
- **Future Bioscience Industry Trends and Skill Needs**

Managers in all three sectors of the bioscience industry—pharmaceutical companies, biotechnology companies, and clinical laboratories—respond in differing ways when asked about their projected labor needs for beginning-level technical workers. Many pharmaceutical managers, who tend to use a four-year B.S. degree as an industry entry criterion, do not foresee a shortage of workers. The labor market is currently glutted with new college graduates in biology or chemistry who are willing to take entry-level jobs that pay $22,000 to $24,000 a year.

Biotechnology managers say they will need increased numbers of manufacturing personnel as more products are approved for production. Although some of these managers support the development of more two-year training programs to meet these projected needs, many feel, as do pharmaceutical managers, that four-year degrees are required for beginning-level occupations, and that there will be plenty of four-year college graduates to fill these jobs.

Clinical laboratory managers are very aware of the growing need for well-trained laboratory practitioners. The recent revision of the Clinical Laboratory Improvement Act (CLIA) regulations, which has relaxed training and skill requirements for entry-level clinical laboratorians, worries many in the field. According to the new CLIA regulations, people who have only high school degrees and no specialized training are eligible for some jobs requiring special skills.[11] The development of skill standards that set high performance benchmarks would help ensure that entering clinical laboratorians are adequately prepared for work.

While it is clear that clinical laboratory employers will benefit from having industrywide skill standards for beginning-level technical workers, how will industry skill standards benefit pharmaceutical or biotechnology employers?

Several Reasons Why Skill Standards Are Needed

1. Many new employees with four-year college degrees in biology, chemistry, or related fields are not interested in or sometimes not prepared for the beginning-level technical jobs they enter.

College courses provide the required theoretical knowledge but often do not provide the practical experience needed in the workplace; some science courses do not even require laboratory experience. One high-level manager in a leading North Carolina-based pharmaceutical company states that his company invests an average of two years of training for new employees with baccalaureate degrees to qualify them for entry-level technical jobs. This is not an isolated tale but a common story that we have heard from other managers and supervisors. Even managers who insist their company would hire only people with four-year college degrees have stated that, in some cases, graduates need extensive hands-on training before they can do their jobs.

Our research shows that bioscience industry representatives from all job levels, in all three subsectors, think that virtually all of the work performed by beginning-level technical specialists requires no more than two years of postsecondary education. (In Appendix A, see Job Analysis Validation, Question 2.) The same North Carolina company executive who lamented spending two years to prepare new workers with B.S. degrees stated that people hired from a local two-year community college program —which the company helped develop—required less than six months of on-the-job training to become proficient in those same jobs.

> *The standards are eye-opening to four-year college and university faculty whose knowledge of the industry is usually restricted to the research side of the industry.*
>
> A. Stephen Dahms, Ph.D.
> Director, California State University System
> Program for Education and Research in
> Biotechnology (CSUPERB)
> San Diego State University

This evidence clearly indicates that there needs to be a shift in thinking about the criteria for industry entry, away from the number of years spent in school and toward the content and relevancy of what is learned. Theoretical learning should be combined with applied, experience-based learning of work-related skills and behaviors.

2. Many programs designed explicitly to prepare people for certain occupations sometimes fail to do so because their planners and teachers do not understand what skills the occupations require.

Employers, workers, and educators tell us that the most successful active occupational preparation programs are those designed with the participation of industry and labor. Any such program planning must begin with a thorough analysis and understanding of what skills, knowledge, and behaviors are required in the occupations for which people will be prepared. Because the knowledge base, information and production technologies, regulatory requirements, and organizational structures in the bioscience industry are changing so rapidly, academic and technical preparation programs need to maintain continuous contact with industry and labor representatives who can help reshape education programs to meet changing work requirements.

The growing trends in bioscience workplaces also need to be understood by education and training program planners if they are to prepare workers for future work in the industry. We asked groups of frontline workers what changes they saw happening in their jobs and workplaces that should be addressed in education programs. Following are some of the most frequently cited changes.

- The fields of knowledge (e.g., genetics, clinical testing, use of computers, regulatory requirements) are changing rapidly; old theories and methods are becoming obsolete; today current and future workers need to continuously update their learning and be flexible to meet new challenges.

- With the reduction of supervisory staff, beginning-level workers are expected to think for themselves more, to troubleshoot and solve problems, and to make more decisions for themselves. These skills need to be learned and practiced before coming on to the job.

- With the growing emphasis on cost containment and the increasing costs of clinical trials and production, people are expected to do their work as efficiently as possible, with virtually no mistakes; this requires a higher level of expertise.

- With the increasing emphasis on producing high-quality products and services, workers are required to pay more attention to detail and to be able to deal with customers, suppliers, and others about their products.

- Because teamwork and peer review are being instituted in many workplaces, people need to develop appropriate interpersonal skills and attitudes.

- As some workplaces downsize, people need to learn a broader range of skills and occupations so that they can take on other people's work as needed.

3. There is a high degree of dissatisfaction among many college graduates in beginning-level jobs, resulting in high turnover rates.

Students with four-year degrees and extensive academic and theoretical knowledge expect to make use of that knowledge in their work, but much of the work in beginning, entry-level laboratory work requires the use of practical, applied skills more than the use of theory. Most beginning-level laboratory work requires a theoretical understanding of the industry, but much of the work requires applied skills more than use of theory. As a result, these new employees often become disillusioned with the actual work required of them on the job and seek other jobs more suited to their education and expectations. Managers must then recruit new workers. The costs of frequent training of replacement workers are an added financial burden for employers.

Likewise, the costs to beginning-level workers, whc have already invested considerably in acquiring four-year degrees, may not be well-spent.

4. Because many education programs are not adequately preparing people to meet employer needs, many work organizations are spending large sums training new workers in basic academic and applied skills (e.g., basic math, laboratory procedures) or in recruiting trained workers from other places.

A manager of employee training in a large Midwest-based pharmaceutical company calculated that the company spent about $70,000 in 1993 to recruit 25 people from other states who were qualified for entry-level technical jobs. This manager felt that investing in local education to prepare people for work in the industry sector would soon yield much higher returns. That company has decided to invest several hundred thousands of dollars over the next few years, in partnership with other companies, schools, and government, to develop a comprehensive program in its own community to prepare people for work in its industry.

> *The bioscience skill standards represent a clear signal about the future of work organization and what we will expect from workers across the board, regardless of an individual state's economy. [In a sense] the skill standards are business's "purchase order" to education.*
>
> Jeff Iacobazzi
> Policy Analyst
> Indiana Department of Workforce Development

Increasingly, employers are realizing they should place value not on inputs, such as time spent in school, but on outcome-based criteria—demonstrated mastery of knowledge, skills, and behaviors required to do the job. New workers who meet these outcome-based criteria not only will be more likely to be hired for beginning-level jobs, but will be more prepared to work efficiently and to interact with their coworkers. Their solid grounding in the fundamentals of the industry will also make them more eligible to acquire the additional skills and knowledge needed to advance to higher-level positions.

The Need for Skill Standards in the United States

The United States is the only advanced industrial country in the world that does not invest adequately and systematically in the preparation of skilled workers to meet the future needs of industry. The creation of industry skill standards is a first critical step in moving this agenda forward. Industry-based skill standards set the benchmarks for what people must know and be able to do to enter and move up within industries. Skill standards are especially necessary in industries such as bioscience, which increasingly are emphasizing the need for high-skilled and multi-skilled workers capable of producing high-quality goods and services.

Project Goals and Guiding Principles

- **The Project's Five Guiding Principles**

Goals

The first goal of the Bioscience Industry Skill Standards Project is to create national, voluntary skill standards for a broad cluster of beginning- to middle-level technical occupations in the bioscience industry. These skill standards will form the benchmarks for education systems to prepare people in both the general work skills and the common core of industry-specific technical knowledge, skills, and behaviors that are required to qualify for gateway occupations and career opportunities in this high-skilled, high-growth industry.

The second goal is to promote the acceptance and creative use of the standards by employers, educators, unions, and others. To accomplish these goals, the project has reached out to and involved all of these stakeholder groups in the development of the standards.

The accomplishment of both these goals will provide bioscience employers with skilled, versatile workers who meet current and future industry needs. It will also give both young people and adults opportunities to enter a range of skilled occupations with career opportunities in an industry of the future.

Guiding Principles

The project has five principles that have guided the process of creating and implementing the skill standards:

1. **Industry, labor, and education must work together.** In order to ensure that work-related education truly prepares people for the requirements of real-life work, employer and worker representatives must work continuously with educators to develop and implement strategies, programs, and systems.

2. **Experienced workers are the experts in regard to their jobs.** To identify and understand the work that is done in particular occupations, along with the skills, knowledge, and behaviors required to do that work well, people who do those jobs must be the source of information on which to build standards and performance criteria for assessment.

3. **People should be prepared not for narrow occupations, as traditionally defined, but for a "Learning Occupation©,"** which encompasses skills and knowledge needed throughout the industry. Traditional occupational education can limit job and career options for people by focusing on preparation for a narrowly defined occupation, often in a single work setting; the Learning Occupation concept (see the following section) focuses on preparing people for a large cluster of occupations that share common performance requirements, thereby opening up a broad range of work and career opportunities.

4. **"Integrated Skill Standards©,"** rather than compartmentalized, task-focused skill standards, are needed to prepare people for real-life work. Traditional skill standards often focus on mastery of a list of tasks, unrelated to each other, or to a work context in which they will be performed; Integrated Skill Standards more closely resemble real-life work situations and therefore can be used to more accurately assess what people must know and be able to do in the workforce. (See the following section.)

5. **School- and work-based learning should begin in the elementary grades.** In order to prepare for real-life work, students should learn both in school classrooms and in work-based experience, such as internships, co-op work, and youth apprenticeships; real-life work applications should be incorporated into the teaching of academic subjects, beginning in the elementary grades, to place the content of learning in the real world.

Two Guiding Concepts: The Learning Occupation and the Integrated Skill Standard

- **Learning Occupation: Definition, Occupations, and Work Settings**
- **Integrated Skill Standards: Definition**
- **Importance of Using Problem Solving to Teach and Assess Mastery**

The Learning Occupation

A Learning Occupation is an invented construct that does not exist in the workplace; nor does it correspond to a specific occupational title or description. A Learning Occupation represents the *combination of all the shared work tasks, knowledge, skills, and attributes* required to perform a range of job functions conducted in a group of related real-life occupations. The Learning Occupation construct draws on best practices in worker training in Japan and Germany, where cross-training of technical workers is considered critical to ensure high-quality work. It is used in the Bioscience Industry Skill Standards Project to symbolize an outcome goal for education and training designed for workers who will be able to perform a broad variety of work suitable to a large cluster of occupations.

The Learning Occupation for a beginning-level worker as defined by workshop participants from the industry and the project Technical Committee is as follows:

The Bioscience Technical Specialist I performs experiments and assays, manufactures products, or assists with research, using a variety of technical skills under supervision.

The following jobs have been identified by representatives from the bioscience industry as entry-level, laboratory-based occupations that share a common base of skill/knowledge requirements. Together, they constitute the Bioscience Technical Specialist I Learning Occupation:

Animal technician
Assay analyst
Clinical/medical lab technician
Cyto-prep technician
Documentation coordinator/clerk
Histotechnician
Instrument technician
Laboratory technician
Maintenance technician
Manufacturing operator
Manufacturing technician
Media-prep technician
Phlebotomist/lab assistant
Pilot plant operator
Pilot plant technician
Quality assurance assistant
Quality control assistant
Research technician
Validation technician

The graphic representation of the Learning Occupation (see the cube, at right) is a three-dimensional model of how work settings and beginning-level occupations in an industry can be combined. Using this model, we can see how the Learning Occupation concept can open up so many more work and career opportunities for people than a more traditional occupational education approach can.

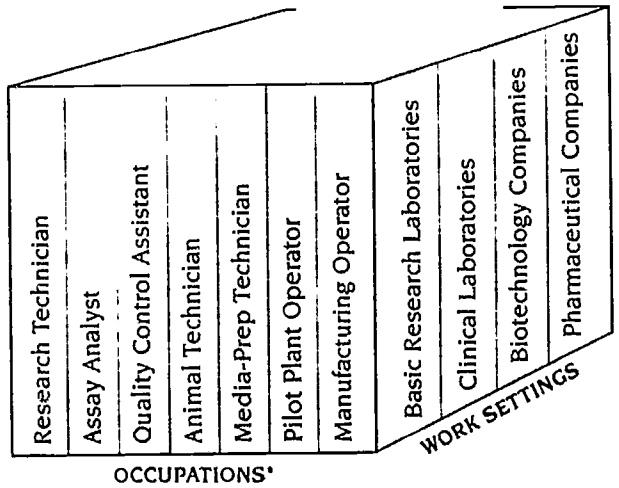
The goal of traditional occupational education is to prepare a person for one occupation (i.e., one cell on the cube's occupation axis, such as "manufacturing operator") and for one work setting (e.g., a pharmaceutical company). A person who is educated in all of the knowledge, skills, attributes, and work tasks required for the Learning Occupation (i.e., all of the substance that forms the connecting base of the cube) is prepared to enter any one of the occupational areas in any of the work settings.

As this person acquires additional skills and knowledge, through on-the-job experience and continued academic work, he or she can move up through the cube (the third dimension) along any one of numerous career paths. **The Learning Occupation is therefore a liberating approach for vocational-technical education. Rather than tracking people into narrow occupational paths, it opens up opportunities at any career stage to move laterally and vertically along a great variety of paths.**

These bioscience skill standards will benefit employers because they have been constructed in a way which is consistent with recruiting trends. Employers are looking for people skilled in multiple areas because companies have more than one operation going on. The skill standards give workers a broader base of skills to bring to the job search.

Catherine M. Crowley
Assistant Vice President
The Maryland Hospital Association

The Learning Occupation: A Graphic Representation©



* These represent sample entry-level occupations.

The Integrated Skill Standard

A key concept of the Bioscience Industry Skill Standards Project is the Integrated Skill Standard. Often standards are written as checklists, discrete skills to be learned and mastered. Although they represent benchmarks for knowledge, skills, and performance criteria required to qualify for entry into an occupation or cluster of occupations, they lack a larger context in which the significance of the skills can be understood. This approach does not emphasize the kind of learning that's required in today's complicated workplace environment, where critical thinking and problem solving intersect with issues like ethics and effective communication skills and, in bioscience, with the necessary scientific knowledge.

The Integrated Skill Standard places duties, tasks, and the know-how needed to perform them in the context of real-life work scenarios, or situations, where mastery of routine performance must be demonstrated and a problem must be solved. Successful performance of the Integrated Skill Standard will demonstrate mastery of a range of required skills and knowledge areas at prescribed, measurable competency levels. This approach simulates especially the high-performance work environment in which students will find themselves in the future.

The Use of Breakdowns in the Routine Reveal Higher-Order Skills

The reason breakdowns are so important as an organizing framework for setting standards for skills and knowledge in high-performance work organizations is that in any successful performance, skills and knowledge are largely invisible. Whether or not the performer has integrated complex skills becomes apparent in how he or she handles the unexpected.

> *What makes an employee valuable is the ability to react to problems. Having these scenarios for educators to use will help students develop problem-solving skills and critical thinking, which make for a very valuable employee.*
>
> Kathleen K. Norris, Ph.D.
> Associate Professor of Biology and Coordinator of Biotechnology
> Baltimore City Community College

Let's imagine the following situation: Sam, a 16 year old you know, has just asked to borrow your brand-new car. How would you know that it's OK to hand over the keys? If you're an educator, you have a number of possible approaches. For example, you could use an academic standard, by seeing how Sam did on the written portion of the driver's test. If Sam got every single question right, would you lend him your car? Probably not. You could also use a more applied standard by taking Sam to a nearby driver's training lab, where Sam could show you that he met the standard for turning the wheel properly, changing a tire, starting and stopping the car, and knowing how to brake. Would you give him your keys? Probably not. After all, you still haven't seen Sam drive.

Next you decide to see if Sam can integrate his academic, technical, and applied skills and knowledge by taking him out on the road while you watch him drive. No problems. Will you give him your keys? At this point, most people are not sure. You still don't know whether Sam can handle the car and himself well enough to make it through a sudden, unexpected problem. What would Sam do if another car cut him off suddenly, or if he hit a spot of unexpected ice or oil on the road?

Taken by themselves, the tasks, such as turning the wheel properly, braking, or signaling require the learning of a complex set of skills and behaviors. Breakdowns in the routine can be used to illuminate a point of intersection among many different tasks and the skills and knowledge necessary to perform those tasks. The breakdown reveals how the individual handles what she or he does not know, "uncovering" the presence or absence of higher-order skills and knowledge, such as problem solving, creativity, effective communication, and prioritizing. It might be said that we really know people are "skilled" when they can successfully work their way out of an unexpected breakdown in the routine.

Cross-Functional Tasks Focus on Processes
The Integrated Skill Standards were developed by EDC researchers working with industry representatives and bioscience educators. They used the 108 actual tasks and required skills, knowledge, and attributes (SKAs) described by frontline workers in biotechnology, pharmaceutical, and clinical laboratory settings during the project's Job Analysis Workshops (see "Job Function and Tasks" list in the following section). These tasks and SKAs are common to beginning-level workers in four broad industry function areas: research and development, quality assurance, manufacturing, and clinical laboratory work. Using the tasks, which had been rated for frequency and criticality (see Appendix A for the validation process), experienced workers, supervisors, and bioscience educators combined the tasks to produce 34 different scenarios, each presenting a routine process followed by an unexpected breakdown. Taken together, the 34 scenarios, with their component tasks and SKAs, form the baseline of successful performance in the bioscience industry at entry.

Integrated Skill Standards Are User-Friendly and Easy to Adapt
The Integrated Skill Standards can lend themselves easily to a variety of learning and assessment situations. For example, employers who now use the Critical Event Interview[12] readily see how the Integrated Skill Standard—with a scenario that includes a routine and a process breakdown—reveals whether the applicant or current worker has the required technical and higher-order skills and knowledge and spotlights which, if any, are missing. Some educators see how the Integrated Skill Standard can help improve classroom and applied learning by providing a problem- and performance-based approach that requires teachers and students to apply rigorous academic knowledge to real-life situations.

However, widespread adoption of Integrated Skill Standards by educators will require that traditional task-focused teaching and assessment approaches be changed. The teaching and assessment of discrete tasks are more familiar and less challenging to some educators than the teaching of tasks and skills that are embedded in complex scenarios. Teaching with scenarios that require decision-making and problem solving calls for new pedagogical strategies (discussed in the "Guidelines for Implementing the Skill Standards" section). The use of Integrated Skill Standards will require new learning by some educators.

> *The bioscience industry demands a workforce prepared to excel in a constantly changing work environment. Preparation must include work ethics, science knowledge, applied skills, problem solving, and critical thinking. An integrated bioscience education allows students, educators, and industry representatives to work together toward common goals.*
>
> Christine Carberry
> Manager, Operations Training
> Biogen, Inc.

Likewise, the acceptance of Integrated Skill Standards by employers will require some of them to relinquish traditional job descriptions, which emphasize mastery of specific knowledge, skills, and tasks divorced from real work applications. New job descriptions and job applicant evaluations will need to emphasize both traditional knowledge, skills, and tasks and "connecting" skills, such as problem solving, decision-making, teamwork, and resource management. All of these tasks, skills, knowledge areas, and behaviors should be considered in applied contexts that most nearly simulate the real work to be done.

The Bioscience Industry Integrated Skill Standards

- Bioscience Skill Standards Development Process
- Integrated Skill Standards: Overview and Format
- Who Can Use the Skill Standards and How They Can Benefit
- List of 34 Skill Standards Scenarios
- Integrated Skill Standards
- Job Functions and Tasks List
- Skills, Knowledge, and Attributes
- Tools and Equipment List

The Skill Standards Development Process

The development of the Integrated Skill Standards was a two-year process, involving nearly 1,000 people from bioscience workplaces and education institutions. Following is a summary of the skill standards development process.

Convened a Technical Committee. A national consortium of representatives from industry trade associations, education associations, employee associations, professional associations, accreditation organizations, and companies advise the project. This exchange between industry and education representatives has built the collaborative aspect of the project from the beginning and has provided linkages both to facilitate the work of the project and to help enroll new organizations throughout the length of the project.

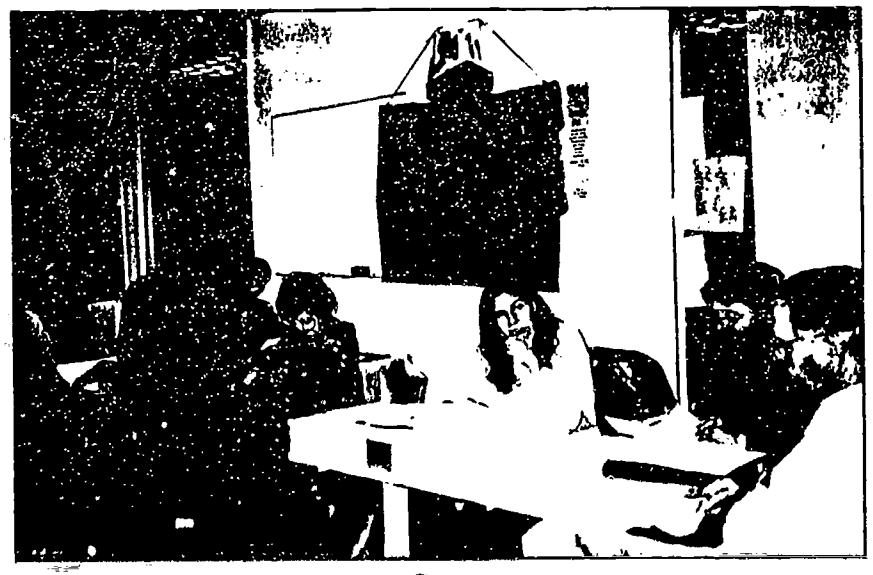
Identified a Learning Occupation. During the first phase of the project, industry managers and labor representatives provided information about industry trends and the future skill and knowledge requirements of a range of technical occupations. From this information, it seemed clear that broadly skilled, entry-level technical workers should have some familiarity with basic laboratory techniques, research methods, and production methods, as well as a range of generic work skills and industry-related skills and knowledge. A Learning Occupation emerged from about 20 related occupations that shared a common core of required skills, knowledge, and behavioral attributes.

Held Job Analysis Workshops. Panels of technical workers from a variety of workplaces around the country participated in four Job Analysis Workshops, in which a modified DACUM (Developing a Curriculum) process and small-group discussions

led to the identification of the job functions and tasks performed by a Bioscience Technical Specialist I and the knowledge, skills, and attributes needed to perform them. Through discussions, future trends in the industry were identified, as were their anticipated impact on the skill and knowledge requirements for technical workers.

Validated information. The results of the Job Analysis Workshops were validated through a survey in which over 150 technical workers, supervisors, and managers responded. They responded to questions to identify the importance of the tasks in the job of a Bioscience Technical Specialist I, to identify the amount of training and/or experience needed to learn each task, and to rate the expected future significance of each task. (See Appendix A for more details and survey results.)

Researched current education and training programs. While information from industry representatives was being developed, a research project was ongoing to identify, describe, and review high school and postsecondary bioscience-related education and training programs currently operating in many sites throughout the country. This report is available separately from the skill standards.



Developed performance criteria and assessment methods. In November 1993, a workshop was held in which industry representatives and educators determined what a person needs to do and show to demonstrate mastery of the tasks identified through the job analysis process. Also identified were appropriate assessment methods for determining successful performance of the tasks.

Developed the skill standards. In the winter and spring of 1994, industry and labor representatives and educators conferred to create the Integrated Skill Standards. They developed 34 situations that require demonstrated mastery of routine procedure and problem solving in research and development, manufacturing, and/or clinical laboratory settings within the bioscience industry. Specific task performance for the routine and problem aspects of the situation were identified, as were the necessary knowledge and skill requirements and recommended attributes.

Validated the Integrated Skill Standards. During the fall and winter of 1994, the draft skill standards were reviewed, revised, and validated in a series of eight workshops by people throughout the industry and by experienced bioscience educators. Participants addressed the accuracy of the situations in real work settings, the appropriateness of the situation for beginning-level technicians, and the effectiveness of the language and wording of the situations. In addition, work settings, key competency areas, and the composition of the task lists for both the routine and the problem parts of the scenario were reviewed. (See Appendix A.)

Skill Standards: Overview

The Integrated Skill Standards include the content and assessment criteria and measures of what people need to know and what they need to be able to do to qualify for beginning-level employment in biotechnology, pharmaceutical, and clinical laboratories and processing facilities.

Each skill standard begins with a scenario that illustrates a typical, routine work situation and a likely, unanticipated problem or breakdown. Each of the 34 scenarios was developed by industry representatives and experienced bioscience educators to be illustrative of one common, major aspect of the work of a Bioscience Technical Specialist I. The entire set of scenarios (see list of 34 scenarios, which follows in this section) represents the whole scope of work of this Learning Occupation, as defined by master workers in the Job Analysis Workshops.

The set of 34 scenarios is not intended to be exhaustive. The scenarios are illustrative. We expect that teachers, mentors, and students will develop additional scenarios of their own. Also, some wording of the scenarios can be modified to fit various specific work settings and occupations.

The other information contained in each skill standard—the workplace setting, key competency areas, tasks, skills, knowledge, attributes, and tools and equipment—will assist educators and employers in using the standards for teaching. The performance criteria and assessment methods (see "Guidelines for Implementing the Skill Standards" section) will guide educators and employers in determining students' or potential employees' mastery of the skill standards.

Skill Standards: Format

Each Integrated Skill Standard is structured with the following components:

Scenario. Each scenario describes a real work situation, including a routine procedure and an unanticipated problem. The student or worker is asked to demonstrate how he or she would successfully handle each part of the situation.

Example: One part of your laboratory responsibilities is to safely unpack and process biological samples. Demonstrate everything you would do to accomplish this.

While unpacking samples one morning, you notice that one of the samples is leaking from the container. According to regulations, what should you do?

Workplace setting. This is a listing of the departments/workplaces where the scenario would occur: research and development, manufacturing/processing, clinical laboratory, or generic (applicable across the three settings). A scenario labeled "generic" is applicable to all the work settings but requires some language modification to fit each site

Key competency areas. These are the major areas of responsibility of a Bioscience Technical Specialist I (see "Key Competency Areas" at the end of this section and related matrix in Appendix B). Each scenario includes at least two key competency areas.

Examples: Documentation/Tracking, Performance of Procedure, Troubleshooting Methods Failure, Safety

Tasks for performing routine procedures. Each skill standard includes a list of the tasks that must be mastered to successfully perform the routine procedure. (See "Job Function and Tasks List" at the end of this section for a complete list of tasks and related matrix in Appendix B.)

Examples: A-4: Determine acceptability and optimum conditions of reagents for tests

K-7: Notify appropriate persons about problems and observations

Tasks for solving problems. Each skill standard includes a list of the tasks that must be mastered to successfully solve the problem in the scenario. (See "Job Function and Tasks List" at the end of this section and related matrix in Appendix B.)

Examples: F-1: Check calibration and perform system diagnostics

I-8: Take and document corrective action according to Standard Operating Procedure (SOP) or as directed

> *I would feel very comfortable taking someone who has a few years working in manufacturing and hiring them for work in a clinical laboratory if they had been broadly trained to these skill standards.*
>
> Jeff Shulkin
> Assistant Laboratory Manager
> Kaiser Permanente Medical Care Program,
> Southern California Region

Skills, knowledge, and attributes. These are the general work knowledge, industry-related knowledge, industry-related skills, and recommended personal attributes (behaviors) that must be developed to master the routine and problem parts of the scenario. (See "Skills, Knowledge and Attributes" list at end of this section and related matrix in Appendix B.)

Examples: General Work Skills: Communication, Critical Thinking
Industry-Related Knowledge: Terminology (Medical/Bioscience), Toxicology
Industry-Related Skills: Aseptic Technique, Detail Orientation
Attributes: Accountability, Meticulousness

Tools and equipment. A list of tools and equipment required for each skill standard will be included in our *Guidelines for Education and Training*. (See section entitled "Guidelines for Implementing the Skill Standards" which follows.)

Who Can Use the Integrated Skill Standards?

The Integrated Skill Standards have been formatted to assist employers, educators, and current or future workers.

> *The standards are based on a series of "scenarios" that are not specific to a particular job. Competence in terms of a "scenario" demonstrates skills, knowledge, and performance ability that is directly applicable to real-world situations.*
>
> Russell Madsen
> Director, Scientific and Technical Affairs
> PDA, Inc. (An International Association for Pharmaceutical Science and Technology)

Employers. The standards will guide employers as they interview prospective employees, assess the readiness of current employees to move into higher-level positions; and develop (in partnership with educators) programs to prepare future employees and for in-house training. Such programs will ensure an adequate supply of qualified workers, and reduce the time and expense of recruitment efforts and basic education programs for workers.

Educators. The standards will serve as benchmarks for educators to create and continuously update education/training programs and performance criteria that meet current and evolving labor market needs. This will ensure that students are prepared for skilled occupations with career opportunities and/or for advanced education and training.

Current and future workers, both young people and adults in need of training or retraining. The standards will help workers to prepare for skilled occupations and career opportunities in a high-growth industry. Program graduates will receive joint certification from education and industry that recognizes their

academic and technical mastery. These portable credentials will be acknowledged by employers throughout the country.

> *The successful high-performance, high-wage workplace draws its strength from workers' broad skills, knowledge, and judgment. A set of national skill standards helps ensure that workers will have opportunities for education and skill development that will not only develop a more productive economy, but also produce secure, well-paying jobs.*
>
> John J. Sweeney
> International President
> Service Employees International Union,
> AFL-CIO, CLC

SCENARIOS

SCENARIO 1

One part of your laboratory responsibilities is to safely unpack and process biological samples. **Demonstrate everything you would do to accomplish this.**

While unpacking samples one morning, you notice that one of the samples is leaking from the container. ***According to regulations, what should you do?***

SCENARIO 2

You are performing routine quality control procedures that evaluate the quality of culture media used in the microbiology lab. **Demonstrate the steps involved.**

You find that the negative control culture yields a positive result on one type of selective media. ***How should you deal with this?***

SCENARIO 3

You are a member of a team involved in monitoring the environmental testing of a cell line. Your responsibilities include the routine observation and maintenance of the cell line. You have a healthy cell culture in a flask. You transfer the culture to a fresh growth medium in a larger vessel for scale up. **Show how you would do this.**

After 24 hours, the new cell culture's viability has dropped to 70 percent. ***What would you do to address this problem in a routine procedure? What would you do in an experimental procedure?***

SCENARIO 4

You have been given a protocol for an established procedure. You must assemble, according to protocol, the equipment, supplies, and reagents necessary to begin the procedure. **Show what you would do.**

You have a rush project that requires a specific vendor kit to be used. You find out that the vendor kit is on back order. ***How do you proceed?***

SCENARIO 5

You are responsible for specimen receipt and processing. A sample is received in the lab for analysis. **Demonstrate the procedure for processing this request.**

The label on the sample does not match the information on the requisition. The results are needed in 30 minutes. ***Recognizing this, how should you proceed?***

SCENARIO 6

During your work on the third shift, you routinely check equipment and perform preventive maintenance. **Demonstrate how you would perform these tasks.**

During a check, one of the pieces of equipment shows a code that indicates a malfunction. ***What do you do?***

SCENARIO 7

After finishing your internship with a bioscience company, you are granted an interview for a full-time position. **What information should you gather and review to prepare for the interview?** ***Role-play an interview.***

SCENARIO 8

You work in a laboratory that uses radioactive compounds. **Describe the safety protocols you need to follow regularly to comply with regulations.**

You have just received a phone call from your supervisor who informs you that the safety officer of the NRC's environmental health and safety department will be inspecting your lab tomorrow morning. As you assist with checking the lab, you find a counter that contains radioactive contamination. ***What do you do?***

SCENARIO 9

You are bringing the chemistry analyzer online at the beginning of your shift. **Demonstrate what needs to be done to bring the analyzer out of standby status.**

You notice that one of the reagents is almost empty. After replenishing the reagent, the instrument no longer performs within control limits. ***How do you deal with this?***

SCENARIO 10

Your company is participating in a career day at a local high school. As a team member, you are asked to assist in a presentation that will include demonstrating a new product available for home testing. **Show how you would perform these tasks.**

SCENARIO 11

You work in a laboratory certifying a manufactured product.
Describe the procedures you use to monitor product performance.

You notice a 5 percent deviation in product performance. ***What do you do?***

SCENARIO 12

You are asked to prepare a slide of a sample and controls.
Show what steps you take to prepare the slides and perform the staining.

When you evaluate the slides, the controls obtained from an external supplier stain weakly or not at all. The sample slide displays a normal staining pattern.
What action do you take based on these results?

SCENARIO 13

You are responsible for following the protocol for purifying your company's product. **Demonstrate the steps you take in product purification.**

The 2 liters of the crude product has a calculated yield of 10 grams per liter. You expect an 80 percent yield. After running the column, you calculate the purified total sample yield as 22 grams per liter. ***Show how you would handle this result.***

SCENARIO 14

You are operating a bioreactor. **Demonstrate the steps involved in obtaining and testing bioreactor samples for pH, cell count, and clarity.**

You perform the tests, and all the results are within specifications. During the visual inspection you observe that the sample is orange, while the previous sample looked red. ***What do you do about this observation?***

SCENARIO 15

Information is needed by your supervisor to update procedure manuals. You are assigned to obtain some information, and you are unsure how to locate the source materials. **What should you do?**

SCENARIO 16

Your job is to assist with cleaning, preparing, sterilizing, and inoculating a bioreactor. **Show what tests and procedures you follow to perform these tasks.**

After inoculation, a coworker points out that the bioreactor exit air filter cartridge is not installed. This means that there is no filter between the recombinant cells in the bioreactor and the outside environment. ***Demonstrate how you would handle this.***

SCENARIO 17

You talk to a vendor who claims to have a new product that will double your throughput. You want your supervisor to consider investigating the new product. **What should you do to make this proposal?**

SCENARIO 18

You receive a brochure announcing a seminar that would enhance your professional development. Funding is tight. **Justify your attendance at this seminar to your supervisor.**

SCENARIO 19

You are responsible for preparing specimens for an assay that requires immediate centrifugation. **What are the steps involved in preparing the material for centrifugation?**

One week ago you reserved time for a 12 hour spin to coincide with the completion of your assay. When you bring your samples to the centrifuge, you discover that it is currently being used. There is no indication of who may be using the centrifuge. ***What would you do?***

SCENARIO 20

You perform animal care at your facility according to protocol. **Describe these duties.**

One morning you notice that the test animals are listless and lethargic. You also notice evidence of diarrhea in some of the cages. ***How do you respond?***

SCENARIO 21

You are performing a quality control check. You are asked to sample a raw material for routine retesting. **Demonstrate the procedure used to verify that the material is still acceptable for use.**

In doing so, you observe that the raw material that is expected to be granular has large clumps in it. ***What actions do you take?***

SCENARIO 22

You are given 25 microliters of DNA in solution for restriction analysis. **Explain what you would do.**

You perform the analysis. Upon visualization with ethidium bromide, you see long smears instead of distinct bands. ***How do you assess and deal with this observation?***

SCENARIO 23

Your responsibilities include filing reports and storing slides. **What is the standard procedure for storing a stained slide and reporting after the pathologist's evaluation?**

Three months ago, a patient had a tumor biopsy. The attending physician has requested an additional copy of the report. After thoroughly searching the storage files, you cannot find the report. ***Explain how you would handle this.***

SCENARIO 24

Your responsibilities include receiving inventory and documentation of central supplies. **Describe the procedure for receipt of a new chemical.**

You receive vendor notification for recall of a reagent. This reagent is being used in several laboratories within the institution. ***What do you do?***

SCENARIO 25

You must remove a test animal from its cage. **What is the procedure that you routinely follow?**

As you are holding it, the animal bites through your glove, cutting your hand. ***How will you proceed?***

SCENARIO 26

You are taking routine readings from a computer screen. You hit the wrong key and the screen goes blank. **What do you do?**

Your efforts have been to no avail. ***What next steps do you take?***

SCENARIO 27

You are monitoring a bioreactor during production. An alarm sounds and you observe that the computer monitor says "pH Too Low." Low pH is normally adjusted by the automatic addition of base controlled through the bioreactor computer. **Tell how you respond to this alarm.**

The cells in the bioreactor will die if the pH stays too low. ***What do you do? Prepare a graph showing the change in pH before and after the event.***

SCENARIO 28

You work in inventory control. You receive an order for your company's product. **What tasks do you perform to fill the order?**

Customer Service informs you that a customer reported that half of the vials you sent her were cracked. She was very upset. ***What do you do?***

SCENARIO 29

Your company renovates your aseptic fill facility. Your fill group must sample the environment, people, and process used to aseptically fill your company's product. **Explain the tasks involved in performing these tests.**

The results of the test fail the acceptance criteria because 10 of the 3,000 vials filled are contaminated. ***How do you identify the source of the problem, and what suggestions do you make to your group?***

SCENARIO 30

You approach a patient to collect a venous blood sample for routine hospital admission tests. **Describe how you would proceed.**

The patient, however, is reluctant to have blood drawn because of a recent difficult venipuncture experience. ***How would you handle this scenario?***

SCENARIO 31

A chemical reaction experiment is set up, utilizing a limited amount of sample as the starting material. **How would you proceed?**

The next morning, you come into the lab and find that the reaction did not work. There is no more starting material to run the experiment again. ***What do you do?***

SCENARIO 32

You are recording data. Your readings are 10.40, 10.31, 10.52, and 10.64. **Calculate the average and record in 3 significant digits.**

Your next reading is 14.75. ***What would you do?***

SCENARIO 33

When you answer your department phone, the caller (physician, supplier, vendor) is angry about the way a situation was handled. **How do you deal with this scenario?**

SCENARIO 34

You are responsible for recording sample test results. **Demonstrate this processs.**

After the reports have been sent out, you realize that a sample result that you recorded at 3.75 should have been 8.75. ***What would you do?***

INTEGRATED SKILL STANDARDS

SCENARIO 1

One part of your laboratory responsibilities is to safely unpack and process biological samples. **Demonstrate everything you would do to accomplish this.**

While unpacking samples one morning, you notice that one of the samples is leaking from the container.
According to regulations, what should you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing
D) Clinical Laboratory ◆

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Quality Systems (QC, QA)
- Regulatory Compliance
- Safety
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-8 Return, archive, or dispose of samples
C-1 Request tests
C-2 Match request to test sample
C-5 Handle, transport, store sample, including legal requirements
C-6 Assess acceptability/appropriateness of specimen
F-4 Clean work area according to SOPs
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-6 Attend required trainings
G-7 Handle, contain, and dispose of hazardous materials
I-1 Inspect, release incoming inventory
I-2 Check, verify integrity of the product, procedure, specimen
I-4 Maintain QA logs
I-5 Follow policies and procedures
K-1 Interact with vendors, colleagues, and clients
K-6 Process information using computers

TASKS FOR SOLVING PROBLEM(S)

I-8 Take and document corrective action according to SOP or as directed
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Problem Solving
Resource Management
TQM/Total Quality Management

Industry-Related Knowledge
Anatomy
Biology/Lab
Clinical Laboratory Sciences
Physiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)
Toxicology

Industry-Related Skills
Aseptic Technique
Detail Orientation
Identifying Irregular Results
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management
Troubleshooting Ability
Upkeep of Equipment/ Work Area

Attributes
Accountability
Alertness
Common Sense
Confidentiality
Conscientiousness
Courteousness
Flexibility
Handles Constructive Criticism
Hard Working
Honesty
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Positive Attitude
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Hazardous Chemicals
Willingness to Work Around Radioactive Materials

SCENARIO 2

You are performing routine quality control procedures that evaluate the quality of culture media used in the microbiology lab.

Demonstrate the steps involved.

You find that the negative control culture yields a positive result on one type of selective media.

How should you deal with this?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking • Performance of Procedure • Quality Systems (QC, QA)
- Regulatory Compliance • Safety
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-4 Determine acceptability and optimum conditions of reagents for tests
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-6 Attend required trainings
G-7 Handle, contain, and dispose of hazardous materials
H–
I-9 Follow regulations
I-2 Check, verify integrity of the product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
K-7 Notify appropriate persons about problems and observations

TASKS FOR SOLVING PROBLEM(S)

A-4 Determine acceptability and optimum conditions of reagents for tests
E-5 Check expiration dates and lot numbers
I-2 Check, verify integrity of the product, procedure, specimen
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Prioritizing Tasks
Problem Solving
Resource Management
TQM/Total Quality Management

Industry-Related Knowledge
Biochemistry/Lab
Clinical Laboratory Sciences
Microbiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Aseptic Technique
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Inventory and Supply Maintenance
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Hard Working
Honesty
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Patience
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Hazardous Chemicals
Willingness to Work Around Radioactive Materials

SCENARIO 3

You are a member of a team involved in monitoring the environmental testing of a cell line. Your responsibilities include the routine observation and maintenance of the cell line. You have a healthy cell culture in a flask. You transfer the culture to a fresh growth medium in a larger vessel for scale up. **Show how you would do this.**

After 24 hours, the new cell culture's viability has dropped to 70 percent.

What would you do to address this problem in a routine procedure? What would you do in an experimental procedure?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Performance of Procedure
- Troubleshooting Methods Failure
- Troubleshooting Equipment Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
B-1 Follow SOP and batch record (protocol or procedure)
B-3 Set up equipment according to process requirements
B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)
B-5 Prepare buffers and solutions
B-6 Start up production
B-7 Operate reactors and recover products
C-4 Obtain and label sample/specimen
F-1 Check calibration and perform system diagnostics
F-2 Validate processes, equipment, facilities, kits, vendor products
F-4 Clean work area according to SOPs
F-7 Maintain equipment logs
F-10 Ensure clean room integrity
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders
H-1 Follow regulations: FDA (GMPs and GLPs)
J-5 Identify abnormal results

TASKS FOR SOLVING PROBLEM(S)

B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
F-1 Check calibration and perform system diagnostics
F-2 Validate processes, equipment, facilities, kits, vendor products
F-4 Clean work area according to SOPs
F-7 Maintain equipment logs
F-8 Troubleshoot and repair equipment (work order)
I-2 Check, verify integrity of the product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Organization Skills
Problem Solving
Teamwork

Industry-Related Knowledge
Biochemistry/Lab
Biology/Lab
Engineering
Microbiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Scientific Method

Industry-Related Skills
Aseptic Technique
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management
Troubleshooting Ability

Attributes
Accountability
Alertness
Conscientiousness
Handles Failure
Independent Worker
Meticulousness
Observant
Responsibility
Takes Initiative
Willingness to Ask for Help
Willingness to Work Around Microbiologic Pathogens
Works Well with Many Different People

SCENARIO 4

You have been given a protocol for an established procedure. You must assemble, according to protocol, the equipment, supplies, and reagents necessary to begin the procedure. **Show what you would do.**

You have a rush project that requires a specific vendor kit to be used. You find out that the vendor kit is on back order.
How do you proceed?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/ Tracking
- Performance of Procedure • Safety

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
D-1 Organize compounds
D-2 Prepare buffers, reagents
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-4 Observe rules of safety with radioactive materials
G-5 Observe rules of electrical safety
G-7 Handle, contain, and dispose of hazardous materials
H-1 Follow regulations: FDA (GMPs and GLPs)
I-2 Check, verify integrity of the product, procedure, specimen
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-3 Write or update protocols, procedure manuals, and reports for validation
K-7 Notify appropriate persons about problems and observations
L-1 Assist with design of research protocol
L-2 Research literature
* M-1 Monitor health and maintain health records
* M-2 Feed and water animals/plants
* M-3 Receive and transport animals/plants
* M-4 Monitor housing conditions
* M-5 Restrain and handle animals
* M-6 Clean housing and sterilize cages
* M-7 Participate as a member of the research team
*M-8 Monitor and maintain animal safety

*** Tasks needed if animals are to be used in the experiment.**

TASKS FOR SOLVING PROBLEM(S)

A-1 Obtain and read protocol, test procedure, SOP
E-2 Order supplies, reagents, animals
I-3 Use test standards, controls
I-5 Follow policies and procedures
J-7 Obtain written or verbal verification
K-1 Interact with vendors, colleagues, and clients
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Prioritizing Tasks
Problem Solving
Resource Management
Teamwork
Time Management
TQM/Total Quality Management

Industry-Related Knowledge
Chemistry/Lab
Clinical Laboratory Sciences
Immunology/Lab
Microbiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Detail Orientation
Instrumentation
Inventory and Supply Maintenance
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols

Attributes
Accountability
Common Sense
Conscientiousness
Flexibility
Independent Worker
Integrity
Interest in Work
Meticulousness
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Works Well with Many Different People

SCENARIO 5

You are responsible for specimen receipt and processing. A sample is received in the lab for analysis. **Demonstrate the procedure for processing this request.**

The label on the sample does not match the information on the requisition. The results are needed in 30 minutes.
Recognizing this, how should you proceed?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing
D) Clinical Laboratory ◆

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Quality Systems (QC, QA)

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
C-1 Request tests
C-2 Match request to test sample
C-5 Handle, transport, store sample, including legal requirements
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-10 Ensure turnaround time
K-2 Coordinate tasks with coworkers
M-3 Receive transport animals/plants
M-5 Restrain and handle animals
M-8 Monitor and maintain animal safety

TASKS FOR SOLVING PROBLEM(S)

I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Prioritizing Tasks
Problem Solving
Teamwork
Time Management
TQM/Total Quality Management

Industry-Related Knowledge
Animal Science
Clinical Laboratory Sciences
Phlebotomy
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Animal Care and Handling
Aseptic Technique
Detail Orientation
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Handles Constructive Criticism
Hard Working
Observant
Reliability
Responsibility
Safety Consciousness
Willingness to Ask for Help
Works Well with Many Different People

SCENARIO 6

During your work on the third shift, you routinely check equipment and perform preventive maintenance. **Demonstrate how you would perform these tasks.**

During a check, one of the pieces of equipment shows a code that indicates a malfunction. ***What do you do?***

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Quality Systems (QC, QA)
- Safety
- Troubleshooting Equipment Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-3 Check equipment
F-1 Check calibration and perform system diagnostics
F-3 Perform or schedule preventive maintenance
F-4 Clean work area according to SOPs
F-6 Implement systems updates
F-7 Maintain equipment logs
F-9 Label equipment and facilities
G-3 Use protective equipment
G-5 Observe rules of electrical safety
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders
H-1 Follow regulations: FDA (GMPs and GLPs)
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-2 Coordinate tasks with coworkers
K-6 Process information using computers
K-8 Document communication of information

TASKS FOR SOLVING PROBLEM(S)

A-3 Check equipment
F-1 Check calibration and perform system diagnostics
F-8 Troubleshoot and repair equipment (work order)
G-3 Use protective equipment
G-5 Observe rules of electrical safety
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-7 Notify appropriate persons about problems and observations
N-5 Read technical literature

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Prioritizing Tasks
Problem Solving

Industry-Related Knowledge
Basic Electronics/Lab
Clinical Laboratory Sciences
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Identifying Irregular Results
Instrumentation
Maintaining Records, Logs, Protocols
Manual Dexterity
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Honesty
Independent Worker
Integrity
Meticulousness
Observant
Patience
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Hazardous Chemicals
Willingness to Work Around Radioactive Materials

SCENARIO 7

After finishing your internship with a bioscience company, you are granted an interview for a full-time position. **What information should you gather and review to prepare for the interview?**

Role-play an interview.

WORKPLACE SETTING FOR THIS SCENARIO:

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Professional Development

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

K-4 Write memos and letters
K-5 Make oral presentations
L-2 Research literature
N-2 Maintain awareness of accreditation and government regulations
N-5 Read technical literature
N-6 Document training
N-8 Maintain professional demeanor

TASKS FOR SOLVING PROBLEM(S)

None

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Problem Solving
TQM/Total Quality Management

Industry-Related Knowledge
Basic Electronics/Lab
Biochemistry/Lab
Chemistry/Lab
Clinical Laboratory Sciences
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Inventory and Supply Maintenance
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/ Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Flexibility
Independent Worker
Integrity
Observant
Patience
Reliability
Responsibility
Safety Consciousness
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Hazardous Chemicals
Willingness to Work Around Radioactive Materials

SCENARIO 8

You work in a laboratory that uses radioactive compounds.
Describe the safety protocols you need to follow regularly to comply with regulations.

You have just received a phone call from your supervisor who informs you that the safety officer of the NRC's environmental health and safety department will be inspecting your lab tomorrow morning. As you assist with checking the lab, you find a counter that contains radioactive contamination.
What do you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Regulatory Compliance
- Safety

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

E-5 Check expiration dates and lot numbers
F-4 Clean work area according to SOPs
F-5 Sample environment
G-1 Maintain and follow chemical hygiene plan
G-3 Use protective equipment
G-4 Observe rules of safety with radioactive materials
G-6 Attend required trainings
G-7 Handle, contain, and dispose of hazardous materials
G-8 Maintain safety equipment
H-2 Follow regulations: OSHA
H-7 Follow regulations: NRC
H-8 Follow state and local regulations
H-9 Follow industry and professional regulations
J-5 Identify abnormal results
J-6 Document and report test results

TASKS FOR SOLVING PROBLEM(S)

F-4 Clean work area according to SOPs
F-5 Sample environment
G-1 Maintain and follow chemical hygiene plan
G-3 Use protective equipment
G-4 Observe rules of safety with radioactive materials
G-7 Handle, contain, and dispose of hazardous materials
H-7 Follow regulations: NRC
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Ethics (Business, Medical, Personal)
Personal Professional Development
Problem Solving
Teamwork

Industry-Related Knowledge
Basic Electronics
Biochemistry/lab
Career Awareness within the Industry
Chemistry lab
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Confidentiality
Conscientiousness
Courteousness
Flexibility
Hard Working
Honesty
Integrity
Interest in Work
Meticulousness
Observant
Positive Attitude
Professional Attitude/Behavior
Reliability
Safety Consciousness
Self-Motivation
Sound Judgement
Tactfulness
Works Well with Many Different People

SCENARIO 9

You are bringing the chemistry analyzer online at the beginning of your shift. **Demonstrate what needs to be done to bring the analyzer out of standby status.**

You notice that one of the reagents is almost empty. After replenishing the reagent, the instrument no longer performs within control limits.

How do you deal with this?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Quality Systems (QC, QA)
- Troubleshooting Equipment Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
E-5 Check expiration dates and lot numbers
F-1 Check calibration and perform system diagnostics
F-3 Perform or schedule preventive maintenance
F-7 Maintain equipment logs
F-9 Label equipment and facilities
G-1 Maintain and follow chemical hygiene plan
G-3 Use protective equipment
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures

TASKS FOR SOLVING PROBLEM(S)

A-3 Check equipment
D-2 Prepare buffers, reagents
F-8 Troubleshoot and repair equipment (work order)
G-7 Handle, contain, and dispose of hazardous materials
I-8 Take and document corrective action according to SOP or as directed
J-5 Identify abnormal results
J-6 Document and report test results
K-7 Notify appropriate persons about problems and observations
N-5 Read technical literature

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Prioritizing Tasks
Problem Solving
TQM/Total Quality Management

Industry-Related Knowledge
Biology/Lab
Chemistry/Lab
Clinical Laboratory Sciences
Immunology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)
Toxicology

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Stress Management
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Honesty
Independent Worker
Integrity
Meticulousness
Observant
Patience
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Willingness to Ask for Help
Willingness to Work Around Radioactive Materials

SCENARIO 10

Your company is participating in a career day at a local high school. As a team member, you are asked to assist in a presentation that will include demonstrating a new product available for home testing.

Show how you would perform these tasks.

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Performance of Procedure
- Professional Development
- Safety

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
A-8 Return, archive, or dispose of samples
E-5 Check expiration dates and lot numbers
F-1 Check calibration and perform system diagnostics
F-2 Validate or confirm processes, equipment, facilities, kits, vendor products
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-7 Handle, contain, and dispose of hazardous materials
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders
I-3 Use test standards, controls
I-5 Follow policies and procedures
J-4 Evaluate validity of results
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-5 Make oral presentations
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
N-5 Read technical literature
N-7 Promote community education
N-8 Maintain professional demeanor

TASKS FOR SOLVING PROBLEM(S)

None

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Personal Professional Development
Prioritizing Tasks
Problem Solving
Resource Management
Teamwork

Industry-Related Knowledge
Anatomy
Biochemistry/Lab
Biology/Lab
Chemistry/Lab
Clinical Laboratory Sciences
Immunology/Lab
Microbiology/Lab
Phlebotomy
Physiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Detail Orientation
Identifying Irregular Results
Instrumentation
Inventory and Supply Maintenance
Laboratory Procedures (Basic)
Maintaining Records, Lo
Protocols
Manual Dexterity
Performance Consistenc
Stress Management
Troubleshooting Ability
Upkeep of Equipment/W
Area

Attributes
Accountability
Alertness
Common Sense
Compassion
Confidentiality
Conscientiousness
Courteousness
Creativity
Handles Constructive Criticism
Hard Working
Honesty
Independent Worker
Integrity
Interest in Work
Leadership
Observant
Patience
Positive Attitude
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Tactfulness
Takes Initiative
Willingness to Ask for H
Willingness to Work Aro
Hazardous Chemicals
Willingness to Work Aro
Radioactive Materials
Works Well with Many Different People

SCENARIO 11

You work in a laboratory certifying a manufactured product.

Describe the procedures you use to monitor product performance.

You notice a 5 percent deviation in product performance.

What do you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Quality Systems (QC, QA)

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-4 Determine acceptability and optimum conditions of reagents for test
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
E-3 Date, label, store supplies and/or reagents; identify animals
E-4 Verify incoming delivery accuracy
E-5 Check expiration dates and lot numbers
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
H-1 Follow regulations: FDA (GMPs and GLPs)
I-1 Inspect, release incoming inventory
I-2 Check, verify integrity of product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures
J-1 Collect data
J-2 Perform calculations
J-3 Perform basic statistical analysis
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
L-3 Maintain laboratory notebook
N-5 Read technical literature

TASKS FOR SOLVING PROBLEM(S)

A-1 Obtain and read protocol, test procedure, SOP
A-4 Determine acceptability and optimum conditions of reagents for tests
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
E-2 Order supplies, reagents, animals
I-2 Check, verify integrity of product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-1 Interact with vendors, colleagues, and clients
K-7 Notify appropriate persons about problems and observations
N-1 Participate in training and cross-training

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Comunication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Prioritizing Tasks
Problem Solving
Resource Management
TQM/Total Quality Management

Industry-Related Knowledge
Chemistry/Lab
Clinical Laboratory Sciences
Immunology/Lab
Math (Graphing, Ratios, Calculus)
Microbiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Following Complex Procedures
Laboratory Procedures (Basic)
Instrumentation
Inventory and Supply Maintenance
Maintaining Records, Logs, Protocols
Manual Dexterity

Attributes
Flexibility
Independent Worker
Reliability
Responsibility
Safety Consciousness
Takes Initiative
Willingness to Ask for Help
Works Well with Many Different People

SCENARIO 12

You are asked to prepare a slide of a sample and controls.

Show what steps you take to prepare the slides and perform the staining.

When you evaluate the slides, the controls obtained from an external supplier stain weakly or not at all. The sample slide displays a normal staining pattern.

What action do you take based on these results?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Performance of Procedure
- Quality Systems (QC, QA)
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
A-4 Determine acceptability and optimum condition of reagents for tests
A-5 Assess acceptability/appropriateness of specimen
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
A-7 Perform histotechniques where needed
A-8 Return, archive, or dispose of samples
D-2 Prepare buffers, reagents
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
H-1 Follow regulations: FDA (GMPs and GLPs)
I-2 Check, verify integrity of the product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures
J-4 Evaluate validity of results

TASKS FOR SOLVING PROBLEM(S)

I-2 Check, verify integrity of the product, procedure, specimen
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Comunication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Problem Solving

Industry-Related Knowledge
Anatomy
Animal Science
Biochemistry/Lab
Biology/Lab
Botany
Chemistry/Lab
Clinical Laboratory Sciences
Immunology/Lab
Microbiology/Lab
Molecular Biology/Lab
Organic Chemistry/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
tail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Handles Failure
Honesty
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Reliability
Responsibility
Safety Consciousness
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Microbiologic Pathogens

SCENARIO 13

You are responsible for following the protocol for purifying your company's product. **Demonstrate the steps you take in product purification.**

The 2 liters of the crude product has a calculated yield of 10 grams per liter. You expect an 80 percent yield. After running the column, you calculate the purified total sample yield as 22 grams per liter.
Show how you would handle this result.

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Documentation/Tracking, Mathematical
- Calculations • Performance of Procedure
- Quality Systems (QC, QA)
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
B-2 Obtain raw material
B-3 Set-up equipment according to process requirements
B-4 Perform cleaning (manual/CIP) and s terilize (autoclave/SIP)
B-5 Prepare buffers and solutions
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
B-9 Purify product
F-1 Check calibration and perform system diagnostics
F-4 Clean work area according to SOPs
F-7 Maintain equipment logs
F-9 Label equipment and facilities
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-7 Handle, contain, and dispose of hazardous materials
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders
H-1 Follow regulations: FDA (GMPs and GLPs)
H-8 Follow state and local regulations
H-9 Follow industry and professional regulations
I-6 Monitor production lines
I-8 Take and document corrective action according to SOP or as directe
J-1 Collect data
J-2 Perform calculations
J-4 Evaluate validity of results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-2 Coordinate tasks with coworkers
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
L-3 Maintain laboratory notebook

TASKS FOR SOLVING PROBLEM(S)

F-1 Check calibration and perform system diagnostics
F-8 Troubleshoot and repair equipment (work order)
I-8 Take and document corrective action according to SOP or as directed
J-2 Perform calculations
J-3 Perform basic statistical analysis
J-4 Evaluate test validity
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Prioritizing Tasks
Problem Solving
TQM/Total Quality Management

Industry-Related Knowledge
Biochemistry/Lab
Biology/Lab
Chemistry/Lab
Math (Graphs, Ratios, Calculus)
Microbiology/Lab
Molecular Biology/Lab
Organic Chemistry/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Terminology (Medical, Bioscience)

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Performance Consistency
Stress Management
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Flexibility
Handles Failure
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Patience
Reliability
Responsibility
Scientific Curiosity
Sound Judgment
Thoroughness

SCENARIO 14

You are operating a bioreactor.
Demonstrate the steps involved in obtaining and testing bioreactor samples for pH, cell count, and clarity.

You perform the tests, and all the results are within specifications. During the visual inspection you observe that the sample is orange, while the previous sample looked red. ***What do you do about this observation?***

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Quality Systems (QC, QA)
- Troubleshooting Equipment Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic
A-7 Perform histotechniques where needed
A-8 Return, archive, or dispose of samples
B-1 Follow SOP and batch record (protocol or procedure)
B-8 Obtain, process, and store samples (applies to all manufacturing steps)
F-1 Check calibration and perform system diagnostics
F-7 Maintain equipment logs
G-3 Use protective equipment
G-7 Handle, contain, and dispose of hazardous materials
H-1 Follow regulations: FDA (GMPs and GLPs)
J-1 Collect data
J-2 Perform calculations
J-4 Evaluate validity of results
J-6 Document and report test results

TASKS FOR SOLVING PROBLEM(S)

F-8 Troubleshoot and repair equipment (work order)
I-5 Follow policies and procedures
J-5 Identify abnormal results
J-6 Document and report test results
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Problem Solving
Teamwork

Industry-Related Knowledge
Animal Science
Basic Electronics/Lab
Biochemistry/Lab
Biology/Lab
Botany
Chemistry/Lab
Engineering
Math (Graphing, Ratios, Calculus)
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Hard Working
Honesty
Independent Worker
Integrity
Meticulousness
Observant
Patience
Reliability
Responsibility
Safety Consciousness
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help

SCENARIO 15

Information is needed by your supervisor to update procedure manuals. You are assigned to obtain some information, and you are unsure how to locate the source materials.

What should you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Professional Development

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
B-1 Follow SOP and batch record (protocol or procedure)
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-5 Observe rules of electrical safety
G-6 Attend required trainings
H–
I-9 Follow regulations
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-3 Write or update protocols, procedure manuals, and reports for validation
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information
L-2 Research literature
L-3 Maintain laboratory notebook
N-2 Maintain awareness of accreditation and government regulations
N-5 Read technical literature

TASKS FOR SOLVING PROBLEM(S)

None

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Organization Skills
Prioritizing Tasks
Problem Solving
Resource Management

Industry-Related Knowledge
Clinical Laboratory Sciences
Math (Graphing, Ratios, Calculus)
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Scientific Method
Terminology (Medical, Bioscience)

Industry-Related Skills
Detail Orientation
Laboratory Procedures (Basic)
Maintain Records. Logs, Protocols
Writing Logical Instructions

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Hard Working
Honesty
Independent Worker
Integrity
Observant
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help

SCENARIO 16

Your job is to assist with cleaning, preparing, sterilizing, and inoculating a bioreactor. **Show what tests and procedures you follow to perform these tasks.**

After inoculation, a coworker points out that the bioreactor exit air filter cartridge is not installed. This means that there is no filter between the recombinant cells in the bioreactor and the outside environment.
Demonstrate how you would handle this.

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Ethics • Performance of Procedure
- Regulatory Compliance • Safety
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
B-3 Set up equipment according to process requirements
B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)
B-6 Start up production
B-7 Operate reactors and recover product
E-5 Check expiration dates and lot numbers
F-1 Check calibration and perform system diagnostics
F-3 Perform or schedule preventive maintenance
F-7 Maintain equipment logs
F-8 Troubleshoot and repair equipment (work order)
F-9 Label equipment and facilities
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-9 Observe procedures for the safe use of instruments and cylinders
H-1 Follow regulations: FDA (GMPs and GLPs)
H-2 Follow regulations: OSHA
I-2 Check, verify the integrity of the product, procedure, specimen

TASKS FOR SOLVING PROBLEM(S)

F-7 Maintain equipment logs
F-9 Label equipment and facilities
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-7 Handle, contain, and dispose of hazardous materials
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders
H-1 Follow regulations: FDA (GMPs and GLPs)
H-2 Follow regulations: OSHA
H-8 Follow state and local regulations
I-2 Check, verify integrity of the product, procedure, specimen
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-3 Write or update protocols, procedure manuals, and reports for validation
K-7 Notify appropriate persons about problems and observations
N-2 Maintain awareness of accreditation and government regulations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organizational Skills
Problem Solving
Resource Management
Time Management
TQM/Total Quality Management

Industry-Related Knowledge
Basic Electronics/Lab
Biology/Lab
Clinical Laboratory Sciences
Engineering
Physiology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Scientific Methods
Terminology (Medical, Bioscience)
Toxicology

Industry-Related Skills
Aseptic Technique
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Performance Consistency
Stress Management
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Confidentiality
Conscientiousness
Courteousness
Handles Constructive Criticism
Hard Working
Honesty
Independent worker
Integrity
Interest in Work
Meticulousness
Observant
Positive Attitude
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help

SCENARIO 17

You talk to a vendor who claims to have a new product that will double your throughput. You want your supervisor to consider investigating the new product.

What should you do to make this proposal?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Professional Development
- Quality Systems (QC, QA)

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

E-2 Order supplies, reagents, animals
F-2 Validate processes, equipment, facilities, kits, vendor products
J-1 Collect data
J-2 Perform calculations
J-3 Perform basic statistical analysis
K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-5 Make oral presentations
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
N-5 Read technical literature
N-8 Maintain professional demeanor

TASKS FOR SOLVING PROBLEM(S)

None

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Organization Skills
Personal Professional Development
Resource Management

Industry-Related Knowledge
Math (Graphing, Ratios, Calculus)
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Scientific Method

Industry-Related Skills
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Performance Consistency
Writing Logical Instructions

Attributes
Common Sense
Confidentiality
Creativity
Handles Constructive Criticism
Handles Failure
Honesty
Independent Worker
Integrity
Observant
Responsibility
Scientific Curiosity
Self-Motivation
Takes Initiative
Thoroughness
Works Well with Many Different People

SCENARIO 18

You receive a brochure announcing a seminar that would enhance your professional development. Funding is tight.

Justify your attendance at this seminar to your supervisor.

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Professional Development

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-5 Make oral presentations
K-6 Process information using computers
N-2 Maintain awareness of accreditation and government regulations
N-3 Participate in continuing education and professional organizations
N-4 Pursue additional certification and degrees
N-5 Read technical literature
N-6 Document training

TASKS FOR SOLVING PROBLEM(S)

None

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Personal Professional Development
Resource Management

Industry-Related Knowledge
Career Awareness Within the Industry
Recognizing Need for Supervisory Assistance

Attributes
Conscientiousness
Honesty
Interest in Work
Professional Attitude/Behavior
Scientific Curiosity
Self-Motivation
Sound Judgment
Tactfulness
Takes Initiative

SCENARIO 19

You are responsible for preparing specimens for an assay that requires immediate centrifugation. **What are the steps involved in preparing the material for centrifugation?**

One week ago you reserved time for a 12-hour spin to coincide with the completion of your assay. When you bring your samples to the centrifuge, you discover that it is currently being used. There is no indication of who may be using the centrifuge.
What would you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking • Ethics
- Performance of Procedure
- Quality Systems (QC, QA)

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
B-7 Operate reactors and recover product
C-4 Obtain and label sample/specimen
F-1 Check calibration and perform system diagnostics
F-2 Validate processes, equipment, facilities, kits, vendor products
F-4 Clean work area according to SOPs
F-7 Maintain equipment logs
F-9 Label equipment and facilities
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-5 Observe rules of electrical safety
G-7 Handle, contain, and dispose of hazardous materials
H-1 Follow regulations: FDA (GMPs and GLPs)
I-2 Check, verify integrity of the product, procedure, specimen
I-4 Maintain QA logs
I-5 Follow policies and procedures
K-2 Coordinate tasks with coworkers
K-7 Notify appropriate persons about problems and observations

TASKS FOR SOLVING PROBLEM(S)

H-2 Follow regulations: OSHA
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-3 Write or update protocols, procedure manuals, and reports for validation
K-4 Write memos and letters
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Ethics
Organization Skills
Problem Solving
Resource Management
Teamwork

Industry-Related Knowledge
Recognizing Need for Supervisory Assistance

Industry-Related Skills
Instrumentation
Laboratory Procedures (Basic)
Stress Management

Attributes
Accountability
Common Sense
Courteousness
Flexibility
Independent Worker
Integrity
Patience
Professional Attitude/Behavior
Tactfulness
Willingness to Ask for Help

SCENARIO 20

You perform animal care at your facility according to protocol.
Describe these duties.

One morning you notice that the test animals are listless and lethargic. You also notice evidence of diarrhea in some of the cages.
How do you respond?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Animal Handling
- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Safety
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
E-1 Monitor and record inventory; keep census of animals
H-1 Follow regulations: FDA (GMPs and GLPs)
M-1 Monitor health and maintain health records
M-2 Feed and water animals/plants
M-3 Receive and transport animals/plants
M-4 Monitor housing conditions
M-5 Restrain and handle animals
M-6 Clean housing and sterilize cages
M-7 Participate as a member of the research team
M-8 Monitor and maintain animal safety

TASKS FOR SOLVING PROBLEM(S)

E-1 Monitor and record inventory; keep census of animals
E-6 Maintain separate in-process, quarantine, and release areas
F-4 Clean work area according to SOPs
F-5 Sample environment
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-6 Attend required trainings
I-8 Take and document corrective action according to SOP or as directed
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Prioritizing Tasks
Problem Solving
TQM/Total Quality Management

Industry-Related Knowledge
Animal Science
Biology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Animal Care and Handling
Aseptic Technique
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Maintaining Records, Logs, Protocols
Performance Consistency
Stress Management
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Compassion
Conscientiousness
Flexibility
Handles Constructive Criticism
Handles Failure
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Patience
Professional Attitude/ Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Thoroughness
Willingness to Ask for Help

SCENARIO 21

You are performing a quality control check. You are asked to sample a raw material for routine retesting.
Demonstrate the procedure used to verify that the material is still acceptable for use.

In doing so, you observe that the raw material that is expected to be granular has large clumps in it.
What actions do you take?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ♦
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Quality Systems (QC, QA)
- Regulatory Compliance
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
A-5 Assess acceptability/appropriateness of specimen
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
E-5 Check expiration dates and lot numbers
E-6 Maintain separate in-process quarantine and release areas
E-7 Maintain and store manufactured products inventory
H-1 Follow regulations: FDA (GMPs and GLPs)
H-2 Follow regulations: OSHA
I-1 Inspect, release incoming inventory
I-2 Check, verify integrity of the product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-6 Monitor production lines
K-2 Coordinate tasks with coworkers

TASKS FOR SOLVING PROBLEM(S)

I-8 Take and document corrective action according to SOP or as directed
I-10 Ensure turnaround time
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-4 Write memos and letters
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Problem Solving
Teamwork
TQM/Total Quality Management

Industry-Related Knowledge
Chemistry/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards

Industry-Related Skills
Identifying Irregular Results
Inventory and Supply Maintenance
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Integrity
Meticulousness
Observant
Reliability
Responsibility
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Work Around Hazardous Chemicals

SCENARIO 22

You are given 25 microliters of DNA in solution for restriction analysis.
Explain what you would do.

You perform the analysis. Upon visualization with ethidium bromide, you see long smears instead of distinct bands.
How do you assess and deal with this observation?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Documentation/Tracking
- Performance of Procedure
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
A-7 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
B-2 Obtain raw material
B-3 Set up equipment according to process requirements
B-5 Prepare buffers and solutions
I-5 Follow policies and procedures
J-6 Document and report test results

TASKS FOR SOLVING PROBLEM(S)

E-5 Check expiration dates and lot numbers
F-1 Check calibration and perform system diagnostics
F-2 Validate processes, equipment, facilities, kits, vendor products
F-3 Perform preventive maintenance
F-4 Clean work area according to SOPs
I-2 Check, verify integrity of the product, procedure, specimen
I-3 Use test standards, controls
I-8 Take and document corrective action according to SOP or as directed
J-4 Evaluate validity of results
J-5 Identify abnormal results
K-4 Write memos and letters
K-7 Notify appropriate persons about problems and observations

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Organization Skills
Problem Solving

Industry-Related Knowledge
Biochemistry/Lab
Biology/Lab
Chemistry/Lab
Molecular Biology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Common Sense
Handles Failure
Hard Working
Honesty
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Responsibility
Safety Consciousness
Willingness to Ask for He
Willingness to Work Arou
Hazardous Chemicals

SCENARIO 23

Your responsibilities include filing reports and storing slides.

What is the standard procedure for storing a stained slide and reporting after the pathologist's evaluation?

Three months ago, a patient had a tumor biopsy. The attending physician has requested an additional copy of the report. After thoroughly searching the storage files, you cannot find the report.

Explain how you would handle this.

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing
D) Clinical Laboratory ◆

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Ethics
- Performance of Procedure
- Quality Systems (QC, QA)
- Regulatory Compliance
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
A-8 Return, archive, or dispose of samples
C-5 Handle, transport, store sample, including legal requirements
H-8 Follow state and local regulations
H-9 Follow industry and professional regulations
I-4 Maintain QA logs
I-5 Follow policies and procedures
K-1 Interact with vendors, colleagues, and clients
K-6 Process information using computers
N-6 Document training

TASKS FOR SOLVING PROBLEM(S)

I-7 Document customer complaints
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Ethics (Business, Medical, Personal)
Organizational Skills
Problem Solving
Teamwork
TQM/Total Quality Management

Industry-Related Knowledge
Clinical Laboratory Sciences
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards

Industry-Related Skills
Maintaining Records, Logs, Protocols
Performance Consistency
Stress Management
Troubleshooting Ability

Attributes
Accountability
Common Sense
Confidentiality
Courteousness
Hard Working
Honesty
Independent Worker
Observant
Patience
Professional Attitude
Reliability
Responsibility
Tactfulness
Thoroughness
Willingness to Ask for Help
Works Well with Many Different People

SCENARIO 24

Your responsibilities include receiving inventory and documentation of central supplies. **Describe the procedure for receipt of a new chemical.**

You receive vendor notification for recall of a reagent. This reagent is being used in several laboratories within the institution.
What do you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Performance of Procedure
- Quality Systems (QC, QA)
- Regulatory Compliance
- Safety

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

E-1 Monitor and record inventory; keep census of animals
E-3 Date, label, store supplies and/or reagents; identify animals
E-4 Verify incoming delivery accuracy
E-5 Check expiration dates and lot numbers
E-6 Maintain separate in-process quarantine and release areas
G-1 Maintain and follow chemical hygiene plan
G-3 Use protective equipment
H-1 Follow Regulations: FDA (GMPs and GLPs)
H-2 Follow Regulations: OSHA
H-8 Follow state and local regulations
I-1 Inspect, release incoming inventory
I-2 Check, verify integrity of the product, procedure, specimen
I-4 Maintain QA logs
K-1 Interact with vendors, colleagues, and clients
K-6 Process information using computers

TASKS FOR SOLVING PROBLEM(S)

E-1 Monitor and record inventory; keep census of animals
E-5 Check expiration dates and lot numbers
G-7 Handle, contain, and dispose of hazardous materials
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Problem Solving
Teamwork
TQM/Total Quality Management

Industry-Related Knowledge
Chemistry/Lab
Clinical Laboratory Sciences
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Detail Orientation
Inventory and Supply Maintenance
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/Work Area
Writing Logical Instructions

Attributes
Accountability
Independent Worker
Integrity
Meticulousness
Observant
Reliability
Responsibility
Safety Consciousness
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Hazardous Chemicals
Wilingness to Work Around Radioactive Materials
Works Well with Many Different People

SCENARIO 25

You must remove a test animal from its cage. **What is the procedure that you routinely follow?**

As you are holding it, the animal bites through your glove, cutting your hand. ***How will you proceed?***

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Animal Handling
- Documentation/Tracking
- Performance of Procedure
- Regulatory Compliance
- Safety
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
C-3 Prepare animals
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-6 Attend required trainings
I-5 Follow policies and procedures
M-5 Restrain and handle animals

TASKS FOR SOLVING PROBLEM(S)

H-2 Follow regulations: OSHA
K-7 Notify appropriate persons about problems and observations
M-1 Monitor health and maintain health records
M-8 Monitor and maintain animal safety
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
Prioritizing Tasks
Problem Solving
TQM/Total Quality Management

Industry-Related Knowledge
Animal Science
Biology/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Animal Care and Handling
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Compassion
Conscientiousness
Handles Failure
Honesty
Independent Worker
Integrity
Meticulousness
Observant
Patience
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Takes Initiative
Willingness to Ask for Help

SCENARIO 26

You are taking routine readings from a computer screen. You hit the wrong key and the screen goes blank.
What do you do?

Your efforts have been to no avail.
What next steps do you take?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Troubleshooting Equipment Failure

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TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
F-1 Check calibration and perform system diagnostics
H-1 Follow regulations: FDA (GMPs and GLPs)

TASKS FOR SOLVING PROBLEM(S)

A-3 Check equipment
F-1 Check calibration and perform system diagnostics
F-8 Troubleshoot and repair equipment (work order)
H-
I-9 Follow regulations
I-4 Maintain QA logs
I-5 Follow policies and procedures
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
N-5 Read technical literature
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Problem Solving
Teamwork

Industry-Related Knowledge
Basic Electronics/Lab
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Instrumentation
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management
Troubleshooting Ability

Attributes
Accountability
Alertness
Common Sense
Handles Failure
Observant
Patience
Self-Motivation
Sound Judgment
Takes Initiative
Willingness to Ask for Help

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SCENARIO 27

You are monitoring a bioreactor during production. An alarm sounds and you observe that the computer monitor says "pH Too Low." Low pH is normally adjusted by the automatic addition of base controlled through the bioreactor computer.

Tell how you respond to this alarm.

The cells in the bioreactor will die if the pH stays too low.

What do you do? Prepare a graph showing the change in pH before and after the event.

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

• Communication (Oral, Written, Electronic)
• Safety • Troubleshooting Equipment Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
B-7 Operate reactors and recover product
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
F-1 Check calibration and perform system diagnostics
F-7 Maintain equipment logs
F-8 Troubleshoot and repair equipment (work order)
H-1 Follow regulations: FDA (GMPs and GLPs)
J-1 Collect data
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations

TASKS FOR SOLVING PROBLEM(S)

B-1 Follow SOP and batch record (protocol or procedure)
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
F-1 Check calibration and perform system diagnostics
F-7 Maintain equipment logs
F-8 Troubleshoot and repair equipment (work order)
F-9 Label equipment and facilities
G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-5 Observe rules of electrical safety
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders
J-1 Collect data
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-2 Coordinate tasks with coworkers
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Problem Solving

Industry-Related Knowledge
Basic Electronics/Lab
Biochemistry/Lab
Biology/Lab
Chemistry/Lab
Math (Graphing, Ratios, Calculus)
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems

Industry-Related Skills
Detail Orientation
Following Complex Procedures
Identifying Irregular Results
Instrumentation
Maintaining Records, Logs, Protocols
Troubleshooting Ability
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Conscientiousness
Meticulousness
Observant
Responsibility
Safety Consciousness
Sound Judgment
Takes Initiative
Thoroughness
Willingness to Ask for Help

SCENARIO 28

You work in inventory control. You receive an order for your company's product. **What tasks do you perform to fill the order?**

Customer Service informs you that a customer reported that half of the vials you sent her were cracked. She was very upset.
What do you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development
C) Manufacturing ◆
D) Clinical Laboratory ◆

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Electronic, Written)
- Documentation/Tracking • Ethics
- Quality Systems (QC, QA)
- Regulatory Compliance • Safety
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
B-11 Label and package product
B-12 Distribute final product
E-1 Monitor and record inventory; keep census of animals
E-4 Verify incoming delivery accuracy
E-5 Check expiration dates and lot numbers
E-6 Maintain separate in-process quarantine and release areas
E-7 Maintain and store manufactured products inventory
H-1 Follow regulations: FDA (GMPs and GLPs)
H-8 Follow state and local regulations
H-9 Follow industry and professional regulations
I-10 Ensure turnaround time
K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-6 Process information using computers

TASKS FOR SOLVING PROBLEM(S)

F-2 Validate processes, equipment, facilities, kits, vendor products
F-3 Perform or schedule preventive maintenance
F-6 Implement systems updates
F-8 Troubleshoot and repair equipment (work order)
I-7 Document customer complaints
I-8 Take and document corrective action according to SOP or as directed
I-10 Ensure turnaround time
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-1 Interact with vendors, colleagues, and clients
K-7 Notify appropriate persons about problems and observations
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Decision-Making
Ethics (Business, Medical, Personal)
Organization Skills
Problem Solving
Resource Management

Industry-Related Knowledge
Quality Control and Quality Assurance Practices
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Identifying Irregular Results
Inventory and Supply Maintenance
Maintaining Records, Logs, Protocols
Performance Consistency
Stress Management
Troubleshooting Ability

Attributes
Accountability
Common Sense
Compassion
Conscientiousness
Courteousness
Flexibility
Handles Constructive Criticism
Patience
Positive Attitude
Professional Attitude/Behavior
Safety Consciousness
Sound Judgment
Tactfulness
Works Well with Many Different People

SCENARIO 29

Your company renovates your aseptic fill facility. Your fill group must sample the environment, people, and process used to aseptically fill your company's product.

Explain the tasks involved in performing these tests.

The results of the test fail the acceptance criteria because 10 of the 3,000 vials filled are contaminated.

How do you identify the source of the problem, and what suggestions do you make to your group?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing ◆
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication • Documentation/Tracking
- Quality Systems (QC, QA)
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
B-2 Obtain raw material
B-3 Set up equipment according to process requirements
B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)
B-5 Prepare buffers and solutions
B-6 Start up production
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
B-10 Formulate, fill, and inspect product
C-5 Handle, transport, store sample, including legal requirements
F-1 Check calibration and perform system diagnostics
F-2 Validate processes, equipment, facilities, kits, vendor products
F-3 Perform or schedule preventive maintenance
F-4 Clean work area according to SOPs
F-5 Sample environment
F-6 Implement systems updates
F-7 Maintain equipment logs
F-8 Troubleshoot and repair equipment (work order)
F-9 Label equipment and facilities
F-10 Ensure clean room integrity
H-1 Follow regulations: FDA (GMPs and GLPs)
I-6 Monitor production lines
I-9 Participate in proficiency testing
K-2 Coordinate tasks with coworkers
N-1 Participate in training and cross-training
N-6 Document training

TASKS FOR SOLVING PROBLEM(S)

B-3 Set up equipment according to process requirements
B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
F-2 Validate processes, equipment, facilities, kits, vendor products
F-4 Clean work area according to SOPs
F-5 Sample environment
F-8 Troubleshoot and repair equipment (work order)
F-10 Ensure clean room integrity
H-1 Follow regulations: FDA (GMPs and GLPs)
H-2 Check, verify integrity of the product, procedure, specimen
I-4 Maintain QA logs
J-1 Collect data
J-2 Perform calculations
J-3 Perform basic statistical analysis
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-3 Write or update protocols, procedure manuals, and reports for validation
K-4 Write memos or letters
K-5 Make oral presentations
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
L-3 Maintain laboratory notebook
N-5 Read technical literature
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Organization Skills
Prioritizing Tasks
Resource Management
Teamwork
TQM/Total Quality Management

Industry-Related Knowledge
Engineering
Microbiology/Lab
Quality Control and Quality Assurance Practices
Regulatory Standards
Safety Systems
Scientific Method

Industry-Related Skills
Aseptic Technique
Identifying Irregular Results
Maintaining Records, Logs, Protocols
Performance Consistency
Troubleshooting Ability
Upkeep of Equipment/ Work Area

Attributes
Alertness
Common Sense
Conscientiousness
Creativity
Handles Constructive Criticism
Handles Failure
Honesty
Integrity
Interest in Work
Leadership
Meticulousness
Observant
Responsibility
Thoroughness
Works Well with Many Different People

SCENARIO 30

You approach a patient to collect a venous blood sample for routine hospital admission tests.

Describe how you would proceed.

The patient, however, is reluctant to have blood drawn because of a recent difficult venipuncture experience.

How would you handle this scenario?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C and D)
B) Research and Development
C) Manufacturing
D) Clinical Laboratory ◆

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

Communication (Oral, Written, Electronic)
Ethics
Performance of Procedure
Safety

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

C-2 Match request to test sample
C-3 Prepare patient (mentally, physically); prepare animals
C-4 Obtain and label sample/specimen
C-5 Handle, transport, store sample, including legal requirements
E-7 Maintain and store manufactured products inventory
G-2 Follow universal precautions for biological hazards
G-3 Use protective equipment
G-6 Attend required training
G-7 Handle, contain, and dispose of hazardous materials
K-1 Interact with vendors, colleagues, and clients
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information
N-8 Maintain professional demeanor

TASKS FOR SOLVING PROBLEM(S)

C-3 Prepare patient (mentally, physically); prepare animals
I-5 Follow policies and procedures
K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Decision-Making
Ethics (Business, Medical, Personal)
Prioritizing Tasks
Problem Solving

Industry-Related Knowledge
Anatomy
Clinical Laboratory Sciences
Physiology/Lab
Phlebotomy
Recognizing Need for Supervisory Assistance
Regulatory Standards
Safety Systems
Terminology (Medical, Bioscience)

Industry-Related Skills
Aseptic Technique
Identifying Irregular Results
Maintaining Records, Logs, Protocols
Manual Dexterity
Performance Consistency
Stress Management
Upkeep of Equipment/Work Area

Attributes
Accountability
Alertness
Common Sense
Compassion
Confidentiality
Conscientiousness
Courteousness
Flexibility
Handles Constructive Criticism
Handles Failure
Hard Working
Honesty
Independent Worker
Integrity
Interest in Work
Meticulousness
Observant
Patience
Positive Attitude
Professional Attitude/Behavior
Reliability
Responsibility
Safety Consciousness
Self-Motivation
Sound Judgment
Tactfulness
Takes Initiative
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Microbiologic Pathogens
Works Well with Many Different People

SCENARIO 31

A chemical reaction experiment is set up, utilizing a limited amount of sample as the starting material.
How would you proceed?

The next morning, you come into the lab and find that the reaction did not work. There is no more starting material to run the experiment again.
What do you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D)
B) Research and Development ◆
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication
- Documentation/Tracking
- Mathematical Calculations
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

None

TASKS FOR SOLVING PROBLEM(S)

A-1 Obtain and read protocol, test procedure, SOP
A-2 Prepare sample for testing
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
D-1 Organize compounds
D-2 Prepare buffers, reagents
E-5 Check expiration dates and lot numbers
F-1 Check calibration and perform system diagnostics
F-2 Validate processes, equipment, facilities, kits, vendor products
F-3 Perform or schedule preventative maintenance
F-4 Clean work area according to SOPs
F-7 Maintain equipment logs
G-1 Maintain and follow chemical hygiene plan
G-3 Use protective equipment
G-4 Observe rules of safety with radioactive materials
G-5 Observe rules of electrical safety
G-7 Handle, contain, and dispose of hazardous materials
G-9 Observe procedures for the safe use of instruments and cylinders
H-2 Follow regulations: OSHA
H-3 Follow regulations: USDA
H-4 Follow regulations: NIH
H-5 Follow regulations: CDC
H-7 Follow regulations: NRC
J-4 Evaluate validity of results
K-5 Make oral presentations/communicate orally
K-7 Notify appropriate persons about problems and observations
L-3 Maintain laboratory notebook

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Critical Thinking
Decision-Making
Organization Skills
Problem Solving
Resource Management
Teamwork

Industry-Related Knowledge
Biochemistry/Lab
Chemistry/Lab
Math (Graphs, Ratios, Calculus)
Recognizing Need for Supervisory Assistance
Scientific Method
Terminology (Medical, Bioscience)

Industry-Related Skills
Detail Orientation
Instrumentation
Laboratory Procedures (Basic)
Maintaining Records, Logs, Protocols
Performance Consistency
Stress Management
Troubleshooting Ability

Attributes
Accountability
Alertness
Common Sense
Creativity
Handles Failure
Honesty
Integrity
Interest in Work
Meticulousness
Observant
Patience
Reliability
Scientific Curiosity
Sound Judgment
Thoroughness
Willingness to Ask for Help
Willingness to Work Around Hazardous Chemicals

SCENARIO 32

You are recording data. Your readings are 10.40, 10.31, 10.52, and 10.64. **Calculate the average and record in 3 significant digits.**

Your next reading is 14.75.
What would you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Mathematical Calculations

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

B-1 Follow SOP and batch record (protocol or procedure)
H-1 Follow regulations: FDA (GMPs and GLPs)
J-1 Collect data
J-2 Perform calculations
J-3 Perform statistical analysis
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-7 Document and report test results
K-6 Process information using computers
K-8 Document communication of information

TASKS FOR SOLVING PROBLEM(S)

J-2 Perform calculations
J-3 Perform statistical analysis
J-5 Identify abnormal results
J-6 Document and report test results
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Problem Solving

Industry-Related Knowledge
Math (Graphing, Ratios, Calculus)
Recognizing Need for Supervisory Assistance

Industry-Related Skills
Detail Orientation
Identifying Irregular Results
Maintaining Records, Logs, Protocols
Performance Consistency

Attributes
Accountability
Alertness
Common Sense
Observant
Reliability
Responsibility
Sound Judgment
Thoroughness
Willingness to Ask for Help

SCENARIO 33

When you answer your department phone, the caller (physician, supplier, vendor) is angry about the way a situation was handled. **How do you deal with this scenario?**

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Ethics

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

H-1 Follow regulations: FDA (GMPs and GLPs)
I-7 Document customer complaints
I-8 Take and document corrective action according to SOP or as directed
K-1 Interact with vendors, colleagues, and clients
K-4 Write memos and letters
K-5 Make oral presentations/communicate orally
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information
N-8 Maintain professional demeanor

TASKS FOR SOLVING PROBLEM(S)

None

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Problem Solving
Teamwork
TQM/Total Quality Management

Industry-Related Knowledge
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance

Industry-Related Skills
Stress Management
Troubleshooting Ability

Attributes
Common Sense
Confidentiality
Courteousness
Handles Constructive Criticism
Handles Failure
Patience
Positive Attitude
Professional Attitude/Behavior
Sound Judgment
Tactfulness
Willingness to Ask for Help
Works Well with Many Different People

SCENARIO 34

You are responsible for recording sample test results.
Demonstrate this process.

After the reports have been sent out, you realize that a sample result that you recorded at 3.75 should have been 8.75.
What would you do?

WORKPLACE SETTING FOR THIS SCENARIO

A) Generic (Applies to B, C, D) ◆
B) Research and Development
C) Manufacturing
D) Clinical Laboratory

KEY COMPETENCY AREA(S) THAT THIS SCENARIO DEMONSTRATES

- Communication
- Documentation/Tracking
- Ethics
- Mathematical Calculations

TASKS FOR PERFORMING ROUTINE PROCEDURE(S)

A-1 Obtain and read protocol, test procedure, SOP
B-1 Follow SOP and batch record (protocol or procedure)
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
H-1 Follow regulations: FDA (GMPs and GLPs)
I-5 Follow policies and procedures
J-2 Perform calculations
J-6 Document and report test results
J-7 Obtain written or verbal verification
K-6 Process information using computers
K-8 Document communication of information

TASKS FOR SOLVING PROBLEM(S)

I-5 Follow policies and procedures
K-4 Write memos and letters
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, ATTRIBUTES

General Work Skills
Basic Math (Fractions, Percentages, Metric System)
Communication (Electronic, Oral, Written)
Computers/Comfort with Automation
Critical Thinking
Decision-Making
Ethics (Business, Medical, Personal)
TQM/ Total Quality Management

Industry-Related Knowledge
Math (Graphing, Ratios, Calculus)
Quality Control and Quality Assurance Practices
Recognizing Need for Supervisory Assistance

Industry-Related Skills
Detail Orientation
Maintaining Records, Logs, Protocols

Attributes
Accountability
Alertness
Conscientiousness
Honesty
Integrity
Observant
Professional Attitude/Behavior
Reliability
Sound Judgment
Takes Initiative
Thoroughness

KEY COMPETENCY AREAS

- Animal Handling
- Communication (Oral, Written, Electronic)
- Documentation/Tracking
- Ethics
- Mathematical Calculations
- Performance of Procedure
- Professional Development
- Quality Systems (QC, QA)
- Regulatory Compliance
- Safety
- Troubleshooting Equipment Failure
- Troubleshooting Methods Failure

JOB FUNCTION AND TASKS LIST

JOB FUNCTION A: PERFORM TESTS/ASSAYS

A-1 Obtain and read protocol, test procedure, Standard Operating Procedures (SOPs)
A-2 Prepare sample for testing
A-3 Check equipment
A-4 Determine acceptability and optimum conditions of reagents for tests
A-5 Assess acceptability/appropriateness of specimen
A-6 Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
A-7 Perform histotechniques where needed
A-8 Return, archive, or dispose of samples

JOB FUNCTION B: MANUFACTURE PRODUCTS

B-1 Follow SOP and batch record (protocol or procedure)
B-2 Obtain raw material
B-3 Set up equipment according to process requirements
B-4 Perform cleaning (manual/Clean in Place [CIP]) and sterilize (autoclave/Sterilize in Place [SIP])
B-5 Prepare buffers and solutions
B-6 Start up production
B-7 Operate reactors and recover product
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)
B-9 Purify product
B-10 Formulate, fill, and inspect product
B-11 Label and package product
B-12 Distribute final product

JOB FUNCTION C: OBTAIN SPECIMENS OR MATERIALS

C-1 Request tests
C-2 Match request to test sample
C-3 Prepare patient (mentally, physically); prepare animals
C-4 Obtain and label sample/specimen
C-5 Handle, transport, store sample, including legal requirements
C-6 Assess acceptability/appropriateness of specimen

JOB FUNCTION D: PROCESS MATERIALS

D-1 Organize compounds
D-2 Prepare buffers, reagents
D-3 Set up and work reactions

JOB FUNCTION E: CONTROL INVENTORY

E-1 Monitor and record inventory; keep census of animals
E-2 Order supplies, reagents, animals
E-3 Date, label, store supplies and/or reagents; identify animals
E-4 Verify incoming delivery accuracy
E-5 Check expiration dates and lot numbers
E-6 Maintain separate in-process, quarantine, and release areas
E-7 Maintain and store manufactured products inventory

JOB FUNCTION F: MAINTAIN EQUIPMENT AND FACILITY

F-1 Check calibration and perform system diagnostics
F-2 Validate or confirm processes, equipment, facilities, kits, vendor products
F-3 Perform or schedule preventive maintenance
F-4 Clean work area according to SOPs
F-5 Sample environment
F-6 Implement systems updates
F-7 Maintain equipment logs
F-8 Troubleshoot and repair equipment (work order)
F-9 Label equipment and facilities
F-10 Ensure clean room integrity

JOB FUNCTION G: OBSERVE AND DOCUMENT SAFE PRACTICES

G-1 Maintain and follow chemical hygiene plan
G-2 Follow universal precautions for biological pathogens
G-3 Use protective equipment
G-4 Observe rules of safety with radioactive materials
G-5 Observe rules of electrical safety
G-6 Attend required trainings
G-7 Handle, contain, and dispose of hazardous materials
G-8 Maintain safety equipment
G-9 Observe procedures for the safe use of instruments and cylinders

JOB FUNCTION H:
COMPLY WITH CURRENT ACCREDITATION AND GOVERNMENT REGULATIONS

H-1 Follow regulations: Food and Drug Administration (FDA) (Good Manufacturing Practices [GMPs] and Good Laboratory Practices [GLPs])
H-2 Follow regulations: Occupational Safety and Health Administration (OSHA)
H-3 Follow regulations: United States Drug Administration (USDA)
H-4 Follow regulations: National Institutes of Health (NIH)
H-5 Follow regulations: Centers for Disease Control and Prevention (CDC)
H-6 Follow regulations: Clinical Laboratory Improvement Act (CLIA)
H-7 Follow regulations: Nuclear Regulatory Commission (NRC)
H-8 Follow state and local regulations
H-9 Follow industry and professional regulations

JOB FUNCTION I:
MAINTAIN QUALITY ASSURANCE

I-1 Inspect, release incoming inventory
I-2 Check, verify integrity of the product, procedure, specimen
I-3 Use test standards, controls
I-4 Maintain Quality Assurance (QA) logs
I-5 Follow policies and procedures
I-6 Monitor production lines
I-7 Document customer complaints
I-8 Take and document corrective action according to SOP or as directed
I-9 Participate in proficiency testing
I-10 Ensure turnaround time

JOB FUNCTION J:
EVALUATE, DOCUMENT, AND REPORT RESULTS

J-1 Collect data
J-2 Perform calculations
J-3 Perform basic statistical analysis
J-4 Evaluate validity of results
J-5 Identify abnormal results
J-6 Document and report test results
J-7 Obtain written or verbal verification

JOB FUNCTION K:
COMMUNICATE AND DOCUMENT INFORMATION (WRITTEN, ORAL, ELECTRONIC)

K-1 Interact with vendors, colleagues, and clients
K-2 Coordinate tasks with coworkers
K-3 Write or update protocols, procedure manuals, and reports for validation
K-4 Write memos and letters
K-5 Make oral presentations
K-6 Process information using computers
K-7 Notify appropriate persons about problems and observations
K-8 Document communication of information

JOB FUNCTION L:
PERFORM INITIAL RESEARCH

L-1 Assist with design of research protocol
L-2 Research literature
L-3 Maintain laboratory notebook

JOB FUNCTION M:
CARE FOR RESEARCH ANIMALS/PLANTS

M-1 Monitor health and maintain health records
M-2 Feed and water animals/plants
M-3 Receive and transport animals/plants
M-4 Monitor housing conditions
M-5 Restrain and handle animals
M-6 Clean housing and sterilize cages
M-7 Participate as a member of the research team
M-8 Monitor and maintain animal safety

JOB FUNCTION N:
MAINTAIN PROFESSIONAL COMPETENCY

N-1 Participate in training and cross-training
N-2 Maintain awareness of accreditation and government regulations
N-3 Participate in continuing education and professional organizations
N-4 Pursue additional certification and degrees
N-5 Read technical literature
N-6 Document training
N-7 Promote community education
N-8 Maintain professional demeanor

SKILLS, KNOWLEDGE, AND ATTRIBUTES FOR BIOSCIENCE TECHNICAL SPECIALIST I

GENERAL WORK SKILLS

- Basic Math
  (Fractions, Percentages, Metric System)
- Communication
  (Electronic, Oral, Written)
- Computers/Comfort with Automation
- Critical Thinking
- Decision-Making
- Ethics (Business, Medical, Personal)
- Organization Skills
- Personal Professional Development
- Prioritizing Tasks
- Problem Solving
- Resource Management
- Teamwork
- Time Management
- TQM/Total Quality Management

INDUSTRY-RELATED SKILLS

- Animal Care and Handling
- Aseptic Technique
- Detail Orientation
- Following Complex Procedures
- Identifying Irregular Results
- Instrumentation
- Inventory and Supply Maintenance
- Laboratory Procedures (Basic)
- Maintaining Records, Logs, Protocols
- Manual Dexterity
- Performance Consistency
- Stress Management
- Troubleshooting Ability
- Upkeep of Equipment/Work Area
- Writing Logical Instructions

INDUSTRY-RELATED KNOWLEDGE

- Anatomy
- Animal Science
- Basic Electronics/Lab
- Biochemistry/Lab
- Biology/Lab
- Botany
- Career Awareness Within the Industry
- Chemistry/Lab
- Clinical Laboratory Sciences
- Engineering
- Immunology/Lab
- Math (Graphing, Ratios, Calculus)
- Microbiology/Lab
- Molecular Biology/Lab
- Organic Chemistry/Lab
- Phlebotomy
- Physiology/Lab
- Quality Control and Quality Assurance Practices
- Recognizing Need for Supervisory Assistance
- Regulatory Standards
- Safety Systems
- Scientific Systems
- Terminology (Medical, Bioscience)
- Toxicology

ATTRIBUTES

- Accountability
- Alertness
- Common Sense
- Compassion
- Confidentiality
- Conscientiousness

ATTRIBUTES (con't.)

- Courteousness
- Creativity
- Flexibility
- Handles Constructive Criticism
- Handles Failure
- Hard Working
- Honesty
- Independent Worker
- Integrity
- Interest in Work
- Leadership
- Meticulousness
- Observant
- Patience
- Positive Attitude
- Professional Attitude/Behavior
- Reliability
- Responsibility
- Safety Consciousness
- Scientific Curiosity
- Self-Motivation
- Sound Judgment
- Tactfulness
- Takes Initiative
- Thoroughness
- Willingness to Ask for Help
- Willingness to Work Around Hazardous Chemicals
- Willingness to Work Around Microbiologic Pathogens
- Willingness to Work Around Radioactive Materials
- Works Well with Many Different People

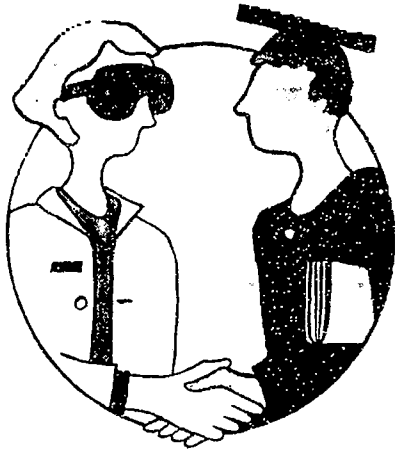
TOOLS AND EQUIPMENT USED BY BIOSCIENCE TECHNICAL SPECIALIST I

Anaerobic hood
Assorted hand tools
Assorted clamps
Assorted cleaning chemicals
Autoclave/sterilizer
Automated urine analyzer
Automated integrity tester
Automated chemical analyzers
Automated coagulation analyzers
Automated microbiology systems
Automatic diluting system
Balance
Bioreactors
Biosensors
Blood gas analyzers
Cages and related equipment
Calculators
Carboys
Cell counters (auto or manual)
Cell washers
Centrifuges
Colorimeter
Columns (reverse phase, ion exchange, affinity, HPLC, FPLC)
Computer hardware
Computer software
Concentrators/ultrafiltration units
Condensers
Conductivity meter
Cryostats
Dark room and equipment (BK: photographic equipment)
Densitometer
Dessicator
Dishwashers
Electron microscope
Electrophoresis equipment
FAX
Filters

Flame photometer
Fluorescent microscope
Freeze driers
Gamma counter
Gas chromotography mass spectrometer
Geiger counter
Glassware
Heating block
Hemocytometer
High pressure vacuum (pumps)
Holding tanks
Hoses/germicides
Hot plates
Incinerator
Incubators
Intercom
Laminar-flow hood
Laser particle counter
Laser
Magnetic stir plates
Mass spectrometer
Microscopes
Microtomes
Mixers/shakers
Multi-meter
Nitrogen storage tanks
NMRs
Oil bath
Oscilloscope
Osmometer
Ovens and driers
Pagers
pH meter
Phosphorimager
Photocopier
Pipettes/micropipettors
Plate reader
Power supplies
Pressure gauges

Printers
Pumps
Reference materials
Refractometer
Refrigerators, freezers
Rotators
Rotovaps
Safety hoods
Safety equipment
Scales, balances
Scintillation counters, coulter counters, gamma/beta counters
Scoopers
Shields
Specimen collection supplies
Spectrometer
Spectrophotometer
Stainer
Sterilizers (large)
Surgical equipment
Syringes and needles
Telephone
Thermocycles/PCR reactors
Thermometer
Timers
Tissue processors/homogenizers
Tubes
Typewriter
Ultracentrifuges
Ultra filtration unit
UV light
Voltmeter
Vortex
Water baths
Water purification systems

Guidelines for Implementing the Skill Standards: Continuing Work and Future Products



- Performance Criteria
- Assessment of Skill Standards Mastery
- Certification and Credentialing
- Education and Training Recommendations
- Education and Training Program Directory
- EDC's Experience: Process and Content Recommendations

Introduction

The development of the Integrated Skill Standards is not the final product of this project. We realize that unless these standards are understood, accepted, and put to use by employers throughout the bioscience industry, unions, and educators in high schools and postsecondary schools, they will be virtually worthless. To ensure that both the concept and the content of the skill standards make sense to industry (employers and workers) and educators (teachers and administrators), we have included in every step of the process the active participation of representatives from these stakeholder groups. (See Appendix D for listing of project participants.) Throughout the development of the standards, we have constantly checked with industry members and educators to ensure that the standards reflect their needs and viewpoints.

There are still several pieces of unfinished work needed to make the bioscience skill standards usable by educators, employers, students, and workers:

1. Further development of *performance criteria* by which to measure mastery of the Integrated Skill Standards and which are endorsed by all sectors of the industry
2. Further identification of *assessment methods* with which to test mastery of the skill standards
3. Creation of a *certification and credentialing* process by which to acknowledge mastery of the standards and which dovetails with existing certification processes

4. Development of *education guidelines, curriculum materials, and recommended strategies* for educators and work-based trainers to prepare people to master the skill standards

5. *Dissemination of information* about the skill standards and guidelines for using them

We have been working in all of these areas. In this section, we describe the work that has been done so far in the project and what still needs to be accomplished.

Performance Criteria

Performance criteria are needed to evaluate people's mastery of all the components of the skill standards. These criteria must stipulate clearly how to determine whether a skill standard has been mastered and if so, to what degree. They must also be stated in terms that are measurable. In discussions with the project's Technical Committee and other technical advisors, we have identified at least three degrees, or levels, of mastery to be measured for the Bioscience Technical Specialist I:

1. Understanding of core concepts and procedures, including the skills, knowledge, and attributes required for proficient performance
2. Ability to apply knowledge of concepts and procedures in a real-life work situation, including both routine work and unanticipated breakdowns
3. Mastery of applied knowledge and skills in a real work context

To be useful for educators and employers, the performance criteria must provide clearly stated indicators of "mastery" and "lack of mastery" for each of these levels. By using these to assess students' achievement, educators can tell what capabilities a student has acquired and what she or he still needs to develop.

Work Already Completed

In a workshop held in winter 1993, a group of 25 industry representatives (supervisors and trainers) and experienced bioscience educators developed performance criteria (indicators of mastery and lack of mastery) for each of the 108 tasks that constitute the work of the Bioscience Technical Specialist I. These tasks had been identified by the frontline workers in the Job Analysis Workshops. Following are some examples of indicators of mastery for several tasks.

EXAMPLES OF PERFORMANCE CRITERIA

JOB FUNCTION B: MANUFACTURE PRODUCTS

Task 5: Prepare buffers and reagents

Indicators of Mastery:

1. Obtains and follows SOPs and batch records.
2. Properly handles chemicals, including aseptic technique.
3. Weighs, prepares, and filters buffers/reagents.
4. Uses metric system, units of weight and volume, conversions, dilutions, molarity and normality.

JOB FUNCTION G: OBSERVE AND DOCUMENT SAFE PRACTICES

Task 4: Observe rules of safety with radioactive materials

Indicators of Mastery:

1. States and practices the appropriate procedures for the storage, handling, and disposal of radioactive isotopes.
2. Uses protective equipment and wears a personal monitoring device.
3. States and can simulate the procedure for decontaminating a radioactive spill.
4. Confirms updated preventive equipment.

JOB FUNCTION N: MAINTAIN PROFESSIONAL COMPETENCY

Task 3: Participate in Continuing Education and Professional Organizations

Indicators of Mastery:

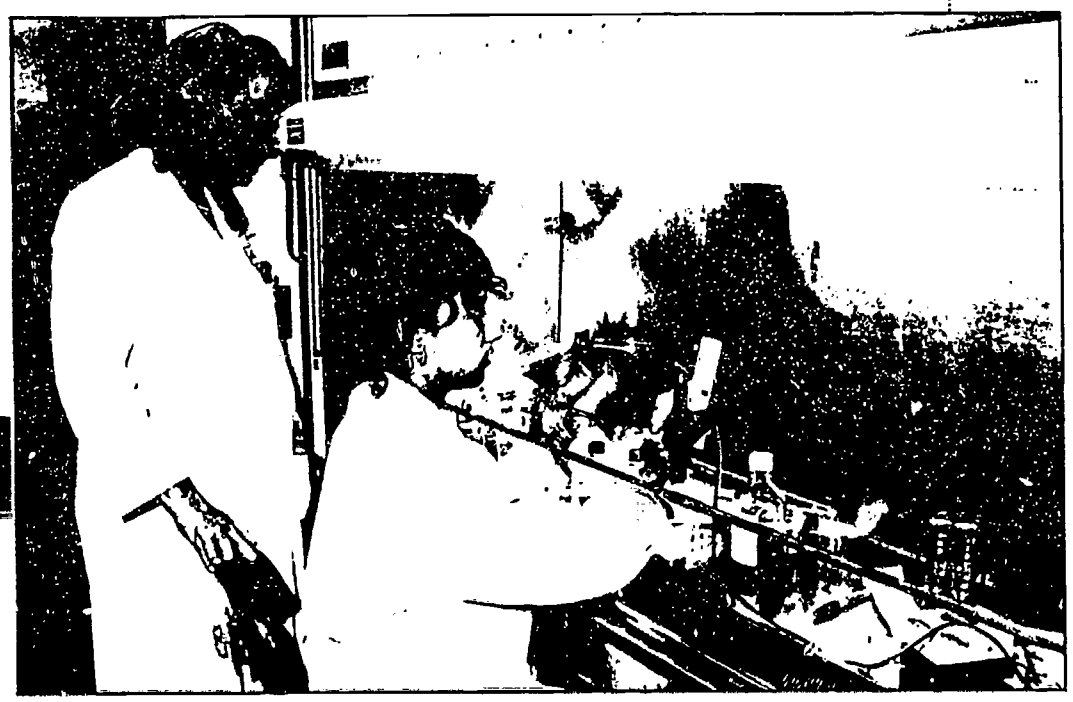
1. Initiates search/respond recommendations for continuing education/professional organization opportunities.
2. Maintains active participation and involvement appropriate to the opportunity, position, and developmental needs.
3. Applies knowledge and skills to workplace.
4. Maintains awareness of licensure or certification issues and/or requirements.

Work Still to Be Done

There are several things we still need to do to make these performance indicators usable:

- The performance indicators must be written to apply not to individual tasks but to entire Integrated Skill Standards.

This will require the development of criteria that measure people's abilities to make the connections among tasks, skills, knowledge, and attributes that are required for complex procedures and problem solving. As we have stressed, one of the critical advantages of the Integrated Skill Standards is that the standards include not a list of discrete, unrelated tasks but **a complex real-life work situation requiring a number of tasks, skills, and abilities to perform a routine procedure or solve an unanticipated problem or breakdown.**



- Each indicator must be written for each of the three levels of mastery—understanding, ability to apply in a work setting, and mastery of work-based application.

At different stages of a person's education and training, educators should be able to measure the student's progress toward mastery (the highest level). If performance indicators exist to measure each level of achievement, educators can tell what a person still needs to learn. In this way, the performance indicators can be used not only as a measure of ultimate mastery but as part of a feedback loop for continuous education. Employers can also use these "stepped" indicators to assess whether an employee is ready to move into training for a higher-level position.

- The levels of performance must be tied to criteria for proficient performance of beginning-level occupations composing the Learning Occupation; however, some occupational areas may require a lower-level mastery of the skill standards, and others may require some additional training.

Project participants have grappled with the question, "At what level of mastery is a person qualified to enter work?" One answer given is, "It is the level of proficiency needed to begin work in a competent manner, as opposed to the level required to be a 'master worker.'" **The Integrated Skill Standards developed for this project pertain to a competent beginning-level technical specialist.**

Achievement of the "master worker" level would not be expected until the person had worked for some time (which may vary, depending on the occupational demands). Achievement of the highest level of performance indicators—those for "mastery"—may be appropriate for use by employers, to determine if current workers are ready to move into additional training for higher-level positions.

Another answer given is, "It depends on the requirements of the work in that occupational cluster." For example, we are told that manufacturing operators require mastery of a smaller range of skills than some research and development assistants or some clinical laboratorians do. It seems clear that some specialties may be entered before all of the skill standards are mastered (or all are mastered but at a lower level), whereas others will require additional course work and practical experience beyond that needed to qualify for the Bioscience Technical Specialist I—the generic Learning Occupation.

Assessment of Skill Standards Mastery

Standards provide direction and mark best accomplishments. In the late twentieth century, members of the workforce need to know where they are in relation to the standards. Assessment, then, is a process of identifying the gap between where one is and where one wants to be.

Work Already Completed

Faced with the challenge of defining how learners perform in relation to the Integrated Skill Standards, the project staff and the Technical Committee identified a number of important questions to consider in developing assessment tools:

1. *What do we want to assess and why?* The most central goal of assessment is to determine the degree to which students have mastered the skill standards. Results of the assessment will enable educators to determine what each student knows and can do and his or her level of proficiency. Educators can then determine what gaps exist and what further education/training is needed. They can also determine if the teaching strategies being used are effective or need modification. Educators can also determine from assessment what students might not be suited to the work of a bioscience technical worker and thus encourage them to explore other fields.

2. *Should we develop a one-time tool, to be applied at the end of the learning process, or a tool that provides continuous feedback at a number of points during the learning process?* As discussed in the section on "Performance Criteria" (above), project staff and advisors think that assessment should take place at various points in the learning process. This will create a continuous feedback loop to allow students to practice what they have not yet mastered and to allow teachers to adapt education strategies, if necessary, to various students' differing learning styles.

   A continuous feedback assessment process will also allow learners to risk making mistakes, given a simulated environment with few if any consequences to their own or public health and safety and little if any loss of investment in expensive materials and equipment.

3. *What assessment methods should we use?* In the Performance Criteria Workshop, participants identified a number of assessment methods to be used to determine people's mastery of the tasks in the Integrated Skill Standards. These methods are listed at the end of this section. Project staff are also working with several leading-edge organizations to develop a multipurpose, multimedia assessment tool. This tool will utilize advancements in performance-based assessment, virtual reality, satellite data transfer of encrypted tests to schools and employers, and cognitive strategies such as simulating the development of mental models. If possible, this assessment tool should be usable for point-in-time (for determination of certification qualification) and continuous feedback purposes (for determination of needs for further learning).

4. *What are the personal and legal consequences of assessing mastery of the skill standards?* The Integrated Skill Standards are based on a thorough analysis of the tasks, skills, knowledge, and behavioral attributes required for competent performance as determined by experienced workers in the various occupations that constitute the Learning Occupation. They have been carefully validated by other experienced workers and their direct supervisors.

One of our intentions in developing the skill standards has been to open up access for greater numbers of people to good jobs with career opportunities. We will work on developing an assortment of teaching methods to assist people with varying types of intelligence and learning styles to master the skill standards. It will also be important that assessment be carried out by neutral parties, who are capable of employing various assessment techniques to determine people's qualifications.

Work Still to Be Done

There are some things we still plan to do regarding assessment.

- As with the performance criteria, the assessment methods, as they are now devised, are attached to each of the 108 tasks. (See Appendix B for "Assessment Methods Matrix.") They need to be combined or reconfigured in ways that will assess mastery of an entire Integrated Skill Standard. Assessing mastery of each discrete task, out of the situational context, will not tell us if a person knows how to integrate all of the multiple tasks, skills, and knowledge with the connections that occur in a real-life work context.

- We plan to explore further the uses of multimedia simulations as assessment tools. These have a number of advantages that are particularly appropriate for assessing the Integrated Skill Standards. They have the value of being standardized and therefore replicable. At the same time, they can be reconfigured, in controlled ways, to accommodate various learning styles and to enable assessment of varying approaches to mastery of problem-centered scenarios. In addition, they can be self-administered, thereby saving the extensive costs of labor-intensive, performance-based assessment.

ASSESSMENT METHODS FOR INDICATORS OF MASTERY

- **Evaluate work-based performance** of procedures or problem responses to determine if appropriate and complete actions are taken.
- **Evaluate performance in classroom setting** through role play, computer-based simulation, or other performance-based techniques to determine if appropriate and complete actions are taken.
- **Review the actual result of process** (sample, equipment, facility, material, parameters, product, document) to see that the person correctly performed the procedure.
- **Review written documentation** (e.g., reports, exams) for accuracy and completeness.
- **Evaluate verbal presentation** for accuracy and demonstration of mastery.
- **Conduct mock situational (scenario-based) interviews** to assess mastery.
- **Evaluate documents/exhibits collected in portfolio** to determine how well they demonstrate mastery.
- **Have people critique their own or peers' journals, other materials, and performances** for accuracy and completeness.
- **Examine reviews or assessments of person, procedure, or document audit** made by others (supervisors, mentors, colleagues, clients).
- **Have other people reproduce activities** (procedures, problem responses, etc.) following peers' journals, documentation, procedure descriptions, and reports to see if the entries are correct and clear.

Certification and Credentialing

Our preliminary discussions about what certification process to recommend, using the performance criteria and assessment methods identified in the previous sections, indicate a number of promising approaches to consider as we move ahead in our work.

Work Already Completed

This section outlines ideas that have been discussed and work that has been done so far.

- **Certification levels.** Certification, like assessment, should be done at various levels of the education process, not only upon completion of mastery of the entire set of Integrated Skill Standards. This "stepped" certification process will enable students to receive official recognition of competence at different levels of mastery.

The first certification level might be of the mastery of "core" competencies—bioscience terminology, understanding of industry regulations and administrative agencies, basic laboratory procedures, documentation requirements and procedures, use of basic laboratory equipment, and other general bioscience knowledge and skills. In addition to these technical achievements, a person at this level will be expected to demonstrate many of the personal behavioral attributes that industry representatives have emphasized are so important (e.g., ability to work well with other people, attention to detail).

A second level of certification might be attained after a student has had sufficient training and work experience to be able to apply his or her knowledge and skills in a work setting. This training and experience probably would include a rotation (much like a medical school rotation) among different departments or work settings, in a variety of occupations that make up the Learning Occupation.

A third level of certification would be attained after a person had obtained additional training and experience in a specialized field, beyond the entry-level Learning Occupation of Bioscience Technical Specialist I. This would satisfy requirements for jobs that need some additional knowledge (e.g., work in research and development or in aspects of clinical laboratory analysis).

- There already exist a number of program accreditation and individual certification requirements and administering agencies for workers in the clinical laboratory subsector of the bioscience industry. Several states also have licensing requirements for individuals working in clinical laboratory facilities.

Workers in pharmaceutical and biotechnology companies must comply with a great number of extremely stringent federal regulations—from the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), and the Clinical Laboratory Improvement Act (CLIA), among others. They must also adhere to state and other regulations. Many of these pervasive and strict regulations are embodied in the Good Laboratory Practices (GLPs), Good Manufacturing Practices (GMPs), and Standard Operating Procedures (SOPs) that govern every aspect of work in each organization. The FDA requires training for GLPs and GMPs. Certain specialty areas, such as toxicology and animal care, require certification.

We have identified existing program accreditation and individual certification agencies and programs in the bioscience industry. (See Appendix C.)

Work Still to Be Done

- We will be examining the certification processes and requirements of existing programs and agencies. We intend to develop certification requirements and processes that support the goals of our Integrated Skill Standards, and are not in conflict with existing certification requirements. We will not be recommending program accreditation requirements or processes.

- In order to ensure that the certification process and credentials are accepted by industry, industry representatives will participate in designing the process. To further ensure that the credential is recognized by the industry, we will recommend a process by which the certification is conferred jointly by the education institution and by industry and labor representatives or agencies recognized by the industry.

- Employers will not be required to hire certified applicants over uncertified people. However, people who have been certified as meeting all of the performance criteria for all of the skill standards should be more attractive to employers than those who have not been certified, because they will have met all of the industry's identified criteria for employment.

During the remainder of the project, these ideas will be developed further. They will be included in the *Guidelines for Education and Training*, to be published by September 1995.

Education and Training Recommendations

To facilitate the use of the standards, we are developing (1) guidelines for creating locally based consortia of the above stakeholders to plan and implement education systems and (2) program guidelines, suggested curriculum units, and strategies for using these materials in schools, workplaces, and other appropriate learning venues.

> *Of all the work-related reforms legislated, such as school-to-work, Tech Prep . . . national, industry-based skill standards will have the greatest impact on occupational programs. The skill standards cut to the heart of what we do.*
>
> James McKenney
> Director, External Programs
> American Association of Community Colleges

The information for these guidelines comes from two sources: (1) the work of the Bioscience Industry Skill Standards Project's Education and Training Team and (2) EDC's experience working with communities to develop industry-based skill standards and the education structures and strategies to achieve them.

The Education and Training Team

The Bioscience Industry Skill Standards Project has organized an Education and Training Team to develop (1) recommendations for teaching the general, work-related and the technical, industry-specific skills, knowledge and attributes required to master the skill standards and (2) innovative education methods, programs, and systems. The general goals of the Education and Training Team are as follows:

- To create the framework for a model program of study for entry into the bioscience industry that uses the Integrated Skill Standards as outcome criteria. The program would begin in the middle grades, continue through high school and postsecondary school, and include work- and community-based learning, as well as classroom learning. The framework may be used in whole, or components may be used to augment existing programs.

- To develop and recommend program components, such as curricula; teaching and learning strategies; teacher, counselor, and work-based mentor development guidelines; ways of integrating academic and work-related learning; and assessment and articulation methods.

The team includes educators from secondary and postsecondary schools, as well as industry- and union-based trainers. Team members have experience in curriculum development, teaching strategies, teacher training, vocational education, and/or assessment and certification. They come from every area of the country.

The Education and Training Team is working in six specialty areas:

- Curriculum development (K–8 and high school)
- Curriculum development (postsecondary)
- Work-based learning
- Assessment and certification
- Teacher, career counselor, and workplace mentor development
- Articulation

Since June 1994, a core team with representatives from each of the six specialty areas has met at EDC for two two-day workshops; it will have one more workshop in June 1995. In addition, through an Internet communication system, each subgroup is examining best practices in current programs, developing its recommendations, and relating them to the work of the other subgroups. This approach builds coherence and consistency as the team develops its recommendations.

Following are descriptions of the work of each of the six specialty subgroups.

Kindergarten through high school curriculum development

Kindergarten through high school curriculum development focuses on guidelines for curricula that integrate academic and work-related content; general workplace and specific bioscience industry awareness; basic technical education; capacity building for teachers, workplace mentors, and counselors; and coordination of school and work-based learning. Topics of work include:

- Bioscience applications for academic subject matter (math, science, English, social studies, history) for elementary and middle grades
- Industry awareness, orientation, and exploration for all students in middle grades
- Examples of teaching and learning methods that prepare students for new work structures (project-based learning, problem-centered learning, team-based teaching and learning) and emphasize integrated, active learning, rather than rote acquisition of information
- Models of curriculum units for basic, industry-related knowledge (e.g., terminology) and skills (e.g., basic laboratory procedures) that can be integrated into science and math courses
- Integration of skill standards with academic standards
- Work-based learning experiences (internships, co-op work, youth apprenticeships), coordinated with school-based learning
- Recommendations for how to obtain or access laboratory materials and equipment
- Models of block scheduling of time to allow for team teaching and interdisciplinary learning
- Ways to tailor learning for specific populations (e.g., the disabled, ESL/EFL)

Postsecondary curriculum development

Postsecondary curriculum development focuses on developing curriculum guidelines that integrate academic and work-related subject matter, integrating work-based and classroom-based learning, and developing the capacities of classroom teachers, work-based mentors, and career counselors. Topics of work include:

- Course sequences that cover the specialized technical knowledge and skills needed to meet requirements for Bioscience Industry Technical Specialist I
- Models of curricula for classroom-based courses
- Recommended instructional methods for curriculum components
- Samples of innovative components of model programs across the country in bioscience education at the certificate and associate degree level
- Work-based learning components (internships, co-op work, apprenticeships)
- Introductory industry-related curricula and course sequences for adults entering the workforce or retraining for the bioscience industry
- Ways to tailor learning for specific populations (e.g., the disabled, ESL/EFL)

Work-based learning

Work-based learning focuses on developing the role of employers and workers in the education process, including development of work-based learning modules that are coordinated with school-based learning, mentor and supervisor development, use of workplace physical resources (laboratories, meeting spaces, equipment), and programs to benefit current workers. Topics of work include:

- Models of work-based learning components that are coordinated with school-based learning
- Recommended ways that workers can facilitate awareness of their industry and teach basic concepts and procedures in schools
- Identification of model working relationships between workplaces, unions, and schools
- Training for mentors and student supervisors
- Recommended uses of skill standards by employers and unions to prepare workers to move within the bioscience "career lattice"

Assessment and certification

Assessment and certification focuses on identifying and developing model assessment strategies to measure mastery of the Integrated Skill Standards; providing information about existing regulatory, certification, and licensing requirements; and recommending approaches for certification based on the skill standards. Topics of work include:

- Collection and analysis of existing assessment models and techniques—particularly those that emphasize performance- and product-based assessment—for possible use in assessing mastery of bioscience skill standards
- Guidelines and methods for assessing student mastery of skill standards at various levels (beginning at grade 11 and continuing up to grade 14 and above)
- Criteria for certification of mastery
- Review of existing regulatory, certification, and licensing requirements within bioscience industry subsectors and recommendations for ways to dovetail with them
- Recommended methods for crediting people for relevant work experience and training in related fields
- Exploration of and recommendations for the use of multimedia assessment tools that can be self-administered and are replicable, and malleable—to conform to varied learning and testing styles

Teacher, career counselor, and workplace mentor development

Teacher, career counselor, and workplace mentor development focuses on recommendations for building the capacities of teachers, counselors, and work-based mentors to enable them to work together and to develop and implement teaching strategies that will realize the goals of the Integrated Skill Standards. Topics of work include:

- Guidelines for teacher development to create and use recommended pedagogical methods (problem-centered teaching/learning, project-based teaching/learning, team teaching/learning)
- Methods for enabling teachers and career counselors to learn about the content of the bioscience industry (workshops, industry internships, partnering with industry mentors)
- Recommended methods to enable teachers to plan and teach together (block scheduling, joint planning time, workshops)
- Development for career counselors to enable them to counsel about the world of work in general and about the bioscience industry in particular
- Guidelines for preparing work-based mentors to supervise and instruct students in their work-based learning and to coordinate this work with that of the classroom instructors

This represents a first for industry and academia to partner in the development of core curricula for the pharmaceutical technologist of the future.

Kenneth A. Martlage
Manager, Performance Improvement
Eli Lilly and Company

Articulation

Articulation focuses on developing and maintaining interinstitutional working relationships and formal agreements among schools at different levels (high schools, community colleges, four-year colleges) and between schools and workplaces where learning occurs. Topics of work include:

- Assembling best practice examples of articulation among different levels of education institutions and between education institutions and work-based learning sites
- Recommending methods for articulation between high schools and postsecondary schools and between schools and workplaces
- Recommending methods for articulation between community colleges/two-year technical schools and four-year colleges and universities
- Recommending assessment strategies that create a seamless system that includes high school, work-based, and postsecondary components

EDC's Experience: Challenges, Strategies, and Lessons Learned
EDC has conducted extensive work in education content and practice in schools and community settings for nearly 40 years. EDC's Institute for Education and Employment has worked in many communities, with consortia of educators (teachers and administrators), industry, unions, and other stakeholders to develop and implement education programs and systems to prepare people for skilled jobs and careers. Consortia of stakeholders in each community have begun by creating industry-based Integrated Skill Standards (e.g., in advanced manufacturing, financial services, health care, legal services) and have continued with the development of curricula and programs for career orientation, integrated academic and vocational learning, and teaching/learning strategies. Programs include work-based learning with supervision by experienced workers.

From this work, the Bioscience Industry Skill Standards Project draws on lessons for developing a local-level process to implement the Integrated Skill Standards, as well as elements of a comprehensive education/training system. The education system elements are included in the work, already described, of the project's Education and Training Team. Following are the lessons EDC has learned in order to implement and maintain a successful system process:

- Build employer/educator/union and other stakeholder relationships early in the process so that all parties feel they co-own the program.
- Secure active and aggressive support from school leadership, combined with strong political support from key stakeholders.
- Select school- and work-based staff who are interested in carrying out the vision of the Integrated Skill Standards, and are willing to try innovative methodologies.
- Employ "principles of best practice" in staff development/training and in creating and sustaining change.
- Assist teachers and others in learning how to work together and exercise leadership in team structures.

- Follow the "Train and Trust" motto of American Steel and Wire Corporation: Train teachers/mentors well, and then trust them to experiment and do the right thing.
- Create opportunities for teachers to have frequent contact and substantive communication among themselves, across levels and disciplines, and with industry-based people, to avoid the isolation often experienced by classroom teachers.
- Maintain continuous communication over time among program designers and on-the-ground implementers, and include all parties in planning, problem solving, and sharing of new learning, to maintain a common vision.

The Education and Training Program Directory

As part of our research, we have assembled information about existing school- and work-based programs and networks that prepare people for beginning-level technical occupations in the bioscience industry. This information incorporates over 60 programs across the country at the high school or postsecondary school level, as well as approximately 30 additional teacher training workshops, student workshops, consortia/centers, or corporate-sponsored training programs for current and future employees.

One such program is the Health and Bioscience Academy at Oakland Technical High School, which prepares high-risk upper-secondary students for the workforce, as well as for future study, in the bioscience industry. The students study a curriculum with twice the general high school science requirements and receive tutoring from students at the University of California at Berkeley, SAT preparation, and assistance with applying for internships, colleges, and jobs. Internships are incorporated into the program between junior and senior year.

Another example is the consortium comprised of Baltimore City Community College, Baltimore City Public Schools, and the Baltimore City Advisory Council of Vocational Technical Education, which recently implemented the Tech Prep

Biotechnology program at both Dunbar and Southern High Schools. The faculty of Baltimore City Community College and Baltimore City Public Schools worked closely with business and industry to develop the curriculum. Students enter the program in ninth grade, participate in apprenticeships in the industry and college-level courses, and prepare for entry into the workforce.

Descriptions of the biotechnology and pharmaceutical programs from every area of the country, as well as references for clinical laboratory programs, have been assembled into the *Directory of Current Bioscience Education and Training Programs*. The directory does not provide information on the hundreds of clinical laboratory programs because these already are well documented.

Each program description in the directory includes information about the type of program (e.g., level, length, school- or work-based), a brief program summary, and contact information. Descriptions also highlight interesting features of each program including connections with local industry, articulation with other schools, and work-based learning components.

The directory also contains a report summarizing major features of existing programs and trends in bioscience education and training. The directory will be available in May 1995.

An Education System That Would Realize Our Goals

An education system that would realize our goals would have several distinctive characteristics. These would include:

- . . . rote learning and compartmentalized instruction replaced by a broad vision and a long view of learning and the application of academic concepts to real-life situations. Students will be focused on developing skills and accessing resources to gather information, rather than on trying to acquire more and more facts.

- . . . teachers as coaches and facilitators of learning, rather than the "experts" or "importers of knowledge." As learning is refocused from acquiring knowledge to developing and integrating skills, the teacher will spend more time and energy assisting students to learn through active inquiry, experimentation, and experience. As new knowledge emerges, students and teachers will learn together.

- . . . students learning in teams that reflect the diversity of teams found in workplaces (gender, culture, ability levels, technical and professional, range of skill levels). Similarly, teachers will teach in heterogeneous teams to integrate vocational and academic learning and to carry out interdisciplinary, problem-based projects. New relationships will emerge among education staff as teachers work together in teams and call upon others for support as coaches/facilitators of student learning.

- . . . employers and frontline workers as coaches and facilitators of learning in workplaces. Workplaces will be seen as learning places linked to schools—an extension of learning in an applied setting. Employers, frontline workers, and teachers will work together to design and carry out learning experiences for both work sites and schools. They will share responsibility to help individuals develop skills and will work together to develop and coordinate learning activities and to monitor and assess learning. Employers and frontline workers will sometimes be found in schools, alongside teachers, facilitating the learning process, assisting with projects, teaching classes, and mentoring teachers/students.

- . . . new assessment processes and tools being used. Achievement will be measured not by the amount of time spent in various courses but by the extent to which students are able to demonstrate that they have mastered required skills, can apply knowledge, and can successfully integrate both in the solving of real-life problems. Assessment that focuses on how successfully students can integrate learning within a problem-solving framework will force all students to develop higher-order thinking skills.

- . . . a system for granting program completers a portable credential, recognized by employment and education communities across the nation. Educators and employers will work together to assess students and maintain a process to award "certificates of mastery" to those who demonstrate they have learned and can apply the academic and technical knowledge, skills, and behaviors necessary to meet education system requirements and qualify for industry entry.

There is a well-documented need for employers and educators to speak the same language. It does a disservice to students to educate them in the name of career advancement and then not adequately prepare them to actually perform on the job. Efforts such as the Bioscience Skill Standards Project will help ensure that our students are employable upon graduation anywhere in the nation.

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Professor of Biology
MiraCosta College

The information being developed by the project staff and the Education and Training Team will be compiled into a *Guidelines for Education and Training*, to be published by EDC by September 1995. Most of its recommendations, sample curricula and school and work-based teaching strategies will be appropriate for use in any school-to-work or industry-specific education/training system, although materials specific to the bioscience industry will be referenced.

Endnotes

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Appendix A: Validation Process and Results

The validation process consisted of two stages. The first was a survey, conducted in fall 1993, of the information provided in the Job Analysis Workshops (the job functions and tasks of a Bioscience Technical Specialist I and the skills, knowledge, and attributes required to master the tasks). The second stage was a series of workshops, conducted in fall 1994, to confirm broader agreement with the Integrated Skill Standards developed by the Skill Standards Development Team.

Job Analysis Validation

The information provided by frontline workers in the Job Analysis Workshops was validated by means of a survey. (See sample survey page.) The survey was sent to workplaces in the bioscience industry throughout the country. We received back 142 completed questionnaires.

For each of the 108 tasks, three questions were asked related to the work of the Bioscience Technical Specialist I (the entry-level learning occupation):

1. How *important* is the performance of this task in the job of a Bioscience Technical Specialist I?
2. How much *training/experience* should a Bioscience Technical Specialist I have to do this task?
3. What is the expected *future significance* of this task?

People were instructed to cross out tasks they considered irrelevant and to add, in spaces provided, tasks they thought should be included. Several demographic questions were also asked to identify the subsectors, workplaces, occupations, work experiences, and geographic distribution of respondents. (See the demographics chart at the end of this appendix.)

Survey Responses

Two general results are important. First, there was a high degree of agreement among respondents regarding all three questions. Second, virtually no respondent deleted existing tasks or recommended that additional job tasks be added. There were also no dissenting comments written on any of the questionnaires. Together, these results present a strong indication that the scope and content of the job functions and tasks identified adequately cover the work of the Bioscience Technical Specialist I.

Question 1

How important is the performance of this task in the job of a Bioscience Technical Specialist I?

1. An asset, but not necessary
2. Useful/helpful
3. Necessary and important
4. Critical to the task

Findings and Implications

Over half of all the tasks were rated with a mean of 3 or higher. This indicates that the majority of the tasks were considered to be either "necessary and important" or "critical to the task" by most respondents. (See "Validation Results: Importance" at the end of this appendix.)

The answers to this question helped the Skill Standards Development Team determine which job function areas and tasks were most important to emphasize in the Integrated Skill Standards scenarios. More important tasks were incorporated more times in varying contexts in the skill standards than less important tasks were. Responses to these questions will also guide curriculum developers (of both school- and work-based learning components) in deciding to what degree to emphasize various tasks and related skill and knowledge areas.

Question 2

How much *training/experience* should a Bioscience Technical Specialist I have?

1. Little training/little experience
2. Some training/some experience
3. Some training/more experience
4. More training/some experience
5. More training/more experience

(little = 0 to 6 months; some = 6 months to 2 years; more = 2+ years)

Findings and Implications

The highest mean ranking was 3.76, indicating that all of the tasks would require no more than two years of training to master. Only 25 of the 108 tasks were ranked with a mean of 3 or more, indicating that respondents felt less than 25 percent of the tasks would require more than two years of experience to obtain proficiency. Only one task (M-2 feed and water animals/plants) had a mean ranking of less than 2, indicating that it would require less than six months of training or experience. (See "Validation Results: Education Requirements" at the end of this appendix.) The information gained from question 2 will enable EDC and the Bioscience Project Education and Training Team to decide at what level of education each of the tasks and related skills, knowledge, and attributes can be taught. These answers will also help determine which tasks are better learned in the classroom (if training is emphasized) and which are better learned from work-based experience (if experience is emphasized). The responses to this question indicate that most of the tasks performed by the Bioscience Technical Specialist I can be learned in a well-planned education program during a two- to three-year period (which could begin in high school) that includes both classroom learning and applied, work-based experience.

Question 3

What is the expected future significance of this task?

+ = more significant in the future
– = less significant in the future

Findings and Implications

The 20 tasks whose significance was expected to increase the most included 5 related to maintaining professional competency; 4 related to complying with accreditation and government regulations; 3 related to maintaining quality assurance; and 3 related to evaluating, documenting, and reporting results. (See "Validation Results: Future Significance" at the end of this appendix).

The answers given to question 3 provide important information about how people in various positions in the bioscience industry perceive future trends in their industry. Clearly, they foresee a context in which there is likely to be increased government and other forms of regulation with which to comply and an increased emphasis on high-quality work. This will require more attention to the documenting and reporting of test findings, and workers will have greater need to maintain their professional competency. This suggests the need in the near future for increased education and training opportunities for current workers as well as new workforce entrants.

Skill Standards Validation

The Integrated Skill Standards were developed and revised by a team of 25 experienced workers, supervisors, and bioscience educators over a period of about six months. They were also reviewed by the project's Technical Committee and by other advisors. However, to be considered valid for the entire bioscience industry, they needed to be verified by many more people from all parts of the industry and from different parts of the country.

This verification was especially important because the draft skill standards were meant to apply to a broad cross-section of occupations in research and development, manufacturing, quality assurance, and clinical testing and diagnostics. They were also intended to apply to three industry subsectors—pharmaceutical companies, biotechnology companies, and clinical laboratories in hospitals, universities, government, and independent settings. A Validation Advisory Committee helped project staff determine the questions to be asked in the review/validation process. A pilot session was held at EDC in fall 1994.

Eight review/validation sessions were held across the country in Massachusetts, Illinois/Wisconsin, Indiana, San Diego, San Francisco, North Carolina, Maryland, and New Jersey. In each workshop, 15 to 20 technical workers, supervisors, and experienced bioscience educators and trainers reviewed the draft skill standards. The workshop participants first reviewed the draft scenarios, considering three questions:

1. Is the situation described a real-life one, one that would occur in your workplace?
2. Is this a situation that a beginning-level technical worker would be expected to have mastered?
3. Is the wording of the scenario clear and understandable?

Each workshop group suggested revisions to the scenarios, if necessary, to make them conform to a positive response to each question.

The groups were then asked to suggest any new scenarios they felt covered a major area of work not covered by the existing scenarios. In each workshop, two to three new scenarios were suggested. Two new key competency areas were added, based on the consensus of several workshops: mathematical calculations and ethics. New scenarios were generated in sessions that emphasized these new competency areas.

In the second half of the sessions, the large group split into smaller working groups, organized by industry subsector (clinical laboratory or biopharmaceutical). Each small group reviewed five complete skill standard packets. They reviewed the composition of the task lists for the routine and problem aspects of the scenario, as well as the skills, knowledge, and attributes lists.

EDC staff, with advice from industry-based advisors, compiled the information from all the validation sessions and made changes in the skill standards and their components. The final document consists of the 34 integrated skill standards included in this book.

Results of the Skill Standards Validation

The recommendations for changes made by participants in the eight review/validation sessions were remarkably similar to each other. There was also agreement among the groups that suggested additional key competencies. With assistance from technical advisors, project staff chose which of the suggested new scenarios to include in the final skill standards package. The results of the review/validation sessions were reviewed once more by the project's Technical Committee, and the final skill standards were prepared.

SAMPLE SURVEY PAGE

Task Statements	1. How *important* is the performance of this task in the job of a Bioscience Technical Specialist I? For each task, circle *one* number and circle + or - if relevant.						2. How much training/ experience should a Bioscience Technical Specialist I have? (Little=0-6 mo.; Some=6 mo.-2+yrs., More=2+yrs.) For each task, circle *one* number.				
Job Function E: Control Inventory	Critical to the task	Necessary and important	Useful/ Helpful	An asset but not necessary	NA	Expected Future Significance + = more, - = less	More training/ more experience	More training/ some experience	Some training/ more experience	Some training/ some experience	Little training/ little experience
1. Monitor and record inventory; keep census of animals	4	3	2	1	NA	+ -	5	4	3	2	1
2. Order supplies, reagents, animals	4	3	2	1	NA	+ -	5	4	3	2	1
3. Date, label, store supplies and/or reagents; identify animals	4	3	2	1	NA	+ -	5	4	3	2	1
4. Verify incoming delivery accuracy	4	3	2	1	NA	+ -	5	4	3	2	1
5. Check expiration dates and lot numbers	4	3	2	1	NA	+ -	5	4	3	2	1
6. Maintain separate in-process, quarantine, and release areas	4	3	2	1	NA	+ -	5	4	3	2	1
7. Maintain and store manufactured products inventory	4	3	2	1	NA	+ -	5	4	3	2	1
8. Other _____	4	3	2	1	NA	+ -	5	4	3	2	1
9. Other _____	4	3	2	1	NA	+ -	5	4	3	2	1

DEMOGRAPHICS OF RESPONDENTS

WORKPLACE

Pharmaceutical Companies	48%
Biotech Companies	23%
Clinical Laboratories	29%

ZIP CODE

0 - New England	27%
1 - NY, PA	16%
2 - Middle Atlantic	10%
3 - South	2%
4 - IN, KY, OH, MI	10%
5 - North Central	5%
6 - Mid Central	3%
7 - South Central	2%
8 - West, Southwest	3%
9 - Far West	22%

SIZE OF WORKPLACE

1–50	15%
51–99	9%
100–299	18%
300–599	7%
600–999	5%
1000+	46%

JOB CATEGORY

Management-Professional	28%
Supervisor	27%
Technician	45%

PRIMARY FIELD OF WORK

Research and Development	50%
Manufacturing	12%
Clinical Testing	30%
Other	8%

TOTAL YEARS EXPERIENCE

2 to 5	17%
6 to 9	18%
10 or more	65%

VALIDATION RESULTS: IMPORTANCE

20 TASKS RANKED AS MOST IMPORTANT
(Most Important Task Listed First)

A-1*	Obtain and read protocol, test procedure, SOP
A-2	Prepare sample for testing
I-5	Follow policies and procedures
K-7	Notify appropriate persons about problems and observations
G-3	Use protective equipment
H-1	Follow regulations: FDA (GMPs and GLPs)
G-2	Follow universal precautions for biological pathogens
G-7	Handle, contain, and dispose of hazardous materials
I-3	Use test standards, controls
H-2	Follow regulations: OSHA
J-6	Document and report test results
J-1	Collect data
A-6	Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
J-2	Perform calculations
B-3	Set up equipment according to process requirements
H-8	Follow state and local regulations
C-4	Obtain and label sample/specimen
I-4	Maintain QA logs
D-2	Prepare buffers, reagents
A-3	Check equipment

* Letters and numbers relate to Job Analysis chart on pp. 110–111.

20 TASKS RANKED AS LEAST IMPORTANT
(Least Important Task Listed First)

N-7	Promote community education
N-4	Pursue additional certification and degrees
L-1	Assist with design of research protocol
K-5	Make oral presentations
C-1	Request tests
K-4	Write memos and letters
L-2	Research literature
N-5	Read technical literature
A-7	Perform histotechniques where needed
F-5	Sample environment
M-7	Participate as a member of the research team
F-9	Label equipment and facilities
I-7	Document customer complaints
B-11	Label and package product
I-6	Monitor production lines
B-2	Obtain raw material
N-6	Document training
N-3	Participate in continuing education and certification degrees
J-3	Perform basic statistical analysis
F-6	Implement systems updates

VALIDATION RESULTS: EDUCATION REQUIREMENTS

20 TASKS REQUIRING THE MOST EDUCATION AND TRAINING
(Task Requiring Most Education/Training Listed First)

J-4	Evaluate validity of results
B-8	Obtain, process, and store product samples (applies to all manufacturing steps)
J-5	Identify abnormal results
F-2	Validate or confirm processes, equipment, facilities, kits, vendor products
B-1	Follow SOP and batch record (protocol or procedure)
L-1	Assist with design of research protocol
K-3	Write or update protocols, procedure manuals, and reports for validation
A-6	Perform tests/assays: chemical, biological, clinical, environmental, robotic, mechanical
J-3	Perform basic statistical analysis
F-8	Troubleshoot and repair equipment (work order)
F-1	Check calibration and perform system diagnostics
B-2	Obtain raw material
B-7	Operate reactors and recover product
K-6	Process information using computers
D-3	Set up and work reactions
B-3	Set up equipment according to process requirements
H-1	Follow regulations: FDA (GMPs and GLPs)
B-9	Purify product
J-6	Document and report test results
J-2	Perform calculations

* Letters and numbers relate to Job Analysis chart on pp. 110–111.

20 TASKS REQUIRING THE LEAST EDUCATION AND TRAINING
(Task Requiring Least Education/Training Listed First)

M-2	Feed and water animals/plants
M-4	Monitor housing conditions
M-6	Clean housing and sterilize cages
M-3	Receive and transport animals/plants
F-9	Label equipment and facilities
E-4	Verify incoming delivery accuracy
E-5	Check expiration dates and lot numbers
N-6	Document training
B-2	Obtain raw material
A-8	Return, archive, or dispose of samples
C-4	Obtain and label sample/specimen
E-2	Order supplies, reagents, animals
E-3	Date, label, store supplies and/or reagents; identify animals
N-7	Promote community education
E-1	Monitor and record inventory; keep census of animals
D-1	Organize compounds
G-6	Attend required trainings
E-7	Maintain and store manufactured products inventory
M-1	Monitor health and maintain health records
F-7	Maintain equipment logs

VALIDATION RESULTS: FUTURE SIGNIFICANCE

20 TASKS MOST LIKELY TO INCREASE IN SIGNIFICANCE IN THE FUTURE
(Task Most Likely to Increase in Significance Listed First)

N-6	Document training
N-4	Pursue additional certification and degrees
N-1	Participate in training and cross-training
K-6	Process information using computers
I-5	Follow policies and procedures
H-1	Follow regulations: FDA (GMPs and GLPs)
G-7	Handle, contain, and dispose of hazardous materials
B-8	Obtain, process, and store product samples (applies to all manufacturing steps)
A-1	Obtain and read protocol, test procedure, SOP
I-10	Ensure turnaround time
I-8	Take and document corrective action according to SOP or as directed
J-4	Evaluate validity of results
J-6	Document and report test results
J-5	Identify abnormal results
H-9	Follow industry and professional regulations
H-8	Follow state and local regulations
H-2	Follow regulations: OSHA
F-1	Check calibration and perform system diagnostics
N-7	Promote community education
N-5	Read technical literature

* Letters and numbers relate to Job Analysis chart on pp. 110–111.

20 TASKS MOST LIKELY TO DECREASE IN SIGNIFICANCE IN THE FUTURE
(Task Most Likely to Decrease in Significance Listed First)

D-1	Organize compounds
C-4	Obtain and label sample/specimen
D-2	Prepare buffers, reagents
B-2	Obtain raw material
C-1	Request tests
A-7	Perform histotechniques where needed
C-3	Prepare patient (mentally, physically); prepare animals
M-2	Feed and water animals/plants
B-5	Prepare buffers and solutions
B-6	Start up production
I-6	Monitor production lines
M-6	Clean housing and sterilize cages
M-3	Receive and transport animals/plants
E-4	Verify incoming delivery accuracy
K-4	Write memos and letters
B-10	Formulate, fill, and inspect product
B-11	Label and package product
D-3	Set up and work reaction
M-4	Monitor room conditions
C-5	Handle, transport, and store sample, including legal requirements

Appendix B: Skill Standards: Charts and Matrices

- **Job Function and Tasks of a Bioscience Technical Specialist I** —Information produced by frontline bioscience workers in Job Analysis Workshops using a modified DACUM process
- **Key Competency Areas and the Skill Standards in Which They Appear**
- **Tasks and the Skill Standards in Which They Appear**
- **Skills, Knowledge, and Attributes and the Skill Standards in Which They Appear**
- **Assessment Methods for Task Mastery**

The information in the charts on pages 110-123 was produced by representatives from bioscience workplaces and experienced bioscience educators in a series of workshops. The information in each chart was reviewed and validated in another series of workshops by workers, supervisors, managers, and educators. The charts represent the consensus of all these people. Individuals may find that certain specific changes may be needed to make some information more relevant to particular work situations.

Job Function and Tasks of a Bioscience Technical Specialist I

Bioscience Technical Specialist: Performs experiments and assays, manufactures products, or assists with research using a variety of technical skills, under supervision.

JOB FUNCTIONS	Tasks				
Job Function A: **Perform Tests/Assays**	A-1 Obtain and read protocol, test procedure, SOP	A-2 Prepare sample for testing	A-3 Check equipment	A-4 Determine acceptability and optimum conditions of reagents for tests	A-5 Assess acceptability/appropriateness of specimen
Job Function B: **Manufacture Products**	B-1 Follow SOP and batch record (protocol or procedure)	B-2 Obtain raw material	B-3 Set up equipment according to process requirements	B-4 Perform cleaning (manual/CIP) and sterilize (autoclave/SIP)	B-5 Prepare buffers and solutions
Job Function C: **Obtain Specimens or Materials**	C-1 Request tests	C-2 Match request to test sample	C-3 Prepare patient (mentally, physically), prepare animals	C-4 Obtain and label sample/specimen	C-5 Handle, transport, store sample, including legal requirements
Job Function D: **Process Materials**	D-1 Organize compounds	D-2 Prepare buffers, reagents	D-3 Set up and work reactions		
Job Function E: **Control Inventory**	E-1 Monitor and record inventory; keep census of animals	E-2 Order supplies, reagents, animals	E-3 Date, label, store supplies and/or reagents, identify animals	E-4 Verify incoming delivery accuracy	E-5 Check expiration dates and lot numbers
Job Function F: **Maintain Equipment and Facility**	F-1 Check calibration and perform system diagnostics	F-2 Validate or confirm processes, equipment, facilities, kits, vendor products	F-3 Perform or schedule preventive maintenance	F-4 Clean work area according to SOPs	F-5 Sample environment
Job Function G: **Observe and Document Safe Practices**	G-1 Maintain and follow chemical hygiene plan	G-2 Follow universal precautions for biological pathogens	G-3 Use protective equipment	G-4 Observe rules of safety with radioactive materials	G-5 Observe rules of electrical safety
Job Function H: **Comply with Current Accreditation and Government Regulations**	H-1 Follow regulations: FDA (GMPs and GLPs)	H-2 Follow regulations: OSHA	H-3 Follow regulations: USDA	H-4 Follow regulations: NIH	H-5 Follow regulations: CDC
Job Function I: **Maintain Quality Assurance**	I-1 Inspect, release incoming inventory	I-2 Check, verify integrity of the product, procedure, specimen	I-3 Use test standards, controls	I-4 Maintain QA logs	I-5 Follow policies and procedures
Job Function J: **Evaluate, Document, and Report Results**	J-1 Collect data	J-2 Perform calculations	J-3 Perform basic statistical analysis	J-4 Evaluate validity of results	J-5 Identify abnormal results
Job Function K: **Communicate and Document Information (Written, Oral, Electronic)**	K-1 Interact with vendors, colleagues, and clients	K-2 Coordinate tasks with coworkers	K-3 Write or update protocols, procedure manuals, and reports for validation	K-4 Write memos and letters	K-5 Make oral presentations
Job Function L: **Perform Initial Research**	L-1 Assist with design of research protocol	L-2 Research literature	L-3 Maintain laboratory notebook		
Job Function M: **Care For Research Animals/Plants**	M-1 Monitor health and maintain health records	M-2 Feed and water animals/plants	M-3 Receive and transport animals/plants	M-4 Monitor housing conditions	M-5 Restrain and handle animals
Job Function N: **Maintain Professional Competency**	N-1 Participate in training and cross-training	N-2 Maintain awareness of accreditation and government regulations	N-3 Participate in continuing education and professional organizations	N-4 Pursue additional certification and degrees	N-5 Read technical literature

Job Function and Tasks of a Bioscience Technical Specialist I

A-6 Perform tests/ assays: chemical, biological, clinical, environmental, robotic, mechanical	A-7 Perform histotechniques where needed	A-8 Return, archive, or dispose of samples				
B-6 Start up production	B-7 Operate reactors and recover product	B-8 Obtain, process, and store product samples (applies to all manufacturing steps)	B-9 Purify product	B-10 Formulate, fill, and inspect product	B-11 Label and package product	B-12 Distribute final product
C-6 Assess acceptability/ appropriateness of specimen						
E-6 Maintain separate in-process, quarantine, and release areas	E-7 Maintain and store manufactured products inventory					
F-6 Implement systems updates	F-7 Maintain equipment logs	F-8 Troubleshoot and repair equipment (work order)	F-9 Label equipment and facilities	F-10 Ensure clean room integrity		
G-6 Attend required trainings	G-7 Handle, contain, and dispose of hazardous materials	G-8 Maintain safety equipment	G-9 Observe procedures for the safe use of instruments and cylinders			
H-6 Follow regulations: CLIA	H-7 Follow regulations: NRC	H-8 Follow state and local regulations	H-9 Follow industry and professional regulations			
I-6 Monitor production lines	I-7 Document customer complaints	I-8 Take and document corrective action according to SOP or as directed	I-9 Participate in proficiency testing	I-10 Ensure turnaround time		
J-6 Document and report test results	J-7 Obtain written or verbal verification					
K-6 Process information using computers	K-7 Notify appropriate persons about problems and observations	K-8 Document communication of information				
M-6 Clean housing and sterilize cages	M-7 Participate as a member of the research team	M-8 Monitor and maintain animal safety				
N-6 Document training	N-7 Promote community education	N-8 Maintain professional demeanor				

Key Competency Areas and the Skill Standards in Which They Appear

Key Competency Areas	Skill Standards																																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Animal Handling																				X					X									
Communication (Oral, Written, Electronic)	X	X		X	X	X	X	X	X	X	X			X	X		X	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X
Documentation/Tracking	X	X		X	X	X		X	X		X		X	X					X	X	X	X	X	X	X			X	X		X	X	X	X
Ethics																X			X				X					X		X			X	X
Mathematical Calculations													X																		X	X		X
Performance of Procedure	X	X	X	X		X		X	X	X		X	X	X		X			X	X	X	X	X	X	X					X				
Professional Development							X			X					X		X	X																
Quality Systems (QC, QA)	X	X			X	X			X		X	X	X	X			X		X		X		X	X				X	X					
Regulatory Compliance	X	X						X								X					X		X	X	X			X						
Safety	X	X		X		X		X		X						X				X				X	X		X	X		X				
Troubleshooting Equipment Failure			X			X			X				X	X		X						X				X	X		X		X			
Troubleshooting Methods Failure	X	X	X									X	X			X				X	X	X	X		X			X	X		X			

Tasks and the Skill Standards in Which They Appear

Tasks	Skill Standards																																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
A-1 Obtain and read protocol, test procedure, SOP	X	X	X	X	X				X	X	X	X		X	X				X	X	X	X	X		X						X			X
A-2 Prepare sample for testing	X	X	X							X		X		X					X		X										X			
A-3 Check equipment			X	X		X			X	X		X		X					X		X	X				X					X			
A-4 Determine acceptability and optimum conditions of reagents for tests		X	X	X					X		X	X		X							X	X									X			
A-5 Assess acceptability/appropriateness of specimen												X									X													
A-6 Perform tests/assays, chemical, biological, clinical, environmental, robotic, mechanical		X	X							X	X	X		X							X										X			
A-7 Perform histotechniques where needed												X		X								X												
A-8 Return, archive, or dispose of samples	X									X		X		X									X											
B-1 Follow SOP and batch record (protocol or procedure)			X										X	X	X	X										X	X	X	X			X		X
B-2 Obtain raw material													X									X							X					
B-3 Set up equipment according to process requirements			X										X			X						X							X					
B-4 Preform cleaning (manual/CIP) and sterilize (autoclave/SIP)			X										X			X													X					
B-5 Prepare buffers and solutions			X										X									X							X					
B-6 Start up production			X													X													X					
B-7 Operate reactors and recover product			X													X			X								X							
B-8 Obtain, process, and store product samples (applies to all manufacturing steps)			X								X		X	X													X		X					X
B-9 Purify product													X																					
B-10 Formulate, fill, and inspect product																													X					
B-11 Label and package product																												X						
B-12 Distribute final product																												X						
C-1 Request tests	X				X																													
C-2 Match request to test sample	X				X																									X				
C-3 Prepare patient (mentally, physically); prepare animals																									X					X				
C-4 Obtain and label sample/specimen			X																X											X				
C-5 Handle, transport, store sample, including legal requirements	X				X																		X						X	X				
C-6 Assess acceptability/appropriateness of specimen	X																																	

Tasks and the Skill Standards in Which They Appear

Tasks (cont.)	Skill Standards																																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
D-1 Organize compounds				X																											X			
D-2 Prepare buffers. reagents				X					X			X																			X			
D-3 Set up and work reactions																																		
E-1 Monitor and record inventory; keep census of animals																				X				X				X						
E-2 Order supplies, reagents, animals				X							X						X																	
E-3 Date, label, store supplies and/or reagents; identify animals											X													X										
E-4 Verify incoming delivery accuracy											X													X				X						
E-5 Check expiration dates and lot numbers		X						X	X	X	X					X					X	X		X				X			X			
E-6 Maintain separate in-process, quarantine, and release areas																				X	X			X				X						
E-7 Maintain and store manufactured products inventory																					X			X				X		X				
F-1 Check calibration and perform system diagnostics			X			X			X	X			X	X		X			X			X				X	X		X		X			
F-2 Validate processes, equipment, facilities, kits, vendor products			X							X							X		X			X						X	X		X			
F-3 Perform or schedule preventive maintenance						X			X							X						X						X	X		X			
F-4 Clean work area according to SOPs	X		X			X		X					X						X	X		X							X		X			
F-5 Sample environment								X												X									X					
F-6 Implement systems updates						X																						X	X					
F-7 Maintain equipment logs			X			X			X				X	X		X			X								X		X		X			
F-8 Troubleshoot and repair equipment (work order)			X			X			X				X	X		X										X	X	X	X					
F-9 Label equipment and facilities						X			X				X			X			X								X		X					
F-10 Ensure clean room integrity			X																										X					
G-1 Maintain and follow chemical hygiene plan			X	X				X	X	X	X	X	X		X	X			X					X			X				X			
G-2 Follow universal precautions for biological pathogens	X	X	X	X	X					X	X	X	X		X	X			X	X					X		X			X				
G-3 Use protective equipment	X	X	X	X	X	X		X	X	X		X	X	X		X			X	X				X	X		X			X	X			
G-4 Observe rules of safety with radioactive materials				X				X																							X			
G-5 Observe rules of electrical safety				X		X									X				X								X				X			
G-6 Attend required trainings	X	X						X							X					X					X					X				
G-7 Handle, contain, and dispose of hazardous materials	X	X		X				X	X	X			X	X		X			X					X						X	X			

Tasks and the Skill Standards in Which They Appear

Tasks (cont.)	Skill Standards																																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
G-8 Maintain safety equipment			X			X		X		X			X			X											X							
G-9 Observe procedures for the safe use of instruments and cylinders			X			X				X			X			X											X				X			
H-1 Follow regulations: FDA (GMPs and GLPs)		X	X	X		X					X	X	X	X	X	X			X	X	X			X		X	X	X	X			X	X	X
H-2 Follow regulations: OSHA		X						X							X	X			X		X			X	X	X			X		X			
H-3 Follow regulations: USDA		X													X											X					X			
H-4 Follow regulations: NIH		X													X											X					X			
H-5 Follow regulations: CDC		X													X											X					X			
H-6 Follow regulations: CLIA		X													X											X								
H-7 Follow regulations: NRC		X						X							X											X					X			
H-8 Follow state and local regulations		X						X					X		X	X							X	X		X		X						
H-9 Follow industry and professional regulations		X						X					X		X								X			X		X						
I-1 Inspect, release incoming inventory	X										X										X			X										
I-2 Check, verify integrity of the product, procedure, specimen	X	X	X	X							X	X				X			X		X	X		X										
I-3 Use test standards, controls		X	X	X					X	X	X	X									X	X												
I-4 Maintain QA logs	X	X	X		X				X		X	X							X		X		X	X		X			X					
I-5 Follow policies and procedures	X	X	X	X	X	X		X	X	X	X	X		X		X			X		X	X	X	X	X	X				X				X
I-6 Monitor production lines													X								X								X					
I-7 Document customer complaints																							X					X					X	
I-8 Take and document corrective action according to SOP or as directed	X	X	X		X	X		X	X			X	X			X				X	X	X	X	X		X		X					X	
I-9 Participate in proficiency testing																													X					
I-10 Ensure turnaround time					X																X							X						
J-1 Collect data											X		X	X			X										X		X			X		
J-2 Perform calculations											X		X	X			X												X			X		X
J-3 Perform basic statistical analysis											X		X				X												X			X		
J-4 Evaluate validity of results		X	X							X	X	X	X	X								X					X		X		X	X		
J-5 Identify abnormal results		X	X					X	X		X	X	X	X							X	X					X	X	X			X		
J-6 Document and report test results		X	X					X	X		X	X	X	X							X	X					X	X	X			X		X
J-7 Obtain written or verbal verification		X	X	X							X	X	X								X						X	X	X			X		X

Tasks and the Skill Standards in Which They Appear

Tasks (cont.)	Skill Standards																																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	3
K-1 Interact with vendors, colleagues, and clients	X			X	X	X				X	X				X	X	X	X	X		X		X	X		X		X	X	X			X	
K-2 Coordinate tasks with coworkers				X	X	X				X	X		X		X	X			X		X						X		X	X				
K-3 Write or update protocols, procedure manuals, and reports for validation				X											X	X			X										X					
K-4 Write memos and letters							X										X	X	X		X	X	X	X		X		X	X				X	
K-5 Make oral presentations							X			X							X	X											X		X		X	
K-6 Process information using computers	X					X				X			X		X		X	X					X	X		X	X	X	X			X	X	
K-7 Notify appropriate persons about problems and observations	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
K-8 Document communication of information	X					X									X				X					X			X			X		X	X	
L-1 Assist with design of research protocol				X																														
L-2 Research literature				X			X								X																			
L-3 Maintain laboratory notebook											X		X		X														X		X			
M-1 Monitor health and maintain health records				X																X					X									
M-2 Feed and water animals/plants				X																X														
M-3 Receive and transport animals/plants				X	X															X														
M-4 Monitor housing conditio..				X																X														
M-5 Restrain and handle animals				X	X															X					X									
M-6 Clean housing and sterilize cages				X																X														
M-7 Participate as a member of the research team				X																X														
M-8 Monitor and maintain animal safety				X	X															X					X									
N-1 Participate in training and cross-training											X																		X					
N-2 Maintain awareness of accreditation and government regulations							X								X	X		X																
N-3 Participate in continuing education and professional organizations																		X																
N-4 Pursue additional certification and degrees																		X																
N-5 Read technical literature						X	X		X	X	X				X		X	X								X			X					
N-6 Document training							X											X					X						X					
N-7 Promote community education										X																								
N-8 Maintain professional demeanor	X						X			X							X						X		X	X		X	X	X			X	

Skills, Knowledge, and Attributes and the Skill Standards in Which They Appear

	Skill Standards																																	
General Work Skills	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Basic Math (Fractions. Percentages, Metric System)	X	X	X					X		X			X	X			X	X	X	X	X	X		X			X	X	X		X	X		X
Communication (Electronic, Oral, Written)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Computers/Comfort with Automation			X	X		X	X			X				X	X	X		X					X	X		X	X	X				X	X	X
Critical Thinking	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X		X	X	X	X		X		X		X	X
Decision-making	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X			X	X	X		X	X	X	X	X	X	X	X		X	X
Ethics (Business, Medical, Personal)	X	X			X			X	X	X		X	X	X		X			X	X			X	X	X			X		X				X
Organization Skills			X		X				X	X		X	X	X	X	X	X		X	X		X	X	X				X	X		X			
Personal Professional Development								X		X							X	X																
Prioritizing Tasks		X		X	X	X			X	X	X		X		X					X					X				X	X				
Problem Solving	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X		X	X	X	X	
Resource Management	X	X		X						X	X				X	X	X	X	X									X	X		X			
Teamwork			X	X	X			X		X				X					X		X		X	X		X			X		X		X	
Time Management				X	X											X																		
TQM/Total Quality Management	X	X		X	X		X		X		X		X			X				X	X		X	X	X				X				X	X
Industry-Related Knowledge																																		
Anatomy	X									X		X																			X			
Animal Science					X							X		X						X					X									
Basic Electronics/Lab						X	X	X						X		X										X	X							
Biochemistry/Lab		X	X				X	X		X		X	X	X								X					X				X			
Biology/Lab	X		X					X	X			X	X	X		X				X		X			X		X							
Botany												X		X																				
Career Awareness Within the Industry								X										X																
Chemistry/Lab				X			X	X	X	X	X	X	X	X							X	X		X			X				X			
Clinical Laboratory Sciences	X	X		X	X	X	X		X	X	X	X			X	X							X	X						X				

Skills, Knowledge, and Attributes and the Skill Standards in Which They Appear

Industry-Related Knowledge (cont.)	Skill Standards 1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	3
Engineering			X											X		X													X					
Immunology/Lab				X					X	X	X	X																						
Math (Graphing, Ratios, Calculus)											X		X	X	X		X										X				X	X		X
Microbiology/Lab		X	X	X						X	X	X	X																X					
Molecular Biology/Lab												X	X									X												
Organic Chemistry/Lab												X	X																					
Phlebotomy					X					X																				X				
Physiology/Lab	X									X						X														X				
Quality Control and Quality Assurance Practices	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X				X	X
Recognizing Need for Supervisory Assistance	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X
Regulatory Standards	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	X				
Safety Systems	X	X		X	X	X	X	X	X	X	X	X		X	X	X				X		X		X	X		X	X	X	X				
Scientific Method			X												X	X	X												X		X			
Terminology (Medical, Bioscience)	X	X		X				X	X	X	X	X	X		X	X				X					X			X		X	X			
Toxicology	X								X							X																		
Industry-Related Skills																																		
Animal Care and Handling					X															X					X									
Aseptic Technique	X	X	X		X											X				X									X	X				
Detail Orientation	X	X	X	X	X		X	X	X	X		X	X	X	X	X				X		X		X		X	X				X	X		X
Following Complex Procedures		X	X				X	X	X		X	X	X	X		X				X		X				X	X							
Identifying Irregular Results	X	X	X			X	X		X	X		X	X	X		X				X	X	X					X	X	X	X		X		
Instrumentation			X	X		X	X		X	X	X	X	X	X		X	X		X			X				X	X				X			
Inventory and Supply Maintenance		X		X			X			X	X										X			X				X						

Skills, Knowledge, and Attributes and the Skill Standards in Which They Appear

Industry-Related Skills (cont.) / Skill Standards	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Laboratory Procedures (Basic)	X	X	X	X			X	X	X	X	X	X	X		X	X	X		X		X	X									X			
Maintaining Records, Logs, Protocols	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X	X	X	X	X		X
Manual Dexterity	X	X	X		X	X	X			X	X	X		X								X		X	X	X				X				
Performance Consistency	X	X	X		X		X	X		X		X	X	X		X	X			X		X	X	X	X	X		X	X	X	X	X		
Stress Management	X	X	X		X				X	X			X			X			X	X			X		X	X		X		X	X		X	
Troubleshooting Ability	X	X	X			X	X	X	X	X		X	X	X		X				X		X	X	X		X	X	X	X		X		X	
Upkeep of Equipment/Work Area	X	X				X	X	X	X	X		X	X	X		X				X		X		X	X		X		X	X				
Writing Logical Instructions															X		X							X										
Attributes																																		
Accountability	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X			X	X	X		X	X	X	X	X	X		X	X	X		X
Alertness	X	X	X		X	X	X	X	X	X		X	X	X	X	X				X	X				X	X	X		X	X	X	X		X
Common Sense	X	X		X	X	X	X	X	X	X		X	X	X	X	X	X		X	X	X	X	X		X	X	X	X	X	X	X	X	X	
Compassion										X										X					X			X		X				
Confidentiality	X							X		X						X	X						X							X			X	
Conscientiousness	X	X	X	X	X	X	X	X	X	X		X	X		X	X		X		X	X				X		X	X	X	X				X
Courteousness	X							X		X						X			X				X					X		X			X	
Creativity										X							X												X		X			
Flexibility	X			X			X	X			X		X						X	X								X		X				
Handles Constructive Criticism	X				X					X						X	X			X								X	X	X			X	
Handles Failure			X									X	X				X			X		X			X	X			X	X	X		X	
Hard Working	X	X			X			X		X				X	X	X						X	X							X				
Honesty	X	X				X		X	X	X		X		X	X	X	X	X				X	X		X				X	X	X			X
Independent Worker	X	X	X	X		X	X		X	X	X	X	X	X	X	X	X		X	X		X	X	X	X					X				
Integrity	X	X		X		X	X	X	X	X		X	X	X	X	X	X		X	X	X	X		X	X				X	X	X			X
Interest in Work	X	X		X				X		X		X	X			X		X				X							X	X	X			
Leadership										X																			X					

Skills, Knowledge, and Attributes and the Skill Standards in Which They Appear

Attributes (cont.)	Skill Standards																																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34
Meticulousness	X	X	X	X		X		X	X			X	X	X		X				X	X	X		X	X		X		X	X	X			
Observant	X	X	X		X	X	X	X	X	X		X	X	X	X	X	X			X	X	X	X	X	X	X	X		X	X	X	X		X
Patience		X				X	X		X	X			X	X					X	X			X		X	X		X		X	X		X	
Positive Attitude	X							X		X						X												X		X			X	
Professional Attitude/Behavior	X			X				X		X					X	X		X	X	X			X		X			X		X			X	X
Reliability	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X				X	X		X	X	X					X	X	X		X
Responsibility	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X			X	X	X	X	X	X		X		X	X		X		
Safety Consciousness	X	X		X	X	X	X	X	X	X	X	X		X	X	X				X		X		X	X		X	X		X				
Scientific Curiosity													X				X	X													X			
Self-Motivation	X	X		X		X		X	X	X					X	X	X	X		X					X	X				X				
Sound Judgment	X	X		X		X	X	X	X	X		X	X	X	X	X		X		X	X			X	X	X	X	X		X	X	X	X	X
Tactfulness								X		X								X	X				X					X		X			X	
Takes Initiative	X	X	X	X		X	X		X	X	X	X		X	X	X	X	X			X			X	X	X	X			X				X
Thoroughness	X	X		X		X	X					X	X	X	X		X			X	X		X	X			X		X	X	X	X		X
Willingness to Ask for Help	X	X	X	X	X	X	X		X	X	X	X		X	X	X			X	X		X	X	X	X	X	X			X	X	X	X	
Willingness to Work Around Hazardous Chemicals	X	X				X	X			X											X	X		X							X			
Willingness to Work Around Microbiologic Pathogens			X									X																		X				
Willingness to Work Around Radioactive Materials	X	X				X	X		X	X														X										
Works Well with Many Different People			X	X	X			X		X	X						X						X	X				X	X	X			X	

Assessment Methods for Task Mastery

Assessment Methods	Job Functions and Tasks																																									
	A 1	A 2	A 3	A 4	A 5	A 6	A 7	A 8	A 9	B 1	B 2	B 3	B 4	B 5	B 6	B 7	B 8	B 9	B 10	B 11	B 12	C 1	C 2	C 3	C 4	C 5	C 6	D 1	D 2	D 3	E 1	E 2	E 3	E 4	E 5	E 6	E 7	F 1	F 2	F 3	F 4	F 5	F 6
1. Evaluate work-based performance of procedures or problem responses to determine if appropriate and complete actions are taken.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X
2. Evaluate performance in classroom setting through role play, computer-based simulation, or other performance-based techniques to determine if appropriate and complete actions are taken.	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X
3. Review the actual result of process (sample, equipment, facility, material, parameters, product, document) to see that the person correctly performed the procedure.								X														X	X	X	X	X							X	X									
4. Review written documentation (e.g., reports/exams) for accuracy and completeness.	X		X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X						X	X	X	X		X	X	X	X	X	X	X	X	X	X
5. Evaluate verbal presentation for accuracy and demonstration of mastery.	X				X			X		X												X	X	X	X	X	X				X												X
6. Conduct mock situational (scenario-based) interviews to assess mastery.					X																						X																
7. Evaluate documents/exhibits collected in portfolio to determine how well they demonstrate mastery.		X		X		X	X				X	X	X	X	X	X	X	X	X										X	X										X	X		X
8. Have people critique their own or peers' journals, other materials, and performances for accuracy and completeness.																				X																							
9. Examine reviews or assessments of person, procedure, or document audit made by others (supervisors, mentors, colleagues, clients).																					X		X	X		X					X	X	X	X									
10. Have other people reproduce activities (procedures, problem responses, etc.) following peers' journals, documentation, procedure descriptions, and reports to see if the entries are correct and clear.	X																																									

F 7	F 8	F 9	F 10	G 1	G 2	G 3	G 4	G 5	G 6	G 7	G 8	G 9	H 1-9	I 1	I 2	I 3	I 4	I 5	I 6	I 7	I 8	I 9	I 10	J 1	J 2	J 3	J 4	J 5	J 6	J 7	K 1	K 2	K 3	K 4	K 5	K 6	K 7	K 8	L 1	L 2	L 3	M 1	M 2	M 3	M 4	M 5	M 6	M 7	M 8	N 1	N 2	N 3	N 4	N 5	N 6	N 7	N 8
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				X					X	X	X		X	X	X	X						X	X	X
X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X				X					X	X	X		X	X	X	X						X		X
																																				X				X		X	X	X	X											
X	X	X	X				X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X				X		X		X	X	X	X	X	X				X		X	X	X			X		X		
	X			X	X	X	X		X			X	X																		X	X	X	X	X		X			X	X						X		X	X	X			X			
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		X	X	X							X		X	X	X	X	X	X	X	X	X		X	X						X	X	X		X	X	X	X	X							X					X		X	X			X	X	

Appendix C: Current Certification Processes

Listed below are the agencies that accredit programs and the types of programs each agency accredits.

Accrediting Bureau of Health Education Schools (ABHES)

Recognized by the Department of Education to accredit

- Histotechnician programs
- Medical laboratory technician programs
- Phlebotomy programs

American Association for Accreditation of Laboratory Animal Care (AAALAC)

Conducts third-party, peer reviews of laboratory animal programs. Any institution maintaining, using, importing, or breeding laboratory animals for research, education, or testing is eligible to apply for AAALAC accreditation.

National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)

Granted independent recognition from the Department of Education; formerly under the "umbrella" of the Committee on Allied Health Education and Accreditation (CAHEA) of the American Medical Association (AMA), this agency accredits:

- Medical laboratory technician programs
- Histotechnician programs
- Phlebotomy programs

Following are the agencies that certify practitioners in the bioscience industry, together with the occupational classifications each certifies. Specialist classification categories and the agencies that certify individuals with advanced training are not included in this listing.

American Association for Laboratory Animal Science (AALAS)

- Assistant laboratory animal technician
- Laboratory animal technician
- Laboratory animal technologist

American Medical Technologists (AMT)

- Medical assistant
- Medical laboratory technician
- Medical technologist
- Phlebotomy technician

American Society of Clinical Pathologists (ASCP)

- Cytotechnologist
- Histologic technician
- Histotechnologist
- Medical laboratory technician
- Medical technologist
- Phlebotomy technician

American Society of Phlebotomy Technicians

- Certified phlebotomy technician

International Society for Clinical Laboratory Technology

- Laboratory technician
- Medical technologist
- Physician office laboratory technician

National Certification Agency for Medical Laboratory Personnel (NCA)

- Clinical laboratory phlebotomist
- Clinical laboratory technician
- Clinical laboratory scientist

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