

Essentials and Guidelines
**Of an Accredited Postgraduate Fellowship Program in
Medical and Public Health Laboratory Microbiology**

**ESTABLISHED BY
THE SUBCOMMITTEE ON POSTGRADUATE EDUCATIONAL PROGRAMS
(CPEP)**

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1. PREAMBLE

The *Essentials* of approved postgraduate fellowship programs in medical and public health laboratory microbiology have been established by the Committee on Postgraduate Educational Programs (CPEP), to which the American Society for Microbiology has delegated responsibility to perform the duties and make the decisions concerning accreditation of training programs in this field. The *Essentials* represent the minimum requirements for CPEP-accredited educational programs. The present document has been developed and revised after extensive review by medical microbiologists and other health professionals. Advice and suggestions were solicited from a broad range of individuals. The *Essentials* are adopted by the American Society for Microbiology, upon the recommendation of CPEP.

1.1 Purpose

The purpose of CPEP is to promote and encourage excellence in the training of medical, clinical, and public health microbiologists through the approval of fellowship programs that can meet these *Essentials*. Ultimately, the goal is to improve the quality of microbiological laboratory services (diagnostic, educational, consultative, and investigative) in health-related fields and, thus, contribute to the health and welfare of the public. CPEP assesses each program's compliance with the *Essentials* through review of its application, by on-site evaluations, and by the monitoring of annual reports from approved programs. Copies of these *Essentials* are available to the public and are provided to Fellows who enter CPEP-approved programs.

1.2. Objective

Essentials are a statement of policy and, as such, constitute minimum standards of quality in educational programs that are recognized by CPEP accreditation. These *Essentials* and accompanying guidelines are intended to assist medical, clinical, and public health microbiology programs in meeting and exceeding minimum standards in the design and conduct of sound educational programs. These *Essentials* represent policy which must be carried out. Strict adherence to the *Essentials* is mandatory. Guidelines present pathways toward fulfilling the *Essentials*. Guidelines usually represent one of many ways to satisfy an *Essential* and, therefore, strict adherence to Guidelines is not mandated.

1.3 Description of Profession

Medical and public health microbiologists are doctoral-level scientists and/or physicians who have developed expertise in microbiology and related subspecialties and sciences. CPEP graduates are prepared for responsible positions in medical and public health laboratories, governmental agencies, industry, and in colleges and universities. Specifically, they are trained to be responsible for providing clinical laboratory data, consulting with physicians and health officials, training medical and allied health personnel, laboratory management, and conducting research. More specifically, they are expected to be able to:

1. Develop and manage a fiscally sound diagnostic microbiology service that will support, enhance, or establish a clinical diagnosis or an epidemiological investigation.
2. Provide, communicate, and interpret microbiological data and other relevant information for use in the diagnosis, management, and treatment of patients with infectious diseases and provide consultation on epidemiological problems.
3. Plan and conduct effective training programs in microbiology for technical and professional personnel.
4. Design and conduct microbiological research relevant to medical and public health problems.
5. Address and meet local, state, and national regulatory requirements as applicable to the practices of medical and public health microbiology.

2. ESSENTIALS AND GUIDELINES FOR ACCREDITATION

2.1. Sponsorship

2.1.1. Institutions – *Essentials*

Postgraduate fellowship programs must be established in institutions with complete clinical laboratories or reference laboratories that perform clinical and/or public health microbiology procedures in sufficient volume at an appropriate level of quality, such as:

1. University and other medical centers
2. Public health laboratories
3. Hospitals and clinics
4. Reference clinical laboratories

2.1.2. Affiliates – *Essentials*

In instances where any aspect of the program cannot be provided by a single sponsoring institution, collaborative arrangements with other institutions must be established.

2.1.3. Accreditation – *Essentials*

In programs where the laboratory bench experience, clinical phases, and didactic instruction are provided by two or more institutions, accreditation will be granted to the sponsoring institution that assumes primary responsibility for curriculum planning and mode of instruction; coordination of the various elements of the program and guidance of individual Fellows; selection of the faculty for the program; admission and registration of Fellows; and verification of successful completion of the program. The sponsoring institution must also be responsible for assuring that the activities assigned to Fellows in the clinical laboratories are appropriately educational and not merely service work.

The sponsoring and collaborating institutions must not be the subject of an interim action by a recognized institutional accrediting agency or state agency potentially leading to the suspension, revocation or termination of its accreditation or have been threatened of a suspension, revocation or termination of its accreditation and the due process procedures required by the action have not been completed. The sponsoring and collaborating institutions must be accredited by the Joint Commission of Accreditation of Health Care Organizations, the College of American Pathologists, or the Center for Medicare and Medicaid Services, as appropriate.

2.1.3.1. Guidelines

In providing a postgraduate fellowship program in medical and public health laboratory microbiology, it is necessary for one institution to assume the major responsibility for the development and management of the program. Sponsoring institutions, however, may need collaborating institutions to provide certain portions of the instruction. In such instances, it may be desirable to have an institution that provides a significant portion of the instruction to be listed as a co-sponsor of the program.

Sponsors may recognize the contribution of collaborating institutions by requesting CPEP to issue appropriate certificates recognizing the collaboration.

2.1.4. Certification – *Essentials*

The sponsoring and collaborating institutions must be accredited, certified, or licensed as required by existing laws or accepted practice by recognized agencies or be otherwise acceptable to CPEP. The program/institution(s) (sponsor and collaborating institutions) must affirm adherence to non-discriminatory

practices with regard to race, color, creed, sex, age, sexual preference, national origin, or disability, in admission and treatment of students and postgraduate Fellows and in appointment and employment of staff.

2.1.5. Responsibilities of the Sponsor and Affiliate Institutions – *Essentials*

Responsibilities of the sponsor and each affiliate/collaborating institution for program administration, instruction, supervision, and documentation must be clearly described in written documents and made available for distribution and inspection.

2.2. Curriculum

2.2.1. Program Length – *Essentials*

The length of the program is 24 months.

2.2.1.1. Guidelines

Although the ABMM and other certification boards may give credit for partial participation in an approved program in the certification of individuals, it is generally agreed that most Fellows need two years to cover the subject matter and develop the desired competencies in medical and public health laboratory microbiology. Fellows should not be required to cover subjects that they have already mastered. Most, if not all, individuals will have other training needs that can fill any available time.

2.2.2. Areas of Training – *Essentials*

The program must provide the necessary education, training, and practice in all of the specialty areas of medical and public health laboratory microbiology, including:

- Bacteriology
- Antimicrobial susceptibility testing
- Mycology
- Mycobacteriology
- Virology
- Parasitology
- Fundamentals of infectious diseases and pathogenesis
- Public health microbiology
- Epidemiology and hospital infection prevention and control
- Laboratory ethics, management, and safety
- Molecular diagnostics
- Immunology and serology
- Research and teaching methodologies

In order for the Fellows to acquire the knowledge and skills of a medical and public health microbiologist, appropriate instruction must be made available through bench training and experience, on-call, clinical consultations, clinical conferences, hospital rounds, workshops, organized courses, self-instructional materials, and administrative training. Ample diagnostic material (quantity and variety) must be available with concomitant opportunity for the Fellow to learn how to correlate laboratory information with patient care and/or public health needs. Emphasis must be placed on laboratory diagnostic practice and clinical experience.

2.2.2.1. Guidelines

While it is CPEP policy that curriculum contents and instructional methods are the prerogative of the sponsoring institutions, CPEP offers the accompanying guidelines to assist the programs in developing sound and appropriate instruction that will enable a Fellow to attain the program objectives.

Major training objectives should be developed for the Fellow to identify the knowledge and skills to be acquired by the end of the two-year fellowship. In preparing objectives, the program directors should consider the *Essentials* and accompanying guidelines in Section 2.2.3.

The first year of the postgraduate training in medical and public health laboratory microbiology should be organized on a broad basis to furnish instruction in each of the specialty areas. While instruction may be provided in organized courses and self-instructional materials, practical bench exercises and training and clinical experience should be emphasized. The Fellow should have in-depth knowledge of clinical aspects of infectious diseases as they apply to laboratory diagnosis and detection of antimicrobial resistance. Fellows accepted in these programs may have had prior training in specific areas, such as microbial physiology, microbial genetics, bacteriology, statistics, pathology, or pathogenesis of infections. Therefore, the program may have to individualize training according to each Fellow's prior experience while still covering the *Essentials*.

The second year should continue broad training but at a substantially higher level with emphasis on clinical significance and interpretation of laboratory results to solve epidemiological problems and to care for patients and populations. The program must also provide training in laboratory management and experience in dealing with management of interpersonal relationships and supervisory aspects of the laboratory. Program directors should draw Fellows into the management decision-making process and provide increasing responsibility for at least some important aspects of the laboratory services. Fellows' attendance at ward rounds and clinical conferences should increase in frequency and level of participation.

To help the Fellows know whether or not an assignment or segment of the program is being adequately covered, modular or rotation objectives should be prepared for the major components of the program. The program director (or designee) should review objectives with the Fellow at the beginning of each component. The modular objectives should also help the faculty to organize content, learning experiences, and performance evaluations for various portions of the program.

If the parent institution cannot provide adequate training in certain areas, arrangements must be made for the Fellows to learn the material at other institutions and through supervised independent study.

The Fellows should have the opportunity to become acquainted with "new" infectious disease problems, epidemics of national or global concern, and major effects or trends in health care and maintenance. Aspects of other laboratory disciplines, such as pathology, molecular pathology, histology, hematology, and clinical chemistry should be an intrinsic component of the basic program in the context of discussions about specific disease processes.

Additional training should be provided in translational or clinical research in clinical and/or public health, but should not be so extensive as to preclude or preempt satisfactory completion of other essential rotations and aspects of the program. Although research and publication are encouraged, it should be understood that this is not primarily a research training program.

Opportunity for attendance and presentation at ASM or other nationally recognized conferences/meetings in clinical/public health science is desirable.

2.2.3. Knowledge to be gained from Specialty Area Training

2.2.3.1. Specimen Collection – *Essentials*

The Fellow must know how to collect and transport clinical specimens for the detection and/or identification of bacteria, mycobacteria, fungi, parasites, and viruses. They must be able to discriminate which specimens are appropriate for testing based on adequacy of specimen, site and manner of collection, transport time, and method of detection. In addition, the Fellow must know how to support or decline specimen send-out requests. Standard precautions must be observed in all phases of collection

and handling. When packaging and shipping Division 6.2 materials, DOT and IATA regulations must be followed.

2.2.3.1.1. Guidelines

The Fellow should be familiar with transport devices and conditions for preserving the viability of microorganisms during a brief or extended transport period.

He/she should be able to recommend optimum blood collection procedures including number of cultures, timing of collections, volume of blood per culture, and proper antisepsis before venipuncture.

He/she should understand the use and content of the Laboratory Test Catalog/Handbook and be able to assist clinicians in the selection of appropriate tests.

The Fellow should be able to evaluate the quality of the specimen based on gross and microscopic examination of the material and apply criteria for specimen rejection.

The Fellow should be able to determine if a shipment classifies as a Category A, Category B or Exempt Human Specimen and define the packaging and shipping requirements associated with each shipment type.

2.2.3.2. Isolation and Identification – *Essentials*

The Fellow must be able to:

- interpret direct stains of clinical material and provide rapid results based on examination of slides prepared by various staining procedures. He/she must be able to correlate commonly used histopathology stains of tissue sections with the presence of infectious agents.
- identify test results that necessitate referral of possible biological threat and/or select agents
- communicate to and consult with clinicians regarding the clinical relevance of culture and other clinical microbiology test results.
- understand the evolution of point of care testing and its increasing impact on infectious disease diagnostics.

The Fellow must be familiar with techniques for specimen preparation and routine and reference procedures to recover bacteria, mycobacteria, fungi, parasites, viruses, and nucleic acid from clinical specimens. He/she must be familiar with procedures for the direct detection of infectious agents (antigen detection by serological methods such as immunofluorescence and enzyme immunoassays, and nucleic acid detection using molecular methods, including contemporary amplification, multiplex, and quantitative methods).

2.2.3.2.1 Guidelines

The Fellow should understand the use and function of basic media and cell lines for the detection of microorganisms from clinical specimens.

The Fellow should be able to devise safe, reliable and cost-effective primary inoculation protocols to ensure the recovery of recognized pathogens from clinical specimens.

The Fellow should be familiar with various methods, techniques and automated instruments, for the isolation and detection of microorganisms in specimens.

The Fellow should demonstrate proficiency in the use and interpretation of microscopy for examination of patient specimens, including microscopic morphology of pathogens, and staining techniques used in Microbiology. Training should also be available in the examination and morphology of pathogens in tissue specimens stained for histopathology studies. This could also involve time spent with a pathologist/microbiologist to develop an understanding of the different tissue types from their microscopic appearance and the basic principles involved in the routine and special stains used in surgical pathology.

The Fellow should be familiar with methods for qualitative screening for individual infectious agents as well as techniques that require quantitative recovery of microorganisms.

The Fellow should know and use algorithms for the presumptive and definitive identification of microorganisms, including conventional biochemical testing, rapid spot testing, automated identification instruments (including MALDI-TOF), and culture independent methodologies for identification (e.g. next generation sequencing, multiplex molecular panels). He/she must know phenotypic profiles of common and very important pathogens.

2.2.3.3. Antimicrobial Susceptibility Testing – *Essentials*

The Fellow must be able to classify commonly used antimicrobial agents as to structural group, mechanism of action, spectrum of antimicrobial activity, and mechanisms of resistance. He/she must be able to describe and perform various methods of qualitative and quantitative susceptibility testing and molecular methods to detect antimicrobial resistance. The Fellow must demonstrate an understanding of the importance of communication between the microbiology laboratory and the pharmacy, the institutional therapeutics committee, infectious disease service, and the infection prevention and control committee, and be able to generate a timely antibiogram.

2.2.3.3.1. Guidelines

The Fellow should be familiar with the various types of manual procedures, automated instruments, and molecular methods for antimicrobial susceptibility testing, their weaknesses and strengths, and how to troubleshoot and verify unusual results generated by them. In addition, he/she should be familiar with the most recent CLSI, FDA, or other guidelines for susceptibility testing and interpreting results (i.e., zone sizes, MIC values and breakpoints).

He/she should be able to apply knowledge of resistance mechanisms and interpret results of antimicrobial susceptibility testing.

The Fellow should be familiar with how their facility interacts with the state's public health lab regarding unusual isolates/resistance patterns. He/she should also be familiar with reporting requirements.

The Fellow should be able to formulate a panel of appropriate antimicrobial agents for testing against rapidly growing gram negative and gram positive bacteria, slow growing fastidious bacteria, rapidly growing and slow growing mycobacteria, and yeasts, and recommend the most appropriate test method for each. He/she should be able to troubleshoot questionable/unusual susceptibility patterns.

The Fellow should be familiar with the principles, procedures, application, and interpretation of minimum inhibitory concentrations, detection of antimicrobial resistance and related mechanisms, methods for bacterial strain typing, serum bactericidal tests, antimicrobial assays, and minimum bactericidal concentration tests. He/she should understand pharmacokinetic and pharmacodynamic concepts used to select appropriate therapies.

The Fellow should be familiar with the recognized and approved agents for treating viral, rickettsial, fungal, and parasitic infectious diseases and be prepared to consult with the physicians caring for the patient.

The Fellow should be familiar with the antimicrobial stewardship committee, infection control committee, and epidemiology/surveillance activities with participation if possible.

2.2.3.4. Infectious Disease Serology and Immunology – *Essentials*

The Fellow must be familiar with the theory and practice of agglutination, precipitation, enzyme immunoassay, immunodiffusion, immunofluorescent, complement fixation, and immunoblotting techniques. He/she must know the application and interpretation of antibody and antigen detection tests for common bacterial, fungal, parasitic, and viral diseases. Additionally, the Fellow must be familiar with newer automation available for serology (e.g., automated instruments for dispensing and diluting reagents and specimens, and for performing automated EIA tests), including automation and instrumentation of hepatitis, syphilis, and HIV testing, as well as application of testing algorithms.

2.2.3.5. Quality Management – *Essentials*

The Fellow must understand and describe the three elements of quality management: structure; process; and outcome of a comprehensive laboratory quality management program. He/she must demonstrate the ability to implement a laboratory quality control and quality management program. The Fellow must understand and be able to articulate the statistical methods needed to evaluate diagnostic tests, including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy. The Fellow must be familiar with the process of root cause analysis and individual quality control plans (IQCP) in the laboratory.

The Fellow must be familiar with the verification and validation required to implement unmodified FDA-approved, modified FDA-approved, and laboratory-developed tests.

The fellow must be familiar with the existence and applications of evidence based guidelines for laboratory practice, including outcome studies, and recommendations for clinical management. Examples may include ASM, EBLMPG, IDSA, etc.

2.2.3.5.1. Guidelines

The Fellow should become familiar with laboratory quality control procedures and be given the responsibility to review quality control data. The Fellow should help in the selection of quality assurance indicators and present the results in a written or verbal presentation, articulating the important phases of the test cycle (pre-analytic, analytic, and post-analytic).

The Fellow should become familiar with a hospital/institution's continuous quality management program, proficiency testing programs, and employee competency testing.

The Fellow should participate in the development and/or review of individual quality control plans (IQCP).

The Fellow should participate in the development of a test verification or a test validation.

2.2.3.6. Laboratory Safety – *Essentials*

The Fellow must be familiar with the theory and practice of laboratory safety that includes local, state, and federal regulations, and the design and implementation of a program that protects the health and safety of all laboratory employees. The Fellow must be familiar with laboratory and hospital or institutional safety committees.

2.2.3.6.1. Guidelines

The Fellow should attend a hospital, university, or institutional safety orientation course.

The Fellow should understand modes of transmission and acquisition of relatively common laboratory acquired infections.

Fellows should understand the principles and practices of the following safety issues:

- Composition and use of a laboratory safety manual
- Principles of biosecurity
- Standard precautions
- How to conduct a risk assessment
- OSHA requirements
- Biosafety hazards, including handling specimens potentially containing highly infectious/pathogenic organisms
- Selection and use of appropriate personal protective equipment (PPE) to include proper donning and doffing
- Waste management, including disposal of biohazard material and sharps
- Safe handling of radioactive materials
- Physical and chemical hazards, including carcinogens
- Methods of disinfection and sterilization
- Baseline medical testing (immune status, protection immunization)
- Laboratory design as it applies to safety
- Biological safety cabinets and biosafety levels
- Policy for managing laboratory accidents, including managing a safety emergency
- Regulations related to packaging and shipping infectious substances and the disposal of biohazardous materials
- Possession and transportation of select agents
- Occupational exposures
- Disaster planning/Continuity of Operations Plan (COOP)

2.2.3.7. Epidemiology of Infectious Disease and Hospital Infection Control – *Essentials*

The Fellow must be familiar with epidemiology and hospital infection control which includes a rotation with the hospital epidemiologist and infection control practitioners and participate in the investigation of a community or hospital outbreak, if possible.

2.2.3.7.1. Guidelines

The Fellow should be familiar with the following principles of epidemiology and hospital infection control:

- Role of clinical microbiology in hospital infection prevention and control
- Retrospective study
- Prospective study
- Case-control study
- Cohort study
- Function of the Infection Control Committee
- Implementation of an infection control program
- Principles of isolation in hospital infection control
- Surveillance, recognition, and control of nosocomial infections
- Immunization of health care workers
- Principles of disinfection and antiseptics
- Recognition and control of nosocomial infection
- Responsibility to the community in terms of public health
- Local, state, and national infectious diseases reporting requirements

2.2.3.8. Laboratory Management – *Essentials*

The Fellow must demonstrate an understanding of:

- Personnel management principles and interpersonal relations
- Legal aspects of both human resource (e.g. ADA, FMLA) and information management (e.g. HIPAA)
- Budgeting
- Cost accounting and test utilization
- Workload assessment
- Space planning and laboratory design
- Techniques of policy change and implementation
- Preparation of job descriptions
- Interviewing
- Performance appraisals
- Disciplinary actions
- Information security

2.2.3.8.1. Guidelines

The Fellow should assume responsibility for direction of a section of the laboratory for a 3-6 month period.

The Fellow should participate in the annual budget planning process, e.g., by preparing a cost analysis of a piece of capital equipment or justification for a new technologist position.

The Fellow, whenever possible, should sit in on personnel actions, including interviewing, performance appraisals, and disciplinary actions. The Fellow should understand the importance of being a good team player. He/she should understand the legal aspects of human resource management (e.g. FMLA and ADA) and information management (e.g. HIPAA and FOIA).

The Fellow should take management training courses that are available. Many institutions provide courses that help develop supervisory skills. He/she is encouraged to participate.

The Fellow should be familiar with basic aspects of healthcare economics as they relate to clinical microbiology (e.g., reimbursement by paying agencies, HMO's, and third parties; CPT codes as they relate to individual tests in clinical microbiology, reimbursement, and compliance issues). He/she should understand reimbursement principles in an overall assessment of laboratory income potential including the differences between inpatient and outpatient billing.

The Fellow should be familiar with the provision of clinical microbiology services to clients outside of the Fellow's laboratory/setting/hospital (e.g. customer service; bringing in new/outside business; establishing a small or satellite laboratory at another site; how services differ among community hospital, academic, commercial/reference, Veterans Administration, and local/state public health laboratories).

2.2.3.9. Laboratory Regulations – *Essentials*

The Fellow must describe the major requirements of private and governmental (federal and local) agencies that accredit or license clinical and public health laboratories or that have standards regarding employer/employee relationships.

2.2.3.9.1. Guidelines

The Fellow should be familiar with the importance of federal agencies, regulations, and acts in clinical microbiology (e.g., CLIA, HCA, Medicare, Medicaid, and appropriate publications in the Federal Register).

The Fellow should be familiar with the select agent rule, Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health (HITECH) Act, and rules and regulations relating to patient confidentiality in research (hospital/university/institutional review board [IRB]).

The Fellow should be familiar with the various types of CLIA certifications (waived, PPM, Moderate and High Complexity) as well as the requirements of accrediting agencies such as CAP and CLEP.

The Fellow should understand the difference between waived tests and nonwaived tests, LDTs and EUAs.

The Fellow should be exposed to the point of care testing environment so that they gain an understanding of the operational issues and challenges unique to this setting.

The Fellow is encouraged to meet and discuss regulations with individuals at the State Department of Health Laboratory who are responsible for monitoring state and federal laws that affect laboratory testing. The fellow should have a general understanding of how requirements may differ from state to state.

The Fellow should complete some or all of the CAP accreditation self-inspection documents and actively participate in the CAP inspection of the laboratory.

If possible, the Fellow should participate with an inspection team in an off-site CAP inspection.

The Fellow should participate in an OSHA self-inspection of the laboratory and be familiar with the requirements of CLIA '88.

The Fellow should understand the role of proficiency testing in the accreditation process.

2.2.3.10. Laboratory Automation and Computerization – *Essentials*

The Fellow must fully understand the application, utilization, and limitations of:

- Automated or semi-automated systems for microbial detection, identification, and antimicrobial susceptibility testing
- Computerized information systems for recording, analyzing, and reporting laboratory data
- Hospital information system and how it communicates with the laboratory information system (LIS)
- Computer and software which provide management, quality control, safety, and infection control data
- Appropriate test utilization (e.g. cost effectiveness, operations, and clinical benefits)

The Fellow must be familiar with at least one contemporary laboratory information system.

2.2.3.10.1. Guidelines

The Fellow should be familiar with verification and validation requirements for laboratory instrumentation and testing, including LIS/EMR test build and reporting.

The Fellow should review literature and manufacturer's specifications which compare different LIS. The Fellow should be familiar with microbiology-specific aspects of a LIS (e.g., specimen receipt and entry, preliminary and final reporting of results, test menu, test ordering, entering results, and recalling epidemiological data).

The Fellow should be able to demonstrate proficiency in generating reports from a LIS (e.g., epidemiological, cost, susceptibility, and QC/QA data). Specifically, the Fellow should be able to query a LIS, generate a report, and format the report to a spreadsheet for data base analysis.

The fellow should have knowledge of HL7, LOINC and SNOMED codes and familiarity with Health Information Exchange

2.2.3.11. Communication of Clinical Consultation – *Essentials*

The Fellow must demonstrate the communication skills necessary to consult and advise clinical staff, instruct technologists, and compose justifications, including requests for personnel, equipment, and laboratory space, to laboratory and/or institutional administration.

2.2.3.11.1. Guidelines

The Fellow should be assigned the responsibility of handling phone calls and electronic communications from clinicians regarding specimen collection and interpretation of laboratory data. The Fellow should participate in the on-call rotations and be responsible for reporting significant results to clinicians. Review of the Fellow's on-call performance by program staff is strongly encouraged.

The Fellow should help update and be familiar with a reporting system for critical values.

The Fellow should outline the steps involved in making and implementing a policy change.

The Fellow should participate in the laboratory's ongoing continuing education program.

The Fellow should be familiar with newly emerging and practical hospital healthcare practices used by physicians and nurses (e.g., clinical pathways, treatment pathways, and hospital administration).

2.2.3.12. Training Methodology – *Essentials*

The Fellow must participate in the design or revision of a competency testing program.

2.2.3.13. Research Methodology – *Essentials*

The Fellow must develop a protocol and describe the research methodology, controls, and statistical considerations to test a hypothesis proposed as an answer to a basic or applied microbiological problem in a clinical or public health laboratory.

2.2.3.13.1. Guidelines

Fellows should be encouraged to attend and participate in local, regional, and national scientific meetings where applicable research data may be submitted for a paper/poster presentation. He/she should participate in an IRB submission. The program should assist with the funding for meeting attendance.

2.2.3.14. Public Health Microbiology – *Essentials*

The Fellow must be familiar with the practices of a public health microbiology laboratory, microbiology from a public health perspective, the unique nature of many public health microbiology tests, and how public health laboratories support disease control and environmental health programs. The Fellow should understand how the laboratory interacts with the public health laboratory. The Fellow must spend at least two weeks in a public health laboratory.

2.2.3.14.1. Guidelines

The Fellow should be familiar with nationally notifiable diseases as well as the reportable disease list utilized by the local public health laboratory. The Fellow should understand how the information and / or specimens that must be sent to the public health laboratory are utilized.

The Fellow should learn to identify microorganisms that cause infectious diseases of public health importance, including agents of bioterrorism.

The Fellow should be familiar with the types of outreach activities that public health entities offer (e.g. APHL teleconferences, laboratory training, etc.).

The Fellow should be familiar with the principles and logistics of the investigation of outbreaks of diseases of public health importance.

The Fellow should be able to provide professional educational assistance to other clinical/diagnostic microbiologists throughout the state and where applicable to the general public.

The Fellow should be familiar with the following public health laboratory methods:

- Potable and waste water testing
- Food and dairy microbiology
- Sexually transmitted diseases testing
- Tuberculosis testing
- Whole genome sequencing; both PulseNet and non-PulseNet methods
- Bioinformatic analysis, molecular epidemiology, and data interpretation
- Identification of unusual isolates
- Rabies virus detection
- Newborn/developmental screening
- Detection of emerging pathogens
- Botulism testing
- Environmental microbiology testing
- Vaccine preventable diseases testing
- Strain typing

The Fellow should be familiar with the following regarding bioterrorism (BT):

- Agents of bioterrorism and the select agent program
- The Laboratory Response Network, including different roles played by LRN Sentinel, Reference, and National labs.
- Identification characteristics of the more likely biological agents associated with BT or any other unusual organism and the rule out/refer process, including chain of custody procedures
- Laboratory safety procedures. e.g., safe handling of these BT agents in clinical microbiology laboratories
- The role of local clinical microbiology laboratories and governmental agencies (local, state, and federal) in response to BT
- The role of the microbiology laboratory in the institutional BT preparedness plan (specifically, the internal lines of communication and documentation depending on who becomes aware of a BT threat/event [police, lab, ER MD])
- Knowledge of local, state, and federal sources of information and emergency help regarding the response of clinical microbiology laboratories during a BT event
- Clinical syndromes produced by agents of bioterrorism and select agents and prophylaxis that may be available in case of an exposure

2.2.3.15. Molecular Diagnostics – *Essentials*

The Fellow must be exposed to the theory and application of contemporary molecular techniques as they are applied to areas of medical and public health laboratory microbiology.

2.2.3.15.1. Guidelines

1. The Fellow should know how to collect and transport clinical specimens for the detection of microbial nucleic acids. He/she should be able to discriminate which specimens are appropriate for testing based on the type, quality and quantity of specimen, collection site, and timing of specimen collection during disease. The Fellow should know the collection devices used, and the appropriate conditions needed to preserve the integrity of nucleic acids during collection, transport, and storage of specimens.
2. The Fellow should know how to prepare specimens for the release and isolation of target nucleic acids. He/she should be familiar with the conditions for maintaining the quality of target nucleic acids during and following isolation, and for reducing or inactivating inhibitory or interfering substances during the isolation process.
3. The Fellow should be familiar with the various targets, probes and signal molecular amplification methods for qualitative detection of individual infectious agents, as well as for quantification or genotyping of microorganisms. Methods may include the following:
 - Contemporary methods of target amplification and detection
 - Contemporary methods of gene sequencing and genotyping
 - Contemporary methods for microbial strain typing
4. The Fellow should understand the principles and practices of the following subjects with regard to nucleic acid amplification and other molecular methods:
 - Nucleic acid probe detection of microbes
 - Restriction analysis of prokaryotic and eukaryotic DNA
 - Plasmid isolation and detection
 - Selection of appropriate target primer and probe sequences
 - Choice and optimal concentration of enzymes (e.g., polymerases and other nucleic acid modification enzymes), deoxyribonucleoside triphosphates, divalent cations, and reaction buffer components (e.g., Tris-HCl, KCl) used
 - Amplicon detection methods
 - Whole genome or high-throughput sequencing technologies
 - Familiarity with databases, curation, and/or database development
 - Sample-to-answer test systems
 - Strengths and limitations of multiplex molecular tests and methods
 - Laboratory design and practices to prevent product contamination
 - Proper use and maintenance of equipment and instruments
 - Quality control and quality assurance programs
 - Verification, validation, and proficiency testing of molecular assays
5. The Fellow must be able to interpret and articulate the results of molecular diagnostic tests, including those obtained from qualitative, quantitative, and genotyping assays.
6. The Fellow should be familiar with various automated instruments for nucleic acid isolation and purification and for amplification and detection of microbial nucleic acids.

2.2.4. Length of Time Each Fellow Must Spend in Specialty Training Areas – *Essentials* and Guidelines

The table below lists the amount of time an individual spends in each of the major training areas during a two-year program. The minimum *Essential* or requirement times are intended for individuals who enter a program with little or no previous experience in clinical microbiology and represent the time needed to achieve the objectives stated in the *Essentials*. The ranges of time or guidelines for each area provide flexibility that may be necessary due to prior experience of the Fellow.

<i>Essentials</i> and Guidelines for Length of Time in Major Training Areas		
Major Training Area	<i>Essentials</i> Minimum Time Spent (Months)	Guidelines Range of Time Spent (Months)
Bacteriology and Antimicrobial Susceptibility Testing	3	3-6
Mycology	1	1-2
Mycobacteriology	1	1-2
Virology, Chlamydia, Mycoplasma, and Ureaplasma	1.5	1.5-3
Parasitology	1	1-2
Clinical Infectious Diseases	1	1-3
Infectious Disease Serology and Immunology	0.5	0.5-1
Public Health Microbiology	0.5	.5-2
Infection Control	0.5	.5-2
Management & LIS/Computer Training	0.5	0.5-1.5
Molecular Diagnostics	1	1-3
Research	Open	
Teaching	Open	

2.2.5. Evaluation of Instruction – *Essentials*

Programs must develop and implement means to evaluate all phases of the instruction. Performance and competence must be documented in relation to stated program objectives that are made known upon entering the program. Performance must be documented and reviewed with the Fellow. Documentation of the review must be maintained for at least seven years.

2.2.5.1. Guidelines

A clear definition of program objectives is essential. A program cannot evaluate the knowledge and proficiency which Fellows have acquired unless it has first defined the specific functions and skills that they are expected to learn (see Section 2.2.3). As a consequence, a program should proactively define the objectives for the rotations and didactic instruction in such a way that the Fellows, faculty, and evaluators can recognize the level of proficiency and knowledge Fellows are expected to attain from various segments and from the program as a whole.

Program directors should develop means for evaluating a Fellow's accomplishments and preparedness for a career as a medical and public health microbiologist (see Preamble). This process should provide evidence that each Fellow has been fully trained and has substantially met all of the program's objectives. Periodic review should occur at the completion of each specialty area. Such evidence should be documented and retained in the file of each Fellow.

2.2.6. Program and Performance Records – *Essentials*

The parent institution must maintain a record of the training program and/or performance of each Fellow for at least seven years.

2.2.6.1. Guidelines

Because a standard curriculum for all individuals is inappropriate, the parent institution should record the bench and clinical rotations, research, organized courses, and individual study that engaged the time of each Fellow. A list of these program components and other information on Fellow activities and performance should be retained by the institution.

2.3. Resources

2.3.1. General Resources – *Essentials*

Resources, as described below, must be adequate to support the number of Fellows admitted to the program.

2.3.1.1. Guidelines

Care should be taken to ensure that the supervisory and instructional staff and other resources are available for all Fellows enrolled in the program and are adequate to provide quality instruction for this advanced, professional level of training.

2.3.2. Program Staff – *Essentials*

The program must have a qualified program director(s) and adequate support staff. The program director must assume overall responsibility. When the program director is changed or is on leave for longer than one month, CPEP must receive immediate notification. The interim/acting director is responsible for all components of the program. The curriculum vitae of the new director, giving details of his/her education, training, and experience, must be submitted to CPEP for inspection and approval by the committee. If the new director's credentials are in order, accreditation of the program will be continued.

2.3.2.1 Guidelines

Primary responsibilities of the program director shall include program development, organization, administration, evaluation, and revision. In some instances, it may be desirable to have an assistant or deputy program director.

Program officials should have time to fulfill the administrative and educational duties of the program. Adequate clerical and other support staff should be available.

2.3.3. Program Director Responsibilities – *Essentials*

The program director must be responsible for the organization, administration, periodic review, continued development, and general effectiveness of the program. In this activity, the program director must cooperate and collaborate fully with the program and instructional officials at the parent and collaborating institutions. The program director shall be responsible for ensuring that appropriate evaluation instruments are developed and applied regularly and consistently and that appropriate records of all Fellows in the program are maintained.

2.3.3.1. Guidelines

The program director shall assume ultimate responsibility for the didactic instruction, laboratory experience, and clinical phase of the program. Although other officials at the sponsoring and collaborating institutions should be delegated specific responsibilities, it is the program director's responsibility that all phases of the program are appropriate and successful in meeting program goals and objectives.

2.3.4. Program Director Qualifications – *Essentials*

The program director must be (a) a medical microbiologist who holds a responsible leadership position in the sponsoring institution and (b) certified (with active status) as a Diplomate by the American Board of Medical Microbiology (ABMM). The program director may be certified by another board that is acceptable to CPEP, provided the program has a deputy director at the sponsoring institution who is certified (with active status) by the ABMM. The program director must be engaged full time in microbiological work (diagnostic, research, teaching, program administration) at the sponsoring institution.

2.3.5. Assistant or Deputy Program Director Qualifications – *Essentials*

If the program has a designated assistant or deputy program director, he/she must be certified by the ABMM or a board that is acceptable to CPEP and the certification must be active. The assistant or deputy program director(s) must have appropriate credentials that are acceptable for faculty appointments at the sponsoring and/or collaborating institutions.

2.3.6. Instructional Staff

2.3.6.1. General Qualifications – *Essentials*

All instructional staff must be qualified through academic preparation, experience, and appointment to effectively teach the subjects assigned.

2.3.6.1.1. Guidelines

The breadth or competency of the staff of the sponsoring and/or collaborating institutions should be such that all areas of medical and public health laboratory microbiology can be covered satisfactorily to meet the objectives of the program. In addition to physicians and scientists who are medical microbiologists, the staff may include specialists in management and education as well as physicians with interest and expertise in clinical and public health microbiology who are specialists in infectious disease, pathology, rheumatology, pediatrics, and epidemiology.

2.3.6.2. Program Officials – *Essentials*

In addition to the program director, the program officials of the sponsoring and/or collaborating institutions must include at least two doctoral level, full-time staff members with expertise and interest in medical microbiology. These people do not have to be part of the microbiology laboratory staff.

2.3.6.2.1. Guidelines

Fields of competence of additional program officials should supplement rather than duplicate those of the program director.

2.3.6.3. Technical and Clinical Personnel – *Essentials*

The program director must be assisted by sufficient professional, technical, and clinical personnel to permit the laboratory to carry out all of the responsibilities in service, teaching, consultation and research in an efficient and effective manner.

2.3.6.3.1. Guidelines

The technical personnel should be certified by appropriate agencies (e.g., The National Registry of Certified Microbiologists, Board of Certification [ASCP], National Registry of Clinical Chemistry), or be eligible for such certification.

2.3.7. Financial Resources – *Essentials*

The financial resources of the sponsoring institution must be such that continued operation of the educational program is assured for completion of the program by current and newly accepted Fellows.

2.3.7.1. Guidelines

In addition to adequate budgetary support for the teaching and diagnostic operations of the laboratory, adequate stipend support for Fellows should be provided.

2.3.8. Physical Resources – *Essentials*

Adequate laboratories, classrooms, office space, computer resources, and other facilities must be provided.

2.3.8.1. Guidelines

The laboratories should have sufficient space to accommodate both the staff and Fellows without interfering with the regular activities of the laboratory. A separate office(s)/laboratory area for Fellows is desirable.

2.3.9. Equipment and Supplies – *Essentials*

Appropriate, modern equipment and supplies in sufficient quantity must be provided.

2.3.9.1. Guidelines

Institutions lacking state-of-the-art automated instruments and computer facilities should make Fellows aware of such technology by having them rotate through other institutions and/or attend lectures and workshops dealing with these subject areas. Adequate instructional materials should be available, including microorganisms and clinical materials that are not available on a regular basis. Programs should also maintain self-instructional materials such as collections of color images, movies, and digital media to supplement the instruction available in the program.

2.3.10. Library – *Essentials*

A library must be readily accessible and contain an adequate supply of up-to-date books, journals, and reference materials related to the curriculum. Computerized search services must be available, and the Fellow must be trained in their application and use.

2.3.10.1. Guidelines

The sponsoring and collaborating institutions should maintain or have available adequate libraries containing electronic or print authoritative textbooks, monographs, and current journals in the various disciplines related to and associated with clinical and public health laboratory medicine.

2.3.11. Records – *Essentials*

Satisfactory records must be maintained on Fellows' admission, attendance, participation, achievement, and evaluation. Detailed records on each Fellow must be on file at the sponsoring institution for at least seven years. A summary record on each Fellow must be permanently kept by the sponsoring institution and sent to the CPEP headquarters office after completion of the training program.

2.3.12. Advisory Committee – *Essentials*

An advisory committee must be composed of key program officials from the parent and collaborative institutions. The purpose of this committee is to review and establish policy, continuing program development and evaluation, and to help maximize utilization of resources at the sponsoring and collaborating institutions. At least one meeting each year must be held to assess the program. More

frequent meetings may be necessary to resolve certain issues that arise during the year. Minutes of these meetings must be prepared and submitted to CPEP with the annual report.

2.3.12.1. Guidelines

The advisory committee should be relatively small, consisting of the program director, one or two of associates at the sponsoring institution, and one representative from each collaborating institution. One of the more senior Fellows in the training program may also serve.

2.4. Fellows

2.4.1. Program Description – *Essentials*

Prospective Fellows must be provided with a clear description of the program and its contents, including the program objectives and competencies that the Fellows are expected to attain. There must be no deceptive publicity concerning job placement or income expectations for Fellows. Fellows must be given a copy of the CPEP *Essentials* upon entering the program, if not before.

The program must have a printed document that clearly describes the training program that is offered. Additional information on stipend, travel, health insurance, and scheduled time off must be disclosed in writing to each Fellow.

2.4.2. Admission – *Essentials*

The Fellow must have earned a doctoral degree (such as Ph.D., M.D., D.O., Sc.D., Dr. P.H., D.V.M.) with graduate education in microbiology or molecular biology to qualify for admission to the training program. At this time, a doctorate in clinical laboratory science is not an acceptable doctoral degree. Fellow recruitment and selection must be nondiscriminatory with respect to race, color, creed, age, sex, sexual preference or national origin; appropriate consideration must be given to the physically handicapped. Matriculation practices must be consistent with all applicable laws regarding nondiscrimination. The decision for selecting a Fellow must be documented in writing and retained for seven years.

2.4.2.1. Guidelines

Educational prerequisites, other criteria for selection, and the method of selection should be explained to prospective candidates. Desirable prerequisites for the postgraduate training programs include courses in epidemiology, immunology, microbiology, molecular biology, histology, pathogenesis of infection, and statistics. Previous work experience in medical and/or public health diagnostic laboratories may be considered when evaluating candidates for the program.

A fellowship selection committee consisting of two, and preferably three, members should participate in the selection process. It is usually desirable to have members of the advisory committee serve on the selection committee. If possible, all members of the fellowship selection committee should interview candidates. Current Fellows should have the opportunity to meet with prospective candidates and answer their questions on all phases of the program.

Documentation of the selection process and the decision to select a candidate may consist of the minutes from the meeting of the Selection Committee. These written minutes should be retained for a period of seven years.

2.4.3. Benefits and Scheduled Time – *Essentials*

Fellows must have available the following benefits equivalent to those received by other postgraduate residents, Fellows, interns, and employees at the institution:

- The option to participate in health and hospitalization insurance programs

- Customary leave, vacation, and holidays
- Eligibility for sick leave, maternity leave, and childcare

The program must be educational, and the Fellows must use their scheduled time for educational experiences. The laboratory diagnostic work performed by the Fellows must be primarily for the purpose of developing competency rather than to provide routine diagnostic services.

2.4.3.1. Guidelines

Exceptions to this *Essential* may be necessary to provide emergency services for brief periods. The Fellows may assume other managerial, supervisory, and professional responsibilities as assignments to meet the training objectives of the program.

2.4.4. Health and Safety – *Essentials*

The program director must assure that the Fellows' health and safety is protected by appropriate immunization, protective clothing, chemical hygiene program, and safe working conditions. The health, safety, and infection prevention and control policies and procedures pertaining to institutional employees and department faculty must also apply to Fellows.

2.4.4.1. Guidelines

A baseline TB screening test is recommended. Additional serological screenings and immunizations following institutional policy should be encouraged.

2.4.5. Costs to Fellows – *Essentials*

Any costs to the Fellows must be reasonable and accurately stated and published upon acceptance of the Fellow to the program.

2.4.5.1. Guidelines

In most approved programs, the Fellows receive stipends and incur no cost for courses and other educational opportunities. Any expenses that the Fellow might incur with regard to travel and subsistence for any phase of the program or for attendance at meetings, transportation of family and personal effects, health and hospital insurance, should be explained to applicants.

2.4.6. Fellow Guidance – *Essentials*

Program directors (or associates) must be readily available to assist the Fellow in meeting the program's training objectives and addressing the Fellow's career goals.

2.4.6.1. Guidelines

Although the program director(s) may see the Fellows in these postgraduate programs almost on a daily basis, it is advisable to have regularly scheduled standing appointments to provide formal guidance. These meetings may be on a monthly basis or coincide with the completion of a rotation.

2.4.7. Appeal Mechanism – *Essentials*

In the event a Fellow has a grievance with the program, an appropriate appeal mechanism must be available and made known to the Fellow.

2.4.7.1. Guidelines

Every attempt should be made to resolve the Fellows' complaints and concerns within the department or within the institution. A more formal appeal mechanism is available through CPEP. Details of this process are described in the *Operational Procedures* of CPEP which may be obtained from a program director or the ASM website.

2.4.8. Withdrawal or Termination – *Essentials*

Policies and procedures for Fellow withdrawal or termination must be fair, published, and made known to all applicants. Written documentation of any disciplinary action must be included as part of the Fellow's record and included in the permanent record forwarded to CPEP.

2.4.8.1. Guidelines

Policies and procedures for withdrawal and termination should be consistent with those of the sponsoring institution.

2.5. Continuing Program Evaluation

2.5.1. Periodic Program Review – *Essentials*

Periodic and systematic review of the program's effectiveness must be performed and documented. A self-study (analysis, evaluation) conducted by the sponsoring institution must be undertaken for initial program accreditation or reaccreditation. Guidelines for Self-Evaluation are available from CPEP. This documentation must be maintained for seven years. The results of these reviews must be carefully considered and reflected in policies and procedures developed for the program.

2.5.1.1. Guidelines

Less formal program evaluation should be conducted on a continuing basis.

An evaluation of the program by all Fellows should be obtained within the first two years after completion of the program. The information obtained in these evaluations should be considered in the annual review by the advisory committee.

2.6. Maintaining Program Accreditation

2.6.1. Annual Report – *Essentials*

The annual report form provided by CPEP must be completed, signed by the program director, and returned by the established deadline.

2.6.2. Annual Meeting of Program Directors – *Essentials*

Each approved program must have a representative attend the annual meeting of program directors. The program director or designated representative must attend a majority of the meetings and must not be absent two consecutive years.

2.6.3. Replacement of Program Director or Deputy Director – *Essentials*

If the program director or deputy director of an accredited program leaves the sponsoring institution or a new program director or deputy director is appointed, CPEP must receive notification within one month.

2.6.4. Accreditation Withdrawal – *Essentials*

CPEP must consider withdrawal of accreditation whenever:

1. The educational program is not maintained in substantial compliance with the *Essentials* and the *Operational Procedures* of CPEP.
2. There are no Fellows in the program for two consecutive years.
3. The program director does not submit the annual report within three months of the deadline.

2.6.5 Notification of Withdrawal – *Essentials*

Accreditation will be withdrawn only after notice (with the reasons for withdrawal) has been given to the Chief Executive Officer of the sponsoring institution and after sufficient time has elapsed to permit a considered response. The CPEP *Operational Procedures* must be followed.

Program Directors are required to notify the Fellows of their withdrawal of CPEP accreditation. Fellows may contact CPEP to ascertain the status of their training to date.