

ILLINOIS DEPARTMENT OF CENTRAL MANAGEMENT SERVICES
CLASS SPECIFICATION

LABORATORY QUALITY SERIES

CLASS TITLE	POSITION CODE
LABORATORY QUALITY SPECIALIST I	23021
LABORATORY QUALITY SPECIALIST II	23022

Effective: 12-20-01

SERIES DISCUSSION:

The Laboratory Quality series encompasses professional positions that are not primarily engaged in conducting laboratory experiments, but are principally concerned with the quality of the public and private laboratories and blood banks and training clinical laboratory personnel. Quality control is an integral part of laboratory operations. As such, responsibility to maintain laboratory quality control within acceptable parameters resides with all levels of laboratory professional and nonprofessional staff. Although the manager of each laboratory administers the quality control program for that particular lab, positions in this series license and/or certify laboratories/personnel complying with rules, regulations and/or quality assurance procedures. Laboratory Quality position duties fall within one or more of the following categories: training, testing, and evaluation. The training aspect assures that personnel employed in laboratories are adequately schooled in the latest techniques by establishing workshops and classes to further the education of the personnel. In the testing portion, check samples are sent to laboratory personnel to test their ability to ascertain the identity, presence and/or quantity of micro-organisms or substances in the sample; results are checked against the returns as a whole, or the findings of an independent, out-of-state laboratory. Evaluation usually consists of a review of documentation on all facets of a laboratory's operations; licensure/certification is granted or withheld as a result of the evaluation.

The Laboratory Quality Specialist I and II evaluate public, private and state laboratories to determine adherence to state and federal rules and regulations and the agency's quality assurance policies; level distinction is based on the allocation factors of supervision received and decisions and commitments. The Laboratory Quality Specialist I reports noncompliance findings to higher level Laboratory Quality staff. In contrast, the Laboratory Quality Specialist II prepares a report detailing noncompliance and provides copies of the report to the evaluated laboratory and the appropriate regulatory agency for action. Positions having responsibilities of directing and/or supervising statewide laboratory testing, training, and/or evaluating agency laboratories and privately owned blood banks or administering a statewide training program for agency and/or private hospital laboratory personnel are allocated to the Senior Public Service Administrator class.

LABORATORY QUALITY SPECIALIST I
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POSITION CODE: 23021

DISTINGUISHING FEATURES OF WORK:

Under direct supervision, performs beginning level evaluations of laboratories and blood banks to ascertain compliance with state and federal laws or agency quality assurance procedures; assists higher level staff in conducting evaluations; reviews preliminary laboratory questionnaires; makes suggestions concerning compliance determinations.

ILLUSTRATIVE EXAMPLES OF WORK:

1. Evaluates preliminary questionnaires submitted by laboratories requesting agency certification; compares answers on questionnaire with rules established by the agency to determine if laboratory is in compliance; sends samples to laboratories in compliance; receives laboratories' test results of samples, compares same to parameters set by an independent laboratory and other laboratories' results; reports abnormal test results to a higher level specialist.
2. Assists higher level specialists on on-site laboratory inspections; reviews proficiency testing records, preventive maintenance documents and other paper work; reports discrepancies found to the higher level specialist.
3. Assists higher level specialists in searches of documents and records to provide background information on the laboratory prior to the on-site visit.
4. Performs other duties as required or assigned which are reasonably within the scope of the duties enumerated above.

DESIRABLE REQUIREMENTS:

Education and Experience

Requires a bachelor's degree in microbiology, chemistry, medical technology or a related field from a recognized college or university, supplemented by two years' professional laboratory or other related experience.

Knowledges, Skills and Abilities

Requires working knowledge of laboratory methods and procedures.

Requires working knowledge of the types of laboratory equipment essential to the operation of clinical laboratories, blood banks or environmental laboratories.

Requires ability to learn the procedures of inspecting and evaluating the operations, personnel and procedures of laboratories or blood banks.

Requires ability to attain effective working relationships with laboratory or blood bank directors.

Requires ability to exercise independent judgment in recommending action on license applications.

Requires ability to assist in the preparation of comprehensive laboratory inspection reports.

Requires ability to acquire knowledge through attendance at training workshops and seminars.

May require possession of an appropriate valid driver's license.

LABORATORY QUALITY SPECIALIST II

POSITION CODE: 23022

DISTINGUISHING FEATURES OF WORK:

Under general supervision, conducts evaluations of state agency, public and/or private laboratories or blood banks to determine compliance with state and federal laws or agency quality assurance procedures; performs proficiency testing; investigates complaints of violation of state and federal rules and regulations; determines if the noncompliance is minor and will be corrected prior to a reinspection visit or should be reported to the regulatory agency; prepares reports detailing a laboratory's noncompliance and issues copies to the laboratory and the appropriate regulatory agency.

ILLUSTRATIVE EXAMPLES OF WORK:

1. Conducts on-site surveys of independent clinical labs, hospital labs and blood banks to ensure compliance with Illinois and federal rules and regulations and to recommend certification and/or licensure; reviews/inspects personnel forms, procedures manuals, quality control records, proficiency testing records and preventive maintenance records to determine if the facility meets Illinois and federal regulations; interprets rules and regulations and provides technical information to the facility as needed; documents own activities by completing reports; performs follow-up visits to assure cited deficiencies have been corrected.
2. Conducts biennial on-site evaluations of the facilities, equipment, personnel and procedures used by laboratories certified to test milk or milk and water; uses federal evaluation forms, American Public Health Association publications and Illinois regulations to conduct the evaluations; performs supplemental surveys due to change of personnel, remodeling of facilities or when certification for new procedures is requested by a facility; travels to sites.
3. Conducts on-site visits to laboratories requesting approval to conduct Superfund testing and to laboratories requesting drinking water certification; evaluates laboratories in accordance with United States Environmental Protection Agency and Illinois Environmental Protection Agency rules and regulations; prepares survey reports; determines approval or denial of a laboratory's compliance with established criteria; issues certification to laboratories in compliance; prepares letters outlining the areas which are not in compliance with established regulations.
4. Prepares and distributes split milk samples to each certified milk laboratory for analysis and then receives, compiles and analyzes statistics of the laboratory's results; compares the laboratory's test results to the parameters set by the United States Food and Drug Administration to determine if the findings are within acceptable limits for compliance purposes.

LABORATORY QUALITY SPECIALIST II (Continued)

5. Inspects, evaluates and reports on laboratory operations concerning laboratory quality assurance policies, practices and procedures; formulates guidelines for ensuring compliance with quality assurance policies.
6. Prepares written evaluation of laboratories requesting certification; issues certification if the laboratory is in compliance with agency criteria.
7. Develops procedures for use in surveys, maintains up-to-date material and removes outdated material from procedures.
8. Performs other duties as required or assigned which are reasonably within the scope of the duties enumerated above.

DESIRABLE REQUIREMENTS:

Education and Experience

Requires a bachelor's degree in microbiology, chemistry, medical technology or a related field from a recognized college or university, supplemented by four years' professional laboratory or other related experience.

Knowledges, Skills and Abilities

Requires extensive knowledge of laboratory methods and procedures.

Requires extensive knowledge of the types of laboratory equipment essential to the operation of clinical laboratories, blood banks or environmental laboratories.

Requires extensive knowledge of methods used to inspect and evaluate the operations, personnel and procedures of laboratories or blood banks.

Requires ability to maintain effective working relationships with laboratory or blood bank directors, to obtain compliance with applicable laws.

Requires ability to exercise independent judgment in recommending action on license applications.

Requires ability to prepare comprehensive laboratory inspection reports.

Requires ability to plan and participate in training workshops and seminars.

May require possession of an appropriate valid driver's license.