


DRUG TESTING LABORATORY MANUAL	 HALCYON MARINE HEALTHCARE SYSTEMS	DOCUMENT NO. DTL 5.0	EFFECTIVITY DATE: May 4, 2018
		PREPARED BY: Marilar F. De Guzman, MD QAM	REVISION NO. 2 APPROVED BY: Glennnda E. Canlas, MD Medical Director
SUBJECT: POLICIES OF HIRING, ORIENTATION, PROMOTION, AND TERMINATION			

All manpower requisitions must be duly approved by the President / Medical Director before it can be processed by the Human Resources Management Department.

Candidates for any position within the drug testing unit should be selected solely based on satisfying the Company's hiring and job specifications.

Newly hired personnel should be oriented to the company and department policies, regulations, and routine protocols. All personnel within the drug testing section should be oriented the current version of the ISO standard.


The Human Resources Management Department and the Chief Medical Technologist with the overall recommendation of the Head of the Laboratory are the ones responsible for identifying employees within the drug testing section that has development and advancement potentials.

All personnel movement within the drug testing section (e.g. change of designation, regularization and promotions) should be properly documented and supported with performance appraisal and recommendation from the Chief Medical Technologist and Head of Laboratory, duly approved by the President prior to implementation by the HRMD.

All candidates to be hired must submit all prescribed pre-employment requirements before he/she can be issued an employment contract by HRMD.

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LABORATORY PERSONNEL QUALIFICATIONS:

1.1 HEAD OF THE LABORATORY

1.1.1 SCREENING LABORATORY:

- a) A licensed physician certified in Clinical Pathology by the Philippine Board of Pathology; or
- b) A licensed physician trained in laboratory management and drug testing operation

1.1.2 CONFIRMATORY LABORATORY:

- a) A licensed physician certified in Clinical Pathology by the Philippine Board of Pathology with at least two years of active laboratory experience in analytical toxicology, or
- b) A licensed chemist with Master's degree in Chemistry, Biochemistry or a branch of chemistry and at least two years of active laboratory experience in analytical chemistry.

Note: In cases where a drug testing laboratory is a division, section or unit of a Clinical Laboratory, it may be headed either by a licensed physician, chemist, medical technologist, pharmacist or chemical engineer.


1.2 ANALYST

The personnel must be a registered:

- a) Chemist
- b) Chemical Engineer
- c) Medical Technologist
- d) Pharmacist

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1.3 AUTHORIZED SPECIMEN COLLECTOR (ASC)

There shall be a designated authorized personnel within the laboratory to collect the specimen

- a) Must be at least high school graduate
- b) Must have undergone appropriate training

DUTIES AND RESPONSIBILITIES:

1.2 HEAD OF THE LABORATORY

ADMINISTRATIVE


- a) Has general and overall supervision of the facility and all aspects of laboratory work;
- b) Has general supervision and conduct of all laboratory personnel;
- c) Formulates and implements standard operation annual that govern the operation of the drug testing laboratory. This shall be periodically reviewed and updated;
- d) Prepares financial and annual reports of the laboratory;
- e) Provides other administrative support services such as communications, security and maintenance services.

TECHNICAL

- a) Supervises and directs all analytical procedures of the laboratory
- b) Assures quality of all laboratory test results;
- c) Issues, signs out and interprets laboratory results;
- d) Evaluates and recommends reagents, supplies and equipment;

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- e) Reviews the CCF and reports received from authorized collector;
- f) Interviews the Client/Donor/Subject, if necessary.
- g) Reviews pertinent medical records of Client/Donor/Subject, if necessary;
- h) Cancels the results of all specimen which are not collected or tested in accordance with the manual;
- i) Reviews, rejects and refers for confirmation and retesting all specimen and test results that are positive, adulterated, substituted or invalid;
- j) Implements remedial actions necessary to maintain satisfactory operation and performance in the laboratory;
- k) Directs protocol for preventive maintenance of equipment
- l) Provides comprehensive, continuing training and education of personnel related to conduct of drug testing laboratory.

1.2 ANALYST


- a) Verifies completeness of CCF;
- b) Prepares specimen for analysis;
- c) Examines, process and analyzes specimen for drug testing;
- d) Interprets, records, releases and signs out laboratory results;
- e) Assists in the implementation of quality assurance program;
- f) Assists in the evaluation of reagents, supplies and equipment;
- g) Refers to the Head of Laboratory as the need arises.

1.3 AUTHORIZED SPECIMEN COLLECTOR

1.3.1 The Authorized Specimen Collector must observe the following to ensure the security of a specimen at the collection site:

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- a) Restricts unauthorized personnel to enter the collection site during collection;
- b) Verifies identity of the Client/Donor/Subject;
- c) Provides security to specimen supplies, records and documents at collection site;
- d) Informs the Client/Donor/Subject the procedures of specimen collection;
- e) Performs only one specimen collection at a time;
- f) Accepts and seals the specimen container in the presence of the Client/Donor/Subject;
- g) Accomplishes CCF

1.3.2 The following are persons who are not authorized to collect the specimen:

- a) Employer of the Client/Donor/Subject
- b) Investigator at the crime scene
- c) Complainant
- d) Owner/Administrator of establishment

CONTINUING PROGRAM FOR STAFF DEVELOPMENT & TRAINING


TRAINING REQUIREMENTS

1.1 HEAD OF THE LABORATORY

He/she must have the following training in:

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- a) Theory and practice of the drug testing procedures used in the laboratory
- b) Chain of custody, reporting, and record keeping;
- c) Review and interpretation of test results;
- d) Quality assurance program
- e) Dangerous drugs regulations and policies.

1.2 ANALYST

Must have training in:

- a) Analytical methods and procedures;
- b) Maintenance of chain and custody;
- c) Reviewing and reporting test results;
- d) Proper remedial action in response to problems that may arise;
- e) Quality control procedures and practice;
- f) Dangerous drugs regulations and policies.

1.3 AUTHORIZED SPECIMEN COLLECTOR


1.3.1 An Authorized Specimen Collector must have undergone training on the following:

- a) Collection procedure for each type of specimen;
- b) Chain of custody and record keeping;
- c) Specimen integrity and security
- d) Dangerous drugs regulations and policies.

1.3.2 Retraining of Authorized Specimen Collector shall be required under the following conditions:

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- a) The collection procedure changes significantly (e.g., a new CCF is used); or
- b) The Authorized Specimen Collector made a mistake that caused a test to be cancelled.

1.4 EVALUATION AND PERSONNEL DEVELOPMENT

- a) The laboratory must establish criteria for evaluation of performance of all personnel.
- b) Training records must be maintained for all personnel. These should include all job related formal trainings taken by the personnel which pertains to any aspect of their responsibilities, including but not limited to analytical methodology, laboratory safety, sampling, quality assurance and data analysis
- c) The Head of the Laboratory must evaluate the performance of all personnel as the need arises.


POLICIES FOR VIOLATION, SUPERVISION & TERMINATION

TERMS AND CONDITION FOR SCREENING DRUG TESTING

1. The BHFS shall be notified in writing of any change in management, name or ownership. For transfer of location, a new application for accreditation shall be required.
2. A separate accreditation shall be required for every laboratory or branch maintained in separate premises but operated under same management.

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3. Failure to report in writing within fifteen (15) days of any substantial change in the condition of the laboratory may be a basis for the suspension and revocation of the accreditation.

POLICY FOR VIOLATION


1. Issuance of Fraudulent Drug Test Results
2. Failure to protect the confidentiality of drug test results.
3. Failure to participate or pass in Proficiency Testing.
4. Conviction of Laboratory Owner/Manager for any criminal offense committed as incident to the laboratory operation.
5. Failure to refer the positive screening test results to a Confirmatory Laboratory.
6. Any cause affecting the ability of the laboratory to ensure full reliability and accuracy of drug tests and results.
7. Refusal to allow survey and monitoring of laboratory by the BHFS/CHD at an appropriate time.
8. Any act contrary to accepted clinical laboratory practices.
9. Failure on the part of the laboratory to submit documentation of Quality Control Program (for screening laboratory) and certification of Quality Standards Systems from a DOH recognized certifying body (for confirmatory laboratory)

POLICY FOR SUSPENSION AND TERMINATION

1. The BHFS shall investigate and, after due hearing, may suspend or revoke the accreditation of a laboratory for such period and under such terms necessary to ensure full reliability and accuracy of drug tests and results.

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2. If upon survey or monitoring visit the drug testing laboratory is found to violating the rules and regulations as well as other violations stipulated in Sec. 6, the Bureau may immediately preventively suspend operation of said laboratory.

3. The BHFS shall investigate and, after due hearing, may suspend or revoke the accreditation of a laboratory for such period and under such terms necessary to ensure full reliability and accuracy of drug tests and results.

4. If upon survey or monitoring visits the drug testing laboratory is found to violating the rules and regulations, as well as other violations is stipulated in section 6, the bureau may immediately preventively suspend operation of said laboratory.

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