



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

201 W. Preston Street • Baltimore, Maryland 21201

Robert L. Ehrlich, Jr., Governor – Michael S. Steele, Lt. Governor – S. Anthony McCann, Secretary

Laboratories Administration
John M. DeBoy, Dr. P.H., Director

January 12, 2005

Dear Laboratory Employee,

Please read the attached "Non-Retaliation Policy for Reporting Problems of Quality, Safety and Security." As stated in the Policy, "the Laboratories Administration is committed to maintaining the highest level of professional and ethical standards in delivering quality services to the citizens of Maryland. To ensure that these standards are achieved and sustained, the Administration wishes to foster an environment in which all employees and other persons feel free to report quality, safety and security problems."

The Policy makes it mandatory for employees at all levels in the Administration to report problems of quality, safety and security. All employees are obliged to "familiarize themselves with, and adhere to all applicable federal and State laws and regulations that apply to quality, safety and security for public health laboratories."

The Policy also requires management to receive and respond to reports, and to protect employees who make appropriate reports in good faith.

Please read through the Policy carefully. We will provide mandatory training sessions on the Policy in the near future, at which time you will have an opportunity to ask questions and/or make comments.

Sincerely,

John M. DeBoy, Dr. P.H., Director



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DHMH Laboratories Administration – POLICY 05.01.01

Version Effective January 10, 2005

**NON-RETALIATION POLICY for
REPORTING PROBLEMS of QUALITY, SAFETY and SECURITY**

SHORT TITLE: NON-RETALIATION POLICY

I. INTRODUCTION

As described in this Non-Retaliation Policy, an employee who reports problems of quality, safety or security will be protected from any form of retaliation. Problems may include, but are not limited to, safety violations or potential hazards, CLIA, EPA or FDA compliance deviations or deficiencies, client complaints, and unsafe conditions.

II. PURPOSE

The Laboratories Administration (Administration) is committed to maintaining the highest level of professional and ethical standards in delivering quality services to the citizens of Maryland. To ensure that these standards are achieved and sustained, the Administration wishes to foster an environment in which all employees and other persons feel free to report quality, safety and security problems.

III. APPLICABILITY

This Policy makes quality, safety and security problem reporting mandatory for all Administration employees including staff, supervisors and management. It requires management to receive and respond to reports, and protects those who make appropriate reports in good faith. It requires all Administration employees to cooperate with problem investigation efforts.

IV. POLICY**A. GENERAL**

The Administration is committed to investigating all reported concerns promptly and, to the extent reasonable, confidentially. No one in the Administration will retaliate through any form of harassment, intimidation, denial of promotion or raises, loss of employment, denial of

continuing education opportunities, threats, coercion, discrimination, or any other form of retaliatory action against employees, or other persons for:

1. Exercising any right under, or participating in any process established by federal, State, or local law or regulations or Administration policies;
2. Identifying, reporting and/or documenting a quality, safety or security problem within the Administration;
3. Admitting mistakes and/or errors;
4. Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing; or
5. Opposing in good faith any act, practice, or procedure that is unlawful by federal, state, or local law or regulation or that is improper according to the Administration's policies or procedures.

B. SCOPE

The applicable laws and regulations covered by this Policy include those the Administration must adhere to in its function as a public health and medical laboratory. Examples include: Clinical Laboratory Improvement Amendments of 1988 (CLIA); Occupational Safety and Health Act; Health Insurance Portability and Accountability Act; Health-General Article, Title 17, Laboratories, Annotated Code of Maryland; Code of Maryland Regulations (COMAR) 10.10.01-.10 ; and the CLIA rules in the Code of Federal Regulations Title 42, Part 493.

This Policy supplements and does not replace the DHMH Corporate Compliance Program Code of Conduct, the State Personnel and Pensions Article or any of the Administration's policies and procedures.

C. EMPLOYEE RESPONSIBILITIES

All employees must help create a culture within the Administration that promotes the highest standards of compliance, and everyone in the Administration is encouraged to address problems when they arise. All Administration employees have an obligation to familiarize themselves with, and adhere to all applicable federal and State laws and regulations that apply to quality, safety and security for public health laboratories. Where any question or uncertainty regarding these standards exists, each affected employee is required to seek guidance from his or her supervisor, Division Chief, the Safety and Security Officer, the Quality Assurance Officer, a Deputy Director, or the Director.

All employees are obligated to identify, report and document quality, safety and security problems. It is the responsibility of all employees of the Administration to report an activity by an employee, contractor, or vendor that the employee has reason to believe violates applicable laws, rules, regulations, this Policy, the DHMH Corporate Compliance Program Code of Conduct, and/or the Administration's policies and procedures. This includes actual or potential problems. An employee may report problems to his or her supervisor, Regional Laboratory Chief or Director, Division Chief, the Safety and Security Officer, the Quality Assurance Officer, a Deputy Director, or the Director. Employees may also use the confidential reporting mechanism as set forth in the DHMH Corporate Compliance Plan.

Adherence to this Policy and participation in related activities and training will be an important factor in evaluating an employee's performance.

D. MANAGEMENT RESPONSIBILITIES

While all Administration employees are obligated to follow this Policy, management will provide access to the information, training and resources needed by employees to comply with applicable federal, State or local laws or regulations, and Administration policies and procedures. For the purposes of this Policy, management includes anyone with supervisory responsibilities or individuals designated by the Director including the Quality Assurance Officer, the Safety and Security Officer, the Regional Lab Chiefs and Directors, the Division Chiefs, and the Deputy Directors.

All management employees shall maintain an "open-door policy" to encourage employees, contractors, vendors, clients, and other persons to report quality, safety and security problems. A management employee who receives a problem report is obligated to investigate it personally or assign it to a designee and forward the report to the Quality Assurance Officer.

E. QUALITY ASSESSMENT: MONITORING AND DOCUMENTATION

Policy oversight is an important element in the evaluation of the Administration's management employees. All investigations will be documented and routinely reviewed as part of the Administration's Quality Assessment Program.

F. REPORTS MUST BE IN GOOD FAITH AND REASONABLE

This Policy applies to all quality, safety and security problem reports that are made in good faith and that are expressed in a manner that is reasonable and that does not violate the law. An employee who makes a quality, safety or security problem report that they know to be false or misleading will be subject to progressive discipline.

G. CORRECTIVE REMEDIAL ACTION

When an investigation identifies a deficiency or a violation from a reported problem, it is the policy of the Administration to initiate appropriate corrective remedial action and to implement system changes to prevent a similar problem from recurring in the future.

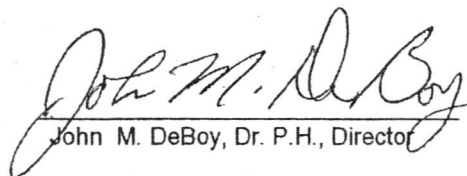
H. DISCIPLINARY ACTION

An Administration employee, including all levels of supervision and management, who violates this Policy will be subject to progressive discipline.

I. ACKNOWLEDGMENT PROCESS

Following training on this Policy or orientation as a new employee, Administration employees will be required to sign a "Policy Acknowledgement Statement" confirming: receipt of this Policy; understanding the obligations and principles of this Policy; recognizing the consequences of breaching this Policy; and agreeing to comply with this Policy as a condition of employment.

Approved:


John M. DeBoy, Dr. P.H., Director

1/5/05
DATE

**NON-RETALIATION POLICY for
REPORTING PROBLEMS of QUALITY, SAFETY and SECURITY**

POLICY ACKNOWLEDGMENT STATEMENT

I hereby acknowledge that I have received the DHMH Laboratories Administration Non-Retaliation Policy for Reporting Problems of Quality, Safety and Security, and I fully understand that I have an obligation to adhere to the principles of this Policy and recognize the consequences that may occur should I breach this Policy, and that I consent to comply with this Policy.

(This Acknowledgement Statement will be kept in the employee's Personnel File.)

EMPLOYEE SIGNATURE _____ DATE _____

PRINTED NAME (Last, First, Middle) _____

ORGANIZATIONAL UNIT _____