

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulations  
Department of Health and Mental Hygiene  
(DLS Control No. 15-037)**

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## **Overview and Legal and Fiscal Impact**

The regulations delete the requirement that a laboratory have a clear procedure describing the process (1) for documentation of unresolved discrepancies in the case record and any other laboratory document, as determined by the laboratory director and (2) for marking items stored in an evidence storage area, which are not evidence. The regulations delete unrelated language regarding workflow from provisions requiring a licensee to ensure that a laboratory has a procedure to uniquely identify evidence. The regulations revise language relating to quality assurance procedures. The regulations add a document control procedure to determine when a technical procedure has been discontinued or retired and clarify the requirements for maintaining a case file. In addition, the regulations add a requirement for technical reviews of case files and reports conducted as determined by the laboratory director or applicable standards.

The regulations present no legal issue of concern.

There is no fiscal impact on State or local agencies.

## **Regulations of COMAR Affected**

### **Department of Health and Mental Hygiene:**

Forensic Laboratories: Quality Assurance:  
COMAR 10.51.05.01, .02, .05, .07, .09, .10, .12, and .15  
Employees: COMAR 10.51.06.07, .14, and .17

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## **Legal Analysis**

### **Background**

According to the Department of Health and Mental Hygiene, the purpose of the regulations is to update and amend the language relating to forensic laboratory procedures to make the language more cohesive, comprehensive, and clear.

### **Summary of Regulations**

#### **Quality Assurance**

To obtain or maintain a permit to operate a forensic laboratory, COMAR 10.51.05.01 requires a person or licensee to ensure that the forensic laboratory establishes and follows procedures for a comprehensive quality assurance program, including a mechanism to address

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unresolved discrepant conclusions between an analyst and the technical reviewer. The regulations delete language that requires documentation of unresolved discrepancies in the case record and any other laboratory document, as determined by the laboratory director.

COMAR 10.51.05.02 require a licensee to develop, establish, maintain, implement, and follow quality assurance procedures that ensure the maintenance of the laboratory's quality system. The regulations delete unrelated language regarding workflow from provisions requiring a licensee to ensure that a laboratory has a procedure to uniquely identify evidence. COMAR 10.51.05.02 also requires a licensee to establish a procedure to define proper packaging and sealing of evidence. The regulations delete the requirement to clearly mark items stored in an evidence storage area, which are not evidence.

### **Control and Review of Documents**

The regulations add a document control procedure to determine when a technical procedure has been discontinued or retired and clarify the requirements for maintaining a case file. In addition, the regulations add a requirement for technical reviews of case files and reports conducted as determined by the laboratory director or applicable standards.

### **Legal Issue**

The regulations present no legal issue of concern.

### **Statutory Authority and Legislative Intent**

The department cites Title 17, Subtitle 2A of the Health – General Article as legal authority for the regulations. Title 17, Subtitle 2A of the Health – General Article governs the regulation of medical laboratories. Section 17-201 defines “medical laboratory” to mean “any facility, entity, or site that offers or performs tests or examinations in connection with the diagnosis and control of human diseases or the assessment of human health, nutritional, or medical conditions or in connection with job-related drug and alcohol testing.” The definition of medical laboratory “includes any laboratory owned or operated by the State or owned or operated by a county or municipal corporation in the State.” Title 17, Subtitle 2A establishes requirements for medical laboratory standards and inspections of laboratories, release of laboratory examination results, qualifications of personnel, issuance of licenses, discipline of license holders, and the establishment of a Laboratory Advisory Committee.

This authority is correct and complete. The regulations comply with the legislative intent of the law.

### **Fiscal Analysis**

There is no fiscal impact on State or local agencies.

### **Agency Estimate of Projected Fiscal Impact**

The department advises that the regulations clarify and simplify requirements related to quality assurance and employees for forensic laboratories, and bring regulations in line with

current practices. Thus, the regulations have no fiscal impact. The Department of Legislative Services concurs.

### **Impact on Budget**

There is no impact on the State operating or capital budget.

### **Agency Estimate of Projected Small Business Impact**

The department advises that the regulations have minimal or no fiscal impact on small businesses in the State. The Department of Legislative Services concurs.

### **Contact Information**

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