

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	03/24/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 5/1/2015

2. COMAR Codification

Title Subtitle Chapter Regulation

10 51 05 01, .02, .05, .07, .09, .10, .12 and .15

10 51 06 07, .14 and .17

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

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5. Name of Person to Call About this Document

Amanda Thomas

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6. Check applicable items:

New Regulations

Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: February 23, 2015.

Repeal of Existing Regulations

Recodification

Incorporation by Reference of Documents Requiring DSD Approval

Reproposal of Substantively Different Text:

: Md. R
(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

7. Is there emergency text which is identical to this proposal:

Yes No

8. Incorporation by Reference

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

10. Children's Environmental Health and Protection

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Paul Ballard, Assistant Attorney General, (telephone #410-767-6918) on March 3, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

March 24, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 51 FORENSIC LABORATORIES

10.51.05 Quality Assurance

Subtitle 51 FORENSIC LABORATORIES

10.51.06 Employees

Authority: See attached.

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend:

- 1) Regulations .01, .02, .05, .07, .09, 10, .12, and .15 under COMAR 10.51.05 Forensic Laboratories—Quality Assurance; and
- 2) Regulations .07, .14, and .17 under COMAR 10.51.06 Employees.

Statement of Purpose

The purpose of this action is to update forensic laboratory procedural regulations as follows:

- (1) Amend the language to be more cohesive, comprehensive and clear;
- (2) Remove the requirement for inclusion of unresolved discrepancies documented in the case record and any other laboratory document as determined by the director;
- (3) Remove the requirement to determine and identify workflow and assign and prioritize work from the policies and procedures;
- (4) Remove the requirement for marking items stored in an evidence storage area, which are not evidence;
- (5) Add a document control procedure to determine when the technical procedure has been discontinued or retired;
- (6) Clarify the requirements for maintaining a case file; and
- (7) Add a requirement for technical reviews of case files and reports conducted as determined by the Director or applicable standards.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to dhmh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through June 1, 2015. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2016

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

The proposed changes do not effect fees or have any financial implications. The changes are solely for the purpose of cohesion across the regulations.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

See E above.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 51 FORENSIC LABORATORIES

10.51.05 Quality Assurance

Authority: Health General Article, Title 17, Subtitle 2A, Annotated Code of Maryland

10.51.05.01 (2/23/15)

.01 Quality Assurance — General.

To obtain or maintain a permit to operate a forensic laboratory, a person or licensee shall ensure that the forensic laboratory:

A.—J. (text unchanged)

K. Establishes a mechanism to[: (1) Address] *address* unresolved discrepant conclusions between an analyst and the technical reviewer [; and

(2) Require that unresolved discrepancies are documented in:

(a) The case record; and

(b) Any other laboratory document as determined by the director].

10.51.05.02

.02 Quality Assurance — Specific.

A. *Policies and Procedure:*

(1) A licensee shall develop, establish, maintain, implement, and follow quality assurance policies and procedures that ensure that the laboratory's quality system is maintained.

[(1)] (2) A licensee shall ensure that the laboratory has a clear procedure describing the process to[:

(a)] uniquely identify evidence [;

(b) Determine and identify workflow; and

(c) Assign and prioritize work].

[(2)] (3) (text unchanged)

B. Identifying and Handling Evidence. A licensee shall:

(1)—(4) (text unchanged)

(5) Establish, maintain, and follow a procedure to define proper packaging and sealing of evidence requiring that:

(a) (text unchanged)

(b) Evidence is protected from:

(i)—(ii) (text unchanged)

(iii) Any harmful change; *and*

(6) Consider evidence containers properly sealed only if:

(a) The contents cannot readily escape; and

(b) Entering the container results in obvious damage or alteration to the container or the container's seal [; and

(7) Clearly mark an item that is not evidence but is stored in an evidence storage area].

C.—I. (text unchanged)

.05 Standard Operating Procedures Manual (SOPM).

A.—B. (text unchanged)

C. A licensee shall develop, establish, maintain, implement, and require that technical procedures meet the following:

(1)—(2) (text unchanged)

(3) [All discontinued technical procedures are signed by the laboratory director] *The laboratory has a document control procedure to determine when the technical procedure has been discontinued or retired.*

(4)—(10) (text unchanged)

D.—E. (text unchanged)

10.51.05.07

.07 Validation and Performance Checks.

A.—B. (text unchanged)

C. A licensee shall ensure that performance checks, if applicable, are performed:

(1)—(3) (text unchanged)

(4) As needed as determined by the [technical leader] *laboratory director or the laboratory director's designee*.

D.—E. (text unchanged)

10.51.05.09

.09 Test Reports — General.

A.—B. (text unchanged)

C. A licensee shall ensure that test reports:

(1)—(3) (text unchanged)

(4) Utilize a page numbering system that includes *either* the total number of pages *or a mark to signify the end of the document*.

D. A licensee shall ensure that amended reports:

(1) (text unchanged)

(2) Reference the [date of the] original report;

(3)—(4) (text unchanged)

E. (text unchanged)

10.51.05.10

.10 Employee Training and Competency.

A. (text unchanged)

B. A licensee shall ensure that available to all technical employees is a discipline-specific training program that includes:

(1)—(4) (text unchanged)

[(5) Expectations of job performance;]

[(6)] (5)—[(7)] (6) (text unchanged)

C. (text unchanged)

10.51.05.12

.12 Case Records.

A. (text unchanged)

B. In regard to examination documents, a licensee shall ensure that:

(1) (text unchanged)

(2) If examination documents consist of multiple pages, a page numbering system that includes *either* the total number of pages *or a mark signifying the end of the document* is used;

(3)—(10) (text unchanged)

10.51.05.15

.15 Facilities.

A. Facility Administration. A licensee shall ensure that a laboratory:

(1)—(2) (text unchanged)

[(3) Has a fire detection system; and]

[(4)] (3) (text unchanged)

B. (text unchanged)

C. Safety. A licensee shall:

(1)—(2) (text unchanged)

(3) Have *appropriate* safety [devices and equipment, e.g., goggles, gloves, face protectors, ear protectors, and fire extinguishers, available and in close proximity to the appropriate areas] *policies and procedures*;

(4) [Have a safety shower, eye washes, and exhaust hoods available in close proximity to the appropriate areas] *Demonstrate appropriate safety policies and procedures*;

(5) Have *appropriate safety devices and equipment* [and materials] available [for handling and storing hazardous and toxic substances and remediating spills of those substances] *and in close proximity to the appropriate areas*; and

[(6) Ensure first aid kits and employees trained in first aid are available;

(7) Ensure adequate space is provided for the safe storage of volatile, flammable, explosive, and otherwise hazardous materials; and]

[(8)] (6) (text unchanged)

10.51.06 Employees

Authority: Health General Article, Title 17, Subtitle 2A, Annotated Code of Maryland

10.51.06.07 (2/24/15)

.07 Director — Specific Duties and Responsibilities.

A forensic laboratory director shall:

A. (text unchanged)

B. Ensure that:

(1)—(10) (text unchanged)

(11) A case file is maintained for a minimum of 10 years after the case is [officially closed] *received*;

(12)—(22) (text unchanged)

C.— F. (text unchanged)

10.51.06.14

.14 Forensic Analysis Employees — Requirement.

A licensee shall ensure:

A. [that a] *The* forensic laboratory has [a sufficient number of individuals] *at least one individual* who [meet] *meets* the employee qualification requirements of this chapter, to perform the functions set forth in this chapter, for the [volume and] type of forensic tests and examinations performed in the laboratory; *and*

B. Technical reviews of case files and reports are conducted as determined by the Director or applicable standards.

10.51.06.17

.17 Forensic Analysis Employee Responsibilities — Specific.

Regardless of the forensic analysis category, an individual who performs a forensic analysis shall:

A.—D. (text unchanged)

E. Be capable of [identifying]:

(1) *Identifying* a problem that may adversely affect performance of a forensic analysis or reporting of a forensic analysis result[.]; and [either:

(1) Correct the problem; or

(2) Immediately notify the quality assurance manager and technical leader or the director that there is a problem.]

(2) *Following the laboratory policy and procedure for addressing nonconforming testing.*

VAN T. MITCHELL

Secretary of Health and Mental Hygiene