Virginia Regulatory Town Hall

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Fast Track Proposed Regulation
Agency Background Document

Agency name	Department of Forensic Science
Virginia Administrative Code (VAC) citation	6 VAC 40-30
Regulation title	Regulations for the Approval of Field Tests for Detection of Drugs
Action title	Amendments to Evaluation Process Verbiage and to Require Manufacturers to Pay Certain Costs
Date this document prepared	June 27, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

The proposed amendments accomplish three important goals. First, the amendments seek to change verbiage relating to the Department of Forensic Science's (DFS or the Department) assessment of field test kits pursuant to Virginia Code §19.2-188.1 from an "approval" process to an "evaluation" process in an effort to more accurately express the neutrality of the evaluation process. Second, the proposed amendments also clarify the procedure for resubmitting requests for evaluation after disapproval and, finally, require manufacturers submitting field test kits for evaluation to pay the actual costs of the "street drug preparations" used in the evaluation process.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

Enter definitions here

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The Department's Forensic Science Board voted to adopt these amendments to the Regulations for the Approval of Field Tests for Detection of Drugs on January 3, 2013 and May 15, 2013.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Virginia Code § 19.2-188.1 requires the Department to evaluate and, where applicable, approve field tests for the detection of drugs, pursuant to regulations adopted in accordance with the Administrative Process Act, for use by law enforcement officials. Law enforcement officers may then testify to the results of DFS approved field tests at certain preliminary hearings. The proposed amendments to the Regulations for the Approval of Field Tests for Detection of Drugs were adopted by the Department's Forensic Science Board pursuant to Virginia Code §§ 9.1-1101 and 9.1-1110(A)(1).

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The Regulations for the Approval of Field Tests for Detection of Drugs assist law enforcement and the criminal justice system by providing information critical to the probable cause determination necessary at the time of the arrest and subsequent preliminary hearing. This process positively impacts judicial economy and Constitutional due process. Ultimately, therefore, the ability of law enforcement and the courts to rely on the results of drug field tests protects the health, safety and welfare of the citizens of the Commonwealth.

The proposed amendments seek to change verbiage relating to the Department's assessment of field test kits pursuant to Virginia Code §19.2-188.1 from an "approval" process to an "evaluation" process. Because approval is not automatic, but rather depends on the kits performance during the evaluation process, these amendments achieve the goal of more accurately expressing the neutrality of the evaluation process.

The proposed amendments also clarify the procedure for resubmitting requests for evaluation after disapproval. If a field test kit is disapproved, there is typically an exchange of information between DFS and the manufacturer regarding why the kit was disapproved and any changes made to the kit upon resubmission. The proposed amendments formalize this process by requiring the kit manufacturer to explain changes or corrections made between DFS' evaluations.

Finally, the proposed amendments require manufacturers submitting field test kits for evaluation to pay the actual costs of the "street drug preparations" used in the evaluation process. The existing $50 fee was originally intended to cover the manpower costs associated with this testing and has not changed since the regulation's 2006 effective date. This fee does not address the cost of the "street drug preparations" used in the evaluation process. The "street drug preparations, or the known substances needed to actually test the efficacy of a particular field test, are also called "standards" in the scientific community. The standards for controlled drugs, particularly standards for newly emerging drugs such as research chemicals (e.g., bath salts), are difficult to obtain and more expensive than other scheduled substances such as heroin or cocaine. For example, the 10mg sample necessary for a single evaluation of a 25C-NBOMe field test costs the Department $ 448. In a recent request for evaluation, the fees to be paid by the kit manufacturer totaled $1000, but the actual cost to DFS for materials alone would be $1700. The Department's budget does not address these costs, nor does the Department have a control over the number and frequency of costly field tests submitted for evaluation. Currently, these rising costs are supported by Virginia tax dollars.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

Please note: If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The proposed amendments to 6 VAC 40-30, involving the change of "approval" language to more neutral "evaluation" terminology as well as a clarification regarding the resubmission process, are minor and do not change existing, substantive procedures. Additionally, the proposed amendment to 6 VAC 40-30-80 requires drug field test kit manufacturers to pay the actual cost of the "street drug preparations." Based on the current information regarding requests for evaluation, this cost would affect only eight out-of-state kit manufacturers. In September 2012, the Department conducted a periodic review of this regulation and received no public comment. Likewise, the Forensic Science Board discussed and voted to adopt these proposed amendments at its January and May 2013 public meetings and no member of the public offered a comment. Given these facts, as well as the clear cost savings to the Commonwealth, the Department does not expect these proposed amendments to be controversial.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

In addition to non-substantive verbiage changes regarding the "evaluation" process, the proposed amendments clarify the resubmission process by noting that resubmitted requests for approval "shall be accompanied by a detailed explanation of all modifications or changes to the test, the test instructions or the manufacturer's claims since the. . . most recent evaluation." This procedure merely formalizes the current practice in which the Department and field test manufacturer(s) discuss issues surrounding the resubmission of a previously disapproved field test.

The proposed amendments to 6 VAC 40-30-80 require the field test manufacturers to pay the actual cost of the "street drug preparations."

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

1. The proposed clarification of the existing regulations' language and resubmission procedure will inform and, therefore, benefit the public, stakeholders and kit manufacturers. The public generally benefits from the efficient and neutral field test evaluation process to the extent the proper use of DFS approved drug field tests assist law enforcement officials with probable cause determinations and facilitate the judicial process. The transfer of the actual cost of the street drug preparations used during the kit evaluation process from the Commonwealth to the manufacturers is a benefit to Virginians, but arguably a disadvantage to the eight out of state kit manufacturers, particularly any manufacturer seeking to transfer their kit quality control responsibilities to DFS because they will be required to pay the actual cost of repeated evaluations.
2. DFS currently bears the cost of the street drug preparations used in the field test kit evaluation process. By transferring this cost to the manufacturers, the Commonwealth will be relieved of a financial burden that is increasingly costly.
3. The Department believes the proposed changes benefit the Commonwealth and its citizens.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

The Department is unaware of any applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

The Department is unaware of any locality affected by the proposed amendments.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The Department is unaware of any alternative regulatory method that will accomplish the objectives of applicable law while also minimizing the adverse impact on small business.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	The Department is aware of eight field test kit manufacturers likely to be affected by this proposal as described above. These manufacturers are: **Armor Holdings, (dba: ODV Inc.),** 13386 International Parkway, Jacksonville, FL 32218, www.forensicssource.com **Sirchie Fingerprint Laboratories**, 100 Hunter Pl, Youngsville, NC 27596, www.sirchie.com **Mistral Security Inc.,** 7910 Woodmont Ave., Suite 820, Bethesda, MD 20814, http://mistralsecurityinc.com/ **Jant Pharmacal Corp.,** 16255 Ventura Blvd., Suite 505, Encino, CA 91436, www.accutest.net/ **Cozart PLC (dba: Concateno or Alere),** 92 Milton Park, Abingdon, Oxfordshire, England OX14 4RY,

	www.concateno.com **Lynn Peavey Co.,** 10749 W. 84th Terrace, Lexexa, KS 66214, www.lynnpeavey.com/ **MMC International BV**, Frankenthalerstraat 16-18, 4816 KA Breda, The Netherlands, www.narcotictests.com/ **RedXDefense**, 7642 Standish Pl., Rockville, MD 20855, www.redxdefense.com
Agency's best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than $6 million.	DFS estimates eight out of state field test kit manufacturers will be affected by the proposed amendments. These manufacturers are listed above. DFS has no information on the small business status of these manufacturers.
Benefits expected as a result of this regulatory proposal.	In addition to clarifying the process and emphasizing the neutrality of the process, the Commonwealth will realize saving by requiring the field test kit manufacturers to pay the actual cost of the "street drug preparations." A cost currently borne by the agency.
Projected cost to the state to implement and enforce this regulatory proposal.	None.
Projected cost to localities to implement and enforce this regulatory proposal.	None.
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	The field test kit manufacturers will pay the cost of the street drug preparations used to evaluate the kits. The cost of these standards varies and is based on the drug to be tested. Additionally, the cost to the manufacturer of a disapproved field test will be greater because additional street drug preparations will be required for resubmitted kits.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Department is unaware of any viable alternatives to the proposed amendments.

Periodic review and small business impact review report of findings

If this fast-track regulation is not the result of a periodic review and/or small business impact review report of the regulation, please delete this entire section.

If this fast-track regulation is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2)

indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

If this fast-track regulation is also a small business impact review report of the regulation, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation is required.

Commenter	Comment	Agency response

1. DFS did not receive any public comment during the periodic review of this regulation.
2. The regulation is both required by statute and necessary to protect the public's safety. It is clearly written and understandable.
3. After a periodic review process in 2012, which was noticed on both Virginia Regulatory Town Hall and with the Register of Regulations and included a public comment period that closed on September 4, 2012 with no public comment, DFS concluded there is a continued need for the regulation, there are no known complaints or comments relevant to the regulation, the regulation is not complex, and the regulation does not overlap, duplicate, or conflict with any other law or regulation. The proposed amendment to 6VAC40-30-80 reflects developments in the illegal drug consumption and trade since the regulation was last evaluated. Specifically, new drugs known as "research chemicals" are rapidly emerging. Known standards for these types of drugs are very expensive and difficult to obtain, and, as a result, the actual cost of field test evaluations have dramatically increased since the last evaluation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The proposed amendments have no impact on the institution of the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre**-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s) or regulations that are being repealed and replaced, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
6VAC40-30-10		The definition of "list of approved field tests" references Virginia Code §19.2-188.1A.	DFS seeks to strike the specific reference to subsection (A). This change will obviate any need to change the regulation if the General Assembly adds or deletes subsections to this Code provision.
6VAC40-30-20		The text again reference Virginia Code §19.2-188.1A	DFS seeks to strike the specific reference to subsection (A). This change will obviate any need to change the regulation if the General Assembly adds or deletes subsections to this Code provision.
6VAC40-30-30		This provision details the process of submitting field test kits for "approval."	DFS seeks to change the "approval" verbiage to "evaluation" verbiage as this wording better reflects the neutrality of the process. These changes are not substantive.
6VAC40-30-40		This provision details the Department's method for notifying manufacturers of approval or disapproval as well as the process for resubmitting disapproved kits for subsequent evaluations.	DFS seeks to change the "approval" verbiage to "evaluation" language as detailed above. In addition, DFS seeks to require the manufacturer(s) to explain all modifications or changes to the tests since the Department's initial disapproval. This amendment would formalize the existing practice.
6VAC40-30-60		This provision details the process of publishing a list of approved field test kits in the Virginia Register of Regulations.	DFS seeks to change the "approval" verbiage to "evaluation" verbiage. These changes promote the neutrality of the process, but do not reflect a substantive change.
6VAC40-30-70		This provision states the Department assumes no liability regarding the safety of the field tests or incorrect results or interpretations from	The Department seeks to strike "inherently tentative" because this phrase and "presumptive," when used together here, are repetitive.

		these “inherently tentative presumptive chemical tests.”	
6VAC40-30-80		This provision details the fee structure for the submission of field tests to the Department for the “approval” process.	The Department seeks to add a provision that field test manufacturers “shall pay the actual cost of the street drug preparations,” meaning the cost of the reference standard of the evaluation compounds through commercial means. This requirement will relieve DFS, and the taxpayers, from the burden associated with purchasing the standards needed for the evaluation process. Additionally, DFS seeks to change the “approval” verbiage to “evaluation” verbiage as detailed above.

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements

Enter any other statement here