

State Budget Office
Office of Regulatory Reinvention
111 S. Capitol Avenue; 8th Floor, Romney Building
Lansing, MI 48933
Phone: (517) 335-8658 FAX: (517) 335-9512

**REGULATORY IMPACT STATEMENT (RIS)
and COST-BENEFIT ANALYSIS**

PART 1: INTRODUCTION

Under the Administrative Procedures Act (APA), 1969 PA 306, the department/agency responsible for promulgating the administrative rules must complete and submit this form electronically to the Office of Regulatory Reinvention (ORR) no less than 28 days before the public hearing (MCL 24.245(3)-(4)). Submissions should be made by the department Regulatory Affairs Officer (RAO) to orr@michigan.gov. The ORR will review the form and send its response to the RAO (see last page). Upon approval by the ORR, the agency shall make copies available to the public at the public hearing (MCL 24.245(4)).

1. ORR-assigned rule set number:

R 325.2671 – R 325.2675

2. ORR rule set title:

Alcohol and Drug Testing of Biological and Nonbiological Specimens

3. Department:

Michigan Department of State Police

4. Division/agency/bureau:

Forensic Science Division Toxicology Unit

5. Name, title, and phone number of person completing this form:

Mr. Nicholas Fillinger, Toxicology Discipline Technical Leader, 517-819-4541

6. Reviewed by department Regulatory Affairs Officer:

Kristie H. Jordan

PART 2: APPLICABLE SECTIONS OF THE APA

MCL 24.207a “Small business” defined.

Sec. 7a.

“Small business” means a business concern incorporated or doing business in this state, including the affiliates of the business concern, which is independently owned and operated and which employs fewer than 250 full-time employees or which has gross annual sales of less than \$6,000,000.00.

MCL 24.240 Reducing disproportionate economic impact of rule on small business; applicability of section and MCL 24.245(3).

Sec. 40.

(1) When an agency proposes to adopt a rule that will apply to a small business and the rule will have a disproportionate impact on small businesses because of the size of those businesses, the agency shall consider exempting small businesses and, if not exempted, the agency proposing to adopt the rule shall reduce the economic impact of the rule on small businesses by doing all of the following when it is lawful and feasible in meeting the objectives of the act authorizing the promulgation of the rule:

- (a) Identify and estimate the number of small businesses affected by the proposed rule and its probable effect on small businesses.
- (b) Establish differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.
- (c) Consolidate, simplify, or eliminate the compliance and reporting requirements for small businesses under the rule and identify the skills necessary to comply with the reporting requirements.
- (d) Establish performance standards to replace design or operational standards required in the proposed rule.

(2) The factors described in subsection (1)(a) to (d) shall be specifically addressed in the small business impact statement required under section 45.

(3) In reducing the disproportionate economic impact on small business of a rule as provided in subsection (1), an agency shall use the following classifications of small business:

- (a) 0-9 full-time employees.
- (b) 10-49 full-time employees.
- (c) 50-249 full-time employees.

(4) For purposes of subsection (3), an agency may include a small business with a greater number of full-time employees in a classification that applies to a business with fewer full-time employees.

(5) This section and section 45(3) do not apply to a rule that is required by federal law and that an agency promulgates without imposing standards more stringent than those required by the federal law.

MCL 24.245 (3) Except for a rule promulgated under sections 33, 44, and 48, the agency shall prepare and include with the notice of transmittal a **regulatory impact statement** which shall contain specific information (information requested on the following pages).

[**Note:** Additional questions have been added to these statutorily-required questions to satisfy the **cost-benefit analysis** requirements of Executive Order 2011-5].

MCL 24.245b Information to be posted on office of regulatory reinvention website.

Sec. 45b. (1) The office of regulatory reinvention shall post the following on its website within 2 business days after transmittal pursuant to section 45:

- (a) The regulatory impact statement required under section 45(3).
- (b) Instructions on any existing administrative remedies or appeals available to the public.
- (c) Instructions regarding the method of complying with the rules, if available.
- (d) Any rules filed with the secretary of state and the effective date of those rules.

(2) The office of regulatory reinvention shall facilitate linking the information posted under subsection (1) to the department or agency website.

PART 3: DEPARTMENT/AGENCY RESPONSE

Please place your cursor in each box, and provide the required information, using complete sentences. Please do not answer the question with “N/A” or “none.”

Comparison of Rule(s) to Federal/State/Association Standards:

1. Compare the proposed rule(s) to parallel federal rules or standards set by a state or national licensing agency or accreditation association, if any exist. Are these rule(s) required by state law or federal mandate? If these rule(s) exceed a federal standard, please identify the federal standard or citation, describe why it is necessary that the proposed rule(s) exceed the federal standard or law, and specify the costs and benefits arising out of the deviation.

There are no parallel federal rules, or standards set by a state or national licensing agency or accreditation association that mandate the acceptable analytical methods for alcohol and drug testing of biological or nonbiological specimens.

2. Compare the proposed rule(s) to standards in similarly situated states, based on geographic location, topography, natural resources, commonalities, or economic similarities. If the rule(s) exceed standards in those states, please explain why and specify the costs and benefits arising out of the deviation.

Although similarly situated states conduct alcohol and drug testing of biological and nonbiological specimens, there are no comparable rules with which to compare standards.

3. Identify any laws, rules, and other legal requirements that may duplicate, overlap, or conflict with the proposed rule(s). Explain how the rule has been coordinated, to the extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter. This section should include a discussion of the efforts undertaken by the agency to avoid or minimize duplication.

There are no known laws, rules, or other legal requirements that may duplicate, overlap, or conflict with the proposed rules. Pursuant to MCL 259.190 and 257.625a(6)(g), the department has exclusive authority in the State of Michigan to promulgate rules for the chemical testing of biological and nonbiological specimens for alcohol and drugs for purposes of the Aeronautics Code of the State of Michigan, 1945 PA 327, and the Michigan Vehicle Code, 1949 PA 300.

Purpose and Objectives of the Rule(s):

4. Identify the behavior and frequency of behavior that the proposed rule(s) are designed to alter. Estimate the change in the frequency of the targeted behavior expected from the proposed rule(s). Describe the difference between current behavior/practice and desired behavior/practice. What is the desired outcome?

Annually, the Toxicology Unit analyzes approximately 6,000 biological and non-biological specimens for the presence of drugs. The proposed rule change would allow all specimens to be analyzed using the added analytical method. The difference between currently used analytical methods and the desired analytical method is that there is a significant per specimen cost-savings in consumables necessary to conduct the analysis and there is a reduction in processing time required per analysis. Additionally, there is increased specificity and

sensitivity of drug detection with the proposed analytical method. The desired outcome is a reduction in the cost of consumables and personnel time per analysis and improved drug detection.

5. Identify the harm resulting from the behavior that the proposed rule(s) are designed to alter and the likelihood that the harm will occur in the absence of the rule. What is the rationale for changing the rule(s) instead of leaving them as currently written?

Changes to the definition of “control sample” in R 325.2671 are intended to provide a more precise definition. As currently defined, the definition of “control sample” could be subject to legal challenge due to the narrowness of the definition.

Changes to R 325.2673 are intended to add an acceptable analytical method of testing for alcohol and drugs in biological and non-biological specimens. The harm is that an analytical method currently employed by the relevant scientific community is not currently authorized under the rules as an acceptable analytical method for use in the State of Michigan for purposes of the Aeronautics Code of the State of Michigan, 1945 PA 327, and the Michigan Vehicle Code, 1949 PA 300. Because this analytical method is not currently authorized, analyses must be conducted using other analytical methods that are more costly and require more time to conduct the analyses. The proposed analytical method provides significant cost and time reductions per analysis.

6. Describe how the proposed rule(s) protect the health, safety, and welfare of Michigan citizens while promoting a regulatory environment in Michigan that is the least burdensome alternative for those required to comply.

These proposed rules protect the health, safety, and welfare of Michigan citizens by ensuring that a generally accepted analytical method for alcohol and drug testing of biological and nonbiological specimens is able to be utilized. The new analytical method in the proposed rule change will allow the Toxicology Unit to improve turnaround time, detect drugs that are currently unable to be detected and test more matrices than are currently able to be tested. Each of those will allow the Toxicology Unit to better serve and protect the people of the State Of Michigan.

7. Describe any rules in the affected rule set that are obsolete or unnecessary and can be rescinded.

The analytical methods listed in R 325.2673 (a) (i) and (ii) are obsolete, and are proposed to be removed and replaced with the proposed analytical method.

Fiscal Impact on the Agency:

Fiscal impact is an increase or decrease in expenditures from the current level of expenditures, i.e. hiring additional staff, an increase in the cost of a contract, programming costs, changes in reimbursement rates, etc. over and above what is currently expended for that function. It would not include more intangible costs or benefits, such as opportunity costs, the value of time saved or lost, etc., unless those issues result in a measurable impact on expenditures.

8. Please provide the fiscal impact on the agency (an estimate of the cost of rule imposition or potential savings for the agency promulgating the rule).

It is estimated that the use of the new analytical method for alcohol and drug testing of biological and nonbiological specimens would save the department approximately \$300,000 annually.

9. Describe whether or not an agency appropriation has been made or a funding source provided for any expenditures associated with the proposed rule(s).

No new appropriations are necessary due to this change in the rules. State forfeiture and Michigan State Police general funds were utilized for the initial purchase of the required instrumentation. Michigan State Police general funds will be utilized for ongoing consumable and maintenance costs. The change will allow for better utilization of existing appropriations.

10. Describe how the proposed rule(s) is necessary and suitable to accomplish its purpose, in relationship to the burden(s) it places on individuals. Burdens may include fiscal or administrative burdens, or duplicative acts. Despite the identified burden(s), identify how the requirements in the rule(s) are still needed and reasonable compared to the burdens.

The proposed rules place no burden on individuals.

Impact on Other State or Local Governmental Units:

11. Estimate any increase or decrease in revenues to other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Estimate the cost increases or reductions for other state or local governmental units (i.e. cities, counties, school districts) as a result of the rule. Please include the cost of equipment, supplies, labor, and increased administrative costs in both the initial imposition of the rule and any ongoing monitoring.

There is no anticipated increase or decrease in revenue to state or local governmental units. There are only cost increases for other state or local government units that operate laboratories if they choose to adopt this analytical method. After the initial cost of instrumentation, cost reductions should be realized by other state or local government unit laboratories that adopt this analytical method due to reductions in required consumables.

12. Discuss any program, service, duty or responsibility imposed upon any city, county, town, village, or school district by the rule(s). Describe any actions that governmental units must take to be in compliance with the rule(s). This section should include items such as record keeping and reporting requirements or changing operational practices.

Laboratories operated by any city, county, town, village, or school district, if any, that perform alcohol and drug testing of biological and nonbiological specimens for purposes of the Aeronautics Code of the State of Michigan, 1945 PA 327, and the Michigan Vehicle Code, 1949 PA 300 must comply with the rules. Use of the specific proposed analytical method, however, is voluntary. In order to comply with the rules, a laboratory must use an acceptable analytical method, report the results of analyses as required, maintain in the laboratory a copy of written method or technique utilized by the laboratory, and perform and maintain records of required calibration of the methods or equipment used as required. Collecting and handling of antemortem blood and urine samples must be done in accordance with R 325.2675. No change to this rule is proposed.

13. Describe whether or not an appropriation to state or local governmental units has been made or a funding source provided for any additional expenditures associated with the proposed rule(s).

There is no appropriation to state or local governmental units. There are no anticipated additional expenditures associated with the proposed rules unless a local governmental unit laboratory wishes to add the proposed voluntary analytical method.

Rural Impact:

14. In general, what impact will the rules have on rural areas? Describe the types of public or private interests in rural areas that will be affected by the rule(s).

There is no anticipated impact on rural areas.

Environmental Impact:

15. Do the proposed rule(s) have any impact on the environment? If yes, please explain.

There is no anticipated impact on the environment.

Small Business Impact Statement:

[Please refer to the discussion of “small business” on page 2 of this form.]

16. Describe whether and how the agency considered exempting small businesses from the proposed rule(s).

MCL 259.190 and MCL 257.625a (6)(g) require that all tests be conducted in accordance with the rules. Therefore, exempting small businesses was not considered. Small businesses are required to meet the current rule set to ensure quality laboratory results.

17. If small businesses are not exempt, describe (a) the manner in which the agency reduced the economic impact of the proposed rule(s) on small businesses, including a detailed recitation of the efforts of the agency to comply with the mandate to reduce the disproportionate impact of the rule(s) upon small businesses as described below (in accordance with MCL 24.240(1)(a-d)), or (b) the reasons such a reduction was not lawful or feasible.

The proposed rule adds an analytical method to the approved analytical methods currently allowed. Utilizing the added analytical method is voluntary, thereby limiting the economic impact of the rule

A. Identify and estimate the number of small businesses affected by the proposed rule(s) and the probable effect on small business.

Alcohol and drug testing of biological and nonbiological specimens for purposes of the Aeronautics Code of the State of Michigan, 1945 PA 327, and the Michigan Vehicle Code, 1949 PA 300 is primarily conducted by Michigan State Police. A private laboratory could perform testing for a person who requests an independent test. There is no way to quantify how many times this occurs. However, those private laboratories likely already use the proposed analytical method in medical testing and would benefit from the addition of another accepted analytical method in the administrative rules. If it is not, the proposed rule change does not mandate that

the analytical method be used; it is an option in addition to the analytical methods already approved in the administrative rules.

B. Describe how the agency established differing compliance or reporting requirements or timetables for small businesses under the rule after projecting the required reporting, record-keeping, and other administrative costs.

The department did not establish differing compliance or reporting requirements or timetables for small businesses under the rules.

C. Describe how the agency consolidated or simplified the compliance and reporting requirements and identify the skills necessary to comply with the reporting requirements.

No entity has to report any compliance requirements to the department.

D. Describe how the agency established performance standards to replace design or operation standards required by the proposed rule(s).

Performance standards cannot replace design or operation standards required by the proposed rules due to the nature of the activity regulated by the proposed rules.

18. Identify any disproportionate impact the proposed rule(s) may have on small businesses because of their size or geographic location.

The department identified no disproportionate impact the proposed rule(s) would have on small businesses because of their size or geographic location.

19. Identify the nature of any report and the estimated cost of its preparation by small businesses required to comply with the proposed rule(s).

The only report requirement related to the proposed rules concerns the manner in which the results of the analyses are expressed and represent the industry standard for reporting of these type analyses. The proposed rule should not result in any additional cost to comply with the proposed rule.

20. Analyze the costs of compliance for all small businesses affected by the proposed rule(s), including costs of equipment, supplies, labor, and increased administrative costs.

If a private laboratory chooses to utilize this analytical method and is not already so equipped, initial purchase of the instrument would be somewhere in the range of \$225,000.00 to \$350,000.00, depending upon the particular specifications of the chosen instrument. The labor costs are unknown as wages are different in every laboratory. The department estimates that it will cost the MSP Toxicology Unit approximately \$5.00 per analysis for ongoing instrumentation costs and consumables.

21. Identify the nature and estimated cost of any legal, consulting, or accounting services that small businesses would incur in complying with the proposed rule(s).

The department identifies no legal, consulting, or accounting services that a laboratory would incur in complying with the proposed rules.

22. Estimate the ability of small businesses to absorb the costs without suffering economic harm and without adversely affecting competition in the marketplace.

Private laboratories likely already use the proposed analytical method in medical testing and would benefit from the addition of another accepted analytical method in the administrative rules. If it is not, the proposed rule change does not mandate that the analytical method be used; it is an option in addition to the analytical methods already approved in the administrative rules.

23. Estimate the cost, if any, to the agency of administering or enforcing a rule that exempts or sets lesser standards for compliance by small businesses.

Due to the nature of the activity regulated by the proposed rules, a rule cannot be adopted that exempts or sets lesser standards for compliance by small business.

24. Identify the impact on the public interest of exempting or setting lesser standards of compliance for small businesses.

Due to the nature of the activity regulated by the proposed rules, it would not impact the public interest of exempting or setting lesser standards of compliance for small businesses.

25. Describe whether and how the agency has involved small businesses in the development of the proposed rule(s). If small businesses were involved in the development of the rule(s), please identify the business(es).

Small businesses were not involved in the development of the proposed rules. The department intends to hold public hearings as necessary to implement the rules.

Cost-Benefit Analysis of Rules (independent of statutory impact):

26. Estimate the actual statewide compliance costs of the rule amendments on businesses or groups. Identify the businesses or groups who will be directly affected by, bear the cost of, or directly benefit from the proposed rule(s). What additional costs will be imposed on businesses and other groups as a result of these proposed rules (i.e. new equipment, supplies, labor, accounting, or recordkeeping)? Please identify the types and number of businesses and groups. Be sure to quantify how each entity will be affected.

There are no actual statewide compliance costs of the rule amendments on businesses or groups. No business or groups are required to change anything as a result of the rule amendments.

27. Estimate the actual statewide compliance costs of the proposed rule(s) on individuals (regulated individuals or the public). Please include the costs of education, training, application fees, examination fees, license fees, new equipment, supplies, labor, accounting, or recordkeeping. How many and what category of? What qualitative and quantitative impact does the proposed change in rule(s) have on these individuals?

There are no actual statewide compliance costs of the rule amendments on individuals or the public. No individuals will be affected by the rules

28. Quantify any cost reductions to businesses, individuals, groups of individuals, or governmental units as a result of the proposed rule(s).

The department expects to see cost reductions of approximately \$300,000 per year due to the decreased costs of consumables necessary to conduct the analyses and a reduction in time to

conduct each analysis. Any lab using this analytical method should see a decreased cost in consumables and time per analysis as well.

29. Estimate the primary and direct benefits and any secondary or indirect benefits of the proposed rule(s). Please provide both quantitative and qualitative information, as well as your assumptions.

Primary and direct benefits of the proposed rules are the reduction in costs of consumables necessary to utilize the analytical method and the reduction in time to conduct the analyses. In addition, the increased specificity and sensitivity of the analytical method will result in a more complete analysis of specimens. An indirect benefit of the proposed rule change is the flexibility of the Michigan State Police Toxicology Unit to test a new type of matrix, oral fluid. The number of oral fluid specimens not tested at this time is unknown, but it may represent a significant number of specimens that would be available for testing under the proposed rule set changes.

30. Explain how the proposed rule(s) will impact business growth and job creation (or elimination) in Michigan.

There are no known impacts on business growth or job creation in Michigan due to the proposed rule set changes.

31. Identify any individuals or businesses who will be disproportionately affected by the rules as a result of their industrial sector, segment of the public, business size, or geographic location.

There are no known individuals or business will be disproportionately affected by the proposed rule set changes.

32. Identify the sources the agency relied upon in compiling the regulatory impact statement, including the methodology utilized in determining the existence and extent of the impact of a proposed rule(s) and a cost-benefit analysis of the proposed rule(s). How were estimates made, and what were your assumptions? Include internal and external sources, published reports, information provided by associations or organizations, etc., which demonstrate a need for the proposed rule(s).

Information from SCIEX, a vendor manufacturing equipment that uses the methodology in the proposed rule change, was relied upon. The Ohio Department of Public Safety Toxicology Unit who is currently using the methodology supplied information that was relied upon.

Alternatives to Regulation:

33. Identify any reasonable alternatives to the proposed rule(s) that would achieve the same or similar goals. In enumerating your alternatives, please include any statutory amendments that may be necessary to achieve such alternatives.

There are no reasonable alternatives that would achieve the same or similar goals.

34. Discuss the feasibility of establishing a regulatory program similar to that proposed in the rule(s) that would operate through private market-based mechanisms. Please include a discussion of private market-based systems utilized by other states.

All states have government operated forensic toxicology services with the vast majority of toxicology services conducted for criminal prosecution being completed by a government

operated facility. Additionally, these rules are required by statute in Michigan. There are no private market-based systems utilized by other states.

35. Discuss all significant alternatives the agency considered during rule development and why they were not incorporated into the rule(s). This section should include ideas considered both during internal discussions and discussions with stakeholders, affected parties, or advisory groups.

The department did not consider significant alternatives during rule development.

Additional Information

36. As required by MCL 24.245b(1)(c), please describe any instructions regarding the method of complying with the rule(s), if applicable.

Michigan State Police form FSD-093 contains guidelines for sample collection on the reverse side of the form. A copy of that form is attached.

PART 4: REVIEW BY THE ORR

Date Regulatory Impact Statement (RIS) received:

4-20-2017

Date RIS approved:	4/26/2017
ORR assigned rule set number:	2017-004 SP

Date of disapproval:	Explain:
More information needed:	Explain:

**DEPARTMENT OF STATE POLICE
FORENSIC SCIENCE DIVISION**

**ALCOHOL AND DRUG TESTING OF BIOLOGICAL AND NONBIOLOGICAL SPECIMENS
Rule Set 2017-004 SP**

**NOTICE OF PUBLIC HEARING
Monday, August 21, 2017
7150 Harris Road, Dimondale, Michigan
10:00 AM**

The Department of State Police, Forensic Science Division, will hold a public hearing on Monday, August 21, 2017, at the Michigan State Police Headquarters, 7150 Harris Drive, Dimondale, Michigan, at 10:00 a.m. The hearing will be held to receive public comments on proposed changes to the Alcohol and Drug Testing of Biological and Nonbiological Specimens rules.

The proposed rule set (2017-004 SP) will amend the current rules to clarify the definition of “control sample,” to allow an additional analytical method of analysis and to delete an obsolete analytical method of analysis.

These rules are promulgated by authority conferred on the department of state police by section 190 of 1945 PA 327, MCL 259.190, section 625a of 1949 PA 300, MCL 257.625a. These rules will take effect immediately upon filing with the Secretary of State.

The rules (2017-004 SP) are published on the Office of Regulatory Reinvention’s website at http://w3.lara.state.mi.us/orr/Files/ORR/1680_2017-004SP_orr-draft.pdf and in the August 1, 2017 issue of the *Michigan Register*. Comments may be submitted by mail or email to the following address and must be received by 5:00 P.M. on Friday, August 18, 2017. Copies of the draft rules may also be obtained by mail or email at the following address:

Department of State Police
Nicholas Fillinger, Forensic Science Division
Lansing Forensic Laboratory
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E-mail: fillingern@michigan.gov

The hearing site is accessible, including handicap parking. People with disabilities requiring additional accommodations in order to participate in the hearing (such as information in alternative formats) should contact the Division at 517-819-4541 at least 14 days prior to the hearing date.