Regulatory Analysis

Notice of Intended Action to be published: 681—Chapter 5
"State Hygienic Laboratory"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 263.7 and 263.8
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 263

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 4, 2025	11260 Aurora Avenue
11 to 11:30 a.m.	Urbandale, Iowa

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Board of Regents no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Aimee Claeys
Board of Regents
11260 Aurora Avenue
Urbandale, Iowa 50322
Phone: 515.281.6456
Email: aimee.claeys@iowaregents.edu

Purpose and Summary

Iowa Code chapter 263 requires rules to be adopted for the State Hygienic Laboratory for examination and investigations and authorizes the laboratory to charge fees covering transportation of samples and the costs of examinations performed. These proposed rules describe the specimens examined, who can submit specimens for examination or investigation and when fees will be charged, waived or deferred. The Board proposes to rescind Chapter 5 and adopt a new chapter in lieu thereof. This new chapter will reflect current practices and eliminate outdated or unnecessary language.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

Fees for processing specimens may be assessed by the laboratory as provided by Iowa Code chapter 263.

- **Classes of persons that will benefit from the proposed rulemaking:**

Health care and related providers or agencies in the State of Iowa will benefit.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

It is difficult to determine the quantitative impact in the aggregate.

- **Qualitative description of impact:**

Fees for processing specimens and tests may be assessed.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

There are no additional or unique costs to the agency related to the implementation of this proposed chapter beyond those administrative expenses necessary to oversee and maintain the State Hygienic Laboratory.

- **Anticipated effect on State revenues:**

There is no fiscal impact.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

This proposed chapter is required by statute; no comparison is necessary.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

The Board has not identified any less costly or less intrusive methods.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable. This proposed chapter is required by statute.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

There is no expected impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 681—Chapter 5 and adopt the following **new** chapter in lieu thereof:

CHAPTER 5
STATE HYGIENIC LABORATORY

GENERAL REGULATIONS

681—5.1(263) Scope of services.

5.1(1) *Scientific.* The laboratory provides analytical and reference services, surveillance information, disaster and terrorism response, population data, microbiological, biological, and chemical examinations and other investigations in the areas of disease, newborn and maternal screening, fieldwork and the assessment of environmental quality.

5.1(2) *Consultative.* The professional staff of the laboratory provide regulatory review, consultative assistance, and data interpretation and evaluation of environmental effects and scientific needs to persons, agencies, and organizations with interest or involvement in public and environmental health.

5.1(3) *Education and training.* As part of the laboratory's academic mission, staff of the laboratory provide education and training for professional colleagues, educators, students, citizens, policymakers and anyone interested in public and environmental health through appropriate educational methods.

5.1(4) *Applied research.* The laboratory conducts scientific research designed to solve practical problems and to translate basic research to improve public and environmental health.

681—5.2(263) Specimens examined.

5.2(1) *Classification.* This being the state public health and environmental laboratory, specimens submitted to it should have a direct or probable significance that is actionable for public health, medical management, or the quality and preservation of the environment.

5.2(2) *Who may submit specimens.*

a. Licensed physicians, osteopathic physicians, and other licensed practitioners may submit specimens for the diagnosis and control of communicable or other diseases in which such tests are required by the state department of public health.

b. Veterinarians may submit animal specimens involving diseases of animals that are communicable to humans.

c. The department of health and human services may submit specimens as stated in Iowa Code section 263.8(2). Other programs, services, and studies may be negotiated on a contractual basis.

d. The natural resources department may submit specimens necessary in the conduct of its fundamental responsibilities relative to municipal water supplies. Other programs, services, and studies may be negotiated on a contractual basis.

e. Other state agencies, institutions, and municipalities may submit specimens, generally under a contractual arrangement if the submission is to be of a regular or routine nature.

f. Local departments of health may submit specimens when performing official functions of state regulatory agencies. The examination of other specimens necessary in the support of locally directed programs are provided only with prior clearance and cost negotiations.

g. Private individuals may submit specimens to address infectious disease or environmental concerns.

h. Privately owned industries and businesses may submit specimens for environmental studies by prior arrangement with the laboratory on a fee-based contractual basis.

i. Public schools may submit specimens at the discretion of the school nurse, consulting physician, principal, or upon recommendations of the local department of health.

j. Any agency, organization, business or individual impacted by a natural disaster may submit specimens that require testing to ensure health and safety.

k. First responders, hazmat teams, the Radiological Emergency Response Team, the 71st Civil Support Team, the FBI, the United States Postal Service and any other officially recognized law enforcement or terrorism response agency may submit samples for identification and confirmation of potential weapons of mass destruction (WMD) according to the Iowa Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) Response Protocol.

681—5.3(263) Charges.

5.3(1) Specimens for which the fee may be waived or deferred by the laboratory:

a. Specimens submitted relating to diseases communicable from human to human, from animals to human, provided such examinations are required by rules of the state department of public health.

b. Specimens submitted under statutory authority by state agencies or designees of state agencies that are involved in investigations or episodes challenging the health of the public or the

quality of the environment. Expenses caused by emergency testing may be eligible for subsequent reimbursement.

c. Any specimen when there is probable cause that a direct threat to public health exists. Such tests may qualify for subsequent reimbursement.

d. Specimens submitted related to the confirmation or identification of potential WMD according to the Iowa CBRNE Response Protocol.

5.3(2) Specimens for which fees are charged:

a. Specimens submitted under no statutory authority that are part of special investigations or surveillance programs and where there is no direct threat to the public health or environmental quality.

b. Specimens submitted for the submitter's private information.

c. Specimens submitted by private concerns and municipalities that are product quality control measures and, therefore, a cost of doing business.

d. Specimens not covered by statute, by rules of the department of health and human services, by rules of the department of natural resources or by this subrule may be examined and charged for at rates to be determined by the laboratory subject to any limitations imposed by law.

These rules are intended to implement Iowa Code chapter 263.