RULES AND REGULATIONS

Title 25—ENVIRONMENTAL PROTECTION

ENVIRONMENTAL QUALITY BOARD

[25 PA. CODE CH. 252]

Environmental Laboratory Accreditation

Order

The Environmental Quality Board (Board) amends 25 Pa. Code Chapter 252 (relating to environmental laboratory accreditation). The final-form rulemaking clarifies existing requirements, eliminates unnecessary requirements and proposes additional requirements necessary for laboratory accreditation. The final-form rulemaking also revises the fee structure found in 25 Pa. Code § 252.204 (relating to fees).

This proposal was adopted by the Board at its meeting of December 15, 2009.

A. *Effective Date*

These final-form rulemaking amendments will go into effect upon publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information, contact Aaren S. Alger, Chief, Laboratory Accreditation Program, P. O. Box 1467, Harrisburg, PA 17105-1467, (717) 346-8212; or Michelle Moses, Assistant Counsel, Bureau of Regulatory Counsel, P. O. Box 8464, Rachel Carson State Office Building, Harrisburg, PA 17105-8464, (717) 787-7060. Persons with a disability may use the Pennsylvania AT&T Relay Service by calling (800) 654-5984 (TDD users) or (800) 654-5988 (voice users). This proposal is available electronically through the Department of Environmental Protection's (Department) web site, http://www.dep.state.pa.us.

C. *Statutory Authority*

This final-form rulemaking is being made under the authority of 27 Pa.C.S. § 4103(a) (relating to establishment of program), which directs the Department to establish an accreditation program for environmental laboratories, 27 Pa.C.S. § 4104 (relating to powers and duties) which directs the Department to establish, administer and enforce an environmental laboratory accreditation program (Program) which includes the standards necessary for a state certification program, 27 Pa.C.S. § 4105 (relating to powers and duties of Environmental Quality Board), delegating the Board the power to adopt the regulations of the Department to implement 27 Pa.C.S. §§ 4101—4113 and section 1920-A of The Administrative Code of 1929 (71 P. S. § 510-20), authorizing and directing the Board to adopt regulations necessary for the proper performance of the work of the Department.

D. *Background and Purpose*

The regulations governing environmental laboratory accreditation in Chapter 252 became effective on January 28, 2006. While completing the first round of laboratory assessments under these regulations, the Program discovered various provisions that are unclear or where the rules are overly restrictive and cost prohibitive to the regulated community. The Program also determined that several necessary standards for accreditation were missing.

Under 27 Pa.C.S. § 4104(6), the accreditation fees must be "in an amount sufficient to pay the Department's cost of implementing and administering the accreditation program." In addition, § 252.204(b) requires the Department to recommend to the Board regulatory changes to the accreditation fees every 3 years to address any disparity between the Program income generated by the fees and Program costs. In accordance with this requirement, the Program performed a workload analysis to evaluate the costs associated with the Program. Based on this workload analysis, the Department determined that the accreditation fees in § 252.204 were not sufficient to recover the Department's costs to implement the Program. These final-form regulations provide a new fee structure to cover the costs of the Program.

The Department worked with the Laboratory Accreditation Advisory Committee (LAAC) to amend Chapter 252 in a manner that ensures appropriate requirements for environmental laboratory accreditation. The Department and the LAAC ensured that the interests, concerns and needs of the regulated community were considered and implemented as appropriate. The LAAC met throughout 2008 and 2009 to review and comment on the Chapter 252 amendments presented by the Department. On September 10, 2009, the LAAC unanimously voted to recommend the final-form Chapter 252 amendments for presentation to the Board.

E. *Summary of Changes Made in the Final-form Rulemaking*

Subchapter A. General Provisions

§ 252.1 (relating to definitions). At final rulemaking, the term and definition for "laboratory notebook" was reinstated throughout the chapter in response to a comment by the Independent Regulatory Review Commission (IRRC) concerning recordkeeping format. A definition for proficiency test reporting limit was also added at final rulemaking. This definition was necessary because the proposed NELAC Institute (TNI) standard does not mandate that proficiency testing samples be evaluated to this level. This term was used in § 252.501 (relating to proficiency test study requirements).

§ 252.5 (relating to NELAP/TNI equivalency). The requirement of NELAP or TNI laboratories to adhere to the provisions of Subchapter E (relating to proficiency test study requirements) was included at final rulemaking. Because TNI's proposed standard does not require NELAP laboratories to meet the Safe Drinking Water Act (SDWA) requirements, it was necessary for the Department to include this requirement at final rulemaking.

Subchapter B. Application, Fees and Supporting Documents

§ 252.205 (relating to out-of-State laboratories). At final rulemaking, all of the terms "accrediting authority" were changed to "accreditation body" to be consistent with the terms used by TNI. The requirement for secondarily accredited laboratories to submit copies of their proficiency testing studies was deleted.

Subchapter C. General Standards for Accreditation

§ 252.301 (relating to laboratory supervisor). Clarification was made at final rulemaking to subsection (g) to specify that a temporary absence of a laboratory supervisor requires notification to the Department within 30 calendar days.

§ 252.304 (relating to personnel requirements). Based on comments received the Department revised § 252.304 to included specific recordkeeping requirements that laboratories must meet to demonstrate that an analyst has demonstrated capability. Additionally, the requirement of a new member of a work cell to work with an experienced member of the work cell has been deleted from the proposed rulemaking.

§ 252.306 (relating to equipment, supplies and reference materials). Editorial changes were made to this section at final rulemaking, such as changing all of the terms "standardization" to "calibration." Subsection (h) was amended to specify that the laboratory may choose to use reagents, standards or reference materials past their expiration dates as long as they are reevaluated and validated by a procedure approved by the Department. The Department will evaluate each laboratory-developed procedure on a case-by-case basis and determine acceptability.

Subchapter D. Quality Assurance and Quality Control Requirements

§ 252.401 (relating to basic requirements). Subsections (j), (k) and (m) were amended at final rulemaking by making minor editorial revisions that provide greater clarity to the regulatory requirements.

§ 252.404 (relating to essential quality control requirement—microbiology). Minor editorial changes and amendments were made throughout this section at final rulemaking. These changes include reinstating the term "laboratory notebook" and clarification to subsection (g) by instructing the laboratory that a sterility blank must be filtered through each membrane filtration unit after every ten samples.

Subchapter E. Proficiency Test Study Requirements

§ 252.501 (relating to proficiency test study requirements). Subsections (n) and (o) were added at final rulemaking to specify that laboratories seeking to obtain or maintain accreditation in the drinking water matrix must also meet the proficiency testing requirements of the SDWA and 40 CFR Part 141 (relating to national primary drinking water regulations). Laboratories must also continue to report proficiency testing results to the proficiency test reporting limit (PTRL) established by the Department. These PTRLs will be published in the *Pennsylvania Bulletin*.

Subchapter G. Miscellaneous Provisions

§ 252.703 (relating to suspension). Clarification to subsection (c)(3) was made at final rulemaking to point the reader to the personnel requirements for a laboratory supervisor.

§ 252.704 (relating to voluntary relinquishment). Subsection (a) was amended at final rulemaking to specify that in addition to a laboratory wishing to voluntarily relinquish its accreditation in full, a laboratory wishing to voluntarily relinquish accreditation for a particular field of accreditation must notify the Department in writing. An editorial change was made to subsection (b) at final rulemaking to change the term "insure" to "ensure."

§ 252.705 (relating to use of accreditation). The requirement to post the fields of accreditation listing in the laboratory was removed at final rulemaking.

§ 252.706 (relating to recordkeeping). Subsection (b) was amended at final rulemaking to include proficiency test studies, initial demonstration of capability, and demonstration of continued proficiency to those records that must be maintained in a manner that allows reconstruction of all laboratory activities. These additions will aid the regulated community in understanding the Department's intent. These additions do not impose additional requirements, but more clearly instruct the reader.

§ 252.708 (relating to reporting and notification requirements). Editorial changes were made throughout this section at final rulemaking. These include changing the terms "inorganic and wet chemistry" to "trace metals and inorganic nonmetals" in subsection (a)(2), adding the term "radiochemistry" to subsection (a)(3), clarifying that the laboratory supervisor notification in subsection (b) relates to a permanent change, and changing the term "accrediting authority" to "accreditation body" in subsection (f).

F. *Summary of Comments and Responses on the Proposed Rulemaking*

The Board approved publication of the proposed rulemaking at its April 21, 2009, meeting. The proposed rulemaking was published at 39 Pa.B. 3051 (June 20, 2009), with a 30-day public comment period. Comments were received from two commentators, including IRRC, as a result of the public comment period. Several comments were received regarding the laboratory supervisor qualifications and recordkeeping requirements. Most of the comments received were requests for clarification.

A description of the comments received and the Department's response follows:

Laboratory Supervisor: One commentator stated that the current regulations should allow additional time to replace a laboratory supervisor. The revised regulations should extend the time to at least 90 days instead of the current 30 days to find a supervisor. Small wastewater treatment laboratories that do not have several chemists with bachelor's degrees on staff do not have the depth to name a person on staff as a supervisor with the resignation of a supervisor. As the current "grandfathered" supervisors retire or seek other positions, or both, it will be harder for the municipal sector to quickly hire qualified applicants.

The Department disagrees with the commentator's argument. The regulation requires designation of an alternate laboratory supervisor for temporary absences greater than 16 days but does not require that the Department be notified unless the temporary absence is greater than 30 days. An absence of a laboratory supervisor for greater than 16 days could adversely affect the quality of the data produced by the laboratory, especially in the case of a laboratory that operates 7 days a week. The Department believes that allowing a laboratory to continue to operate unsupervised for longer than 16 days would create a situation that could result in unacceptable data generation. In the case of permanent changes to a laboratory supervisor, the Department expects the laboratory to provide notification within 20 days of the change. The notification of a permanent change within 20 days allows the Department to be made aware earlier in the replacement process and available to offer guidance to the laboratory with regard to the laboratory supervisor qualification requirements.

One commentator requested that consideration should be made to allow supervisors to take a test in the laboratory methods to be certified as a supervisor. The Operator Certification Program does not have anything to do with the current job responsibilities of a laboratory supervisor. There needs to be a way to certify supervisors with a specific laboratory test to allow those with extensive experience to be qualified.

The Department agrees with the commentator. The Department is currently developing the laboratory supervisor subclassification under the Water and Wastewater Systems Operators' Certification Act (63 P. S. §§ 1001—1015.1). The provision in § 252.302(h)(2) and (3) (relating to qualifications of the laboratory supervisor) is included because the regulations authorizing the subclassification are also in the regulatory development process and are expected to be completed in the near future.

One commentator stated that the current regulations require extensive education for the laboratory supervisor or the operator's exam, stating that additional education has been added to § 252.302 to require that supervisors have 4-semester hours of general microbiology, and that now supervisors must have educational credits in microbiology as well as chemistry. Thus placing an additional burden on wastewater treatment plants that now have one person in charge of the laboratory.

The Department disagrees with the commentator. Section 252.302(d) does not include additional requirements. The Department made the educational requirements more lenient by changing the requirement for semester credit hours in "general microbiology" to "biology."

Record Retention and Documentation: One commentator stated that several sections of this chapter require record retention or recording of information, but are unclear in regard to a specific method of retention or recording and that the duration of the required retention is not set forth.

The Department agrees with the commentator. Section 252.706(d) requires that all records that are required by Chapter 252 regulations be maintained for a minimum of 5 years. The Department reinstated the definition for a "laboratory notebook" and included the phrase "in a laboratory notebook" where the proposed rulemaking deleted these phrases.

One commentator stated that § 252.304(b)(3)(vi)(F) requires labs to retain "all data necessary" to reproduce the initial demonstration of capability and suggested that the regulation include the specific recordkeeping requirements necessary to meet this requirement.

The Department agrees with the commentator. The Department added the specific documentation to be maintained by the laboratory to document initial demonstration of capability and demonstrations of continued proficiency. Section 252.706(b) requires each "environmental laboratory to maintain records that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples." The Department added "proficiency test study samples, initial demonstrations of capability and demonstrations of continued proficiency" to this section.

General Comments: One commentator stated that the quality control requirements in the regulations are extensive. The Department should consider additional training to allow the small water and wastewater treatment plants to continue to operate their laboratories. The requirements may be forcing plants to abandon their laboratories and contract work out at a high cost to the utility customers. There needs to be a balance on quality control. There should be consideration for more outreach to help the small laboratories.

The Department agrees with the commentator. The Department continues to develop and provide training courses to assist applicant laboratories in remaining compliant with the laboratory accreditation requirements. These courses are approved for continuing education credits for the Operators' Certification Program. Further opportunities for assistance are available through the Program's web site, direct contact with the laboratory's accreditation officer, and the onsite assessment process.

One of the commentators stated that § 252.304(b)(3)(vi)(E) allows laboratory methods used prior to January 1, 2005, to be exempt from the initial demonstration of capability and asked why this date was chosen.

The Department disagrees. This language is the same language from the January 28, 2006, version of Chapter 252; it has been relocated to this section to keep all demonstration of capability requirements located in the same section of the regulation. The January 1, 2005, date was chosen because it was 1 year before the environmental laboratory accreditation rulemaking was originally promulgated.

One of the commentators stated that under the provisions of § 252.304(b)(3)(vi)(G)(I), a new employee in a work cell must work with an experienced analyst, but does not include a specified time frame for how long this must occur.

The Department agrees with this commentator and deleted § 252.304(b)(3)(G)(I).

One of the commentators stated that § 252.304(b)(3)(vi)(G)(II) mentions "acceptable" quality control performance checks but does not instruct the regulated laboratory as to an acceptable procedure.

The Department disagrees with the commentator. The term "acceptable" refers to the requirements of the specific method, regulation, laboratory standard operating procedures, or client-specific requirement. The next sentence in this clause specifies that the quality control must meet acceptance criteria. "Acceptable quality control" is a term that is well understood by environmental laboratory personnel and must be defined in each laboratory standard operating procedure.

One of the commentators requested clarification for § 252.306(f)(9)(i), asking what is an "appropriate" method for checking delivery volumes of mechanical volumetric dispensing devices?

The Department agrees with the commentator and deleted the phrase, "using an appropriate method."

One commentator requested clarification regarding § 252.306(h)(6) and the term "Department approved procedure" used to reevaluate and validate certain materials used past their expiration date.

The wording was changed to clarify that it is not a procedure developed by the Department, but a laboratory-developed procedure that is approved by the Department. A laboratory would apply for permission by submitting a request in writing to the Department. The Department is not requiring a specific format at this time to allow laboratories the flexibility to use laboratory-developed procedures. The method for validation of an expired chemical would be dependent upon the chemical. The Department will notify the laboratory by mail of its decision.

G. *Benefits, Costs and Compliance*

Benefits

The most significant benefit of these final-form regulations will be the benefit of clear, concise and improved regulations for the regulated community. The final-form

amendments will allow for better understanding and increased compliance with the requirements and thus result in an improvement in the overall quality of the data produced by environmental laboratories.

Improved data quality will allow the Department, the regulated community, and the citizens of this Commonwealth to make better decisions concerning the protection of the environment and the protection of public health, safety and welfare. Accurate laboratory results are critical to achieving the goals of the environmental laws.

Compliance Costs

The direct costs of the final-form regulations will be payment of the required fees. The Department is required to set fees in an amount sufficient to cover the cost of establishing and maintaining a laboratory accreditation program. These costs will vary depending upon the type of testing and analyses that the environmental laboratory chooses to perform. Laboratories that require extensive staff time to accredit such as large commercial laboratories and NELAP laboratories will pay a higher accreditation fee. The final-form regulations contain a fee structure that is responsive to the needs of small laboratories. Categories of testing for basic drinking water parameters and for basic wastewater parameters have been increased by only $50 per category. These smallest environmental laboratories currently pay $1,200 annually and the final-form fee structure will require an annual fee of $1,250. In addition, changes to the fee structure include payment of fees based on the number of matrices requested rather than a fee for a specific type of matrix. This structure allows for a laboratory performing a combination of matrices to pay a lower fee.

Compliance Assistance Plan

The final-form amendments are minor and in most cases clarify existing requirements or eliminate unnecessary requirements. As such, the Department does not believe that a compliance assistance plan tailored to the final-form regulations is necessary. However, the Department will continue its ongoing compliance assistance efforts.

The ultimate goal of the compliance assistance effort will be improving an environmental laboratory's ability to produce valid and defensible data for use by the Department, the regulated community, and the public. Several areas where compliance assistance is necessary are general laboratory operation, correct performance of specific test procedures, and documentation of laboratory activities. Compliance assistance in these areas has been made available to all environmental laboratories regardless of size throughout this Commonwealth.

H. *Sunset Review*

These regulations will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulations effectively fulfill the goals for which they were intended.

I. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Department submitted a copy of the notice of proposed rulemaking, published at 39 Pa.B. 3051, to IRRC and to the House and Senate Environmental Resources and Energy Committees (Committees) for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing these final-form regulations, the Department has considered all comments from IRRC, the Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act, on February 24, 2010, these final-form regulations were deemed approved by the Committees. Under section 5.1(e) of the Regulatory Review Act, IRRC met on February 25, 2010, and approved the final-form regulations.

J. *Findings of the Board*

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968, (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and regulations promulgated there under at 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law, and all comments were considered.

(3) These regulations do not enlarge the purpose of the proposal published at 39 Pa.B. 3051.

(4) These regulations are necessary and appropriate for administration and enforcement of the authorizing acts identified in Section C of this order.

K. *Order of the Board*

The Board, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, 25 Pa. Code Chapter 252, are amended by amending §§ 252.4, 252.6, 252.202, 252.204, 252.307, 252.402, 252.403, 252.405, 252.601 and 252.707 to read as set forth at 39 Pa.B. 3051; and by amending §§ 252.1, 252.5, 252.205, 252.301, 252.302, 252.304, 252.306, 252.401, 252.404, 252.501, 252.703, 252.704, 252.706 and 252.708 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(b) The Chairperson of the Board shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for review and approval as to legality and form, as required by law.

(c) The Chairperson of the Board shall submit this order and Annex A to IRRC and the Committees as required by the Regulatory Review Act.

(d) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau, as required by law.

(e) This order shall take effect immediately.

JOHN HANGER,
Chairperson
Environmental Quality Board

(*Editor's Note*: The amendment of §§ 252.703 and 252.704 was not included in the proposal at 39 Pa.B. 3051.)

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 40 Pa.B. 1471 (March 13, 2010).)

Fiscal Note: Fiscal Note 7-434 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 25. ENVIRONMENTAL PROTECTION

PART I. DEPARTMENT OF ENVIRONMENTAL PROTECTION

Subpart D. ENVIRONMENTAL HEALTH AND SAFETY

ARTICLE VI. GENERAL HEALTH AND SAFETY

CHAPTER 252. ENVIRONMENTAL LABORATORY ACCREDITATION

Subchapter A. GENERAL PROVISIONS

§ 252.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

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Accreditation body—A territorial, State or Federal agency having responsibility and accountability for environmental laboratory accreditation and which grants accreditation.

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Action level—The concentration of a contaminant which, if exceeded, triggers a treatment or other requirement which a water system must follow.

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Laboratory notebook—A chronological record of observations, results of testing or analysis, equipment maintenance or calibration or other environmental laboratory data. A laboratory notebook may be maintained in an electronic format.

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NELAP accreditation body—An accreditation body that has been recognized as meeting the requirements of the NELAC Standard or the TNI Standard and has the authority to grant NELAP or TNI accreditation.

Nonpotable water—

(i) Any aqueous sample excluded from the definition of drinking water matrix.

(ii) The term includes wastewater, ambient water, surface water, groundwater, effluents, water treatment chemicals and leachates.

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Primary accreditation—Accreditation received from the Department that is not based upon accreditation from another accreditation body.

Proficiency test reporting limit—The value that corresponds to the lowest acceptable result that could be obtained from the lowest spike level for each analyte in a proficiency test sample.

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Secondary accreditation—Accreditation received from the Department based upon the accreditation status granted by another accreditation body.

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TNI—The NELAC Institute or its successor organization/Standard.

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§ 252.5. NELAP/TNI equivalency.

(a) An environmental laboratory may apply to the Department for NELAP accreditation for the fields of accreditation for which the Department offers accreditation.

(b) An environmental laboratory seeking NELAP accreditation shall:

(1) Submit a complete application as provided in Subchapter B (relating to application, fees and supporting documents).

(2) Comply with Subchapter E (relating to proficiency test study requirements).

(3) Comply with Subchapter F (relating to onsite assessment requirements).

(4) Comply with Subchapter G (relating to miscellaneous provisions).

(5) Comply with the current edition of the NELAC Standard or TNI Standard.

(c) An environmental laboratory receiving NELAP accreditation from the Department may apply for accreditation under the remainder of this chapter for the fields of accreditation that are not included in NELAP accreditation and for which the Department offers accreditation.

(d) An environmental laboratory receiving NELAP accreditation from the Department may only test or analyze environmental samples within the fields of accreditation authorized by the accreditation received from the Department.

Subchapter B. APPLICATION, FEES AND SUPPORTING DOCUMENTS

§ 252.205. Out-of-State laboratories.

(a) Out-of-State environmental laboratories may apply for primary accreditation or secondary accreditation from the Department.

(1) *Primary accreditation*. Out-of-State environmental laboratories may apply to the Department for primary accreditation under this chapter.

(2) *Secondary accreditation*.

(i) The Department will recognize accreditation granted by a primary NELAP/TNI accreditation body for the same fields of accreditation for which the Department is a primary NELAP/TNI accreditation body.

(ii) The Department may recognize the accreditation of an environmental laboratory by another state accreditation body if the standards for accreditation are substantially equivalent to those established under this chapter and the laboratory is physically located within the state granting accreditation.

(iii) An environmental laboratory seeking secondary accreditation from the Department shall:

(A) Submit a properly completed application on forms provided by the Department.

(B) Pay the appropriate fee.

(C) Submit a copy of a valid accreditation certificate from the primary accreditation body.

(D) Submit a copy of all onsite assessment reports conducted by the primary accreditation body within the last 3 years.

(E) Submit any other material relevant to accreditation, upon request of the Department.

(b) The Department may conduct an onsite assessment or require analysis of a proficiency test study by an out-of-State environmental laboratory seeking secondary accreditation for reasons which may include addressing complaints from the public or Department personnel, discrepancies with environmental sample results, onsite assessment deficiencies, frequent errors in reporting data to the Department and suspicions of fraud regarding data quality. If the Department determines that an onsite assessment is required, the environmental laboratory shall pay the Department's travel costs associated with the onsite assessment in accordance with § 252.206 (relating to out-of-State onsite reimbursement).

(c) If any portion of the out-of-State environmental laboratory's accreditation is denied, revoked or suspended by the primary accreditation body, the laboratory's authorization to perform testing or analysis is automatically revoked for the same fields of accreditation.

Subchapter C. GENERAL STANDARDS FOR ACCREDITATION

§ 252.301. Laboratory supervisor.

(a) The Department will consider the laboratory supervisor of an environmental laboratory as the individual listed on the laboratory's application for accreditation for which the Department has reviewed and approved the individual's qualifications.

(b) Testing, analysis and reporting of data by an environmental laboratory shall be under the direct supervision of a laboratory supervisor.

(c) The laboratory supervisor shall certify that each test or analysis is accurate and valid and the test or analysis was performed in accordance with all conditions of accreditation. A laboratory supervisor may certify a test or analysis by signing the final laboratory report. A laboratory may use other mechanisms to certify a test or analysis, provided the mechanism is documented in the laboratory quality manual.

(d) The laboratory supervisor shall ensure that the records required by this chapter are maintained.

(e) The Department may disqualify a laboratory supervisor who is responsible for the submission of inaccurate test or analysis results.

(f) The Department will disqualify a laboratory supervisor convicted of any crime or offense related to violations of State or Federal laws or regulations related to the provision of environmental laboratory services or reimbursement for the services.

(g) An environmental laboratory may appoint one or more laboratory supervisors for the appropriate fields of accreditation for which they are seeking accreditation.

(h) An environmental laboratory shall designate another staff member meeting the qualifications of a laboratory supervisor to temporarily perform this function when a laboratory supervisor is absent for a period of time exceeding 16 consecutive calendar days. If this temporary absence exceeds 30 consecutive calendar days, the environmental laboratory shall notify the Department in writing under § 252.708 (relating to reporting and notification requirements).

(i) An individual may not be the laboratory supervisor of more than one environmental laboratory without authorization from the Department. Circumstances to be considered in the decision to grant the authorization will include at least the following:

(1) The extent to which operating hours of the laboratories to be supervised overlap.

(2) The adequacy of supervision in each laboratory.

§ 252.302. Qualifications of the laboratory supervisor.

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(c) A laboratory supervisor of an environmental laboratory engaged in microbiological or biological analysis shall have the following qualifications:

(1) A bachelor's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) At least 16-college semester credit hours in general microbiology or biology.

(3) At least 2 years of experience in the testing or analysis of environmental samples in representative microbiological or biological fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation. A master's or doctoral degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering may be substituted for 1 year of experience.

(d) A laboratory supervisor of an environmental laboratory engaged in microbiological analysis limited to fecal coliform, total coliform and heterotrophic bacteria shall have the following qualifications:

(1) At least an associate's degree in chemistry, biochemistry, physics, environmental science, biology, microbiology, physical sciences or engineering.

(2) A minimum of 4-college semester credit hours in biology.

(3) At least 2 years of equivalent and successful college education, including a minimum of 4-college semester credit hours in biology may be substituted for the associate's degree.

(4) At least 2 years of experience in the testing or analysis of environmental samples in representative fields of accreditation for which the environmental laboratory seeks to obtain or to maintain accreditation.

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§ 252.304. Personnel requirements.

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(b) *Laboratory management responsibilities.* The environmental laboratory management shall be responsible for:

(1) Defining the minimal level of qualification, experience and skills necessary for all positions or work cells in the environmental laboratory.

(2) Ensuring and documenting that the environmental laboratory technical staff members or work cells have demonstrated capability in the activities for which they are responsible. This documentation must include:

(i) An identification of the analysts involved in the preparation or analysis, or both.

(ii) The sample matrix.

(iii) The analyte, class of analyte, or measured parameter.

(iv) An identification of the test method performed.

(v) An identification of the laboratory-specific standard operating procedure used for analysis, including revision number and effective date.

(vi) The dates of preparation or analysis, or both.

(vii) The summary of analyses, including results.

(3) Ensuring and documenting that the training and competency of each member of the environmental laboratory technical staff is kept up to date by maintaining records demonstrating the following:

(i) That each employee has read, understood and is using the latest version of the environmental laboratory's quality manual that relates to each employee's job responsibilities.

(ii) That each employee has read, understood and is using the latest versions of the environmental laboratory's standard operating procedures that relate to each employee's job responsibilities.

(iii) Participation in training courses or workshops on specific equipment, analytical techniques or laboratory procedures that relate to each employee's job responsibilities.

(iv) Participation in training courses in ethical and legal responsibilities including the potential liabilities for improper, unethical or illegal actions.

(v) That each employee has read, understood and acknowledged his personal ethical and legal responsibilities including the potential punishments and penalties for improper, unethical or illegal actions.

(vi) An initial demonstration of capability for each method that relates to the employee's job responsibilities has been performed. The initial demonstration of capability requirements are as follows:

(A) An initial demonstration of capability is required prior to the use of any method.

(B) An initial demonstration of capability shall be completed each time there is a change in instrument type, personnel or method.

(C) An initial demonstration of capability must include all sample preparation and analytical steps contained in the method.

(D) If the method or State or Federal regulations specify a procedure for the initial demonstration of capability, that procedure shall be followed; otherwise, an initial demonstration of capability shall be performed as follows:

(I) The analyte shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified in the method. If the method does not specify a concentration, the concentration must be approximately ten times the detection limit.

(II) At least four aliquots of the quality control sample shall be prepared and analyzed according to the method.

(III) Using all of the results, calculate the mean recovery and the standard deviation of the mean recovery for the population sample in the same units used to report environmental samples. When it is not possible to determine mean and standard deviation, such as for presence-absence and logarithmic values, the environmental laboratory shall assess method performance using criteria from the method or other established and documented criteria.

(IV) Compare the information from subclause (III) to the corresponding acceptance criteria for precision and accuracy in the method. To be considered acceptable, an initial demonstration of capability must meet all acceptance criteria.

(E) When a method has been in use by an environmental laboratory prior to January 1, 2005, and there have been no changes in instrument type, personnel or method, the environmental laboratory shall have records on file to demonstrate that an initial demonstration of capability is not required.

(F) The laboratory shall retain all data necessary to reproduce the initial demonstration of capability.

(G) The work cell as a unit shall meet the following requirements:

(I) When a member of a work cell changes, the new work cell shall demonstrate capability by means of acceptable quality control performance checks on four consecutive batches. The acceptable performance shall be documented. If any quality control performance check within the four consecutive batches following the change in personnel fails to meet acceptance criteria, an initial demonstration of capability shall be completed.

(II) If the entire work cell is changed, an initial demonstration of capability shall be completed.

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§ 252.306. Equipment, supplies and reference materials.

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(f) The following pieces of equipment shall be maintained according to this subsection.

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(2) *Working thermometers.*

(i) Working thermometers must have appropriate graduations and a range that spans the requirements of the method.

(ii) Working thermometers may be glass, dial or electronic and shall be calibrated against a certified NIST-reference thermometer as follows:

(A) Glass, liquid filled thermometers shall be calibrated every 12 months at the temperature used.

(B) Dial and electronic thermometers shall be calibrated every 3 months at the temperature used. Electronic thermometers accompanied by a valid NIST traceable certificate of acceptance may be used for 12 months from the date of receipt before re-calibration.

(C) An environmental laboratory shall maintain records in a laboratory notebook for each working thermometer that document the date of calibration, NIST reference thermometer identification, working thermometer identification, reference thermometer temperature reading, working thermometer temperature reading, correction factor and the initials of the individual conducting the calibration.

(D) Working thermometers shall be uniquely identified and labeled with the date of calibration and correction factor.

(iii) The fluid column in glass thermometers may not be separated.

(iv) A working thermometer that differs by more than 2.0°C from the reference thermometer may not be used.

(3) *ASTM class 1, 2 or 3 (Class S or S-1), or better certified reference weights.*

(i) The mass of ASTM class 1, 2 or 3 (Class S or S-1), or better certified reference weights shall be recertified at least once every 5 years.

(ii) An environmental laboratory shall retain a certificate documenting traceability of the calibration to ASTM standards.

(4) *Analytical or pan balances.*

(i) Analytical or pan balances must provide sufficient accuracy and sensitivity for the weighing needs of the method.

(ii) An environmental laboratory shall verify the calibration of a balance daily or before each use, whichever is less frequent.

(iii) A reference weight that is damaged or corroded may not be used for calibration of balances.

(iv) Balance calibration shall be verified using a minimum of three ASTM class 1, 2 or 3 (Class S or S-1) certified reference weights that bracket the effective range of the balance's use.

(v) An environmental laboratory shall maintain records in a laboratory notebook of balance calibrations that document the balance identification, date of calibration verification, reference weights used and initials of the individual performing the calibration.

(vi) A qualified person shall service and calibrate analytical balances at least once per year.

(vii) Records of annual service shall be maintained and the service date shall be recorded on the balance.

(5) *pH meter.*

(i) A pH meter must be equipped with an appropriate electrode and have scale graduators and accuracy appropriate to the method.

(ii) An environmental laboratory shall utilize either a thermometer or a temperature sensor for automatic compensation to make corrections for pH measurements.

(iii) The pH meter shall be calibrated daily or before each use, whichever is less frequent, by one of the following:

(A) With at least three standard buffers which are at least three pH units apart and which bracket the expected pH range of the samples.

(B) Use a pH 7.0 and either a pH 4.0 or 10.0 standard buffer; whichever range covers the desired pH range of use.

(iv) Aliquots of standard buffers may not be used for longer than 1 analysis day.

(v) Records of pH meter calibration shall be maintained in a laboratory notebook that document the date of calibration, calibration buffers used and initials of the individual conducting the calibration.

(6) *Conductivity meter.*

(i) A conductivity meter must have a probe of sufficient sensitivity for the method. The scale must have readability in appropriate units, for example micromhos or microsiemens per centimeter.

(ii) An in-line conductivity meter that cannot be calibrated may not be used.

(iii) An environmental laboratory shall calibrate the conductivity meter daily or before each use whichever is less frequent, by one of the following:

(A) With certified and traceable standard solutions within the range of interest.

(B) By determining the cell constant utilizing the method described in currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005.)

(iv) Records of conductivity meter calibrations shall be maintained in a laboratory notebook that documents the date of calibration, standards used, results of calibration or cell constant determined and the initials of the individual conducting the calibration.

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(8) *Incubators, water baths, heating blocks and ovens.*

(i) An environmental laboratory shall control and monitor the temperature of incubators, water baths, heating blocks and ovens in accordance with the method or as specified by regulations.

(ii) An environmental laboratory shall maintain a minimum of one thermometer per incubator, water bath, heating block or oven immersed in liquid or sand for ovens (except electronic thermometers) to the appropriate immersion line. When used as an incubation unit for microbiology, a minimum of one working thermometer shall be on the top and bottom shelf of the use area in each incubator.

(iii) When used as an incubation unit for microbiology, a water bath must be equipped with a gable cover and a pump or paddles to circulate the water.

(iv) Calibration-corrected temperatures for each incubator, water bath, heating block or oven shall be recorded once a day for each day in use for all laboratory activities. When used as an incubation unit for microbiology, the calibration-corrected temperature shall be recorded at least twice per day in use with the readings separated by at least 4 hours. The incubator, water bath, heating block or oven identification, date, time, calibration corrected temperature and the initials of the responsible individual shall be recorded.

(9) *Volumetric dispensing devices.*

(i) Except for Class A glassware, mechanical volumetric dispensing devices including burettes, autopipetors and dilutors, must be of sufficient sensitivity for the application. Delivery volumes of mechanical volumetric dispensing devices shall be checked at least once every 3 months.

(ii) Verification will be considered acceptable if the accuracy of the volumetric dispensing device is within 2.5% of expected values. Volumetric dispensing devices that do not meet this criterion may not be used.

(10) *Graduated sample containers.*

(i) Except for Class A glassware, when graduation marks on filter funnels, sample bottles or labware are used to measure sample volume, an environmental laboratory shall verify and document the accuracy of the volume of use for each lot or at least once per year, whichever is more frequent.

(ii) Verification will be considered acceptable if the accuracy of the graduated sample container is within 2.5% of expected values. Graduated sample containers that do not meet this criterion may not be used to measure sample volumes.

(g) An environmental laboratory shall maintain records for all reference materials, reagents and support services utilized by the laboratory for testing or analysis.

(h) Reference materials, reagents, media and laboratory supplies that are essential to obtain analytical results (such as filters, solid-phase extraction disks/cartridges, presterilized filtration units, certified precleaned laboratory supplies, disposable volumetric equipment, prepreserved sample containers) must meet the following minimum requirements:

(1) Analytical reagent grade chemicals or equivalent are acceptable, unless a method specifies other reagent purity grade requirements.

(2) Standard, reagent and laboratory supply receipt records shall be maintained. These records must include vendor, lot number, amount received, date of receipt, expiration date and certificates of analysis or purity, if available.

(3) Purchased chemicals, solutions, standards, media and laboratory supplies shall be labeled with date of receipt, expiration date and the date when the container is opened. Purchased chemicals, solutions and standards without an expiration date on the original container shall be discarded after 10 years from the date of receipt.

(4) An environmental laboratory shall maintain records of standard, reagent and media preparation. Standard and reagent preparation records must contain identification of the compound, manufacturer, lot number, concentration, amount prepared, date prepared, final pH if used for microbiology testing, initials of the individual preparing the solution and expiration date.

(5) Reagent and standard solution containers shall be labeled with identification of the compound, traceability to the preparation record, such as unique identifier, and expiration date.

(6) Standards, reagents and media may not be used past the date of expiration unless reevaluated and validated by a procedure approved by the Department prior to use.

(7) Reagent and standard solutions shall be checked regularly for signs of decomposition and evaporation. Reagent and standard solutions exhibiting signs of decomposition or evaporation shall be discarded.

(8) When reagents are removed from a container, the amount removed shall be used entirely or the unused portion discarded.

(9) Compressed gases must be of commercial grade, unless a method specifies other requirements.

(i) Plastic and glassware shall be cleaned to meet the sensitivity of the test method. Any cleaning and storage procedures that are not specified by the method shall be documented in a laboratory standard operating procedure.

Subchapter D. QUALITY ASSURANCE AND QUALITY CONTROL REQUIREMENTS

§ 252.401. Basic requirements.

(a) An environmental laboratory shall develop and maintain a quality manual appropriate to the type, range and volume of testing and analysis of environmental samples. The quality manual shall be available to and used by environmental laboratory personnel. The quality manual must contain the following:

(1) The full name and physical address of the laboratory.

(2) The name, address (if different from paragraph (1)), and telephone number of the laboratory supervisors.

(3) A revision number and effective date.

(4) A table of contents, and applicable lists of references, glossaries and appendices.

(b) The quality manual must state the environmental laboratory's policies, operational procedures, protocols and practices established to meet the requirements of this chapter. These policies and procedures must include:

(1) An ethics policy statement as specified in subsection (d).

(2) A document control system as specified in subsection (c).

(3) Recordkeeping as specified in § 252.706 (relating to recordkeeping).

(4) The procedures for termination of operations and transfer of records as specified in § 252.706.

(5) The procedures for detecting and permitting departures from established procedures as specified in subsections (i) and (h).

(6) The procedures for detecting and preventing improper practices as specified in § 252.304 (relating to personnel requirements).

(7) The sample handling and acceptance procedures as specified in subsections (f) and (g).

(8) The reporting of analytical results as specified in subsection (j).

(9) The monitoring of the quality of analysis as specified in subsection (l).

* * * * *

(d) An environmental laboratory shall develop and maintain an ethics policy statement relevant to the employee's duties and responsibilities under the act.

(1) The laboratory shall implement procedures for educating and training personnel in their ethical and legal responsibilities under the act.

(2) The laboratory shall provide training in ethical and legal responsibilities within 2 months of employment to the laboratory and at least every 14 months thereafter for all employees.

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(f) An environmental laboratory shall establish procedures for handling environmental samples.

(1) The environmental laboratory shall implement procedures for checking the thermal or chemical, or both, preservation and the sample container. The results of these checks shall be recorded.

(2) The laboratory shall utilize a recordkeeping system that meets the requirements of § 252.706 to document receipt of all sample containers. The recordkeeping system must include the following:

(i) The client/project name.

(ii) The date, time and location of sample collection, name of sample collector and field identification code.

(iii) The date and time of laboratory receipt.

(iv) Any comments resulting from inspection for sample rejection shall be linked to the laboratory ID code.

(v) A unique laboratory ID code that corresponds to the information required by this paragraph.

(vi) An identification of the person making the entries.

* * * * *

(j) An environmental laboratory shall develop procedures for reporting results of testing or analysis of environmental samples. Each test report must include at least the following information, except as specified in subsection (k).

(1) The name and address of the laboratory.

(2) The total number of pages in the report, including any addendums, in the format of Page x of y.

(3) The name and address of the client.

(4) An identification of the test method used.

(5) An identification of the samples including the client identification code.

(6) The date and time of sample collection.

(7) The date of sample analysis.

(8) The time of sample preparation or analysis, or both, if the holding time requirement for either activity is less than or equal to 72 hours.

(9) The test results and units of measurement.

(10) The quantitation limit.

(11) The names, functions and signatures of the persons authorizing the test report.

(12) An identification of results reported on a basis other than as received (for example, dry weight).

(13) An identification of testing or analysis results not covered by the laboratory's scope of accreditation.

(14) An identification of results that do not meet the requirements of this chapter.

(15) An identification of subcontracted results.

(k) Tests performed by an environmental laboratory operated by a facility that provides results to the facility management for compliance purposes do not need to be reported under subsection (j) regarding procedures for reporting results, provided the information required by subsection (j) is maintained under § 252.706.

(l) An environmental laboratory shall implement procedures or practices to monitor the quality of the laboratory's analytical activities. Examples of the procedures or practices are:

(1) Internal quality control procedures using statistical techniques.

(2) Participation in proficiency testing, other interlaboratory comparisons, or round robin testing.

(3) Analysis of split samples by different laboratories.

(4) Use of certified reference materials or in-house quality control using secondary reference materials, or both.

(5) Replicate testing using the same or different test methods.

(6) Retesting of retained samples.

(7) Correlation of results for different but related analysis of a sample (for example, total phosphorus should be greater than or equal to orthophosphate).

(m) To the extent possible, results of testing or analysis of environmental samples shall be reported only if all quality control, analytical testing and sample acceptance measures are acceptable. If a quality control, analytical testing or sample acceptance measure is found to be out of control and the results of the testing or analysis of environmental samples are to be reported, all environmental samples associated with the failed quality control measure shall be documented and the results flagged in an unambiguous manner on the sample analysis report with the appropriate data qualifiers.

(n) Policies, procedures, protocols and practices specified in this section must be in writing and be followed.

§ 252.404. Essential quality control requirement—microbiology.

* * * * *

(c) The following pieces of equipment shall be maintained according to this subsection:

(1) *Autoclave.*

(i) An environmental laboratory shall use autoclaves that meet specified temperature tolerances of the method. Because of safety concerns and difficulties with operational control, pressure cookers should not be used. Pressure cookers may not be used for sterilization of media.

(ii) A continuous temperature-recording device or a maximum-temperature-registering thermometer shall be used during each autoclave cycle.

(iii) An environmental laboratory shall verify the sterilization capability of each autoclave by utilizing appropriate biological indicators (for example, spore strips or ampoules) once a month. Records of biological indicator tests shall be maintained in a laboratory notebook and include the autoclave identification, date, incubation time and temperature, results and initials of the responsible individual.

(iv) An environmental laboratory shall verify the mechanical timing device, if used, for each autoclave every 3 months. Records of mechanical timer verification shall be maintained in a laboratory notebook and include the autoclave identification, date, mechanical timing device time, actual time and initials of the responsible individual. Correction factors shall be documented and used.

(v) Autoclaves shall be properly cleaned and maintained. Copies of service contracts or internal maintenance protocols and maintenance records shall be kept.

(vi) Required times for autoclaving items at 121°C are set forth in this subparagraph. The following items must be at temperature for the required amount of time. Except for membrane filters and pads and carbohydrate-containing media, indicated times are minimum times and may necessitate adjustment depending upon volumes, containers and loads. For autoclave runs that include membrane filters and pads and media, the total cycle time may not exceed 45 minutes. Autoclaved membrane filters and pads and media shall be removed immediately after completion of the autoclave cycle.

(vii) Records of each autoclave run shall be maintained in a laboratory notebook and include the date, contents, sterilization time and temperature, total cycle time (recorded as time in and time out) and initials of the responsible individual.

(viii) If an autoclave cycle fails to meet any requirement, corrective action shall be documented. Media may not be reautoclaved.

(2) *Hot air oven.*

(i) An environmental laboratory shall maintain a thermometer, graduated in 10°C increments or less with the bulb placed in sand, in each hot air oven.

(ii) An environmental laboratory shall verify the sterilization capability of each hot air oven by utilizing appropriate biological indicators (for example, spore strips) once a month. Records of biological indicator tests shall be maintained in a laboratory notebook and include the hot air oven identification, date, incubation time and temperature, results and initials of the responsible individual.

(iii) An environmental laboratory shall sterilize items in a hot air oven maintaining a temperature of 170°—180°C for a minimum of 2 hours. Only dry items may be sterilized in a hot air oven.

(iv) Records of each hot air oven operation shall be maintained and include the date, contents, sterilization time and temperature, and initials of the responsible individual.

(3) *Inoculating equipment.*

(i) An environmental laboratory shall use appropriate sterile inoculating equipment.

(ii) Metal loops and needles must be made of nickel alloy or platinum.

(iii) Wooden applicator sticks must be sterilized using dry heat.

(iv) For oxidase tests, nickel alloy loops may not be used.

(4) *Membrane filtration equipment.*

(i) Membrane filtration funnels must be stainless steel, glass, porcelain or autoclaveable or presterilized plastic. Membrane filtration funnels may not be scratched or corroded and may not leak.

(ii) Membrane filtration units shall be sterilized before the beginning of a filtration series. A filtration series ends when 30 minutes or longer elapses after a sample is filtered.

* * * * *

(v) An environmental laboratory using an ultraviolet sanitation lamp to sanitize filtration funnels between successive filtrations shall test the ultraviolet sanitation lamp every 3 months for effectiveness with an appropriate UV light meter or by plate count agar spread plates. Records of ultraviolet lamp tests shall be maintained and bulbs shall be replaced if output is less than 70% of original for light tests or if count reduction is less than 99% for a plate containing 200 to 300 organisms.

(5) *Culture dishes.*

(i) Culture dishes must be presterilized plastic or sterilizable glass and of appropriate size for the method.

(ii) Stainless steel canisters, aluminum canisters or a wrap of heavy aluminum foil or char-resistant paper, shall be used for autoclave sterilization of glass culture dishes.

(iii) Loose-lid culture dishes shall be incubated in a tight fitting container containing a moistened paper towel.

(iv) Opened packs of disposable culture dishes shall be resealed between use periods.

(6) *Culture tubes and closures.* Culture tubes and containers must be of sufficient size to contain medium and sample without being more than three quarters full. Tube closures must be stainless steel, aluminum, plastic or a screw cap with a nontoxic liner.

(7) *Pipettes.*

(i) Pipettes must have legible markings and may not be chipped or etched and must be accurate to within 2.5% tolerance.

(ii) Stainless steel canisters, aluminum canisters or a wrap of heavy aluminum foil or char-resistant paper shall be used for autoclave sterilization of pipettes.

(iii) Opened packs of disposable sterile pipettes shall be resealed between use periods.

(8) *Sample containers.*

(i) Sample containers must be sterile plastic bags or wide-mouth plastic or noncorrosive glass bottles with nonleaking ground glass stoppers or caps with nontoxic liners that can withstand repeated sterilization. Sample containers must be capable of holding sufficient volume of sample for all required tests while maintaining adequate air space for mixing.

(ii) Glass stoppers must be covered with aluminum foil or char-resistant paper for sterilization.

(iii) Glass and plastic bottles that have not been presterilized shall be sterilized by autoclaving. Glass bottles may be sterilized by dry heat. Empty containers shall be moistened with several drops of water prior to autoclaving.

(9) *Plastic and glassware washing procedure.*

(i) Prior to the initial use of a lot of detergent or washing procedure, an environmental laboratory shall perform an inhibitory residue test utilizing the method described in the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005). Records of inhibitory residue tests shall be maintained and include the detergent identification, date, calculations, results and initials of responsible individual.

(ii) Washed plastic and glassware shall be tested at least once each month for possible acid or alkaline residue by testing at least one piece of plastic and glassware with a suitable pH indicator such as 0.04% bromothymol blue. Records of pH tests shall be maintained.

(10) *Ultraviolet lamp.* An environmental laboratory shall use a 365-nm, 6-watt ultraviolet lamp in a darkened room to view sample fluorescence.

(11) *Quanti-Tray™ Sealer.*

(i) An environmental laboratory shall perform a sealer check on each Quanti-Tray Sealer once a month by adding a dye to a water sample and performing the sealing procedure.

(ii) Records of the sealer check shall be maintained and include the sealer identification, date, results and initials of responsible individual. If dye is observed outside the wells, the Quanti-Tray Sealer may not be used.

(d) The requirements for reagent water are as follows:

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(4) The metals analyses may only be performed by an environmental laboratory accredited under this chapter for those fields of accreditation.

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(6) The bacteriological water quality test need not be performed if the environmental laboratory can supply documentation to show that their laboratory pure water

or reagent water meets the criteria, as specified in section 1080 of the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005), for Type I (high-quality) or Type II (medium-quality) reagent water.

(e) The requirements for dilution/rinse water are as follows:

(1) Stock buffer solution or peptone water shall be prepared as specified in the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005).

(2) Stock buffers shall be autoclaved or filter-sterilized. Stock buffers shall be refrigerated and must be free from turbidity.

(3) Dilution/rinse water solutions shall be prepared as specified in the currently approved editions of *Standard Methods for the Examination of Water and Wastewater* (available from American Public Health Association, 1015 Fifteenth Street NW, Washington, D.C. 20005).

(f) The requirements for media are as follows:

(1) An environmental laboratory shall use dehydrated or commercially manufactured prepared media. Dehydrated media shall be stored in a cool, dry location. Caked or discolored dehydrated media shall be discarded.

(2) An environmental laboratory that prepares media from dehydrated stock shall follow method specifications.

(3) Media may not be reautoclaved.

(4) After preparation, media shall be stored and maintained as follows:

(i) Stored away from sources of direct light.

(ii) Prepared plates shall be stored in sealed plastic bags or containers.

(iii) Each bag, container or rack of broth or agar media shall be labeled with the date prepared or expiration date.

(iv) Fermentation media stored in a refrigerator shall be incubated overnight at room temperature before use. Media that shows growth or bubbles may not be used.

(v) Prepared liquid media shall be discarded if evaporation exceeds 10% of the original volume.

(vi) Poured agar plates and broth in tubes, bottles or flasks with loose-fitting closures shall be discarded if not used within 2 weeks of sterilization unless otherwise specified by the method.

(vii) Broth in tightly closed screw-cap tubes, bottles or flasks shall be discarded if not used within 3 months of sterilization unless otherwise specified by the method.

(g) An environmental laboratory shall demonstrate that the filtration equipment and filters, sample containers, media and reagents have not been contaminated through improper handling or preparation, inadequate sterilization or environmental exposure as follows:

(1) A sterility blank shall be analyzed for each lot of preprepared, ready-to-use medium and for each batch of medium prepared in the laboratory prior to first use of the medium. Records shall be maintained and include media identification, date, results and initials of responsible individual. If sterility blank indicates contamination, the media may not be used.

(2) For each reusable membrane filtration unit used during a filtration series, the laboratory shall prepare at least one sterility blank at the beginning and at the end of the series. A series is considered ended when more than 30 minutes elapses between filtrations. The laboratory shall insert a sterility blank after every 10 samples filtered through each membrane filration unit or sanitize filtration units by UV light after each sample filtration in addition to the regular rinsing procedure. Records of sterility blank results must be maintained. If sterility blanks indicate contamination, the laboratory must treat each affected sample according to program requirements.

(3) For presterilized single use filtration funnel units, a sterility check shall be performed on one funnel unit per lot.

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(h) The requirements for positive and negative culture control checks are as follows:

(1) Each preprepared, ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested by the laboratory with at least one pure culture of a known positive reaction prior to first use of the medium. Records shall be maintained and include the date, media lot or batch number, type of media, positive culture control organism identification, results and initials of responsible individual. If positive culture control checks do not meet expected results, the affected media may not be used.

(2) Each preprepared, ready-to-use lot of selective medium and each batch of selective medium prepared in the laboratory shall be tested by the laboratory with at least one pure culture of a known negative reaction prior to first use of the medium. Records shall be maintained and include the date, media lot or batch number, type of media, negative culture control organism identification, results and initials of the responsible individual. If negative culture control checks do not meet expected results, the affected media may not be used.

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(5) Culture controls may be single use or cultures maintained by the laboratory using a documented procedure that maintains the purity and viability of the organisms.

(6) For cultures maintained by the laboratory, the following criteria must be met:

(i) Reference control cultures may be revived and subcultured once to provide reference stocks.

(ii) Reference stocks shall be preserved using a method which maintains the characteristics of the organism strains. If reference stocks are thawed, they may not be refrozen and reused.

(iii) Working stocks shall be prepared from reference stocks for routine laboratory work.

(iv) If the laboratory sequentially cultures working stocks, the laboratory shall prepare a second working stock. Sequential culturing may not be performed from a working stock that has been used for routine laboratory work

(v) Working stocks may not be used for more than 30 days.

(vi) Working stocks may not be sequentially cultured more than five times and may not be subcultured to replace reference stocks.

(vii) Secondary working stocks shall be used to prepare sequential working stocks.

(i) For test methods that specify colony counts, duplicate counts shall be performed monthly on one positive sample for each month that the test is performed. If the laboratory has two or more analysts, each analyst shall count typical colonies on the same plate. Counts may not differ by more than 10%. In an environmental laboratory with only one analyst, the analyst shall count the same plate twice. Counts may not differ by more than 5%.

(j) Records of all equipment, reference materials, reagents, media and supplies shall be maintained in accordance with § 252.306 (relating to equipment, supplies and reference materials).

Subchapter E. PROFICIENCY TEST STUDY REQUIREMENTS

§ 252.501. Proficiency test study requirements.

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(l) An environmental laboratory shall direct the proficiency test study provider to report the proficiency test study performance results directly to the Department's Laboratory Accreditation Program at the same time that the provider reports the results to the environmental laboratory.

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(n) An environmental laboratory seeking to obtain or maintain accreditation in the drinking water matrix shall participate in proficiency test studies that meet the requirements of 40 CFR Part 141 (relating to national primary drinking water regulations).

(o) An environmental laboratory shall evaluate and report the analytical result of each proficiency test study sample to the proficiency test reporting limit for each field of accreditation, when available, as outlined in subsection (a).

Subchapter G. MISCELLANEOUS PROVISIONS

§ 252.703. Suspension

(a) Denial of access to the Department during normal business hours will result in immediate suspension of accreditation for all fields of accreditation. Upon notice from the Department, the laboratory shall immediately cease testing or analysis of environmental samples.

(b) The Department will suspend an environmental laboratory's accreditation in total or in part for one or more of the following reasons:

(1) The Department finds that protection of the environment or the public health, safety or welfare requires emergency action.

(2) The environmental laboratory fails to successfully complete a proficiency test study within the previous 12 months.

(3) The environmental laboratory fails two consecutive proficiency test studies for a field of accreditation.

(c) The Department may suspend a laboratory's accreditation in total or in part for one or more of the following reasons:

(1) Failure to comply with the reporting and notification requirements as specified in § 252.708 (relating to reporting and notification requirements).

(2) Failure to implement a quality assurance program.

(3) Failure to employ staff that meets the personnel qualifications for education, training and experience as specified in § 252.302 (relating to qualifications of the laboratory supervisor).

(d) A laboratory may continue to test or analyze environmental samples for those fields of accreditation not affected by the suspension.

(e) Within 72 hours of receiving notice of the suspension of accreditation from the Department, the environmental laboratory shall notify each of its customers affected by the suspension in writing of the suspension on a form approved by the Department.

§ 252.704. Voluntary Relinquishment.

(a) An environmental laboratory wishing to voluntarily relinquish its certificate of accreditation or accreditation for fields of accreditation shall notify the Department in writing.

(b) An environmental laboratory that voluntarily relinquishes its certificate of accreditation shall ensure records are maintained in accordance with § 252.706 (relating to recordkeeping).

(c) Within 72 hours of voluntarily relinquishing its certificate of accreditation, the laboratory shall notify each of its customers affected by the voluntary relinquishment in writing of the relinquishment on a form approved by the Department.

§ 252.706. Recordkeeping.

(a) An environmental laboratory shall maintain records in an organized manner accessible by the Department.

(b) An environmental laboratory shall maintain records, including original handwritten data, that allow reconstruction of all laboratory activities associated with the testing or analysis of environmental samples, proficiency test studies, initial demonstration of capability, or demonstration of continued proficiency.

(c) All generated data, except data generated by automated data collection systems, shall be recorded promptly and legibly in permanent ink or in an electronic format. Changes to records shall be made so that the original entry remains visible. The individual making the change shall sign or initial and date the correction. These criteria also shall apply to electronically maintained records.

(d) Records required under this chapter shall be maintained for a minimum of 5 years unless otherwise specified.

(e) An environmental laboratory shall have a written plan that specifies how records will be maintained or transferred if the laboratory transfers ownership or terminates operations.

§ 252.708. Reporting and notification requirements.

(a) An environmental laboratory conducting testing or analysis of drinking water under Chapter 109 (relating to safe drinking water) shall:

(1) Meet the reporting and notification requirements of that chapter.

(2) Review all sample analysis data within 24 hours of acquisition of the initial sample results for microbiological, inorganic nonmetals and trace metals analyses. The 24-hour deadline may be extended to a maximum of 72 hours to accommodate a holiday or weekend when the laboratory is closed for business.

(3) Review all sample analysis data within 7 days of acquisition of the initial sample results for organic and radiochemical analyses.

(b) An environmental laboratory shall notify the Department, in writing, within 20 calendar days of a permanent change in laboratory supervisor.

(c) An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in the legal name of the laboratory.

(d) An environmental laboratory shall notify the Department, in writing, within 30 calendar days of a change in any item contained on the application for accreditation.

(e) An environmental laboratory shall notify the Department, in writing, if a change in the laboratory's capability to produce valid analytical results persists for more than 90 calendar days for any field of accreditation listed on the laboratory's scope of accreditation.

(f) An out-of-State environmental laboratory with either primary or secondary accreditation from the Department shall notify, in writing, the Department within 48 hours of any changes in the laboratory's accreditation status from any other primary accreditation body.

(g) The Department may require additional information or proof of continued capability to perform the testing or analysis for affected fields of accreditation upon receipt of notification under this subsection.

(h) The Department may require an onsite assessment under § 252.601 (relating to onsite assessment requirements) upon receipt of notification under this subsection.

[Pa.B. Doc. No. 10-638. Filed for public inspection April 9, 2010, 9:00 a.m.]

Title 58—RECREATION

PENNSYLVANIA GAMING CONTROL BOARD

[58 PA. CODE CHS. 535 AND 567]

Table Game Rules for Pai Gow and War

The Pennsylvania Gaming Control Board (Board), under its general authority in 4 Pa.C.S. § 1303A (relating to temporary table game regulations) enacted by the act of January 7, 2010 (Act 1) and the specific authority in 4 Pa.C.S. § 1302A(1), (2) and (4) (relating to regulatory authority), adopts temporary regulations in Chapters 535 and 567 (relating to Pai Gow; and War) to read as set forth in Annex A. The Board's temporary regulations will be added to Part VII (relating to Gaming Control Board) as part of Subpart K (relating to table games).

Purpose of the Temporary Rulemaking

This temporary rulemaking contains table game rules for Pai Gow and War.

Explanation of Chapters 535 and 567

Chapter 535 (relating to Pai Gow) is being amended by adding a new § 535.3(e) (relating to Pai Gow tiles; physical characteristics) which requires tiles used for the play of Pai Gow to be changed at least once every 12 hours. Changing tiles is a standard practice in the industry to diminish the potential for anyone to mark the tiles.

Chapter 567 (relating to War) contains the rules governing the play of War, which is a card game where players compete against the dealer. The provisions in this chapter address: physical characteristics of War tables and the number of decks of cards used to play the game; the opening of War tables and shuffling procedures; the ranking of the cards and permissible wagers; procedures for dealing cards and completion of each round of play; payment and collection of wagers; payout odds; and how irregularities in play are to be handled.

Affected Parties

Slot machine licensees who elect to become certificate holders will be required to comply with the rules for conducting these table games if they are offered at their facilities. They will also have to hire and train dealers for the table games they wish to offer and purchase equipment necessary to conduct the table games.

The Board will experience increased regulatory demands resulting from the implementation of table games. The most significant increases will be the hiring of additional casino compliance agents to oversee the operation of the table games at the licensed facilities and increased number of license and occupation permit applications that will have to be processed by the Bureau of Licensing.

Fiscal Impact

Commonwealth

The Board expects that it will experience increased costs related to adding additional staff at the licensed facilities and at its offices to handle the increased licensing and oversight requirements that will result from the introduction of table games. Because the Board is just starting to receive petitions from slot machine licensees seeking permission to conduct table games, the extent of these additional costs are not known. However, the Board does not expect these increased costs to exceed the additional funding provided to the Board under Act 1.

Political Subdivisions

This rulemaking will have no direct fiscal impact on political subdivisions of this Commonwealth. Eventually, host municipalities and counties will benefit from the local share funding that is mandated by Act 1.

Private Sector

This rulemaking will result in additional costs for slot machine licensees who elect to become certificate holders. More specifically, certificate holders will be required to pay a table games licensing fee, purchase equipment conduct the table games they elect to offer and to hire and train employees to operate table games. While these costs will be significant, they will be offset by the revenues generated from the table games.

General Public

This rulemaking will have no direct fiscal impact on the general public.

Paperwork requirements

This rulemaking will require certificate holders to file a Rules Submission form for the game of War, if they offer it.

Effective Date

This temporary rulemaking will become effective upon final publication in the *Pennsylvania Bulletin*.

Public Comments

While this rulemaking will be effective upon publication, the Board is seeking comments from the public and affected parties as to how this temporary regulation might be improved. Interested persons are invited to submit written comments, suggestions or objections regarding this temporary rulemaking within 30 days after the date of publication in the *Pennsylvania Bulletin* to Richard Sandusky, Director of Regulatory Review, Penn-

sylvania Gaming Control Board, P. O. Box 69060, Harrisburg, PA 17106-9060, Attention: Public Comment on Regulation #125-115.

Contact Person

The contact person for questions about this rulemaking is Richard Sandusky, Director of Regulatory Review at (717) 214-8111.

Regulatory Review

Under 4 Pa.C.S. § 1303A, the Board is authorized to adopt temporary regulations which are not subject to the provisions of: sections 201—205 of the act of July 31, 1968 (P. L. 769, No. 240), referred to as the Commonwealth Documents Law; the Regulatory Review Act (71 P. S. §§ 745.1—745.12); and sections 204(b) and 301(10) of the Commonwealth Attorneys Act (71 P. S. §§ 732-204(b) and 732-301(10)). These temporary regulations expire 2 years after publication in the *Pennsylvania Bulletin*.

Findings

The Board finds that:

(1) Under 4 Pa.C.S. § 1303A, the temporary regulations are exempt from the requirements of the Regulatory Review Act, sections 201—205 of the Commonwealth Documents Law and sections 204(b) and 301(10) of the Commonwealth Attorney Act.

(2) The adoption of the temporary regulations is necessary and appropriate for the administration and enforcement of 4 Pa.C.S. Part II (relating to gaming).

Order

The Board, acting under 4 Pa.C.S. Part II, orders that:

(1) The regulations of the Board, 58 Pa. Code Chapters 535 and 567, are amended by amending § 535.3 and adding §§ 567.1—567.11 to read as set forth in Annex A, with ellipses referring to the text of the existing regulations.

(2) The temporary regulations are effective April 10, 2010.

(3) The temporary regulations will be posted on the Board's web site and published in the *Pennsylvania Bulletin*.

(4) The temporary regulations shall be subject to amendment as deemed necessary by the Board.

(5) The Chairperson of the Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

GREGORY C. FAJT,
Chairperson

Fiscal Note: 125-115. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 58. RECREATION

PART VII. GAMING CONTROL BOARD

Subpart K. TABLE GAMES

CHAPTER 535. PAI GOW

§ 535.3. Pai Gow tiles; physical characteristics.

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(e) Tiles used for the play of Pai Gow shall be changed at least every 12 hours.

CHAPTER 567. WAR

Sec.
567.1. Definitions.
567.2. War table; physical characteristics.
567.3. Cards; number of decks; dealing shoe.
567.4. Opening of the table for gaming.
567.5. Shuffle and cut of the cards.
567.6. War card rankings.
567.7. Wagers.
567.8. Procedure for dealing the cards.
567.9. Procedures for completion of each round of play; collection and payment of wagers.
567.10. Payout odds.
567.11. Irregularities.

§ 567.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Initial wager—The wager that must be made by a player prior to any cards being dealt to participate in the round of play.

Original deal—The first card that is dealt to each player and the dealer to determine the result for the Initial wager in a round of play.

Round of play—One complete cycle of play during which each player playing at the table has placed an Initial wager, has been dealt a card, has surrendered or gone to War, if appropriate, and has had his wagers paid or collected in accordance with this chapter.

Tie hand—A hand in the original deal or War deal where the rank of a player's card and the rank of the dealer's card are equal.

War—The decision of a player, in accordance with the option offered under § 567.9(c)(2) (relating to procedures for completion of each round of play; collection and payment of wagers), to place a War wager when there is a tie hand on the original deal.

War deal—The deal of the cards that follows the placement of a War wager.

War wager—A wager that is required to be made if the player elects to go to War.

§ 567.2. War table; physical characteristics.

(a) War shall be played at a table having betting positions for no more than seven players on one side of the table and a place for the dealer on the opposite side of the table.

(b) The layout for a War table shall be approved by the Bureau of Gaming Operations and have imprinted thereon, at a minimum, the following:

(1) The name or logo of the certificate holder.

(2) A separate designated betting area at each betting position for the placement of Initial and War wagers.

(3) A separate designated betting area for the placement of Tie wagers.

(4) The payout odds for a Tie wager and War wager.

(c) Each War table must have a drop box and a tip box attached to it on the same side of the gaming table as, but on opposite sides of, the dealer, in locations approved by the Bureau of Gaming Operations.

§ 567.3. Cards; number of decks; dealing shoe.

(a) War shall be played with six to eight decks of cards with backs of the same color and design. Each deck of cards must consist of 52 cards. The game of War also

requires two cover cards to be used in accordance with the procedures in § 567.5 (relating to shuffle and cut of the cards).

(b) All cards used in War shall be dealt from a manual dealing shoe. The dealing shoe shall be located on the table to the left of the dealer.

(c) If an automated card shuffling device is utilized, War shall be played with 12 to 16 decks of cards in accordance with the following requirements:

(1) Each deck of cards must meet the requirements of subsection (a).

(2) The cards shall be separated into two batches, with an equal number of decks included in each batch.

(3) The backs of the cards in each batch must be of the same color and design, but of a different color than the cards included in the other batch.

(4) One batch of cards shall be shuffled and stored in the automated card shuffling device while the other batch is being dealt or used to play the game.

(5) Both batches of cards shall be continuously alternated in and out of play, with each batch being used for every other dealing shoe.

(6) The cards from only one batch shall be placed in the discard rack at any given time.

(d) The decks of cards opened for use at a War table shall be changed at least once every 24 hours.

§ 567.4. Opening of the table for gaming.

(a) After receiving six or more decks of cards at the table, the dealer shall sort and inspect each deck of cards separately, face down, and the floorperson assigned to the table shall verify the inspection.

(b) Following the inspection of the cards by the dealer and the verification by the floorperson assigned to the table, the cards shall be spread out face up on the table for visual inspection by the first player to arrive at the table. The cards shall be spread out according to suit and in sequence.

(c) After the first player is afforded an opportunity to visually inspect the cards, the cards shall be turned face down on the table, mixed thoroughly by a washing of the cards and stacked.

(d) If an automated shuffling device is utilized, all the decks in one batch of cards shall be spread for inspection on the table separate from the decks in the other batch of cards. After the first player to arrive at the table is afforded an opportunity to visually inspect the cards, each batch of cards shall separately be turned face downward on the table and stacked.

§ 567.5. Shuffle and cut of the cards.

(a) Immediately prior to commencement of play, unless the cards were preshuffled, and after each dealing shoe of cards is dealt or when directed by a floorperson or above, the dealer shall shuffle the cards, either manually or by use of an automated card shuffling device, so that the cards are randomly intermixed. Upon completion of the shuffle, the dealer or device shall place the deck of cards in a single stack.

(b) After the cards have been shuffled and stacked, the dealer shall offer the stack of cards to be cut, with the backs facing away from the dealer, to players in the following order:

(1) The first player to the table, if the game is just beginning.

(2) The player on whose betting area the cover card appeared during the last round of play.

(3) The player at the farthest point to the right of the dealer if the cover card appeared on the dealer's hand during the last round of play.

(4) The player at the farthest point to the right of the dealer if the reshuffle was initiated at the discretion of a floorperson or above.

(c) If the player designated in subsection (b) refuses to cut, the dealer shall offer the cut to each other player moving clockwise around the table until a player accepts the cut. If no player accepts the cut, the dealer shall cut the cards.

(d) The player or dealer making the cut shall place a cover card in the stack at least 10 cards in from the top or the bottom of the stack.

(e) Once the cover card has been inserted, the dealer shall take all cards above the cover card and the cover card and place them on the bottom of the stack. The dealer shall then insert the second cover card in the stack at a position at least approximately one-quarter of the way in from the bottom of the stack. The stack of cards shall then be inserted into the dealing shoe for commencement of play.

(f) After the cards have been cut and before the cards have been placed in the dealing shoe, a floorperson or above may require the cards to be recut if the floorperson or above determines that the cut was performed improperly or in any way that might affect the integrity or fairness of the game. If a recut is required, the cards shall be recut by the next person entitled to cut the cards, as determined under subsection (b)(4).

(g) A reshuffle of the cards in the shoe shall take place after the cover card is reached in the shoe as required under § 567.8(d) (relating to procedure for dealing the cards).

(h) If there is no gaming activity at the War table, the cards shall be removed from the dealing shoe and the discard rack, and spread out on the table either face up or face down. If the cards are spread face down, they shall be turned face up once a player arrives at the table. After the first player is afforded an opportunity to visually inspect the cards, the cards shall be turned face downward on the table and:

(1) If there is no automated shuffling device in use, the cards shall be mixed thoroughly by a washing of the cards, stacked, then shuffled and cut in accordance with this section.

(2) If an automated shuffling device is in use, the cards shall be stacked and placed into the automated shuffling device to be shuffled. The batch of cards already in the shuffler shall then be removed. Unless a player so requests, the batch of cards removed from the shuffler need not be spread for inspection and reshuffled prior to being dealt, if:

(i) The automated card shuffling device stores a single batch of shuffled cards inside the shuffler in a secure manner approved by the Bureau of Gaming Operations.

(ii) The shuffled cards have been secured, released and prepared for play in accordance with procedures approved by the Bureau of Gaming Operations.

§ 567.6. War card rankings.

The rank of the cards used in War, for the purpose of determining a winning hand, shall be, in order from the highest to lowest rank: ace, king, queen, jack, 10, 9, 8, 7, 6, 5, 4, 3 and 2. The suit of a card shall have no effect on its rank.

§ 567.7. Wagers.

(a) Wagers at War shall be made by placing gaming chips or plaques on the appropriate betting area of the War layout. A verbal wager accompanied by cash may not be accepted at the game of War.

(b) To participate in a round of play, a player shall be required to place an Initial wager.

(c) Players shall have the option of placing a Tie wager, at the same time as an Initial wager or a War wager, that the deal on which the Tie wager is made will result in a tie hand.

(d) Except as provided in § 567.9(e) (relating to procedures for completion of each round of play; collection and payment of wagers), all wagers at War shall be placed prior to the dealer announcing "no more bets" in accordance with the dealing procedures in § 567.8 (relating to procedure for dealing the cards). Once a wager has been placed, players may not handle, remove or alter the wager unless the dealer indicates that the wager has been decided in the player's favor as provided in this chapter.

(e) A certificate holder may, if specified in the certificate holder's Rules Submission under § 521.2 (relating to table games Rules Submissions), permit a player to simultaneously play and place wagers at up to two additional adjacent player positions.

§ 567.8. Procedure for dealing the cards.

(a) Prior to starting the first round of play after the cards have been cut and placed in the dealing shoe under § 567.5 (relating to shuffle and cut of the cards), the dealer shall remove the first card from the shoe face down and, without revealing its rank to anyone, place it in the discard rack. Each new dealer who comes to the table shall also remove the first card from the shoe face down and, without revealing its rank to anyone, place it in the discard rack.

(b) Prior to dealing any cards, the dealer shall announce "no more bets." Each card shall then be removed from the dealing shoe with the left hand of the dealer and placed face up on the appropriate area of the layout with the right hand of the dealer.

(c) The dealer shall, starting with the player farthest to the dealer's left and continuing in a clockwise manner, deal the cards as follows:

(1) One card face up to each player who has placed an Initial wager in accordance with § 567.7 (relating to wagers).

(2) One card face up to the dealer.

(d) Whenever the cover card is reached in the deal of the cards, the dealer shall continue dealing the cards until that round of play is completed after which the cards shall be reshuffled.

(e) Players may not touch any card used in the game of War other than a cover card.

§ 567.9. Procedures for completion of each round of play; collection and payment of wagers.

(a) After the dealing procedures required under § 567.8 (relating to procedure for dealing the cards) have been completed, the dealer shall, beginning from the dealer's left and proceeding around the table in a clockwise direction, compare the rank of each player's card with that of the dealer's card and settle all Initial and Tie wagers as follows:

(1) If a player's card is lower in rank than the dealer's card, the player shall lose his Initial wager and, if applicable, his Tie wager.

(2) If a player's card is higher in rank than the dealer's card, the player shall win his Initial wager and, if applicable, lose his Tie wager.

(3) If the player's card and the dealer's card are of equal rank (a tie hand), the player shall be afforded the options specified in subsection (c) as to his Initial wager and, if applicable, win his Tie wager.

(b) Losing Initial and Tie wagers made on the original deal shall be collected by the dealer and placed in the table inventory container. Winning Initial and Tie wagers made on the original deal shall be paid by the dealer in accordance with the payout odds provided in § 567.10 (relating to payout odds).

(c) If a player has a tie hand, the player shall select one of the following options:

(1) The player may surrender one-half of his Initial wager and end his participation in that round of play. If a player selects this option, the dealer shall collect one-half of the player's Initial wager and place it in the table inventory container. The dealer shall then return the remaining one-half of the Initial wager to the player. The dealer shall then proceed around the table in a clockwise direction, repeating the process for each player with a tie hand who selects this option.

(2) The player may surrender his entire Initial wager and place a War wager, in an amount equal to the player's Initial wager, in accordance with subsection (e).

(d) After settling Initial wagers and Tie wagers on the original deal, the dealer shall collect the cards of all players except for the cards of those players with a tie hand who have elected to go to War. The collected cards shall be placed in the discard rack in a manner that permits the reconstruction of each hand of the original deal in case of a question or dispute.

(e) If any player elects to make a War wager upon the occurrence of a tie hand, the dealer shall confirm the placement of the War wager and collect the full amount of the player's Initial wager and place it in the table inventory container. The player's card and the dealer's card from the original deal shall remain exposed during the war deal. The dealer shall offer any player who has elected to go to War the opportunity to also place a Tie wager on the War deal.

(f) The War deal shall begin with the dealer removing three cards from the shoe face down and, without revealing the rank of the three cards to anyone, placing them in the discard rack and then dealing the next card face up to the player farthest to the dealer's left who has placed a War wager. The player's War deal card shall be placed on the table adjacent to the player's card from the original deal. The dealer shall then proceed around the table in a clockwise direction, repeating the process for each player who has placed a War wager and the dealer.

(g) After the dealing procedures required by subsection (f) have been completed, the dealer shall, beginning from the dealer's left and proceeding around the table in a clockwise direction, compare the rank of each player's

card from the War deal to the dealer's card from the War deal and settle all War and Tie wagers as follows:

(1) If the player's card in the War deal is lower in rank than the dealer's card in the War deal, the player shall lose his War wager and, if applicable, his Tie wager.

(2) If the player's card in the War deal is higher in rank than the dealer's card in the War deal, the player shall win his War wager and, if applicable, lose his Tie wager.

(3) If the player's card and the dealer's card in the War deal are of equal rank, the player shall win his War wager and, if applicable, his Tie wager.

(h) Losing War and Tie wagers shall be collected by the dealer and placed in the table inventory container. Winning War and Tie wagers shall then be paid in accordance with the payout odds set forth in § 567.10 (relating to payment odds). After the collection of all losing wagers and the payment of all winning wagers from the War deal, the dealer shall remove all remaining cards from the table and place them in the discard rack in a manner that permits the reconstruction of each hand of the War deal in case of a question or dispute.

§ 567.10. Payout odds.

Winning wagers shall be paid as follows:

(1) An Initial wager shall be paid at odds of 1 to 1.

(2) A Tie wager shall be paid at odds of 10 to 1.

(3) A War wager shall be paid at odds of 2 to 1, unless the War deal results in a tie hand, in which case a War wager shall be paid at odds of 3 to 1.

§ 567.11. Irregularities.

(a) A card found face up in the dealing shoe while the cards are being dealt may not be used in the game and shall be placed in the discard rack. If more than one card is found face up in the dealing shoe while the cards are being dealt, all hands shall be void and the cards shall be reshuffled.

(b) A card drawn from the dealing shoe in error without its face being exposed shall be used as though it was next card from the dealing shoe.

(c) If a card is not dealt to a player's Initial wager or Tie wager in the original deal, the wager shall be void and returned to the player. The player shall be included in the next round of play.

(d) If an automated card shuffling device is being used and the device jams, stops shuffling during the shuffle, or fails to complete a shuffle cycle, the cards shall be reshuffled.

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