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SALUS POPULI SUPREMA LEX ESTO

"The welfare of the people shall be the supreme law."

JASON KANDER
SECRETARY OF STATE

MISSOURI REGISTER

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The rules are codified in the *Code of State Regulations* in this system—

Title	***Code of State Regulations***	**Division**	**Chapter**	**Rule**
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific area regulated

They are properly cited by using the full citation , i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division within the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—The most recent version of the statute containing the section number and the date.

Rules appearing under this heading are filed under the authority granted by section 536.025, RSMo 2000. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety, or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the *Missouri* and the *United States Constitutions*; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons, and findings which support its conclusion that there is an immediate danger to the public health, safety, or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

Rules filed as emergency rules may be effective not less than ten (10) days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

All emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

EMERGENCY AMENDMENT

11 CSR 45-8.140 Application and Verification Procedures for Granting Credit. The commission is amending section (4) and adding new sections (5) and (6).

PURPOSE: This amendment changes regulatory procedures for the Class B licensees to follow regarding standards for establishing lines of credit.

EMERGENCY STATEMENT: This emergency amendment is necessary to address statutory sections enacted in SB 833 (2016), specifically, sections 313.800 and 313.817, which become law on August 28, 2016. This legislation modified the manner in which Class B licensees determined a patron's credit worthiness and the amount of credit the Class B licensee can extend to patrons applying for a credit instrument.

This bill modifies the definition of "qualified person" to mean a person who qualifies for a line of credit in an amount determined by the Class B licensee based on the person's demand deposit accounts, including any checking or savings accounts. The bill sets criteria for credit instruments of ten thousand dollars ($10,000) or less as well as for credit instruments of more than ten thousand dollars ($10,000). This amendment will allow the thirteen (13) casinos to extend credit to more patrons; however, we have no estimate on how many patrons this will affect. The submitted regulation was drafted to explain the standards for determining the amount of credit to issue based on the credit worthiness of an individual applying for credit under sections 313.800–313.850, RSMo. Patrons will benefit from consistent standards as well, in that they can be secure in knowing that all casinos within the state comply with and operate within the same framework; these regulations will provide a level playing field for all parties involved.

*In addition, Chapter H of the **Minimum Internal Control Standards** (MICS) was revised to include the new definition of a "qualified person" and the amount of credit that can be extended based on a patron's credit worthiness. The Missouri Gaming Commission (MGC) is responsible for establishing MICS to provide a framework from which each casino is required to develop its own internal control system. MGC requested input from the gaming industry regarding the new provisions for lines of credit, and used their feedback to modify the standards and procedures to ensure fairness to the industry. Without the emergency MICS the casinos would be required to submit their internal controls for credit without any regulatory guidelines or minimum standards.*

Specifically, this emergency amendment updates the procedure for determining a patron's creditworthiness, and it adds the new regulations for extending credit based on a patron's creditworthiness.

*As such, the MGC finds an immediate threat to the public welfare and a compelling governmental interest to regulate the extension of credit by Class B licensees by August 28, 2016, which requires this emergency action. A proposed amendment which covers the same material is published in this issue of the **Missouri Register**. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri** and **United States Constitutions**. The Missouri Gaming Commission believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed July 28, 2016, becomes effective August 28, 2016, and expires February 23, 2017.*

(4) Prior to a Class B licensee's approval of a person's credit limit, an employee of the credit department or other employee as designated in the Class B licensee's internal control system shall—

(C) Perform a credit check and apply usual standards to determine the dollar amount of credit for which the person qualifies. *[If the person does not qualify for at least a ten thousand dollar ($10,000) line of credit, the application shall be denied]*;

(5) A person's credit worthiness shall be based on the amount of funds in the person's demand deposit account or accounts including any checking account and savings account.

(6) If the person's credit worthiness is ten thousand dollars ($10,000) or more, the Class B Licensee may accept a credit instrument of more than ten thousand dollars ($10,000) only if the qualified person's creditworthiness is equal to or in excess of the amount of the credit instrument. If the person's credit worthiness is less than ten thousand dollars ($10,000), the Class B Licensee may only accept credit instruments that are equal to or less than half the amount of the person's creditworthiness.

*AUTHORITY: section 313.004, RSMo 2000, and sections 313.800, 313.812, 313.817, and 313.830, RSMo Supp. 2014, **section** 313.805, **RSMo Supp. 2013, and section 313.930, RSMo SB 833, Second Regular Session, Ninety-eighth General Assembly, 2016**. Emergency rule filed July 31, 2014, effective Aug. 28, 2014, expired Feb. 26, 2015. Original rule filed July 31, 2014, effective Feb. 28, 2015. Emergency amendment filed July 28, 2016, effective Aug. 28, 2016, expires Feb. 23, 2017. A proposed amendment covering this same material is published in this issue of the **Missouri Register**.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 9—Internal Control System

EMERGENCY AMENDMENT

11 CSR 45-9.108 Minimum Internal Control Standards (MICS)—Chapter H. The commission is amending section (1).

*PURPOSE: This amendment changes the internal controls for Chapter H of the **Minimum Internal Control Standards**.*

EMERGENCY STATEMENT: This emergency amendment is necessary to address statutory sections enacted in SB 833 (2016), specifically, sections 313.800 and 313.817, which become law on August 28, 2016. This legislation modified the manner in which Class B licensees determined a patron's credit worthiness and the amount of credit the Class B licensee can extend to patrons applying for a credit instrument.

This bill modifies the definition of "qualified person" to mean a person who qualifies for a line of credit in an amount determined by the Class B licensee based on the person's demand deposit accounts, including any checking or savings accounts. The bill sets criteria for credit instruments of ten thousand dollars ($10,000) or less as well as for credit instruments of more than ten thousand dollars ($10,000). This amendment will allow the thirteen (13) casinos to extend credit to more patrons; however, we have no estimate on how many patrons this will affect. The submitted regulation was drafted to explain the standards for determining the amount of credit to issue based on the credit worthiness of an individual applying for credit under sections 313.800–313.850, RSMo. Patrons will benefit from consistent standards as well, in that they can be secure in knowing that all casinos within the state comply with and operate within the same framework; these regulations will provide a level playing field for all parties involved.

*In addition, Chapter H of the **Minimum Internal Control Standards** (MICS) was revised to include the new definition of a "qualified person" and the amount of credit that can be extended based on a patron's credit worthiness. The Missouri Gaming Commission (MGC) is responsible for establishing MICS to provide a framework from which each casino is required to develop its own internal control system. MGC requested input from the gaming industry regarding the new provisions for lines of credit, and used their feedback to modify the standards and procedures to ensure fairness to the industry. Without the emergency MICS the casinos would be required to submit their internal controls for credit without any regulatory guidelines or minimum standards.*

Specifically, this emergency amendment updates the procedure for determining a patron's creditworthiness, and it adds the new regulations for extending credit based on a patron's creditworthiness.

*As such, the MGC finds an immediate threat to the public welfare and a compelling governmental interest to regulate the extension of credit by Class B licensees by August 28, 2016, which requires this emergency action. A proposed amendment which covers the same material is published in this issue of the **Missouri Register**. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri** and **United States Constitutions**. The Missouri Gaming Commission believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed July 28, 2016, becomes effective August 28, 2016, and expires February 23, 2017.*

(1) The commission shall adopt and publish minimum standards for internal control procedures that**,** in the commission's opinion**,** satisfy 11 CSR 45-9.020, as set forth in *Minimum Internal Control Standards* (MICS) Chapter H—Casino Cashiering and Credit, which has been incorporated by reference herein, as published by the Missouri Gaming Commission, 3417 Knipp Dr., PO Box 1847, Jefferson City, MO 65102. Chapter H does not incorporate any subsequent amendments or additions as adopted by the commission on *[October 29, 2014]* **July 27, 2016**.

*AUTHORITY: section 313.004, RSMo 2000, and sections 313.800, 313.812, 313.817, and 313.830, RSMo Supp. 2014, **section** 313.805, **RSMo Supp. 2013, and section 313.930, RSMo SB 833 Second Regular Session, Ninety-eighth General Assembly, 2016**. Original rule filed Oct. 31, 2011, effective June 30, 2012. Emergency amendment filed July 31, 2014, effective Aug. 28, 2014, expired Feb. 26, 2015. Amended: Filed July 31, 2014, effective Feb. 28, 2015. Emergency amendment filed July 28, 2016, effective Aug. 28, 2016, expires Feb. 23, 2017. A proposed amendment covering this same material is published in this issue of the **Missouri Register**.*

Title 13—DEPARTMENT OF SOCIAL SERVICES
Division 70—MO HealthNet Division
Chapter 10—Nursing Home Program

EMERGENCY AMENDMENT

13 CSR 70-10.016 Global Per Diem Adjustments to Nursing Facility and HIV Nursing Facility Reimbursement Rates. The division is amending paragraph (3)(A)20.

PURPOSE: This amendment provides for a continuance of the per diem increase to nursing facility and HIV nursing facility per diem reimbursement rates of two dollars and nine cents ($2.09) which was granted for the period January 1, 2016 through June 30, 2016. This increase was to expire after June 30, 2016. The amendment also provides for a per diem increase for State Fiscal Year 2017 by granting a trend adjustment of two dollars and eighty-three cents ($2.83). Both rate increases are effective for dates of service beginning July 1, 2016 and are contingent upon approval by the Centers for Medicare and Medicaid Services.

EMERGENCY STATEMENT: The Department of Social Services, MO HealthNet Division, by rule and regulation, must define the reasonable costs, manner, extent, quantity, quality, charges, and fees of medical assistance. Effective for dates of service beginning July 1, 2016, the appropriation by the General Assembly included additional funds to nursing facilities' and HIV nursing facilities' reimbursements to account for the continuance of the per diem increase granted for the period January 1, 2016 through June 30, 2016 and for an additional trend adjustment for SFY 2017. The MO HealthNet Division is carrying out the General Assembly's intent by providing for a per diem increase to nursing facility and HIV nursing facility reimbursement rates by continuing the two dollars and nine cents ($2.09) per diem increase and implementing a trend adjustment of two dollars and eighty-three cents ($2.83) effective for dates of service beginning July 1, 2016. The rate continuance and trend adjustment are necessary to ensure that payments for nursing facility and HIV nursing facility per diem rates are in line with the funds appropriated for that purpose. There is a total of five hundred and three (503) nursing facilities and HIV nursing facilities currently enrolled in MO HealthNet which will receive a per diem increase to its reimbursement rate effective for dates of service beginning July 1, 2016. This emergency amendment will ensure payment for nursing facility and HIV nursing facility services to approximately twenty-four thousand (24,000) senior Missourians in accordance with the appropriation authority. For the State Fiscal Year 2017 payment to be made, a Medicaid State Plan Amendment was required to be submitted and approved by the Centers for Medicare and Medicaid Services (CMS). The State Plan Amendment was approved by CMS on July 6, 2016, but the proposed state regulation amendment will not be effective until November 30, 2016. This emergency amendment must be implemented on a timely basis to ensure that quality nursing facility and HIV nursing facility services continue to be provided to MO HealthNet participants in nursing facilities and HIV nursing facilities

*during state fiscal year 2017 in accordance with the appropriation authority. As a result, the MO HealthNet Division finds an immediate danger to public health, safety and/or welfare, and a compelling governmental interest, which requires emergency action. The MO HealthNet Division has a compelling governmental interest in providing continued cash flow for nursing facility and HIV nursing facility services. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended by the **Missouri** and **United States Constitutions**. The MO HealthNet Division believes this emergency amendment is fair to all interested persons and parties under the circumstances. A proposed amendment covering this same material was published in the **Missouri Register** on June 15, 2016 (41 MoReg 776–780). This emergency amendment was filed July 18, 2016, becomes effective July 28, 2016, and expires January 23, 2017.*

(3) Adjustments to the Reimbursement Rates. Subject to the limitations prescribed in 13 CSR 70-10.015, a nursing facility's reimbursement rate may be adjusted as described in this section. Subject to the limitations prescribed in 13 CSR 70-10.080, an HIV nursing facility's reimbursement rate may be adjusted as described in this section.

(A) Global Per Diem Rate Adjustments. A facility with either an interim rate or a prospective rate may qualify for the global per diem rate adjustments. Global per diem rate adjustments shall be added to the specified cost component ceiling.

1. FY-96 negotiated trend factor—

A. Facilities with either an interim rate or prospective rate in effect on October 1, 1995, shall be granted an increase to their per diem effective October 1, 1995, of four and six-tenths percent (4.6%) of the cost determined in paragraphs (11)(A)1., (11)(B)1., (11)(C)1., and the property insurance and property taxes detailed in subsection (11)(D) of 13 CSR 70-10.015; or

B. Facilities that were granted a prospective rate based on paragraph (12)(A)2. of 13 CSR 70-10.015 that is in effect on October 1, 1995, shall have their increase determined by subsection (3)(S) of 13 CSR 70-10.015.

2. FY-97 negotiated trend factor—

A. Facilities with either an interim rate or prospective rate in effect on October 1, 1996, shall be granted an increase to their per diem effective October 1, 1996, of three and seven-tenths percent (3.7%) of the cost determined in paragraphs (11)(A)1., (11)(B)1., (11)(C)1., and the property insurance and property taxes detailed in subsection (11)(D) of 13 CSR 70-10.015; or

B. Facilities that were granted a prospective rate based on paragraph (12)(A)2. of 13 CSR 70-10.015 that is in effect on October 1, 1995, shall have their increase determined by subsection (3)(S) of 13 CSR 70-10.015.

3. Nursing Facility Reimbursement Allowance (NFRA). Effective October 1, 1996, all facilities with either an interim rate or a prospective rate shall have its per diem adjusted to include the current NFRA as an allowable cost in its reimbursement rate calculation.

4. Minimum wage adjustment. All facilities with either an interim rate or a prospective rate in effect on November 1, 1996, shall be granted an increase to their per diem effective November 1, 1996, of two dollars and forty-five cents ($2.45) to allow for the change in minimum wage. Utilizing Fiscal Year 1995 cost report data, the total industry hours reported for each payroll category was multiplied by the fifty-cent (50¢) increase, divided by the patient days for the facilities reporting hours for that payroll category and factored up by eight and sixty-seven hundredths percent (8.67%) to account for the related increase to payroll taxes. This calculation excludes the director of nursing, the administrator, and assistant administrator.

5. Minimum wage adjustment. All facilities with either an interim rate or a prospective rate in effect on September 1, 1997, shall be granted an increase to their per diem effective September 1, 1997, of one dollar and ninety-eight cents ($1.98) to allow for the change in minimum wage. Utilizing Fiscal Year 1995 cost report data, the total industry hours reported for each payroll category was multiplied by the forty-cent (40¢) increase, divided by the patient days for the facilities reporting hours for that payroll category and factored up by eight and sixty-seven hundredths percent (8.67%) to account for the related increase to payroll taxes. This calculation excludes the director of nursing, the administrator, and assistant administrator.

6. FY-98 negotiated trend factor—

A. Facilities with either an interim rate or prospective rate in effect on October 1, 1997, shall be granted an increase to their per diem effective October 1, 1997, of three and four-tenths percent (3.4%) of the cost determined in paragraphs (11)(A)1., (11)(B)1., (11)(C)1., and the property insurance and property taxes detailed in subsection (11)(D) of 13 CSR 70-10.015 for nursing facilities and 13 CSR 70-10.080 for HIV nursing facilities; or

B. Facilities that were granted a prospective rate based on paragraph (12)(A)2. of 13 CSR 70-10.015 that is in effect on October 1, 1995, shall have their increase determined by subsection (3)(S) of 13 CSR 70-10.015.

7. FY-99 negotiated trend factor—

A. Facilities with either an interim rate or prospective rate in effect on October 1, 1998, shall be granted an increase to their per diem effective October 1, 1998, of two and one-tenth percent (2.1%) of the cost determined in paragraphs (11)(A)1., (11)(B)1., (11)(C)1., the property insurance and property taxes detailed in subsection (11)(D) of 13 CSR 70-10.015 for nursing facilities and 13 CSR 70-10.080 for HIV nursing facilities, and the minimum wage adjustments detailed in paragraphs (3)(A)4. and (3)(A)5. of this regulation; or

B. Facilities that were granted a prospective rate based on paragraph (12)(A)2. of 13 CSR 70-10.015 that is in effect on October 1, 1998, shall have their increase determined by subsection (3)(S) of 13 CSR 70-10.015.

8. FY-2000 negotiated trend factor—

A. Facilities with either an interim rate or prospective rate in effect on July 1, 1999, shall be granted an increase to their per diem effective July 1, 1999, of one and ninety-four hundredths percent (1.94%) of the cost determined in subsections (11)(A), (11)(B), (11)(C), the property insurance and property taxes detailed in subsection (11)(D) of 13 CSR 70-10.015 for nursing facilities and 13 CSR 70-10.080 for HIV nursing facilities, and the minimum wage adjustments detailed in paragraphs (3)(A)4. and (3)(A)5. of this regulation; or

B. Facilities that were granted a prospective rate based on paragraph (12)(A)2. of 13 CSR 70-10.015 that is in effect on July 1, 1999, shall have their increase determined by subsection (3)(S) of 13 CSR 70-10.015.

9. FY-2004 nursing facility operations adjustment—

A. Facilities with either an interim rate or prospective rate in effect on July 1, 2003, shall be granted an increase to their per diem effective for dates of service beginning July 1, 2003, through June 30, 2004, of four dollars and thirty-two cents ($4.32) for the cost of nursing facility operations. Effective for dates of service beginning July 1, 2004, the per diem adjustment shall be reduced to three dollars and seventy-eight cents ($3.78); and

B. The operations adjustment shall be added to the facility's current rate as of June 30, 2003, and is effective for payment dates after August 1, 2003.

10. FY-2007 quality improvement adjustment—

A. Facilities with either an interim rate or prospective rate in effect on July 1, 2006, shall be granted an increase to their per diem effective for dates of service beginning July 1, 2006, of three dollars and seventeen cents ($3.17) to improve the quality of life for nursing facility residents; and

B. The quality improvement adjustment shall be added to the facility's current rate as of June 30, 2006, and is effective for dates of service beginning July 1, 2006, and after.

11. FY-2007 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on February 1, 2007, shall be granted an increase to their per diem rate effective for dates of service beginning February 1, 2007, of three dollars and zero cents ($3.00) to allow for a trend

adjustment to ensure quality nursing facility services; and

B. The trend adjustment shall be added to the facility's reimbursement rate as of January 31, 2007, and is effective for dates of service beginning February 1, 2007, for payment dates after March 1, 2007.

12. FY-2008 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2007, shall be granted an increase to their per diem rate effective for dates of service beginning July 1, 2007, of six dollars and zero cents ($6.00) to allow for a trend adjustment to ensure quality nursing facility services; and

B. The trend adjustment shall be added to the facility's current rate as of June 30, 2007, and is effective for dates of service beginning July 1, 2007.

13. FY-2009 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2008, shall be granted an increase to their per diem rate effective for dates of service beginning July 1, 2008, of six dollars and zero cents ($6.00) to allow for a trend adjustment to ensure quality nursing facility services; and

B. The trend adjustment shall be added to the facility's current rate as of June 30, 2008, and is effective for dates of service beginning July 1, 2008.

14. FY-2010 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2009, shall be granted an increase to their per diem rate effective for dates of service beginning July 1, 2009, of five dollars and fifty cents ($5.50) to allow for a trend adjustment to ensure quality nursing facility services; and

B. The trend adjustment shall be added to the facility's current rate as of June 30, 2009, and is effective for dates of service beginning July 1, 2009.

15. FY-2012 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on October 1, 2011, shall be granted an increase to their per diem rate effective for dates of service beginning October 1, 2011, of six dollars and zero cents ($6.00) to allow for a trend adjustment to ensure quality nursing facility services;

B. The trend adjustment shall be added to the facility's current rate as of September 30, 2011, and is effective for dates of service beginning October 1, 2011; and

C. This increase is contingent upon the federal assessment rate limit increasing to six percent (6%) and is subject to approval by the Centers for Medicare and Medicaid Services.

16. FY-2013 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2012, shall be granted an increase to their per diem rate effective for dates of services beginning July 1, 2012, of six dollars and zero cents ($6.00) to allow for a trend adjustment to ensure quality nursing facility services;

B. The trend adjustment shall be added to the facility's current rate as of June 30, 2012, and is effective for dates of service beginning July 1, 2012; and

C. This increase is contingent upon approval by the Centers for Medicare and Medicaid Services.

17. FY-2014 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2013, shall be granted an increase to their per diem rate effective for dates of services beginning July 1, 2013, of three percent (3.0%) of their current rate, less certain fixed cost items. The fixed cost items are the per diem amounts included in the facility's current rate from the following: subsection (2)(O) of 13 CSR 70-10.110, paragraphs (11)(D)1., (11)(D)2., (11)(D)3., (11)(D)4., (13)(B)3. and (13)(B)10. of 13 CSR 70-10.015;

B. The trend adjustment shall be added to the facility's current rate as of June 30, 2013, and is effective for dates of service beginning July 1, 2013; and

C. This increase is contingent upon approval by the Centers for Medicare and Medicaid Services.

18. FY-2015 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2014, shall be granted an increase to their per diem rate effective for dates of services beginning July 1, 2014, of one dollar and twenty-five cents ($1.25) to allow for a trend adjustment to ensure quality nursing facility services;

B. The trend adjustment shall be added to the facility's current rate as of June 30, 2014, and is effective for dates of service beginning July 1, 2014; and

C. This increase is contingent upon approval by the Centers for Medicare and Medicaid Services.

19. January 1, 2016 – June 30, 2016 trend adjustment—

A. Facilities with either an interim rate or a prospective rate in effect on January 1, 2016, shall be granted an increase to their per diem rate effective for dates of services beginning January 1, 2016, of two dollars and nine cents ($2.09) to allow for a trend adjustment to ensure quality nursing facility services;

B. The trend adjustment will not be added to the facility's rate after June 30, 2016; and

C. This increase is contingent upon approval by the Centers for Medicare and Medicaid Services and sufficient funding available through the Tax Amnesty Fund.

20. *[Trend adjustment after June 30, 2016]* **Continuation of FY-2016 trend adjustment and FY-2017 trend adjustment**—

A. Facilities with either an interim rate or a prospective rate in effect on July 1, 2016**,** *[or after shall be granted an increase to their per diem rate effective for dates of services on or after July 1, 2016 as calculated by the state based on monies available as approved by the Missouri General Assembly and governor divided by the most current estimated annual Medicaid patient days. The trend adjustment to ensure quality nursing facility services and any annual/periodic adjustment shall be published at http://dss.mo.gov/mhd/ prior to the adjustment's effective date; and]* **shall continue to be granted an increase to their per diem rate effective for dates of service beginning July 1, 2016, of two dollars and nine cents ($2.09);**

B. *[The trend adjustment is the same for both public and private nursing facilities.]* **Facilities with either an interim rate or a prospective rate in effect on July 1, 2016, shall be granted an increase to their per diem rate effective for dates of services beginning July 1, 2016, of two dollars and eighty-three cents ($2.83) to allow for a trend adjustment to ensure quality nursing facility services;**

C. The trend adjustment of two dollars and eighty-three cents ($2.83) shall be added to the facility's rate as of June 30, 2016, which includes the two dollars and nine cents ($2.09) increase, and is effective for dates of service beginning July 1, 2016; and

D. These increases are contingent upon approval by the Centers for Medicare and Medicaid Services.

AUTHORITY: section 208.159, RSMo 2000, and sections 208.153 and 208.201, RSMo Supp. 2013. Original rule filed July 1, 2008, effective Jan. 30, 2009. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed May 16, 2016. Emergency amendment filed July 18, 2016, effective July 28, 2016, expires Jan. 23, 2017.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

EMERGENCY AMENDMENT

20 CSR 2220-2.200 Sterile *[Pharmaceuticals]* ***Compounding***. The board is amending the title, purpose statement, and all sections of

this rule. Additionally, the board is deleting sections (5), (6), (8), and (15) of the current rule and adding new sections (5), (6), (7), (10), (17), (20), and (21).

PURPOSE: This board is amending all sections of this rule to update, clarify, and delineate requirements for sterile compounding pharmacies.

*PURPOSE: This rule establishes standards for the [preparation] **handling**, labeling [and], distribution, **and dispensing** of [sterile pharmaceuticals] **compounded sterile preparations** by licensed pharmacies, pursuant to a physician's order or prescription.*

EMERGENCY STATEMENT: Pursuant to section 338.200, RSMo, the board licenses and regulates sterile compounding pharmacies operating in the state of Missouri. Sterile compounding is the act of compounding a drug that must be sterile and free of harmful microorganisms prior to administration to a patient. Sterile compounding requires the use of aseptic technique in a properly controlled environment to eliminate the risk of preparation contamination. The United States Food and Drug Administration (FDA) has indicated: "Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved which means they have not undergone FDA premarket review for safety, effectiveness and quality."

In 2012, the FDA reported that a Massachusetts sterile compounding pharmacy shipped contaminated injectable drug products to patients and healthcare practitioners that caused a nationwide fungal meningitis outbreak that resulted in more than sixty (60) deaths and seven hundred fifty (750) cases of infection. In its recent April 2016 Guidance Document, the FDA reported that since the 2012 outbreak it has "investigated numerous outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly."

*In response to the 2012 event, the board initiated a review of its sterile compounding rule that included multiple open meetings where the board solicited public input on future rule changes. The review culminated in 2014 with a comprehensive rule draft that contained expansive revisions to the current sterile compounding requirements. The proposed revision was subsequently taken under advisement by the board pending announced changes to the **United States Pharmacopeia** (USP) Chapter 797 which establishes nationwide standards for pharmacy sterile compounding. In the interim, the FDA and the board increased inspections of sterile compounding pharmacies throughout the state. The board also hired a sterile compounding pharmacist in the fall of 2015 to perform focused sterile compounding inspections statewide.*

During inspections in December 2015 and January 2016, board staff observed multiple instances of environmental conditions or improper aseptic technique that could pose a significant risk to the public health and to the sterility or chemical/microbiological stability of sterile compounding preparations dispensed to Missouri citizens. Observations included, but were not limited to, improper sterile compounding, inadequate environmental conditions/controls, improper garbing, inadequate sterile technique, and improper/nonexistent sterility or environmental testing. In December 2015 and January 2016, the board also received multiple notices from the FDA regarding national recalls of sterile preparations dispensed or distributed by nonresident pharmacies licensed in Missouri because of potentially contaminated preparations and/or an inability to guarantee or confirm preparation sterility.

In February 2016, the board convened a sterile compounding board subcommittee to draft an emergency amendment to address the immediate patient safety concerns identified in the recent board inspections and FDA notices. The board's current rule does not contain sufficient enforcement standards to address or prevent the dissemination of potentially life-threatening sterile preparations in Missouri. Due to the highly technical and specialized subject matter, additional time was required to consult with state and national sterile compounding, certification, and microbiological experts/practitioners to determine the appropriate requirements to address the emergency concerns. The subcommittee also held multiple open session meetings in February, March, April, and May of 2016 to receive public comments on the proposed emergency amendment and to assess fiscal impact. In the interim, the board continued to observe improper pharmacy conditions during inspections conducted in February, March, and April of 2016. The board also received additional FDA notices during the first quarter of 2016 regarding national sterile compounding recalls.

In addition to the public meetings held by the board subcommittee in February, March, April, and May 2016, the proposed emergency amendment was also provided to, and reviewed by, the Missouri Hospital Advisory Committee in March and April of 2016. The Missouri Hospital Advisory Committee consists of representatives from the Missouri Hospital Association, the Missouri Society of Health System Pharmacists, the Missouri Pharmacy Association, and representatives from both small and large hospitals throughout the state. Comments from the public and the Hospital Advisory Committee have been incorporated into the emergency amendment.

Significantly, the proposed emergency amendment was derived from the comprehensive rule revision drafted by the board in 2014. However, the emergency amendment has been narrowly tailored to only incorporate those provisions needed to address the emergency issues identified by board staff/the FDA in late 2015 and early 2016. To allow sufficient time for public comment and an assessment of fiscal impact, provisions in the comprehensive 2014 draft that would have required significant facility, structural, or operational changes for Missouri pharmacies have been removed from both the emergency amendment and the corresponding amendment. The board anticipates conducting further rule review once USP Chapter 797 is finalized.

*Absent an emergency amendment, the board would not be able to establish or enforce minimum safety standards that are necessary to protect the lives of Missouri citizens. As a result, the Missouri State Board of Pharmacy finds there is an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. A proposed amendment, which covers the same material, is published in this issue of the **Missouri Register**. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri** and **United States Constitutions**. The Missouri State Board of Pharmacy believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed July 25, 2016, becomes effective August 4, 2016, and expires February 23, 2017.*

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Definitions.

(B) Batch: Compounding of multiple sterile *[product]* **preparation** units in a single discrete process, by the same individuals, carried out during one (1) limited time period.

(D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the *[product]* **preparation**, personnel**,** and environment, according to National Sanitation Foundation (NSF) International standards.

[(E) Class 100 environment: an atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal

standards.

(F) Class 10,000 environment: An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(G) Clean room: A room—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(H) Clean zone: Dedicated space—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner that minimizes the introduction, generation, and retention of particles inside the zone; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

This zone may be open or enclosed and may or may not be located within a clean room.]

(E) Buffer area: An ISO Class 7 or better area where the primary engineering control is physically located that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

*[(I)]***(F)** Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR 2220-2.400(1). Compounded sterile medications may include, but are not limited to*[, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.]***:**

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must or are required to be sterile when they are administered to patients, including, but not limited to the following dosage forms: bronchial and inhaled nasal preparations intended for deposition in the lung, baths and soaks for live organs and tissues, epidural and intrathecal solutions, bladder/wound solutions, injectables, implantable devices and dosage forms, inhalation solutions, intravenous solutions, irrigation solutions, ophthalmic preparations, parenteral nutrition solutions, and repackaged sterile preparations. Nasal sprays and irrigations intended for deposit in the nasal passages may be prepared as nonsterile compounds;

2. An FDA approved manufactured sterile product that is either prepared according to the manufacturers' approved labeling/recommendations or prepared differently than published in such labeling; and

3. Assembling point-of-care assembled systems.

(G) Compounding aseptic containment isolator (CACI): A Restrictive Access Barrier System (RABS) that is designed for compounding sterile hazardous drugs and designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment for Compounded Sterile Preparation (CSPs).

(H) Compounding aseptic isolator (CAI): A RABS specifically designed for compounding sterile non-hazardous pharmaceutical ingredients or CSPs and designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

[(J) Controlled area: For purposes of these regulations, a controlled area is the area designated for preparing sterile products. This is referred to as the buffer zone (i.e., the clean room in which the laminar airflow workbench is located) by the United States Pharmacopoeia (USP).]

(I) Controlled area: For purposes of these regulations, a controlled area is a separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations.

*[(K)]***(J)** Critical area: Any area in the controlled area where *[products]* **preparations** or containers are exposed to the environment.

[(L) Critical site: An opening providing a direct pathway between a sterile product and the environment or any surface coming into contact with the product or environment.]

(K) Critical site: Any surface, pathway, or opening (e.g., vial septa, injection ports, beakers, needle hubs) that provides a direct pathway between a compounded sterile preparation or other ingredient used to compound a sterile preparation and the air, environment or moisture, or that poses a risk of touch contamination.

(L) CSP: Compounded sterile preparation.

[(M) Critical surface: Any surface that comes into contact with previously sterilized products or containers.]

*[(N)]***(M)** Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system**,** and the alteration of a host's inflammatory response system.

*[(O)]***(N)** Emergency dispensing: Is a situation where a Risk Level 3 *[product]* **preparation** is necessary for immediate administration of the *[product]* **preparation** and no alternative product **or preparation** is available and the prescriber is informed that the *[product]* **preparation** is being dispensed prior to appropriate testing. Documentation of the dispensing of the *[product]* **preparation**, the prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.

*[(P)]***(O)** High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for a *[Class 100 clean room]* **ISO Class 5 environment**.

(P) In-use time/date: The time/date before which a conventionally manufactured product or a CSP must be used after it has been opened or needle-punctured.

[(Q) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits.]

(Q) ISO Class 5: An area with less than three thousand five hundred twenty (3,520) particles (0.5 μm and larger in size) per cubic meter.

(R) ISO Class 7: An area with less than three hundred fifty-two thousand (352,000) particles (0.5 μm and larger in size) per cubic meter.

(S) Multiple-dose container: A multiple unit container for articles or compounded sterile preparations that contains more than one (1) dose of medication and usually contains an antimicrobial preservative.

*[(R)]***(T)** Parenteral: A sterile preparation of drugs for injection

through one (1) or more layers of skin.

(U) Point-of-care assembled system: A closed system device that creates a physical barrier between diluents, fluids, or other drug components and is designed to be activated by the end user by allowing the components to mix prior to administration.

(V) Primary engineering control (PEC): A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but may not be limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, RABS such as compounding aseptic isolators (CAIs), or compounding aseptic containment isolators (CACIs).

*[(S)]***(W)** Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the *[product]* **preparation** and with the same container or closure system.

*[(T)]***(X)** Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug *[products]* **preparations** lead to *[products]* **preparations** that meet predetermined standards of quality.

*[(U)]***(Y)** Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components**,** and final sterile *[products]* **preparations** prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity**,** and sterility.

(Z) Restricted access barrier system (RABS): A primary engineering control that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a CAI or CACI.

*[(V)]***(AA)** Repackaging: The subdivision or transfer of a compounded *[product]* **preparation** from one **(1)** container or device to a different container or device.

[(W) Sterile pharmaceutical: A dosage form free from living microorganisms.]

(BB) Single-dose/single-unit container/vial: A container/vial of medication intended for administration that is meant for use in a single patient for a single case, procedure, or injection.

*[(X)]***(CC)** Sterilization: A validated process used to render a *[product]* **preparation** free of viable organisms.

*[(Y)]***(DD)** Temperatures:

1. Frozen means temperatures between twenty**-five degrees** below zero and ten degrees **below zero** Celsius (-*[20]***25** and **-**10°C) (*[four]* **thirteen degrees** below zero and fourteen degrees Fahrenheit *(-[4]***13** and 14°F))*[.]***;**

2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8°C) (thirty-six and forty-six degrees Fahrenheit (36 and 46°F))*[.]***; and**

3. *[Room temperatures means room temperatures between fifteen and thirty degrees Celsius (15 and 30°C) (fifty-nine and eighty-six degrees Fahrenheit (59 and 86°F)).]* **Controlled room temperatures means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25° Celsius (68 to 78° F). Excursions between 15° and 30° Celsius (59 to 86° F) as commonly experienced in pharmacies and other facilities shall be deemed compliant.**

(EE) USP: ***The United States Pharmacopeia and the National Formulary*** **(USP-NF) as adopted and published by the United States Pharmacopeial Convention, effective May 2013. Copies of the USP-NF are published by, and available from, USP, 12601 Twinbrook Parkway, Rockville, MD 20852-1790 or online at http://www.usp.org/. The USP-NF is incorporated herein by reference. This rule does not include any later amendments or additions to the USP-NF.**

*[(Z)]***(FF)** Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a *[product]* **preparation** meeting predetermined specifications and quality attributes.

*[(AA)]***(GG)** Definitions of sterile compounded *[products]* **preparations** by risk level:

1. Risk Level 1: Applies to compounded sterile *[products]* **preparations** that exhibit characteristics A., B., *[and]* **or** C., stated below. All Risk Level 1 *[products]* **preparations** shall be prepared with sterile equipment*[,]* **and** sterile ingredients and solutions *[and sterile contact surfaces for the final product]* **in an ISO Class 5 environment**. Risk Level 1 includes the following:

A. *[Products]* **Preparations**:

(I) Stored at **controlled** room temperature and *[completely administered within]* **assigned a beyond-use date of** forty-eight (48) hours *[after preparation]* **or less**; or

(II) Stored under refrigeration *[for]* **and assigned a beyond-use date of** seven (7) days or less *[before complete administration to a patient over a period not to exceed forty-eight (48) hours]*; or

(III) *[Frozen for thirty (30) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours.]* **Stored frozen and assigned a beyond-use date of thirty (30) days or less;**

B. Unpreserved sterile *[products]* **preparations** prepared for administration to one (1) patient or batch-prepared *[products]* **preparations** containing suitable preservatives prepared for administration to more than one (1) patient **with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule***[.]***;**

C. *[Products]* **Preparations** prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers **with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule***[.]***;**

2. Risk Level 2: Sterile *[products]* **preparations** exhibit characteristic A., B., or C., stated below. All Risk Level 2 *[products]* **preparations** shall be prepared with sterile equipment*[,]* **and** sterile ingredients *[and solutions and sterile contact surfaces for the final product]* **in an ISO Class 5 environment** and with closed-system transfer methods. Risk Level 2 includes the following:

A. *[Products stored beyond seven (7) days under refrigeration, stored beyond thirty (30) days frozen or administered beyond forty-eight (48) hours after preparation and storage at room temperature.]* **Preparations stored under refrigeration and assigned a beyond-use date greater than seven (7) days, or preparations stored frozen and assigned a beyond-use date greater than thirty (30) days, or preparations stored at controlled room temperature and assigned a beyond-use date greater than forty-eight (48) hours;**

B. Batch-prepared *[products]* **preparations** without preservatives that are intended for use by more than one (1) patient*[.]***;**

C. *[Products]* **Preparations** compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder)*[.]***;**

3. Risk Level 3: Sterile *[products]* **preparations** exhibit either characteristic A. or B.:

A. *[Products]* **Preparations** compounded from nonsterile ingredients or compounded with nonsterile components, containers**,** or equipment before terminal sterilization*[.]***;**

B. *[Products]* **Preparations** prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or

open reservoir before terminal sterilization.

(2) Policy and Procedure Manual/Reference Manuals.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2**,** and 3 *[products]* **compounding**, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis. The pharmacy shall have current reference materials related to sterile *[products]* **preparations**.

(3) Personnel Education, Training**,** and Evaluation.

(A) Risk Level 1: All pharmacy personnel preparing sterile *[products]* **preparations** must receive suitable didactic and experiential training **in aseptic technique and procedures and shall be skilled and trained to accurately and competently perform the duties assigned. Additional training must be provided if the risk level of sterile activity conducted by the individual changes or if there is a change in compounding methods performed. To ensure competency, individuals preparing sterile preparations must successfully pass an Aseptic Technique Skill Assessment that complies with section (10) of this rule. The pharmacy shall establish policies and procedures for staff training and assessment.**

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training **must** include*[s]* assessment of competency in all Risk Level 2 procedures via process simulation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training**,** and experience to prepare Risk Level 3 *[products]* **preparations**. The pharmacist knows principles of good compounding practice for risk level *[products]* **preparations**, including—

1. Aseptic processing;
2. Quality assurance of environmental, component, and *[end-product]* **end-preparation** testing;
3. Sterilization; and
4. Selection and use of containers, equipment, and closures.

(4) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies**,** and **compounding** equipment must be stored *[according to manufacturer or USP requirements]* **and maintained in a manner that will maintain the chemical and microbiological stability of CSPs**. Refrigeration *[and]***,** freezer **and, if applicable, incubator** temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of *[products]* **drugs and supplies** from boxes shall be done outside **the** controlled **and buffer** areas. Removal of used supplies from the controlled area shall be done at least daily. *[Product]* **Preparation** recall procedures must **comply with section (21) of this rule and must** permit retrieving affected *[products]* **preparations** from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, **the pharmacy must establish** procedures *[include]* **for** procurement, identification, storage, handling, testing, and recall of components and finished *[products]* **preparations**. Finished *[but untested]* Risk Level 3 *[products]* **preparations awaiting test results** must be quarantined under minimal risk for contamination **in a manner that will maintain chemical and microbiological stability**.

[(5) Facilities and Equipment.

(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled area must be clean and well lit. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected regularly. Sterile products must be prepared in at least a Class 100 environment (the critical area). Computer entry, order processing, label generation, and record keeping shall be performed outside the critical area. The critical area must be disinfected prior to use. A workbench shall be recertified every six (6) months and when it is moved; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, the controlled area must meet Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room standards; critical area work surface must be cleaned between batches; floors should be disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental monitoring of air and surfaces. Automated compounding devices must be calibrated and verified as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis must be cleaned prior to use as stated above.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, products must be prepared in a Class 100 workbench in a Class 10,000 clean room, in a Class 100 clean room or within a positive pressure barrier isolator. Access to the clean room must be limited to those preparing the products and who are in appropriate garb. Equipment must be cleaned, prepared, sterilized, calibrated, and documented according to manufacturer's standards. Walls and ceilings must be disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final product must be sterilized before introduction in the clean room. Appropriate cleaning and disinfection of the environment and equipment are required.

(6) Apparel.

(A) Risk Level 2: In the controlled area, personnel wear low particulate, clean clothing covers. Head and facial hair is covered. Gloves, gowns, and masks are required. During sterile preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is compromised.

(B) Risk Level 3: In addition to Risk Level 2 requirements, clean room apparel must be worn inside the controlled area at all times during the preparation of Risk Level 3 sterile products except when positive pressure barrier isolation is utilized. Attire shall consist of a low-shedding coverall, head cover, face mask, and shoe covers.]

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas.

(A) Risk Level 1: Risk Level 1 preparations must be prepared in a PEC located in a controlled area that meets the requirements of this rule. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected as provided in section (17) of this rule. Activities within the critical area shall be kept to a minimum to maintain the ISO classified environment. Primary engineering controls shall meet the requirements of section (6) of this rule; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, Risk Level 2 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. Applicable environmental monitoring of air and surfaces must be conducted. Risk Level 2 preparations shall at a minimum remain a Risk Level 2 for the life of the preparation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC

located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS. Once compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation.

(D) Automated compounding devices shall be tested for content, volume, and weight accuracy prior to both initial and daily use according to manufacturer procedures. Test results shall be reviewed by a pharmacist to ensure compliance. The identity of the reviewing pharmacist and the review date shall be documented in the pharmacy's records.

(E) All PECs and ISO classified areas shall be certified to ensure compliance with the requirements of this rule prior to beginning sterile compounding activities and every six (6) months thereafter. Certification shall be conducted by competent staff/vendors using recognized and appropriate certification and testing equipment. Certification results shall be reviewed by a pharmacist once received. Deficiencies or failures shall be investigated and corrected prior to further compounding which may include recertification of the PEC/ISO classified area.

1. The PEC and ISO classified areas must be recertified when— 1) any changes or major service occurs that may affect airflow or environmental conditions or 2) the PEC or room is relocated or the physical structure of the ISO classified area has been altered.

2. Corrections may include, but are not limited to, changes in the use of the affected PEC or ISO classified area or initiating a recall. The identity of the pharmacist conducting the required review and the review date shall be documented in the pharmacy's records.

(F) Pressure differential: If the controlled area is equipped with a device to monitor pressure differential, pressure differential results must be recorded and documented each day that the pharmacy is open for pharmacy activities. Alternatively, a continuous monitoring system may be used to record pressure differential results if the system maintains ongoing documentation of pressure recordings or maintains pressure alerts that are reviewed daily.

(6) Primary Engineering Controls (PECs).

(A) PECs must be properly used, operated, and maintained and must be located out of traffic patterns and away from conditions that could adversely affect their operation or disrupt intended airflow patterns (e.g., ventilation systems or cross-drafts).

(B) PECs shall maintain ISO Class 5 or better conditions during dynamic operating conditions and while compounding sterile preparations, including, when transferring ingredients into and out of the PEC and during exposure of critical sites.

(C) PECs shall provide unidirectional (laminar flow) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

(D) The recovery time to achieve ISO Class 5 air quality in any PEC shall be identified in the pharmacy's policies and procedures. Procedures must be developed to ensure adequate recovery time is allowed before or during compounding operations and after material transfer.

(7) Controlled Areas. The controlled area shall be designed, maintained, and controlled to allow effective cleaning and disinfection and to minimize the risk of contamination and the introduction, generation, and retention of particles inside the PEC.

(A) Controlled areas must be clean and well-lit and shall be free of infestation by insects, rodents, and other vermin. Trash shall be disposed of in a timely and sanitary manner and at least daily. Tacky mats or similar articles are prohibited in the controlled area or any ISO classified environment.

(B) Traffic flow in or around the controlled area shall be minimized and controlled. Food items, chewing gum, eating, drinking, and smoking are prohibited in the area.

(C) Nonessential objects that shed particles shall not be brought into the controlled area, including, but not limited to, pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads). Furniture, carts, supplies, and equipment shall be removed from shipping cartons/containers and properly cleaned and disinfected with sterile alcohol before entering any ISO classified area. No shipping or other external cartons may be taken into the controlled area or an ISO classified area.

(D) Only supplies essential for compounding shall be stored in the controlled area. Supplies or other non-essential equipment shall not be stored in or on the PEC.

(8) Garbing and Hand Hygiene. Individuals engaged in, or assisting with, CSPs shall be trained and demonstrate competence in proper personal garbing, gloving, and hand hygiene. Competence must be documented and assessed through direct visual observation as part of the aseptic technique skill assessment required by this rule.

(A) Risk Level 1: Low-particulate and non-shedding gowns, hair covers, gloves, face masks, and beard covers must be worn during compounding and cleaning. All head and facial hair must be covered. During sterile preparation, gloves shall be disinfected before use and frequently thereafter with a suitable agent and changed when integrity is compromised. All personnel in the controlled area must be appropriately garbed as required by this section.

(B) Risk Level 2 and Risk Level 3: In addition to Risk Level 1 requirements, shoe covers and sterile gloves must be worn while compounding and cleaning, including, over RABS gloves. All personnel in the controlled or buffer area must garb as required by this section.

*[(7)]***(9)** Aseptic Technique and *[Product]* Preparation. **Appropriate quality control methods shall be maintained over compounding methods at all times to ensure proper aseptic technique.**

(A) Risk Level 1: Sterile *[products]* **preparations** must be prepared in *[a Class 100]* **an ISO Class 5** environment. Personnel shall scrub their hands and forearms *[for an appropriate period at the beginning of each aseptic compounding process]* **a minimum of thirty (30) seconds and remove debris from underneath fingernails under warm running water before donning the required gloves**. Eating, drinking**,** and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the *[product]* **preparation** to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration**,** and integrity before use. Only materials essential for aseptic compounding shall be placed in the *[workbench]* **PEC**. *[Surfaces of ampules and vials shall be disinfected before placement in the workbench.]* **Supplies, equipment, and the surfaces of ampules and vials shall be disinfected before entering the PEC by wiping the outer surface with sterile alcohol or an equivalently effective non-residue generating disinfectant.** Sterile components shall be arranged in the *[workbench]* **PEC** to allow **a clear,** uninterrupted *[laminar airflow]* **path of HEPA-filtered air** over critical *[surfaces of needles, vials, ampules, etc]* **sites**. Automated devices and equipment shall be cleaned, disinfected**,** and placed in the *[workbench]* **PEC** to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions**, if applicable**. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

(B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing **the** formula, components, procedures, sample label, and

final evaluation shall be made for each *[product]* **preparation** batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile *[products]* **preparations**, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end *[product]* **preparation** for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet **compendial** standards *[if available, as]* **or must be** verified by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining *[product]* **preparation** integrity throughout the shelf life. Sterilization methods must be based on properties of the *[product]* **preparation, and must be conducted in a method recognized for the preparation and confirmed through sterility testing according to USP requirements**.

(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container.

(E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an antimicrobial preservative may be used in compounding until the assigned in-use date which shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g., needle-puncture). The in-use date must be placed on the vial/container.

[(8) Process Validation.

(A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process validation of aseptic technique before compounding sterile products. Pharmacy personnel competency must be reevaluated by process validation at least annually, whenever the quality assurance program yields an unacceptable result, or whenever unacceptable techniques are observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective action taken, and the process simulation test performed again.

(B) Risk Level 2: In addition to Risk Level 1 requirements, process simulation procedures shall cover all types of manipulations, products and batch sizes.

(C) Risk Level 3: In addition to all Risk Level 1 and 2 requirements, written policies shall be maintained to validate all processes, procedures, components, equipment and techniques.]

(10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must take and successfully pass an aseptic technique skill assessment to verify aseptic competency. The assessment must include a direct visual observation of the individual's aseptic competency during a process simulation that represents the most challenging or stressful conditions encountered or performed by the person being evaluated. The assessment must include media fill testing for all risk levels.

(A) The required visual observation shall assess:

1. Proper aseptic technique, manipulations, and work practices, including, but not limited to, avoiding touch contamination, proper use of first air, and if applicable, sterilizing high risk CSPs;

2. Cleaning and disinfection;

3. Hand hygiene, gloving, and garbing;

4. Identifying, weighing, and measuring of ingredients;

5. Maintaining sterility in ISO Class 5 areas;

6. Labeling and inspecting CSPs for quality.

(B) Media-Fill Testing. Pharmacies shall establish and follow policies and procedures for media-fill testing. Media-fill testing shall comply with USP Chapter 797's recommended procedures and methods and must be conducted using the most challenging or stressful conditions/compounding actually encountered or performed by the person being evaluated using the same container or closure. A minimum of three media-fill tests must be completed during initial media-fill testing and one (1) media-fill test completed for ongoing testing.

(C) Frequency: The required Aseptic Technique Skill Assessment must be conducted prior to initial compounding and every twelve (12) months thereafter for Risk Levels 1 and 2 compounding and every six (6) months thereafter for Risk Level 3 compounding. Additionally, an Aseptic Technique Skill Assessment must be conducted whenever the quality assurance program yields an unacceptable result, whenever unacceptable techniques are observed, if the risk level of sterile activity conducted by the individual changes, or if there is a change in compounding methods performed.

(D) Individuals who fail written tests; visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must undergo immediate requalification through additional training by competent compounding personnel. Individuals who fail visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must pass three (3) successive reevaluations in the deficient area before they can resume compounding of sterile preparations.

*[(9)]***(11)** Record Keeping.

(A) Risk Level 1: The following must be documented:

1. Training and competency evaluation of pharmacy personnel involved in sterile *[product preparation]* **compounding, including, the dates and results of the required aseptic technique training, aseptic technique skill assessment, and media-fill testing**;

2. Refrigerator**,** *[and]* freezer **and, if applicable, incubator** temperature logs;

3. Certification *[of workbenches]* **dates and results for any PEC or ISO classified area**;

4. *[Copies of any m]***M**anufacturer *[standards]* **manuals** that are relied upon to maintain compliance with this rule; *[and]*

5. Other facility quality control logs as appropriate including all maintenance, cleaning, and calibration records*[.]***; and**

6. If applicable, pressure recordings including documentation of the review of continuous monitoring system results as required by subsection (5)(F).

(B) Risk Level 2: In addition to Risk Level 1 requirements, records of any *[end-product]* **end-preparation** testing and batch preparation records must be maintained.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 *[products]* **preparations** must include:

1. Preparation work sheet;

2. Sterilization records;

3. Quarantine records, if applicable;

4. *[End-product]* **End-preparation** evaluation and testing records as required in section *[(12)]* **(14)**; and

5. Ingredient validation records as required in section *[(12)]* **(14)**.

(D) All records and reports shall be maintained **either electronically or physically** for two (2) years and shall be readily retrievable*[,]* **and** subject to inspection*[s]* by the board of pharmacy or its agents. **At a minimum, records shall be physically or electronically produced immediately or within two (2) hours of a request from the board or the board's authorized designee.**

*[(10)]***(12)** Labeling.

(A) *[Risk Level 1:]* Sterile *[products dispensed to patients]*

preparations shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information *[affixed to a permanent label]*:

1. Beyond-use date;

2. Storage requirements **if stored at other than controlled room temperature**;

3. Any device specific instructions; *[and]*

4. Auxiliary labels, when applicable*[.]***; and**

5. If applicable, a designation indicating the preparation is hazardous.

[(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: All requirements for Risk Level 1 must be met.]

*[(11)]***(13)** Beyond-Use Dating.

(A) Risk Level 1 **and Risk Level 2**: All sterile *[products]* **preparations** must bear a beyond-use date. Beyond-use dates *[are]* **must be** assigned based on current drug **and microbiological** stability information and sterility considerations.

[(B) Risk Level 2: All requirements for Risk Level 1 must be met.]

*[(C)]***(B)** Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all *[expiration]* **beyond-use** dates, including laboratory testing of *[product]* **preparation** stability, pyrogenicity, particulate contamination**,** and potency. *[Expiration dating not specifically referenced in the product's approved labeling or not established by product specific instrumental analysis, shall be limited to thirty (30) days.]* Beyond-use dating not specifically referenced in the products approved labeling or not established by *[product]* **preparation** specific instrumental analysis shall be limited to thirty (30) days. There must be a reliable method for establishing all beyond-use dating. *[Products maintaining beyond-use dating]* **Preparations assigned a beyond-use date** of greater than thirty (30) days shall have lab testing of *[product]* **preparation** stability and potency.

*[(12)]***(14)** End-*[product]***Preparation** Evaluation.

(A) Risk Level 1: The final *[product]* **preparation** must be inspected for **clarity,** container leaks, integrity*[,]* **and appropriate** solution cloudiness or phase separation, *[particulates in solution, appropriate]* solution color, and solution volume. The pharmacist must verify that the *[product]* **preparation** was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of *[products]* **preparations** for any particulate and/or foreign matter must be used as part of the inspection process**, provided an alternate means of inspection shall be used if a visual inspection or exposure to the preparation may pose a health hazard**.

(B) Risk Level 2: All Risk Level 1 requirements must be met.

(C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of *[end-product]* **end-preparation** sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch *[products]* **preparations** shall be established if *[end-product]* **preparation** testing results are unacceptable. *[All sterile products]* **A sample from each sterile preparation/batch** must be tested for sterility. *[All parenteral sterile products]* **A sample from each parenteral sterile preparation/batch** must also be tested for pyrogenicity. *[Sterile products compounded from nonsterile components]* **Risk Level 3 preparations** must be quarantined **and stored to maintain chemical and microbiological stability** pending results of *[end-product]* **end-preparation** testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted according to *[one (1) of the USP methods]* **a method recognized for the preparation by USP Chapter 71**.

2. Pyrogen/Endotoxin testing: *[Each s]***S**terile parenteral *[product]* **preparations** prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to *[recommended USP methods]* **a method recognized by USP Chapter 151 for pyrogen testing and recognized by USP Chapter 85 for endotoxin testing**.

3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile *[product]* **preparation** prepared from non-sterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:

A. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis**,** and other relevant qualities;

B. All weighings, volumetric measurements, and additions of ingredients were carried out properly;

C. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct; and

D. The final potency is confirmed by instrumental analysis for sterile *[products]* **preparations** that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile *[Product]* **Preparation**: When a compounded Risk Level 3 *[product]* **preparation** must be released prior to the completion of testing, the sterile *[product]* **preparation** may be dispensed pending test results. **Emergency dispensing shall be defined as, and comply with, subsection (1)(N) of this rule.**

*[(13)]***(15)** *[Handling Sterile Products Outside the Pharmacy]* **Storage, Handling, and Transport**.

[(A) Risk Level 1:] **Sterile preparations shall be packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability until the assigned beyond-use date or until delivery to the patient or intended recipient.** The pharmacist-in-charge shall assure the environmental control of all sterile compounded *[products]* **preparations** shipped. Sterile *[products]* **preparations** shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile *[products]* **preparations**. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of *[products]* **preparations** with common storage characteristics and for specific *[products]* **preparations** where unique storage conditions are required to retain adequate stability and *[product]* **preparation** quality.

[(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: All requirements for Risk Level 1 must be met.]

(16) Point-of-Care Assembled Systems. Assembly of point-of-care assembled systems shall be considered Risk Level 1 compounding. Point-of-care assembled systems shall be assigned a beyond-use date which may exceed the beyond-use-date authorized for Risk Level 1 preparations provided the date is assigned in accordance with the manufacturer's recommendations or labeling.

(A) When dispensed, an assembled non-activated system shall be labeled with beyond-use dates for both activated and non-activated states. The compounding record must document both dates. The beyond-use date of an assembled non-activated system shall be limited to a maximum of fifteen (15) days unless the pharmacy has documentation from the system's manufacturer that a longer date is acceptable.

(B) Point-of-care assembled systems shall be assembled and stored in accordance with the manufacturer's labeling and recommendations.

(17) General Cleaning and Disinfection Requirements. Except as otherwise provided herein, cleaning and disinfection of controlled and buffer areas, supplies, and equipment shall be performed and conducted in accordance with USP Chapter 797 timeframes and procedures. Controlled areas that do not meet ISO air classifications shall be cleaned and disinfected as required by USP Chapter 797 for segregated compounding areas. If compounding is done less frequently than the cleaning and disinfection timeframes specified in USP Chapter 797, cleaning and disinfection must occur before each compounding session begins.

(A) The pharmacy shall establish and follow written policies and procedures governing all aspects of cleaning and disinfection, including approved cleaning/disinfecting agents and materials, schedules of use and methods of application.

(B) Individuals shall be trained in proper cleaning and disinfection procedures prior to performing such activities. Training shall include direct visual observation of the individual's cleaning and disinfecting process by qualified staff. The individual shall be annually reassessed for competency through direct visual observation. Documentation of the required training and training dates shall be maintained in the pharmacy's records. Individuals who fail to demonstrate competency shall be reinstructed and successfully reevaluated prior to any further cleaning or disinfection.

(C) Cleaning and disinfection activities shall be performed using approved cleaning/disinfection agents and procedures described in the pharmacy's written policies and procedures. Manufacturers' directions for minimum contact time shall be followed.

(D) All cleaning tools (e.g., wipes, sponges, and mop heads) must be low-lint and dedicated for use in the controlled area and buffer area.

(E) Primary engineering controls shall be cleaned with a germicidal agent followed by sterile alcohol. Sterile water for irrigation shall be used to dilute germicidal agents used inside the PEC that require dilution.

(F) At a minimum, the critical area shall be cleaned and disinfected prior to compounding, between batches and whenever contamination is suspected using sterile alcohol which is allowed to dry immediately prior to compounding.

*[(14)]***(18)** Cytotoxic Drugs.

(A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:

1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or *[an isolator]* **an CACI**. If used for other *[products]* **preparations**, the cabinet must be thoroughly cleaned;

2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves**,** and gowns with tight cuffs;

3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile *[products]* **preparations. Chemotherapy preparations should be compounded using a closed system transfer device**;

4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state**,** and federal requirements;

5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual; **and**

6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

[(15) Exemption: Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.]

*[(16)]***(19)** In addition to the requirements outlined in this rule, all standards and requirements as outlined in 20 CSR 2220-2.400 must be maintained. Pharmacies that are registered with the Food and Drug Administration (FDA) are exempt from the distribution restrictions in 20 CSR 2220-2.400(12) for compounded sterile pharmaceuticals distributed with FDA's knowledge and enforcement discretion. This exemption applies only to a twenty-four (24)-hour course of therapy which is needed:

(A) To treat an emergency situation; or

(B) For an unanticipated procedure for which a time delay would negatively affect a patient outcome. In order to continue beyond twenty-four (24) hours, the pharmacy must obtain a prescription and comply with all record and labeling requirements as defined by law or regulation.

(20) Remedial Investigations: A remedial investigation shall be required if: 1) any sampling or testing required by this rule demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling/testing or 2) if a highly pathogenic microorganism is detected in any preparation or ISO classified area (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, fungus, or yeasts).

(A) CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. All affected areas shall be resampled to ensure a suitable state of microbial control prior to further compounding. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(B) The pharmacy shall notify the board in writing within seven (7) days if any preparation or environmental monitoring/testing detects a highly pathogenic microorganism, regardless of CFU count.

(21) Recalls. A recall must be initiated when a CSP is deemed to be misbranded, adulterated, or non-sterile or if end-preparation testing results are out of specification. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety. In cases where the CSP has the potential to harm the patient, the same notification shall be provided to all patients that received the recalled CSP(s). Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days. The pharmacy shall document their activities related to the recall.

*AUTHORITY: sections 338.140[,] **and** 338.240, **RSMo Supp. 2013,** [and] **section** 338.280, RSMo 2000**,** and section 338.010, RSMo Supp. [2007] **2014**. This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. For intervening history, please consult the **Code of State Regulations**. Emergency amendment filed July 25, 2016, effective Aug. 4, 2016, expires Feb. 23, 2017. A proposed amendment covering this same material is published in this issue of the **Missouri Register**.*

Under this heading will appear the text of proposed rules and changes. The notice of proposed rulemaking is required to contain an explanation of any new rule or any change in an existing rule and the reasons therefor. This is set out in the Purpose section with each rule. Also required is a citation to the legal authority to make rules. This appears following the text of the rule, after the word "Authority."

Entirely new rules are printed without any special symbology under the heading of proposed rule. If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission. Rules which are proposed to be amended will have new matter printed in boldface type and matter to be deleted placed in brackets.

An important function of the *Missouri Register* is to solicit and encourage public participation in the rulemaking process. The law provides that for every proposed rule, amendment, or rescission there must be a notice that anyone may comment on the proposed action. This comment may take different forms.

If an agency is required by statute to hold a public hearing before making any new rules, then a Notice of Public Hearing will appear following the text of the rule. Hearing dates must be at least thirty (30) days after publication of the notice in the *Missouri Register.* If no hearing is planned or required, the agency must give a Notice to Submit Comments. This allows anyone to file statements in support of or in opposition to the proposed action with the agency within a specified time, no less than thirty (30) days after publication of the notice in the *Missouri Register*.

An agency may hold a public hearing on a rule even though not required by law to hold one. If an agency allows comments to be received following the hearing date, the close of comments date will be used as the beginning day in the ninety- (90-) day-count necessary for the filing of the order of rulemaking.

If an agency decides to hold a public hearing after planning not to, it must withdraw the earlier notice and file a new notice of proposed rulemaking and schedule a hearing for a date not less than thirty (30) days from the date of publication of the new notice.

Proposed Amendment Text Reminder:
Boldface text indicates new matter.
[Bracketed text indicates matter being deleted.]

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 45—Division of Developmental Disabilities
Chapter 3—*[Care and Habilitation]* ***Services and Supports***

PROPOSED AMENDMENT

9 CSR 45-3.030 *[Individualized Supported Living Services—]* **Individual Rights**. The department is amending the title of the chapter, the title of the rule, the rule purpose, and sections (1)–(5).

PURPOSE: This amendment adds language to broaden the application of the rule to cover all individuals eligible for division services and to more clearly define individual rights. Additionally, this amendment updates the rule with more current terminology in the field of developmental disabilities.

PURPOSE: This rule [assures] ***defines*** *the rights of persons [receiving individualized supported living]* ***eligible for*** *services* ***from the Division of Developmental Disabilities (Division of DD)***.

[(1) Each individualized supported living provider shall have policies and procedures that enhance and protect the human, civil and statutory rights of all individuals served.]

*[(2)]***(1)** All *[persons receiving individualized supported living services]* **individuals served by the Division of DD** shall be entitled to the following rights and privileges without limitation**, unless otherwise provided by law**:

(A) To be treated with respect and dignity as a human being;

(B) To have the same legal rights and responsibilities as any other citizen*[, unless otherwise stated by law]*;

(C) To receive services regardless of race, creed, marital status, national origin, disability**, religion, sexual orientation, gender,** or age;

(D) To be free from physical**, emotional, sexual,** and verbal abuse**, and financial exploitation**;

(E) To receive *[appropriate]* services and supports **to achieve the maximum level of independence**;

(F) To have *[reasonable]* access to **all** rules, policies**,** and procedures *[pertaining to services and supports provided by the agency]* **governing the operations of the Division of DD in an accessible format, and to have those rules, policies, and procedures explained in a manner that is easily understood**;

(G) Within one's financial means, to have a choice where to live and whether or not to share a home with other people;

(H) To direct one's own person-centered planning process and to choose others to be included in that process;

(I) To participate fully in the community;

(J) To communicate in any form and to have privacy of communications;

(K) To accept or decline supports and services;

(L) To have freedom of choice among Division of DD approved providers;

(M) To seek employment and work in competitive integrated settings;

(N) To participate or decline participation in any study or experiment;

(O) To choose where to go to church or place of worship, or to refuse to go to a church or place of worship;

*[(G)]***(P)** To have **rights,** services, supports, and clinical records regarding services explained in a manner that is easily understood **and in an accessible format**; *[and]*

*[(H)]***(Q)** To have *[clinical]* **all of an individual's** records *[regarding services]* maintained in a confidential manner*[.]***;**

(R) To report any violation of one's rights free from retaliation and without fear of retaliation; and

(S) To be informed on how to make an inquiry, file a complaint or report a violation of one's rights, and to be assisted in these processes, if requested.

(2) Adults who do not have a legal guardian have the right to designate a representative to act on one's behalf for purposes of receiving services from the Division of DD.

[(3) An individual receiving services or his/her parent, guardian or authorized representative shall be informed of his/her rights in language that is easily understood.

(A) At the time of enrollment and anytime changes are made to the description of rights, the provider agency shall give each individual or his/her parent, guardian or legal representative a written description of the individual's rights and how to exercise them.

(B) Individualized supported living providers shall read and

explain the description of rights to individuals who require assistance because they are unable to read or do not understand the written description.]

(3) An individual's rights as outlined in section one (1) may not be restricted, including, but not limited to, by a provider of targeted case management or home and community based services, without due process. Due process under this provision includes the right to be notified and heard on the limitation or restriction, the right to be assisted through external advocacy if an individual disagrees with the limitation or restriction, and the right to be informed of available options to restore the individual's rights.

[(4) Each provider shall have policies and procedures for the behavioral management of individuals served.

(A) Provider staff shall deal with disruptive, destructive and inappropriate behaviors by providing information, instruction and guidance on appropriate and acceptable behavior.

(B) Behavior management shall be conducted in a manner that does not demean the individual but rather promotes and builds positive growth, controlled behavior and positive self-image.

(5) Each individual shall be given the name, address and phone number of the department's client rights monitor and informed that the client rights monitor may be contacted regarding complaints of abuse, neglect or violation of rights.]

*AUTHORITY: section 630.050, RSMo [(1994)] **Supp. 2013**. This rule was previously filed as 9 CSR 30-5.040. Emergency rule filed Aug. 4, 1992, effective Sept. 1, 1992, expired Dec. 29, 1992. Original rule filed Aug. 4, 1992, effective Feb. 26, 1993. Amended: Filed May 25, 1995, effective Dec. 30, 1995. Amended: Filed July 25, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Amber L. Daugherty, Assistant General Counsel, Department of Mental Health, PO BOX 687, 1706 E. Elm Street, Jefferson City, MO 65102. To be considered, comments must be delivered by regular mail, express or overnight mail, or by courier within thirty (30) days after publication in the **Missouri Register**. If to be hand-delivered, comments must be brought to the Department of Mental Health at 1706 E. Elm, Jefferson City, Missouri. No public hearing is scheduled.*

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 45—Division of Developmental Disabilities
Chapter 3—*[Care and Habilitation] Services and Supports*

PROPOSED AMENDMENT

9 CSR 45-3.040 Rights of *[Protectors,] Designated Representatives,* Parents, and Guardians. The department is amending the title of the chapter, the title of the rule, the rule purpose, and sections (1)–(5).

PURPOSE: This amendment updates the rule with current terminology in the field of developmental disabilities and to be in compliance with the final Home and Community-Based Services regulation published in January 2014 by the Center for Medicare and Medicaid Services.

*PURPOSE: This rule prescribes policies for designation of [protectors] **representatives** and recognition of certain rights of [protectors] **designated representatives**, parents and guardians of [clients of] **individuals receiving services from** the Division of [Mental Retardation and] Developmental Disabilities **(Division of DD)**.*

(1) **Definitions.**

(A) *[The term protector means]* **Designated representative—** a parent, relative**,** or other person designated by an adult *[client that]* **who** does not have a guardian. The *[protector shall be recognized by the division to assist the client in planning and participating in habilitation]* **designated representative may participate in the person-centered planning process and development of the individual support plan, at the request of, and as directed by, the individual**.

(B) Circle of support—team supporting the individual and participating in the person centered planning process.

(C) Person centered planning process—a process directed by the individual, with the inclusion of a circle of support created by or with the individual, which may include a guardian, public administrator, the individual, and/or persons freely chosen by the individual who are able to serve as important contributors to the process. The person-centered planning process enables and assists the individual to access a personalized mix of paid and non-paid services and supports that will assist him/her to achieve personally defined outcomes. These trainings, supports, therapies, treatments, and/or other services will become part of the individualized support plan.

(D) Individual Support Plan (ISP)—A document that results from the person centered planning process, which identifies the strengths, capacities, preferences, needs, and personal outcomes of the individual. The ISP includes a personalized mix of paid and non-paid services and supports that will assist the person to achieve personally defined outcomes.

(2) The *[d]**D***ivision **of DD** shall recognize *[and encourage]* **that the ISP process is directed by the individual and their circle of support.** *[p]**P***arents **and legal guardians,** who are willing and able to exercise their rights, *[to be involved in clients' comprehensive evaluations, care, habilitation, placement]* **may participate in person-centered planning, development and implementation of the ISP, and**/or referral as set out in this rule.

(3) As set out in section 633.110, RSMo, parents of minor *[clients]* **children and youth** and legal guardians have the right to approve or refuse *[care, habilitation, referral]* **supports** or placement of their children or wards.

(4) Adult**s** *[clients]* who have not been declared legally incapacitated may give their written consent for parents, relatives**,** or other persons to serve as their *[protectors]* **designated representative** to advocate for and advise, guide and encourage the *[clients]* **individual** and members of the *[interdisciplinary]* **individual support plan** team in developing and *[providing habilitation]* **implementing individual support** plans. **Written consent for designated representatives shall include written authorization to disclose protected health information.**

(A) In accordance with **the federal Health Insurance Portability and Accountability Act of 1996, as amended, and** departmental policy, the consent shall authorize the *[protectors']* **designated representatives'** access to those *[client]* **individual** records specified by the *[clients]* **individual** and for periods of time specified by the *[clients]* **individual**.

(B) *[Protectors]* **Designated representatives** shall not have the right to approve or refuse *[care, habilitation,]* referral, **support,** or

placement of *[clients]* **individuals and should act as the individual's advocate against or in support of recommended changes**.

(C) *[Clients]* **Individuals** may revoke their consent *[verbally or]* in writing at any time and *[facility staff]* **the Division of DD and all parties responsible for the implementation of the ISP** shall recognize the revocations immediately.

(D) **Written** *[C]***c**onsents and revocations shall be *[documented]* **maintained** in *[clients' records]* **the individual's ISP** and *[heads of facilities]* **copies** shall **be** give**n** *[copies]* to *[protectors]* **designated representatives**.

[(5) If facility staff finds that a parent, guardian or protector is acting contrary to the best interest of a client by preventing or disrupting the client's care or habilitation, the staff shall notify the head of the facility of their findings. If the head of the facility concurs with the findings, s/he shall provide written notification of the findings to the parent, guardian or protector.

(A) If the client is a minor, the head of the facility may consult with juvenile court about the findings and then take appropriate action as authorized by law.

(B) In the case of a legal guardian, the head of the facility shall consult about the matter with department attorneys and the probate division judge supervising the guardian and, if indicated, take appropriate action through the court.

(C) In the case of a protector, the head of the facility shall allow the protector to present an appeal in person or in writing regarding the findings. If the head of the facility continues to concur with the findings, the protector may further appeal the notice of nonrecognition to the division director, who shall review the decision of the head of the facility and suspend, modify, affirm or reverse the action of the head of the facility. The division director shall notify the head of the facility and the protector in writing of the decision. The decision of the division director shall be final.]

*AUTHORITY: section 630.050, RSMo [1994] **Supp. 2013**. This rule was previously filed as 9 CSR 50-1.055. Original rule filed March 4, 1992, effective Aug. 6, 1992. Amended: Filed May 25, 1995, effective Dec. 30, 1995. Amended: Filed July 25, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Amber L. Daugherty, Assistant General Counsel, Department of Mental Health, PO BOX 687, 1706 E. Elm Street, Jefferson City, MO 65102. To be considered, comments must be delivered by regular mail, express or overnight mail, or by courier within thirty (30) days after publication in the **Missouri Register**. If to be hand-delivered, comments must be brought to the Department of Mental Health at 1706 E. Elm, Jefferson City, Missouri. No public hearing is scheduled.*

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 45—Division of Developmental Disabilities
Chapter 3—*[Care and Habilitation]* ***Services and Supports***

PROPOSED AMENDMENT

9 CSR 45-3.060 *[Autism]* **Services *for Individuals with Autism Spectrum Disorder***. The department is amending the title of the chapter, the title of the rule, and sections (1)–(6).

PURPOSE: This amendment modifies the rule to comply with section 633.220, RSMo and updates the rule with more current terminology in the field of developmental disabilities.

(1) Terms defined in sections 630.005, *[and]* 633.005, **and 633.220,** RSMo are incorporated by reference for use in this rule. Also, the following terms mean:

(A) Autism **spectrum disorder (ASD)**—*[a lifelong developmental disability that typically appears during the first three (3) years of life resulting from a neurological disorder that affects brain functioning which interferes with communication, learning, behavior and social development;]* **a group of neurodevelopmental disorders characterized by persistent deficits in social communication and social interaction across multiple contexts as well as by restricted, repetitive patterns of behaviors, interests, or activities. Symptoms of ASD must be present in the early developmental period and cause significant impairment in social, occupational, or other important areas of functioning;**

(B) Family support—services and helping relationships for the purpose of maintaining and enhancing family caregiving. Family support may be any combination of services that enable individuals with autism to reside within their family homes and remain integrated within their communities. Family support services are—

1. Based on individual and family needs;
2. Easily accessible for the family;
3. Family-centered and culturally sensitive;
4. Flexible and varied to meet the changing needs of the family members;
5. Identified by the family; and
6. Provided in a timely manner contingent upon availability of resources; and

(C) Service provider—**a person or** an entity which provides and receives reimbursement for autism programs and services as specified in section (3) of this rule.

(2) The Division of *[Mental Retardation and]* Developmental Disabilities (*[d]***D**ivision **of DD**) shall establish programs and services for persons with autism. The **Division of DD shall establish such** programs and services *[shall be established]* in conjunction with **persons with ASD and their** families**. The programs and services** *[of persons with autism and]* shall be designed to enhance the **abilities of persons with ASD and their** families' abilities to meet needs they identify. The programs and services shall—

(A) Develop skills for persons with autism through *[training]* **supports, services, and teaching**;

(B) *[Train]* **Teach** families to *[manage behaviors of members with autism]* **provide behavioral supports to members with autism**; **and**

(C) Provide needed family support*[; and]***.**

[(D) Cooperate with other agencies.]

[(3) The division shall establish autism programs and services as follows:

(A) Central Missouri Autism Project to serve clients of the Kirksville, Hannibal, Rolla, and Central Missouri Regional Centers;

(B) East Missouri Autism Project to serve clients of the St. Louis Regional Center;

(C) Northwest Missouri Autism Project to serve clients of the Albany and Kansas City Regional Center;

(D) Southeast Missouri Autism Project to serve clients of the Poplar Bluff and Sikeston Regional Centers; and

(E) Southwest Missouri Autism Project to serve clients of the Joplin and Springfield Regional Centers.]

(3) The Division of DD Director, with input from the Missouri

Parent Advisory Committee on Autism, shall divide the state into at least five (5) regions and establish autism programs and services which are responsive to the needs of persons with autism and families consistent with contemporary and emerging best practices. The boundaries of such regions, to the extent practicable, shall be contiguous with relevant boundaries of political subdivisions and health service areas. Such regions shall be referred to as regional autism projects in this rule.

(4) *[The Central, East, Northwest, Southeast, and Southwest Missouri Autism Projects]* **Regional Autism Projects** may provide **or purchase**, but shall not be limited to, the following services:

(M) Respite care; *[and]*

(N) Staff training*[.]***;**

(O) Social skills training; and

(P) Other contemporary and emerging evidence based practices.

(5) *[The Central, East, Northwest, Southeast, and Southwest Missouri]* **Regional** Autism Projects shall each have **regional** parent advisory *[committees]* **councils** composed of from seven to nine (7–9) persons that have family members with autism, including family members that are young children, school-age children, and adults. The members shall be Missouri residents and their family members with autism shall have met the *[d]***D**ivision*['s]* **of DD's** eligibility requirements specified under 630.005, RSMo.

(B) Upon expiration of members' terms, new members shall be nominated by the *[committees]* **councils** for three**-** (3-)*[-]* year terms or until their successors have been elected. New members of each of the five (5) **regional** parent advisory *[committees]* **councils** shall be appointed by the *[respective district deputy]* **Division of DD** *[d]***D**irector **or designee** from nominations submitted by the **regional** parent advisory *[committee]* **councils**. No member shall serve more than two (2) consecutive three**-** (3-)*[-]* year terms. No *[committee]* **council** member shall be a service provider, a member of a service provider's board of directors, or an employee of a service provider **or the Division of DD**. *[The Central, Northwest, Southeast, and Southwest Missouri Autism Projects]* **Regional parent** advisory *[committees]* **councils** shall be encouraged to maintain membership from each region within their project boundaries. *[The East Missouri advisory committee shall be encouraged to maintain membership from each county within the region and from the City of St. Louis.]* The *[committees]* **councils** shall make every effort to elect members to represent the cultural diversity of the project areas and to represent persons with autism of all ages and capabilities.

(C) Each *[committee]* **council** shall elect a chairperson, vice-chairperson, and secretary. Annual elections shall occur in July. The *[committees]* **councils** shall meet bimonthly or more often at the call of the chairpersons. A simple majority of the membership shall constitute a quorum.

(D) Each *[committee]* **council** shall establish bylaws specific to the *[committee's]* **council's** project area and consistent with parameters established by the Missouri **Parent** Advisory *[Committee]* **Council** on Autism set out in section (6).

(E) The *[committees']* **councils'** responsibilities shall include, but not be limited to, the following:

1. Advocacy;

2. Contract monitoring;

3. Review of annual Department of Mental Health *[(department)]* audits of projects;

4. Recommendation of services to be provided based on input from families;

5. Recommendation of policy, budget**,** and service priorities;

6. Monthly review of service delivery;

7. Planning;

8. Public education and awareness;

9. Recommendation of service providers to the *[d]***D**ivision **of DD** for administration of the projects; and

10. Recommendation of contract cancellation.

(F) In the event a parent advisory *[committee]* **council** disagrees with a decision of the *[district deputy]* **Division of DD Regional** *[d]***D**irector**'s designee** related to operation of the autism project, the issue may be referred to the Missouri **Parent** Advisory Committee on Autism for its recommendation to the *[d]***D**ivision **of DD** *[d]***D**irector.

(6) The *[d]***D**ivision **of DD** shall establish the Missouri **Parent** Advisory Committee on Autism. It shall be composed of two (2) representatives and one (1) alternate from each of the five (5) **regional** parent advisory *[committees]* **councils** set out in this rule. It shall also include one (1) person with autism and one (1) alternate, a person with autism, who are not members of a **regional** parent advisory *[committee]* **council**. The committee shall be appointed by the *[d]***D**ivision **of DD** *[d]***D**irector.

(A) The *[d]***D**ivision **of DD** *[d]***D**irector shall make every effort to appoint members nominated by the **regional** parent advisory *[committees]* **councils**. The membership should represent the cultural diversity of the state and represent persons with autism of all ages and capabilities;

(C) Upon expiration of the terms, members shall be appointed by the *[d]***D**ivision **of DD** *[d]***D**irector for three**-** (3-)*[-]* year terms or until their successors have been appointed. **No member shall serve more than two (2) consecutive three- (3-) year terms.**

(D) At its annual meeting in July, the **Missouri Parent Advisory** *[c]***C**ommittee **on Autism** shall elect a chairperson, a vice-chairperson**,** and a secretary**.** The committee shall meet quarterly or more often at the call of the chairperson. A simple majority of the membership shall constitute a quorum.

(E) The committee's responsibilities shall include, but not be limited to, the following:

1. Communication with the projects set out in section (3) to provide up-to-date information to them and the families they serve;

2. Determining project outcomes for autism services;

3. Determining roles and responsibilities of the **regional** parent advisory *[committees]* **councils** set out in section (5);

4. Development of positive relationships with the Department of Elementary and Secondary Education and local school districts;

5. Establishing *[statewide]* policy **for the Missouri Parent Advisory Committee on Autism**;

6. Fostering unity with and among the project**s** set out in section (3) to ensure joint support for legislative, budget**,** and other issues;

7. Planning and sponsorship of statewide activities;

8. Provision of program recommendations to the *[d]***D**ivision **of DD**;

9. Recommendation of service providers to the *[d]***D**ivision **of DD** *[d]***D**irector in the event a **regional** parent advisory *[committee]* **council** and *[district deputy director]* **Division of DD Director's designee** cannot reach consensus; *[and]*

10. Recommendation of issue resolutions to the *[d]***D**ivision **of DD** *[d]***D**irector*[.]***; and**

11. Submission of an annual report to the Missouri Commission on Autism Spectrum Disorders, the governor, the director of the Department of Mental Health, and the director of the Division of DD.

AUTHORITY: sections 630.050 ***and 633.220****, RSMo Supp. [1997]* ***2013****. Original rule filed Feb. 6, 1995, effective Sept. 30, 1995. Amended: Filed July 31, 1998, effective Jan. 30, 1999. Amended: Filed July 25, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Amber L. Daugherty, Assistant General Counsel, Department of Mental Health, PO BOX 687, 1706 E. Elm Street, Jefferson City, MO 65102. To be considered, comments must be delivered by regular mail, express or overnight mail, or by courier within thirty (30) days after publication in the ***Missouri Register****. If to be hand-delivered, comments must be brought to the Department of Mental Health at 1706 E. Elm, Jefferson City, Missouri. No public hearing is scheduled.*

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 60—Research
Chapter 1—Rules for Conducting Research and Program Evaluation

PROPOSED AMENDMENT

9 CSR 60-1.010 Application for Client Research. The department is amending sections (1), (2), and (3). The department is also removing the Application for Research with Clients of the Missouri Department of Mental Health.

PURPOSE: This amendment removes references to the Deputy Director of the Office of Departmental Affairs and updates language to reflect current department procedures for applying to conduct client research. This amendment deletes in its entirety the Application for Research with Clients of the Missouri Department of Mental Health.

(1) The terms defined in section 630.005, RSMo are incorporated into this regulation. As used in this administrative rule the following terms mean:

[(D) Deputy director is the deputy director of the Office of Departmental Affairs;]

*[(E)]***(D)** Professional review committee (PRC) is the ten**-** (10-)*[-]* person committee established under section 630.19*[2]***3**, RSMo and appointed by the **department** director **or designee** to review and recommend approval or disapproval of proposed research projects;

*[(F)]***(E)** Pharmacological research is experimentation with patients, clients**,** or residents to determine responses to drugs or other substances;

*[(G)]***(F)** Program evaluation is an activity designed to assess or evaluate policies, procedures**,** or programs currently in operation to determine their effectiveness or usefulness or to identify needed changes, including survey research and specifically limited to instances where no manipulation of variables or conditions is involved; and

*[(H)]***(G)** Research is experimentation or intervention with or on departmental patients, clients**,** or residents, including behavioral or psychological research, biomedical research, pharmacological research**,** and program evaluation. Excluded are those instances where the manipulation or application is intended solely and explicitly for individual treatment of a condition, falls within the prerogative of accepted practice**,** and is subject to appropriate quality assurance review. Also excluded are activities limited to program evaluation conducted by staff members as a regular part of their jobs, the collection or analysis of management information system data, archival research**,** or the use of departmental statistics.

(2) Any person may request to do research on departmental clients by requesting the application for research with clients from the *[Office of Departmental Affairs (DMH form 8114)]* **department director or designee**. It is incumbent on the individual wishing to conduct research to seek and gain approval for research before initiating the project.

(3) The person requesting to do research shall send an application *[and ten (10) copies]* to the *[deputy]* **department** director or designee **as indicated on the application**. Based on the completed application, the *[deputy]* **department** director or designee may exempt from PRC review those projects which do not meet the criteria of research as defined in section (1). In the case of projects approved by the facility director which are exempted from review, the facility director accepts the responsibility of insuring client confidentiality, informed consent**,** and the right to refuse to participate.

*AUTHORITY: section[s] 630.192****, RSMo Supp. 2013, and 630.193*** *to 630.198, RSMo [1994]* ***2000****. Original rule filed March 18, 1987, effective Aug. 15, 1987. Amended: Filed July 17, 1995, effective March 30, 1996. Amended: Filed July 26, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Amber L. Daugherty, Assistant General Counsel, Department of Mental Health, PO Box 687, 1706 E. Elm Street, Jefferson City, MO 65102. To be considered, comments must be delivered by regular mail, express or overnight mail, or by courier within thirty (30) days after publication in the ***Missouri Register****. If to be hand-delivered, comments must be brought to the Department of Mental Health at 1706 E. Elm, Jefferson City, Missouri. No public hearing is scheduled.*

Title 9—DEPARTMENT OF MENTAL HEALTH
Division 60—Research
Chapter 1—Rules for Conducting Research and Program Evaluation

PROPOSED AMENDMENT

9 CSR 60-1.015 Review of Research in Progress. The department is amending section (1).

PURPOSE: This amendment removes a reference to the Director of Research and Evaluation and updates a statutory citation.

(1) The terms defined in section 630.005, RSMo are incorporated into this rule. As used in this administrative rule, the following terms mean:

(A) Professional review committee (PRC) is the ten**-** (10-)*[-]* person committee established under section 630.19*[2]***3**, RSMo and appointed by the **department** director **or designee** to review and recommend approval or disapproval of proposed research projects;

(D) PRC coordinator is *[the director of Research and Evaluation or other designee of]* **appointed by** the department director **or designee**.

AUTHORITY: section 630.194, RSMo [1994] ***2000****. Original rule filed Nov. 30, 1987, effective May 12, 1988. Rescinded: Filed Sept. 1, 1995, effective March 30, 1996. Readopted: Filed May 20, 1996, effective Dec. 30, 1996. Amended: Filed July 26, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment by writing to Amber L. Daugherty, Assistant General Counsel, Department of Mental Health, PO Box 687, 1706 E. Elm Street, Jefferson City, MO 65102. To be considered, comments must be delivered by regular mail, express or overnight mail, or by courier within thirty (30) days after publication in the ***Missouri Register****. If to be hand-delivered, comments must be brought to the Department of Mental Health at 1706 E. Elm, Jefferson City, Missouri. No public hearing is scheduled.*

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 20—Clean Water Commission
Chapter 8—Design Guides

PROPOSED AMENDMENT

10 CSR 20-8.500 *[Secondary Containment]* ***Design Requirements*** **for Agrichemical Facilities**. The director proposes to amend the rule title, purpose statement, and sections (2)–(9), (12), (14), and (15), and remove section (16).

PURPOSE: This proposed amendment is necessary as a result of changes in section 644.051, effective August 28, 2013, removing the current permitting requirement for a construction permit for some agrichemical facilities. The rulemaking includes several clarifications.

[PURPOSE: The following criteria have been prepared as a guide for the design, construction and operation of secondary and operational area containment structures at bulk agrichemical facilities. This rule is to be used with rules 10 CSR 20-8.110–10 CSR 20-8.220 for the planning and design of the complete storage and containment facility. This rule reflects the minimum requirements of the Missouri Clean Water Commission regarding adequacy of design, submission of plans, approval of plans and approval of completed storage and containment facility. Deviation from these minimum requirements will be allowed where sufficient documentation is presented to justify the deviation. A facility need only to comply with these rules when it comes within the definition of an agrichemical facility. Any new agrichemical facility shall be in compliance with all of these rules before the commencement of any operational activities or any storage or use of agrichemicals. Upon adoption of these rules, all existing agrichemical facilities shall be in compliance with them as follows: secondary and operational area containment for pesticides—five (5) years from the date the rule is adopted; and secondary and operational area containment for fertilizers—five (5) years from the date the rule is adopted. Any facility that has a discharge of agrichemicals or process generated wastewater which results in damage to the environment may be required to take immediate steps to implement the secondary and operational containment requirements contained in this rule. All agrichemical facilities shall be registered and issued a general operating permit from the department on forms furnished by the department. Registration shall be valid for the life of the permit, terminated by the department or voluntarily withdrawn by the applicant. These criteria are based on the best information presently available and are similar to secondary containment regulations that have been implemented in other states. It is anticipated that they will be subject to review and revision periodically as additional information and methods appear. Addenda or supplements to this publication will be furnished to the regulated community. If others desire to receive addenda or supplements, please advise the Clean Water Commission so that your name can be added to the mailing list.

Editor's Note: The secretary of state has determined that the publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the material referenced has been filed with the secretary of state. This material may be found at the Office of the Secretary of State or at the headquarters of the agency and is available to any interested person at a cost established by state law.]

PURPOSE: The following criteria serve as a guide for the design, construction, and operation of primary, secondary, and operational containment structures at bulk agrichemical facilities.

(2) General. A facility need only to comply with these rules when they come within the definition of an agrichemical facility. Any *[new agrichemical facility]* **construction after the effective date of this rule** shall be in compliance with all of these rules before the commencement of any operational activities or any storage or use of agrichemicals. *[All existing agrichemical facilities shall be in compliance with these rules as follows: secondary and operational area containment for pesticides— five (5) years from the date the rule is adopted; and secondary and operational area containment for fertilizers—five (5) years from the date the rule is adopted.]* Any existing agrichemical facility that has a discharge of agrichemicals or process generated wastewater to the environment *[will be]* **is** required to take immediate steps to implement the secondary and operational containment requirements contained in this rule **in addition to any other remedy required**. *[All agrichemical facilities shall apply for an operating permit on forms furnished by the department. Storage of bulk liquid fertilizer in a mobile container for more than thirty (30) days is prohibited unless the mobile storage container is located within a secondary containment or operational containment area. Deviation from the requirements contained in this rule will be considered by the department on a case-by-case basis. Sufficient documentation shall be submitted justifying the need for the deviation.]* **All new operations shall be designed to be no discharge.**

(3) Exceptions. The following exceptions shall apply to agrichemical facilities:

(B) Liquid fertilizer storage tanks*[,]* that *[are]* **were** in use *[when this rule is adopted]* **prior to January 13, 1992**, having a storage capacity greater than forty thousand (40,000) gallons shall be exempt from the requirement of installing a liner underneath the tank itself. Spill containment diking is required around these tanks. These facilities shall submit to the department for approval a program outlining the monitoring, tank testing**,** and record keeping that will be done at the facility to document that a release of agrichemicals from these tanks has not occurred either to surface or subsurface waters of the state.

(4) *[Engineering services are performed in three (3) steps: engineering report or facilities plan, preparation of construction plans, specifications and contractual documents and construction compliance, inspection, administration and acceptance. These services are generally performed by engineering firms in private practice but may be performed by state or federal agencies. All reports, plans and specifications should be submitted at least sixty (60) days prior to the date upon which action by the agency is desired or in accordance with the National Pollutant Discharge Elimination System (NPDES) or other schedules. The documents should be submitted for formal approval at the appropriate times and should include the engineer's report (facilities plan) and design drawings and specifications. For unusual or complex projects, it is suggested that the engineer meet with the appropriate department staff to discuss the project and that preliminary reports be submitted for review prior to the*

preparation of final plans and specifications. These documents are used by the owner in programming future action and by the agency to evaluate probable compliance with statutes and regulations. The preliminary reports and plans shall broadly describe existing problems, consider methods for alternate solutions including site and/or facility relocation estimate capital and annual costs and outline steps for further project implementation including approval by regulatory agencies. No approval for construction can be issued until final, detailed plans and specifications have been submitted to the agency and found to be satisfactory.] **Deviations. The department may require a construction permit with a substantial deviation from these requirements as addressed in 10 CSR 20-6.010. Deviations from these rules may be approved by the department when engineering justification satisfactory to the department is provided. Justification must substantially demonstrate in writing and through calculations that a variation(s) from the design rules will result in either at least equivalent or improved effectiveness. Deviations are subject to case-by-case review with individual project consideration. Containment structures for agrichemical facilities that are not addressed or covered in this design guide are considered deviations. A written request for any deviation must include a certification that indicates compliance with all other design guide requirements.**

(5) Engineering Report **for new construction or modifications to existing facilities as required in 10 CSR 20-6.010**. The engineering report assembles basic information, presents design criteria and assumptions, examines alternate projects with preliminary layouts and cost estimates, offers a conclusion with a proposed project for client consideration**,** and outlines official actions and procedures to implement the project. *[The concept, including process description and sizing, factual data and controlling assumptions and considerations for the functional planning of secondary and operational containment facilities are presented for each process at the facility as well as the overall operation of the agrichemical facility as a whole system. These data form the continuing technical basis for detail design and preparation of construction plans and specifications. Architectural, structural, mechanical and electrical designs are usually excluded. Sketches may be desirable to aid in presentation of a project. Outline specifications of process units, special equipment, etc. are occasionally included.]* **Engineering reports shall contain the following information and other pertinent information and may be combined with other engineering documentation:**

[(A) Engineering Report Content. It is urged that the following paragraphs be utilized as a guideline for the content of the project engineering report to be submitted to the agency for review and approval:

1. Letter of transmittal. A one (1)-page letter typed on design engineer's letterhead should be included in the submission of the report to the client;

2. Title page. Title of project, agrichemical facility name and address, name and address of firm preparing the report, seal and signature of the professional engineer in charge of project;

3. Table of contents shall include section headings, chapter headings and subheadings, maps, graphs, illustrations, exhibits, diagrams and appendices. Number all pages and cross-reference by page number;

4. Introduction. Purpose—reasons for the report and circumstances leading up to the report;

5. Existing conditions at the agrichemical facility and discussion about proposed expansions or modifications to the facility;

6. Technical information and design criteria—

A. Process facilities. The process by which bulk chemicals are received, unloaded and transferred within the facility should be discussed. The mixing, loading and unloading of spreading or spraying equipment should be discussed. Design and sizing of secondary and operational containment structures should be discussed. All cleaning of chemical handling equipment, spraying or spreading vehicles, nurse vehicles and containment areas should be discussed. Collection, storage and disposal of rinsates, process generated wastewaters and collected precipitation should be discussed. Collection, treatment and disposal of all domestic wastewater flows associated with the facility should be discussed; and

B. Process diagrams. A process configuration showing the interconnection of all pumps, piping and storage tanks associated with the operation of the agrichemical facility should be shown; and

7. Summary. Highlight very briefly what was found from the evaluation of the facility and what the proposed recommendations are for the facility—

A. Findings. Method of operation, estimation of the number of cropping programs for which agrichemical services will be provided, sources of wastewater, proposed disposal or treatment practices;

B. Conclusions. Project recommended to client for construction; and

C. Recommendations. Summarized, step-by-step actions for client to follow to implement conclusions and submission of the report to the agency for review and approval.]

(A) Title of project, agrichemical facility name and address, name and address of firm preparing the report, seal and signature of the professional engineer in charge of project;

(B) Introduction. Reasons for the report and circumstances leading up to the report;

(C) Existing conditions at the agrichemical facility and proposed expansions or modifications to the facility shall be discussed;

(D) Design criteria—

1. Design and sizing of secondary and operational containment structures should be discussed;

2. Process diagrams. A process configuration showing the interconnection of all pumps, piping, and storage tanks associated with the operation of the agrichemical facility should be shown;

(E) The process by which bulk chemicals are received, unloaded, and transferred within the facility should be discussed. The mixing, loading, and unloading of spreading or spraying equipment should be discussed. All cleaning of chemical handling equipment, spraying or spreading vehicles, nurse vehicles, and containment areas should be discussed. Collection, storage and disposal of rinsates, process generated wastewaters, and collected precipitation should be discussed. Collection, treatment, and disposal of all domestic wastewater flows associated with the facility should be discussed;

(F) Method of operation, estimation of the number of cropping programs for which agrichemical services will be provided, sources of wastewater, proposed disposal or treatment practices, and the project recommended to client for construction shall be included; and

(G) Antidegradation must be implemented according to the procedures in 10 CSR 20-7.031(3)(D).

(6) Primary Containment for Bulk Agrichemicals **for new construction or modifications to an existing facility**. Containers and appurtenances used as the primary containment in the storage and handling of bulk agrichemicals shall be constructed, installed**,** and maintained to prevent a discharge and shall be of materials and construction compatible with the specifications of the product stored.

(7) Secondary Containment for Bulk Agrichemicals **for new construction or modifications to an existing facility**. Secondary containment for nonmobile bulk pesticides and nonmobile bulk fertilizers shall be designed to contain any spilled product **and prevent a discharge** from the primary containers or rainfall from the operational containment area and secondary containment area for the amount of time required for proper cleanup and recovery.

(C) Nonmobile Bulk Dry Fertilizer Storage.

1. Dry fertilizer shall be stored inside a sound structure to prevent contact with precipitation. All surface water runoff shall be diverted away from the storage structure.

2. All unloading, loading, mixing**,** and handling of dry bulk fertilizers should be done on an operational containment area.

3. Pesticide impregnation of dry fertilizer shall take place within an operational containment area adequate in size to hold the volume of pesticides used and impregnation equipment.

[4. Unloading of bulk dry fertilizers may be satisfied by individual catchment basins.]

*[5.]***4.** Daily cleanup of the dry fertilizer loading, unloading, mixing**,** and handling areas shall take place.

*[6.]***5.** Whenever feasible, dry fertilizer spreading equipment should be cleaned in the field to minimize containment and disposal requirements at the operational containment area.

*[7.]***6.** The floors of the bulk dry fertilizer storage area shall be paved with concrete or other approved materials that will prevent the downward movement of fertilizer materials and moisture through the floor. For concrete floors and walls, expansion joints shall be placed on a close enough spacing to prevent cracks from forming. The expansion joints shall be sealed with a material resistant to agrichemicals. Cracks that occur in the floors and walls shall be sealed to prevent the downward or lateral movement of fertilizer materials and moisture.

7. A mixing and loading pad shall extend beneath any conveyor used to load or unload dry bulk fertilizer unless the conveyor is fully enclosed within a housing that contains all spillage from the conveyor.

(D) Nonmobile Bulk Dry Pesticide Storage.

1. Dry pesticides shall be stored inside a sound structure to prevent contact with precipitation. All surface water runoff shall be diverted away from the storage structure.

2. All loading, mixing**,** and handling of bulk dry pesticides should be done on an operational containment area.

[3. Unloading of bulk dry pesticides may be satisfied by individual catchment basins.]

*[4.]***3.** Daily cleanup of the bulk dry pesticide loading, unloading, mixing**,** and handling areas shall take place.

*[5.]***4.** Whenever feasible, bulk dry pesticide spreading equipment should be cleaned in the field to minimize containment and disposal requirements at the operational containment area.

*[6.]***5.** The floors of the bulk dry pesticide storage area shall be paved with concrete or other approved materials that will prevent the downward movement of pesticide materials and moisture through the floor. For concrete floors and walls, expansion joints shall be placed on a close enough spacing to prevent cracks from forming. The expansion joints shall be sealed with a material resistant to agrichemicals. Cracks that occur in the floors and walls shall be sealed to prevent the downward or lateral movement of pesticide materials and moisture.

6. A mixing and loading pad shall extend beneath any conveyor used to load or unload dry bulk pesticide unless the conveyor is fully enclosed within a housing that contains all spillage from the conveyor.

(8) **Operational Containment for bulk liquid pesticides and bulk liquid fertilizers for new construction or modifications to an existing facility.** The operational containment area for bulk liquid pesticides and bulk liquid fertilizers shall be designed to contain any product discharged or collected precipitation for the amount of time required for proper cleanup and recovery.

(C) The volume of the operational containment area shall be one hundred ten percent (110%) of the volume of the largest *[application]* vehicle that will be loaded or unloaded in the operational containment area. This volume may be achieved through the use of above ground tank(s) located within the secondary containment area connected to an automatic sump pump in the operational containment area.

(E) *[Unloading containment may be satisfied by the operational containment area or with individual catchment basins or portable pans/containers. The individual basins or portable containers shall be placed to catch or recover spillage and leakage from transfer connections and pumps.]* **The operational containment area shall extend beneath any pump, appurtenance, or plumbing connection not located within the secondary containment area and that is used to transfer liquid fertilizer or pesticide.**

(9) **Operational Containment Area for bulk dry pesticides and bulk dry fertilizers for new construction or modifications to an existing facility.** The operational containment area for bulk dry pesticides and bulk dry fertilizers shall be sized and designed to contain any spillage or leakage of dry materials that occurs from the loading and unloading of hauling or spreading equipment and from the mixing and blending equipment or precipitation that comes in contact with the operational containment area for the amount of time required for proper cleanup and recovery.

(C) *[Unloading containment may be satisfied by the operational containment area or with i]***I**ndividual catchment basins or portable pans/containers **may be used to satisfy the requirement for operational containment**. The individual basins or portable containers shall be placed to catch or recover spillage and leakage from transfer connections and conveyors.

(D) For unloading dry pesticides and dry fertilizers from rail cars, a catchment basin or concrete pad that can effectively contain the dry fertilizer or pesticide that may be discharged during the unloading process shall be used. The operator shall clean up a spill immediately after unloading occurs.

(12) Operation and Management of Agrichemical Facilities. Bulk agrichemicals shall be stored, handled, transported, loaded**,** and unloaded in a manner to prevent discharge that may result in unreasonable adverse *[affects]* **effects** to humans or the environment. All applicable hazards of the pesticide shall be considered in the handling and loading practices to ensure proper protection of facility personnel and the environment.

(A) *[Discharges]* **Spills** occurring *[to]* **within** the secondary containment and operational containment area shall be recovered promptly. All waste and wastewater associated with the recovery process shall be disposed of in accordance with the permit for the facility and the product labeling.

(F) Prior to repackaging or refilling *[bulk]* **mobile** containers, the containers must be thoroughly cleaned and inspected except when a dedicated pesticide container is refilled and the tamper indicator is otherwise intact.

(14) Plans.

(A) General. All plans for **primary,** secondary**, and operational** containment structures *[at]* **for new construction or modifications to existing** agrichemical facilities shall bear the name of the agrichemical facility and shall show the scale in feet, a graphic scale, the north point, *[data]* **date,** and the name of the engineer, certificate number and imprint of his/her registration seal. The plans shall be clear and legible. They shall be drawn to a scale which will permit all necessary information to be plainly shown. The size of the plans generally should not be larger than thirty inches by forty-two inches (30" × 42") (76 cm × 107 cm). Datum used should be indicated. Locations and logs of test borings and when made shall be shown on

the plans. *[Blueprints shall not be submitted.]* Detail plans shall consist of plan views, elevations, sections**,** and supplementary views which, together with the specifications and general layouts, provide the working information for the contract and construction of the containment facilities. **Plans shall** *[l]***i**nclude dimensions and relative elevations of structures, the location and outline form of equipment, storage tanks, location and size of piping**,** and ground elevations.

(B) Plans *[of]* **for new construction or modifications to existing** *[A]***a**grichemical *[F]***f**acilities.

1. Location plan. A plan shall *[be submitted]* show*[ing]* the location of the agrichemical facility in relation to streams, roads, water supply systems, property lines**,** and any dwellings or structures not owned by the agrichemical facility in the immediate area of the facility.

2. General layout. Layouts of the proposed agrichemical containment facility shall *[be submitted]* show*[ing]* topography of the site, size**,** and location of storage tanks and containment structures, schematic flow diagram showing the flow through the various agrichemical mixing and handling systems, piping including any arrangements for bypassing individual systems, agrichemical handled and direction of flow through pipes, pumps and valves used for handling agrichemicals, storage areas for waste materials that cannot be reused (mud and sediment from sumps, dry fertilizer**,** and pesticide materials accumulated during clean up processes, etc.), any test borings showing soil and rock elevations and composition at the proposed site**,** and information showing existing groundwater elevations in relation to proposed liner installation and containment area floors shall be provided.

3. Detail plans. Unless otherwise covered by the specifications or engineer's report, detail plans shall show location, dimensions**,** and elevations of all existing and proposed facilities; elevations of high and low groundwater level; size, pertinent features**,** and operating capacity of all pumps, tanks, containment areas**,** and other mechanical devices associated with the operation of the agrichemical facility and adequate description of any other features pertinent to the design and operation of the agrichemical containment facility.

(15) Specifications. Complete technical specifications for *[the construction of the]* **new construction or modifications to an existing** agrichemical containment facility shall *[accompany]* **be included with** the plans. The specifications *[accompanying]* **included with** construction drawings shall include, but not be limited to, all construction information not shown on the drawings which is necessary to inform the builder in detail of the design requirements as to the quality of materials and workmanship and fabrication of the project and type, size, strength, operating characteristics**,** and rating of equipment; the complete requirements for all mechanical and electrical equipment, including machinery, valves, piping and jointing of pipe; electrical apparatus, wiring**,** and instrumentation; operating tools; construction materials; special construction materials such as clay, sand, concrete**,** or steel; miscellaneous appurtenances; instructions for testing materials and equipment as necessary to meet design standards and performance tests for the completed works and component units. It is suggested that these performance tests be conducted at the design conditions for the operation of the agrichemical facility whenever practical.

[(16) Modifications During Construction. Any deviations or changes from the approved plans or specifications affecting capacity or operation of the agrichemical facility shall be noted on a set of as-built plans clearly showing the alternations. The as-built plans shall be submitted to the department at the completion of the project along with an application for issuance of an operating permit for the facility].

AUTHORITY: section[s] 644.026, RSMo Supp. [1990] ***2014,*** *and* ***section*** *644.036, RSMo [1986]* ***Supp. 2013****. Original rule filed July 15, 1991, effective Jan. 13, 1992. Amended: Filed Aug. 1, 2016.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions forty-two thousand nine hundred eighty-seven dollars ($42,987) in the aggregate.

PRIVATE COST: This proposed amendment is expected to save private entities fifty-one thousand twenty-six dollars ($51,026) in the aggregate.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Natural Resources, Division of Environmental Quality, Water Protection Program, Diane Reinhardt, PO Box 176, Jefferson City, MO 65102. Comments may be sent with name and address through email to diane.reinhardt @dnr.mo.gov. To be considered, comments must be received by November 17, 2016. A public hearing is scheduled at a meeting of the Clean Water Commission to be held at 10 a.m., on October 5, 2016, at the Echo Bluff State Park Lodge, 34489 Echo Bluff Drive, Eminence, MO 65466.

FISCAL NOTE
PUBLIC COST

I. Department Title: Department of Natural Resources
Division Title: Clean Water Commission
Chapter Title: Design Guides

Rule Number and Title:	10 CSR 20-8.500, Secondary Containment Design Requirements f or Agrichemical Facilities
Type of Rulemaking:	Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Department of Natural Resources	Net loss of revenue of $ 42,987.14

III WORKSHEET

The reduction in construction permitting will reduce the amount of fees collected by the Department. Based on historic data, the department estimates that as many as 8 construction permit applications were issued for agrichemical facilities each year. The fees associated with these projects ($1,000) will not be collected resulting in an estimated fee loss of $13,000. This loss in collected fees, however, is offset by the fact that the department no longer has to issue these permits or review these applications. Any loss of revenue to a state agency is considered a public cost.

Lost revenue to the department.
Reduced number of construction permits.
$1000 application fee X 13 applications/year = $ 13,000

Terminations of permits and resulting loss of $100 annual fee
400 of terminated permits x $100/year fee = $40,000

Cost savings to the department.
No construction permit reviews by department staff.
20 hours/application $35.01/hourly wage for EEII@ 13 applications/year = $9,102.60

No as-built or Statement of Work Completed review by department staff.
2 hour/application $35.01/hourly wage for EEII @ 13 applications/year = $910.26

TOTAL LOST REVENUE	$ 53,000.00
TOTAL COST SAVINGS	$ 10,012.86
NET LOSS TO THE DEPARTMENT	$ 42,987.14

IV. ASSUMPTIONS

1. An annualized aggregate cost of this rulemaking is used for the purposes of providing the aggregate cost for the life of the rule. The annualized aggregate cost is the agency estimate of the average costs that will be incurred in any future year, no matter how far distant. For convenience of calculating this fiscal note over a reasonable time period, the life of the rule is assumed to be indefinite. If the life of the rule extends beyond 1 year, the annual costs for additional years will be consistent with the assumptions used to calculate annual costs as identified in this fiscal note.

2. It is difficult to estimate the cost for the department to comply with this rulemaking as it is impossible to predict how many applications will be received in a year. Therefore, the number of applications is based on recent applications. The estimated average cost was determined on a per application basis. Operating permit applications for minor modifications such as facility name change and ownership transfer are not included in this estimate as these requirements have not changed.

3. The reduction of construction permit applications and the elimination of voluntary operating permit applications will result in a loss of revenue to the department. Construction and operating permit fees are based on the fee structure effective January 1, 2015.

4. Construction permit and as-constructed plans or a Statement of Work Completed is no longer required for agrichemical facilities that are not constructing an earthen basin. The reduction of construction permit applications will reduce the amount of time spent by engineering staff for review of applications. The hourly rate for an Environmental Engineer II (EEII) is based on the Office of Administration, Division of Personnel pay grid.

5. Facilities with SIC code 5191 will no longer need to obtain or maintain an operating permit. A search of the database show there are 456 permitted agrichemical facilities with their primary SIC code of 5191. This number was used in the loss of revenue calculations for the department.

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Natural Resources
Division Title: Clean Water Commission
Chapter Title: Permits

Rule Number and Title:	10 CSR 20-8.500, Secondary Containment Design Requirements for Agrichemical Facilities
Type of Rulemaking:	Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
8 facility owners per year	**SIC NAICS** **5191 farm retail** **2873** **2874** **2875 fertilizer mixing and storage** **2879**	**$51,026 savings**

III. WORKSHEET

Cost Savings (to applicant)
No construction permit required.
$1000 application fee x 8 applications = $8,000

No construction permit application preparation and associated engineering fees incurred
2 hours/application X $120/ hourly engineering fee* x 8 applications = $1,920

No as-built or Statement of Work Completed required
2 hours/application X $120.00/hourly engineering fee* x 8 application = $1,920

Terminations of permits and resulting in a savings of $100 annual fee
400 terminated permits** x $100/year fee = $40,000

Additional Costs (to applicant)
Additional costs will be incurred by dry fertilizer storage facilities for the construction of a loading pad.

3.7 cy. X $110/cubic yard concrete*** X 2 facilities per year = $814

TOTAL COST SAVINGS	$ 51,840
TOTAL COST INCREASES	$ 814
TOTAL NET SAVINGS	$51,026

ASSUMPTIONS

1. An annualized aggregate cost of this rulemaking is used for the purposes of providing the aggregate cost for the life of the rule. The annualized aggregate cost is the agency estimate of the average costs that will be incurred in any future year, no matter how far distant. For convenience of calculating this fiscal note over a reasonable time period, the life of the rule is assumed to be indefinite. If the life of the rule extends beyond 1 year, the annual costs for additional years will be consistent with the assumptions used to calculate annual costs as identified in this fiscal note.

2. The number of agrichemical facility applications submitted to the department varies from year to year. For cost estimates of this fiscal note, the number of applications is based on recent submittals and each application is submitted by a different owner. The estimated cost was determined on a per application basis.
3. Construction permit fees are based on the fee structure effective January 1, 2015.

4. It is impossible to determine cost savings for each classification of business because there is no way of knowing which ones will submit operating permit applications. For new or expanding agrichemical facilities that do not construct an earthen storage basin, the cost savings would be the same per application regardless of the classification. Based on current issued permits, that majority of cost savings would be in the NAICS Classifications of 5191 and 2875.

5. This fiscal note accounts for costs associated with permit application. It does not account for costs associated with the engineering design of the agrichemical facility as design requirements in this rule have not changed.

Only facilities that store and mix agrichemicals will be required to be permitted. Facilities with a primary SIC code 5191 will no longer need to obtain or maintain an operating permit. A search of the database show there are 456 permitted agrichemical facilities with their primary SIC code of 5191. This number was used in the calculations for savings to the facility owner.

* Basis of hourly fee is from information provided by 2 consulting engineers
**Assumption made that 90% of existing permitted facilities will terminate their permit.
***Based on delivered rate of $110 per yard of concrete to site 10 miles from concrete plant for Sandridge Concrete in Jefferson City, MO.

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 8—Accounting Records and Procedures; Audits

PROPOSED AMENDMENT

11 CSR 45-8.140 Application and Verification Procedures for Granting Credit. The commission is amending section (4) and adding new sections (5) and (6).

PURPOSE: This amendment changes regulatory procedures for the Class B licensees to follow regarding standards for establishing lines of credit.

(4) Prior to a Class B licensee's approval of a person's credit limit, an employee of the credit department or other employee as designated in the Class B licensee's internal control system shall—

(C) Perform a credit check and apply usual standards to determine the dollar amount of credit for which the person qualifies. *[If the person does not qualify for at least a ten thousand dollar ($10,000) line of credit, the application shall be denied]*;

(5) A person's credit worthiness shall be based on the amount of funds in the person's demand deposit account or accounts including any checking account and savings account.

(6) If the person's credit worthiness is ten thousand dollars ($10,000) or more, the Class B Licensee may accept a credit instrument of more than ten thousand dollars ($10,000) only if the qualified person's creditworthiness is equal to or in excess of the amount of the credit instrument. If the person's credit worthiness is less than ten thousand dollars ($10,000), the Class B Licensee may only accept credit instruments that are equal to or less than half the amount of the person's creditworthiness.

*AUTHORITY: section 313.004, RSMo 2000, and sections 313.800, 313.812, 313.817, and 313.830, RSMo Supp. 2014, **section** 313.805, **RSMo Supp. 2013, and section 313.930, RSMo SB 833, Second Regular Session, Ninety-eighth General Assembly, 2016**. Emergency rule filed July 31, 2014, effective Aug. 28, 2014, expired Feb. 26, 2015. Original rule filed July 31, 2014, effective Feb. 28, 2015. Emergency amendment filed July 28, 2016, effective Aug. 28, 2016, expires Feb. 23, 2017. Amended: Filed July 28, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for Tuesday, October 4, at 10:30 a.m., in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 9—Internal Control System

PROPOSED AMENDMENT

11 CSR 45-9.108 Minimum Internal Control Standards (MICS)—Chapter H. The commission is amending section (1).

*PURPOSE: This amendment changes the internal controls for Chapter H of the **Minimum Internal Control Standards**.*

(1) The commission shall adopt and publish minimum standards for internal control procedures that**,** in the commission's opinion**,** satisfy 11 CSR 45-9.020, as set forth in *Minimum Internal Control Standards* (MICS) Chapter H—Casino Cashiering and Credit, which has been incorporated by reference herein, as published by the Missouri Gaming Commission, 3417 Knipp Dr., PO Box 1847, Jefferson City, MO 65102. Chapter H does not incorporate any subsequent amendments or additions as adopted by the commission on *[October 29, 2014]* **July 27, 2016**.

*AUTHORITY: section 313.004, RSMo 2000, and sections 313.800, 313.812, 313.817, and 313.830, RSMo Supp. 2014, **section** 313.805, **RSMo Supp. 2013, and section 313.930, RSMo SB 833, Second Regular Session, Ninety-eighth General Assembly, 2016**. Original rule filed Oct. 31, 2011, effective June 30, 2012. Emergency amendment filed July 31, 2014, effective Aug. 28, 2014, expired Feb. 26, 2015. Amended: Filed July 31, 2014, effective Feb. 28, 2015. Emergency amendment filed July 28, 2016, effective Aug. 28, 2016, expires Feb. 23, 2017. Amended: Filed July 28, 2016.*

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Title 16—RETIREMENT SYSTEMS
Division 20—Missouri Local Government Employees' Retirement System (LAGERS)
Chapter 4—Actuarial Assumptions

PROPOSED AMENDMENT

16 CSR 20-4.010 Actuarial Assumptions. The Missouri Local Government Employees' Retirement System is amending sections (1)–(5).

PURPOSE: This amendment updates the actuarial assumptions in the rule.

(1) The investment return rate used in making the valuations is seven and twenty-five hundredths percent (7.25%) per year, compounded annually. This rate of return is not the assumed real rate of return. The real rate of return is the rate of investment return in excess of the **wage** inflation rate. Considering other financial assumptions, the seven and twenty-five hundredths percent (7.25%) investment return rate translates to an assumed real rate of return of *[three and seventy-five hundredths percent (3.75%)]* **four percent (4.00%)**. Adopted *[2011]* **2016**.

(2) The mortality table used in evaluating allowances to be paid is *[one hundred five percent (105%) of the 1994 Group Annuity Mortality Table setback zero (0) years for men and*

zero (0) years for women.] **RP-2014 Healthy Annuitant Table (adjusted backward to 2006) with base year of 2017 for males and 2006 for females. Future mortality improvements are assumed each year based on the two- (2-) dimensional sex-distinct mortality improvement scale MP-2015.** Adopted *[2011]* **2016**.

(3) The probabilities of retirement with an age and service allowance are shown in Table 1, included herein. Adopted *[2011]* **2016**.

(4) The probabilities of withdrawal from service together with individual pay increase assumptions are shown in Table 2, included herein. Adopted *[2011]* **2016**.

(5) Total active member payroll is assumed to increase *[three and fifty hundredths percent (3.5%]* **three and twenty-five hundredths percent (3.25%)** per year, which is the portion of the individual pay increase assumptions attributable to inflation. In effect, this assumes no change in the number of active members per employer. Adopted *[2011]* **2016**.

[Table 1

PERCENT OF ELIGIBLE ACTIVE MEMBERS RETIRING WITHIN THE NEXT YEAR

	Without Rule of 80 Eligibility				*With Rule of 80 Eligibility*			
	*General**				*General*			
Ages	*Men*	*Women*	*Police**	*Fire**	*Men*	*Women*	*Police*	*Fire*
50			*3.0%*	*2.5%*	*15%*	*15%*	*25%*	*25%*
51			*3.0*	*2.5*	*15*	*15*	*25*	*15*
52			*3.0*	*2.5*	*15*	*15*	*15*	*15*
53			*3.0*	*2.5*	*15*	*15*	*15*	*15*
54			*3.0*	*2.5*	*15*	*15*	*15*	*15*
55	*2.5%*	*3.0%*	*10*	*15*	*15*	*15*	*15*	*15*
56	*2.5*	*3.0*	*10*	*15*	*15*	*15*	*15*	*15*
57	*2.5*	*3.0*	*10*	*10*	*15*	*15*	*15*	*15*
58	*2.5*	*3.0*	*10*	*15*	*15*	*15*	*15*	*15*
59	*2.5*	*3.0*	*10*	*15*	*15*	*15*	*15*	*20*
60	*10*	*10*	*10*	*20*	*15*	*15*	*15*	*30*
61	*10*	*10*	*10*	*10*	*15*	*15*	*25*	*30*
62	*25*	*15*	*25*	*30*	*30*	*15*	*30*	*45*
63	*25*	*15*	*20*	*30*	*30*	*15*	*30*	*45*
64	*20*	*15*	*20*	*25*	*30*	*20*	*30*	*45*
65	*25*	*20*	*100*	*100*	*30*	*25*	*100*	*100*
66	*25*	*25*			*30*	*25*		
67	*20*	*20*			*30*	*25*		
68	*20*	*20*			*30*	*25*		
69	*20*	*15*			*30*	*25*		
70	*100*	*100*			*100*	*100*		

**First 5 years of retirement pattern only apply to early retirement. Early retirement rates are also applicable if Rule of 80 is adopted.]*

[Table 2

All Divisions
Separations from Active Employment Before Age & Service Retirement
& Individual Pay Increase Assumptions

Sample Ages	Years of Service	Percent of Active Members Separating within the Next Year: Death [1] Men	Death [1] Women	Other: General Men	General Women	Other Police	Other Fire	Pay Increase Assumptions for an Individual Employee: Fire	Others [2]
ALL	0			18.00%	21.00%	18.00%	8.00%		
	1			16.00	20.00	17.00	7.00		
	2			14.00	16.00	16.00	6.00		
	3			11.00	13.00	13.00	6.00		
	4			9.00	12.00	12.00	5.00		
25	5 & Over	0.03%	0.02%	7.50	10.70	10.10	5.00	8.6%	6.8%
30		0.03	0.02	6.50	9.40	8.00	4.00	6.7	6.0
35		0.06	0.04	5.10	7.20	6.10	2.80	5.4	5.5
40		0.08	0.05	3.80	5.50	4.70	2.20	4.7	5.0
45		0.11	0.08	3.00	4.20	3.60	1.80	4.4	4.5
50		0.16	0.13	2.40	3.40	1.80	1.00	4.1	4.1
55		0.27	0.20	1.80	2.50	1.00	0.50	3.9	3.9
60		0.51	0.38	1.00	1.20	0.00	0.00	3.8	3.8
65		0.96	0.73	0.00	0.00	0.00	0.00	3.5	3.5

1 General, Police, Fire
2 General, Police]

Table 1 ***PERCENT OF ELIGIBLE ACTIVE MEMBERS RETIRING WITHIN THE NEXT YEAR***

	Without Rule of 80 Eligibility				With Rule of 80 Eligibility			
	General*				General			
Ages	Men	Women	Police*	Fire*	Men	Women	Police	Fire
50			2.5%	2.5%	15.0%	15.0%	25.0%	25.0%
51			2.5	2.5	15.0	15.0	25.0	20.0
52			2.5	2.5	15.0	15.0	15.0	20.0
53			2.5	2.5	15.0	15.0	15.0	20.0
54			2.5	2.5	15.0	15.0	15.0	20.0
55	3.0%	3.0%	10.0	13.0	15.0	15.0	15.0	20.0
56	3.0	3.0	10.0	13.0	15.0	15.0	15.0	20.0
57	3.0	3.0	10.0	13.0	15.0	15.0	15.0	25.0
58	3.0	3.0	10.0	13.0	15.0	15.0	15.0	25.0
59	3.0	3.0	10.0	13.0	15.0	15.0	15.0	25.0
60	10.0	10.0	10.0	15.0	15.0	15.0	15.0	35.0
61	10.0	10.0	10.0	15.0	15.0	15.0	25.0	35.0
62	25.0	15.0	25.0	20.0	30.0	15.0	30.0	45.0
63	20.0	15.0	20.0	20.0	30.0	15.0	30.0	45.0
64	20.0	15.0	20.0	20.0	30.0	20.0	30.0	45.0
65	25.0	25.0	100.0	100.0	30.0	25.0	100.0	100.0
66	25.0	25.0			30.0	25.0		
67	20.0	25.0			30.0	25.0		
68	20.0	25.0			30.0	25.0		
69	20.0	20.0			30.0	25.0		
70	100.0	100.0			100.0	100.0		

*****First 5 years of retirement pattern only apply to early retirement. Early retirement rates are also applicable if Rule of 80 is adopted.

Table 2

All Divisions
Separations from Active Employment Before Age & Service Retirement
& Individual Pay Increase Assumptions

		Percent of Active Members Separating within the Next Year										Pay Increase Assumptions for an Individual Employee	
				Disability [2]				Other					
Sample	Years of	Death [1]		General				General					
Ages	Service	Men	Women	Men	Women	Police	Fire	Men	Women	Police	Fire	Fire	Others [3]
ALL	0							19.00%	22.00%	18.00%	10.00%		
	1							17.00	20.00	17.00	8.00		
	2							15.00	17.00	16.00	7.00		
	3							13.00	14.00	13.00	6.00		
	4							11.00	13.00	12.00	6.00		
25	5 & Over	0.06%	0.01%	0.09%	0.02%	0.10%	0.06%	7.30	10.80	9.80	5.00	7.15%	6.55%
30		0.05	0.02	0.12	0.03	0.11	0.10	6.50	8.90	7.80	4.00	6.05	5.75
35		0.06	0.03	0.15	0.06	0.16	0.23	5.00	7.40	6.10	2.80	5.15	5.25
40		0.08	0.04	0.21	0.10	0.22	0.35	3.70	5.70	4.40	2.20	4.45	4.75
45		0.13	0.06	0.30	0.16	0.34	0.56	3.00	4.20	3.20	1.80	4.15	4.25
50		0.21	0.11	0.44	0.24	0.53	0.85	2.40	3.30	1.80	1.00	3.85	3.85
55		0.31	0.17	0.68	0.34			1.80	2.50	1.00	0.50	3.65	3.65
60		0.50	0.25					1.00	1.20	0.00	0.00	3.25	3.55
65		0.97	0.37					0.00	0.00	0.00	0.00	3.25	3.25

1 General, Police, Fire; Mortality rates for calendar year 2015. Future calendar year mortality rates incorporate mortality improvement factors from the 2-dimensional sex-distinct mortality improvement scale MP-2015.

2 General disabilities are assumed to be 70% non-duty related and 30% duty related. Police disabilities are assumed to be 55% non-duty related and 45% duty related. Fire disabilities are assumed to be 35% non-duty related and 65% duty related.

3 General, Police

*AUTHORITY: section 70.605.14, RSMo Supp. [2011] **2013**. Original rule filed Dec. 29, 1975, effective Jan. 8, 1976. For intervening history, please consult the **Code of State Regulations**. Amended: Filed July 29, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Any interested person or entity may submit written comments in support of or in opposition to the proposed amendment. Comments should be directed to the Missouri Local Government Employees Retirement System (LAGERS), ATTN: Robert Franson, Chief Counsel, PO Box 1665, Jefferson City, MO 65102-1665. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

Title 16—RETIREMENT SYSTEMS
Division 50—The County Employees' Retirement Fund
Chapter 2—Membership and Benefits

PROPOSED AMENDMENT

16 CSR 50-2.035 Payment of Benefits. The board is amending section (3).

PURPOSE: This amendment revises the benefit application and election procedures for members of the County Employees' Retirement Fund.

(3) Election **Process and** Period. Generally, a participant must complete **a two- (2-) step election process before he or she will receive benefits. A participant must complete** an **initial** application for benefits at least thirty (30), but not more than ninety (90), days prior to the date he or she wishes benefits to commence. **After the board receives the initial application, the board or its designee will provide the participant with a final benefit calculation. The participant must elect a payment option in accordance with section (2) above within ninety (90) days after such final benefit calculation is sent to the participant.** The annuity starting date for such a participant shall be the first of the month coincident with or following the date specified by the participant, or, if earlier, the participant's required beginning date. If the participant does not submit an application at least thirty (30) days prior to his or her separation from service**, or a payment option election form no later than ninety (90) days after the final benefit calculation is sent to the participant**, the payments will not be retroactive to the date of separation from service. Once a participant has submitted *[an]* **the initial** application, if supporting documentation has been requested but has not been obtained by the annuity starting date selected by the participant and the application has not been completely processed, the participant will not receive the first benefit payment until the additional documentation has been received and **both** the application *[has]* **and the payment option election form have** been completely processed. The payments will, however, be retroactive to the annuity starting date designated by the participant in his or her application**, provided that the payment option election form is received within ninety (90) days after the final benefit calculation is sent to the participant**. **If a participant fails to complete the two- (2-) step election process within ninety (90) days after the final benefit calculation is sent to the participant, the participant's application shall be canceled and deemed void and the first benefit payment will not be paid on or retroactive to the annuity starting date designated by the participant in such application. Such a participant will be required to submit a new initial application for benefits at least thirty (30), but not more than ninety (90), days prior to the date he or she wishes benefits to commence and a payment option election form in the time and manner described in this section, as though such participant had never submitted an initial application previously**. If a participant has not submitted an application upon his or her separation from service, his or her benefits will start on the first of the month following *[a thirty (30) day period from the date of the application]* **the submission and complete processing of an initial application and payment option election form as described in this section, but in no event later than the participant's required beginning date**.

*AUTHORITY: section 50.1032, RSMo 2000. Original rule filed July 29, 1997, effective Jan. 30, 1998. For intervening history, please consult the **Code of State Regulations**. Amended: Filed July 20, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the County Employees' Retirement Fund, 2121 Schotthill Woods Drive, Jefferson City, MO 65101. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2115—State Committee of Dietitians
Chapter 2—Licensure Requirements

PROPOSED RULE

20 CSR 2115-2.060 Military Training to Meet Requirements for Licensure

PURPOSE: This rule requires the committee to accept evidence of military education, training, or service to be applied toward the requirements for licensure.

(1) Any applicant for licensure may, as part of the evidence of meeting the requisite educational and/or training requirements for licensure, submit evidence of military experience as a member of the military.

(2) The committee shall review the evidence submitted and, if appropriate, make additional inquiry of the applicant to determine the scope and duties of the military experience to determine whether the military experience shall be counted towards the qualifications for licensure.

(3) In its review of the military experience, the committee shall evaluate the content and nature of the military experience to determine whether that military experience shall count towards the education, training, or service requirements for licensure. The committee shall construe liberally the military experience in determining whether it will count towards the education, training, or service requirements for licensure.

(4) "Military experience" shall mean education, training, or service completed by an applicant while a member of the United States armed forces or reserves, the national guard of any state, the military reserves of any state, or the naval militia of any state.

AUTHORITY: section 324.007, RSMo Supp. 2013, and section 324.228, RSMo 2000. Original rule filed July 25, 2016.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the State Committee of Dietitians, PO Box 1335, Jefferson City, MO 65102, via facsimile at (573) 526-3489, or via email at diet@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2115—State Committee of Dietitians
Chapter 2—Licensure Requirements

PROPOSED RULE

20 CSR 2115-2.061 Renewal of License or Registration for Military Members

PURPOSE: This rule sets forth the procedures for licensees and registrants who are members of any United States or State of Missouri military, pursuant to section 41.950, RSMo, who have served on active military duty, pursuant to section 41.950, RSMo. Specifically, the rule sets forth procedures for the renewal of a license or registration, for completing obligations of the board, and for discipline of a license or registration.

(1) Any individual holding a current license or registration that is engaged in the performance of active military duty who has their license or registration lapse while performing such military service, may renew or reinstate such license or registration without penalty by—

(A) Filing with the board a Notice of Active Military Duty on a form provided by the board or by written communication accepted by the board that shall be signed and dated by the individual and shall contain the individual's name, address, the type of license or registration, license or registration number, and the date of active duty activation, and shall be accompanied by a copy of the individual's active duty orders or other evidence sufficient for the board to determine the dates of active military duty; and

(B) Filing such Notice of Active Military Duty or accepted written communication with the board no later than sixty (60) days after completion of the active duty military service.

(2) Upon receipt and approval of the Notice of Active Military Duty or accepted written communication, the board shall reinstate the individual's license or registration with no further requirements.

(3) If a licensee or registrant fails to take any required action or fails to meet any required obligation of the board while the licensee or registrant is on active military duty, the licensee or registrant shall have at least one hundred eighty (180) days after the end of his or her active military duty to take those actions or fulfill those obligations before any administrative action can be taken by the board.

(4) If the board desires to initiate disciplinary action, administrative action, or any other proceeding where the licensee or registrant is a necessary party and the licensee or registrant is on active military duty, the board shall stay such action or proceeding until at least sixty (60) days after the licensee or registrant returns from active duty.

AUTHORITY: section 41.950, RSMo Supp. 2013, and section 324.228, RSMo 2000. Original rule filed July 25, 2016.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the State Committee of Dietitians, PO Box 1335, Jefferson City, MO 65102, via facsimile at (573) 526-3489, or via email at diet@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2115—State Committee of Dietitians
Chapter 2—Licensure Requirements

PROPOSED RULE

20 CSR 2115-2.062 Issuance of Temporary Courtesy License to Nonresident Military Spouse

PURPOSE: This rule states the requirements and procedures for a nonresident spouse of an active duty member of the military who is transferred to this state in the course of the member's military duty to obtain a temporary courtesy license to practice for one hundred eighty (180) days.

(1) The division shall grant a temporary courtesy license without meeting further requirements for licensure to a "nonresident military spouse" as defined in section 324.008.1, RSMo who provides the committee the following:

(A) A completed application form;

(B) A non-refundable application fee, as established by the division pursuant to rule, made payable to the State Committee of Dietitians;

(C) Verification sent directly to the division from the state, district, or territory in which the applicant holds a current and active license verifying that the applicant holds a current and active license;

(D) Proof that the applicant has been engaged in active practice in the state, district, or territory of the United States in which the applicant is currently licensed for at least (2) years in the five (5) years immediately preceding this application;

(E) Verification sent directly to division from each state, district or territory of the United States in which the applicant has ever been licensed verifying that—

1. The applicant is, or was at the time of licensure, in good standing;

2. The applicant has not committed an act in any jurisdiction where the applicant has or had a license that would have constituted grounds for the refusal, suspension, or revocation of a license or certificate to practice at the time the act was committed; and

3. The applicant has not been disciplined by a licensing or credentialing entity in another jurisdiction and is not the subject of an unresolved complaint, review procedure, or disciplinary proceeding by a licensing or credentialing entity in another jurisdiction;

(F) If the division is unable to determine if the licensing requirements of the state, district, or territory in which the applicant is currently licensed are equivalent to Missouri's licensing requirements, the applicant shall submit documentation regarding the licensing requirements equivalency;

(G) Such additional information as the division may request to determine eligibility for a temporary courtesy license.

(2) Any temporary courtesy license issued pursuant to this rule shall be valid for one hundred eighty (180) days from the date of issuance and may be extended for another one hundred eighty (180) days upon submission of a written request by the holder of the temporary courtesy license.

(3) If a nonresident military spouse seeks full licensure in this state during the time while the temporary courtesy license is valid, he or she may request full licensure by filing a written request with the division. Any fees paid for a temporary courtesy license shall be credited towards the application fees due for full licensure.

AUTHORITY: section 324.008, RSMo Supp. 2013, and section 324.228, RSMo 2000. Original rule filed July 25, 2016.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the State Committee of Dietitians, PO Box 1335, Jefferson City, MO 65102, via facsimile at (573) 526-3489, or via email at diet@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2193—Interior Design Council
Chapter 2—Registration Requirements

PROPOSED RULE

20 CSR 2193-2.050 Renewal of License or Registration for Military Members

PURPOSE: This rule sets forth the procedures for licensees and registrants who are members of any United States or State of Missouri military, pursuant to section 41.950, RSMo, who have served on active military duty, pursuant to section 41.950, RSMo. Specifically, the rule sets forth procedures for the renewal of a license or registration, for completing obligations of the board, and for discipline of a license or registration.

(1) Any individual holding a current license or registration that is engaged in the performance of active military duty who has their license or registration lapse while performing such military service, may renew or reinstate such license or registration without penalty by—

(A) Filing with the board a Notice of Active Military Duty on a form provided by the board or by written communication accepted by the board that shall be signed and dated by the individual and shall contain the individual's name, address, the type of license or registration, license or registration number, and the date of active duty activation, and shall be accompanied by a copy of the individual's active duty orders or other evidence sufficient for the board to determine the dates of active military duty; and

(B) Filing such Notice of Active Military Duty or accepted written communication with the board no later than sixty (60) days after completion of the active duty military service.

(2) Upon receipt and approval of the Notice of Active Military Duty or accepted written communication, the board shall reinstate the individual's license or registration with no further requirements.

(3) If a licensee or registrant fails to take any required action or fails to meet any required obligation of the board while the licensee or registrant is on active military duty, the licensee or registrant shall have at least one hundred eighty (180) days after the end of his or her active military duty to take those actions or fulfill those obligations before any administrative action can be taken by the board.

(4) If the board desires to initiate disciplinary action, administrative action, or any other proceeding where the licensee or registrant is a necessary party and the licensee or registrant is on active military duty, the board shall stay such action or proceeding until at least sixty (60) days after the licensee or registrant returns from active duty.

AUTHORITY: section 41.950, RSMo Supp. 2013, and section 324.412, RSMo 2000. Original rule filed July 21, 2016.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Interior Design Council, PO Box 1335, Jefferson City, MO 65102, via facsimile at (573) 526-3489, or via email at intdesn@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2193—Interior Design Council
Chapter 2—Registration Requirements

PROPOSED RULE

20 CSR 2193-2.055 Military Training to Meet Requirements for Licensure

PURPOSE: This rule requires the division to accept evidence of military education, training, or service to be applied toward the requirements for licensure.

(1) Any applicant for licensure may, as part of the evidence of meeting the requisite educational and/or training requirements for licensure, submit evidence of military experience as a member of the military.

(2) The division shall review the evidence submitted and, if appropriate, make additional inquiry of the applicant to determine the

scope and duties of the military experience to determine whether the military experience shall be counted towards the qualifications for licensure.

(3) In its review of the military experience, the division shall evaluate the content and nature of the military experience to determine whether that military experience shall count towards the education, training, or service requirements for licensure. The division shall construe liberally the military experience in determining whether it will count towards the education, training, or service requirements for licensure.

(4) "Military experience" shall mean education, training, or service completed by an applicant while a member of the United States armed forces or reserves, the national guard of any state, the military reserves of any state, or the naval militia of any state.

AUTHORITY: section 324.007, RSMo Supp. 2013, and section 324.412, RSMo 2000. Original rule filed July 21, 2016.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Interior Design Council, PO Box 1335, Jefferson City, MO 65102, via facsimile at (573) 526-3489, or via email at intdesn@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2210—State Board of Optometry
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2210-2.030 License Renewal. The board is amending section (11) by adding a new subsection (E) and renumbering as needed.

PURPOSE: This amendment clarifies the number of continuing education hours which may be obtained by a method where the licensee is not physically present.

(11) The following guidelines govern the attendance of educational optometric programs for license renewal:

(E) Of the thirty-two (32) hours of board-approved continuing education required for license renewal, no more than sixteen (16) hours may be obtained through distance learning methods such as correspondence courses, online only courses, magazine articles, or other methods where the licensee is not physically present with the course speaker or presenter;

*[(E)]***(F)** Individuals who obtain a license by endorsement during the second year of a two- (2-)*[-]* year reporting period will only be required to obtain sixteen (16) hours of continuing education in order to renew the license for the initial license renewal. Individuals who obtain a license by endorsement during the first year of a two- (2-)*[-]* year reporting period will be required to obtain thirty-two (32) hours of board-approved continuing education in order to renew the license for the initial license renewal;

*[(F)]***(G)** Individuals who obtain a license by examination shall be considered to have satisfied the continuing education requirement for the first renewal after their initial license date;

*[(G)]***(H)** Licensees who present Council on Optometric Practitioner Education (COPE)-approved continuing education will be allowed one (1) hour of continuing education credit for each hour of the continuing education presented. Each COPE numbered course may be used one (1) time for continuing education credit during the reporting period;

*[(H)]***(I)** Licensees who are enrolled in a postgraduate residency program accredited by the Council on Optometric **Practitioner** Education will receive sixteen (16) hours of continuing education credit to satisfy one (1) year of the two- (2-)*[-]* year reporting period; and

*[(I)]***(J)** The board will consider requests for exemption from the educational requirements only if the request for exemption is filed with the board's executive director and actually approved by the board before the end of the reporting period. The request for exemption must be by sworn affidavit and must clearly set out the reasons asserted for noncompliance, including at least a listing of all other years for which the board has exempted the licensee and a listing of the dates upon which the licensee's reasons for exemption required his/her absence from active practice. In its discretion, the board may refuse to exempt a licensee from the required attendance, notwithstanding the existence of a valid reason, if the board determines that the licensee has or had other reasonable opportunities to meet the requirements of this rule.

*AUTHORITY: sections 336.080 and 336.160.1, RSMo Supp. 2013. This rule originally filed as 4 CSR 210-2.030. Original rule filed Dec. 19, 1975, effective Dec. 29, 1975. For intervening history, please consult the **Code of State Regulations**. Amended: Filed July 18, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will not cost private entities more than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Optometry, PO Box 1335, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 751-8216, or via email at optometry@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

20 CSR 2220-2.200 Sterile *[Pharmaceuticals]* ***Compounding***. The board is amending the title, purpose statement, and all sections of this rule. Additionally, the board is deleting sections (5), (6), (8), (15), and (16) of the current rule and adding new sections (5), (6), (7), (10), (17), (18), (20), and (21).

PURPOSE: This board is amending all sections of this rule to update, clarify, and delineate requirements for sterile compounding pharmacies.

PURPOSE: This rule establishes standards for the [preparation]

***handling**, labeling [and], distribution, **and dispensing** of [sterile pharmaceuticals] **compounded sterile preparations** by licensed pharmacies, pursuant to a physician's order or prescription.*

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Definitions.

(B) Batch: Compounding of multiple sterile *[product]* **preparation** units in a single discrete process, by the same individuals, carried out during one (1) limited time period.

(D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the *[product]* **preparation**, personnel**,** and environment, according to National Sanitation Foundation (NSF) International standards.

[(E) Class 100 environment: an atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(F) Class 10,000 environment: An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

(G) Clean room: A room—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(H) Clean zone: Dedicated space—

1. In which the concentration of airborne particles is controlled;

2. That is constructed and used in a manner that minimizes the introduction, generation, and retention of particles inside the zone; and

3. In which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

This zone may be open or enclosed and may or may not be located within a clean room.]

(E) Buffer area: An ISO Class 7 or better area where the primary engineering control is physically located that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

*[(I)]***(F)** Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR 2220-2.400(1). Compounded sterile medications may include, but are not limited to*[, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.]***:**

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must or are required to be sterile when they are administered to patients, including, but not limited to the following dosage forms: bronchial and inhaled nasal preparations intended for deposition in the lung, baths and soaks for live organs and tissues, epidural and intrathecal solutions, bladder/wound solutions, injectables, implantable devices and dosage forms, inhalation solutions, intravenous solutions, irrigation solutions, ophthalmic preparations, parenteral nutrition solutions, and repackaged sterile preparations. Nasal sprays and irrigations intended for deposit in the nasal passages may be prepared as nonsterile compounds;

2. An FDA approved manufactured sterile product that is either prepared according to the manufacturers' approved labeling/recommendations or prepared differently than published in such labeling; and

3. Assembling point-of-care assembled systems.

(G) Compounding aseptic containment isolator (CACI): A restricted access barrier system (RABS) that is designed for compounding sterile hazardous drugs and designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment for Compounded Sterile Preparation (CSPs).

(H) Compounding aseptic isolator (CAI): A RABS specifically designed for compounding sterile non-hazardous pharmaceutical ingredients or CSPs and designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

[(J) Controlled area: For purposes of these regulations, a controlled area is the area designated for preparing sterile products. This is referred to as the buffer zone (i.e., the clean room in which the laminar airflow workbench is located) by the United States Pharmacopoeia (USP).]

(I) Controlled area: For purposes of these regulations, a controlled area is a separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations.

*[(K)]***(J)** Critical area: Any area in the controlled area where *[products]* **preparations** or containers are exposed to the environment.

[(L) Critical site: An opening providing a direct pathway between a sterile product and the environment or any surface coming into contact with the product or environment.]

(K) Critical site: Any surface, pathway, or opening (e.g., vial septa, injection ports, beakers, needle hubs) that provides a direct pathway between a compounded sterile preparation or other ingredient used to compound a sterile preparation and the air, environment or moisture, or that poses a risk of touch contamination.

(L) CSP: Compounded sterile preparation.

[(M) Critical surface: Any surface that comes into contact with previously sterilized products or containers.]

*[(N)]***(M)** Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system**,** and the alteration of a host's inflammatory response system.

*[(O)]***(N)** Emergency dispensing: Is a situation where a Risk Level 3 *[product]* **preparation** is necessary for immediate administration of the *[product]* **preparation** and no alternative product **or preparation** is available and the prescriber is informed that the *[product]* **preparation** is being dispensed prior to appropriate testing. Documentation of the dispensing of the *[product]* **preparation**, the prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.

*[(P)]***(O)** High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench,

an environment can be created consistent with standards for a *[Class 100 clean room]* **ISO Class 5 environment**.

(P) In-use time/date: The time/date before which a conventionally manufactured product or a CSP must be used after it has been opened or needle-punctured.

[(Q) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits.]

(Q) ISO Class 5: An area with less than three thousand five hundred twenty (3,520) particles (0.5 μm and larger in size) per cubic meter.

(R) ISO Class 7: An area with less than three hundred fifty-two thousand (352,000) particles (0.5 μm and larger in size) per cubic meter.

(S) Multiple-dose container: A multiple unit container for articles or compounded sterile preparations that contains more than one (1) dose of medication and usually contains an antimicrobial preservative.

*[(R)]***(T)** Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of skin.

(U) Point-of-care assembled system: A closed system device that creates a physical barrier between diluents, fluids, or other drug components and is designed to be activated by the end user by allowing the components to mix prior to administration.

(V) Primary engineering control (PEC): A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but may not be limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, RABS such as compounding aseptic isolators (CAIs), or compounding aseptic containment isolators (CACIs).

*[(S)]***(W)** Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the *[product]* **preparation** and with the same container or closure system.

*[(T)]***(X)** Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug *[products]* **preparations** lead to *[products]* **preparations** that meet predetermined standards of quality.

*[(U)]***(Y)** Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components**,** and final sterile *[products]* **preparations** prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity**,** and sterility.

(Z) Restricted access barrier system (RABS): A primary engineering control that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a CAI or CACI.

*[(V)]***(AA)** Repackaging: The subdivision or transfer of a compounded *[product]* **preparation** from one **(1)** container or device to a different container or device.

[(W) Sterile pharmaceutical: A dosage form free from living microorganisms.]

(BB) Single-dose/single-unit container/vial: A container/vial of medication intended for administration that is meant for use in a single patient for a single case, procedure, or injection.

*[(X)]***(CC)** Sterilization: A validated process used to render a *[product]* **preparation** free of viable organisms.

*[(Y)]***(DD)** Temperatures:

1. Frozen means temperatures between twenty**-five degrees** below zero and ten degrees **below zero** Celsius (-*[20]***25** and **-**10°C) (*[four]* **thirteen degrees** below zero and fourteen degrees Fahrenheit *(-[4]***13** and 14°F))*[.]***;**

2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8°C) (thirty-six and forty-six degrees Fahrenheit (36 and 46°F))*[.]***; and**

3. *[Room temperatures means room temperatures between fifteen and thirty degrees Celsius (15 and 30°C) (fifty-nine and eighty-six degrees Fahrenheit (59 and 86°F)).]* **Controlled room temperatures means a temperature maintained thermostatically that encompasses the usual and customary working environment 20° to 25° Celsius (68 to 78° F). Excursions between 15° and 30° Celsius (59 to 86° F) as commonly experienced in pharmacies and other facilities shall be deemed compliant.**

(EE) USP: *The United States Pharmacopeia and the National Formulary* (USP-NF) as adopted and published by the United States Pharmacopeial Convention, effective May 2013. Copies of the USP-NF are published by, and available from, USP, 12601 Twinbrook Parkway, Rockville, MD 20852-1790 or online at http://www.usp.org/. The USP-NF is incorporated herein by reference. This rule does not include any later amendments or additions to the USP-NF.

*[(Z)]***(FF)** Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a *[product]* **preparation** meeting predetermined specifications and quality attributes.

*[(AA)]***(GG)** Definitions of sterile compounded *[products]* **preparations** by risk level:

1. Risk Level 1: Applies to compounded sterile *[products]* **preparations** that exhibit characteristics A., B., *[and]* **or** C., stated below. All Risk Level 1 *[products]* **preparations** shall be prepared with sterile equipment*[,]* **and** sterile ingredients and solutions *[and sterile contact surfaces for the final product]* **in an ISO Class 5 environment**. Risk Level 1 includes the following:

A. *[Products]* **Preparations**:

(I) Stored at **controlled** room temperature and *[completely administered within]* **assigned a beyond-use date of** forty-eight (48) hours *[after preparation]* **or less**; or

(II) Stored under refrigeration *[for]* **and assigned a beyond-use date of** seven (7) days or less *[before complete administration to a patient over a period not to exceed forty-eight (48) hours]*; or

(III) *[Frozen for thirty (30) days or less before complete administration to a patient over a period not to exceed forty-eight (48) hours.]* **Stored frozen and assigned a beyond-use date of thirty (30) days or less;**

B. Unpreserved sterile *[products]* **preparations** prepared for administration to one (1) patient or batch-prepared *[products]* **preparations** containing suitable preservatives prepared for administration to more than one (1) patient **with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule***[.]***;**

C. *[Products]* **Preparations** prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers **with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule***[.]***;**

2. Risk Level 2: Sterile *[products]* **preparations** exhibit characteristic A., B., or C., stated below. All Risk Level 2 *[products]* **preparations** shall be prepared with sterile equipment*[,]* **and** sterile

ingredients *[and solutions and sterile contact surfaces for the final product]* **in an ISO Class 5 environment** and with closed-system transfer methods. Risk Level 2 includes the following:

A. *[Products stored beyond seven (7) days under refrigeration, stored beyond thirty (30) days frozen or administered beyond forty-eight (48) hours after preparation and storage at room temperature.]* **Preparations stored under refrigeration and assigned a beyond-use date greater than seven (7) days, or preparations stored frozen and assigned a beyond-use date greater than thirty (30) days, or preparations stored at controlled room temperature and assigned a beyond-use date greater than forty-eight (48) hours;**

B. Batch-prepared *[products]* **preparations** without preservatives that are intended for use by more than one (1) patient*[.]***;**

C. *[Products]* **Preparations** compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder)*[.]***;**

3. Risk Level 3: Sterile *[products]* **preparations** exhibit either characteristic A. or B.:

A. *[Products]* **Preparations** compounded from nonsterile ingredients or compounded with nonsterile components, containers**,** or equipment before terminal sterilization*[.]***;**

B. *[Products]* **Preparations** prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

(2) Policy and Procedure Manual/Reference Manuals.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2**,** and 3 *[products]* **compounding**, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis. The pharmacy shall have current reference materials related to sterile *[products]* **preparations**.

(3) Personnel Education, Training**,** and Evaluation.

(A) Risk Level 1: All pharmacy personnel preparing sterile *[products]* **preparations** must receive suitable didactic and experiential training **in aseptic technique and procedures and shall be skilled and trained to accurately and competently perform the duties assigned. Additional training must be provided if the risk level of sterile activity conducted by the individual changes or if there is a change in compounding methods performed**. **To ensure competency, individuals preparing sterile preparations must successfully pass an Aseptic Technique Skill Assessment that complies with section (10) of this rule. The pharmacy shall establish policies and procedures for staff training and assessment.**

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training **must** include*[s]* assessment of competency in all Risk Level 2 procedures via process simulation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training**,** and experience to prepare Risk Level 3 *[products]* **preparations**. The pharmacist knows principles of good compounding practice for risk level *[products]* **preparations**, including—

1. Aseptic processing;

2. Quality assurance of environmental, component, and *[end-product]* **end-preparation** testing;

3. Sterilization; and

4. Selection and use of containers, equipment, and closures.

(4) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies**,** and **compounding** equipment must be stored *[according to manufacturer or USP requirements]* **and maintained in a manner that will maintain the chemical and microbiological stability of CSPs**. Refrigeration *[and]***,** freezer **and, if applicable, incubator** temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of *[products]* **drugs and supplies** from boxes shall be done outside **the** controlled **and buffer** areas. Removal of used supplies from the controlled area shall be done at least daily. *[Product]* **Preparation** recall procedures must **comply with section (21) of this rule and must** permit retrieving affected *[products]* **preparations** from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, **the pharmacy must establish** procedures *[include]* **for** procurement, identification, storage, handling, testing, and recall of components and finished *[products]* **preparations**. Finished *[but untested]* Risk Level 3 *[products]* **preparations awaiting test results** must be quarantined under minimal risk for contamination **in a manner that will maintain chemical and microbiological stability**.

[(5) Facilities and Equipment.

(A) Risk Level 1: The controlled area shall be separated from other operations. The controlled area must be clean and well lit. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected regularly. Sterile products must be prepared in at least a Class 100 environment (the critical area). Computer entry, order processing, label generation, and record keeping shall be performed outside the critical area. The critical area must be disinfected prior to use. A workbench shall be recertified every six (6) months and when it is moved; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, the controlled area must meet Class 10,000 clean room standards; cleaning supplies should be selected to meet clean room standards; critical area work surface must be cleaned between batches; floors should be disinfected daily; equipment surfaces weekly; and walls monthly; with applicable environmental monitoring of air and surfaces. Automated compounding devices must be calibrated and verified as to accuracy, according to manufacturer procedures. Clean rooms not utilized on a daily basis must be cleaned prior to use as stated above.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, products must be prepared in a Class 100 workbench in a Class 10,000 clean room, in a Class 100 clean room or within a positive pressure barrier isolator. Access to the clean room must be limited to those preparing the products and who are in appropriate garb. Equipment must be cleaned, prepared, sterilized, calibrated, and documented according to manufacturer's standards. Walls and ceilings must be disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final product must be sterilized before introduction in the clean room. Appropriate cleaning and disinfection of the environment and equipment are required.

(6) Apparel.

(A) Risk Level 2: In the controlled area, personnel wear low particulate, clean clothing covers. Head and facial hair is covered. Gloves, gowns, and masks are required. During sterile preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is compromised.

(B) Risk Level 3: In addition to Risk Level 2 requirements, clean room apparel must be worn inside the controlled area at all times during the preparation of Risk Level 3 sterile products except when positive pressure barrier isolation is utilized. Attire shall consist of a low-shedding coverall, head

cover, face mask, and shoe covers.]

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas.

(A) Risk Level 1: Risk Level 1 preparations must be prepared in a PEC located in a controlled area that meets the requirements of this rule. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected as provided in section (17) of this rule. Activities within the critical area shall be kept to a minimum to maintain the ISO classified environment. Primary engineering controls shall meet the requirements of section (6) of this rule; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, Risk Level 2 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. Applicable environmental monitoring of air and surfaces must be conducted. Risk Level 2 preparations shall at a minimum remain a Risk Level 2 for the life of the preparation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS. Once compounded, Risk Level 3 preparations shall at a minimum remain Risk Level 3 for the life of the preparation.

(D) Automated compounding devices shall be tested for content, volume, and weight accuracy prior to both initial and daily use according to manufacturer procedures. Test results shall be reviewed by a pharmacist to ensure compliance. The identity of the reviewing pharmacist and the review date shall be documented in the pharmacy's records.

(E) All PECs and ISO classified areas shall be certified to ensure compliance with the requirements of this rule prior to beginning sterile compounding activities and every six (6) months thereafter. Certification shall be conducted by competent staff/vendors using recognized and appropriate certification and testing equipment. Certification results shall be reviewed by a pharmacist once received. Deficiencies or failures shall be investigated and corrected prior to further compounding which may include recertification of the PEC/ISO classified area.

1. The PEC and ISO classified areas must be recertified when— 1) any changes or major service occurs that may affect airflow or environmental conditions or 2) the PEC or room is relocated or the physical structure of the ISO classified area has been altered.

2. Corrections may include, but are not limited to, changes in the use of the affected PEC or ISO classified area or initiating a recall. The identity of the pharmacist conducting the required review and the review date shall be documented in the pharmacy's records.

(F) Pressure differential: If the controlled area is equipped with a device to monitor pressure differential, pressure differential results must be recorded and documented each day that the pharmacy is open for pharmacy activities. Alternatively, a continuous monitoring system may be used to record pressure differential results if the system maintains ongoing documentation of pressure recordings or maintains pressure alerts that are reviewed daily.

(6) Primary Engineering Controls (PECs).

(A) PECs must be properly used, operated, and maintained and must be located out of traffic patterns and away from conditions that could adversely affect their operation or disrupt intended airflow patterns (e.g., ventilation systems or cross-drafts).

(B) PECs shall maintain ISO Class 5 or better conditions during dynamic operating conditions and while compounding sterile preparations, including, when transferring ingredients into and out of the PEC and during exposure of critical sites.

(C) PECs shall provide unidirectional (laminar flow) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

(D) The recovery time to achieve ISO Class 5 air quality in any PEC shall be identified in the pharmacy's policies and procedures. Procedures must be developed to ensure adequate recovery time is allowed before or during compounding operations and after material transfer.

(7) Controlled Areas. The controlled area shall be designed, maintained, and controlled to allow effective cleaning and disinfection and to minimize the risk of contamination and the introduction, generation, and retention of particles inside the PEC.

(A) Controlled areas must be clean and well-lit and shall be free of infestation by insects, rodents, and other vermin. Trash shall be disposed of in a timely and sanitary manner and at least daily. Tacky mats or similar articles are prohibited in the controlled area or any ISO classified environment.

(B) Traffic flow in or around the controlled area shall be minimized and controlled. Food items, chewing gum, eating, drinking, and smoking are prohibited in the area.

(C) Nonessential objects that shed particles shall not be brought into the controlled area, including, but not limited to, pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads). Furniture, carts, supplies, and equipment shall be removed from shipping cartons/containers and properly cleaned and disinfected with sterile alcohol before entering any ISO classified area. No shipping or other external cartons may be taken into the controlled area or an ISO classified area.

(D) Only supplies essential for compounding shall be stored in the controlled area. Supplies or other non-essential equipment shall not be stored in or on the PEC.

(8) Garbing and Hand Hygiene. Individuals engaged in, or assisting with, CSPs shall be trained and demonstrate competence in proper personal garbing, gloving, and hand hygiene. Competence must be documented and assessed through direct visual observation as part of the aseptic technique skill assessment required by this rule.

(A) Risk Level 1: Low-particulate and non-shedding gowns, hair covers, gloves, face masks, and beard covers must be worn during compounding and cleaning. All head and facial hair must be covered. During sterile preparation, gloves shall be disinfected before use and frequently thereafter with a suitable agent and changed when integrity is compromised. All personnel in the controlled area must be appropriately garbed as required by this section.

(B) Risk Level 2 and Risk Level 3: In addition to Risk Level 1 requirements, shoe covers and sterile gloves must be worn while compounding and cleaning, including, over RABS gloves. All personnel in the controlled or buffer area must garb as required by this section.

*[(7)]***(9)** Aseptic Technique and *[Product]* Preparation. **Appropriate quality control methods shall be maintained over compounding methods at all times to ensure proper aseptic technique.**

(A) Risk Level 1: Sterile *[products]* **preparations** must be prepared in *[a Class 100]* **an ISO Class 5** environment. Personnel shall scrub their hands and forearms *[for an appropriate period at the beginning of each aseptic compounding process]* **a minimum of thirty (30) seconds and remove debris from underneath**

fingernails under warm running water before donning the required gloves. Eating, drinking**,** and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the *[product]* **preparation** to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration**,** and integrity before use. Only materials essential for aseptic compounding shall be placed in the *[workbench]* **PEC**. *[Surfaces of ampules and vials shall be disinfected before placement in the workbench.]* **Supplies, equipment, and the surfaces of ampules and vials shall be disinfected before entering the PEC by wiping the outer surface with sterile alcohol or an equivalently effective non-residue generating disinfectant.** Sterile components shall be arranged in the *[workbench]* **PEC** to allow **a clear,** uninterrupted *[laminar airflow]* **path of HEPA-filtered air** over critical *[surfaces of needles, vials, ampules, etc]* **sites**. Automated devices and equipment shall be cleaned, disinfected**,** and placed in the *[workbench]* **PEC** to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions**, if applicable**. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

(B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing **the** formula, components, procedures, sample label, and final evaluation shall be made for each *[product]* **preparation** batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile *[products]* **preparations**, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end *[product]* **preparation** for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet **compendial** standards *[if available, as]* **or must be** verified by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining *[product]* **preparation** integrity throughout the shelf life. Sterilization methods must be based on properties of the *[product]* **preparation, and must be conducted in a method recognized for the preparation and confirmed through sterility testing according to USP requirements**.

(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container.

(E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an antimicrobial preservative may be used in compounding until the assigned in-use date which shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g., needle-puncture). The in-use date must be placed on the vial/container.

[(8) Process Validation.

(A) Risk Level 1: All pharmacy personnel who prepare sterile products shall pass a process validation of aseptic technique before compounding sterile products. Pharmacy personnel competency must be reevaluated by process validation at least annually, whenever the quality assurance program yields an unacceptable result, or whenever unacceptable techniques are observed. If microbial growth is detected, the entire sterile process must be evaluated, corrective action taken, and the process simulation test performed again.

(B) Risk Level 2: In addition to Risk Level 1 requirements, process simulation procedures shall cover all types of manipulations, products and batch sizes.

(C) Risk Level 3: In addition to all Risk Level 1 and 2 requirements, written policies shall be maintained to validate all processes, procedures, components, equipment and techniques.]

(10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must take and successfully pass an aseptic technique skill assessment to verify aseptic competency. The assessment must include a direct visual observation of the individual's aseptic competency during a process simulation that represents the most challenging or stressful conditions encountered or performed by the person being evaluated. The assessment must include media fill testing for all risk levels.

(A) The required visual observation shall assess:

1. Proper aseptic technique, manipulations, and work practices, including, but not limited to, avoiding touch contamination, proper use of first air, and if applicable, sterilizing high risk CSPs;

2. Cleaning and disinfection;

3. Hand hygiene, gloving, and garbing;

4. Identifying, weighing, and measuring of ingredients;

5. Maintaining sterility in ISO Class 5 areas;

6. Labeling and inspecting CSPs for quality.

(B) Media-Fill Testing. Pharmacies shall establish and follow policies and procedures for media-fill testing. Media-fill testing shall comply with USP Chapter 797's recommended procedures and methods and must be conducted using the most challenging or stressful conditions/compounding actually encountered or performed by the person being evaluated using the same container or closure. A minimum of three (3) media-fill tests must be completed during initial media-fill testing and one (1) media-fill test completed for ongoing testing.

(C) Frequency: The required Aseptic Technique Skill Assessment must be conducted prior to initial compounding and every twelve (12) months thereafter for Risk Levels 1 and 2 compounding and every (6) months thereafter for Risk Level 3 compounding. Additionally, an Aseptic Technique Skill Assessment must be conducted whenever the quality assurance program yields an unacceptable result, whenever unacceptable techniques are observed, if the risk level of sterile activity conducted by the individual changes, or if there is a change in compounding methods performed.

(D) Individuals who fail written tests; visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must undergo immediate requalification through additional training by competent compounding personnel. Individuals who fail visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must pass three (3) successive reevaluations in the deficient area before they can resume compounding of sterile preparations.

*[(9)]***(11)** Record Keeping.

(A) Risk Level 1: The following must be documented:

1. Training and competency evaluation of pharmacy personnel involved in sterile *[product preparation]* **compounding, including, the dates and results of the required aseptic technique training, aseptic technique skill assessment, and media-fill testing**;

2. Refrigerator**,** *[and]* freezer **and, if applicable, incubator** temperature logs;

3. Certification *[of workbenches]* **dates and results for any PEC or ISO classified area**;

4. *[Copies of any m]***M**anufacturer *[standards]* **manuals** that are relied upon to maintain compliance with this rule; *[and]*

5. Other facility quality control logs as appropriate including all maintenance, cleaning, and calibration records*[.]***; and**

6. If applicable, pressure recordings including documentation of the review of continuous monitoring system results as required by subsection (5)(F).

(B) Risk Level 2: In addition to Risk Level 1 requirements, records of any *[end-product]* **end-preparation** testing and batch preparation records must be maintained.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 *[products]* **preparations** must include:

1. Preparation work sheet;
2. Sterilization records;
3. Quarantine records, if applicable;
4. *[End-product]* **End-preparation** evaluation and testing records as required in section *[(12)]* **(14)**; and
5. Ingredient validation records as required in section *[(12)]* **(14)**.

(D) All records and reports shall be maintained **either electronically or physically** for two (2) years and shall be readily retrievable*[,]* **and** subject to inspection*[s]* by the board of pharmacy or its agents. **At a minimum, records shall be physically or electronically produced immediately or within two (2) hours of a request from the board or the board's authorized designee.**

*[(10)]***(12)** Labeling.

(A) *[Risk Level 1:]* Sterile *[products dispensed to patients]* **preparations** shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information *[affixed to a permanent label]*:

1. Beyond-use date;
2. Storage requirements **if stored at other than controlled room temperature**;
3. Any device specific instructions*; [and]*
4. Auxiliary labels, when applicable*[.]***; and**
5. If applicable, a designation indicating the preparation is hazardous.**

[(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: All requirements for Risk Level 1 must be met.]

*[(11)]***(13)** Beyond-Use Dating.

(A) Risk Level 1 **and Risk Level 2**: All sterile *[products]* **preparations** must bear a beyond-use date. Beyond-use dates *[are]* **must be** assigned based on current drug **and microbiological** stability information and sterility considerations.

[(B) Risk Level 2: All requirements for Risk Level 1 must be met.]

*[(C)]***(B)** Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all *[expiration]* **beyond-use** dates, including laboratory testing of *[product]* **preparation** stability, pyrogenicity, particulate contamination**,** and potency. *[Expiration dating not specifically referenced in the product's approved labeling or not established by product specific instrumental analysis, shall be limited to thirty (30) days.]* Beyond-use dating not specifically referenced in the products approved labeling or not established by *[product]* **preparation** specific instrumental analysis shall be limited to thirty (30) days. There must be a reliable method for establishing all beyond-use dating. *[Products maintaining beyond-use dating]* **Preparations assigned a beyond-use date** of greater than thirty (30) days shall have lab testing of *[product]* **preparation** stability and potency.

*[(12)]***(14)** End-*[product]***preparation** Evaluation.

(A) Risk Level 1: The final *[product]* **preparation** must be inspected for **clarity,** container leaks, integrity*[,]* **and appropriate** solution cloudiness or phase separation, *[particulates in solution, appropriate]* solution color, and solution volume. The pharmacist must verify that the *[product]* **preparation** was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of *[products]* **preparations** for any particulate and/or foreign matter must be used as part of the inspection process**, provided an alternate means of inspection shall be used if a visual inspection or exposure to the preparation may pose a health hazard**.

(B) Risk Level 2: All Risk Level 1 requirements must be met.

(C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of *[end-product]* **end-preparation** sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch *[products]* **preparations** shall be established if *[end-product]* **preparation** testing results are unacceptable. *[All sterile products]* **A sample from each sterile preparation/batch** must be tested for sterility. *[All parenteral sterile products]* **A sample from each parenteral sterile preparation/batch** must also be tested for pyrogenicity. *[Sterile products compounded from nonsterile components]* **Risk Level 3 preparations** must be quarantined **and stored to maintain chemical and microbiological stability** pending results of *[end-product]* **end-preparation** testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test, including the sampling scheme, shall be conducted according to *[one (1) of the USP methods]* **a method recognized for the preparation by USP Chapter 71**.

2. Pyrogen/Endotoxin testing: *[Each s]***S**terile parenteral *[product]* **preparations** prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to *[recommended USP methods]* **a method recognized by USP Chapter 151 for pyrogen testing and recognized by USP Chapter 85 for endotoxin testing**.

3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile *[product]* **preparation** prepared from non-sterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:

A. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis**,** and other relevant qualities;

B. All weighings, volumetric measurements, and additions of ingredients were carried out properly;

C. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct; and

D. The final potency is confirmed by instrumental analysis for sterile *[products]* **preparations** that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile *[Product]* **Preparation**: When a compounded Risk Level 3 *[product]* **preparation** must be released prior to the completion of testing, the sterile *[product]* **preparation** may be dispensed pending test results. **Emergency dispensing shall be defined as, and comply with, subsection (1)(N) of this rule.**

*[(13)]***(15)** *[Handling Sterile Products Outside the Pharmacy]* **Storage, Handling, and Transport**.

[(A) Risk Level 1:] **Sterile preparations shall be packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability until the assigned beyond-use date or until delivery to the patient or intended recipient.** The pharmacist-in-charge shall assure the environmental control of all sterile compounded *[products]* **preparations** shipped. Sterile *[products]* **preparations** shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile *[products]* **preparations**. The pharmacy shall follow written procedures that

specify packing techniques, configuration, and materials for groups of *[products]* **preparations** with common storage characteristics and for specific *[products]* **preparations** where unique storage conditions are required to retain adequate stability and *[product]* **preparation** quality.

[(B) Risk Level 2: All requirements for Risk Level 1 must be met.

(C) Risk Level 3: All requirements for Risk Level 1 must be met.]

(16) Point-of-Care Assembled Systems. Assembly of point-of-care assembled systems shall be considered Risk Level 1 compounding. Point-of-care assembled systems shall be assigned a beyond-use date which may exceed the beyond-use-date authorized for Risk Level 1 preparations provided the date is assigned in accordance with the manufacturer's recommendations or labeling.

(A) When dispensed, an assembled non-activated system shall be labeled with beyond-use dates for both activated and non-activated states. The compounding record must document both dates. The beyond-use date of an assembled non-activated system shall be limited to a maximum of fifteen (15) days unless the pharmacy has documentation from the system's manufacturer that a longer date is acceptable.

(B) Point-of-care assembled systems shall be assembled and stored in accordance with the manufacturer's labeling and recommendations.

(17) General Cleaning and Disinfection Requirements. Except as otherwise provided herein, cleaning and disinfection of controlled and buffer areas, supplies, and equipment shall be performed and conducted in accordance with USP Chapter 797 timeframes and procedures. Controlled areas that do not meet ISO air classifications shall be cleaned and disinfected as required by USP Chapter 797 for segregated compounding areas. If compounding is done less frequently than the cleaning and disinfection timeframes specified in USP Chapter 797, cleaning and disinfection must occur before each compounding session begins.

(A) The pharmacy shall establish and follow written policies and procedures governing all aspects of cleaning and disinfection, including approved cleaning/disinfecting agents and materials, schedules of use, and methods of application.

(B) Individuals shall be trained in proper cleaning and disinfection procedures prior to performing such activities. Training shall include direct visual observation of the individual's cleaning and disinfecting process by qualified staff. The individual shall be annually reassessed for competency through direct visual observation. Documentation of the required training and training dates shall be maintained in the pharmacy's records. Individuals who fail to demonstrate competency shall be reinstructed and successfully reevaluated prior to any further cleaning or disinfection.

(C) Cleaning and disinfection activities shall be performed using approved cleaning/disinfection agents and procedures described in the pharmacy's written policies and procedures. Manufacturers' directions for minimum contact time shall be followed.

(D) All cleaning tools (e.g., wipes, sponges, and mop heads) must be low-lint and dedicated for use in the controlled area and buffer area.

(E) Primary engineering controls shall be cleaned with a germicidal agent followed by sterile alcohol. Sterile water for irrigation shall be used to dilute germicidal agents used inside the PEC that require dilution.

(F) At a minimum, the critical area shall be cleaned and disinfected prior to compounding, between batches, and whenever contamination is suspected using sterile alcohol which is allowed to dry immediately prior to compounding.

(18) Environmental Sampling/Testing. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas. Applicable environmental monitoring of air and surfaces must be conducted. Air monitoring must be conducted prior to initial compounding and every six (6) months thereafter. Surface sampling/monitoring must be conducted every six (6) months for Risk Level 2 and every thirty (30) days for Risk Level 3 compounding.

*[(14)]***(19)** Cytotoxic Drugs.

(A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:

1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or *[an isolator]* **an CACI**. If used for other *[products]* **preparations**, the cabinet must be thoroughly cleaned;

2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves**,** and gowns with tight cuffs;

3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile *[products]* **preparations. Chemotherapy preparations should be compounded using a closed system transfer device**;

4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state**,** and federal requirements;

5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual; **and**

6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

[(15) Exemption: Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.]

[(16) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 20 CSR 2220-2.400 must be maintained. Pharmacies that are registered with the Food and Drug Administration (FDA) are exempt from the distribution restrictions in 20 CSR 2220-2.400(12) for compounded sterile pharmaceuticals distributed with FDA's knowledge and enforcement discretion. This exemption applies only to a twenty-four (24)-hour course of therapy which is needed:

(A) To treat an emergency situation; or

(B) For an unanticipated procedure for which a time delay would negatively affect a patient outcome. In order to continue beyond twenty-four (24) hours, the pharmacy must obtain a prescription and comply with all record and labeling requirements as defined by law or regulation.]

(20) Remedial Investigations: A remedial investigation shall be required if: 1) any sampling or testing required by this rule demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling/testing or 2) if a highly pathogenic microorganism is

detected in any preparation or ISO classified area (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, fungus, or yeasts).

(A) CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. All affected areas shall be resampled to ensure a suitable state of microbial control prior to further compounding. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(B) The pharmacy shall notify the board in writing within seven (7) days if any preparation or environmental monitoring/testing detects a highly pathogenic microorganism, regardless of CFU count.

(21) Recalls. A recall must be initiated when a CSP is deemed to be misbranded, adulterated, or non-sterile or if end-preparation testing results are out of specification. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety. In cases where the CSP has the potential to harm the patient, the same notification shall be provided to all patients that received the recalled CSP(s). Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days. The pharmacy shall document their activities related to the recall.

*AUTHORITY: sections 338.140[,] **and** 338.240, **RSMo Supp. 2013,** [and] **section** 338.280, RSMo 2000, and section 338.010, RSMo Supp. [2007] **2014**. This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. For intervening history, please consult the **Code of State Regulations**. Emergency amendment filed July 25, 2016, effective Aug. 4, 2016, expires Feb. 23, 2017. Amended: Filed July 25, 2016.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities ninety-nine thousand two hundred forty-five dollars ($99,245) during the first year of implementation, two million eight hundred sixty-one thousand two hundred fifty-nine dollars and thirty-five cents ($2,861,259.35) annually for the life of the rule as the result of the proposed amendment.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Board of Pharmacy, PO Box 625, 3605 Missouri Boulevard, Jefferson City, MO 65102, by facsimile at (573) 526-3464, or via email at pharmacy@pr.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this rule in the **Missouri Register**. No public hearing is scheduled.*

FISCAL NOTE
PRIVATE COST

I. Department: Department of Insurance, Financial Institutions and Professional Registration
Division Title: State Board of Pharmacy
Chapter Title: General Rules

Rule Number and Title:	**20 CSR 2220-2.200 (Sterile Pharmaceuticals)**
Type of Rulemaking:	**Proposed Amendment**

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
97-123	Missouri Sterile Compounding Pharmacies	$ 99,245 *(Y1 Implementation)*
97-123	Missouri Sterile Compounding Pharmacies	$ 2,289,007.48 *recurring annually over the life of the rule*
125	Non-Resident Sterile Compounding Pharmacies	$ 572,251.87 *recurring annually over the life of the rule*

III. ASSUMPTIONS/WORKSHEETS

The following general estimations were used to calculate private fiscal costs:

1. The board conducted a survey in 2014 of all Missouri resident and non-resident sterile compounding pharmacies. Private fiscal costs were estimated based on survey results which reflect the most recent board data on the scope of sterile compounding activities performed by Missouri licensed pharmacies. According to survey results, a significant number of pharmacies are currently complying with the majority, if not all, of the proposed rule requirements. Accordingly, fiscal impact will likely be significantly lower than estimated, however, costs have been estimated as reflected herein to ensure full compliance with Chapter 536, RSMo.
2. Approximately 123 pharmacies were licensed by the board to perform sterile compounding as of May 1, 2016. Based on survey results and Board licensing data, the Board estimates:
   - Twenty-eight (28) pharmacies are/will be engaged in only Risk Level 1 compounding (approx. 23% of sterile compounding pharmacies)
   - Sixty-eight (68) pharmacies are/will be engaged in Risk Level 2 or lower compounding (55% of sterile compounding pharmacies)
   - Twenty-seven (27) pharmacies are/will be engaged in Risk Level 3 compounding or lower compounding (22% of sterile compounding pharmacies)
3. The proposed amendment substantively incorporates current United States Pharmacopeia (USP) Chapter 797 requirements. After consultation with Missouri hospital pharmacy directors, the

Missouri Hospital Advisory Commission and representatives from the Missouri Hospital Association, the Board understands the majority of Class-B hospital pharmacies licensed with the Board are currently required to comply with USP Chapter 797 by the Centers for Medicare and Medicaid Services (CMS) and/or the Joint Commission which governs hospital accreditation.

4. Approximately 24% of Missouri sterile compounding pharmacies are licensed Class-B hospital pharmacies and are estimated to be engaged in Risk Level 2 and 3 compounding. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies impacted by proposed requirements that mirror USP Chapter 797 has been reduced by 20% to:
   - Twenty-eight (28) Risk Level 1 pharmacies
   - Fifty-Four (54) Risk Level 2 pharmacies, and
   - Twenty-two (22) Risk Level 3 pharmacies
5. The 20% reduction represents Class-B hospital pharmacies that are currently required to comply with Chapter 797 and would not incur any additional fiscal costs. The reduction has been adjusted to account for license duplication and other allied entities under common ownership or control of the hospital that may also be licensed as a Class-B hospital pharmacy.
6. An hourly pharmacist salary of $59.24 and an hourly pharmacy technician salary of $18.47 was utilized which represents an average of the mean hourly wage for pharmacists/technicians practicing in a General Medical and Surgical Hospital setting ($57.43) and pharmacists/technicians practicing in an Outpatient Care Center setting ($61.05) as reflected in the United States Bureau of Labor Statistics Occupational Employment and Wages data for May 2015. An average of the identified hourly rates was selected due to the variant practice settings of Board licensees/registrants.
7. Where applicable, costs were projected using the estimated hourly pharmacy technician salary for activities not required to be performed by a pharmacist.
8. Compounding staff per pharmacy can fluctuate widely depending on the scope and level of compounding services performed. The Board estimates the average pharmacy will be required to perform initial training/assessment for two (2) new sterile compounding technicians per year and further estimates a total of three (3) sterile compounding employees per pharmacy.
9. The Board estimates 261 business days per year based on the United States Office of Personal Management's 28-year work-calendar study.
10. Except as otherwise provided herein, fiscal costs were estimated based on Board licensing data as of May 1, 2016. The number of sterile compounding pharmacies and scope of sterile compounding activities is estimated to remain consistent over the life of the rule.
11. Fiscal costs were also based on estimates from selected sterile compounding pharmacies, current market prices and current vendor/certification fees and have been adjusted to reflect compliance costs required by the current rule.
12. Based on current licensing data and 2014 survey results, the Board estimates non-resident sterile compounding pharmacies will incur 25% of total fiscal costs estimated for Missouri resident pharmacies.
13. The Board anticipates the total estimated costs may vary with inflation and increase at the rate projected by the Legislative Oversight Committee.

Facilities/Equipment Costs:

14. The proposed certification/recertification requirements for ISO classified areas will primarily be applicable to Risk Level 2 and 3 pharmacies and are similar to current USP Chapter 797 requirements. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been adjusted to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
15. Due to the potential longevity of properly functioning primary engineering controls, the Board estimates 25-new primary engineering controls will be purchased annually by sterile compounding pharmacies. Additionally, the Board estimates 25 pharmacies will be required to recertify primary engineering controls (PECs) because of deficiencies, relocation or other PEC changes.
16. The Board estimates seven (7) new Missouri sterile compounding pharmacies will require initial certification of ISO classified areas per year.
17. An estimated 50 pharmacies will be required to place or install a line of demarcation.

Description of Cost	Calculation	Total
Line of Demarcation	• Tape/Marker Costs: $ 3.00 per tape roll/marking equipment x 50 pharmacies	**$ 150** (Y1 implementation)
PEC Initial Certification (all risk levels)	• Certification Costs: 25 pharmacies X $ 200 certification fee	**$5,000** annually
PEC Recertification (all risk levels)	• Certification Costs: 25 pharmacies X $ 200 certification fee	**$5,000** annually
ISO Classified Areas Certification (New)	• Certification Costs: $ 2,750 x 7 new pharmacies	**$19,250** annually
ISO Classified Areas Certification (Ongoing)	• Certification Costs: $ 2,750 x 76 Risk Level 2 & 3 pharmacies x 2 times per year	**$418,000** annually
	TOTAL	**$ 150 (Y1 implementation) $ 447,250 (annually)**

Garbing/Hand Hygiene Costs:

18. The proposed garbing/hand hygiene requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
19. The Board estimates the average pharmacy will employ approximately 3 staff people to perform sterile compounding daily and further estimates two (2) garbing changes per person/per day.
20. The Board estimates a total cost of $4.80 for Risk Level 1 garbing and $5.65 for Risk Level 2 and three (3) garbing based on the following estimated costs: beard covers ($.08), face mask ($.32), gown ($ 3.50), gloves ($.55), hair cover ($.35), sterile gloves ($1.20) and shoe covers ($.20)

Description of Cost	Calculation	Total
Garbing (Risk Level 1: Beard cover, face mask, gloves, gown, hair cover)	• Garbing ($ 4.80) x 28 pharmacies x 3 staff people x 2 changes per day x 261 business days.	**$ 210,470.40** annually
Garbing (Risk Level 2 & 3: Beard cover, face mask, sterile gloves, gown, hair cover, shoe covers)	• Garbing ($ 5.65) x 76 pharmacies x 3 staff people x 2 changes per day x 261 business days.	**$ 672,440.40** annually
	TOTAL	**$ 882,910.80** annually

Environmental Monitoring/Sampling Costs:

21. The proposed amendment delineates specific time intervals for the air monitoring and surface sampling currently required for Risk Level 2 and Risk Level 3 pharmacies.
22. The proposed air monitoring requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.
23. An average of two (2) surface samples is estimated per pharmacy during each required sampling using settling plates. Costs to incubate samples have been later reflected in the aseptic technique skill assessment section which includes costs for purchasing an incubator which could also be used for settling plates.
24. The Board estimates 15-minutes of technician time will be separately required to perform/document the required air monitoring and the required surface sampling.

Description of Cost	Calculation	Total
Air Monitoring (every six (6) months)	• Technician Salary Costs: $4.62 (¼ of 18.47 hourly wage) x 76 Risk Level 2 & 3 pharmacies x 2 air monitoring collections per year.	**$ 702.24** annually
Surface Sampling (Risk Level 2)	• Sample Costs: $2.00 per settling plate x 2 samples per year x 68 Risk Level 2 pharmacies = $ 272 annually + • Technician Salary Costs: $4.62 (¼ of 18.47 hourly wage) x 68 Risk Level 2 pharmacies x 2 samples per years = $ 628.32 annually	**$ 900.32** annually
Surface Sampling (Risk Level 3)	• Sample Costs: $2.00 per settling plate x 2 samples x 12 samples per year x 27 Risk Level 3 pharmacies = $ 1,296 annually + • Technician Salary Costs: $4.62 (¼ of 18.47 hourly wage) x 12 samples per year x 27 Risk Level 3 pharmacies= $ 1,496.88 annually	**$ 2,792.88** annually
	TOTAL	**$ 4,395.44** annually

Aseptic Technique Skill Assessment Costs:

25. Sterile compounding pharmacies are currently required to perform both initial and ongoing process validation which has been renamed media-fill testing in the proposed amendment. Accordingly, media-fill testing costs have been estimated only to the extent the proposed amendment exceeds the current process validation requirements.
26. The Board estimates approximately two (2) new personnel will be hired and require an annual aseptic technique skill assessment per pharmacy. The Board estimates the average aseptic technique skill assessment will require one (1) hour of both pharmacist and technician time.
27. The current rule requires Risk Level 2 and 3 pharmacies to perform a competency assessment via process simulation. Accordingly, initial assessment costs have not been estimated for Risk Level 2 and 3 pharmacies.
28. Absent specific data, the Board estimates approximately one (1) pharmacy technician per year will require an aseptic technique reevaluation assessment under section (10)(C).
29. While media-fill testing can be outsourced, in-house media fill testing through the use of media-fill kits and an incubator is currently the most cost-efficient method for testing. The Board estimates 70% of pharmacies already have equipment for media fill testing and has consequently estimated only 30% of affected pharmacies may opt to purchase an incubator.
30. The proposed aseptic technique skill assessment requirements are similar to USP Chapter 797. Accordingly, the number of Risk Level 2 and Risk Level 3 pharmacies has been reduced to reflect Class-B pharmacies currently required to comply with USP Chapter 797 as described above.

Description of Cost	Calculation	Total
Initial aseptic skill assessment evaluation (Risk Level 1)	• Pharmacist Observation Costs: $59.24 per hour x 2 employees per year x 28 pharmacies = $ 3,317.44 + • Technician Salary Costs ($1,034.32): $18.47 per hour x 2 employees x 28 pharmacies	**$ 4,351.76** annually
Annual aseptic skill assessment evaluation (all risk levels)	• Pharmacist Observation Costs ($ 18,482.88): $59.24 per hour x 3 employees per year x 104 pharmacies + • Technician Salary Costs ($ 5,762.64): $ 18.47 per hour x 3 employees x 104 pharmacies	**$ 24,245.52** annually
Additional 6-month aseptic skill assessment (Risk Level 3)	• Pharmacist Observation Costs: $59.24 per hour x 3 employees per year x 22 pharmacies = $ 3,909.84 + • Technician Salary Costs: $ 18.47 per hour x 3 employees x 22 pharmacies = $1,219.02	**$ 5,128.86** annually
Reevaluation of aseptic technique	• Pharmacist Observation Costs ($ 6,160.96): $59.24 per hour x 1 employee per year x 104 pharmacies + • Technician Salary Costs ($ 1,920.88): $ 18.47 per hour x 1 employee x 104 pharmacies	**$ 8,081.84** annually

Media-Fill Equipment	• Incubator: $345 per incubator x 31 pharmacies (30% of 104 pharmacies w/ reduction in Risk Level 2 and 3 pharmacies)	**$ 10,695** (Y1 implementation)
Additional 6-Month Media-fill Test (Risk Level 3)	• Media-Fill Test Kits: $ 65 per kit x 22 pharmacies x 1 additional test x 3 employees	**$4,290** annually
Reevaluation of aseptic technique media-fill	• Media-Fill Test Kits: $ 65 per kit x 1 employee x 104 pharmacies	**$ 6,760** annually
	TOTAL	**$ 10,695** (Y1 implementation) **$ 52,857.98** annually

Cleaning and Disinfection Costs:

31. The proposed amendment incorporates current USP Chapter 797 cleaning and disinfection requirements. Accordingly, the number of Risk Level 2 pharmacies has been adjusted as described above. The proposed cleaning/disinfection intervals for Risk Level 3 pharmacies will remain consistent. Accordingly, no additional costs have been calculated.
32. The Board estimates the average pharmacy will hire/train two (2) new sterile compounding technicians per year to perform the required cleaning and further estimates annual cleaning/disinfection training will be required for three (3) sterile compounding employees per pharmacy.
33. The Board estimates the current training/observation requirements will require a total of one (1) hour staff time for both the trainee and the observing training pharmacist.
34. The Board estimates cleaning times will be increased by 1-hour daily and 2-hours monthly for Risk Level 1 pharmacies. For Risk Level 2, the Board estimates cleaning times will be increased by 30-minutes daily and 1-hour monthly.
35. Approximately 88% of sterile compounding pharmacies reported using sterile alcohol for disinfection in the Board's 2013 sterile compounding survey. The total number of sterile compounding pharmacies required to buy sterile alcohol has been correspondingly decreased by 88% to 15 pharmacies. The Board estimate an average of three (3) gallons of sterile alcohol will be required per pharmacy per month.
36. The Board estimates pharmacies will be required to expend an additional $5 per month in cleaning supplies not already required or used by the pharmacy to meet current rule requirements.

Description of Cost	Calculation	Total
Daily Cleaning (Risk Level 1)	• Technician Salary Costs: $ 18.47 per hour x 28 pharmacies x 1-hour x 261 business days.	**$ 134,978.76** annually
Monthly Cleaning (Risk Level 1)	• Technician Salary Costs: $ 18.47 per hour x 2-hours x 28 pharmacies x 261 business days.	**$ 269,957.52** annually
Daily Cleaning (Risk Level 2)	• Technician Salary Costs: $ 9.24 (½ of $18.47 per hour) x 54 pharmacies x 261 business days.	**$ 130,228.56** annually
Monthly Cleaning (Risk Level 2)	• Technician Salary Costs: $ 18.47 per hour x 54 pharmacies x 1-hour x 261 business days.	**$ 260,316.18** annually
Initial Cleaning training and direct visual observation (All risk levels)	• Pharmacist Observation Costs ($12,321.92): $59.24 per hour x 2 employees per year x 104 pharmacies + • Technician Salary Costs (43,841.76): $18.47 per hour x 2 employees x 104 pharmacies	**$ 16,163.68** annually
Annual Cleaning training and direct visual observation (All risk levels)	• Pharmacist Observation Costs ($18,482.88): $59.24 per hour x 3 employees per year x 104 pharmacies + • Technician Salary Costs ($5,762.64): $18.47 per hour x 3 employees x 104 pharmacies	**$ 24,245.52** annually
Sterile alcohol	• Purchase costs: $ 55 per gallon x 3 gallons per month x 15 pharmacies x 12 months	**$ 29,700** annually
Other cleaning supplies (germicidal agents, low-lint supplies)	• $5 per month x 104 pharmacies	**$ 520** annually
	TOTAL	**$ 866,110.22** annually

Miscellaneous Costs:

37. The rule requires compliance with selected provisions of USP Chapter 797. Accordingly, costs have been estimated for purchasing a current copy of the United States Pharmacopeia and the National Formulary (USP-NF). The Board estimates the total number of pharmacies required to purchase the USP-NF will include 28 Risk Level 1 pharmacies, 54 Risk Level 2 pharmacies and 22 Risk Level 3 pharmacies (104 pharmacies). The number of affected pharmacies has been reduced to reflect Class-B hospital pharmacies that are currently required to comply with USP Chapter 797 and presumably already have access to the current USP-NF.
38. The proposed aseptic technique, cleaning and training requirements are intended to reduce incidences of environmental and microbial contamination and the need for the proposed

remedial investigation. In the absence of more specific data, the Board estimates the average pharmacy will spend two (2) hours of pharmacist staff time to conduct remedial investigations per year.

39. The Board estimates an additional one (1) hour of pharmacist time would be required to comply with the additional documentation and policy and procedure requirements of the rule.
40. The Board estimates an additional thirty (30) minutes of pharmacy technician time would be required to comply with the additional documentation, verification and recording requirements per month.

Description of Cost	Calculation	Total
USP-NF	• Purchase Costs: $ 850 x 104 pharmacies	**$ 88,400** Y1 implementation
Remedial Investigations	• Pharmacist Costs: $59.24 per hour x 2-hours per year x 123 pharmacies	**$ 14,573.04** annually
Pharmacist Misc. activities	• Pharmacist Costs: $59.24 per hour x 1-hour per year x 123 pharmacies	**$ 7,286.52**
Technician Misc. Activities	• Technician Salary Costs: $ 9.24 (½ of $18.47 per hour) x 123 pharmacies x 12-months.	**$ 13,623.48** annually
	TOTAL	**$ 88,400** (Y1 implementation) **$ 35,483.04** (annually)