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SALUS POPULI SUPREMA LEX ESTO

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

ROBIN CARNAHAN

SECRETARY OF STATE

MISSOURI REGISTER

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ROBIN CARNAHAN

Administrative Rules Division

James C. Kirkpatrick State Information Center

600 W. Main

Jefferson City, MO 65101

(573) 751-4015

DIRECTOR

WAYLENE W. HILES

•

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ASSOCIATE EDITOR

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•

PUBLICATION TECHNICIAN

JACQUELINE D. WHITE

•

ADMINISTRATIVE ASSISTANT

LUKE RIEKE

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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the website at http://www.sos.mo.gov/adrules/pubsched.asp

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RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 28, *Missouri Register*, page 27. The approved short form of citation is 28 MoReg 27.

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.

The Secretary of State shall publish all executive orders beginning January 1, 2003, pursuant to section 536.035.2, RSMo Supp. 2007.

EXECUTIVE ORDER
08-04

WHEREAS, the Department of Health and Senior Services is authorized under Chapter 192, RSMo; and

WHEREAS, Section 191.225, RSMo, requires the Department of Health and Senior Services to pay for forensic examinations provided to victims of sexual offenses; and

WHEREAS, these payments currently are processed by the Department of Health and Senior Services, Division of Community and Public Health; and

WHEREAS, the Missouri Department of Public Safety is authorized under Article IV, Section 12, of the Missouri Constitution and Chapter 650, RSMo; and

WHEREAS, the Missouri State Highway Patrol is housed in the Department of Public Safety and currently distributes victim sexual assault kits to law enforcement and hospitals throughout the state; and

WHEREAS, the Crime Victims' Compensation Fund Program is within the Department of Public Safety and is the state agency that coordinates and provides financial assistance to victims of crime; and

WHEREAS, the administration of sexual assault examination payments would be strengthened by a move to the Department of Public Safety where other statewide programs providing services to crime victims are located; and

WHEREAS, I am committed to integrating executive branch operations to ensure that the state delivers quality services in the most accessible manner and at the lowest cost to taxpayers.

NOW, THEREFORE, I, MATT BLUNT, GOVERNOR OF THE STATE OF MISSOURI, by virtue of the authority vested in me by the Constitution and the Laws of the State of Missouri, do hereby order the Department of Health and Senior Services and the Department of Public Safety to:

1. Transfer all the authority, powers, duties, functions, records, personnel, property, contracts, budgets, matters pending, and other pertinent vestiges of the sexual assault evidentiary kit and exam payment program to the Department of Public Safety by Type I transfer, as defined under the Reorganization Act of 1974;

2. Develop mechanisms and processes necessary to effectively transfer the sexual assault evidentiary kit and exam payment program to the Crime Victims' Compensation Fund Program in the Department of Public Safety; and

3. Transfer the responsibility for staff support for the program to the Department of Public Safety's Crime Victims' Compensation Fund Program.

This Order shall become effective no sooner than August 28, 2008, unless disapproved within sixty days of its submission to the Second Regular Session of the 94th General Assembly.

IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Missouri, in the City of Jefferson, on this 6th day of February, 2008.

Matt Blunt
Governor

ATTEST:

Robin Carnahan
Secretary of State

EXECUTIVE ORDER
08-05

WHEREAS, the severe winter weather that began on December 8, 2007, created a condition of distress and hazards to the safety and welfare of the citizens of the state of Missouri beyond the capabilities of some local jurisdictions and other established agencies; and

WHEREAS, Executive Order 07-34 was issued on December 9, 2007, declaring a State of Emergency within the state of Missouri; and

WHEREAS, Executive Order 07-36 was issued on December 10, 2007, authorizing the Director of the Missouri Department of Natural Resources to waive or suspend temporarily the operation of statutory or administrative rules or regulations in order to expedite the cleanup and recovery process; and

WHEREAS, in response to Executive Order 07-36, the Director of the Missouri Department of Natural Resources issued a waiver on December 11, 2007, suspending specific air pollution and solid waste regulations to address wastes generated by the severe storm systems; and

WHEREAS, several communities in the state of Missouri continue to clear debris caused by the severe storm systems; and

WHEREAS, Executive Orders 07-34 and 07-36 expired on January 7, 2008; and

WHEREAS, Executive Order 07-39 was issued on December 28, 2007, to extend Executive Orders 07-34 and 07-36 in whole or in part to February 15, 2008; and

WHEREAS, some communities continue to clear storm debris and have requested an extension of the February 15, 2008, deadline; and

NOW THEREFORE, I, Matt Blunt, Governor of the State of Missouri, by virtue of the authority vested in me by the Constitution and laws of the State of Missouri, hereby extend the declaration of emergency contained in Executive Order 07-34 and the terms of Executive Orders 07-36 and 07-39 through March 15, 2008, for the purpose of continuing the cleanup efforts in the affected Missouri communities.

IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Missouri, in the City of Jefferson, on this 11th day of February, 2008.

Matt Blunt
Governor

ATTEST:

Robin Carnahan
Secretary of State

EXECUTIVE ORDER
08-06

WHEREAS, I have been advised by the Director of the State Emergency Management Agency that severe winter storm systems causing damages associated with snow, freezing rain, sleet, and ice have impacted communities across the state of Missouri; and

WHEREAS, interruption of public services are occurring as a result of the severe weather that began on February 10, 2008, and continues; and

WHEREAS, the severe weather that began on February 10, 2008, has created a condition of distress and hazard to the safety, welfare, and property of the citizens of the state of Missouri beyond the capabilities of some local and other established agencies; and

WHEREAS, the resources of the state of Missouri may be needed to assist affected jurisdictions and to help relieve the condition of distress and hazard to the safety and welfare of our fellow Missourians; and

WHEREAS, protection of the safety and welfare of the citizens of the state requires an invocation of the provisions of Section 44.100 and 44.110, RSMo.

NOW, THEREFORE, I, MATT BLUNT, GOVERNOR OF THE STATE OF MISSOURI, by virtue of the authority vested in me by the Constitution and laws of the State of Missouri, including Section 41.480.2, RSMo, order and direct the Adjutant General of the State of Missouri, or his designee, to call and order forthwith into active service such portions of the organized militia as he deems necessary to aid the executive officials of Missouri, to protect life and property, and it is further ordered and directed that the Adjutant General or his designee, and through him, the commanding officer of any unit or other organization of such organized militia so called into active service take such action and employ such equipment as may be necessary in support of civilian authorities, and provide such assistance as may be authorized by the Governor of this state.

This order shall terminate on March 10, 2008, unless extended in whole or in part.

IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Missouri, in the City of Jefferson, on this 12th day of February, 2008.

Matt Blunt
Governor

ATTEST:

Robin Carnahan
Secretary of State

EXECUTIVE ORDER
08-07

WHEREAS, I have been advised by the Director of the State Emergency Management Agency that severe winter storm systems causing damages associated with snow, freezing rain, sleet, and ice have impacted communities across the state of Missouri; and

WHEREAS, interruption of public services are occurring as a result of the severe weather that began on February 10, 2008, and continues; and

WHEREAS, the severe weather that began on February 10, 2008, has created a condition of distress and hazard to the safety, welfare, and property of the citizens of the state of Missouri beyond the capabilities of some local and other established agencies; and

WHEREAS, the resources of the state of Missouri may be needed to assist affected jurisdictions and to help relieve the condition of distress and hazard to the safety and welfare of our fellow Missourians; and

WHEREAS, protection of the safety and welfare of the citizens of the state requires an invocation of the provisions of Section 44.100 and 44.110, RSMo.

NOW, THEREFORE, I, MATT BLUNT, GOVERNOR OF THE STATE OF MISSOURI, by virtue of the authority vested in me by the Constitution and laws of the State of Missouri, including Sections 44.100 and 44.110, RSMo, do hereby declare that a State of Emergency exists in the State of Missouri. I do hereby direct that the Missouri State Emergency Operations Plan be activated.

I further authorize the use of state agencies to provide assistance, as needed.

This order shall terminate on March 10, 2008, unless extended in whole or part.

IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Missouri, in the City of Jefferson, on this 12th day of February, 2008.

Matt Blunt
Governor

ATTEST:

Robin Carnahan
Secretary of State

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 the 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 2—DEPARTMENT OF AGRICULTURE
Division 70—Plant Industries
Chapter 40—Missouri Treated Timber Products Law Rules

PROPOSED AMENDMENT

2 CSR 70-40.015 Standards for Treated Timber. The director of agriculture is amending sections (1), (2), (3) and (4).

PURPOSE: This amendment updates the required standards to be used by anyone selling or offering for sale treated timber products in the state of Missouri.

(1) *[The preservatives and preservative solution used shall meet the American Wood Preservers' Association (AWPA) Standard P-Preservative, as published in the 2004 AWPA Book of Standards, as incorporated by reference in this rule. This material may be obtained by contacting the AWPA at PO Box 388, Selma, Alabama 36702-0388.]* **Unless otherwise noted, all wood preservatives and preservative solutions used shall be approved and or standardized by the American Wood Protection Association (AWPA) and listed in the current *AWPA Book of Standards*, published annually in May as incorporated by reference in this rule. This material may be obtained by contacting the AWPA at PO Box 388, Selma, AL 36702 or by contacting the Missouri Department of Agriculture at PO Box 630, Jefferson City, MO 65101. This rule does not incorporate any subsequent amendments or additions.**

(A) Wood preservatives and preservative solutions not standardized by AWPA that do have an approved National Evaluation Report issued by the International Code Council may also be used if product meets AWPA evaluation criteria in *Appendix A* of the current *AWPA Book of Standards*, published annually in May.

(2) Standards for Treatment of Coniferous, Softwood Species. The requirements for retention and penetration of preservatives used shall not be less than the *[published 2004]* **current** *American Wood [Preservers'] **Protection** Association Book of Standards*, **published annually in May** as incorporated by reference in this rule, except that—

[(A) For ponderosa pine, red pine and southern yellow pine, the minimum net retention level of copper naphthenate shall be .055 pounds per cubic foot, copper as metal, for round poles and posts used as structural members. This section shall expire when use category standards are established by AWPA for these products;]

[(B)] **(A)** Softwoods not listed in the *AWPA Use Category Tables* as treatable species shall be labeled, "Does not conform to AWPA Standards." Furthermore, products that fall under this classification and are intended for ground contact use shall also include the statement, "Not recommended for structural purposes."

[(C)] **(B)** Softwood peeler core landscape timbers shall be exempted from meeting AWPA standards, if treater puts tags on each individual timber that states the following, "Does not conform to AWPA *[s]***S**tandards, not recommended for structural purposes." Companies who fail to label these products with this disclaimer will be regulated based on AWPA standards.

1. All products as defined by this rule shall be labeled with a tag in accordance to the following requirements:

A. Tags shall remain attached at each point of sale and may only be removed by the final purchaser;

B. Each tag shall be placed on the surface of each product so that it is readily visible to the purchaser;

C. Each tag shall be legible;

D. Tags shall be constructed of water resistant material.

(3) Standards for Treatment of Deciduous, Hardwood Species. The requirement for retention and penetration of preservatives used shall not be less than the *[published 2004]* **current** *American Wood [Preservers'] **Protection** Association **Book of** Standards*, **published annually in May,** as incorporated by reference in this rule, except that—

[(D) Effective March 30, 2003, all hardwoods, five inches (5") and greater in thickness and treated according to subsections (3)(A)–(C) or up to the levels of the AWPA Use Category Tables, shall be labeled with a tag as follows:

1. Hardwoods listed in the AWPA manual shall be labeled with a tag stating the percentage of AWPA ground contact or above ground contact retention level guaranteed and a statement of treatment to refusal for white oak. For example, a mixed bundle of white and red oak timbers, five inches (5") in thickness and greater, treated with a five percent (5%) solution of pentachlorophenol to 0.20 pounds of

active ingredient per cubic foot, for ground contact, shall be tagged "Treated to 66% of AWPA Ground Contact Standards. White Oak Treated to Refusal." Furthermore, the same mixed bundle of white and red oak timbers, treated under the same conditions to 0.25 pounds of active ingredient per cubic foot could also be tagged, "Treated to 100% of AWPA Above Ground Contact Standards. White Oak Treated to Refusal";

2. Hardwoods not listed in the AWPA Use Category Tables as treatable species shall be labeled "Does not conform to AWPA Standards." Furthermore, products that fall under this classification and are intended for ground contact use shall also include the statement, "Not recommended for structural purposes."

3. All products as defined by this rule shall be labeled with a tag in accordance to the following requirements:

A. Tags shall remain attached at each point of sale and may only be removed by the final purchaser;

B. Each tag shall be placed on the surface of each product so that it is readily visible to the purchaser;

C. Each tag shall be legible;

D. Tags shall be constructed of water resistant material.]

(D) The minimum net retention for water borne copper azole in the treatment of hardwoods other than white oak shall be 0.10 pounds per cubic foot (pcf). White oak shall be treated to refusal.

(E) All hardwood posts, lumber and timbers treated under the exemptions listed shall be labeled with a tag indicating the retention level of the product. An example of proper labeling for penta treated hardwoods is the following: "Red oak treated to retention level of 0.20 pcf, white oak treated to refusal."

(F) Hardwoods not listed in the *AWPA Use Category Tables* as "treatable species" shall be labeled, "Does not conform to AWPA Standards." Furthermore, products that fall under this classification and are intended for ground contact use shall also include the statement, "Not recommended for structural purposes."

1. All products as defined by this rule shall be labeled with a tag in accordance to the following requirements:

A. Tags shall remain attached at each point of sale and may only be removed by the final purchaser;

B. Each tag shall be placed on the surface of each product so that it is readily visible to the purchaser;

C. Each tag shall be legible;

D. Tags shall be constructed of water resistant material.

(4) Other Treatment Standards. All other standards for treatment of timber or timber products with preservatives not covered by 2 CSR 70-40.015 shall not be less than the *[published 2004]* **current** *American Wood [Preservers'] **Protection** Association Book of Standards*, **published annually in May,** as incorporated by reference in this rule.

*AUTHORITY: section 280.050, RSMo 2000. Original rule filed Oct. 10, 1980, effective Feb. 1, 1981. For intervening history, please consult the **Code of State Regulations**. Amended: Filed Feb. 6, 2008.*

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 Department of Agriculture, Forest Resources Program, Jimmy Williams, Program Coordinator, PO Box 630, 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 2—DEPARTMENT OF AGRICULTURE
Division 70—Plant Industries
Chapter 40—Missouri Treated Timber Products Law Rules

PROPOSED RULE

2 CSR 70-40.017 Preservatives Required to be Registered Pesticides

PURPOSE: This rule clarifies that all wood preservatives used must be registered with or exempted from registration with the Environmental Protection Agency before they may be used.

(1) All wood treating preservatives used must be registered with or exempted from registration with the Environmental Protection Agency before they may be used.

AUTHORITY: section 280.050, RSMo 2000. Original rule filed Feb. 6, 2008.

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 Missouri Department of Agriculture, Forest Resources Program, Jimmy Williams, Program Coordinator, PO Box 630, 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 2—DEPARTMENT OF AGRICULTURE
Division 70—Plant Industries
Chapter 40—Missouri Treated Timber Products Law Rules

PROPOSED AMENDMENT

2 CSR 70-40.025 Standards for Inspection, Sampling and Analyses. The director of agriculture is amending sections (1), (2), and (3).

PURPOSE: This amendment updates the required standards of inspection, sampling and analysis of treated wood products.

(1) The standards for inspection procedures shall be in accordance with the *American Wood [Preservers] **Protection** Association (AWPA) Standard M2-Inspection of Treated Timber Products*, as *[published]* **listed** in the *[2004]* **current** *AWPA Book of Standards*, **published annually in May,** as incorporated by reference in this rule. This material may be obtained by contacting the AWPA at PO Box 388, Selma, *[Alabama]* **AL** 36702*[-0388]* **or by contacting the Missouri Department of Agriculture at PO Box 630, Jefferson City, MO 65101**.

(2) The standards for sampling and quality control procedures shall be in accordance with the *[published 2004]* **current** *American Wood [Preservers'] **Protection** Association **Standards***, **published annually in May,** as incorporated by reference in this rule, except that—

[(B) The number of core samples taken during inspection of coniferous, softwood species shall be twenty (20) per lot. The samples shall be selected randomly from the lot being inspected;]

(B) "Regulatory" samples will be collected from a minimum of two (2) units or bundles of treated material, however, "service" samples may be collected from any quantity of material available during the inspection.

[(C) The number of core samples taken during inspection of deciduous, hardwood species shall be eight (8) per lot. The samples shall be randomly selected from the lot being inspected.]

(C) Hardwood species treated with pentachlorophenol or creosote covered under 2 CSR 70-40.015(2)(A)–(D), will be analyzed for retention by assay.

(D) Effective March 30, 2003, all treated timber producers will be required to maintain an eighty percent (80%) compliance rating. Samples will be taken from a minimum of two (2) units or bundles of treated material. *[No more than three (3) samples from separate lots will be taken during any inspection of an individual treating company's product.]* After ten (10) samples *[(twenty (20) cores per sample for softwood species, eight (8) cores per sample for hardwood species)]* have been taken from separate lots, compliance rates will be calculated. Every effort will be made to ensure that separate lots are sampled, however, if bundles are not marked with a lot number or if the treater is unsure of the lot number, samples will simply be taken from available material of the same dimensions, treated by the same treater with the same preservative. If a producer has three (3) or more stop sales based on either retention or penetration failures within these ten (10) samples, the producer will be contacted and informed that if an eighty percent (80%) compliance rating is not met after an additional ten (10) samples *[(twenty (20) cores per sample for softwood species, eight (8) cores per sample for hardwood species)]* have been taken, the director or his/her representative will hold a hearing to determine if the producer's license should be suspended or revoked. If it is determined that the producer has not made a good faith effort to gain compliance, the director may suspend or revoke the license of the treated timber producer as provided under section 280.040, RSMo.

(3) The standards for methods of analysis for all type preservatives used shall be in accordance with the *American Wood [Preservers'] **Protection** Association (AWPA) Standard A-Analysis Methods*, *[as published in the 2004]* **as listed in the current** *AWPA Book of Standards*, **published annually in May,** as incorporated by reference in this rule.

*AUTHORITY: section 280.050, RSMo 2000. Original rule filed Oct. 10, 1980, effective Feb. 1, 1981. For intervening history, please consult the **Code of State Regulations**. Amended: Filed Feb. 6, 2008.*

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 Department of Agriculture, Forest Resources Program, Jimmy Williams, Program Coordinator, PO Box 630, 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 2—DEPARTMENT OF AGRICULTURE
Division 70—Plant Industries
Chapter 40—Missouri Treated Timber Products Law Rules

PROPOSED AMENDMENT

2 CSR 70-40.040 Branding of Treated Timber. The director of agriculture is amending sections (1), (2), (3), (4) and (5).

PURPOSE: This amendment updates the requirements for branding treated timber products sold in Missouri.

[(1) All treated timber, as defined in section 280.010, RSMo 2000, two inches (2") thick and over shall be branded clearly and with reasonable permanency by one (1) of the following methods before being sold or offered for sale in the state of Missouri:

(A) Hammerstamp branding

(B) Water-proof labels;

(C) Ink-stamp branding.]

(1) All treated timber, as defined in section 280.010, RSMo 2000, shall be labeled clearly with a waterproof end tag before being sold or offered for sale except that—

(A) commercial products such as railroad ties, utility poles and crossarms may be branded.

[(2) All treated timber, as defined in section 280.010, RSMo 2000, less than two inches (2") in nominal thickness shall not have less than twenty percent (20%) of the pieces within a bundle branded before being sold or offered for sale in the state of Missouri.]

[(3)] **(2)** All *[brands]* **end tags** shall be registered with the director of agriculture**.** *[and shall not be identical to nor closely resemble any other company's brand or brands registered with the director of agriculture.]*

(3) All commercial product brands shall be registered with the director of agriculture and shall not be identical to nor closely resemble any other company's brand or brands registered with the director of agriculture.

(4) *[The brand]* **All end tags** used under this regulation shall not be less than one-half inch (1/2") in diameter.

(5) *[Labels or ink stamps]* **End tags** must possess the following requirements:

AUTHORITY: section 280.050, RSMo 2000. Original rule filed March 8, 1962, effective March 18, 1962. Amended: Filed Sept. 12, 1984, effective Jan. 1, 1985. Amended: Filed Dec. 16, 1985, effective March 13, 1986. Rescinded and readopted: Filed Aug. 6, 2002, effective March 30, 2003. Amended: Filed Aug. 30, 2004, effective March 30, 2005. Amended: Filed Feb. 6, 2008.

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 Department of Agriculture, Forest Resources Program, Jimmy Williams, Program Coordinator, PO Box 630, 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 2—DEPARTMENT OF AGRICULTURE
Division 70—Plant Industries
Chapter 40—Missouri Treated Timber Products Law Rules

PROPOSED RESCISSION

2 CSR 70-40.055 Sale or Distribution of Wood Products Similar in Appearance to Treated Timber—Identification—Penalties. This rule provided a method of distinguishing between products dipped in non-preservatives and timber products treated according to the Missouri Treated Timber Law.

PURPOSE: This rule is being rescinded to eliminate the exemption of allowing wood products to be dipped in non-preservative solutions and sold to Missouri consumers.

AUTHORITY: section 280.050, RSMo Supp. 2006. Original rule filed Dec. 16, 1985, effective May 15, 1986. Rescinded: Filed Feb. 6, 2008.

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

PRIVATE COST: This proposed rescission 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 rescission with the Missouri Department of Agriculture, Forest Resources Program, Jimmy Williams, Program Coordinator, PO Box 630, 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 10—DEPARTMENT OF NATURAL RESOURCES
Division 10—Air Conservation Commission
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri

PROPOSED AMENDMENT

10 CSR 10-6.020 Definitions and Common Reference Tables. The commission proposes to amend and renumber subsections (2)(A), (2)(C)–(F), (2)(H), (2)(I), (2)(L)–(N), and (2)(R)–(W); and amend subsections (2)(K), (2)(O), (2)(P), and (3)(C). The evidence supporting the need for this proposed rulemaking is available for viewing at the Missouri Department of Natural Resources' Air Pollution Control Program at the address and phone number listed in the Notice of Public Hearing at the end of this rule. More information concerning this rulemaking can be found at the Missouri Department of Natural Resources' Environmental Regulatory Agenda website, www.dnr.mo.gov/regs/ruleindex.htm.

*PURPOSE: This rule defines key words and expressions used in chapters 1 through 6 and provides common reference tables. The purpose of this rulemaking is to update rule definitions for general maintenance of the rule by adding definitions for stage I/II vapor recovery systems and outstate area, updating the lists of volatile organic compounds and hazardous air pollutants for consistency with the latest U.S. Environmental Protection Agency lists along with removing unused definitions and making typographical corrections. The evidence supporting the need for this proposed rulemaking, per section 536.016, RSMo, is the **Federal Register** Notice dated December 19, 2005, pp. 75047–75059 and the **Federal Register** Notice dated January 18, 2007, pp. 2193–2196.*

(2) Definitions.

(A) All terms beginning with "A."

1. Abatement project designer—An individual who designs or plans Asbestos Hazard Emergency Response Act (AHERA) asbestos abatement.

[2. Accumulator—The reservoir of a condensing unit receiving the condensate from the condenser.]

*[3.]***2.** Act—The Clean Air Act, 42 U.S.C. 7401. References to the word Title pertain to the titles of the Clean Air Act Amendments of 1990, P.L. 101–595.

*[4.]***3.** Actual emissions—The actual rate of emissions of a pollutant from a source operation is determined as follows: 1) actual emissions as of a particular date shall equal the average rate, in tons per year, at which the source operation or installation actually emitted the pollutant during the previous two (2)-year period and which represents normal operation. A different time period for averaging may be used if the director determines it to be more representative. Actual emissions shall be calculated using actual operating hours, production rates and types of materials processed, stored or combusted during the selected time period; 2) the director may presume that source-specific allowable emissions for a source operation or installation are equivalent to the actual emissions of the source operation or installation; and 3) for source operations or installations which have not begun normal operations on the particular date, actual emissions shall equal the potential emissions of the source operation or installation on that date.

*[5.]***4.** Adequately wet—To sufficiently mix or penetrate with liquid to prevent the release of particulates. If visible emissions are observed coming from asbestos-containing material, then that material has not been adequately wetted. However, the absence of visible emissions is not sufficient evidence of being adequately wet.

*[6.]***5.** Administrator—The regional administrator for Region VII, U.S. Environmental Protection Agency (EPA).

*[7.]***6.** Adsorption cycle—The period during which the adsorption system is adsorbing and not desorbing.

*[8.]***7.** Adverse impact on visibility—The visibility impairment which interferes with the protection, preservation, management or enjoyment of the visitor's visual experience of a Class I area, which is an area designated as Class I in 10 CSR 10-6.060(11)(A)*[2.]* **Table 1.** This determination must be made on a case-by-case basis taking into account the geographic extent, intensity, duration, frequency and time of visibility impairments, and how these factors correlate with the times of visitor use of the Class I area and the frequency and timing of natural conditions that reduce visibility.

[9. Aerospace assembly and components—The fabricated part, assembly of parts or completed unit of aircraft, helicopter, missile or space vehicle or associated equipment.]

*[10.]***8.** Affected source—A source that includes one (1) or more emission units subject to emission reduction requirements or limitations under Title IV of the Act.

*[11.]***9.** Affected states—All states contiguous to the permitting state whose air quality may be affected by the modification, renewal or issuance of, or is within fifty (50) miles of, a source subject to permitting under Title V of the Act.

*[12.]***10.** Affected unit—A unit that is subject to emission reduction requirements or limitations under Title IV of the Act.

[13. Aggressive air sampling—Sweeping of floors, ceilings and walls and other surfaces with the exhaust of a minimum of one (1) horsepower leafblower or equivalent immediately prior to air monitoring.]

[14. Agricultural incinerator—An incinerator which is located on a farm or ranch and which has a rated burning

capacity of less than one hundred pounds (100 lbs.) per hour of Type IV waste as defined by the Incinerator Standards of the Incinerator Institute of America (11A–STDS66) and is located more than fifteen hundred feet (1500') from the nearest inhabited dwelling not on the farm or ranch.]

*[15.]***11.** AHERA—Asbestos Hazard Emergency Response Act of 1986 (P.L. 99–519).

*[16.]***12.** Air cleaning device—Any method, process or equipment which removes, reduces or renders less obnoxious air contaminants discharged into the ambient air.

*[17.]***13.** Air contaminant—Any particulate matter or any gas or vapor or any combination of them.

*[18.]***14.** Air contaminant source—Any and all sources of emission of air contaminants whether privately or publicly owned or operated.

*[19.]***15.** Air-dried coating—The coatings which are dried by the use of air or forced warm air at temperatures up to ninety degrees Celsius (90°C) (one hundred ninety-four degrees Fahrenheit (194°F)).

*[20.]***16.** Air pollution—The presence in the ambient air of one (1) or more air contaminants in quantities, of characteristics and of a duration which directly and approximately cause or contribute to injury to human, plant or animal life or health, or to property or which unreasonably interfere with the enjoyment of life or use of property.

*[21.]***17.** Allowable emissions—The emission rate calculated using the maximum rated capacity of the installation (unless the source is subject to enforceable permit conditions which limit the operating rate or hours of operation, or both) and the most stringent of the following: 1) emission limit established in any applicable emissions control rule including those with a future compliance date or 2) the emission rate specified as a permit condition.

*[22.]***18.** Allowance—An authorization, allocated to an affected unit by the administrator under Title IV of the Act, to emit, during or after a specified calendar year, one (1) ton of sulfur dioxide (SO_2).

*[23.]***19.** Alternate site analysis—An analysis of alternative sites, sizes, production processes and environmental control techniques for the proposed source which demonstrates that benefits of the proposed installation significantly outweigh the environmental and social costs imposed as a result of its location, construction or modification.

*[24.]***20.** Ambient air—All space outside of buildings, stacks or exterior ducts.

*[25.]***21.** Ambient air increments—The limited increases of pollutant concentrations in ambient air over the baseline concentration.

*[26.]***22.** Anode bake plant—A facility which produces carbon anodes for use in a primary aluminum reduction installation.

*[27.]***23.** Applicable requirement—All of the following listed in the Act:

A. Any standard or requirement provided for in the implementation plan approved or promulgated by EPA through rulemaking under Title I of the Act that implements the relevant requirements, including any revisions to that plan promulgated in 40 CFR part 52;

B. Any term or condition of any preconstruction permit issued pursuant to regulations approved or promulgated through rulemaking under Title I, including part C or D of the Act;

C. Any standard or requirement under section 111 of the Act, including section 111(d);

D. Any standard or requirement under section 112 of the Act, including any requirement concerning accident prevention under section 112(r)(7);

E. Any standard or requirement of the acid rain program under Title IV of the Act or the regulations promulgated under it;

F. Any requirements established pursuant to section 504(b) or section 114(a)(3) of the Act;

G. Any standard or requirement governing solid waste incineration, under section 129 of the Act;

H. Any standard or requirement for consumer and commercial products, under section 183(e) of the Act;

I. Any standard or requirement for tank vessels under section 183(f) of the Act;

J. Any standard or requirement of the program to control air pollution from outer continental shelf sources, under section 328 of the Act;

K. Any standard or requirement of the regulations promulgated to protect stratospheric ozone under Title VI of the Act, unless the administrator has determined that these requirements need not be contained in a Title V permit;

L. Any national ambient air quality standard or increment or visibility requirement under part C of Title I of the Act, but only as it would apply to temporary sources permitted pursuant to section 504(e); and

M. Any standard or requirement established in sections 643.010–643.190, RSMo of the Missouri Air Conservation Law and rules adopted under them.

[28. Appropriate warning sign—Any asbestos hazard warning sign that complies with the regulations of the United States Occupational Safety and Health Administration (OSHA) or the EPA rules.]

*[29.]***24.** Approved source—A source of fuel which has been found by the department director, after the tests as s/he may require, to be in compliance with these rules.

[30. Approved waste disposal site—A solid waste disposal area that is authorized by the department to receive friable asbestos containing solid wastes.]

*[31.]***25.** Area of the state—Any geographical area designated by the commission.

*[32.]***26.** Asbestos—The asbestiform varieties of chrysotile, crocidolite, amosite, anthophyllite, tremolite and actinolite.

*[33.]***27.** Asbestos abatement—The encapsulation, enclosure or removal of asbestos-containing materials, in or from a building, or air contaminant source; or preparation of friable asbestos-containing material prior to demolition.

*[34.]***28.** Asbestos abatement contractor—Any person who by agreement, contractual or otherwise, conducts asbestos abatement projects at a location other than his/her own place of business.

*[35.]***29.** Asbestos abatement project—An activity undertaken to encapsulate, enclose or remove ten (10) square feet or sixteen (16) linear feet or more of friable asbestos-containing materials from buildings and other air contaminant sources, or to demolish buildings and other air contaminant sources containing ten (10) square feet or sixteen (16) linear feet or more.

*[36.]***30.** Asbestos abatement supervisor—An individual who directs, controls or supervises others in asbestos abatement projects.

*[37.]***31.** Asbestos abatement worker—An individual who engages in asbestos abatement projects.

*[38.]***32.** Asbestos air sampling professional—An individual who by qualifications and experience is proficient in asbestos abatement air monitoring. The individual shall conduct, oversee or be responsible for air monitoring of asbestos abatement projects before, during and after the project has been completed.

*[39.]***33.** Asbestos air sampling technician—An individual who has been trained by an air sampling professional to do air monitoring. That individual conducts air monitoring of an asbestos abatement project before, during and after the project has been completed.

[40. Asbestos caution label—A label that complies with applicable EPA, Department of Transportation (DOT) and OSHA rule requirements and is to be securely affixed to a waste container that contains friable asbestos materials.]

*[41.]***34.** Asbestos-containing material (ACM)—Any material or product which contains more than one percent (1%) asbestos, by weight.

*[42.]***35.** Asbestos debris—Material that results from removal or deterioration of asbestos-containing material.

[43. Asbestos dismantling project—An asbestos abatement project that includes the disassembling, handling and moving of the components of any structural or equipment item that has been coated with friable asbestos-containing material without first removing this material.

44. Asbestos encapsulation project—An asbestos abatement project involving the coating of a friable asbestos-containing surface material with a sealing substance with the intended purpose of preventing the continued release of asbestos fibers from the material into the air. This definition shall not include:

A. The repainting of a previously painted asbestos-containing surface primarily for the purpose of improving appearance;

B. The application of a sealing material to a surface subsequent to the removal of asbestos from it;

C. The application of an encapsulant to asbestos-containing material while the material is being removed;

D. The application of a sealing substance to less than ten (10) square feet or less than sixteen (16) linear feet of friable asbestos-containing material that is contiguous to other types of material;

E The application of a sealing substance to asbestos-containing material that has previously been enclosed or encapsulated; or

F. The painting of nonfriable asbestos-containing material.

45. Asbestos enclosure project—An asbestos abatement project that involves the construction of an airtight impact resistant barrier to isolate a surface coated with asbestos-containing material.]

*[46.]***36.** Asbestos Hazard Emergency Response Act—(AHERA) of 1986 (P.L. 99–519).

[47. Asbestos maintenance operation—Any operation that involves the removal or cleanup of less than ten (10) square feet or less than sixteen (16) linear feet of friable asbestos-containing material from any type of structural or equipment item in order to repair, replace or maintain the item and anything attached to it.]

*[48.]***37.** Asbestos projects—An activity undertaken to remove or encapsulate one hundred sixty (160) square feet or two hundred sixty (260) linear feet or more of friable asbestos-containing materials or demolition of any structure or building or a part of it containing the previously mentioned quantities of asbestos-containing materials.

*[49.]***38.** Asbestos removal project—An asbestos abatement project consisting of activities that involve, and are required, to take out friable asbestos-containing materials from any facility. This definition includes, but is not limited to, activities associated with the cleanup of loose friable asbestos-containing debris or refuse, or both, from floors and other surfaces.

*[50.]***39.** ASME—American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

*[51.]***40.** Asphalt prime coat—Application of low-viscosity liquid asphalt to an absorbent surface such as a previously untreated surface.

*[52.]***41.** Asphalt seal coat—An application of a thin asphalt surface treatment used to waterproof and improve the texture of an absorbent surface or a nonabsorbent surface such as asphalt or concrete.

*[53.]***42.** ASTM—American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

*[54.]***43.** Automobile—A four (4)-wheel passenger motor vehicle or derivative capable of seating no more than twelve (12) passengers.

*[55.]***44.** Automobile and light duty truck surface coating operations—The application, flashoff and curing of prime, primer-surfacer, topcoat and final repair coatings during the assembly of passenger cars and light duty trucks excluding the following operations:

A. Wheel coatings;

B. Miscellaneous antirust coatings;

C. Truck interior coatings;

D. Interior coatings;

E. Flexible coatings;

F. Sealers and adhesives; and

G. Plastic parts coatings. (Customizers, body shops and other repainters are not part of this definition.)

*[56.]***45.** Automotive underbody deadeners—Any coating applied to the underbody of a motor vehicle to reduce the noise reaching the passenger compartment.

(C) All terms beginning with "C."

[1. Can coating—A surface coating applied to a cylindrical steel or aluminum container. The container can be two (2) pieces (made by a drawn and wall-ironed shallow cup with only one (1) end) or three (3) pieces (made by a rectangular material rolled into a cylinder and the attachment of two (2) end pieces).]

*[2.]***1.** Carbon adsorption system—A device containing adsorbent material (for example, activated carbon, aluminum, silica gel); an inlet and outlet for exhaust gases; and a system to regenerate the saturated adsorbent. The carbon adsorption system must provide for the proper disposal or reuse of all volatile organic compounds (VOC) adsorbed.

[3. Carbon bed breakthrough—A concentration of VOC in the carbon adsorption device exhaust that exceeds ten percent (10%) by weight of the inlet VOC concentration.]

*[4.]***2.** Catalytic incinerator—A control device using a catalyst to allow combustion to occur at a lower temperature.

*[5.]***3.** Category I nonfriable ACM— Asbestos-containing packings, gaskets, resilient floor covering and asphalt roofing products containing more than one percent (1%) asbestos as determined using the method specified in 40 CFR part 763, subpart F, Appendix A, section 1, Polarized Light Microscopy.

*[6.]***4.** Category II nonfriable ACM—Any material, excluding category I nonfriable ACM, containing more than one percent (1%) asbestos as determined using the method specified in 40 CFR part 763, subpart F, Appendix A, section 1, Polarized Light Microscopy that, when dry, cannot be crumbled, pulverized or reduced to powder by hand pressure.

*[7.]***5.** Circumvention—Building, erecting, installing or using any article, machine, equipment, process or method which, when used, would conceal an emission that would otherwise constitute a violation of an applicable standard or requirement. That concealment includes, but is not limited to, the use of gaseous adjutants to achieve compliance with a visible emissions standard, and the piecemeal carrying out of an operation to avoid coverage by a standard that applies only to operations larger than a specific size.

*[8.]***6.** Clean room—An uncontaminated area or room which is a part of the worker decontamination enclosure system.

*[9.]***7.** Clear coat—A coating which lacks color and opacity or is transparent and uses the undercoat as a reflectant base or undertone color. This term also includes corrosion preventative coatings used for the interior of drums or pails.

*[10.]***8.** Closed container—A container with a cover fastened in place so that it will not allow leakage or spilling of the contents.

*[11.]***9.** Coating applicator—An apparatus used to apply a surface coating.

*[12.]***10.** Coating line—One (1) or more apparatus or operations which include a coating applicator, flash-off area and oven where a surface coating is applied, dried or cured, or a combination of these.

[13. Coil coating—The coating of any flat metal sheet or strip that comes in rolls or coils.]

*[14.]***11.** Cold cleaner—Any device or piece of equipment that

contains and/or uses liquid solvent, into which parts are placed to remove soils from the surfaces of the parts or to dry the parts. Cleaning machines that contain and use heated nonboiling solvent to clean the parts are classified as cold cleaning machines.

*[15.]***12.** Commenced—An owner or operator has undertaken a continuous program of construction or modification or that an owner or operator has entered into a binding agreement or contractual obligation to undertake and complete within a reasonable time, a continuous program of construction or modification.

*[16.]***13.** Commenced operation—The initial setting into operation of any air pollution control equipment or process equipment.

*[17.]***14.** Commercial vehicle—A motor vehicle designed or regularly used for carrying freight and merchandise or more than eight (8) passengers.

*[18.]***15.** Commission—The Missouri Air Conservation Commission established pursuant to section 643.040, RSMo.

*[19.]***16.** Condensate (hydrocarbons)—A hydrocarbon liquid separated from natural gas which condenses due to changes in the temperature or pressure, or both, and remains liquid at standard conditions.

*[20.]***17.** Condenser—Any heat transfer device used to liquefy vapors by removing their latent heats of vaporization including, but not limited to, shell and tube, coil, surface or contact condensers.

*[21.]***18.** Conservation vent—Any valve designed and used to reduce evaporation losses of VOC by limiting the amount of air admitted to, or vapors released from, the vapor space of a closed storage vessel.

*[22.]***19.** Construction—Fabricating, erecting, reconstructing or installing a source operation. Construction shall include installation of building supports and foundations, laying of underground pipe work, building of permanent storage structures and other construction activities related to the source operation.

*[23.]***20.** Containment—The area where an asbestos abatement project is conducted. The area must be enclosed either by a glove bag or plastic sheeting barriers.

[24. Control curtain—Any of the three (3) following types of closure devices that are to be constructed of not less than four (4) mil thick plastic sheeting material and installed in an entryway of an area that is considered to be contaminated with free asbestos fibers.

A. A ventilation curtain that allows unrestricted air flow movement into a contaminated area when it is being ventilated with an exhaust fan. This curtain consists of a single flap that opens into the contaminated area and is securely fastened across the top of the entryway framework so that it overlaps both sides of the entryway by not less than twelve inches (12″) and the base of the entryway by not less than three inches (3″);

B. A confinement curtain that restricts the movement of air into, and from, an unventilated and contaminated area. This curtain consists of three (3) constructed baffles that cover the entire area of the entryway and are securely fastened along the top of the entryway framework and along alternate sides of locations in a manner that will allow two (2) of the curtains to fully cover the entryway opening while a person passes through the third curtain. An airlock arrangement consisting of two (2) confinement curtain entryways that are located at least three feet (3′) apart may be substituted for the triple baffle arrangement; or

C. A closure device for which written department approval is required.]

*[25.]***21.** Conveyorized degreaser—A type of degreaser in which the parts are loaded continuously.

*[26.]***22.** Criteria pollutant—Air pollutants for which air quality standards have been established in 10 CSR 10-6.010.

*[27.]***23.** Crude oil—A naturally occurring mixture which consists of hydrocarbons and sulfur, nitrogen or oxygen derivatives, or a combination of these, of hydrocarbons which is a liquid at standard conditions.

*[28.]***24.** Custody transfer—The transfer of produced crude oil or condensate, or both, after processing or treating, or both, in the producing operations, from storage tanks or automatic transfer facilities to pipelines or any other forms of transportation.

*[29.]***25.** Cutback asphalt—Any asphaltic cement that has been liquefied by blending with VOC liquid diluents.

(D) All terms beginning with "D."

[1. Decontamination facility—The serial arrangement of rooms or spaces for the purpose of separating the work site from the building environment upon entering the work site and for the cleaning of persons, equipment and contained waste prior to returning to the clean environment.]

*[2.]***1.** Degreasing—A solvent metal cleaning in which nonaqueous solvents are used to clean and remove soils from metal surfaces.

*[3.]***2.** Delivery vessel—A tank truck, trailer*[,]* **or** railroad tank car*[or drums].*

*[4.]***3.** *De minimis* levels—Any emissions level less than or equal to the rates listed in Table 1, subsection (3)(A) of this rule.

*[5.]***4.** Demolition project—The wrecking, razing, burning or removing of any load-supporting structural member or portion of a structure together with any related handling operation.

*[6.]***5.** Department-approved inhouse project—An asbestos abatement project in a person's own facility using their own trained facility employees; the project has received departmental approval as part of planned renovation operations.

*[7.]***6.** Designated representative—A responsible individual authorized by the owner or operator of an affected source and of all affected units at the source, as evidenced by a certificate of representation submitted in accordance with subpart B of 40 CFR part 72, to represent and legally bind each owner and operator, as a matter of federal law, in matters pertaining to the Acid Rain Program. Whenever the term "responsible official" is used in 40 CFR part 70, 10 CSR 10-6.065 or in any other regulations implementing Title V of the Act, it shall be deemed to refer to the "designated representative" with regard to all matters under the Acid Rain Program.

*[8.]***7.** Diammonium phosphate—A product resulting from the reaction between phosphoric acid and ammonia having the molecular formula $(NH_4)_2HPO_4$.

*[9.]***8.** Director or department director— Director of the Department of Natural Resources.

*[10.]***9.** Dispersion technique—

A. A dispersion technique is any technique designed to affect the concentration of a pollutant in the ambient air by—

(I) Using that portion of a stack which exceeds good engineering practice stack height;

(II) Varying the rate of emission of a pollutant according to atmospheric conditions or ambient concentrations of that pollutant; or

(III) Increasing final exhaust gas plume rise by manipulating source process parameters, exhaust gas parameters, stack parameters or combining exhaust gases from several existing stacks into one (1) stack; or other selective handling of exhaust gas streams so as to increase the exhaust gas plume rise; and

B. This definition does not include:

(I) The reheating of a gas stream, following use of a pollution control system, for the purpose of returning the gas to the temperature at which it was originally discharged from the installation generating the gas stream;

(II) The merging of exhaust gas streams where—

(a) The installation owner or operator demonstrates that the installation was originally designed and constructed with the merged gas streams;

(b) After July 8, 1985, the merging is part of a change in operation at the installation that includes the installation of emissions control equipment and is accompanied by a net reduction in the allowable emissions of a pollutant. This exclusion from the definition

of dispersion technique shall apply only to the emission limitation for the pollutant affected by a change in operation; or

(c) Before July 8, 1985, the merging was part of a change in operation at the installation that included the installation of emissions control equipment or was carried out for sound economic or engineering reasons. Where there was an increase in the emission limitation or in the event that no emission limitation was in existence prior to the merging, the director shall presume that merging was significantly motivated by an intent to gain emissions credit for greater dispersion. Without a demonstration by the source owner or operator that merging was not significantly motivated by that intent, the director shall deny credit for the effects of merging in calculating the allowable emissions for the source;

(III) Smoke management in agricultural or silvicultural prescribed burning programs;

(IV) Episodic restrictions on residential woodburning and open burning; or

(V) Techniques under part (2)(D)10.A.(III) of this definition which increase final exhaust gas plume rise where the resulting allowable emissions of sulfur dioxide from the installation do not exceed five thousand (5,000) tons per year.

*[11.]***10.** Draft permit—The version of a permit for which the permitting authority offers public participation or affected state review.

*[12.]***11.** Drum—Any cylindrical container of thirteen to one hundred ten (13–110) gallon capacity.

*[13.]***12.** Dry cleaning installation—An installation engaged in the cleaning of fabrics in an essentially nonaqueous solvent by means of one (1) or more washes in solvent, extraction of excess solvent by spinning and drying by tumbling in an airstream. The installation includes, but is not limited to, any washer, dryer, filter and purification systems, waste disposal systems, holding tanks, pumps, and attendant piping and valves.

(E) All terms beginning with "E."

1. Emergency asbestos abatement project—An asbestos abatement project that must be undertaken immediately to prevent imminent severe human exposure or to restore essential facility operation.

2. Emission—The release or discharge, whether directly or indirectly, into the atmosphere of one (1) or more air contaminants.

3. Emission limitation—A regulatory requirement, permit condition or consent agreement which limits the quantity, rate or concentration of emissions on a continuous basis, including any requirement which limits the level of opacity, prescribes equipment, sets fuel specifications or prescribes operation or maintenance procedures for an installation to assure continuous emission reduction.

4. Emissions unit—Any part or activity of an installation that emits or has the potential to emit any regulated air pollutant or any pollutant listed under section 112(b) of the Act. This term is not meant to alter or affect the definition of the term unit for the purposes of Title IV of the Act.

5. Emulsified asphalt—An emulsion of asphalt cement and water that contains a small amount of an emulsifying agent, as specified in ASTM D (977-77) or ASTM D (2397-73).

6. Enamel—A surface coating that is a mixture of paint and varnish, having vehicles similar to those used for varnish, but also containing pigments.

[7. End exterior coating (two (2)-piece)—A surface coating used to cover the outside surface of the end of a two (2)-piece can.]

*[8.]***7.** End seal compound—The gasket forming coating used to attach the end pieces of a can during manufacturing or after filling with contents.

*[9.]***8.** Equipment—Any item that is designed or intended to perform any operation and includes any item attached to it to assist in the operation.

[10. Equivalent phosphorous pentoxide feed—The quantity of phosphorous, expressed as phosphorous pentoxide, fed to the process.]

*[11.]***9.** Excess emissions—The emissions which exceed the requirements of any applicable emission control regulation.

*[12.]***10.** Excessive concentration—

A. For installations seeking credit for reduced ambient pollutant concentrations from stack height exceeding that defined in subparagraph (2)(G)3.B., an excessive concentration is a maximum ground level concentration due to emissions from a stack due in whole or part to downwash, wakes or eddy effects produced by nearby structures or nearby terrain features which are at least forty percent (40%) in excess of the maximum concentration experienced in the absence of the downwash, wakes or eddy effects, and that contributes to a total concentration due to emissions from all installations that is greater than an ambient air quality standard. For installations subject to the prevention of significant deterioration program as set forth in 10 CSR 10-6.060(8), an excessive concentration means a maximum ground level concentration due to emissions from a stack due to the same conditions as mentioned previously and is greater than a prevention of significant deterioration increment. The allowable emission rate to be used in making demonstrations under this definition shall be prescribed by the new source performance regulation as referenced by 10 CSR 10-6.070 for the source category unless the owner or operator demonstrates that this emission rate is infeasible. Where demonstrations are approved by the director, an alternative emission rate shall be established in consultation with the source owner or operator;

B. For installations seeking credit after October 11, 1983, for increases in stack heights up to the heights established under subparagraph (2)(G)3.B., an excessive concentration is either—

(I) A maximum ground level concentration due in whole or part to downwash, wakes or eddy effects as provided in subparagraph (2)(E)12.A. of this rule, except that the emission rate used shall be the applicable emission limitation (or, in the absence of this limit, the actual emission rate); or

(II) The actual presence of a local nuisance caused by the stack, as determined by the director; and

C. For installations seeking credit after January 12, 1979, for a stack height determined under subparagraph (2)(G)3.B. where the director requires the use of a field study of fluid model to verify good engineering practice stack height, for installations seeking stack height credit after November 9, 1984, based on the aerodynamic influence of cooling towers and for installations seeking stack height credit after December 31, 1970, based on the aerodynamic influence of structures not represented adequately by the equations in subparagraph (2)(G)3.B., a maximum ground level concentration due in whole or part to downwash, wakes or eddy effects that is at least forty percent (40%) in excess of the maximum concentration experienced in the absence of downwash, wakes or eddy effects.

*[13.]***11.** Existing—As applied to any equipment, machine, device, article, contrivance or installation shall mean in being, installed or under construction in the Kansas City metropolitan area on September 25, 1968 (Buchanan County, January 21, 1970), in the St. Louis metropolitan area on March 24, 1967 (Franklin County, January 18, 1972), in the Springfield metropolitan area on September 24, 1971, and in the outstate Missouri area on February 24, 1971, except that if equipment, machine, device, article, contrivance or installation subsequently is altered, repaired or rebuilt at a cost of fifty percent (50%) or more of its replacement cost exclusive of routine maintenance, it shall no longer be existing, but shall be considered new as defined in this regulation. The cost of installing equipment designed principally for the purpose of air pollution control is not to be considered a cost of altering, repairing or rebuilding existing equipment for the purpose of this definition.

*[14.]***12.** Exterior coating (two (2)-piece)—A surface coating used to coat the outside face of a two (2)-piece can. Used to provide protection from the lithograph or printing operations.

*[15.]***13.** External floating roof—A storage vessel cover in an open top tank consisting of a double-deck or pontoon single deck which rests upon and is supported by petroleum liquid being contained

and is equipped with a closure seal(s) to close the space between the roof edge and tank wall.

*[16.]***14.** Extreme environmental conditions— The exposure to any of—the weather all of the time, temperatures consistently above ninety-five degrees Celsius (95°C), detergents-abrasive and scouring agents, solvents, corrosive atmospheres or similar environmental conditions.

[17. Extreme performance coating—A coating designed for extreme environmental conditions.]

(F) All terms beginning with "F."

[1. Fabric coating—The coating of a textile substrate with a knife or roller spreader to impart properties that are not initially present, such as strength, stability, water or acid repellency or appearance.]

*[2.]***1.** Federally enforceable—All limitations and conditions which are enforceable by the administrator, including those requirements developed pursuant to 40 CFR parts 55, 60, 61 and 63; requirements within any applicable state implementation plan; requirements in operating permits issued pursuant to 40 CFR parts 70 or 71, unless specifically designated as non-federally enforceable; and any permit requirements established pursuant to 40 CFR sections 52.10, 52.21, or part 55, or under regulations approved pursuant to 40 CFR part 51, subpart I, including operating permits issued under an EPA-approved program that is incorporated into the state implementation plan and expressly requires adherence to any permit issued under such program.

*[3.]***2.** Final permit—The version of a part 70 permit issued by the permitting authority that has completed all review procedures as required in part 70 sections 70.7 and 70.8.

*[4.]***3.** Final repair—The final coatings applied to correct topcoat imperfections after the complete assembly of the automobile.

*[5.]***4.** Firebox—The chamber or compartment of a boiler or furnace in which materials are burned but does not mean the combustion chamber of an incinerator.

*[6.]***5.** Flash off area—The space between the application area and the oven.

*[7.]***6.** Flexographic printing—The application of words, designs and pictures to a substrate by means of a roll printing technique in which the pattern to be applied is raised above the printing roll and the image carrier is made of rubber or other elastomeric materials.

*[8.]***7.** Freeboard height—The distance from the solvent (cold cleaner) or solvent vapor level (vapor degreaser) to the top edge of the solvent container.

*[9.]***8.** Freeboard ratio—The freeboard height divided by the width of the degreaser.

*[10.]***9.** Friable asbestos-containing material—Any material that contains more than one percent (1%) asbestos, by weight, which is applied to ceilings, walls, structural members, piping, ductwork or any other part of a building or facility and which, when dry, may be crumbled, pulverized or reduced to powder by hand pressure.

*[11.]***10.** Fugitive emissions—Those emissions which according to good engineering practice could not pass through a stack, chimney, vent or other functionally equivalent opening.

[12. Furnishings—Removable furniture, drapes, rugs and decorative items.]

(H) All terms beginning with "H."

1. Hazardous air pollutant—Any of the air pollutants listed in subsection (3)(C) of this rule.

2. HHV—A higher heating value as determined by 10 CSR 10-6.040(2) (ASTM Standard: D 2015-66, Part 19, 1972, *Standard Method for Determining Gross Heating Values of Solid Fuels*).

[3. High efficiency particulate air filter—A HEPA filter found in respirators and vacuum systems capable of filtering three-tenths (0.3) micron particles with at least ninety-nine and ninety-seven hundredths percent (99.97%) efficiency.]

*[4.]***3.** High terrain—Any area having an elevation nine hundred feet (900') or more above the base of the stack of the installation.

[5. Homogeneous area—An area of surfacing material, thermal system insulation material or miscellaneous material that is uniform in color and texture.]

*[6.]***4.** Hot car—A vehicle which transfers hot coke from the oven to the area of quenching.

[7. Hot well—The reservoir of a condensing unit receiving the warm condensate from the condenser.]

(I) All terms beginning with "I."

1. Incinerator—Any article, machine, equipment, contrivance, structure or part of a structure used to burn refuse or to process refuse material by burning other than by open burning as defined in this rule.

2. Indirect heating source—A source operation in which fuel is burned for the primary purpose of producing steam, hot water or hot air, or other indirect heating of liquids, gases or solids where, in the course of doing so, the products of combustion do not come into direct contact with process materials.

[3. Individual source monitoring—A system as specified in EPA document EPA-450/2-78-036 entitled Control of Volatile Organic Compound Leaks from Petroleum Refinery Equipment, which utilizes a portable hydrocarbon monitor to measure levels of volatile hydrocarbons emitted from individual process equipment.]

*[4.]***3.** Innovative control technology—Any system of air pollution control that has not been adequately demonstrated in practice but would have a substantial likelihood of achieving greater continuous emission reduction than any control system in current practice or of achieving at least comparable reductions at lower cost in terms of energy, economics or non-air quality environmental impacts.

*[5.]***4.** Insignificant activity—An activity or emission unit in which the only applicable requirement would be to list the requirement in an operating permit application under 10 CSR 10-6.065 and is either of the following:

A. Emission units whose aggregate emission levels for the installation do not exceed that of the *de minimis* levels; and

B. Emission units or activities listed in 10 CSR 10-6.061 as exempt or excluded from construction permit review under 10 CSR 10-6.060.

*[6.]***5.** Inspector—An individual, under AHERA, who collects and assimilates information used to determine whether asbestos-containing material is present in a building or other air contaminant sources.

*[7.]***6.** Installation—All source operations including activities that result in fugitive emissions, that belong to the same industrial grouping (that have the same two (2)-digit code as described in the *Standard Industrial Classification Manual*, 1987), and any marine vessels while docked at the installation, located on one (1) or more contiguous or adjacent properties and under the control of the same person (or persons under common control).

*[8.]***7.** Interior body spray (two (2)- and three (3)-piece)—The surface coating for the interior and ends of a two (2)-piece formed can or the surface coating of the side of the rectangular material to be used as the interior and ends of a three (3)-piece can.

*[9.]***8.** Internal floating roof—A product cover in a fixed roof tank which rests upon or is floated upon the VOC liquid being contained and which is equipped with a sliding seal(s) to close the space between the edge of the covers and tank shell.

*[10.]***9.** Inventory—A quantification of emissions by installation and by source operation.

(K) All terms beginning with "K."

1. Kansas City metropolitan area—The geographical area comprised of Jackson, Cass, Clay, Platte, Ray and Buchanan Counties.

[2. Knife coating—The application of a coating material to a substrate by means of drawing the substrate between a knife that spreads the coating evenly over the full width of the substrate.]

(L) All terms beginning with "L."

1. Lacquers—A surface coating that is basically solutions of

nitrocellulose in VOCs, with plasticizers and other resins added to improve the quality of the film.

2. Light-duty truck—Any motor vehicle rated at eight thousand five hundred pounds (8**,**500 lbs.) gross weight or less or a derivation of this vehicle which is designed primarily for the purpose of transportation of property.

[3. Liquefied cutback asphalt (LCA)—An asphalt cement which has been liquefied by blending with petroleum solvents (diluents).]

*[4.]***3.** Liquid-mounted seal—A primary seal mounted in continuous contact with the liquid between the tank wall and the floating roof around the circumference of the tank.

[5. Low terrain—Any area other than high terrain.]

*[6.]***4.** Lower explosive limit (LEL)—The lower limit of flammability of a gas or vapor at ordinary ambient temperatures expressed in percent of the gas or vapor in air by volume.

*[7.]***5.** Lowest achievable emission rate (LAER)—That rate of emissions which reflects—1) the most stringent emission limitation which is contained in any state implementation plan for a class or category of source, unless the owner or operator of the proposed source demonstrates that the limitations are not achievable or 2) the most stringent emission limitation which is achieved in practice by the class or category of source, whichever is more stringent. LAER shall not be less stringent than the new source performance standard limit.

(M) All terms beginning with "M."

1. MACT (Maximum achievable control technology)—The maximum degree of reduction in emissions of the hazardous air pollutants listed in subsection (3)(C) of this rule (including a prohibition on these emissions where achievable), taking into consideration the cost of achieving emissions reductions and any non-air quality health and environmental impacts and requirements, determines is achievable for new or existing sources in the category or subcategory to which this emission standard applies, through application of measures, processes, methods, systems or techniques including, but not limited to, measures which—

A. Reduce the volume of or eliminate emissions of pollutants through process changes, substitution of materials or other modifications;

B. Enclose systems or processes to eliminate emissions;

C. Collect, capture or treat pollutants when released from a process, stack, storage or fugitive emissions point;

D. Are design, equipment, work practice or operational standards (including requirements for operational training or certification); or

E. Are a combination of subparagraphs (2)(M)1.A.–D.

[2. Magnet wire coating—The process of applying a coating of electrically insulating varnish or enamel to aluminum or copper wire for use in electrical machinery.]

*[3.]***2.** Major modification—Any physical change or change in the method of operation at an installation or in the attendant air pollution control equipment that would result in a significant net emissions increase of any pollutant. A physical change or a change in the method of operation, unless previously limited by enforceable permit conditions, shall not include:

A. Routine maintenance, repair and replacement of parts;

B. Use of an alternative fuel or raw material by reason of an order under Sections 2(a) and (b) of the Energy Supply and Environmental Coordination Act of 1974, a prohibition under the Power Plant and Industrial Fuel Use Act of 1978 or by reason of a natural gas curtailment plan pursuant to the Federal Power Act;

C. Use of an alternative fuel or raw material, if prior to January 6, 1975, the source was capable of accommodating the fuel or material, unless the change would be prohibited under any enforceable permit condition which was established after January 6, 1975;

D. An increase in the hours of operation or in the production rate unless the change would be prohibited under any enforceable permit condition which was established after January 6, 1975; or

E. Use of an alternative fuel by reason of an order or rule under Section 125 of the Clean Air Act.

*[4.]***3.** Malfunction—A sudden and unavoidable failure of air pollution control equipment or process equipment or of a process to operate in a normal and usual manner. Excess emissions caused by improper design shall not be deemed a malfunction.

*[5.]***4.** Management planner—An individual, under AHERA, who devises and writes plans for asbestos abatement.

*[6.]***5.** Manure storage and application systems—Any system that includes but is not limited to lagoons, manure treatment cells, earthen storage ponds, manure storage tanks, manure stockpiles, composting areas, pits and gutters within barns, litter used in bedding systems, all types of land application equipment, and all pipes, hoses, pumps and other equipment used to transfer manure.

*[7.]***6.** Maskant—A coating applied directly to an aerospace component to protect those areas when etching other parts of the component.

[8. Metal furniture coating—The surface coating of any furniture made of metal or any metal part which will be assembled with other metal, wood, fabric, plastic or glass parts to form a furniture piece.]

*[9.]***7.** Model year—The annual production period of new motor vehicles designated by the calendar year in which the period ends, provided that if the manufacturer does not so designate vehicles manufactured by him/her, the model year with respect to the vehicles shall mean the twelve (12)-month period beginning January 1 of the year specified in this rule.

*[10.]***8.** Modification—Any physical change, or change in method of operation of, a source operation or attendant air pollution control equipment which would cause an increase in potential emissions of any air pollutant emitted by the source operation.

*[11.]***9.** Modification, Title I—See Title I modification.

*[12.]***10.** Motor tricycle—A motor vehicle operated on three (3) wheels, including a motorcycle with any conveyance, temporary or otherwise, requiring the use of a third wheel.

*[13.]***11.** Motor vehicle—Any self-propelled vehicle.

*[14.]***12.** Motorcycle—A motor vehicle operated on two (2) wheels.

[15. Multiple chamber incinerator—Any incinerator consisting of two (2) or more refractory lined combustion furnaces in series, physically separated by refractory walls, interconnected by gas passage ports or ducts and employing adequate design parameters necessary for maximum combustion of the material to be burned, the refractories having a Pyrometric Cone Equivalent of 31, tested according to the method described in the ASTM Method C-24-56 or other method approved by the department director.

16. Multiple fixed-point monitoring—A system for monitoring VOCs where stationary monitors are placed throughout the petroleum refinery which measure atmospheric concentrations of VOCs.]

(N) All terms beginning with "N."

1. Nearby—Nearby as used in the definition GEP stack height in subparagraph (2)(G)2.B. is defined for a specific structure or terrain feature—

A. For purposes of applying the formula provided in subparagraph (2)(G)3.B., nearby means that distance up to five (5) times the lesser of the height or the width dimension of a structure, but not greater than one-half (1/2) mile; and

B. For conducting fluid modeling or field study demonstrations under subparagraph (2)(G)3.C., nearby means not greater than one-half (1/2) mile, except that the portion of a terrain feature may be considered to be nearby which falls within a distance of up to ten (10) times the maximum height of the feature, not to exceed two (2) miles if feature achieves a height one-half (1/2) mile from the stack that is at least forty percent (40%) of the GEP stack height determined by the formula provided in subparagraph (2)(G)3.B. or

twenty-six meters (26 m), whichever is greater, as measured from the ground level elevation at the base of the stack. The height of the structure or terrain feature is measured from the ground level elevation at the base of the stack.

2. Net emissions increase—This term is defined in 40 CFR 52.21(b)(3), promulgated as of July 1, 2003 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20408. This rule does not incorporate any subsequent amendments or additions.

[3. New tepee burner—One not in existence as of September 18, 1970.

4. NIOSH—National Institute of Occupational Safety and Health.]

*[5.]***3.** Nonattainment area—Those geographic areas in Missouri that have officially been designated by the U.S. Environmental Protection Agency in 40 CFR part 81 as nonattainment areas.

(O) All terms beginning with "O."

1. Offset—A decrease in actual emissions from a source operation or installation that is greater than the amount of emissions anticipated from a modification or construction of a source operation or installation. The decrease must be of the same pollutant and have substantially similar environmental and health effects on the impacted area. Any ratio of decrease to increase greater than one to one (1:1) constitutes offset. The exception to this are ozone nonattainment areas where VOC and NO_x emissions will require an offset ratio of actual emission reduction to new emissions according to the following schedule: marginal area = 1.1:1; moderate area = 1.15:1; serious area = 1.2:1; severe area = 1.3:1; and extreme area = 1.5:1.

2. Offtake—Any set of piping (for example, standpipes, goosenecks) that interconnects a coke oven with a collecting main which is common to all systems. The offtake system extends from the connection on top of the coke oven to the connection on the collecting main.

3. Opacity—The extent to which airborne material obstructs the transmission of incident light and obscures the visual background. Opacity is stated as a percentage of light obstructed and can be measured by a continuous opacity monitoring system or a trained observer. An opacity of one hundred percent (100%) represents a condition in which no light is transmitted, and the background is completely obscured.

4. Open burning—The burning of any materials where air contaminants resulting from combustion are emitted directly into the ambient air without passing through a stack or chimney from an enclosed chamber. For purposes of this definition, a chamber shall be regarded as enclosed, when, during the time combustion takes place, only those apertures, ducts, stacks, flues or chimneys as are necessary to provide combustion air and to permit the escape of exhaust gases are open.

5. Open-top vapor degreaser—A type of degreaser which consists of a tank where solvent is heated to its boiling point which creates a zone of solvent vapor contained by a set of cooling coils. Condensation of the hot solvent vapor cleans or degreases the colder metal parts.

6. *[Outside air—Air outside the containment area.]***Outstate area—Any area throughout the state except the City of St. Louis and St. Charles, St. Louis, Jefferson, Franklin, Clay, Cass, Buchanan, Ray, Jackson, Platte and Greene Counties.**

7. Owner or operator—Any person who owns, leases, operates, controls or supervises an air contaminant source.

(P) All terms beginning with "P."

1. Pail—Any nominal cylindrical container of one to twelve (1–12) gallon capacity.

2. Paint—A pigmented surface coating using VOCs as the major solvent and thinner which converts to a relatively opaque solid film after application as a thin layer.

3. Part 70—U.S. Environmental Protection Agency regulations, codified at 40 CFR part 70, setting forth requirements for state operating permit programs pursuant to Title V of the Act.

4. Particulate matter—Any material, except uncombined water, that exists in a finely divided form as a liquid or solid and as specifically defined as follows:

A. PM—any airborne, finely divided solid or liquid material with an aerodynamic diameter smaller than one hundred (100) micrometers as measured in the ambient air as specified in 10 CSR 10-6.040(4)(B); and

B. PM_{10}—particulate matter with an aerodynamic diameter less than or equal to a nominal ten (10) micrometers as measured in the ambient air as specified in 10 CSR 10-6.040(4)(J); and

C. $PM_{2.5}$—particulate matter with an aerodynamic diameter less than or equal to a nominal two and one-half (2.5) micrometers including the filterable component as measured in the ambient air as specified in 10 CSR 10-6.040(4)(L).

5. Permanent shutdown—The permanent cessation of operation of any air pollution control equipment or process equipment, not to be placed back into service or have a start-up.

6. Permitting authority—Either the administrator or the state air pollution control agency, local agency or other agency authorized by the administrator to carry out a permit program as intended by the Act.

7. Person—Any individual, partnership, association, corporation including the parent company of a wholly-owned subsidiary, municipality, subdivision or agency of the state, trust, estate or other legal entity either public or private. This shall include any legal successor, employee or agent of the previous entities.

8. Petroleum liquid—Petroleum, condensate and any finished or intermediate products manufactured in a petroleum refinery with the exception of Numbers 2–6 fuel oils as specified in ASTM D(396-69), gas turbine fuel oils Number 2-GT—4-GT, as specified in ASTM D(2880-71), and diesel fuel oils Number 2-D and 4-D, as specified in ASTM D(975-68).

9. Petroleum refinery—Any facility which produces gasoline, kerosene, distillate fuel oils, residual fuel oils, lubricants or other products through distillation, cracking, extraction or reforming of unfinished petroleum derivatives.

10. Pharmaceutical—Any compound or preparation included under the Standard Industrial Classification Codes 2833 (Medicinal Chemicals and Botanical Products) and 2834 (Pharmaceutical Preparations), excluding products formulated by fermentation, extraction from vegetable material or animal tissue or formulation and packaging of the final product.

11. Pilot plants—The installations which are of new type or design which will serve as a trial unit for experimentation or testing.

12. Plant-mix—A mixture produced in an asphalt mixing plant that consists of mineral aggregate uniformly coated with asphalt cement, cutback asphalt or emulsified asphalt.

13. Pollutant—An air contaminant listed in 10 CSR 10-6.020(3)(A), Table 1 without regard to levels of emission or air quality impact.

14. Polyethylene bag sealing operation—Any operation or facility engaged in the sealing of polyethylene bags, usually by the use of heat.

15. Polystyrene resin—The product of any styrene polymerization process, usually involving heat.

16. Portable equipment—Any equipment that is designed and maintained to be movable, primarily for use in noncontinuous operations. Portable equipment includes rock crushers, asphaltic concrete plants and concrete batching plants.

17. Portable equipment installation—An installation made up solely of portable equipment, meeting the requirements of or having been permitted according to 10 CSR 10-6.060(4).

18. Positive crankcase ventilation system—Any system or device which prevents the escape of crankcase emissions to the ambient air.

19. Potential to emit—The emission rates of any pollutant at maximum design capacity. Annual potential shall be based on the maximum annual-rated capacity of the installation assuming continuous year-round operation. Federally enforceable permit conditions on the type of materials combusted or processed, operating rates, hours of operation *[or]* **and** the application of air pollution control equipment shall be used in determining the annual potential. Secondary emissions do not count in determining annual potential.

20. Potroom—A building unit which houses a group of electrolytic cells in which aluminum is produced.

21. Potroom group—An uncontrolled potroom, a potroom which is controlled individually or a group of potrooms or potroom segments ducted to a common or similar control system.

22. Primary aluminum reduction installation—Any facility manufacturing aluminum by electrolytic reduction of alumina.

23. Primer—The first surface coating applied to the surface.

24. Primer-surfacer—The surface coatings applied over the primer and beneath the topcoat.

25. Process weight—The total weight of all materials introduced into a source operation including solid fuels, but excluding liquids and gases used solely as fuels and excluding air introduced for purposes of combustion.

26. Production equipment exhaust system—A device for collecting and directing out of the work area fugitive emissions from reactor openings, centrifuge openings and other vessel openings and equipment for the purpose of protecting workers from excessive exposure.

27. Publication rotogravure printing—Rotogravure printing upon paper which is subsequently formed into books, magazines, catalogues, brochures, directories, newspaper supplements and other types of printed materials.

28. Pushing operation—The process of removing coke from the coke oven. The coke pushing operation begins when the coke-side oven door is removed and is completed when the hot car enters the quench tower and the coke-side oven door is replaced.

(R) All terms beginning with "R."

1. Reactor—A vat or vessel, which may be jacketed to permit temperature control, designed to contain chemical reactions.

2. Reconstruction—Where the fixed capital cost of the new components exceeds fifty percent (50%) of the fixed capital cost of a comparable entirely new source of operation or installation; the use of an alternative fuel or raw material by reason of an order in effect under Sections 2(a) and (b) of the Energy Supply and Environmental Coordination Act of 1974, by reason of a natural gas curtailment plan in effect pursuant to the Federal Power Act, or by reason of an order or rule under Section 125 of the Clean Air Act, shall not be considered reconstruction. In determining whether a reconstruction will occur, the provisions of 40 CFR 60.15, December 1, 1979, shall be considered by the director.

[3. Refinery fuel gas—Any gas which is generated by a petroleum refinery process unit and which is combusted including any gaseous mixture of natural gas and fuel gas.]

*[4.]***3.** Refuse—The garbage, rubbish, trade wastes, leaves, salvageable material, agricultural wastes or other wastes.

*[5.]***4.** Regulated air pollutant—All air pollutants or precursors for which any standard has been promulgated.

*[6.]***5.** Regulated asbestos-containing material (RACM)—Friable asbestos material; category I nonfriable asbestos-containing material (ACM) that has become friable; category I nonfriable ACM that will be or has been subjected to sanding, grinding, cutting, or abrading, or category II nonfriable ACM that has a high probability of becoming or has become crumbled, pulverized or reduced to powder by the forces expected to act on the material in the course of demolition or renovation operations regulated by this rule.

*[7.]***6.** Regulated pollutant—Any regulated air pollutant except carbon monoxide and pollutants regulated exclusively under section 112(r) or Title VI of the Act.

*[8.]***7.** Reid vapor pressure (RVP)—The absolute vapor pressure of a petroleum liquid as determined by "Tests for Determining Reid Vapor Pressure (RVP) of Gasoline and Gasoline-Oxygenate Blends" 40 CFR part 80, Appendix E as in effect July 1, 1990.

*[9.]***8.** Renewal—The process by which an operating permit is reissued at the end of its term.

*[10.]***9.** Repair—The restoration of asbestos material that has been damaged. Repair consists of the application of rewettable glass cloth, canvas, cement or other suitable material. It may also involve filling damaged areas with nonasbestos substitutes and reencapsulating or painting previously encapsulated materials.

*[11.]***10.** Residual fuel oil—The fuel oil variously known as Bunker C, PS 400 and Number 6 as defined in ASTM D(396–487) (1959).

*[12.]***11.** Responsible official—Includes one (1) of the following:

A. The president, secretary, treasurer or vice-president of a corporation in charge of a principal business function, any other person who performs similar policy and decision-making functions for the corporation or a duly authorized representative of this person if the representative is responsible for the overall operation of one (1) or more manufacturing, production or operating facilities applying for or subject to a permit and either—

(I) The facilities employ more than two hundred fifty (250) persons or have a gross annual sales or expenditures exceeding twenty-five (25) million dollars (in second quarter 1980 dollars); or

(II) The delegation of authority to this representative is approved in advance by the permitting authority;

B. A general partner in a partnership or the proprietor in a sole proprietorship;

C. Either a principal executive officer or ranking elected official in a municipality, state, federal or other public agency. For the purpose of this subparagraph, a principal executive officer of a federal agency includes the chief executive officer having responsibility for the overall operations of a principal geographic unit of the agency; or

D. The designated representative of an affected source insofar as actions, standards, requirements or prohibitions under Title IV of the Act or the regulations promulgated under the Act are concerned and the designated representative for any other purposes under part 70.

*[13.]***12.** Retail outlet—Any establishment where gasoline is sold, offered for sale or used as a motor vehicle fuel.

*[14.]***13.** Road-mix—An asphalt course produced by mixing mineral aggregate and cutback or emulsified asphalt at the road site by means of travel plants, motor graders, drags or special road-mixing equipment.

*[15.]***14.** Roll printing—The application of words, designs and pictures to a substrate usually by means of a series of hard rubber or steel rolls each with only partial coverage.

*[16.]***15.** Roller spreader—The device used for the application of a coating material to a substrate by means of hard rubber or steel rolls.

*[17.]***16.** Rotogravure printing—The application of words, designs and pictures to a substrate by means of a roll printing technique which involves an intaglio or recessed image areas in the form of cells.

(S) All terms beginning with "S."

1. Salvage operation—Any business, trade, industry or other activity conducted in whole or in part for the purpose of salvaging or reclaiming any product or material.

2. Sealing material—A liquid substance that does not contain asbestos which is used to cover a surface that has previously been coated with a friable asbestos-containing material for the intended purpose of preventing any asbestos fibers remaining on the surface from being disbursed into the air. This substance shall be distinguishable from the surface to which it is applied.

3. Secondary emissions—The emissions which occur or would occur as a result of the construction or operation of an installation or

major modification but do not come from the installation or major modification itself. Secondary emissions must be specific, well-defined, quantifiable and impact the same general area as the installation or modification which causes the secondary emissions. Secondary emissions may include, but are not limited to:

A. Emissions from trucks, ships or trains coming to or from the installation or modification; and

B. Emissions from any off-site support source which would not be constructed or increase its emissions except as a result of the construction or operation of the major stationary source or major modification.

4. Section 502(b)(10) changes—Changes that contravene an express permit term. These changes do not include those that would violate applicable requirements or contravene federally-enforceable permit terms and conditions that are monitoring (including test methods), record keeping, reporting or compliance certification requirements.

5. Sheet basecoat—The roll coated primary interior surface coating applied to surfaces for the basic protection of buffering filling material from the metal can surface.

[6. Shower room—A room between the clean room and the equipment room in the worker decontamination enclosure. This room shall be equipped with running hot and cold water that is suitably arranged for complete showering during decontamination.]

*[7.]***6.** Shutdown—The cessation of operation of any air pollution control equipment or process equipment, excepting the routine phasing out of process equipment.

*[8.]***7.** Shutdown, permanent—See permanent shutdown.

[9. Side seam coating (three (3)-piece)—A can surface coating to seal the connecting edge of a formed metal sheet in the manufacture of a three (3)-piece can.]

*[10.]***8.** Significant—A net emissions increase or potential to emit at a rate equal to or exceeding the *de minimis* levels or create an ambient air concentration at a level greater than those listed in 10 CSR 10-6.060(11)(D) Table 4, or any emissions rate or any net emissions increase associated with an installation subject to 10 CSR 10-6.060 which would be constructed within ten kilometers (10 km) of a Class I area and have an air quality impact on the area equal to or greater than one microgram per cubic meter (1 $\mu g/m^3$) (twenty-four (24)-hour average). For purposes of new source review under 10 CSR 10-6.060 sections (7) and (8), net emission increases of hazardous air pollutants exceeding the *de minimis* levels are considered significant only if they are also criteria pollutants.

*[11.]***9.** Smoke—Small gas-borne particles resulting from combustion, consisting of carbon, ash and other material.

*[12.]***10.** Solvent—Organic materials which are liquid at standard conditions and which are used as dissolves, viscosity reducers or cleaning agents.

*[13.]***11.** Solvent metal cleaning—The process of cleaning soils from metal surfaces by cold cleaning or open-top vapor degreasing or conveyorized degreasing.

[14. Solvent volatility—Reid vapor pressure.]

*[15.]***12.** Source gas volume—The volume of gas arising from a process or other source operation.

*[16.]***13.** Source operation—See emission unit.

*[17.]***14.** Springfield-Greene County area—The geographical area contained within Greene County.

*[18.]***15.** St. Louis metropolitan area—The geographical area comprised of St. Louis, St. Charles, Jefferson and Franklin Counties and the City of St. Louis.

*[19.]***16.** Stack—Any spatial point in an installation designed to emit air contaminants into ambient air. An accidental opening such as a crack, fissure, or hole is a source of fugitive emissions, not a stack.

[20. Stack in existence—The owner or operator had—1) begun, or caused to begin, a continuous program of physical on-site construction of the stack; or 2) entered into binding agreements or contractual operations, which could not be cancelled or modified without substantial loss to the owner or operator, to undertake a program of construction of the stack to be completed in a reasonable time.]

*[21.]***17.** Staff director—Director of the Air Pollution Control Program of the Department of Natural Resources.

18. Stage I vapor recovery system—A system used to capture the gasoline vapors that would otherwise be emitted when gasoline is transferred from a loading installation to a delivery vessel or from a delivery vessel to a storage tank.

19. Stage II vapor recovery system—A system used to capture the gasoline vapors that would otherwise be emitted when gasoline is dispensed into a vehicle fuel tank by routing vapors back to the fuel storage tank.

*[22.]***20.** Standard conditions—A gas temperature of seventy degrees Fahrenheit (70°F) and a gas pressure of 14.7 pounds per square inch absolute (psia).

*[23.]***21.** Start-up—The setting into operation of any air pollution control equipment or process equipment, except the routine phasing in of process equipment.

*[24.]***22.** State—Any nonfederal permitting authority, including any local agency, interstate association or statewide program. When clear from its context, state shall have its conventional territorial definition.

*[25.]***23.** State implementation plan—A series of plans adopted by the commission, submitted by the director, and approved by the administrator, detailing methods and procedures to be used in attaining and maintaining the ambient air quality standards in Missouri.

*[26.]***24.** Storage tank—Any tank, reservoir or vessel which is a container for liquids or gases, where no manufacturing process or part of it, takes place.

[27. Structural item—Roofs, walls, ceilings, floors, structural supports, pipes, ducts, fittings and fixtures that have been installed as an integral part of any structure.]

*[28.]***25.** Submerged fill pipe—Any fill pipe the discharge opening of which is entirely submerged when the liquid level is six inches (6") above the bottom of the tank. Submerged fill pipe when applied to a tank which is loaded from the side is defined as any fill pipe, the discharge opening of which is entirely submerged when the liquid level is eighteen inches (18") or twice the diameter of the fill pipe, whichever is greater, above the bottom of the tank.

*[29.]***26.** Synthesized pharmaceutical manufacturing—Manufacture of pharmaceutical products by chemical synthesis.

(T) All terms beginning with "T."

1. Temporary installation—An installation which operates or emits pollutants less than two (2) years.

[2. Third-party air monitoring—Air monitoring conducted in accordance with Chapter 643, RSMo and 10 CSR 10-6.240 and 10 CSR 10-6.250 by a person who is not under the direct control of the person carrying out the asbestos abatement project and who has been selected by the owner or operator of the property on which the project is conducted.]

*[3.]***2.** Title I modification—Any modification that requires a permit under 10 CSR 10-6.060 section (7) or (8), or that is subject to any requirement under 10 CSR 10-6.070 or 10 CSR 10-6.080.

*[4.]***3.** Topcoat—The surface coatings applied for the purpose of establishing the color or protective surface, or both, including groundcoat and paint sealer materials, base coat and clear coat.

*[5.]***4.** Total fluoride—The elemental fluorine and all fluoride compounds as measured by reference methods specified in 10 CSR 10-6.030(12) or equivalent or alternative methods.

*[6.]***5.** Trade waste—The solid, liquid or gaseous material resulting from construction or the prosecution of any business, trade or industry or any demolition operation including, but not limited to, plastics, cardboard cartons, grease, oil, chemicals or cinders.

*[7.]***6.** Transfer efficiency (TE)—Ratio of the amount of coating solids transferred onto a product to the total of coating solids

used. In any surface coating operation, TE is the ratio of solids in a coating that adhere on a target surface to the total solids used in the process for coating the target surface.

*[8.]***7.** True vapor pressure—The equilibrium partial pressure exerted by a petroleum liquid as determined in American Petroleum Institute Bulletin 2517, *Evaporation Loss from Floating Roof Tanks*, 1962.

(U) All terms beginning with "U."

1. Uncombined water—The visible condensed water which is not bound, physically or chemically, to any air contaminant.

2. Unit—A fossil fuel-fired combustion device.

[3. Unit turnaround—The procedure of shutting a refinery process unit down to do necessary maintenance and repair work and putting the unit back on stream.

4. Unit walk through monitoring—The system for monitoring volatile organic hydrocarbons which utilizes a portable hydrocarbon monitor to measure ambient hydrocarbon levels in the areas of all process equipment.]

(V) All terms beginning with "V."

[1. Vacuum producing system—Any reciprocating, rotary or centrifugal blower or compressor or any jet ejector device that takes suction from a pressure below atmospheric on a system containing volatile hydrocarbons.]

*[2.]***1.** Vapor recovery system—A vapor gathering system capable of collecting the hydrocarbon vapors and gases discharged and a vapor disposal system capable of processing the hydrocarbon vapors and gases so as to limit their emission to the atmosphere.

[3. Vapor-mounted seal—A primary seal mounted so there is an annular vapor space underneath the seal. The annular vapor space is bounded by the bottom of the primary seal, the tank wall, the liquid surface and the floating roof.]

*[4.]***2.** Vapor tight—When applied to a delivery vessel or vapor recovery system as one that sustains a pressure change of no more than seven hundred fifty (750) pascals (three inches (3") of H_2O) in five (5) minutes when pressurized to a gauge pressure of four thousand five hundred (4,500) pascals (eighteen inches (18") of H_2O) or evacuated to a gauge pressure of one thousand five hundred (1,500) pascals (six inches (6") of H_2O).

*[5.]***3.** Varnish—An unpigmented surface coating containing VOC and composed of resins, oils, thinners and driers used to give a glossy surface to wood, metal, etc.

*[6.]***4.** Vehicle—Any mechanical device on wheels, designed primarily for use on streets, roads or highways, except those propelled or drawn by human or animal power or those used exclusively on fixed rails or tracks.

*[7.]***5.** Vinyl coating—The application of a decorative or protective topcoat, or printing or vinyl coated fabric or vinyl sheet.

*[8.]***6.** Visible emission—Any discharge of an air contaminant, including condensibles, which reduces the transmission of light or obscures the view of an object in the background.

*[9.]***7.** Volatile organic compounds (VOC)—For all areas in Missouri VOC means any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, that participates in atmospheric photochemical reactions to produce ozone.

A. The following compounds are not considered VOCs because of their known lack of participation in the atmospheric reactions to produce ozone:

CAS #	Compound
138495428	1,1,1,2,3,4,4,5,5,5-decafluoropentane (HFC 43-10mee)
431890	1,1,1,2,3,3,3-heptafluoropropane (HFC 227ea)
375031	1,1,1,2,2,3,3-heptafluoro-3-methoxy-propane (n-$C_3F_7OCH_3$, HFE-7000)
690391	1,1,1,3,3,3-hexafluoropropane (HFC-236fa)
679867	1,1,2,2,3-pentafluoropropane (HFC-245ca)
24270664	1,1,2,3,3-pentafluoropropane (HFC-245ea)
431312	1,1,1,2,3-pentafluoropropane (HFC-245eb)
460731	1,1,1,3,3-pentafluoropropane (HFC-245fa)
431630	1,1,1,2,3,3-hexafluoropropane (HFC-236ea)
406586	1,1,1,3,3-pentafluorobutane (HFC-365mfc)
422560	3,3-dichloro-1,1,1,2,2-pentafluoro-propane (HCFC-225ca)
507551	1,3-dichloro-1,1,2,2,3-pentafluoro-propane (HCFC-**22**5cb)
354234	1,2-dichloro-1,1,2-trifluoroethane (HCFC-123a)
1615754	1*[-]*chloro-1-fluorethane (HCFC-151a)
163702076	1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxybutane ($C_4F_9OCH_3$ or HFE-7100)
163702087	2-(difluromethoxymethyl)-1,1,1,2,3,3,3-heptafluoropropane (($CF_3)_2CFCF_2OCH_3$)
163702054	1-ethoxy-1,1,2,2,3,3,4,4,4-non-afluorobutane ($C_4F_9OC_2H_5$ or HFE-7200)
163702065	2-(ethoxydifluoromethyl)-1,1,1,2,3,3,3-heptafluoropropane (($CF_3)_2CFCF_2OC_2H_5$)
297730939	3-ethoxy-1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoro-methyl) *[-]*hexane (HFE-7500)
71556	1,1,1-trichloroethane (methyl chloroform)
67641	acetone
25497294	*[chlorodifluoroethane]* **1-chloro-1,1-difluoroethane** (HCFC-142b)
75456	chlorodifluoromethane (HCFC-22)
593704	chlorofluoromethane (HCFC-31)
76153	chloropentafluoroethane (CFC-115)
63938103	*[chlorotetrafluoroethane]* **2-chloro-1,1,1,2-tetrafluoroethane** (HCFC-124)
75718	dichlorodifluoromethane (CFC-12)
1717006	*[dichlorofluoroethane]* **1,1-dichloro-1-fluoroethane** (HCFC-141b)
1320372	*[dichlorotetrafluoroethane]* **1,2-dichloro-1,1,2,2-tetrafluo-roethane** (CFC-114)
34077877	*[dichlorotrifluoroethane]* **1,1,1-trifluoro-2,2-dichloroethane** (HCFC-123)
75376	*[difluoroethane]* **1,1-difluoroethane** (HFC-152a)
75105	difluoromethane (HFC-32)
74840	ethane
353366	ethylfluoride (HFC-161)
74828	methane
79209	methyl acetate
[107313]	*[methyl formate ($HCOOCH_3$)]*
75092	methylene chloride **(**dichloromethane**)**
98566	parachlorobenzotrifluoride (PCBTF)

354336	pentafluoroethane (HFC-125)
127184	perchloroethylene**tetrachloroethylene**
359353	**1,1,2,2-**tetrafluoroethane (HFC-134)
811972	**1,1,1,2-**tetrafluoroethane (HFC-134a)
75694	trichlorofluoromethane (CFC-11)
26523648	*[trichlorotrifluoroethane]* **1,1,2-trichloro-1,2,2-trifluoroethane** (CFC-113)
306832	**1,1,1-**trifluoro**-2,2-**dichloroethane (HCFC-123)
27987060	**1,1,1-**trifluoroethane (HFC-143a)
75467	trifluoromethane (HFC-23)
107313	**methyl formate ($HCOOCH_3$), (1) 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-trifluoromethyl-pentane ($C_2F_5CF(OCH_3)CF(CF_3)_2$ or HFE-7300)**
0	cyclic, branched or linear, completely fluorinated alkanes
0	cyclic, branched or linear, completely fluorinated ethers with no unsaturations
0	cyclic, branched or linear, completely methylated siloxanes
0	cyclic, branched or linear, completely fluorinated tertiary amines with no unsaturations
0	sulfur-containing perfluorocarbons with no unsaturations and with sulfur bonds only to carbon and fluorine*[s]*

VOC may be measured by a reference method, an equivalent method, an alternative method or by procedures specified in either 10 CSR 10-6.030 or 40 CFR 60. These methods and procedures may measure nonreactive compounds so an owner or operator must exclude these nonreactive compounds when determining compliance.

B. The following compound(s) are considered VOC for purposes of all record keeping, emissions reporting, photochemical dispersion modeling and inventory requirements which apply to VOC and shall be uniquely identified in emission reports, but are not VOC for purposes of VOC emissions limitations or VOC content requirements.

CAS #	Compound
540885	t-butyl acetate

(W) All terms beginning with "W."

1. Waste generator—The business entity that is directly responsible for the supervision of activities that result in the accumulation of friable asbestos-containing waste materials.

[2. Wastewater (oil/water) separator—Any device which constitutes a primary treatment step for separation of free oil from oily waste waters, such as an American Petroleum Institute (API) oil/water separator, and the like, prior to further treatment of the waste water.]

*[3.]***2.** Waxy, heavy pour crude oil—A crude oil with a pour point of fifty degrees Fahrenheit (50°F) or higher as determined by the ASTM Standard D(97–66), *Test for Pour Point of Petroleum Oils*.

[4. Water base paint—A pigmented surface coating using water as a thinner and with the binder an oil-resin combination or a latex.]

*[5.]***3.** Wet cleaning—The process of using water or other liquid and a wet brush, mop, cloth, sponge or similar wet cleaning device to completely remove any residue of asbestos-containing materials from surfaces on which they may be located. This definition does not include the use of a wet vacuum cleaner.

[6. Wetting agent—Any chemical that is added to water to decrease its surface tension and allow it to spread more easily over or penetrate into friable asbestos-containing materials.]

*[7.]***4.** Work area—A specific room or physically isolated portion of a room, other than the space enclosed within a glove bag, in which friable asbestos-containing material is required to be handled in accordance with 10 CSR 10-6.240. The area is designated as a work area from the time that the room, or portion of it, is secured and access restrictions are in place. The area remains designated as a work area until the time that it has been cleaned in accordance with any requirements applicable to these operations.

(3) General Provisions. Common reference tables are provided in this section of the rule.

(C) Table 3—Hazardous Air Pollutants.

CAS #	Hazardous Air Pollutant
75070	Acetaldehyde
60355	Acetamide
75058	Acetonitrile
98862	Acetophenone
53963	2-Acetylaminofluorene
107028	Acrolein
79061	Acrylamide
79107	Acrylic acid
107131	Acrylonitrile
107051	Allyl chloride
92671	4-Aminobiphenyl
62533	Aniline
90040	o-Anisidine
1332214	Asbestos
71432	Benzene (including from gasoline)
92875	Benzidine
98077	Benzotrichloride
100447	Benzyl chloride
192524	Biphenyl
117817	Bis(2-ethylhexyl)phthalate (DEHP)
542881	Bis(chloromethyl)ether
75252	Bromoform
106990	1,3-Butadiene
156627	Calcium cyanamide
133062	Captan
63252	Carbaryl
75150	Carbon disulfide
56235	Carbon tetrachloride
463581	Carbonyl sulfide
120809	Catechol
133904	Chloramben
57749	Chlordane
7782505	Chlorine
79118	Chloroacetic acid
532274	2-Chloroacetophenone
108907	Chlorobenzene
510156	Chlorobenzilate
67663	Chloroform
107302	Chloromethyl methyl ether
126998	Chloroprene
1319773	Cresols/Cresylic acid (isomers and mixture)
108394	m-Cresol
95487	o-Cresol
106445	p-Cresol
98828	Cumene
94757	2,4-D, salts and esters
3547044	DDE
334883	Diazomethane
132649	Dibenzofurans
96128	1,2-Dibromo-3-chloropropane

84742	Dibutylphthalate
106467	1,4-Dichlorobenzene(p)
91941	3,3-Dichlorobenzidine
111444	Dichloroethyl ether (Bis(2-chloroethyl)ether)
542756	1,3-Dichloropropene
62737	Dichlorvos
111422	Diethanolamine
121697	N,N-Dimethylaniline
64675	Diethyl sulfate
119904	3,3-Dimethoxybenzidine
60117	Dimethyl aminoazobenzene
119937	3,3-Dimethyl benzidine
79447	Dimethyl carbamoyl chloride
68122	Dimethyl formamide
57147	1,1-Dimethyl hydrazine
131113	Dimethyl phthalate
77781	Dimethyl sulfate
534521	4,6-Dinitro-o-cresol and salts
51285	2,4-Dinitrophenol
121142	2,4-Dinitrotoluene
123911	1,4-Dioxane (1,4-Diethyleneoxide)
122667	1,2-Diphenylhydrazine
106898	Epichlorohydrin (1-Chloro-2,3-epoxypropane)
106887	1,2-Epoxybutane
140885	Ethyl acrylate
100414	Ethyl benzene
51796	Ethyl carbamate (Urethane)
75003	Ethyl chloride (Chloroethane)
106934	Ethylene dibromide (1,2-Dibromoethane)
107062	Ethylene dichloride (1,2-Dichloroethane)
107211	Ethylene glycol
151564	Ethylene imine (Aziridine)
75218	Ethylene oxide
96457	Ethylene thiourea
75343	Ethylidene dichloride (1,1-Dichloroethane)
50000	Formaldehyde
76448	Heptachlor
118741	Hexachlorobenzene
87683	Hexachlorobutadiene
77474	Hexachlorocyclopentadiene
67721	Hexachloroethane
822060	Hexamethylene-1,6-diisocyanate
680319	Hexamethylphosphoramide
110543	Hexane
302012	Hydrazine
7647010	Hydrochloric acid
7664393	Hydrogen fluoride (hydrofluoric acid)
123319	Hydroquinone
78591	Isophorone
58899	Lindane (all isomers)
108316	Maleic anhydride
67561	Methanol
72435	Methoxychlor
74839	Methyl bromide (Boimomethane)
74873	Methyl chloride (Chloromethane)
71556	Methyl chloroform (1,1,1-Trichloromethane)
[78933]	*[Methyl ethyl ketone (2-Butanone)]*
60344	Methyl hydrazine
74884	Methyl iodide (Iodomethane)
108101	Methyl isobutyl ketone (Hexone)
624839	Methyl isocyanate
80626	Methyl methacrylate
1634044	Methyl tert butyl ether
101144	4,4-Methylene bis (2-chloroaniline)
75092	Methylene chloride (Dichloromethane)
101688	Methylene diphenyldiisocyanate (MDI)
101779	4,4-Methylenedianiline
91203	Naphthalene
[12035722]	*[Nickel subsulfide]*
98953	Nitrobenzene
92933	4-Nitrobiphenyl
100027	4-Nitrophenol
79469	2-Nitropropane
684935	N-Nitroso-N-methylurea
62759	N-Nitrosodimethylamine
59892	N-Nitrosomorpholine
56382	Parathion
82688	Pentachloronitrobenzene (Quintobenzene)
87865	Pentachlorophenol
108952	Phenol
106503	p-Phenylenediamine
75445	Phosgene
7803512	Phosphine
7723140	Phosphorus
85449	Phthalic anhydride
1336363	Polychlorinated biphenyls (Arochlors)
1120714	1,3-Propane sultone
57578	beta-Propiolactone
123386	Propionaldehyde
114261	Propoxur (Baygon)
78875	Propylene dichloride (1,2-Dichloropropane)
75569	Propylene oxide
75558	1,2-Propylenimine (2-Methylaziridine)
91225	Quinoline
106514	Quinone
100425	Styrene
96093	Styrene oxide
1746016	2,3,7,8-Tetrachloro-dibenzo-p-dioxin
79345	1,1,2,2-Tetrachloroethane
127184	Tetrachloroethylene (Perchloroethylene)
7550450	Titanium tetrachloride
108883	Toluene
95807	2,4-Toluene diamine
584849	2,4-Toluene diisocyanate
95534	o-Toluidine
8001352	Toxaphene (Chlorinated camphene)
120821	1,2,4-Trichlorobenzene
79005	1,1,2-Trichloromethane
79016	Trichloroethylene
95954	2,4,5-Trichlorophenol
88062	2,4,6-Trichlorophenol
121448	Triethylamine
1582098	Trifluralin
540841	2,2,4-Trimethylpentane
108054	Vinyl acetate
593602	Vinyl bromide (bromoethene)
75014	Vinyl chloride
75354	Vinylidene chloride (1,1-Dichloroethylene)
1330207	Xylenes (isomers and mixture)
108383	m-Xylenes
95476	o-Xylenes
106423	p-Xylenes

0	Antimony compounds
0	Arsenic compounds (inorganic)
0	Beryllium compounds
[0]	*[Beryllium salts]*
0	Cadmium compounds
0	Chromium compounds
0	Cobalt compounds
0	Coke oven emissions
0	Cyanide compounds[1]
0	Glycol ethers[2]
0	Lead compounds
0	Manganese compounds
0	Mercury compounds
0	**Fine** Mineral fibers[3]
0	Nickel compounds
[0]	*[Nickel refinery dust]*
0	Polycyclic organic matter[4]
0	Radionuclides (including radon)[5]
0	Selenium compounds

Note: For all listings in this table that contain the word compounds and for glycol ethers, the following applies: Unless otherwise specified, these listings are defined as including any unique chemical substance that contains the named chemical (that is, antimony, arsenic and the like) as part of that chemical's infrastructure.

[1] X'CN where X–H' or any other group where a formal dissociation may occur, for example, KCN or $Ca(CN)_2$.

[2] Includes mono- and diethers of ethylene glycol, diethylene glycol and triethylene glycol R-(OCH_2CH_2)n-OR' where n = 1, 2 or 3; R = Alkyl or aryl groups; R' = R, H or groups which, when removed, yield glycol ethers with the structure R-(OCH_2CH_2)n-OH. Polymers and ethylene glycol monobutyl ether are excluded from the glycol category.

[3] Includes glass microfibers, glass wool fibers, rock wool fibers and slag wool fibers, each characterized as respirable (fiber diameter less than three and one-half (3.5) micrometers) and possessing an aspect ratio (fiber length divided by fiber diameter) greater than or equal to three (3), as emitted from production of fiber and fiber products.

[4] Includes organic compounds with more than one (1) benzene ring, and which have a boiling point greater than or equal to one hundred degrees Celsius (100°C).

[5] A type of atom which spontaneously undergoes radioactive decay.

AUTHORITY: sections 643.050 and 643.055, RSMo 2000. Original rule filed Aug. 16, 1977, effective Feb. 11, 1978. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Feb. 4, 2008.*

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: A public hearing on this proposed amendment will begin at 9:00 a.m., April 24, 2008. The public hearing will be held at the Harry S Truman Building, Room 490, 301 W. High Street, Jefferson City, Missouri. Opportunity to be heard at the hearing shall be afforded any interested person. Written request to be heard should be submitted at least seven (7) days prior to the hearing to Director, Missouri Department of Natural Resources' Air Pollution Control Program, PO Box 176, Jefferson City, MO 65102-0176, (573) 751-4817. Interested person, whether or not heard, may submit a written statement of their views until 5:00 p.m., May 1, 2008. Written comments shall be sent to Chief, Operations Section, Missouri Department of Natural Resources' Air Pollution Control Program, PO Box 176, Jefferson City, MO 65102-0176.

Title 10—DEPARTMENT OF NATURAL RESOURCES
Division 10—Air Conservation Commission
Chapter 6—Air Quality Standards, Definitions, Sampling and Reference Methods and Air Pollution Control Regulations for the Entire State of Missouri

PROPOSED AMENDMENT

10 CSR 10-6.220 Restriction of Emission of Visible Air Contaminants. The commission proposes to amend subsections (1)(H), (1)(I), and (3)(F); amend section (5); delete subsections (1)(J), (2)(C), and (2)(D); renumber and amend original subsection (2)(E); and renumber original subsections (2)(F)–(2)(H). If the commission adopts this rule action, it will be submitted to the U.S. Environmental Protection Agency to replace the current rule in the Missouri State Implementation Plan. The evidence supporting the need for this proposed rulemaking is available for viewing at the Missouri Department of Natural Resources' Air Pollution Control Program at the address and phone number listed in the Notice of Public Hearing at the end of this rule. More information concerning this rulemaking can be found at the Missouri Department of Natural Resources' Environmental Regulatory Agenda website, www.dnr.mo.gov/regs/ruleindex.htm.

PURPOSE: This rule specifies the maximum allowable opacity of visible air contaminant emissions, unless specifically exempt or regulated by 10 CSR 10-6.070 and requires the use of continuous opacity monitor systems (COMS) on certain air contaminant sources. This amendment will remove redundant definitions, remove an outdated exemption, clarify use of methods, and update test method. The evidence supporting the need for this proposed rulemaking, per section 536.016, RSMo, is Order of Rulemaking response to comment for 10 CSR 10-6.220 published in October 1, 1999, ***Missouri Register****; June 20, 2000, email suggesting removal of outstate definition; rule comment form dated December 19, 2002 suggesting an alternate opacity test method; September 21, 2006* ***Federal Register****, pp. 55119–55128; and May 8, 2003* ***Federal Register****, pp. 24692–24700.*

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) Applicability. This rule applies to all sources of visible emissions throughout the state of Missouri with the exception of the following:

(H) Emission sources regulated by **10 CSR 10-6.070 and** 40 CFR part 60 **promulgated as of July 1, 2006 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20480. This rule does not incorporate any subsequent amendments or additions** *[and 10 CSR 10-6.070]*; **and**

(I) Any open burning that is exempt from *[applicable]* open burning rule*[s 10 CSR 10-2.100, 10 CSR 10-3.030, 10 CSR 10-4.090 and 10 CSR 10-5.070; and]* **10 CSR 10-6.045.**

[(J) Incinerators used to burn refuse in the outstate area of Missouri.]

(2) Definitions.

[(C) Opacity—The extent to which airborne material obstructs the transmission of incident light and obscures the visual background. Opacity is stated as a percentage of light obstructed and can be measured by a continuous opacity monitoring system or a trained observer. An opacity of one hundred percent (100%) represents a condition in which no light is transmitted, and the background is completely obscured.]

[(D) Outstate area—Any area throughout the state except the City of St. Louis and St. Charles, St. Louis, Jefferson, Franklin, Clay, Cass, Buchanan, Ray, Jackson, Platte and Greene Counties.]

*[(E)]***(C)** Six-minute period—A three hundred sixty (360) consecutive second time interval. Six-minute block averages **shall be utilized for COMS data** per **Appendix B to** 40 CFR part 60, Performance Specification 1**, promulgated as of July 1, 2006 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20480. This rule does not incorporate any subsequent amendments or additions** *[shall be utilized for COMS data]*.

*[(F)]***(D)** Smoke generating device—A specialized piece of equipment which is not an integral part of a commercial, industrial or manufacturing process and whose sole purpose is the creation and dispersion of fine solid or liquid particles in a gaseous medium.

*[(G)]***(E)** Source—Any part or activity of an installation that emits or has the potential to emit any regulated air pollutant.

*[(H)]***(F)** Definitions of certain terms specified in this rule, other than those specified in this rule section, may be found in 10 CSR 10-6.020.

(3) General Provisions.

(F) All sources *[that do not fall under the requirements of subsection (3)(E) of this rule]* shall have the opacity of visible emissions determined by one of the methods in section (5) of this rule.

(5) Test Methods.

(A) Emissions from Stationary Sources—Use one of the following four (4) methods:

1. Qualified observer in accordance with 10 CSR 10-6.030(9), Reference Method 9—Visual Determination of the Opacity of Emissions from Stationary Sources;

2. Qualified observer in accordance with *[proposed]* Test Method 203A—Visual Determination of Opacity of Emissions from Stationary Sources for Time-Averaged Regulations *[(as proposed in the November 22, 1993 Federal Register, Volume 58, pp. 61640–61649)]* **promulgated as of July 1, 2007 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20480. This rule does not incorporate any subsequent amendments or additions**;

3. Qualified observer in accordance with *[proposed]* Test Method 203B—Visual Determination of Opacity of Emissions from Stationary Sources for Time-Exception Regulations *[(as proposed in the November 22, 1993 Federal Register, Volume 58, pp. 61640–61649)]* **promulgated as of July 1, 2007 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20480. This rule does not incorporate any subsequent amendments or additions**; or

4. Continuous Opacity Monitoring System that complies with and is installed, calibrated, maintained and operated in accordance with proposed *[Test Method 203—Visual Determination of the Opacity of Emissions from Stationary Sources by Continuous Opacity Monitoring Systems (as proposed in the October 7, 1992 Federal Register, Volume 57, pp. 46114–46119)]* **Procedure 3—Quality Assurance Requirements for Continuous Opacity Monitoring Systems at Stationary Sources (as proposed in the May 8, 2003 *Federal Register,* Volume 68, pp. 24696–24700)**.

(B) Emissions from Mobile Internal Combustion Engines—Use a qualified observer in accordance with 40 CFR part 60, Appendix A—Reference Methods, Method 22—Visual Determination of Fugitive Emissions from Material Sources and Smoke Emissions from Flares **promulgated as of July 1, 2006 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20480. This rule does not incorporate any subsequent amendments or additions**.

(C) Fugitive Emissions from Material Sources, Smoke Emissions from Flares and As Required by Permit Condition—Use a qualified observer in accordance with 40 CFR part 60, Appendix A—Reference Methods, Method 22—Visual Determination of Fugitive Emissions from Material Sources and Smoke Emissions from Flares **promulgated as of July 1, 2006 and hereby incorporated by reference in this rule, as published by the Office of the Federal Register, U.S. National Archives and Records, 700 Pennsylvania Avenue NW, Washington, D.C. 20480. This rule does not incorporate any subsequent amendments or additions**.

AUTHORITY: section 643.050, RSMo 2000. Original rule filed March 31, 1999, effective Nov. 30, 1999. Amended: Filed Feb. 28, 2002, effective Nov. 30, 2002. Amended: Filed Feb. 4, 2008.

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: A public hearing on this proposed amendment will begin at 9:00 a.m., April 24, 2008. The public hearing will be held at the Harry S Truman Building, Room 490, 301 W. High Street, Jefferson City, Missouri. Opportunity to be heard at the hearing shall be afforded any interested person. Written request to be heard should be submitted at least seven (7) days prior to the hearing to Director, Missouri Department of Natural Resources' Air Pollution Control Program, PO Box 176, Jefferson City, MO 65102-0176, (573) 751-4817. Interested persons, whether or not heard, may submit a written or email statement of their views until 5:00 p.m., May 1, 2008. Written comments shall be sent to Chief, Operations Section, Missouri Department of Natural Resources' Air Pollution Control Program, PO Box 176, Jefferson City, MO 65102-0176. Email comments shall be sent to apcprulespn@dnr.mo.gov.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2200—State Board of Nursing
Chapter 4—General Rules

PROPOSED RULE

20 CSR 2200-4.025 Definitions

PURPOSE: This rule provides definitions for specific terms used throughout the rules.

(1) MNIT—Missouri Nurse Intervention and Treatment Program.

(2) MNIT Board of Directors—Composed of a maximum of seven (7) members and the MNIT administrator to promote the early identification, intervention, treatment and rehabilitation of licensed practical nurses or registered professional nurses who may be impaired by reasons of substance abuse and/or mental disorders.

(3) Contractor—A nonprofit corporation or association with whom the Missouri State Board of Nursing contracts for the purpose of creating, supporting, and maintaining the MNIT Program.

(4) MNIT Administrator—The person(s) who is hired by the contractor to oversee and manage the MNIT Program.

(5) Nurse—Registered professional nurse or licensed practical nurse licensed in the state of Missouri.

AUTHORITY: sections 335.036 and 335.067, RSMo Supp. 2007. Original rule filed Feb. 11, 2008.

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 Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075 or via email at nursing@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 2200—State Board of Nursing
Chapter 4—General Rules

PROPOSED RULE

20 CSR 2200-4.026 Membership and Organization

PURPOSE: This rule establishes the membership and organization of the MNIT Board of Directors.

(1) The Missouri Nurse Intervention and Treatment (MNIT) Program Board of Directors shall be composed of:

(A) Psychiatric or mental health professional (medical doctor, doctor of osteopathy, nurse practitioner, clinical nurse specialist, registered professional nurse) designated by the Missouri Hospital Association;

(B) Member who is in recovery designated by the Missouri Nurses Association;

(C) Member who is in recovery designated by the Missouri State Association of Licensed Practical Nurses;

(D) Licensed practical nurse designated by the Missouri State Association of Licensed Practical Nurses;

(E) Registered professional nurse designated by the Missouri Nurses Association;

(F) Advanced practice registered nurse designated by an advanced practice registered nurse organization through the Missouri Nurses Association;

(G) Public member designated by the Missouri Center for Patient Safety; and

(H) MNIT administrator.

(2) The MNIT Board of Directors shall serve staggered three (3)-year terms and shall serve at the discretion of their respective agencies and serve as many terms as their respective agencies deem appropriate. The first board of directors' terms will be decided by random draw at the Board of Nursing office. The MNIT Board of Directors shall annually elect a chairperson. The chairperson is responsible for notifying the respective agencies six (6) months prior to the expiration of a term.

(3) The MNIT Board of Directors shall meet at least two (2) times annually.

(4) The MNIT Board of Directors shall serve without compensation other than that allowed by law for service as a board member. Each member of the MNIT Board of Directors shall be entitled to reimbursement for travel expenses as deemed appropriate by the MNIT Board of Directors.

(5) The MNIT Board of Directors shall oversee all aspects of the general operation of the contractor including, but not limited to, oversight of the administration, staffing, financial operations and case management as it pertains to the Missouri Nurse Intervention and Treatment Program.

(6) The MNIT administrator shall be a non-voting member of the MNIT Board of Directors.

AUTHORITY: sections 335.036 and 335.067, RSMo Supp. 2007. Original rule filed Feb. 11, 2008.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions approximately eight thousand four hundred forty-four dollars ($8,444) in its first year of implementation and approximately six hundred forty-three thousand, three hundred seventy-seven dollars and sixty cents ($643,377.60) annually thereafter. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

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 Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075 or via email at nursing@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.*

PUBLIC ENTITY FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2200 - Missouri State Board of Nursing
Chapter 4 - General Rules
Proposed Rule - 20 CSR 2200-4.026 Membership and Organization
Prepared December 27, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Annual Cost of Compliance	
Missouri State Board of Nursing	Total Cost During First Year of Implementation of Rule Beginning in FY08	$8,444.00
	Total Annual Cost of Compliance for the Life of the Rule Beginning in FY09	$643,377.60

III. WORKSHEET

The MNIT Board of Directors will have 5 meetings in the first year of implementation to get the program set up and 2 meetings per year thereafter. Per diem, travel, and postage expenses were based on the MNIT Board of Directors having eight members. The board estimates that approximately 200 licensees will participate in the program per year. Based on the expenses of the Dental Well-Being Committee and the Physician Well-Being Committee, the Board of Nursing estimates that it will cost approximately $3,200 per licensee enrolled in the program.

Expenses	FY 08	FY 09	FY 10
Well Being Committee Expenses - Program Setup	$8,444.00		
Well Being Committee Meeting Expenses		$3,377.60	$3,377.60
Well Being Committee Program Cost		$640,000.00	$640,000.00
	$8,444.00	$643,377.60	$643,377.60

1st Year Per Diem Expenses for Members of the MNIT Board of Directors

8	Members
$50	Per Diem/Per Day
5	Meetings
$2,000	for 1st year per diem expenses

1st Year Expenses for Members of the MNIT Board of Directors

$99.60	Mileage Per Board Member (.415 X Average of 240 Miles/Meeting)
$14	Meal Per Board Member/Per Meeting
$47.50	Postage Per Board Member/Per Meeting
$161.10	Total Expenses Per Board Member/Meeting
5	Meetings
8	Board Members
$6,444.00	Total Expenses
$8,444.00	Total Costs to Board for 1st Year of Implementation

2nd Year and Thereafter Per Diem Expenses for Members of the MNIT Board of Directors

8	Members
$50	Per Diem/Per Day
2	Meetings
$800	for 2nd year per diem expenses

2nd Year and Thereafter Expenses for Members of the MNIT Board of Directors

$99.60	Mileage Per Board Member (.415 X Average of 240 Miles/Meeting)
$14	Meal Per Board Member/Per Meeting
$47.50	Postage Per Board Member/Per Meeting
$161.10	Total Expenses Per Board Member/Meeting
2	Meetings
8	Board Members
$2,577.60	Total Expenses
$3,377.60	Total Costs to Board for 2nd Year of Implemention and Annually Thereafter

IV. ASSUMPTION

1. Pursuant to Section 335.067 the board may enter into a contractual agreement with a nonprofit corporation or a nursing association for the purpose of creating, supporting, and maintaining a program to be designated as the impaired nurse program. Based on expenses of the Dental Well-Being Committee and the Physician Well-Being Committee, the Board of Nursing estimates that it will cost approximately $3200 per licensee enrolled in the program.
2. It is anticipated that the total cost will recur annually for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2200—State Board of Nursing
Chapter 4—General Rules

PROPOSED RULE

20 CSR 2200-4.027 MNIT Board of Directors/Contractor Duties

PURPOSE: This rule establishes the duties of the MNIT Board of Directors and contractor.

(1) The Missouri Nurse Intervention and Treatment (MNIT) Program Board of Directors/contractor shall provide a written and/or oral report to the State Board of Nursing at each quarterly State Board of Nursing meeting or upon request of the State Board of Nursing. The report shall outline the status of each nurse in treatment referred to the MNIT Board of Directors by the State Board of Nursing in such detail as requested by the State Board of Nursing. The identity of the nurses who voluntarily submit to the MNIT Board of Directors/contractor shall remain anonymous for purposes of these reports.

(2) The MNIT Board of Directors/contractor shall provide written and/or oral reports to the State Board of Nursing, including quarterly income and expense reports. These reports must be itemized and account for all income from any and every source and each expense to any and every vendor that relates to the Missouri Nurse Intervention and Treatment Program in any way.

(3) The MNIT Board of Directors/contractor shall enter into written contracts with each nurse in treatment. The contract between the MNIT Board of Directors/contractor and the nurse shall include, but not be limited to, the following:

(A) Each contract shall be a minimum of five (5) years in duration;

(B) Each nurse in treatment will abstain from the possession or consumption of controlled substances except as prescribed by a treating physician;

(C) Each nurse in treatment shall abstain from the possession or consumption of alcohol or illegal drugs;

(D) Each nurse in treatment shall submit to random drug testing unless otherwise specified by the State Board of Nursing;

(E) Each nurse in treatment shall report all relapses to the MNIT Board of Directors;

(F) Upon request of the MNIT Board of Directors, each nurse in treatment shall report to the MNIT Board of Directors;

(G) Each nurse in treatment shall attend support meetings as requested by the MNIT Board of Directors or treatment providers;

(H) Each nurse in treatment referred to the Missouri Nurse Intervention and Treatment Program by the State Board of Nursing shall authorize the MNIT Board of Directors to release any and all information regarding the nurse in treatment to the State Board of Nursing;

(I) Each nurse in treatment voluntarily enrolled in the Missouri Nurse Intervention and Treatment Program shall authorize the MNIT Board of Directors to release any and all information regarding the nurse in treatment to the State Board of Nursing upon a violation of Chapter 335, RSMo or the rules promulgated pursuant thereto or the contract with the MNIT Board of Directors;

(J) Each nurse in treatment shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the nurse in treatment; and

(K) The following paragraph shall be contained in each written agreement:

1. In consideration of my being allowed to participate in the Missouri Nurse Intervention and Treatment Program, I expressly release the contractor, the MNIT administrator, the MNIT Board of Directors and the State Board of Nursing and all of their employees, board members, agents and independent contractors from any and all claims, whether now existing or hereafter arising, related to or arising from my participation in the Missouri Nurse Intervention and Treatment Program or any services provided to me hereunder, including but not limited to claims that I might hereafter assert that the contractor, the MNIT administrator, the MNIT Board of Directors or State Board of Nursing, any of the agents or independent contractors, board members or employees were negligent or that any of said persons or entities committed any acts of omission or commission that I claim are or were negligent or that I claim were acts of professional malpractice, it being the intent hereof that I will be forever barred from asserting any such claims hereafter. In the event I hereafter assert any such claim, I agree that such assertion will disqualify me from further participation in the Missouri Nurse Intervention and Treatment Program and that the MNIT Board of Directors will be absolutely entitled to discharge me from said program.

(4) The MNIT Board of Directors/contractor shall provide services when appropriate to nurses in treatment which include, but are not limited to, the following:

(A) Monitoring compliance of the contract between the MNIT Board of Directors and the nurse in treatment;

(B) Administering drug screens;

(C) Assisting the nurse in treatment in obtaining evaluation and treatment; and

(D) Requiring evaluators to provide written reports which address whether a member of the Missouri Nurse Intervention and Treatment Program suffers from an impairment, identifies the impairment, provides recommendations for treatment of the impairment and whether the member's practice of nursing should be restricted due to the impairment.

(5) The MNIT Board of Directors/contractor shall report, in writing, to the State Board of Nursing all violations of State Board of Nursing disciplinary orders or the Nursing Practice Act which occur after the date of the disciplinary order or the date of the nurse entering the Missouri Nurse Intervention and Treatment Program, whichever occurs first. All violations shall be reported promptly but no later than ten (10) days after obtaining knowledge of the violation.

(6) The MNIT Board of Directors/contractor shall assist the State Board of Nursing in carrying out the terms of any disciplinary order pertaining to a nurse in treatment.

(7) The MNIT Board of Directors/contractor shall obtain a written release from all nurses referred to the Missouri Nurse Intervention and Treatment Program by the State Board of Nursing. The release shall authorize the MNIT Board of Directors/contractor to release all information and documents pertaining to the nurse to the State Board of Nursing and MNIT Board of Directors and to communicate all information regarding the nurse in treatment to the State Board of Nursing and MNIT Board of Directors.

(8) The MNIT Board of Directors/contractor shall provide the State Board of Nursing access to all information and documents pertaining to the nurse in treatment referred to the Missouri Nurse Intervention and Treatment Program by the State Board of Nursing.

(9) The contractor shall require the administrator to supply information and documentation with regard to the identification, intervention, treatment and rehabilitation of all nurses who participate or are assisted by the Missouri Nurse Intervention and Treatment Program to the MNIT Board of Directors as directed by the MNIT Board of Directors.

(10) The contractor shall require the MNIT administrator to supply all reports provided to the State Board of Nursing to the MNIT Board of Directors. The information and documentation as described herein shall only be released to the State Board of Nursing pursuant to Chapter 335, RSMo and the rules promulgated thereto.

(11) The contractor shall require the MNIT administrator to provide the MNIT Board of Directors with all information on nurses participating in or assisted by the contractor as directed by the MNIT Board of Directors.

(12) The MNIT Board of Directors/contractor shall prepare and implement an action plan and budget as directed by and approved by the State Board of Nursing. The MNIT Board of Directors/contractor shall report on progress with regard to preparing and implementing the action plan and budget as directed by the State Board of Nursing and MNIT Board of Directors.

(13) The MNIT Board of Directors/contractor shall require the MNIT administrator to submit progress and performance reports to the MNIT Board of Directors and the State Board of Nursing as requested by the MNIT Board of Directors or the State Board of Nursing. Reports of those voluntarily participating in the program shall be for statistical purposes only.

(14) The contractor shall coordinate activities of the MNIT Board of Directors, oversee and manage the daily operations of the MNIT Board of Directors and assist with the administrative duties of the MNIT Board of Directors.

AUTHORITY: sections 335.036 and 335.067, RSMo Supp. 2007. Original rule filed Feb. 11, 2008.

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 Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075 or via email at nursing@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 2200—State Board of Nursing
Chapter 4—General Rules

PROPOSED RULE

20 CSR 2200-4.028 Confidentiality

PURPOSE: This rule establishes the guidelines regarding the confidentiality of the records and information of the impaired professional.

(1) The Missouri Nurse Intervention and Treatment (MNIT) Program Board of Directors shall provide the State Board of Nursing access to all information pertaining to each nurse in treatment referred to the MNIT Board of Directors by the State Board of Nursing.

(2) The MNIT Board of Directors shall obtain a written release from each nurse in treatment in the Missouri Nurse Intervention and Treatment Program authorizing the release of all information and documents pertaining to the nurse in treatment to the State Board of Nursing authorizing the MNIT Board of Directors to communicate all information pertaining to the nurse in treatment to the State Board of Nursing. The information and documentation as described herein shall only be released to the State Board of Nursing pursuant to Chapter 335, RSMo and the rules promulgated thereto relating to violation of the MNIT contract.

(3) In regards to a participant referred by the State Board of Nursing and the voluntary participants who have violated their MNIT contract, the State Board of Nursing and MNIT Board of Directors may exchange privileged and confidential information, interviews, reports, statements, memoranda and other documents including information on investigations, findings, conclusions, interventions, treatment, rehabilitation and other proceedings of the State Board of Nursing and MNIT Board of Directors and other information closed to the public to promote the identification, interventions, treatment, rehabilitation and discipline (accountability) of nurses who may be impaired.

(4) All privileged and confidential information and other information not considered to be public records or information pursuant to Chapter 610, RSMo shall remain privileged and confidential and closed to the public after such information is exchanged.

AUTHORITY: sections 335.036 and 335.067, RSMo Supp. 2007. Original rule filed Feb. 11, 2008.

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 Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075 or via email at nursing@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 2200—State Board of Nursing
Chapter 4—General Rules

PROPOSED RULE

20 CSR 2200-4.029 MNIT Administrator

PURPOSE: This rule establishes the qualifications and duties of the MNIT administrator.

(1) The Missouri Nurse Intervention and Treatment (MNIT) Program administrator shall possess a combination of education and experience in the area of addiction counseling and be licensed in Missouri in a related field.

(2) The MNIT administrator shall be familiar with nursing professionals suffering from impairment which include, but shall not be limited to, the following:

(A) Dependency;
(B) Alcohol addiction;
(C) Drug addiction; and
(D) Mental health issues.

(3) The duties of the MNIT administrator shall include, but not be limited to, the following:
(A) Organizing and carrying out interventions;
(B) Referring nurses for appropriate assessment, or evaluation and seeing that treatment recommendations based on the assessment are followed;
(C) Monitoring treatment progress and re-entry contractual compliance. Said monitoring shall include random drug screens;
(D) Assisting nurses to reenter practice from treatment;
(E) Assisting with aftercare issues;
(F) Any and all reporting of these areas to appropriate agencies;
(G) Program development;
(H) Outreach education; and
(I) Other necessary services as determined by the MNIT Board of Directors.

(4) The MNIT administrator shall supply information and documentation with regard to the identification, intervention, treatment and rehabilitation of all nurses who participate or are assisted by the Missouri Nurse Intervention and Treatment Program to the MNIT Board of Directors as directed by the MNIT Board of Directors.

(5) The MNIT administrator shall supply all reports provided to the State Board of Nursing and to the MNIT Board of Directors. The contractor shall provide all reports, including reports on nurses who participate in or are assisted by the Missouri Nurse Intervention and Treatment Program, and fiscal reports to the MNIT Board of Directors as directed by the MNIT Board of Directors.

(6) The MNIT administrator shall provide the MNIT Board of Directors with all information on nurses participating in or assisted by the contractor as directed by the MNIT Board of Directors.

(7) The MNIT Board of Directors/contractor shall provide the State Board of Nursing access to all information and documents pertaining to the nurse in treatment referred to the Missouri Nurse Intervention and Treatment Program by the State Board of Nursing.

AUTHORITY: sections 335.036 and 335.067, RSMo Supp. 2007. Original rule filed Feb. 11, 2008.

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 Board of Nursing, Lori Scheidt, Executive Director, PO Box 656, Jefferson City, MO 65102, by fax at (573) 751-0075 or via email at nursing@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 2220-2.010 Pharmacy Standards of Operation. The board is proposing to amend subsections (1)(A) and (1)(B), add paragraph (1)(F)3., amend subsection (1)(G) and paragraph (1)(I)2., add a new subsection (J) and renumber the remaining subsections, amend sections (2), (3), and (5), add a new section (7) and renumber the sections thereafter, and amend new paragraphs (10)(B)2. and (10)(C)2.

PURPOSE: Pursuant to Executive Order 06-04 the Division of Professional Registration was transferred from the Department of Economic Development, Title 4, to the Department of Insurance, Financial Institutions and Professional Registration, Title 20. Therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also clarifies the conditions necessary for the operation of a pharmacy as well as corrects grammatical errors.

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in *[4 CSR 220-2.900]* **20 CSR 2220-2.900** the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in *[4 CSR 220-2.900]* **20 CSR 2220-2.900** the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.

(F) All pharmacies shall be maintained in a clean and sanitary condition at all times. Any procedures used in the dispensing, compounding and admixture of drugs or drug-related devices must be completed under clean and, when recommended, aseptic conditions.

1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available.

2. Appropriate housekeeping and sanitation of all areas where drugs are stored or dispensed must be maintained.

3. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in pharmacies.

(G) **The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the USP.** Adequate refrigeration must be available to insure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both. Drugs and drug-related devices must be stored separately from food and other items.

(I) Pharmacies which maintain storage sites or warehouse facilities for the storage of pharmaceuticals at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services**,** and a certified statement that the facility is used for the sole purpose of distributing drugs only within its own pharmacy operations.

1. Records must be maintained at these facilities to guarantee security, storage and accountability of all drugs and drug-related devices under proper conditions.

2. All storage and warehouse locations will be considered facilities of a pharmacy *[as defined in]* **pursuant to** section 338.240*[(2)]*, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (1)(I) of this rule.

(J) Pharmacies that maintain storage sites or warehouse facilities for the storage of confidential pharmacy records at a separate address or premises from the main pharmacy that holds a pharmacy permit shall register those sites as storage facilities of the licensed pharmacy. Information required for proper registration of a storage facility shall include the address of the facility, hours of operation (if applicable), pharmacy permit numbers of the pharmacies that it services, and a statement that the facility is used for the sole purpose of storing records within its own pharmacy operations.

1. All storage and warehouse locations must maintain adequate security including an alarm system. Any breach in security must be documented and reported in writing via facsimile, e-mail communication, or letter to the board within fifteen (15) days of the breach of confidentiality.

2. All storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo and shall be subject to inspection by the board as defined in section 338.150, RSMo.

3. No fee will be charged by the board for registering a facility as defined in subsection (1)(J) of this rule.

4. All storage and warehouse locations must comply with 19 CSR 30-1.

5. No records less than two (2) years old may be stored offsite.

6. All storage and warehouse locations storing confidential pharmacy records must make records retrievable within two (2) business days when requested by the board or its representatives.

*[(J)]***(K)** All pharmacists will be required to have a photo of themselves not smaller than two inches by two inches (2" × 2") in the upper right-hand corner of the current renewal licenses. This photo and license renewal shall be conspicuously exposed in the pharmacy or drug store or place of business in which the pharmacist is employed as required by law.

*[(K)]***(L)** Pharmacists regularly working as relief persons for more than one (1) store shall have in their possession proper identification of their pharmacy licensure.

*[(L)]***(M)** Pharmacy operations must be conducted at all times under the supervision of a properly designated pharmacist-in-charge. When a licensed pharmacist leaves the employment of a pharmacy where s/he has been pharmacist-in-charge, s/he immediately shall notify the executive director of the board of the termination of his/her services in the pharmacy. Likewise, the holder of the permit shall notify the executive director of the board of the termination of the services and give the name of the new licensed pharmacist-in-charge.

*[(M)]***(N)** Pharmacists are responsible to inform the executive director of the board in the case of changed address. Any mail or communications returned to the executive director's office marked Unknown, Incorrect Address, and the like, will not be sent out a second time until the correct address is sent in.

*[(N)]***(O)** When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(P) When required by section 338.013(10), RSMo, to report technician disciplinary action, the pharmacy must notify the board in writing within fifteen (15) days of the action. The notification must include:

1. The name and permit number of pharmacy;

2. Name of person making the notification;

3. Name of technician;

4. Technician registration number;

5. Date of action; and

6. Reason for action.

*[(O)]***(Q)** Pharmacists must inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following any effective change.

(3) A pharmacy using a record keeping system other than an electronic system meeting the requirements of *[4 CSR 220-2.080]* **20 CSR 2220-2.080** to record its dispensing of drugs, medicines and poisons shall provide a method of recording all of the following information concerning the refill of any prescription medication on the back or reverse side of every prescription order:

(5) Pharmacies *[that distribute legend drugs separate from prescription services and the distributions fall below the threshold established for licensure as a drug distributor]* shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of *[prescription]* **legend** drugs. Said records shall be maintained for two (2) years **and be readily retrievable upon request by the board or its representatives**.

(7) All records required by Chapters 195 and 338, RSMo or divisions 20 CSR 2220 and 19 CSR 30 shall be available for photocopying by a board of pharmacy representative.

*[(7)]***(8)** Except as provided for in section 21 U.S.C. section 353(d)(1)(A)–(C), (d)(2)(A)(i)–(ii), (B)(i)–(iv) and (d)(3)(A)(i)–(ii) of the Federal Food, Drug and Cosmetic Act, drug samples shall not be maintained in pharmacies.

*[(8)]***(9)** A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The list of drugs that may be possessed by a home health or hospice agency without a license or permit, as defined in section *[(8)]***(9)**, is as follows:

1. Injectable dosage forms of sodium chloride and water;

2. Irrigation dosage forms of sodium chloride and water that carry a federal prescription only restriction;

3. Injectable dosage forms or heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;

4. Injectable dosage forms of diphenhydramine and epinephrine;

5. Vaccines indicated for public health needs, such as influenza, pneumonia, hepatitis A and hepatitis B; and

6. Tuberculin test material.

(B) The agency shall have a policy and procedure that addresses at least the following:

1. Specific drugs authorized to be possessed by the agency and the nurse;

2. Indications for use of the drugs possessed;

3. Receiving physicians' orders for administration of the drugs;

4. Leaving drugs with the patient for routine care procedures;

5. Conditions for storage and transport of the drugs by the agency and the nurse; and

6. Quantity of drugs possessed by the agency and the nurse.

(C) The nurse must have a physician's authorization, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) When the patient or the patient's representative has been instructed, verbally and in writing, in the performance of routine care procedures, up to a two (2)-week supply of sodium chloride, water and heparin, may be left with the patient for these procedures. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient's medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer's storage requirements. Refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to that necessary to meet the needs of the agency's patient population for two (2) weeks.

*[(9)]***(10)** Class I: Consultant Pharmacies as defined in 20 CSR 2220-2.020(9)(I) and *[are]* approved by the board to be located within a residence shall be required to address and comply with the following minimum standards of practice:

(A) Location Requirements—

1. The pharmacy must be located in a separate room that provides for a door with suitable lock;

2. Sufficient storage for securing confidential documents and any hardware used in accessing a central pharmacy by electronic connection must be provided;

3. Ceiling and walls must be constructed of plaster, drywall, brick or other substantial substance that affords a design that makes the room separate and distinct from the remainder of the domicile. Drop down ceilings that allow access into the room are not allowed;

4. All locations must be inspected and have approval by the board prior to the initiation of services; and

5. Patients are not allowed in the pharmacy.

(B) Documentation—

1. Maintain a current policy and procedure manual that is attested by the signature and date of review of the pharmacist-in-charge to its accuracy. All pharmacists working at the pharmacy shall be required to sign the manual attesting to their review and understanding of all policies and procedures in force;

2. Maintain documentation that *[the pharmacist-in-charge or]* the permit holder has provided training to all personnel on all operations associated with the pharmacy;

3. The permit holder must complete an audit to ensure compliance with pharmacy policy and procedures and this regulation at a minimum of twice per year, through physical visits by representatives of the permit holder. Audit results must be maintained by the permit holder for a period of three (3) years; and

4. If the pharmacist is working under a contract for the permit holder, a copy of the contract shall be available during an inspection.

(C) Security—Records and Internet—

1. All electronic data processing systems must meet all applicable state and federal confidentiality laws and regulations;

2. Data processing systems must utilize sufficient security software; *[and]*

3. Any breach in the security of the system must be documented and reported to the board of pharmacy within seven (7) days of the breach of confidentiality. Such documentation shall be available during an inspection.

(D) Licensure and Inspection—

1. Each location must maintain and display a current Class I permit. The permit holder for this permit must be the pharmacy the individual pharmacist is employed by or contracted with;

2. Routine inspections for in-state pharmacies shall be arranged ahead of time. Notification by the inspector to the permit holder will be provided a minimum of seventy-two (72) hours ahead of the scheduled inspection. The permit holder must arrange for a designated representative to be present that is not a resident of the location under inspection;

3. A pharmacy located outside the state must maintain a pharmacist-in-charge with a current and active pharmacist license with the state of Missouri;

4. The audits required in paragraph *[(9)(B)3.]* **(10)(B)3.** shall be available for review during the inspection; and

5. The pharmacy shall provide copies of inspections completed by the state in which they are located if such inspections are required within seven (7) business days of the inspection date.

AUTHORITY: sections 338.140, 338.240 and 338.280, RSMo 2000 and sections 338.010 and 338.210, RSMo Supp. 2007. This rule originally filed as 4 CSR 220-2.010. Original rule filed July 18, 1962, effective July 28, 1962. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Feb. 6, 2008.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions approximately fifteen dollars and seven cents ($15.07) annually for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

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 State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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.*

PUBLIC FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - State Board of Pharmacy
Chapter 2 - General Rules
Proposed Amendment - 20 CSR 2200-2.010 Pharmacy Standards of Operation
Prepared November 20, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance	
Missouri Board of Pharmacy	Total Annual Cost of Compliance for the Life of the Rule	$15.07

III. WORKSHEET

The licensing technician I will update PROMO with offsite storage facility information.

STAFF	ANNUAL SALARY	SALARY TO INCLUDE FRINGE BENEFIT	HOURLY SALARY	COST PER MINUTE	TIME PER APPLICATION	NUMBER OF APPLICATIONS	TOTAL COST
Licensing Tech I	$21,050	$31,341.35	$15.07	$0.25	5 minutes to update PROMO	12	$15.07
						Total Annual Personal Service Costs for the Life of the Rule	$15.07

IV. ASSUMPTION

1. Employee's salaries were calculated using the annual salary multiplied by 48.89% for fringe benefits and then divided by 2080 hours per year to determine the hourly salary. The hourly salary was then divided by 60 minutes to determine the cost per minute. The cost per minute was then multiplied by the amount of time individual staff spent on the processing of applications or renewals. The total cost was based on the cost per application multiplied by the estimated number of applications.

2. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

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

PROPOSED AMENDMENT

20 CSR 2220-2.030 Educational and Licensing Requirements. The board is proposing to amend section (2), paragraph (3)(B)1., subsection (3)(H) and subsection (7)(A) and delete subsection (7)(B).

PURPOSE: This amendment clarifies the requirements for training as a pharmacy intern and makes a grammatical correction.

(2) Application shall be made on forms provided by the *[executive director]* **State Board of Pharmacy**. The candidate shall furnish satisfactory evidence on the application that s/he has graduated from an approved school of pharmacy and present affidavits certifying the completion of all practical experience programs that are required and are approved by the board. An application will be considered filed even though it may have to be returned to the applicant for minor correction or completion. However, an application will not be considered filed if it has to be returned to the applicant for any one (1) or more of the following reasons:

(3) Requirements for Practical Experience.

(B) Requirements for Training as a Pharmacy Intern.

1. Every person who desires to gain practical experience in Missouri toward licensure as a pharmacist must apply for a license as an intern pharmacist. An application for licensure shall be made on forms provided by the *[Missouri]* **State** Board of Pharmacy and must be accompanied by the appropriate licensure fee. **An application for an intern pharmacist license will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.**

2. An applicant for licensure as a pharmacy intern shall be currently enrolled in or graduated from a college that is approved by the *[Missouri]* **State** Board of Pharmacy and that applicant may apply for licensure after the completion of thirty (30) hours of college course work in an approved school of pharmacy.

3. Advanced practice experience hours shall include a minimum of one hundred sixty (160) hours in a community/ambulatory pharmacy practice component, an institutional pharmacy practice component and a clinical and/or related area of pharmacy practice component.

4. Advanced practice experience may be gained within non-licensed programs, provided these programs have received prior approval by the board. The board shall make its determination concerning program approval and the number of hours to grant to an approved program through review of an application. The board may request additional information, interview program participants or complete site inspections before a decision on an application is made.

(H) The provisions of this rule are not applicable to those students who gain their advanced practice experience in another state. The minimum practical experience shall be fifteen hundred (1,500) hours of advanced practice experience to qualify to take the examination for licensure as a pharmacist. If any portion of the required fifteen hundred (1,500) hours are to be earned in Missouri, the applicant must be licensed as an intern under the provisions of this rule. When intern hours are to be earned within the state of Missouri by a student enrolled in or by a graduate of an out-of-state accredited school of pharmacy, the candidate must apply directly to the board of pharmacy to seek approval of any site and preceptor to be used. Any pharmacy that is submitted for approval as an intern training site for an out-of-state student or graduate shall meet the criteria outlined in *[(4)(B)1.–3.]* **(4)(A)1.–3.**

(7) Licenses.

(A) No duplicate certificates or renewals for licenses or permits shall be issued except upon the return of the original or upon the *[sworn]* statement that the certificate has been lost or destroyed. The duplicate certificate or renewal fee shall accompany the affidavit.

[(B) No assistant or apprentice-pharmacist license is recognized by the board inasmuch as the members of the State Missouri Board of Pharmacy in session in Kansas City, Missouri on January 24, 1938, ruled, and the adopted minutes so state, that March 1, 1938, would be the last day a license as a pharmacist could legally be issued to an assistant pharmacist as per Missouri statutes, section no. 13151 and the secretary was ordered at that time to accept no fees and to issue no license as a pharmacist to assistant pharmacists after that date. Furthermore, this portion of section no. 13151, relating to converting over of assistant pharmacists to registered pharmacists, was deleted by the 66th General Assembly, effective as of August 1, 1952.]

*AUTHORITY: sections 338.020, 338.040, 338.070, 338.140 and 338.280, RSMo 2000 and sections 338.030 and 338.035, RSMo Supp. [2004] **2007**. This rule originally filed as 4 CSR 220-2.030. This version of rule filed July 18, 1962, effective July 28, 1962. For intervening history, please consult the **Code of State Regulations**. Amended: Filed Feb. 6, 2008.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions approximately twenty-two dollars and forty-one cents ($22.41) annually for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will cost private entities approximately three hundred seventy-five dollars ($375) annually for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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.*

PUBLIC FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - State Board of Pharmacy
Chapter 2 - General Rules
Proposed Amendment - 20 CSR 2200-2.030 Educational and Licensing Requirements
Prepared November 20, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance	
Missouri Board of Pharmacy	Total Annual Cost of Compliance for the Life of the Rule	$22.41

III. WORKSHEET

The licensing technician II will update PROMO to void applications that are pending more than six months from the date the board received the application, and will scan the document for future reference.

STAFF	ANNUAL SALARY	SALARY TO INCLUDE FRINGE BENEFIT	HOURLY SALARY	COST PER MINUTE	TIME PER APPLICATION	NUMBER OF APPLICATIONS	TOTAL COST
Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	5 Minutes	15	$22.41
			Total Annual Personal Service Costs for the Life of the Rule				$22.41

IV. ASSUMPTION

1. Employee's salaries were calculated using the annual salary multiplied by 48.89% for fringe benefits and then divided by 2080 hours per year to determine the hourly salary. The hourly salary was then divided by 60 minutes to determine the cost per minute. The cost per minute was then multiplied by the amount of time individual staff spent on the processing of applications or renewals. The total cost was based on the cost per application multiplied by the estimated number of applications.

2. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - State Board of Pharmacy
Chapter 2 - General Rules
Proposed Amendment - 20 CSR 2200-2.030 Educational and Licensing Requirements
Prepared November 20, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimate the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by type of the business entities which would likely be affected:	Estimated cost of compliance with the rule by affected entities:
15	Intern Reapplication (Application @ $25.00)	$375
	Estimated Annual Cost of Compliance for the Life of the Rule	**$375**

III. WORKSHEET
See table above.

IV. ASSUMPTION

1. The office estimates that the number of pharmacy interns will increase between 16% and 18% from 2007 to 2008, based on FY05-FY07 actuals.
2. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

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

PROPOSED AMENDMENT

20 CSR 2220-2.036 Temporary License. The board is proposing to amend sections (3), (7), (8), (11), add a new section (12) and renumber the old section (12) to section (13).

PURPOSE: Pursuant to Executive Order 06-04 the Division of Professional Registration was transferred from the Department of Economic Development, Title 4, to the Department of Insurance, Financial Institutions and Professional Registration, Title 20. Therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also clarifies acceptable proof of licensure that can be used until a hard copy of the license is received by the applicant.

(3) In the event that an applicant for temporary licensure is not a graduate of a board approved school or college of pharmacy as outlined in *[4 CSR 220-2.030(1)]* **20 CSR 2220-2.030(1)**, then all the requirements as outlined in *[4 CSR 220-2.032]* **20 CSR 2220-2.032** must be completed.

(7) The temporary licensing program is not intended to replace or conflict with any requirements or provisions of *[4 CSR 220-2.030]* **20 CSR 2220-2.030** as regards internship or externship. Students who rotate through a licensed pharmacy or other accredited internship site shall apply for a temporary license when the student is not currently licensed as an intern or registered as a technician. For purposes of this section to qualify for a temporary license the rotation shall be no more than six (6) weeks in length and the student cannot have been previously licensed as an intern by the board.

(8) If a temporary licensee desires to acquire a permanent license or desires to practice pharmacy outside of the provisions of this rule, then all provisions as outlined in *[4 CSR 220-2.030]* **20 CSR 2220-2.030** must be completed.

(11) Any temporary license issued in lieu of a permanent license while a criminal background check is completed shall remain in effect until the permanent license is issued or denied. *[If a permanent license is denied, the board shall inform the applicant in writing of the denial. The temporary license will be considered invalid after notification is sent to the applicant by certified mail.]* **A copy of proof of licensure from the Division of Professional Registration, Board of Pharmacy website may be used as proof of licensure by an applicant until delivery of a hard copy license is completed to the applicant.**

(12) If a permanent license is denied, the board shall inform the applicant in writing of the denial. The temporary license will be considered invalid after notification is sent to the applicant by certified mail.

*[(12)]***(13)** All fees are nonrefundable.

*AUTHORITY: section 338.140, RSMo [Supp. 1999] **2000** and section 338.043, **RSMo Supp. 2007**. This rule originally filed as 4 CSR 220-2.036. Original rule filed May 24, 1993, effective Dec. 9, 1993. For intervening history, please consult the **Code of State Regulations**. Amended: Filed Feb. 6, 2008.*

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 State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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 2220-2.120 Transfer of Prescription Information for the Purpose of Refill. The board is proposing to amend section (1), add subsection (1)(E), amend paragraph (2)(B)10. and add section (3).

PURPOSE: Pursuant to Executive Order 06-04 the Division of Professional Registration was transferred from the Department of Economic Development, Title 4, to the Department of Insurance, Financial Institutions and Professional Registration, Title 20. Therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also makes grammatical corrections, clarifies the criteria for prescription transfers, and gives the time frame for which it should be completed.

(1) Prescription information *[may]* **shall** be transferred for the purposes of refill between licensed pharmacies, provided the prescription information to be transferred meets all of the following criteria:

(E) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one (1)-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) When a prescription on record is transferred, the following record keeping is required:

(B) The prescription record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information of an original prescription:

1. The prescription record is a transferred prescription record from another licensed location;
2. Date of original issuance;
3. Date of original filling, if different from original issuance date;
4. Original number of refills authorized on the original prescription and the number of remaining authorized refills;
5. Date of last refill;
6. Prescription label number;
7. Identity of licensed pharmacy from which the record was transferred;
8. The identity of the transferring pharmacist provided that pharmacies that share the same database and are under the same ownership may, instead of transferring prescriptions directly between two (2) pharmacists, transfer a prescription electronically by generating a computer-based report at the transferring pharmacy of any

prescriptions that have been transferred out. This record shall be readily retrievable to the transferring pharmacy and board representatives and comply with all of the requirements of this rule, except that the requirement to document pharmacist identity shall not be required unless otherwise required by federal law;

9. If the transfer involves a controlled substance, the address and DEA registration number from the transferring pharmacy must be recorded; and

10. Any electronic transfer must maintain patient confidentiality in accordance with *[4 CSR 220-2.300]* **20 CSR 2220-2.300**; and

(3) A pharmacy shall complete the transfer within one (1) business day of receiving the request.

AUTHORITY: sections 338.100 [and], 338.140, [RSMo Supp. 1999] and 338.280, RSMo [1994] 2000. This rule originally filed as 4 CSR 220-2.120. Original rule filed April 16, 1985, effective Aug. 11, 1985. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Feb. 6, 2008.*

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 State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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. The board is proposing to delete sections (1) through (10), renumber the sections thereafter, amend new subsection (1)(I), new section (2), new subsection (2)(A), new section (16) and add subsections (16)(A) and (16)(B).

PURPOSE: Pursuant to Executive Order 06-04 the Division of Professional Registration was transferred from the Department of Economic Development, Title 4, to the Department of Insurance, Financial Institutions and Professional Registration, Title 20. Therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also deletes obsolete information, clarifies requirements for sterile product reference materials, and provides an exemption for pharmacies that are registered with the Food and Drug Administration (FDA).

[(1) The provisions of sections (2)–(9) expire June 30, 2004.]

[(2) Definitions.

(A) 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, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(B) 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 Standard 209B.

(C) Compounded sterile drug—a sterile drug dosage form that has been prepared by a pharmacist, to include a commercially prepared sterile drug dosage form which has been altered by a pharmacist.

(D) Cytotoxic Therapeutic Class—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 the host's inflammatory response system.

(E) Parenteral—sterile preparation of drugs for injection through one (1) or more layers of skin.

(F) Sterile pharmaceutical—a dosage form free from living microorganisms (aseptic).]

[(3) Policy and Procedure Manual. A policy and procedure manual, as it relates to sterile products, shall be available for inspection at the pharmacy. The manual shall be reviewed and revised on an annual basis and shall include, but is not limited to, policies and procedures for any of the following services provided by the pharmacy:

(A) Clinical services;

(B) Cytotoxics handling, storage and disposal;

(C) Disposal of unused supplies and medications;

(D) Drug destruction and returns;

(E) Drug dispensing;

(F) Drug labeling/relabeling;

(G) Drug storage;

(H) Duties and qualifications for professional and nonprofessional staff;

(I) Equipment;

(J) Handling of infectious wastes;

(K) Infusion devices and drug delivery systems;

(L) Investigational drugs;

(M) Obtaining a protocol on investigational drugs from the principal investigator;

(N) Quality assurance procedures to include:

1. Recall procedures;

2. Storage and dating;

3. Educational procedures for professional staff, nonprofessional staff and patient;

4. Sterile procedures to include a log of the temperature of the refrigerator, routine maintenance and report of hood certification; and

5. Sterility testing;

(O) Record keeping;

(P) Reference material;

(Q) Sanitation;

(R) Security;

(S) Sterile product preparation procedures; and

(T) Transportation.]

[(4) Physical Requirements.

(A) Space. The licensed pharmacy shall have a designated area with entry restricted to designated personnel for preparing compounded, sterile products. This area shall be isolated from other areas and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. It shall be used only for the preparation of sterile pharmaceutical products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security.

(B) Equipment. The licensed pharmacy preparing sterile products shall have—

1. Appropriate environmental control devices capable of maintaining at least Class 100 conditions in the work area where critical objects are exposed and critical activities are performed; furthermore, the devices are capable of maintaining Class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow systems of high efficiency particulate air filter (HEPA)-filtered air;

2. A sink with hot and cold running water and proper sewage disposal that is convenient to the compounding area for the purpose of hand scrubs prior to compounding;

3. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients' homes;

4. When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;

5. Refrigerator/freezer with a thermometer;

6. Temperature-controlled delivery container; and

7. Infusion devices, if appropriate.

(C) Supplies.

1. Disposable needles syringes and other supplies needed for aseptic admixture;

2. Disinfectant cleaning solutions;

3. Hand washing agent with bactericidal action;

4. Disposable, lint free towels or wipes;

5. Appropriate filters and filtration equipment;

6. Oncology drug spill kit; and

7. Disposable masks, caps, gowns and sterile disposable gloves.

(D) Reference Library. The pharmacy shall have adequate current reference materials related to sterile products. Some suggested sources include: Handbook on Injectable Drugs, America Society for Hospital Pharmacists (ASHP); King's Guide to Parenteral Admixtures; United States Pharmacopeia (USP)/Negative Formulary (NF); American Hospital Formulary Service; Procedures for Handling Cytotoxic Drugs, American Society for Hospital Pharmacists (ASHP). In addition, the pharmacy shall maintain copies of current Occupational Safety and Health Administration (OSHA) requirements.]

[(5) Drug Distribution and Control.

(A) Medication Record System. A pharmacy generated medication record system must be separate from the prescription file. The patient medication record system shall be maintained under the control of the pharmacist-in-charge for a period of sixty (60) days after the last dispensing activity. The medication record system, at a minimum, shall contain:

1. Patient's full name;

2. Date of birth or age;

3. Weight;

4. Sex;

5. Sterile products dispensed;

6. Date dispensed;

7. Drug content and quantity;

8. Patient direction;

9. Identifying prescription number;

10. Identification of dispensing pharmacist;

11. Other drugs patient is receiving;

12. Known drug sensitivities and allergies to drugs and food; and

13. Primary diagnosis.

(B) Labeling (supplemental). Each sterile pharmaceutical dispensed to patients shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information affixed to a permanent label:

1. Directions for administration including infusion rate, where applicable;

2. Date of compounding;

3. Expiration date and time;

4. Identity of pharmacist compounding and dispensing;

5. Storage requirements;

6. Auxiliary labels, where applicable; and

7. Cytotoxic drug auxiliary labels, where applicable.

(C) Records and Reports. The pharmacist-in-charge shall maintain access to, and submit as appropriate, records and reports required to insure the patient's health, safety and welfare. These reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the State Board of Pharmacy or its agents. Such shall include, at a minimum, the following:

1. Purchase records;

2. Policy and procedure manual;

3. Training manuals, where applicable;

4. Policies and procedures for cytotoxic waste, where applicable;

5. Other records and reports as may be required by law and the rules of the State Board of Pharmacy; and

6. Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with federal or state laws, or both.

(D) Delivery Service. The pharmacist-in-charge shall assure the environmental control of all products shipped. A sterile pharmaceutical product must be shipped or delivered to a patient in appropriate temperature controlled delivery containers (as defined by USP standards) and assurances must be made that appropriate storage facilities are available. Chain of possession for the delivery of Schedule II controlled substances via couriers must be documented and a receipt required.]

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

(A) All cytotoxic drugs should be compounded in a vertical flow, Class II biological safety cabinet. If used for other products, the cabinet must be thoroughly cleaned;

(B) Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves and gowns with tight cuffs;

(C) Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;

(D) Disposal of cytotoxic waste shall comply with all applicable local, state and federal requirements;

(E) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and must be included in the policy and procedure manual; and

(F) 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.]

[(7) Quality Assurance.

(A) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment and facilities. Appropriate samples of finished products shall be examined to assure that the pharmacy is capable of consistently preparing sterile products meeting specifications. These examinations shall include: visual

inspection under a direct light source in the preparation of products in order to determine the presence of inappropriate particulate matter or signs of deterioration; policies and procedures for monitoring of sterile products whereby any untoward effects exhibited by a patient that may be due to the product, are reported to the pharmacy; and appropriate samples are collected and microbial tests are completed to ascertain the presence of microbial contamination of suspect products. Quality assurance procedures shall include:

1. Recall procedures;

2. Storage and dating; and

3. Environmental procedures which include a log of the temperature of the refrigerator, routine maintenance and report of any hood certification.

(B) Clean Room and Hood Certification. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209B or National Sanitation Foundation Standard 49 for operational efficiency at a minimum of every twelve (12) months. Certification records shall be maintained as a part of the pharmacy record.

(C) Prefilters. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented.

(D) Nonsterile Compounding. If bulk compounding is performed utilizing nonsterile chemicals, extensive end-product testing, as referenced in the Remington Reference Manual, must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter and testing for pyrogens.

(E) Expiration Dates. There shall be written justification of the chosen expiration date for compounded products. If a written standard is not available, a maximum of twenty-four (24) hours expiration date shall be used.

(F) Quality Assurance Audits. There shall be documentation of quality assurance audits at regular, planned intervals and should include infection control and sterile technique audits.]

[(8) Pharmacists and pharmacies where sterile compounding is provided may be exempt from this rule when that compounding is restricted to the following:

(A) The method of compounding utilizes 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; or

(B) The amount of compounding provided by the pharmacy is for emergency situations. An emergency is defined as—

1. Situations where the sterile compound is needed and is unavailable from or inconvenient to obtain from other sources;

2. Compounding will be provided to the patient immediately and used within a twenty-four (24)-hour period; and

3. Products are provided to the patient as a single dosage unit and the drug is not intended to be provided beyond an immediate emergency period.]

[(9) This rule is not intended to include any pharmacy that provides sterile pharmaceuticals on a prescription order that has not been compounded by the pharmacy or had the packaging or labeling of the product altered by the pharmacy.]

[(10) The provisions of sections (11)–(26) become effective July 1, 2004.]

*[(11)]***(1)** Definitions.

(A) Aseptic processing: The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

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

(C) Beyond-Use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(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, 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.

(I) Compounding: For the purposes of this regulation, compounding is defined as in *[4 CSR 220-2.400(1)]* **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.

(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).

(K) Critical area: Any area in the controlled area where products 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.

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

(N) 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) Emergency dispensing: Is a situation where a Risk Level 3 product is necessary for immediate administration of the product and no alternative product is available and the prescriber is informed that the product is being dispensed prior to appropriate testing. Documentation of the dispensing of the product, 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) 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.

(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.

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

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

(T) 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 lead to products that meet predetermined standards of quality.

(U) 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 prepared meet predetermined requirements with respect to identity, purity, nonpyrogenicity and sterility.

(V) Repackaging: The subdivision or transfer of a compounded product from one container or device to a different container or device.

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

(X) Sterilization: A validated process used to render a product free of viable organisms.

(Y) Temperatures:

1. Frozen means temperatures between twenty below zero and ten degrees Celsius (–20 and 10°C) (four below zero and fourteen degrees Fahrenheit (–4 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)).

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)).

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

(AA) Definitions of sterile compounded products by risk level:

1. Risk Level 1: Applies to compounded sterile products that exhibit characteristics A., B., and C., stated below. All Risk Level 1 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Risk Level 1 includes the following:

A. Products:

(I) Stored at room temperature and completely administered within forty-eight (48) hours after preparation; or

(II) Stored under refrigeration for 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.

B. Unpreserved sterile products prepared for administration to one (1) patient or batch-prepared products containing suitable preservatives prepared for administration to more than one (1) patient.

C. Products 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.

2. Risk Level 2: Sterile products exhibit characteristic A., B., or C., stated below. All Risk Level 2 products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product 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.

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

C. Products 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 exhibit either characteristic A. or B.:

A. Products compounded from nonsterile ingredients or compounded with nonsterile components, containers or equipment before terminal sterilization.

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

*[(12)]***(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, 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.**

*[(13)]***(3)** Personnel Education, Training and Evaluation.

(A) Risk Level 1: All pharmacy personnel preparing sterile products must receive suitable didactic and experiential training**.**

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training includes 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. The pharmacist knows principles of good compounding practice for risk level products, including—

1. Aseptic processing;

2. Quality assurance of environmental, component, and end-product testing;

3. Sterilization; and

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

*[(14)]***(4)** Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies and equipment must be stored according to manufacturer or USP requirements. Refrigeration and freezer 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 from boxes shall be done outside controlled areas. Removal of used supplies from the controlled area shall be done at least daily. Product recall procedures must permit retrieving affected products from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements,

procedures include procurement, identification, storage, handling, testing, and recall of components and finished products. Finished but untested Risk Level 3 products must be quarantined under minimal risk for contamination.

*[(15)]***(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.

*[(16)]***(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.

*[(17)]***(7)** Aseptic Technique and Product Preparation.

(A) Risk Level 1: Sterile products must be prepared in a Class 100 environment. Personnel shall scrub their hands and forearms for an appropriate period at the beginning of each aseptic compounding process. 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 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. Surfaces of ampules and vials shall be disinfected before placement in the workbench. Sterile components shall be arranged in the workbench to allow uninterrupted laminar airflow over critical surfaces of needles, vials, ampules, etc. Automated devices and equipment shall be cleaned, disinfected and placed in the workbench 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. 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 formula, components, procedures, sample label, and final evaluation shall be made for each product batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile products, 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 for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet standards if available, as 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 integrity throughout the shelf life. Sterilization methods must be based on properties of the product.

*[(18)]***(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.

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

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

1. Training and competency evaluation of pharmacy personnel involved in sterile product preparation;
2. Refrigerator and freezer temperature logs;
3. Certification of workbenches;
4. Copies of any manufacturer standards 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.

(B) Risk Level 2: In addition to Risk Level 1 requirements, records of any end-product 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 must include:

1. Preparation work sheet;
2. Sterilization records;
3. Quarantine records, if applicable;
4. End-product evaluation and testing records as required in section *[(22)]***(12)**; and
5. Ingredient validation records as required in section *[(22)]***(12)**.

(D) All records and reports shall be maintained for two (2) years and shall be readily retrievable, subject to inspections by the board of pharmacy or its agents.

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

(A) Risk Level 1: Sterile products dispensed to patients 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;
3. Any device specific instructions; and
4. Auxiliary labels, when applicable.

(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.

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

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

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

(C) Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all expiration dates, including laboratory testing of product 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 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 of greater than thirty (30) days shall have lab testing of product stability and potency.

*[(22)]***(12)** End-Product Evaluation.

(A) Risk Level 1: The final product must be inspected for container leaks, integrity, solution cloudiness or phase separation, particulates in solution, appropriate solution color, and solution volume. The pharmacist must verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of products for any particulate and/or foreign matter must be used as part of the inspection process.

(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 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 shall be established if end-product testing results are unacceptable. All sterile products must be tested for sterility. All parenteral sterile products must also be tested for pyrogenicity. Sterile products compounded from nonsterile components must be quarantined pending results of end-product 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.

2. Pyrogen/Endotoxin testing: Each sterile parenteral product prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to recommended USP methods.

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 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 that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile Product: When a compounded Risk Level 3 product must be released prior to the completion of testing, the sterile product may be dispensed pending test results.

*[(23)]***(13)** Handling Sterile Products Outside the Pharmacy.

(A) Risk Level 1: The pharmacist-in-charge shall assure the environmental control of all sterile compounded products shipped. Sterile products 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. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of products with common storage characteristics and for specific products where unique storage conditions are required to retain adequate stability and product 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.

*[(24)]***(14)** 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. If used for other products, 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;

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;

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.

*[(25)]***(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.

*[(26)]***(16)** In addition to the requirements outlined in this rule, all standards and requirements as outlined in *[4 CSR 220-2.400]* **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.

*AUTHORITY: sections 338.140, 338.240 and 338.280, RSMo 2000 and section 338.010, **RSMo Supp. 2007**. 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**. Amended: Filed Feb. 6, 2008.*

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 approximately fifty-three thousand, seven hundred fifty dollars ($53,750) annually for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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.*

PRIVATE FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - State Board of Pharmacy
Chapter 2 - General Rules
Proposed Amendment - 20 CSR 2200-2.200 Sterile Pharmaceuticals
Prepared November 20, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimate the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by type of the business entities which would likely be affected:	Estimated cost of compliance with the rule by affected entities:
215	Reference Materials (Sterile Product Manuals @ $250)	$53,750
	Estimated Annual Cost of Compliance for the Life of the Rule	**$53,750**

III. WORKSHEET

See table above.

IV. ASSUMPTION

1. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

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

PROPOSED AMENDMENT

20 CSR 2220-2.450 Fingerprint Requirements. The board is proposing to amend subsections (1)(F) and (1)(G), add subsection (1)(H), add a new section (4) and renumber the remaining section.

PURPOSE: This amendment establishes fingerprinting requirements for intern pharmacists.

(1) Applicants for licensure or registration that must provide fingerprints to the Board of Pharmacy shall include:

(F) Pharmacy technician; *[and]*

(G) Owners with a ten percent (10%) or more interest in a drug distributor entity (applying to non-publicly held companies only)*[.]*; **and**

(H) Intern pharmacist.

(4) The board may require an applicant to be fingerprinted again and pay any required fingerprinting fees, if the application process is not completed within six (6) months of the board's receipt of the application.

*[(4)]***(5)** The board may, in the course of an investigation of a licensee, require that fingerprints be submitted for a background check as provided for in this rule.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.450. Original rule filed Jan. 6, 1997, effective July 30, 1997. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Feb. 6, 2008.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions approximately four hundred sixty-five dollars and seventy-two cents ($465.72) during the first year of implementation beginning in fiscal year 2008 and approximately three hundred sixty-three dollars and thirty-nine cents ($363.39) annually thereafter for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will cost private entities approximately thirty-three thousand one hundred eighteen dollars ($33,118) annually for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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.*

PUBLIC FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - Missouri Board of Pharmacy
Chapter 2 - General Rules
Proposed Amendment - 20 CSR 2220-2.450 Fingerprint Requirements
Prepared November 14, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance	
Missouri Board of Pharmacy	Total Cost During First Year of Implementation of Amendment Beginning in FY08	$465.72
	Total Annual Cost of Compliance for the Life of the Amendment Beginning in FY09	$363.39

III. WORKSHEET

The Intern Pharmacist Application form and instruction sheet will need to be revised by the Executive I to incorporate fingerprint requirements. The Licensing Technician II will be required to ensure receipt of criminal history background check reports, rejecting applications for fingerprints, and rejecting fingerprints, prior to licensure. The Executive Director will be required to review those that have positive criminal history results.

First Year of Implementation

STAFF	ANNUAL SALARY	SALARY TO INCLUDE FRINGE BENEFIT	HOURLY SALARY	COST PER MINUTE	TIME PER APPLICATION	NUMBER OF APPLICATIONS	TOTAL COST
Executive I	$33,636	$50,080.64	$24.08	$0.40	2 hours to revise Intern Pharmacist Application	1	$102.33
Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	1 minute to check applications for completeness	537	$160.45
Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	10 minutes to reject applications for fingerprints	27	$80.67

Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	10 minutes to reject fingerprints	1	$2.99
Executive Director	$74,061	$110,269.42	$53.01	$0.88	5 minutes to review intern applications with positive criminal history reports	27	$119
						Total Annual Personal Services Cost for 1st Year Implementation of this Amendment	**$465.72**

The Licensing Technician II will be required to ensure receipt of criminal history background check reports, rejecting applications for fingerprints, and rejecting fingerprints, prior to licensure. The Executive Director will be required to review those that have positive criminal history results.

Second Year of Implementation of the Amendment and Annually Thereafter

STAFF	ANNUAL SALARY	SALARY TO INCLUDE FRINGE	HOURLY SALARY	COST PER MINUTE	TIME PER APPLICATION	NUMBER OF APPLICATIONS	TOTAL COST
Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	1 minute to check applications for completeness	537	$160.45
Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	10 minutes to reject applications for fingerprints	27	$80.67
Licensing Tech II	$25,044	$37,288.01	$17.93	$0.30	10 minutes to reject fingerprints	1	$2.99
Executive Director	$74,061	$110,269.42	$53.01	$0.88	5 minutes to review intern applications with positive criminal history reports	27	$119
						Total Annual Personal Services Cost for this Amendment Following the 1st Year of Implementation	**$363.39**

IV. ASSUMPTION

1. Employee's salaries were calculated using the annual salary multiplied by 48.89% for fringe benefits and then divided by 2080 hours per year to determine the hourly salary.
2. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE FISCAL NOTE

I. RULE NUMBER

Title 20 - Department of Insurance, Financial Institutions and Professional Registration
Division 2220 - Missouri Board of Pharmacy
Chapter 2 - General Rules
Proposed Amendment - 20 CSR 2220-2.450 Fingerprint Requirements
Prepared November 20, 2007 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Estimate the number of entities by class which would likely be affected by the adoption of the proposed rule:	**Classification by type of the business entities which would likely be affected:**	**Estimated cost of compliance with the rule by affected entities:**
650	Pharmacy Intern Applicants (Identix Identification Services Fee @ $50.95)	$33,118
	Estimated Annual Cost of Compliance for the Life of the Rule	**$33,118 with a continuous growth rate of 16%**

III. WORKSHEET

See table above.

IV. ASSUMPTION

1. The figures reported above are based on FY03 - FY07 actuals.
2. The board estimates that there will be an average of a sixteen percent (16%) increase in pharmacy intern applicants annually based on the last five (5) years actual data.
3. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 3—Negative Generic Drug Formulary

PROPOSED AMENDMENT

20 CSR 2220-3.040 Return and Reuse of Drugs and Devices. The board is proposing to add section (3).

PURPOSE: This amendment clarifies labeling and storage requirements for prescriptions that are not claimed.

(3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. The drug must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known.

AUTHORITY: section 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-3.040. Original rule filed Dec. 12, 1983, effective May 11, 1984. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Feb. 6, 2008.*

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 State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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 4—Fees Charged by the Board of Pharmacy

PROPOSED AMENDMENT

20 CSR 2220-4.010 General Fees. The board is proposing to amend section (1).

PURPOSE: Pursuant to section 338.070.1, RSMo, the board shall set the amount of the fees which this chapter authorizes and requires by rules and regulations promulgated pursuant to Chapter 536, RSMo. The fees shall be set at a level to produce revenue which shall not substantially exceed the cost and expense of administering this chapter.

(1) The following fees are established by the State Board of Pharmacy:

(A) Licensure by Examination Fee	*[$105.00]* **$150**
1. Exam candidate shall contact the National Association of Boards of Pharmacy and pay any fee required directly by that agency.	
(B) Licensure by Transfer of License (Reciprocity)	*[$350.00]* **$375**
(C) Original Pharmacy Permit Fee	*[$250.00]* **$300**
(D) Pharmacist License Renewal Fee	*[$160.00]* **$225**
(E) Pharmacy Permit Renewal Fee	*[$400.00]* **$450**
(F) Delinquent Pharmacist Renewal Fee (in addition to the Pharmacist License Renewal Fee)	*[$ 50.00]* **$250**
(G) Duplicate License/Permit/Registration Fee	*[$ 10.00]* **$20**
(H) Change of Pharmacy or Drug Distributor Name Fee	$ 25*[.00]*
(I) Fee for Retake of Multistate Pharmacy Jurisprudence Examination (MPJE)	*[$100.00]* **$150**
(J) Foreign Graduate Preliminary Filing Fee (Candidates for licensure by examination, who are graduates of schools/colleges of pharmacy not accredited by the board)	*[$ 50.00]* **$250**
(K) Change of Pharmacy or Drug Distributor Location Fee	*[$125.00]* **$175**
(L) Original Pharmacy Distributor/Wholesale Drug Distributor License Fee (includes both temporary and permanent license)	*[$250.00]* **$300**
(M) Pharmacy Distributor/Wholesale Drug Distributor License Renewal Fee	*[$400.00]* **$450**
(N) Original Drug Distributor (Manufacturer) Registration Filing Fee	$ 10*[.00]*
(O) Renewal of Drug Distributor (Manufacturer) Registration Filing Fee	$ 10*[.00]*
(P) Original Intern Pharmacist License	*[$ 40.00]* **$50**
(Q) Intern Pharmacist License Renewal	*[$ 25.00]* **$80**
(R) Temporary Pharmacist License Fee (original issue/renewal)	*[$ 50.00]* **$100**
(S) Fingerprint Fee for Criminal Background Check—Determined by Federal Bureau of Investigation (FBI) and Missouri State Highway Patrol (MSHP)	(pass through fee)
(T) Pharmacy Technician Initial Registration Fee	*[$ 10.00]* **$35**
(U) Pharmacy Technician Annual Renewal Fee	*[$ 10.00]* **$35**
(V) Delinquent Continuing Education Pharmacist Fee	*[$500.00]* **$1,000**
(W) Score Transfer Fee	**$150**
(X) Pharmacy Classification Change Fee	**$50**
(Y) Manager-in-Charge Change Fee	**$50**
(Z) Pharmacist-in-Charge Change Fee	**$50**
(AA) Verification Fee	**$25**
(BB) Returned Check Fee	**$25**
(CC) Certification of Medication Therapeutic Plan Authority	**$50**

AUTHORITY: sections 338.020, 338.040, 338.060, 338.070, 338.140, 338.185, ***and*** *338.280 [and 338.350], RSMo 2000 and sections 338.013, 338.035 and 338.220, RSMo Supp. [2004]* ***2007****. This rule originally filed as 4 CSR 220-4.010. Emergency rule filed July 15, 1981, effective Aug. 3, 1981, expired Nov. 11, 1981. Original rule filed Aug. 10, 1981, effective Nov. 12, 1981. For intervening history, please consult the* ***Code of State Regulations****. Amended: Filed Feb. 14, 2008.*

PUBLIC COST: This proposed amendment will generate revenue of approximately six hundred seventy-two thousand three hundred seventy dollars ($672,370) annually and seven hundred twenty-one thousand six hundred seventy-five dollars ($721,675) biennially for the life of the rule. It is anticipated that the revenue will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE COST: This proposed amendment will cost private entities approximately six hundred seventy-two thousand three hundred

seventy dollars ($672,370) annually and seven hundred twenty-one thousand six hundred seventy-five dollars ($721,675) biennially for the life of the rule. It is anticipated that the costs will recur for the life of the rule, may vary with inflation and are expected to increase at the rate projected by the Legislative Oversight Committee.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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.*

PUBLIC ENTITY FISCAL NOTE

I. RULE NUMBER

Title 20 -Department of Insurance, Financial Institutions, and Professional Registration

Division 2220 - Board of Pharmacy

Chapter 4 - Fees Charged by the Board of Pharmacy

Proposed Amendment - 20 CSR 2220-4.010 General Fees

Prepared January 23, 2008 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance	
State Board of Pharmacy	$672,370.00	Annually
	$721,675.00	Biennially

III. WORKSHEET

The division is statutorily obligated to enforce and administer the provisions of sections 338.010-338.550, RSMo. Pursuant to Section 338.070, RSMo, the division shall by rule and regulation set the amount of fees authorized by sections 338.010 - 338.550, RSMo so that the revenue produced is sufficient, but not excessive, to cover the cost and expense to the board for administering the provisions of sections 338.010-338.550, RSMo. The board estimates the projections calcuated in the Private Entity Fiscal Notes will be total increase of revenue for the board.

IV. ASSUMPTION

1. It is anticipated that the total cost will recur for the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

PRIVATE ENTITY FISCAL NOTE

I. RULE NUMBER

Title 20 -Department of Insurance, Financial Institutions, and Professional Registration
Division 2220 - Board of Pharmacy
Chapter 4 - Fees Charged by the Board of Pharmacy
Proposed Amendment - 20 CSR 2220-4.010 General Fees

Prepared January 23, 2008 by the Division of Professional Registration

II. SUMMARY OF FISCAL IMPACT

Annual

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	Classification by type of the business entities which would likely be affected:	Estimated annual cost of compliance with the rule by affected entities:
271	Licensure by Examination Fee $45 increase	$12,195
160	Licensure by Transfer of License (Reciprocity) $25 increase	$4,000
150	Original Pharmacy Permit Fee $50 increase	$7,500
44	Delinquent Pharmacist Renewal Fee (in addition to the Pharmacist License Renewal Fee) $200 increase	$8,800
185	Duplicate License/Permit/Registration Fee $10 increase	$1,850
11	Fee for Retake of Multistate Pharmacy Jurisprudence Examination (MPJE) $50 increase	$550
20	Foreign Graduate Preliminary $200 increase	$4,000
75	Change of Pharmacy or Drug Distributor Location Fee $50 increase	$3,750

130	Original Pharmacy Distributor/Wholesale Drug Distributor License Fee $50 increase	$6,500
620	Original Inter Pharmacist License $10 increase	$6,200
5	Temporary Pharmacist License Fee $50 increase	$250
5,140	Pharmacy Technician Initial Registration Fee $25 increase	$128,500
14,800	Pharmacy Technician Annual Renewal Fee $25 increase	$370,000
150	Score Transfer $150 increase	$22,500
372	Pharmacy Classification Change Fee $50 increase	$18,600
672	Pharmacist In Charge/Manager In Charge Change Fee $50 increase	$33,600
372	Verification Fee $25 increase	$9,300
35	Returned Check Fee $25 increase	$875
668	Certification of Medication Therapeutic Plan Authority $50 increase	$33,400
	Estimated Annual Cost of Compliance for the Life of the Rule	**$672,370**

Biennial

Estimate the number of entities by class which would likely be affected by the adoption of the proposed amendment:	**Classification by type of the business entities which would likely be affected:**	**Estimated biennial cost of compliance with the rule by affected entities:**
7,850	Pharmacist License Renewal Fee $65 increase	$510,250

1,700	Pharmacy Permit Renewal Fee $50 increase	$85,000
1,100	Pharmacy Distributor/Wholesale Drug Distributor License Renewal Fee $50 increase	$55,000
935	Intern Pharmacist License $55 increase	$51,425
40	Delinquent Continuing Education Pharmacist Fee $500 increase	$20,000
	Estimated Biennal Cost of Compliance for the Life of the Rule	**$721,675**

III. WORKSHEET

See table above.

IV. ASSUMPTION

1. The figures reported above are based on the five year projections for the board.
2. It is anticipated that the total cost will recur or the life of the rule, may vary with inflation and is expected to increase at the rate projected by the Legislative Oversight Committee.

NOTE:. The division is statutorily obligated to enforce and administer the provisions of sections 338.010-338.550, RSMo. Pursuant to Section 338.070, RSMo, the division shall by rule and regulation set the amount of fees authorized by sections 338.010 - 338.550, RSMo so that the revenue produced is sufficient, but not excessive, to cover the cost and expense to the board for administering the provisions of sections 338.010-338.550, RSMo.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2220—State Board of Pharmacy
Chapter 5—Drug Distributor

PROPOSED AMENDMENT

20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors. The board is proposing to amend subsection (3)(B), paragraph (3)(C)10., and subsection (3)(K).

PURPOSE: This amendment requires thermostatically controlled temperatures within drug distributor facilities; prohibits animals, except for service animals, in drug storage areas; and requires records to be made available to a Board of Pharmacy representative upon request.

(3) Minimum standards of practice for drug distributors shall include the following:

(B) The temperature of the facility where drugs are stored must be maintained **thermostatically** within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs;

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

1. All aisles and walkways must be free and clear of debris, dirt or filth.

2. Dust shall be kept at low levels through adequate ventilation, cleaning procedures, or both.

3. All shelves and storage areas shall be kept free of debris, dirt, dust and filth.

4. Full cases of drug products shall be raised above floor level and placed on a pallet or similar device.

5. Upon receipt of legend drugs, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

6. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

7. Drugs stored in a facility or being processed for distribution must be physically separated at all times from articles, supplies or other drugs that are outdated, distressed, misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances or accumulated waste/garbage. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier. If a drug is received or further distributed, either directly or through a secondary broker (paper) transaction, that is wholly or in part found to be counterfeit, a report which includes the name of the drug, quantity and lot number(s) must be forwarded to the Board of Pharmacy within seven (7) days of gaining knowledge of the transaction. Any recall of a product that is initiated by the Food and Drug Administration (FDA) or by a vendor licensed with the state of Missouri shall not be subject to the reporting requirement.

8. Flammable articles must be stored separately and away from drug products held for later wholesale distribution.

9. Drugs which may be held for later distribution that are labeled for veterinary use must be stored separately from those drugs that are to be distributed for human use.

10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind. **Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in the drug storage areas.**

11. Appropriate sewage disposal and a hot and cold water supply must be available.

12. The outside perimeter of the premises shall be well-lighted.

13. All facilities shall be equipped with an alarm system to detect entry after hours.

14. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(K) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by *[an authorized official of a federal, state or local law enforcement agency]* **the board or its representatives**;

AUTHORITY: sections 338.333, 338.343 and 338.350, RSMo 2000. This rule originally filed as 4 CSR 220-5.030. Original rule filed Feb. 4, 1991, effective June 10, 1991. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Feb. 6, 2008.*

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 State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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 5—Drug Distributor

PROPOSED AMENDMENT

20 CSR 2220-5.070 Standards of Operation for Medical Gas Distributors. The board is proposing to amend section (3).

PURPOSE: Pursuant to Executive Order 06-04 the Division of Professional Registration was transferred from the Department of Economic Development, Title 4, to the Department of Insurance, Financial Institutions and Professional Registration, Title 20. Therefore, references to 4 CSR 220 are being amended throughout the rule. This amendment also deletes obsolete information.

(3) Medical gas distributors that are not involved in the storage or transfer of any other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are

exempt from the following regulation sections: *[4 CSR 220-5.030(3)(B)]* **20 CSR 2220-5.030(3)(B)**; (3)(C)4., 9., *[11.,]* 12., 13.; (3)(E); *[(3)(H)]* and (3)(M)4. Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from *[4 CSR 220-5.030(3)(B)]* **20 CSR 2220-5.030(3)(B)**; (3)(C)4., 9.*[, 11.]*; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board's regulations shall be considered applicable to medical gas distributors.

*AUTHORITY: sections 338.050, 338.333, 338.337 [and], 338.340, [RSMo 1994] and 338.335, [RSMo Supp. 1999] **RSMo 2000**. This rule originally filed as 4 CSR 220-5.070. Original rule filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-5.070, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008.*

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 State Board of Pharmacy, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@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.*