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 If an existing rule is to be amended or rescinded, it will have a heading of proposed amendment or proposed rescission.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 1—OFFICE OF ADMINISTRATION
Division 40—Purchasing and Materials Management
Chapter 1—Procurement

PROPOSED RULE

1 CSR 40-1.090 Waiver of Procedures Contained in Chapter 34, RSMo, Related to Cost and Pricing

PURPOSE: This rule waives the procedures in Chapter 34, RSMo, related to cost and pricing for the purchase of services for patients, residents, and clients.

(1) The commissioner of administration has determined that the Department of Mental Health's services for its patients, residents and clients can best be purchased by the department with funds appropriated for that purpose and waives procedures of Chapter 34, RSMo, related to cost and pricing, so that the department may evaluate competitive proposals on the basis of quality and other variables exclusive of price.

AUTHORITY: section 630.405.5, RSMo Supp. 2001. Original rule filed Nov. 26, 2002.

PUBLIC COST: This proposed rule is anticipated to cost state agencies and political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule is anticipated to cost private entities less than five hundred dollars ($500) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may submit comments in support of or opposition to this proposed rule. In preparing your comments, please include the regulatory citation and the **Missouri Register** page number. Please explain why you agree or disagree with the proposed change and include alternative language. Comments may be mailed or faxed to Mr. Jim Miluski, Office of Administration, PO Box 809, Jefferson City, MO 65102. The fax number is (573) 526-5985. 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 3—DEPARTMENT OF CONSERVATION
Division 10—Conservation Commission
Chapter 1—Wildlife Code: Organization

PROPOSED AMENDMENT

3 CSR 10-1.010 Organization and Methods of Operation. The commission proposes to amend sections (2) and (3) of this rule.

PURPOSE: This amendment outlines organizational changes as approved by the Conservation Commission at its August 21, 2002 meeting.

(2) The commission appoints a director who serves as the administrative officer of the Department of Conservation. The director appoints other employees and is assisted by a deputy director**-field and a deputy director-administration** with programs and activities carried out by the divisions of fisheries, wildlife, forestry, protection, *[design and development,]* outreach and education, administrative services, private land services, *[natural history]* **science** and human resources. An assistant director **supervises the policy coordination section, and** provides leadership for special projects and initiatives as assigned by the director; notably legislative liaison*[,]* **and** partnerships with other entities*[, etc]*.

(3) The department carries out its programs through the following major administrative units:

[(E) Design and Development administers the department's construction/development program and is responsible for development of areas owned and/or leased by the department. The staff consists of professional engineering, architecture, land surveying and support staff in the areas of drafting, computer applications, clerical and an in-house construction work force. All work is highly specialized in direct relation to the department's resource programs; typically, development of wetlands, reservoirs, hatcheries, buildings, nature centers, river and lake public use access areas, stream corridor improvements and hunter safety training facilities, including shooting ranges. Related services include property surveys of all department lands by registered surveyors, feasibility studies and provision of data for environmental

assessments. The cartography unit archives all department lands and produces department maps.]

[(F)] **(E)** Outreach and Education administers the department's public information and education programs. Education services and programs include operating nature and visitor centers, developing interpretive exhibits, administering urban fishing programs, teaching outdoor skills, acting as a clearing house for conservation education projects, and providing conservation **education** curricula, training and materials to teachers and youth leaders. Outreach produces the department's monthly magazine, popular and technical publications, radio and television programs and video productions; issues news releases and coordinates with new media. Metropolitan services in St. Louis, Kansas City and Springfield include coordinators and media information specialists who provide information to the public, work with urban personnel from other divisions to deliver services to the public, and assess public opinion on conservation issues and public demand for conservation programs.

[(G)] **(F)** Administrative Services administers the department's support services of information technology, *[policy coordination, fiscal services and general services.]* **design and development, and business and support.** Information technology provides directions and management of the department's information technology assets*[; defines technology solutions to meet business needs; supports employees' use of those assets]*, including computer hardware and software systems, telephone systems, two-way radio and other telecommunications systems; and coordination of those systems with other state agencies. *[Policy coordination provides liaison with federal, state and private concerns on activities involving fish, wildlife and forestry resources; facilities and coordinates department strategic and other long-range planning; conducts constituency surveys; coordinates geographical information system functions; negotiates for purchase of real property; and manages in-lieu-of-tax payments.]* **Design and development administers the department's construction/development program and is responsible for development of areas owned and/or leased by the department. Related services include property surveys of all department lands by registered surveyors, feasibility studies and provision of data for environmental assessments. Business and support** *[Fiscal services]* collects and processes funds received; processes accounts payable; distributes hunting, fishing and special permits; audits permit distributors; maintains inventory records, including the department's real property holdings; *[and]* coordinates federal aid programs and funds**; coordinates***[. General services is responsible for]* procurement, repair and disposition of fleet, **aircraft,** marine and other mechanical equipment; *[management of the aircraft fleet; maintenance of]* **maintains** a distribution center and warehouse for department publications*[, products and media loan service; operation of]* **; operates** offset printing, mailing and sign production services; and provides building and grounds maintenance.

[(H)] **(G)** Private Land Services provides technical assistance and resource training to private landowners; participates in media and other outreach efforts for resource management; coordinates with other governmental agencies and private organizations to integrate fish, forest, wildlife and natural community considerations with agriculture and other private land initiatives; provides cost-share to assist landowners with priority resource needs; and provides wildlife damage control assistance.

[(I)] **(H)** *[Natural History administers the department's program; coordinates]* **Science Division is the center of the department's resource inventory, monitoring, and research. The division helps department area, regional, and issue managers understand and conserve the biological diversity of Missouri's fish, forests, and wildlife. Other programs administered by this division include water pollution impact investigations,** natural areas **designation and management,** endangered species activities; *[and provides]* specialized service in natural history interpretation and coordination of management for nonconsumptive uses of wildlife resources and lands.

[(J)] **(I)** Human Resources recruits employees; maintains personnel records, benefits and compensation; administers the group insurance program, workers' compensation and safety programs; conducts the affirmative action program and new employee orientation, as well as in-service training in human relations, personal communications and supervisory skills.

[(K)] **(J)** General Counsel provides legal advice to the commission and administrative staff; aids in formulating policy; advises in the formulation of regulations; and performs title search related to the acquisition of real property.

[(L)] **(K)** Internal Auditor reviews operations and programs to assure that resources are used efficiently, and provides the commission and administration with information useful in directing and controlling department operations.

AUTHORITY: sections 40 and 45 of Art. IV, Mo. Const. Original rule filed June 28, 1974, effective July 8, 1974. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Nov. 26, 2002.*

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 John W. Smith, Deputy Director, Department of Conservation, PO Box 180, Jefferson City, MO 65102. 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 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

4 CSR 220-2.020 Pharmacy Permits. The board is proposing to amend subsection (9)(H).

PURPOSE: This rule is being amended to be consistent with the changes proposed in the board's rule 4 CSR 220-2.200.

(9) The following classes of pharmacy permits or licenses are hereby established:

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a sterile pharmaceutical as defined in 4 CSR 220-2.200(1) **and (15)**. Pharmacies providing sterile pharmaceuticals within the exemptions outlined in 4 CSR 220-2.200*[(7) and (8)]* shall not be considered a Class H pharmacy; and

AUTHORITY: sections 338.140, RSMo 2000 and 338.220, RSMo Supp. 2001 and Omnibus State Reorganization Act of 1974 (Appendix B). Original rule filed July 18, 1962, effective July 28, 1962. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Dec. 3, 2002.*

PUBLIC COSTS: 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, Kevin Kinkade, Executive Director, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@mail.state.mo.us. 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 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED RESCISSION

4 CSR 220-2.200 Sterile Pharmaceuticals. This rule established standards for the preparation, labeling and distribution of sterile pharmaceuticals by licensed pharmacies, pursuant to a physician's order or prescription.

PURPOSE: This rule is being rescinded and readopted in order to redefine sterile pharmaceuticals.

AUTHORITY: sections 338.140 and 338.280, RSMo 1994. Original rule filed May 4, 1992, effective Feb. 26, 1993. Amended: Filed Oct. 28, 1994, effective May 28, 1995. Rescinded: Filed Dec. 3, 2002.

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

PRIVATE COST: The 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 State Board of Pharmacy, Kevin Kinkade, Executive Director, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@mail.state.mo.us. 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 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED RULE

4 CSR 220-2.200 Sterile Pharmaceuticals

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

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

(C) 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) standards.

(D) 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.

(E) 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.

(F) 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.

(G) 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.

(H) Compounding: For purposes of these regulations, compounding simply means the mixing of ingredients to prepare a medication for patient use. The activity would include dilution, admixture, repackaging, reconstitution, and other manipulations of sterile products. Compounded sterile medications may include, but are not limited to injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.

(I) 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).

(J) Critical area: Any area in the controlled area where products or containers are exposed to the environment.

(K) 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.

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

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

(N) Expiration date: The date (and time, when applicable) beyond which a product should not be used (i.e. the product should be discarded beyond this date and time). Expiration date and time shall be assigned on the basis of both stability and risk level, which ever is a shorter period.

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

(P) Isolator (or barrier isolator): A closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are

designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits.

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

(R) 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.

(S) 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.

(T) 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, non-pyrogenicity and sterility.

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

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

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

(X) 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)).

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

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

1. Risk Level 1: Products that are sterile throughout the entire compounding process and are stored at room temperatures and completely administered within twenty-eight (28) hours from preparation.

2. Risk Level 2: Products that are sterile throughout the entire compounding process and are administered beyond twenty-eight (28) hours after preparation and storage at room temperatures.

3. Risk Level 3: Products that are—

A. Compounded from non-sterile ingredients or with non-sterile containers, or equipment before terminal sterilization; or

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

(2) Policy and Procedure Manual.

(A) A manual, outlining policies and procedures for compounding Risk Level 1, 2 and 3 products, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis.

(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.

(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. Disposal of used supplies 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 products must be quarantined under minimal risk for contamination or loss of identity in an identified quarantine area.

(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 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 manufacturers 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.

(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 manufacturers standards. Walls and ceilings must be disinfected weekly. All non-sterile equipment that is to come in contact with the sterilized final product must be sterilized before introduction in the clean room. Appropriate cleaning and disinfection of the environment and equipment are required.

(6) Apparel.

(A) Risk Level 1: In the controlled area, personnel shall wear low particulate, clean clothing covers. Head and facial hair shall be covered.

(B) Risk Level 2: In addition to Risk Level 1 requirements, gloves, gowns, and masks are required. During sterile preparation gloves shall be rinsed frequently with a suitable agent and changed when integrity is compromised.

(C) Risk Level 3: In addition to Risk Level 1 and 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.

(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 ampuls 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, final evaluation, and testing 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 USP standards for identity, purity, and endotoxin levels, as verified by a pharmacist. 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.

(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.

(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.

(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, if applicable:
3. Quarantine records, if applicable;
4. End-product evaluation and testing records; and
5. Ingredient validation records.

(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.

(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. Expiration date (and time when applicable);
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.

(11) Expiration Dating.

(A) Risk Level 1: All sterile products must bear an appropriate expiration date. Expiration 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.

(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 adequate to reasonably ensure that batches are sterile. A method for recalling batch products shall be established if end product testing yields unacceptable results. Each sterile preparation or batch must be tested for sterility, pyrogenicity, and potency. Sterile products compounded from non-sterile 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 product prepared from non-sterile drug components or from an intermediate compound from a non-sterile component 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 identity, potency, purity 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.

(D) Emergency Dispensing of a Risk Level 3 Sterile Product: When a compounded non-sterile to sterile product must be released prior to the completion of the sterility, pyrogenicity, particulate and potency test results, the sterile product may be conditionally released. The quantity of sterile product shall be limited to a quantity of product to meet the needs of the patient until all sterility and pyrogenicity tests are known.

(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 temperature-controlled delivery containers (as defined by USP standards). 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.

(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. 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.

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

(16) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.400 must be maintained.

AUTHORITY: sections 338.010, 338.140, 338.240 and 338.280, RSMo 2000. Original rule filed May 4, 1992, effective Feb. 26, 1993. Amended: Filed Oct. 28, 1994, effective May 28, 1995. Rescinded and readopted: Filed Dec. 3, 2002.

PUBLIC COST: This proposed rule will cost the State Board of Pharmacy an estimated twelve thousand five hundred ninety-seven dollars ($12,597) annually for the life of the rule. It is anticipated that the cost will recur annually for the life of the rule, may vary with inflation and is expected to increase annually at the rate projected by the Legislative Oversight Committee. A detailed fiscal note, which estimates the cost of compliance with this rule, has been filed with the Secretary of State.

PRIVATE COST: This proposed rule will cost private entities an estimated $1,351,600 during the first year of implementation of the rule and an estimated $3,322,500 annually for the life of the rule. 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 annually at the rate projected by the Legislative Oversight Committee. A detailed fiscal note, which estimates the cost of compliance with this rule, has been filed with the Secretary of State.

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the State Board of Pharmacy, Kevin Kinkade, Executive Director, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or email at pharmacy@mail.state.mo.us. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. A public hearing is scheduled for 5:00 p.m., Tuesday, February 4, 2003 at the Holiday Inn Select, 2200 I-70 Drive SW, Columbia, Missouri.*

FISCAL NOTE
PUBLIC ENTITY COST

I. RULE NUMBER

Title: 4 – Department of Economic Development
Division: 30 – State Board of Pharmacy
Chapter: 2 -- General Rules
Type of Rulemaking: Proposed Rule
Rule Number and Name: 4 CSR 220-2.200 Sterile Pharmaceuticals

Prepared October 22, 2002 by the State Board of Pharmacy

II. SUMMARY OF FISCAL IMPACT	
Affected Agency or Political Subdivision	**Estimated Annual Cost of Compliance**
State Board of Pharmacy (inspection of 29 Risk Level 1 Pharmacies)	$726.00
State Board of Pharmacy (inspection of 61 Risk Level 2 & 3 Pharmacies)	$3,055.00
State Board of Pharmacy (Inspector Training)	$2,016.00
State Board of Pharmacy (Training Video)	$200.00
State Board of Pharmacy (Purchase of Refractometers)	$6,000.00
State Board of Pharmacy (unknown costs estimates at $100 per inspector)	$600.
Total Annual Cost for the Life of the Rule	**$12,597.00**

WORKSHEET

Inspector time to inspect:

Risk Level 1 – 29 Pharmacies
1 extra hour x $25.04 per hour (average Inspector Salary)
x 29 pharmacies = $ 726.16 (cents rounded off) $ 726.00

Risk Level 2 & 3 – 61 Pharmacies
2 extra hours x $25.04 x 61 pharmacies = $3,054.88 (cents rounded up) $ 3,055.00

Training for Inspectors

Seminar Cost (est)	$200.00	
1 Night Hotel (est)	$ 90.00 (St. Louis CONUS)	
Meals 1 day (est)	$ 46.00 (St. Louis CONUS)	
Total	$ 336.00 x 6 inspectors =	$ 2,016.00

Purchase of Training Videos 1 set to be shared (est)	$ 200.00
Purchase of Refractometers estimated. at $1,000 x 6 –	$ 6,000.00
Unknown costs estimated at $100 per inspector –	$ 600.00

ASSUMPTIONS:

1. It will take an inspector approximately 1 extra hour of inspection time to inspect Risk Level 1 and 2 pharmacies providing sterile pharmaceutical products.

2. It will take an inspector approximately 1-2 extra hours of inspection time to inspect Risk Level 3 pharmacies providing sterile pharmaceutical products. This is the level where all non-sterile to sterile compounding of products will occur and will require the extra time for the inspector to inspect.

3. Based on the table in Assumption 1 of the Private Entity Fiscal Note, the breakdown of Risk Level 1 and 2 (combined) and Risk Level 3 was used to calculate the number of pharmacies that will require extra inspection time.

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

FISCAL NOTE
PRIVATE ENTITY COST

I. RULE NUMBER

Title: 4 – Department of Economic Development
Division: 30 – State Board of Pharmacy
Chapter: 2 – General Rules
Type of Rulemaking: Proposed Rule
Rule Number and Name: 4 CSR 220-2.200 Sterile Pharmaceuticals

Prepared October 22, 2002 by the State Board of Pharmacy

II. SUMMARY OF FISCAL IMPACT

First Year of Implementation

Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by types of the business entities which would likely be affected:	Estimate annual cost of compliance with the rule by the affected entities:
8	Class C: Long Term Care Pharmacies (barrier isolator - $8,950)	$71,600.00
8	Class C: Long Term Care Pharmacies (air conditioning, lighting, etc - $4,000	$32,000.00
39	Pharmacies (construction of clean room - $32,000)	$1,248,000.00
	Total Cost Incurred During First Year of Implementation of the Rule	**$1,351,600.00**

Annual Costs

Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by types of the business entities which would likely be affected:	Estimate annual cost of compliance with the rule by the affected entities:
61	Pharmacies (apparel/clothing - $250 per pharmacy each month)	$183,000.00
15	Pharmacies (testing of batches - 260 batches per pharmacy per year x $850 per batch)	$3,139,500.00
	Total Annual Cost for the Life of the Rule	**$3,322,500.00**

WORKSHEET:

1. Apparel/Clothing: Estimated at $250 per month per pharmacy. The cost will be dependent on the number of individuals employed by the pharmacy.

   $250 x 61 Pharmacies x 12 months = $ 183,000.00

2. Testing: A batch is defined as one mixture or lot of one product. A batch can effectively be one (1) dose of a medication or it could consist of a large number of multiple doses of one product. Each batch must be tested for sterility, potency and pyrogenicity. The costs of testing will be determined by the number of batches prepared by a pharmacy. In many instances, 1 set of tests can be done. The Board of Pharmacy has no accurate method to measure the exact number of batches prepared in pharmacies. The number will be determined by the volume of compounding done in a pharmacy.

   For the purposes of this fiscal note, it is estimated that an average sterile compounding pharmacy would prepare 1 batch per day.

Costs are:	
Sterility Testing, per Batch	$175
Potency Testing	$300 per active ingredient
x 2 average active ingredients	$600
Pyrogenicity Testing (per batch)	$ 30.....Total per batch $805.00

   1 Batch per day x 5 days x 52 weeks = 260 batches

   260 batches x 15 pharmacies = 3,900 batches

   3,900 batches x $805 per batch = $ 3,139,500.00

3. Class C: Long Term Care Pharmacies classified as a Risk Levels 2 and 3 may require the use of a barrier isolator. It is estimated that 50% of the 29 total Class C: Long Term Care pharmacies already comply with this rule and can be taken out of this equation. (29-14 = 15 pharmacies) This results in the estimated number of pharmacies affected to be 15 pharmacies. It is estimated that 50% of these 15 pharmacies may choose to purchase a barrier isolator in order to comply with new environmental standards. This would be 7.5 pharmacies, rounded to 8 pharmacies. The board estimates that each barrier isolator will cost approximately $8,950.

   8 Class C: Long Term Care Pharmacies x $8,950 = $ 71,600.00

   Estimated additional costs for air conditioning, lighting, etc
   $4,000 x 8 Pharmacies = $ 32,000.00

4. The following classes of pharmacies which are Risk Level 2 and 3, will be required to maintain a clean room if a barrier isolator is deemed insufficient for compounding needs:

1	Class B: Hospital/Outpatient
7	Class C: Long Term Care Pharmacies
23	Class D: Home Health
8	Class H: Sterile Product Compounding
39	

   A reasonable sized clean room is 8' x 10' x 10'. The board estimates the current cost to be $40.00 per cubic foot. 8' x 10' x 10' x $40.00 - $32,000.00

   39 pharmacies x $32,000 = $1,248,000.00

ASSUMPTIONS:

1. Pharmacies must maintain compliance with the class of pharmacy which they will practice, both when they complete a new application and when the renewal is submitted. Pharmacies may also complete a form to add to or delete classifications from their license at any time. The statistics used in this fiscal note are taken from the PROMO licensing system and is based on information provided to the Board by pharmacies.

Type of Pharmacy	Total Number	Percent that will Provide Sterile Products	Number that will Provide Sterile Products	Risk level	Inspector Breakdown Risk Level	
					1	2 & 3
Class B: Hospital Outpatient + Class D Home Health	1	100%	1	1 – RL 2/3		1
Class C: Long Term Care + C combinations	231	25%	57.75 rounded to 58	29 – RL1 29 – RL 2 and 3	29	29
Class D: Home Health – D Combinations	31	75%	23	23 – RL 2 and 3		23
Class H: Sterile Product Compounding – H combinations	8	100%	8	8 – RL 2 and 3		8
			90			61

2. There are categories of Risk Level 1, 2 and 3 in the field of sterile product compounding.

   A. Risk Level 1 : Products that are sterile throughout the entire compounding process and are stored at room temperatures and completely administered within 28 hours from preparation.

   B. Risk Level 2: Products that are sterile throughout the entire compounding process and are administered beyond 28 hours after preparation and storage at room temperatures.

   C. Risk Level 3: Products that are (1) compounded from non-sterile ingredients or with non-sterile containers, or equipment before terminal sterilization or (2) prepared by combining multiple ingredients (sterile or non-sterile) by using an open system transfer or open reservoir before terminal sterilization

   It is estimated that 50% of Class C: Long Term Care Pharmacies will be at Risk Level 1 and 50% will be at Risk Levels 2-3.

   It is estimated that 75% of Class D: Home Health and 100% of Class H: Sterile Product Pharmacies will be at Risk Levels 2 and 3.

   Risk Level 1 pharmacies that prepare I.V's currently will already have the equipment required and are in compliance with the existing regulation.

   These estimates are based on the fact that a licensee has the option to select the types of products that s/he chooses to compound. The licensee may choose to operate at a specific risk level, depending on his/her choice on issues such as expiration dating, i.e., the shorter expiration date on a product requires that the pharmacy operate as a Risk Level 1.

   It is estimated that a total of 61 pharmacies could be affected by this rule. It is further estimated that 25% of these 61 pharmacies which is equal to 15 pharmacies, are involved in sterile product compounding which includes non-sterile to sterile product compounding.

3. There is a great variance in the type of products involved in sterile product compounding, including but not limited to, antibiotics, parenteral nutrition products, chemotherapy and pain management medications. There is also a wide range of scenarios and it is virtually impossible to determine an "average" per pharmacy.

4. Sterile to sterile compounding does not require additional testing above present regulatory requirements. Non-sterile to sterile compounding does require testing. Since no average can be calculated and the size of a batch can be virtually any size and given that the majority of pharmacies directly affected by the requirement are small or part-time compounders. A reasonable estimate for batch testing is set at one (1) batch per day per 5 day work week.

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

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

4 CSR 220-2.400 Compounding Standards of Practice. The board is amending sections (1), (2) and (5)–(8) and adding new sections (6)–(8).

PURPOSE: The purpose of this amendment is to further define compounding and provide for more stringent guidelines for compounded products to assure public health and safety.

(1) Compounding is defined as the preparation, incorporation, mixing *[or assembling,]* **and** packaging or labeling of a drug or device as the result of a prescriber's prescription or drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing *[or assembling,]* **and** packaging or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.

(2) Manufacturing is defined as the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of *[commercially available]* **compounded** products *[from bulk compounds]* for *[resale by]* **distribution to other** pharmacies, practitioners or other persons.

(5) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the drug compounding process**. A separate log shall be maintained which includes**:

1. Methods for the compounding of drug products to insure that the finished products have the identity, strength, quality and purity they purport or are represented to possess;

2. Date of compounding;

3. Identity of the compounding pharmacist;

[4. Description of the compounding process; and

5. For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that also include, but are not limited to:

A. A listing of the drug products/ingredients, their amounts by weight or volume;

B. The order of drug product/ingredient addition, if necessary for proper compounding; and

C. The identity of the source, lot number and the expiration date of each drug product/ingredient, as well as an in-house lot number.]

5. A listing of the drug products/ingredients, their amounts by weight or volume;

6. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

7. The identity of the source, lot number and the expiration date of each drug product/ingredient, as well as an in-house lot number and an expiration date for bulk compounded products; and

8. An identifying prescription number or a readily retrievable unique identifier.

(C) *[In the case where a quantity of a compounded drug product in excess of that to be initially dispensed is prepared, the excess product shall be labeled or documentation referenced with the complete list of drug products/ingredients and the preparation date. 1.]* Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.

1. The compounding of drug products in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need, shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched product that represents a three (3)-month supply.

2. Creams, ointments, lotions, liniments or other compounded products intended for external use may be batched in the same manner as provided for in paragraph (5)(C)1. of this rule that represents a one (1)-year supply.

[3. In the event that any excess of a compounded product should require an expiration date that is less than three (3) months, the appropriate date should be placed on the container label of the excess product or documentation referenced with the expiration date noted.]

(D) Any excess compounded products shall be stored and accounted for under conditions dictated by its composition and stability characteristics to insure its strength, quality and purity. **Excess product shall be labeled with the name of the drug(s), an in-house lot number and an expiration date.**

(E) Records as outlined in this *[section]* **rule** shall be retained and made readily retrievable for inspection for two (2) years from the date of compounding.

(F) The actual name of each active or therapeutic ingredient contained in a compound shall be listed on the label of any product provided to a consumer.

(6) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. These responsibilities apply equally to commercially available products that are dispensed to patients without compounding or other manipulation and to products that have been repackaged, diluted, blended, mixed or otherwise manipulated in any way prior to dispensing. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

1. Personnel are capable and qualified to perform their assigned duties;

2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards. This may be established by maintaining a certificate of analysis when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed on a routine basis;

3. There is assurance that processes are always carried out as intended or specified;

4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors;

5. There is adequate separation of quality control functions and decisions from those of production; and

6. All finished products, as a condition of release, must be individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

(B) The pharmacy is responsible for developing a drug monitoring system for compounded products. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services. This shall include but not be limited to infection rates, incidence of adverse drug reactions, incidence of recalls and complaints from prescribers or clients. In the case of a recall or complaint, the pharmacy shall document the nature of the recall, identity of any patients involved, the problem identified and any corrective action taken to assure public health and safety.

(7) Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal Drug Administration (FDA) approved drug products is prohibited. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In such a case, there shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for the particular variation of the compound for the particular patient.

(8) Any alteration, change or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription order from an authorized prescriber.

[(6)] **(9)** Any person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with drug products/ingredients, drug product containers, container closures and in-process materials, until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the products being compounded.

[(7)] **(10)** In accordance with federal law, pharmacists shall not offer compounded drug products to other pharmacies, practitioners or commercial entities for subsequent resale*[,]* **or administration,** except in the course of professional practice for a prescriber to administer to an individual patient by prescription. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded products.

[(8)] **(11)** In addition to the requirements outlined in this rule, all standards and requirements as outlined in 4 CSR 220-2.200 Sterile Pharmaceuticals must be adhered to whenever compounding involves the need for aseptic procedures or requires the use of or results in an intended sterile pharmaceutical product.

*AUTHORITY: sections 338.010, 338.140, 338.240 and 338.280, RSMo [1994] **2000**. Original rule filed Aug. 25, 1995, effective April 30, 1996. Amended: Filed Dec. 3, 2002.*

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

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

*NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the State Board of Pharmacy, Kevin Kinkade, Executive Director, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or e-mail at pharmacy@mail.state.mo.us. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. A public hearing is scheduled for 5:00 p.m., Tuesday, February 4, 2003 at the Holiday Inn Select, 2200 I-70 Drive SW, Columbia, Missouri.*

Title 4—DEPARTMENT OF ECONOMIC DEVELOPMENT
Division 220—State Board of Pharmacy
Chapter 2—General Rules

PROPOSED AMENDMENT

4 CSR 220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy. The board is proposing to delete section (2).

PURPOSE: This rule is being amended to be consistent with the changes proposed in the board's rule 4 CSR 220-2.200.

[(2) Pharmacies that participate in shared services are hereby exempt from the provisions of 4 CSR 220-2.200 Sterile Pharmaceuticals, subsection (4)(D) regarding the delivery of such products directly to the patient.]

AUTHORITY: sections 338.140, 338.240, and 338.280, RSMo 2000 and 338.210 and 338.220, RSMo Supp. 2001. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002.

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

PRIVATE COST: The 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, Kevin Kinkade, Executive Director, PO Box 625, Jefferson City, MO 65102, via facsimile to (573) 526-3464 or e-mail at pharmacy@mail.state.mo.us. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.010 Definitions. The commission is adding new definitions at sections (1) and (16) and is amending previously numbered sections (1), (2), (5), (6), (7), (15), (17), (20), and (21).

PURPOSE: This amendment includes definitions of additional terms used in this chapter and provides for deleting and/or clarifying other definitions.

(1) Active project. Any contract of which final acceptance has not been made.

[(1)] **(2)** Affiliate. *[A person, firm or corporation is an affiliate of another person, firm or corporation]* **Persons are affiliates of each other** if, directly or indirectly, either one controls or has the power to control the other*[,]***;** or **a** third person*[s or a firm]* controls or has the power to control both. *[Examples]* **Indicia** of control include, but are not limited to: interlocking management or

ownership, identity *[or]* **of** interests among family members, shared facilities *[or]* **and** equipment, *[or]* common use of employees**, or a business entity organized following the suspension, debarment, or disqualification of a person which has the same or similar management, ownership or principal employees as the suspended, debarred, or disqualified person**.

[(2)] **(3)** Bidder. Any individual, partnership, corporation or *[any person or firm participating as part of a]* joint venture *[in]* submitting a *[proposal]* **bid** to *[the commission to perform the work contemplated]* **supply goods or to perform the work contemplated**.

[(3)] **(4)** Chief engineer. The chief engineer of the Missouri Department of Transportation.

[(4)] **(5)** Commission. The Missouri Highways and Transportation Commission.

[(5)] **(6)** Construction **and materials**. The functional unit within the department which is responsible for administering all construction contracts awarded by the commission.

[(6)] **(7)** Contractor. *[The individual proprietorship, partnership, limited partnership, corporation, limited liability company, limited liability partnership, limited liability corporation or firm of whatever organizational form participating in a joint venture, undertaking performance of the work under the terms of a contract with the commission and acting directly or through his/her/its agents, employees or subcontractors.]* **Any individual or any legal entity including its officers and directors, that submits bids or proposals for or is awarded or may reasonably be expected to submit bids or proposals for or be awarded a commission contract. This definition includes any subcontractor that conducts business with the commission or department as an agent or representative of a contractor and any individual or legal entity that conducts business with the department as an agent or representative of a contractor.**

[(7)] **(8)** Contractor performance review committee consists of the following: director of operations, chairperson; director of project development; state design engineer; state construction **and materials** engineer; state bridge engineer; or an authorized representative acting on behalf of any one of them.

[(8)] **(9)** Contractor representative. A general partner, officer of a corporation or other proper term depending on the company or organization, as one having authority of position, stated in writing.

[(9)] **(10)** Department. The Missouri Department of Transportation (MoDOT).

[(10)] **(11)** District. One (1) of ten (10) geographic regions of Missouri established for administrative purposes within the department.

[(11)] **(12)** District engineer. The engineer in charge of a district.

[(12)] **(13)** Mean. The sum of all of the individual contractor's ratings divided by the total number of ratings.

[(13)] **(14)** Nonresponsible contractor. A contractor determined by the commission to lack one (1) or more of the qualities associated with a responsible bidder or responsible contractor.

[(14)] **(15)** Notice of rating. Notice of the rating by the resident engineer in a contractor performance questionnaire or of the annual rating shall be sent by mailing a copy of the contractor performance questionnaire or of a writing containing the annual rating to the contractor at the contractor's address contained in its most recent contractor questionnaire required by the Missouri Standard Specifications for Highway Construction. The department will keep a written record of the persons to whom such notices of ratings were sent and of the address and date they were sent for a period of at least ten (10) years in the case of the contractor performance questionnaire and at least ten (10) years in the case of the notice of the annual rating, which record shall prove the mailing of the notice of rating. Further, it shall be presumed that a notice of rating sent by mail was received by the contractor on the second day, which is not a Sunday or holiday, after the day the written record states it was sent excepting only if a different date is shown by a delivery receipt of the United States Postal Service.

(16) Person. Any individual, corporation, partnership, association, unit of government or legal entity, however organized.

[(15)] **(17)** Principal. *[A person is a principal of a firm if s/he is an officer, director, owner, partner or other person with that firm who has primary management, supervisory or bidding duties or authority.]* **Officer, director, owner, partner, key employee, or other person within an organization with primary management or supervisory responsibilities; or a person who has critical influence on or substantive control over a transaction, whether or not employed by the participant.**

[(16)] **(18)** Resident engineer. The individual employed by the department and assigned to a district, holding that title, who is the department's representative assigned the immediate control and administration of a commission project awarded by contract to a contractor for construction. Whenever appropriate, it also refers to his/her designated representative.

[(17)] **(19)** Responsible bidder or responsible contractor. *[A contractor, or any contractor or firm which participates collectively in a joint venture, which is capable financially, skilled and has sufficient integrity, experience and resources of all kinds, to promptly complete a project awarded, to provide a satisfactory quality of work, in compliance with the contract, in cooperation with the department and others, and in a safe manner.]* **A person who has the capability in all respects to perform fully the contract requirements, and the integrity and reliability which will assure good faith performance.**

[(18)] **(20)** Sample. A statistical subset of the total number of contractors doing work for MoDOT during the rated year.

[(19)] **(21)** Specialty contractors. Those contractors who have performed eighty-five percent (85%) or more of their work in one specification area as set forth in Divisions 200–900 in the Missouri Standard Specifications for Highway Construction.

[(20)] **(22)** Standard deviation. The square root of the average **of the squared** difference between the individual ratings and their mean.

[(21)] **(23)** State construction **and materials** engineer. The registered professional engineer in charge of *[the]* construction *[unit]* **and materials administration** within the department.

[(22)] **(24)** Subcontractor. Any individual, partnership, corporation or a person or firm participating as part of a joint venture, to whom the contractor sublets any part of the work under a commission contract.

[(23)] **(25)** Successor. A person, firm or corporation is a successor to another if it is a business entity organized following the disqualification of the other, and it has the same or similar management, ownership or principal employees as the disqualified person, firm or corporation.

[(24)] **(26)** Weighted average. The weighted average is the sum of a sample lot's adjusted individual ratings. The adjustment factor is ($ volume of sample)/($ volume of sample lot total).

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000 and 227.100 RSMo Supp. 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency amendment filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Amended: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Nov. 9, 1999, effective Nov. 19, 1999, expired May 16, 2000. Amended: Filed Nov. 9, 1999, effective May 30, 2000. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.030 Rating Categories for Evaluating the Performance of a Contractor. The commission is amending section (1) and subsections (1)(B) and (C), sections (3) and (4), and adding subsection (1)(D).

PURPOSE: This amendment provides for an additional category for rating contractors performance, clarifies the determination of the individual category ratings, and revises the categories importance factors and includes the factor for the additional category.

(1) Contractors awarded commission projects shall be rated on the following *[three (3) basic]* **four (4)** categories:

(B) Contract compliance includes, but is not limited to, timely compliance, compliance with traffic control, handling of traffic, *[submittal of required documents,]* maintenance of the work site and adherence to environmental requirements; *[and]*

(C) Prosecution and progress includes, but is not limited to, proper planning and execution, achieving the progress schedule, coordinating subcontractors and timely completion*[.]***; and**

(D) Contract administration includes, but is not limited to submittal of required documents.

(3) A contractor's individual category ratings in the category of "Quality" **and "Contract Compliance"** will be determined by comparing the total number of points awarded to the total number of points *[assigned, to]* **possible for** each question completed, based on the weighted average of the total dollar value of work completed *[to date]* **during the rated period** and pertaining to *[each]* **applicable** sections of the questionnaire. A contractor's individual category ratings, *[for the remaining categories,]* **in the category of "Prosecution & Progress" and "Contract Administration"** will be determined by comparing the total number of points awarded *[in each category]* to the total number of points *[assigned to]* **possible for** each question completed *[in that category]***, based on the weighted average of the contract dollar value**.

(4) For overall rating purposes, the categories are assigned importance factors as follows: quality of work, *[thirty-three and one-third percent (33.33%)]* **thirty percent (30%)**; contract compliance, *[thirty-three and one-third percent (33.33%)]* **twenty percent (20%)**; *[and]* prosecution and progress, *[thirty-three and one-third percent (33.33%)]* **thirty percent (30%), and contract administration, twenty percent (20%)**.

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000 and 227.100, ***RSMo Supp. 2002****. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency amendment filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Amended: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.*

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.040 Contractor Performance Questionnaire Used in Evaluating Contractor Performance. The commission is amending sections (3) and (5).

PURPOSE: This amendment provides for an additional evaluation category.

(3) The Contractor Performance Questionnaire contains questions that are assigned to the *[three (3)]* **four (4)** evaluation categories: quality of work; prosecution and progress; *[and]* contract compliance**; and contract administration**. Not all questions will be applicable on any certain project and will, therefore, not be completed.

(5) A copy of the Contractor Performance Questionnaire may be obtained by submitting a written request to the following address: Missouri Department of Transportation, Construction **and Materials**, P*[.]*O*[.]* Box 270, Jefferson City, MO 65102.

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000 and 227.100, RSMo Supp. 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency rescission and rule filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Rescinded and

readopted: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Nov. 9, 1999, effective Nov. 19, 1999, expired May 16, 2000. Amended: Filed Nov. 9, 1999, effective May 30, 2000. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.050 Procedure and Schedule for Completing the Contractor Performance Questionnaire. The commission is amending sections (2), (3) and (4), and adding subsections (3)(A), (3)(B), and (3)(C).

PURPOSE: This amendment provides for three (3) separate contractor performance reports and provides a brief description of each.

(2) The Contractor Performance Questionnaire shall be completed in accordance with this chapter and with written instructions given the resident engineer by the Construction **and Materials** unit. A copy of the current instructions may be obtained from the state construction **and materials** engineer.

(3) Each Contractor Performance Report shall be completed *[on all projects that were active during the rated year and will be completed within thirty (30) days after final project acceptance, but shall be completed no later than January 15, whichever comes first. Prior reports on the same contract shall not bind or govern the completion of a final report.]* **as an Interim Report, Annual Report, or Final Report. The report shall note which type of report it is. The following criteria govern each type of report and when it is completed:**

(A) Interim Report. This midseason report is completed on all contractors currently on probation or which have been disqualified when approximately fifty percent (50%) of the work on the project for the year is completed or by September 1, whichever comes first. An Interim Report may also be completed at any time, at the discretion of the engineer, for any contractor when there is a serious concern regarding contractor performance on the project. This report is for informational purposes only.

(B) Annual Report. This report is completed on all active projects. Each Annual Report shall be completed on all projects that were active during the rated year and shall be completed no later than January 15.

(C) Final Report. This report is completed on all projects having received final acceptance during the rated year. The Final Contractor Performance Reports will be completed within thirty (30) days after final project acceptance, but shall be completed no later than January 15, whichever comes first. Prior reports on the same contract shall not bind or govern the completion of a final report.

(4) The resident engineer shall sign and date the Contractor Performance Questionnaire when *[s/he]* **he/she** completes his/her rating. The contractor's representative, at his/her election, may meet privately with the resident engineer to review the questionnaire. If the contractor's representative does review the questionnaire, *[s/he]* **he/she** shall sign and date it as an acknowledgment that *[s/he]* **he/she** has reviewed it. A copy of the questionnaire shall be furnished to the contractor by the resident engineer. If the contractor's representative does not return a signed questionnaire to the resident engineer within two (2) weeks after it has been mailed to him/her, the questionnaire shall be final, with no further comment to be considered by the contractor's representative.

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000 and 227.100, RSMo 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency rescission and rule filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Rescinded and readopted: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Nov. 9, 1999, effective Nov. 19, 1999, expired May 16, 2000. Amended: Filed Nov. 9, 1999, effective May 30, 2000. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.060 Explanation of Standard Deviation Rating System for all Contractors. The commission is amending section (3).

PURPOSE: This amendment provides for a fourth category in the rating of contractors.

(3) Overall and Category Ratings. On an annual basis, each contractor who has done work for the commission and which the commission has completed a Contractor Performance Questionnaire, shall be given a rating for each of the *[three (3)]* **four (4)** categories: quality of work, prosecution and progress *[and]***,** and contract compliance**, and contract administration** as well as receiving an overall rating which combines the ratings of all of the *[three (3)]* **four (4)** categories.

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000, and 227.100, RSMo 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Amended: Filed April 13, 1994, effective Oct. 30, 1994. Amended: Filed June 12, 1996, effective Jan. 30, 1997. Emergency rescission and rule filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Rescinded and readopted: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.070 Procedure for Annual Rating of Contractors. The commission amends sections (1) through (5).

PURPOSE: This amendment makes reference to the current name of the unit responsible for determination of annual ratings of contractors and provides that annually, a contractor's overall and category performance will be for all contracts on all active projects rather than limiting to work performed during a specific time period. This amendment also provides that upon determination of a contractor's rating, action recommendations will be made to the chief engineer and that all contractors shall be notified of their annual ratings and any probation or disqualification shall become effective upon the date of the notification. Further, this amendment adds that the final annual ratings propose a level of performance on the contractor's status to bid or perform work as a subcontractor or vendor.

(1) Annual Rating of Contractors. The *[C]***construction and materials** unit shall be responsible for the determination of the annual ratings of contractors. The *[C]***construction and materials** unit will annually determine a contractor's overall and category performance rating for all contracts on *[which work was performed during the period, January 1 through December 31]* **all active projects**. The ratings for the categories Quality, *[and]* Contract Compliance**, and Contract Administration** will be based on a weighted average of the dollar value of all work completed during the rated year on all contracts. The categor*[y]***ies**, Prosecution and Progress **and Contract Administration**, shall use contract dollar totals for determining the contractor's performance rating.

(2) Contractor Rating Groups. For purposes of *[evaluating]* **recognizing outstanding** contractor performance, contractors shall be divided into *[two (2)]* **four (4)** sample groups based upon whether the contractor is a specialty contractor and on the dollar value of the work completed during the rated year.

(A) Contractor Groups. Group one contractors shall be the ten (10) contractors who have the largest dollar value of work completed during the rated year. Contractors not included in group one or the specialty contractor group shall be divided in half as group two, medium volume, contractors and group three, light volume, contractors.

[1. Sample lot one. Sample lot one shall include all contractors belonging in group one contractors and group two, medium volume contractors.

2. Sample lot two. Sample lot two shall include all contractors belonging in group three, light volume contractors and specialty contractors.]

(B) *[Commission]* Determination of Contractor *[Groups and Sample Lots]* **Ratings**. *[The commission shall determine all contractor groups and sample lots for the purposes of grouping contractors.]* **The construction and materials unit shall determine contractor ratings and make action recommendations to the chief engineer.**

(3) *[Upon the Construction unit's annual rating of all contractors, the ratings shall be reviewed by the state construction engineer.]* Upon the *[Construction unit's]* **chief engineer's review and** approval, all contractors shall be notified in writing of their annual ratings. The *[C]***c**onstruction **and materials** unit will act on each contractor or not, based on the overall and category ratings the contractor receives. These actions may range from recognizing very outstanding performance, to recommending that a contractor be declared nonresponsible. **Probation or disqualification shall become effective upon the date stated in the written notification.**

(4) Review Process. If the contractor disagrees with any particular response on the questionnaire and cannot resolve the dispute with the resident engineer, *[s/he]* **it** may request in writing that the district engineer review the matter. Such request must be made to the district engineer within twenty-eight (28) days from the date of the mailing of the questionnaire form to the contractor. However, the contractor's representative shall first have discussed the questionnaire response with the resident engineer in order to resolve the dispute. Upon receiving the contractor's written request to review the particular area of discrepancy on the questionnaire, the district engineer shall review the matter and provide the contractor with a written response regarding the particular area of dispute between the contractor and the resident engineer. All reports shall be submitted to the *[C]***c**onstruction **and materials** unit before, but no later than, February 15.

(A) "Unacceptable" Rating. No request for review to the committee or to the department regarding the contractors' performance ratings is permitted or is provided under this chapter, with the exception of contractors who receive an unacceptable performance rating.

1. The contractor must have received either an unacceptable category or overall performance rating and timely discussed the dispute with the resident engineer and made a timely written request for review by the district engineer of the particular rating on the questionnaire that the contractor disagrees with as provided in this chapter.

2. **If the contractor has complied with the requirements of paragraph (4)(A)1. above,** *[T]***t**he contractor shall have ten (10) working days to request an informal hearing to review an unacceptable performance rating.

3. The contractor shall submit its request for an informal hearing to the following address: Missouri Department of Transportation, Construction **and Materials**, P*[.]*O*[.]* Box 270, Jefferson City, MO 65102.

(5) No Further Commission Action. As to contractor performance ratings of which no review is requested or permitted under this rule, upon the determination by the *[C]***c**onstruction **and materials** unit regarding the annual ratings of all contractors and the approval of the chief engineer of the annual ratings, the ratings of the contractors

shall become final for purposes of this chapter and the effect of **this chapter on** a level of performance **on the contractor's status to bid or perform work as a subcontractor or vendor on commission contracts**. No commission action is necessary regarding the annual ratings of the contractors.

AUTHORITY: sections 226.020, 226.130 227.030, RSMo 2000 and 227.100, RSMo 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency rescission and rule filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Rescinded and readopted: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Nov. 9, 1999, effective Nov. 19, 1999, expired May 16, 2000. Amended: filed Nov. 9, 1999, effective May 30, 2000. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.080 Determination of Nonresponsibility. The commission amends sections (1) and (2).

PURPOSE: This amendment provides that contractors shall be disqualified as opposed to suspended or debarred when a determination of nonresponsibility has been made and that in addition to being disqualified from bidding, the contractor may also be disqualified from performing work as a subcontractor or vendor. This amendment clarifies the effect and consequences that a determination of nonresponsibility has upon the contractor which has been disqualified under the provisions of this chapter.

(1) Unacceptable Category or Overall Rating. A contractor who receives an initial unacceptable rating shall be placed on probation. Any contractor who is on probation and receives a second unacceptable rating shall be declared nonresponsible and shall be *[suspended]* **disqualified from bidding and, may be declared disqualified from performing work as a subcontractor or vendor,** for a period of one (1) year. *[During this suspension period, no bids shall be accepted from the contractor.]* At the conclusion of this *[suspension]* **disqualification** period, the contractor shall be reinstated on a probationary basis and be allowed to bid on commission projects. Any contractor who *[has previously been suspended]* **is currently disqualified** for unacceptable performance*[, has a current deficiency status,]* and receives a subsequent unacceptable rating shall be declared nonresponsible and *[shall be barred]* **disqualified** from bidding on commission projects **and, may be declared disqualified from performing work as a subcontractor or vendor,** for a period of three (3) years. After the three (3) year *[debarment]* **disqualification** period has ended, the contractor may be reinstated on a probationary basis. Any deficiency status shall remain in effect until the contractor obtains an annual average category rating in all categories.

(2) Affiliates of the Contractor. Any probation*[, suspension or debarment]* **or disqualification** of the contractor shall be equally applicable to all affiliates of the contractor.

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000 and 227.100, RSMo 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency rescission and rule filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Rescinded and readopted: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 7—DEPARTMENT OF TRANSPORTATION
Division 10—Missouri Highways and Transportation Commission
Chapter 10—Contractor Performance Rating to Determine Responsibility

PROPOSED AMENDMENT

7 CSR 10-10.090 Reservation of Rights to Recommend or Declare Persons or Contractors Nonresponsible on Other Grounds. The commission amends sections (1) and (2).

PURPOSE: This amendment provides for a fourth rating category.

(1) Nothing in this chapter shall be construed to waive, limit or restrict the right of the *[chief engineer]* **department** to *[recommend]* **determine** that a contractor be declared nonresponsible, if any individual rating on one (1) or more of the *[three (3)]* **four (4)** rating categories specified in 7 CSR 10-10.030 is so low that *[the chief engineer has]* **there is** cause to believe that the contractor cannot responsibly or competently perform contract work generally, or of a particular type or description. The *[commission]* **department** reserves the right to declare *[nonresponsible]* **disqualified** any contractor which it finds to be incompetent or nonresponsible, with *[those]* **such** terms and conditions governing the disqualification as it deems appropriate.

(2) Nothing in this chapter shall be construed to waive, limit or restrict the right of the *[chief engineer]* **department or of the commission** to *[recommend]* **determine** that a person, firm, corporation or contractor be *[declared nonresponsible]* **disqualified** for any other legal reason, circumstance, or for financial irresponsibility that would support a finding that the person, firm, corporation, or contractor was nonresponsible. The commission reserves the right to

declare nonresponsible any person, firm, corporation or contractor which it finds to be nonresponsible **or ineligible** upon sufficient legal grounds, with those terms and conditions governing *[the disqualification]* **that action** as it deems appropriate.

AUTHORITY: sections 226.020, 226.130, 227.030, RSMo 2000 and 227.100, RSMo 2002. Original rule filed Dec. 31, 1990, effective July 8, 1991. Emergency rescission and rule filed Nov. 20, 1997, effective Jan. 1, 1998, expired June 29, 1998. Rescinded and readopted: Filed Nov. 20, 1997, effective May 30, 1998. Emergency amendment filed Dec. 1, 2000, effective Jan. 1, 2001, expired June 29, 2001. Amended: Filed Dec. 1, 2000, effective May 30, 2001. Amended: Filed Nov. 20, 2002.

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 Transportation, Mari Ann Winters, Secretary to the Commission, PO Box 270, Jefferson City, MO 65102. 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 11—DEPARTMENT OF PUBLIC SAFETY
Division 40—Division of Fire Safety
Chapter 5—Elevators

PROPOSED AMENDMENT

11 CSR 40-5.020 Scope and Application. The division is amending section (2).

PURPOSE: This amendment adds equipment exemptions per state statute change.

(2) These rules and regulations do not apply to—

(B) Tiering, piling, feeding, or similar machines or devices giving service within only one (1) story; *[or]*

(C) Elevator equipment installed in a single-family residence or those installed completely within a single unit of a multi-family residence. These regulations do apply to elevator equipment installed in the common areas of multi-family residences*[.]***;**

(D) Any device inaccessible to the public, not used to transport passengers and built prior to January 1, 1940; or

(E) Single person elevator lifts and belt manlifts operating only in grain elevators or feed mills unless inspection is requested by the owner.

*AUTHORITY: section 701.355, RSMo [1994] **2000**. Original rule filed Aug. 26, 1998, effective July 1, 1999. Amended: Filed Dec. 16, 2002.*

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 Division of Fire Safety, PO Box 844, Jefferson City, MO 65102. 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 11—DEPARTMENT OF PUBLIC SAFETY
Division 40—Division of Fire Safety
Chapter 5—Elevators

PROPOSED AMENDMENT

11 CSR 40-5.050 New Installations. The division is amending sections (1) and (4).

PURPOSE: This amendment specifies codes and editions adopted by the Elevator Safety Board.

(1) Minimum Standards. All new elevator equipment installed on or after the effective date of these rules and regulations shall be constructed and installed in conformity with the standards prescribed in the American Society of Mechanical Engineers, ASME A17.1, **1996 edition** *Safety Code for Elevators and Escalators,* A18.1, **1999 edition,** *Safety Standards for Platform Lifts and Stairway Chair Lifts,* **ASME A17.2.1 1996 edition, Inspector's Manual for Electric Elevators, ASME A17.2.2 1997 edition, Inspector's Manual for Hydraulic Elevators, ASME A17.2.3 1998 edition, Inspector's Manual for Escalators and Moving Walks,** *American National Standard Safety Code for Manlifts* ANSI A90.1, **1998 edition,** *American National Safety Code for Personnel Hoist* ANSI A10.4 *[latest version adopted and amended by the Elevator Safety Board,]* **1990 edition,** unless as exempted by section 701.359, RSMo. *[These standards are hereby adopted by reference and incorporated herein.]*

(4) Operating Certificate for New Installations. Prior to operating*[,]* a new installation**, an** operating certificate must be obtained in accordance with 11 CSR 40-5.100 as listed herein.

*AUTHORITY: section 701.355, RSMo [1994] **2000**. Original rule filed Aug. 26, 1998, effective July 1, 1999. Amended: Filed Aug. 17, 2000, effective Feb. 28, 2001. Amended: Filed Dec. 16, 2002.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred ($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 Division of Fire Safety, PO Box 844, Jefferson City, MO 65102. 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 11—DEPARTMENT OF PUBLIC SAFETY
Division 40—Division of Fire Safety
Chapter 5—Elevators

PROPOSED AMENDMENT

11 CSR 40-5.065 Missouri Minimum Safety Codes for Existing Elevator Equipment. The division is amending section (1) and changing section (2) to subsection (1)(T).

PURPOSE: This amendment clarifies purposes and provides more specific direction.

(1) **In a political subdivision or municipality that had adopted an edition of ASME A17.1 code, annual safety inspections and tests shall be performed to the code adopted and enforced at the time the elevator equipment was installed.** The following standards apply to all existing elevator equipment installed prior to *[the effective date of these rules and regulations]* **July 1, 1999** as provided in 11 CSR 40-5.060. Any installation which is in compliance with the latest ASME A17.1 version adopted and amended by the Elevator Safety Board, unless as exempted by 701.359, RSMo shall be considered to be in compliance with 11 CSR 40-5.065. *[The foregoing standards are incorporated by reference in this rule.]*

(A) Hoistways.

1. Each passenger elevator hoistway landing shall be protected with a door or gate. The door or gate shall be of solid construction and shall guard the entire entrance.

2. All automatic passenger elevators with power doors shall have non-vision panels on hoistway doors.

3. Each hoistway landing in any elevator hoistway shall be continuously provided with a properly working door or gate.

4. Where freight elevator hoistway doors or gates are of open or lattice construction they shall be at least six feet (6') high and shall come within two inches (2") of the floor when closed. Gates shall be constructed as to reject a ball two inches (2") in diameter. They shall withstand a force of two hundred fifty (250) pounds pressure applied in the center of the gate without breaking or forcing it out of its guides.

5. Manually operated bi-parting entrances of elevators which can be operated from the landings shall be provided with pull straps on the inside and outside of the upper panel where the lower edge of the upper panel is more than six feet six inches (6'6") above the landing when the panel is in the fully opened position.

[6. All freight elevators having wooden hoistway gates in an area where power loading equipment, such as fork trucks, electric mules, etc. are used shall have an acceptable means to restrain the power equipment from running through such wooden gates.]

[7.] **6.** Each hoistway door or gate shall be provided with interlocks designed to prevent the car from moving unless the doors or gates are closed. Where doors or gates do not lock when closed they shall lock when the elevator is not more than twelve inches (12") away from the floor. Passenger elevator hoistway doors shall be closed and locked before the car leaves the floor.

[8.] **7.** All hoistway-door interlocks shall be of the hoistway unit type.

[9.] **8.** Automatic fire doors shall not lock any landing opening in the hoistway enclosure from the hoistway side nor lock any exit leading from any hoistway landing to the outside of the building.

[10.] **9.** Emergency keys for hoistway doors and service keys shall be kept readily accessible to authorized persons.

[11.] **10.** Access means shall be provided at one upper landing to permit access to the top of the car, and at the lowest landing if this landing is the normal point of access to the pit.

[12.] **11.** Each hoistway door or gate, which is counterweighted, shall have its weights enclosed in a box-type guide or run in metal guides. The bottom of the guides or boxes shall be so constructed as to retain the counterweight if the counterweight suspension means breaks.

[13.] **12.** Hoistways containing freight elevators shall be fully enclosed. Enclosures shall be unperforated to a height of six feet (6') above each floor or landing and above the treads of adjacent stairways. Unperforated enclosures shall be so supported and braced as to deflect not over one inch (1") when subjected to a force of one hundred (100) pounds applied horizontally to any point. Open work enclosure may be used above the six-foot (6') level and shall reject a ball two inches (2") in diameter.

[14.] **13.** Hoistways containing passenger elevators shall be fully enclosed and the enclosure shall be of solid construction to its full height.

[15.] **14.** Except where vertical opening bi-parting doors are provided, all elevators provided with automatic leveling, inching or teasing devices and where the landing sills project within the hoistway, shall be equipped with a bevel on the underside of the landing sill. Bevels shall be constructed of smooth concrete or not less than sixteen (16) gauge metal securely fastened to the hoistway entrance. Bevels shall extend the full depth of the leveling zone plus three inches (3").

[16.] **15.** Every hoistway window opening seven (7) stories or less on an outside wall above a thoroughfare and every such window three (3) stories or less above a roof of the building or of an adjacent building shall be guarded to prevent entrance by fire or emergency rescue persons. Each such window shall be marked "hoistway" in a readily visible manner.

16. All electrical wiring in the hoistway shall be enclosed in metal conduit, flexible conduit or metal raceways or be in compliance with NFPA 70, *National Electric Code*.

17. No pipes conveying liquids, gases or vapors shall be located in a hoistway. Exception: branch lines for sprinkler system and low pressure steam lines for heating.

(B) Car Enclosure: Passenger.

1. Each passenger car shall be fully enclosed except on the sides used for entrance and exit. The enclosure shall be of solid construction. Grill work at the top of the sides shall not be more than eight inches (8") high. If the car is provided with a solid door and there is no grill work in the enclosure, adequate means of ventilation shall be provided.

2. Each passenger car enclosure shall have a top constructed of solid material. The top shall be capable of sustaining a load of three hundred (300) pounds on any area of two feet (2') on a side and one hundred (100) pounds applied at any point. Simultaneous application of these loads is not required.

3. Passenger car enclosure tops shall have an emergency exit with cover. Opening size shall be as set forth in ASME A17.1, rule 204.1E**, 1955 edition**. Exception: Hydraulic elevators provided with a manual lowering valve.

4. Each passenger car shall have a door or gate at each entrance. Doors or gates shall be of the horizontally sliding type. Doors shall be of solid construction. Gates shall be of the collapsible type. Gates and doors shall conform to ASME A17.1, rule 204.4**, 1955 edition**.

5. Each passenger car door or gate shall have an electric contact to prevent the car from running with doors or gates open. Exceptions:

A. By a car-leveling or truck-zoning device;

B. By a combination hoistway access switch and operating device; or

C. When a hoistway access switch is operated.

6. All automatic passenger elevators with power doors shall have reopening devices on the doors, designed to reopen doors in the event the doors should become obstructed.

7. Where a car door or gate of an automatic or continuous-pressure operation passenger elevator is closed by power, or is of the automatically released self-closing type, and faces a manually operated or self-closing hoistway door, the closing of the car door or gate shall not be initiated unless the hoistway door is in the closed position; and the closing mechanism shall be so designed that the force necessary to prevent closing of a horizontally sliding car door or gate from rest shall be not more than thirty (30) pounds. Exception: Where a car door or gate is closed by power through continuous pressure of a door-closing switch, or of the car operating device, and where the release of the closing switch or operating device will cause the car door or gate to stop or to stop and reopen.

8. Each passenger car shall have lighting inside the enclosure of not less than five (5) foot-candles. Bulbs and tubes shall be guarded to prevent breakage.

9. Each passenger elevator shall have a capacity plate prominently displayed in its enclosure. The capacity plate shall list its capacity in pounds.

10. All passenger elevator car floors shall be maintained so that persons are not exposed to the hazards of tripping or falling.

11. All automatic passenger elevators shall be provided with an alarm bell capable of being activated from inside the car and audible outside the hoistway. If the elevator is not equipped with a bell, a two (2)-way conversation device to the elevator and a ready accessible point outside the hoistway may be acceptable.

12. All automatic passenger elevators shall have their door open zones adjusted to where the door shall not open unless the car has stopped within six inches (6") of floor level.

(C) Car Enclosure: Freight.

1. Each freight elevator car shall have a solid enclosure of at least *[sixty-six inches (66")]* **six feet (6")** in height. The space between the solid section and the car top shall be covered solid or with perforated or lattice-type work. The perforated or lattice work shall reject a ball one and one-half (1 1/2") inches in diameter. The portion of open-type enclosure, which passes the counterweights, shall be of solid construction the entire width of the counterweights plus six inches (6") on either side. The enclosure top shall be provided with an emergency exit. Exception: Hydraulic elevators provided with a manual-lowering valve.

2. Each freight car enclosure shall have doors or gates at each entrance and shall be not less than six feet (6') high. Each door or gate shall be constructed in accordance with ASME A17.1, rule 204.4**, 1955 edition**.

3. Each car door or gate on a freight elevator shall have electric contacts to prevent the car from running with doors or gates open. Exceptions:

A. By a car-leveling or truck-zoning device;

B. By a combination hoistway access switch and operating device; or

C. When a hoistway access switch is operated.

4. Each freight elevator car enclosure shall be provided with a top. The top may be solid or open-work construction and shall be of metal. The open work shall reject a ball two inches (2") in diameter. Car tops shall be constructed to sustain a load of two hundred (200) pounds applied at any point on the car top. The top shall not have hinged or folding panels other than the emergency exit cover.

5. Each freight car enclosure shall have lighting not less than two and one-half (2 1/2) foot-candles. Bulbs or tubes shall be guarded to prevent breakage.

6. Each freight car enclosure shall have capacity plate, loading class plates, and a "No Passengers" sign conspicuously posted. Letters shall not be less than one-half inch (1/2") high.

7. Freight elevators shall not be loaded to exceed the rated load as stated on their capacity plates.

8. Each freight elevator car floor shall be maintained so that personnel will not readily slip or trip. The floor shall be maintained so that it will hold its rated load without breaking through at any place in the car.

9. Freight elevators shall not be permitted to carry passengers other than persons to load and unload material and the operator. Permission may be granted to allow the carrying of employees on freight elevators. Application shall be submitted and may be approved by the authorized representative after which the installation shall be tested as determined by the Department of Public Safety.

(G) Maintenance, Repair and Alterations.

1. All maintenance shall comply with ASME A17.1, **1996 edition,** section *[1002]* **1200**.

2. All repairs and alterations shall comply with ASME A17.1, **1996 edition,** section 1200.

3. All maintenance, repair and alterations to platform lifts and stairway chair lifts must comply with ASME A18.1, **1999 edition**, *Safety Standard for Platform Lifts and Stairway Chair Lifts*. *[The foregoing standard is incorporated by reference in this rule.]*

(H) Machine Rooms.

1. All means of access to elevator machine rooms shall be of a permanent nature and shall be constructed and maintained in a clear and unobstructed manner.

2. The elevator machine and control equipment shall be located in a separate room or separated space designed as an elevator machine room or space and shall be accessible only to authorized personnel. Existing machines and equipment essential to the operation and purpose of the building are permitted but must not interfere with the safety and work area for maintaining elevator equipment. Where other existing machines and equipment essential to the operation and purpose of the building are located in the machine room or space, the elevator related equipment and machines shall be separated by a substantial grill constructed of non-combustible material not less than six feet (6') high and the grill shall be of a design that will reject a ball two inches (2") in diameter. All rooms or enclosures shall have a self-closing and self-locking door and shall be operable from the interior space without use of a key. After the effective date of this rule, no equipment shall be added to the machine room or space that is not used in connection with the operation of the elevator.

3. All elevator machine rooms shall be provided with a floor. The floor shall cover the entire area of the machine room and hoistway.

4. Machine room floors shall be kept clean and free of grease and oil. Articles or materials not necessary for the maintenance or operation of the elevator shall not be stored therein. Flammable liquids having a flash point of less than one hundred ten degrees Fahrenheit (110°F) shall not be stored in the machine room.

5. Lighting in the machine room shall be not less than ten (10) foot-candles at floor level.

6. Where there is more than one machine in a room, each machine shall have a different number conspicuously marked on it. The controller, disconnect switch and relay panels for each machine shall be conspicuously numbered to correspond to the machine it controls.

7. All electrical equipment in the machine room shall be grounded which shall conform to ASME A17.1**, 1996 edition** and NFPA 70 *[(NEC)]* ***National Electric Code***.

8. All electrical wiring in the machine room *[and hoistway]* shall be enclosed in metal conduit, flexible conduit or metal raceways **or be in compliance with NFPA 70,** ***National Electric Code***.

9. Each elevator having polyphase alternating current power supply shall be provided with means to prevent the starting of the elevator motor if:

A. The phase rotation is in the wrong direction; or

B. There is a failure of any phase. This protection shall be considered provided in the case generator-field control having alternating current motor-generator driving motors, provided a reversal of phase will not cause the elevator driving-machine motor to operate in the wrong direction. Controllers whose switches are operated by polyphase torque motors provide inherent protection against phase reversal or failure.

(I) Pits.

1. All pits shall be kept **dry,** clean and free of equipment or material not relating to the operation of the elevator. Exception: Sump pumps.

2. Buffers (spring or oil type) under cars and counterweights shall be permanently fastened to the floor or their supporting beams.

3. All elevators shall have counterweight guards. Guards shall be of unperforated metal of at least the strength of or braced to the equivalent strength of number fourteen (14) gauge sheet steel. Guards shall extend from a point not more than twelve inches (12") above the pit floor to a point not less than seven feet (7') above the

pit floor. Where guards are not feasible, warning chains shall be installed on the bottom of the counter-weights and shall extend no less than five feet (5') below counterweight. Chains shall be of a number ten (10) U.S. gauge wire or of equal size. Exception: When compensating chains or ropes are used, a counterweight guard is not required.

4. Buffers shall be installed where elevator pits are not provided with buffers and where the pit depth will permit*[.]*, *[B]***b**uffers shall comply with ASME A17.1, **1955 edition,** section 201.

5. Where the depth of any pit is *[in excess of]* four feet (4') **or more,** it shall have a ladder permanently installed. The ladder shall extend not less than thirty inches (30") above the sill of the access door, or hand grips shall be provided to the same height. Ladder shall be of noncombustible material.

6. A permanent lighting fixture shall be provided in all pits to provide an illumination of not less than five (5) foot-candles at the pit floor. The fixture switch shall be provided and accessible from the pit access door.

7. An enclosed stop switch meeting the requirements of ASME A17.1, 1995 edition, rule 210.2(e) shall be installed in the pit of all power elevators and be accessible from the pit access door.

(L) Wire Ropes-Hoisting, Governor and Tiller.

1. All hoisting and governor ropes, when replaced, shall have rope tags. The tags shall provide the following information:

A. The diameter in inches;

B. The manufacturer's rated breaking strength;

C. The grade of material used;

D. The month and year ropes were installed;

E. Whether preformed or non-preformed;

F. Construction classification;

G. Name of person or firm who installed ropes; **and**

H. Name of manufacturer of ropes.

2. Wire ropes on drum-type machines shall be resocketed in compliance with ASME A17.1, **1996 edition,** rule *[1002.3]* **1206.3**.

3. Suspension ropes on drum-type machines shall have not less than one (1) turn of the rope on the drum when the car is resting on the fully compressed buffers.

4. Winding drum machines shall not be used unless they are provided with not less than two (2) hoisting ropes. Each counterweight stack shall be provided with not less than two (2) ropes.

5. Tiller cables on cable-operated elevators shall be kept free of breaks.

6. On tiller-cable operations, the cable shall pass through a guiding or stopping device mounted on the car. The cable shall be provided with adjustable stop balls and be provided with means to lock and hold the car at a floor. Stop balls at top and bottom shall be adjusted to automatically stop the car. The tiller cable shall be completely enclosed in the hoistway.

7. All hoisting or counterweight ropes located outside of the hoistway that are exposed shall be covered with a box-type guard. The guard shall be not less than six feet (6') high from floor level.

8. Hoisting, governor and tiller ropes shall not be lengthened or repaired by splicing.

9. Suspension means of chains other than a roller chain type shall not be allowed. Any elevator suspended by a roller chain type shall not be used for the carrying of passengers. Exception: Elevators for the disabled.

10. Hoisting ropes for power elevators shall not be less than three-eighths inch (3/8") in diameter.

11. Hoisting rope fastening means shall be of the socket, babbitting or wedge type. Clamps shall not be used.

12. Rope (cable) replacement. Hoisting, governor and tiller ropes shall be replaced when *[the American National Standards Practice for]* the Inspection of Elevators, Escalators and Moving Walks, ASME A17.2, **1996 edition** Inspectors' Manual, Division 103, Item 103.4 dictates they shall be changed.

(M) Car Safeties and Speed Governors.

1. Each elevator suspended by ropes shall be provided with mechanically applied car safeties which shall be capable of stopping and sustaining its rated load.

2. Broken rope or slack rope safeties may be allowed if the car speed is not in excess of fifty feet per minute (50 fpm).

3. Elevators which are provided solely with broken rope or slack rope safeties shall not be used for passenger service. Exception: Elevators for the disabled.

4. All safeties shall be adjusted so that clearances from the rail shall be in accordance with ASME A17.1, **1955 edition,** rule 1001.2.

5. All slack cable safeties shall be provided with an electrical switch which disconnects power to the elevator machine and brake when setting of the safeties occurs.

6. All safeties operated by a speed governor shall be provided with a speed switch operated by the governor when used with type B or C car safeties on elevators having a rated speed exceeding one hundred fifty (150) fpm. A switch shall be provided on the speed governor when used with a counterweight safety for any car speed.

7. Speed governors shall have their means of speed adjustment sealed.

8. For hoistways not extending to the lowest floor and where space below the hoistway is used for a passageway or is occupied by persons, or if unoccupied but not secured against unauthorized access, the counter-weights of the elevator shall be provided with safeties. Safeties shall be tripped by a speed governor if the car speed is in excess of one hundred fifty (150) fpm. Speed governors shall be set to trip above the car governor tripping speed but not more than ten percent (10%) greater.

(N) Guide Rails.

1. All guide rails and brackets whether of wood or steel shall be firmly and securely anchored or bolted in place. Where T rail is used all fish-plate bolts shall be tight. This shall comply with ASME A17.1, **1955 edition,** section 200.

2. Where guide rails which are worn to such a point that proper clearance of safety jaws cannot be maintained, the worn sections shall be replaced to achieve clearances as specified in ASME A17.1, **1996 edition,** rule 1001.2.

(O). Existing Hydraulic Elevators.

1. Cylinders of hydraulic-elevator machines shall be provided with a means for releasing air or other gas.

2. Each pump or group of pumps shall be equipped with a relief valve conforming to the following requirements:

A. Type and location. The relief valve shall be located between the pump and the check valve and shall be of such a type and so installed in the bypass connection that the valve cannot be shut off from the hydraulic system;

B. Setting. The relief valve shall be preset to open at a pressure not greater than that necessary to maintain one hundred and twenty-five percent (125%) of working pressure;

C. Size. The size of the relief valve and bypass shall be sufficient to pass the maximum rated capacity of the pump without raising the pressure more than twenty percent (20%) above that at which the valve opens. Two (2) or more relief valves may be used to obtain the required capacity; and

D. Sealing. Relief valves having exposed pressure adjustments if used, shall have their means of adjustment sealed after being set to the correct pressure. Exception: No relief valve is required for centrifugal pumps driven by induction motors, provided the shut-off, or maximum pressure which the pump can develop, is not greater than one hundred and thirty-five percent (135%) of the working pressure at the pump.

3. Storage and discharge tanks shall be covered and suitably vented to the atmosphere.

4. Hydraulic elevators shall be governed by the rules contained in ASME A17.1, **1955 edition,** Part III.

5. All repair and alterations of hydraulic elevators shall comply with ASME A17.1, **1996 edition,** section 1201 with supplements thereto.

(P) Existing Sidewalk Elevators.

1. Hoistways shall be permanently enclosed. The enclosures shall conform to ASME A17.1, **1955 edition,** rule 401.1.

2. All interior landings shall have a door or gate which shall be provided with an interlock.

3. Doors opening in sidewalks or other areas exterior to the building shall be of the hinged type. Doors or covers shall be designed to hold a static load of three hundred pounds per square foot (300 ppsf). Doors shall always be closed unless elevator is at the landing.

4. Stops shall be provided to prevent the cover in the opening of the sidewalk from opening more than ninety degrees (90°) from its closed position.

5. Covers in sidewalk shall be designed to close when the car descends from the top landing.

6. Recesses or guides which will securely hold the cover in place on the car stanchions shall be provided on the under side of the cover.

7. All electrical wiring shall be enclosed in metal conduit, flexible conduit or metal raceways. If hoistway opens in the sidewalk, the wiring shall be weatherproof.

8. Operating devices and control equipment shall comply with ASME A17.1, **1955 edition,** rule 402.4.

9. All electric sidewalk elevators shall have upper and lower final limit switches. Open-type switches shall not be allowed.

10. Cars shall have enclosures which shall be not less than six feet (6') in height provided the stanchions and bow iron are of sufficient height. The enclosure shall be provided with electric contacts to prevent the car from running with doors or gates open.

11. Cars shall have safeties. Where the speed of the elevator does not exceed fifty (50) fpm, car safeties which operate as a result of breaking or slackening of the hoisting ropes may be used. Such safeties may be of the inertia type or approved type without governors. Governors shall not be required when car speed does not exceed fifty (50) fpm.

12. Car enclosures and car gates shall not be required for hand-powered sidewalk elevators.

13. All repair and alterations shall comply with ASME A17.1, **1955 edition,** section 1200.

(Q) Existing Hand Elevators.

1. Hand-pow*/d/*ered elevators shall have hoistway doors. Doors shall be of the self-closing and self-locking type.

2. Hoistway doors shall have signs attached to them indicating elevator hoistway. Sign shall be as follows in not less than two-inch (2") letters: DANGER ELEVATOR—KEEP CLOSED.

3. All hand-powered elevators shall be provided with safeties or slack cable devices. Safeties do not have to be operated by a speed governor unless the speed is in the excess of fifty (50) fpm.

4. Hand-powered elevators shall have a car enclosure which shall be constructed of metal or sound seasoned wood. The enclosure shall cover all sides which are not used for entrance or exit. The enclosure shall be secured to the car platform or frame in such a manner that it cannot work loose or become displaced in ordinary service.

5. Each hand-pow*/d/*ered elevator shall be provided with a brake which shall be capable of stopping and sustaining the car whether loaded or unloaded.

6. Hand-powered elevators shall not be converted or changed to electric powered unless the complete facility is brought into conformity with ASME A17.1**, 1996 edition**.

7. Repair or replacement of worn or broken parts shall be in compliance with ASME A17.1, **1996 edition,** rule 1202.2.

(R) Power Operated Special Purpose Elevators.

1. Elevators complying with the following requirements may be installed in any structure where the elevator is not accessible to the general public, is used exclusively for designated operating and maintenance employees only, and where transportation of one (1) or two (2) persons is required to attend machinery or equipment frequently.

2. The inside platform area of the car shall not exceed nine (9) square feet. The rated speed shall not exceed one-hundred (100) fpm. The rated load shall not exceed six hundred fifty (650) pounds.

3. Hoistways shall be enclosed to their full width, to a height of not less than seven feet (7') with solid or perforated noncombustible material braced to deflect not more than one inch (1") when subjected to a force of one hundred (100) pounds applied horizontally at any point. Open work enclosures shall be at least number thirteen (13) steel wire gauge or expanded metal at least number thirteen (13) U.S. gauge and shall reject a ball two inches (2") in diameter. Where counterweights pass, landing and stairway side shall be of solid construction.

4. Wiring shall comply with the requirements of ASME A17.1**, 1978 edition** and NFPA 70.

5. Counterweights shall comply with the requirements of ASME A17.1, **1978 edition,** Part XV.

6. Hoistway doors shall comply with rules ASME A17.1, **1978 edition,** Part XV.

7. Cars shall be solidly constructed in accordance with ASME A17.1, **1978 edition,** Part XV.

8. Car enclosure.

A. Except at the entrance, the car shall be enclosed on all sides and the top. The enclosure at the sides shall be solid or open work. All open work shall reject a ball one inch (1") in diameter. The enclosure shall be constructed of sufficient strength that it will not deflect more than one inch (1") at any one (1) point.

B. There shall be an electric light to illuminate the car or hoistway with the switch placed on or near the operating panel.

C. There shall be no glass used in the elevator car except for the car light.

9. A car door shall be provided at each car entrance. Door or gate shall guard the complete entrance. The door or gate shall be at least seven feet (7') high, of metal construction with solid or open construction to reject a ball one inch (1") in diameter. A contact switch shall be provided to prevent the operation of the elevator with doors or gates open. The door or gate shall be provided with interlocks.

10. Guide rails shall comply with ASME A17.1, **1978 edition,** Part XV.

11. The means and methods of suspension shall comply with ASME A17.1, **1978 edition,** Part XV.

12. Electrical switches shall comply with ASME A17.1, **1978 edition,** Part XV.

13. Brakes shall comply with ASME A17.1, **1978 edition,** Part XV.

14. Emergency signal or communication shall comply with ASME A17.1, **1978 edition,** Part XV.

(S) Fire Service.

1. Elevators with fire service features shall comply with the edition of ASME A17.1 that was in print at the time of installation.

[(2)] **(T)** Existing Dumbwaiters, Escalators and Moving Walks.

[(A)] **1.** Dumbwaiters. All dumbwaiters whether electric or hand powered shall conform to ASME A17.1, **1971 edition,** section 700. Exceptions: Required rules for hoistway construction as set forth in ASME A17.1, **1971 edition** shall not apply to existing installations.

[(B)] **2.** Escalators.

[1.] **A.** Each escalator shall be provided with an electrically released mechanically applied brake capable of stopping the up and down traveling escalator with any load up to and including the rated load. The brake shall be located either on the driving machine or on the main drive shaft.

[2.] **B.** Starting switches shall be of the key operated type. Starting switches shall be located on or near the escalator.

[3.] **C.** Emergency stop buttons or other type manually operated switches having red buttons or handles shall be accessibly located at or near the bottom and top landings. The buttons or levers shall be protected to prevent accidental operation.

[4.] **D.** A broken step-chain device shall be provided on each escalator that will cause interruption of power to the driving machine if a step chain breaks or if excessive sag occurs in either step chain.

[5.] **E.** Each escalator shall have comb plates at top and bottom landings of the escalator. Comb plate teeth shall be meshed with and set into slots in the tread surface of the steps so that the points of the teeth are always below the upper surface of the treads.

[6.] **F.** Each escalator balustrade or molding on the balustrade shall have a smooth surface. Screw heads shall set flush with the surface or be of the oval head type without any burrs or rough places on their surface.

[7.] **G.** The clearance on either side of the steps between the step tread and the adjacent skirt panel shall be not more than three-sixteenths inch (3/16").

[8.] **H.** Step treads shall be illuminated throughout their run. The light intensity shall be not less than two (2) foot-candles.

[9.] **I.** An enclosed fused disconnect switch or circuit breaker arranged to disconnect the power supply to the escalator shall be in each machine room or wherever the controller is located.

[10.] **J.** A stop switch shall be provided in each machinery space where means of access to the space is provided. The switch when opened shall cause electric power to be removed from the escalator driving-machine motor and brake. The switch shall be of the manually opened and closed type and shall be marked "STOP."

[11.] **K.** Hand or finger guards shall be provided at the point where the handrail enters the balustrade.

[12.] **L.** Where the clearance of the upper outside edge of the balustrade and a ceiling or scaffold is less than twelve inches **(12")** or where the intersection of the outside balustrade and a ceiling or soffit is less than twenty-four inches (24") from the centerline of the handrail, a solid guard shall be provided in the intersection of the angle of the outside balustrade and the ceiling or soffit. The vertical front edge of the guard shall project a minimum of fourteen inches (14") horizontally from the apex of the angle. The escalator side of the vertical face of the guard shall be flush with the face of the wellway. The exposed edge of the guard shall be rounded.

[(C)] **3.** Moving Walks.

[1.] **A.** Each moving walk shall be provided with an electrically released, mechanically applied brake capable of stopping and holding treadway with a load up to and including the rated load.

[2.] **B.** Starting switches shall be of the key-operated type and shall be located within sight of the exposed treadway.

[3.] **C.** Each moving walk shall be provided with an emergency stop button or manually operated switch at each entrance and exit. The switches shall be protected to prevent the accidental operation of them. The operation of any of these switches shall interrupt the power to the driving-machine motor and brake.

[4.] **D.** A device shall be provided which will cause interruption of power to the driving-machine motor and brake if the connecting means between pallets break.

[5.] **E.** The entrance to and exit from a moving treadway shall be provided with a threshold plate which shall have teeth and be adjusted so that the teeth are below the treadway.

[6.] **F.** An enclosed fused disconnect switch or a circuit breaker arranged to disconnect the power supply to the moving walk shall be provided in the space where the controller is located.

[7.] **G.** If the balustrade covers the edge of the treadway the clearance between the top surface of the treadway and the underside of the balustrade shall not exceed one-fourth inch (1/4"). Where skirt panels are used the horizontal clearance on either side of the treadway and the adjacent skirt panel shall be not more than one-fourth inch (1/4").

[8.] **H.** A stop switch shall be provided in each machinery space where means of access to the space is provided. The switch when opened shall cause electrical power to be removed from the driving-machine motor and brake. The switch shall be of the manually operated type, and shall be marked "STOP."

[9.] **I.** Hand or finger guards shall be provided at the point handrails enter the balustrade.

[10.] **J.** All balustrades shall be smooth and free of rough surfaces. All screws shall be flush or oval head. Screw heads shall be smooth and free of burrs.

[11.] **K.** On pallet type treadways adjacent ends of the pallets shall not vary in elevation more than one-sixteenth inch (1/16"). The distance between pallets shall not exceed five thirty-seconds inch (5/32").

[12.] **L.** All repairs and alterations shall comply with ASME A17.1, **1996 edition**.

AUTHORITY: section 701.355, RSMo 2000. Original rule filed Aug. 26, 1998, effective July 1, 1999. Amended: Filed Aug. 17, 2000, effective Feb. 28, 2001. Emergency amendment filed April 30, 2001, effective May 10, 2001, expired Nov. 5, 2001. Amended: Filed April 30, 2001, effective Oct. 30, 2001. Amended: Filed Dec. 16, 2002.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred ($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 Division of Fire Safety, PO Box 844, Jefferson City, MO 65102. 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 11—DEPARTMENT OF PUBLIC SAFETY
Division 40—Division of Fire Safety
Chapter 5—Elevators

PROPOSED AMENDMENT

11 CSR 40-5.070 Accessibility to the Disabled. The division is amending sections (1) and (2).

PURPOSE: This amendment clarifies accessibility issues and includes code edition years adopted by the Elevator Safety Board.

(1) New Installations of Accessible Passenger Elevators and Wheelchair Lifts. *[In addition to the standards imposed, the board hereby adopts and incorporates herein the American National Standards Institute Standard for Buildings and Facilities Providing Accessibility and Usability for Physically Disabled People,]* **New installations of accessible passenger elevators and wheelchair lifts shall be installed to meet the requirements of** ANSI A117.1 **1998 edition**, Sections 4.10.1 through 4.10.14 and 4.11 latest version adopted and amended by the Elevator Safety Board.

[(2) Existing passenger elevators and wheelchair lifts required to be accessible, shall comply with 4.10.2.1–4.10.2.7 of ANSI A117.1, latest version adopted and amended by the Elevator Safety Board. The owner, operator, lessee or agent of either, of any existing elevator equipment, subject to this section shall have one (1) year from the effective date of these rules and regulations, or when notice is given to comply; or within one (1) year the owner, operator, lessee, or agent of either, of any existing elevator equipment, subject to this section shall submit a plan to the

board, for approval, outlining the dates to which the requirements of this section will be complied with.]

(2) All elevator equipment installed prior to the development and adoption by the authority having jurisdiction of national accessibility standards are not required to meet this rule unless the equipment undergoes a major alteration.

AUTHORITY: section 701.355, RSMo [1994] 2000. Original rule filed Aug. 26, 1998, effective July 1, 1999. Amended: Filed Dec. 16, 2002.

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.

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Title 11—DEPARTMENT OF PUBLIC SAFETY
Division 40—Division of Fire Safety
Chapter 5—Elevators

PROPOSED AMENDMENT

11 CSR 40-5.080 Alterations*[, Repairs, Replacements, and Maintenance]*. The division is amending the title and sections (1) and (4).

PURPOSE: This amendment is for clarification of requirements for alterations to existing elevators.

(1) Minimum Standards. When any alterations*[, repairs, replacements or maintenance]* are made, all elevator equipment, as a minimum, shall conform to the **applicable** requirements of Part XII of the ASME A17.1, of the latest version adopted and amended by the Elevator Safety Board. *[The foregoing standard is incorporated by reference in this rule.]*

(4) Operating Certificate for Alterations*[, Repairs, Replacement and Maintenance]*. Prior to operating, any altered elevator equipment an operating certificate must be obtained in accordance with 11 CSR 40-5.100 as listed herein.

AUTHORITY: section 701.355, RSMo [1994] 2000. Original rule filed Aug. 26, 1998, effective July 1, 1999. Amended: Filed Dec. 16, 2002.

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 Division of Fire Safety, PO Box 844, Jefferson City, MO 65102. 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 11—DEPARTMENT OF PUBLIC SAFETY
Division 40—Division of Fire Safety
Chapter 5—Elevators

PROPOSED AMENDMENT

11 CSR 40-5.120 Inspectors. The division is amending the Purpose and sections (2) and (11).

PURPOSE: This amendment is to clarify requirements for insurance and educational requirements for inspectors.

PURPOSE: This rule identifies qualifications for inspectors employed by the state, private industry and authorized jurisdictions. [The majority of inspections will be by private industry and authorized jurisdictions.]

(2) Qualification of Special Inspector. To be eligible for a license to inspect elevator equipment, the applicant or licensee shall—

(D) Have submitted proof of insurance coverage insuring the applicant against **professional** liability *[for injury or death for any acts or]* **insurance covering the errors and** omissions *[on the part]* of the applicant **and commercial general liability coverage, with an occurrence limit of not less than one (1) million dollars and a general aggregate limit of not less than three (3) million dollars**. *[The insurance policy shall be in the amount of not less than one (1) million dollars for bodily injury to or death of one person in any one accident, and, subject to the limit for one (1) person, in an amount of not less than three (3) million dollars for bodily injury to or death of two (2) or more persons in any one (1) accident, and in an amount of not less than fifty thousand dollars ($50,000) for damage to or destruction of property in any one (1) accident.]* Additionally, insurance coverage of an employer for whom the special inspector is employed shall be considered to comply with the aforementioned, if the coverage provides equivalent coverage for each special inspector; and

(11) Revocation *[and Suspension]* of License.

(A) The board may revoke *[or suspend]* any license for cause. Such cause shall include, but not be limited to the following:

1. Failure to comply with the provisions of sections 701.350–701.380, RSMo, or these rules and regulations; *[and]*

2. Falsifying or making a material misstatement or omission on any application for license, financial disclosure statement, or inspection report*[.]***; and**

3. Failure to attend at least one (1) Missouri State elevator code update meeting per calendar year conducted by the department.

AUTHORITY: section 701.355, RSMo [1994] 2000. Original rule filed Aug. 26, 1998, effective July 1, 1999. Emergency amendment filed Aug. 24, 2000, effective Sept. 4, 2000, expired March 2, 2001. Amended: Filed Aug. 29, 2000, effective Feb. 28, 2001. Amended: Filed Dec. 16, 2002.

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred ($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 Division of Fire Safety, PO Box 844, Jefferson City, MO 65102. 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 11—DEPARTMENT OF PUBLIC SAFETY
Division 45—Missouri Gaming Commission
Chapter 4—Licenses

PROPOSED AMENDMENT

11 CSR 45-4.260 Occupational Licenses. The commission is amending section (4).

PURPOSE: The commission proposes to amend this rule by providing that municipal ordinance violations constitute offenses for which an occupational gaming license may be denied or revoked.

(4) The commission may refuse an occupational license to any person or revoke **or suspend** an occupational license of any person—

(A) Who has been convicted of a crime **or municipal ordinance violation** or has been found guilty of, plead guilty to or plead *nolo contendere* to a crime **or municipal ordinance violation,** including such findings or pleas in a suspended imposition of sentence;

AUTHORITY: sections 313.004 and 313.805, RSMo 2000. Emergency rule filed Sept. 1, 1993, effective Sept. 20, 1993, expired Jan. 17, 1994. Emergency rule filed Jan. 5, 1994, effective Jan. 18, 1994, expired Jan. 30, 1994. Original rule filed Sept. 1, 1993, effective Jan. 31, 1994. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Nov. 21, 2002.*

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

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

NOTICE OF PUBLIC HEARING AND NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Missouri Gaming Commission, PO Box 1847, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the ***Missouri Register****. A public hearing is scheduled for 10:00 a.m., February 5, 2003, in the Missouri Gaming Commission's Hearing Room, 3417 Knipp Drive, Jefferson City, Missouri.*

Title 12—DEPARTMENT OF REVENUE
Division 10—Director of Revenue
Chapter 24—Drivers License Bureau Rules

PROPOSED AMENDMENT

12 CSR 10-24.448 Proof of Identity and Proof of Social Security Number Required for Issuance of a Driver*[′s]* or Nondriver*[′s]* License. The director proposes to amend the title and section (2).

PURPOSE: This amendment requires driver license office personnel to ask for additional documentation when using a previously stored image to verify identification of a driver license, nondriver license, or instruction permit applicant.

(2) A renewal applicant is required to show only his or her current driver*[′s]* or nondriver*[′s]* license. If the license is unavailable, the license office clerk must obtain the digital image of the applicant's previous license transaction where a comparison of the image on the file can be made to the person in the office **and require one (1) secondary document**, or the clerk must require the applicant to submit two (2) primary documents or one (1) primary and one (1) secondary document for proof of identity.

AUTHORITY: section 302.171, RSMo [Supp. 1997] 2000. Original rule filed March 27, 1998, effective Sept. 30, 1998. Emergency amendment filed Dec. 16, 2002, effective Dec. 26, 2002, expires June 23, 2003. Amended: Filed Dec. 16, 2002.

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 Department of Revenue, Office of Legislation and Regulations, PO Box 629, Jefferson City, MO 65105. 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 13—DEPARTMENT OF SOCIAL SERVICES
Division 40—Division of Family Services
Chapter 31—Child Abuse

PROPOSED AMENDMENT

13 CSR 40-31.025 Child Abuse and Neglect Review Process. The Division of Family Services is amending section (2) by deleting the word "Probate" and replacing it with the word "Probable".

PURPOSE: This amendment is a correction to a typographical error.

(2) The alleged perpetrator will receive written notification as to the decision of the local division office. This notification will include a statement that if the alleged perpetrator disagrees with the *[Probate]* **Probable** Cause decision, s/he may request a review.

AUTHORITY: section 207.020, RSMo [1994] 2000. Original rule filed June 30, 1988, effective Sept. 29, 1988. Amended: Filed Sept. 26, 1989, effective Dec. 28, 1989. Amended: Filed June 14, 1996, effective Dec. 30, 1996. Amended: Filed Nov. 20, 2002.

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 Randall McDermit, Program Development Specialist, Children's Services, 615 Howerton, Jefferson City, MO 65103. 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 15—ELECTED OFFICIALS
Division 30—Secretary of State
Chapter 50—General

PROPOSED AMENDMENT

15 CSR 30-50.030 Fees. The Commissioner of Securities is proposing to amend subsection (1)(B).

PURPOSE: This amendment changes to whom checks, drafts, and money orders should be made payable.

(1) General Provisions.

(B) Fees shall be remitted by check, draft or money order (cash is not acceptable) payable to the *[Director of Revenue, State of Missouri]* **Missouri Secretary of State**, or if the application is submitted through the Central Registration Depository (CRD) System or Investment Adviser Registration Depository (IARD) system, fees shall be remitted by check or wire transfer to the financial institution designated by the National Association of Securities Dealers (NASD).

AUTHORITY: sections 409.202(b), 409.305(b) and (j), 409.413 and 409.414(d) and (e), RSMo 2000. Original rule filed June 25, 1968, effective Aug. 1, 1968. For intervening history, please consult the ***Code of State Regulations****. Amended: Filed Nov. 26, 2002.*

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 Secretary of State's Office, Doug Ommen, Commissioner of Securities, 600 West Main Street, 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 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 10—Office of the Director
Chapter 4—Coordinated Health Care Services

PROPOSED AMENDMENT

19 CSR 10-4.020 J-1 Visa Waiver Program. The Department proposes to amend subsections (1)(A)–(1)(C); delete paragraphs of (2)(A)10. and 11. and to renumber the affected paragraph; amend section (5); amend subsection (6)(B); amend section (14); and delete Appendices A, B, C and D.

PURPOSE: This proposed amendment is to amend: 1) the ability and the criteria necessary for physicians trained in other specific high need specialties besides primary care to participate in the J-1 Visa Program; 2) the documentation required by applicants; 3) prioritization of certain specialties; and 4) the application and reporting requirements for facilities that participate in the J-1 Visa Program.

(1) The following definitions shall be used in the interpretation and enforcement of this rule:

(A) Department means the Missouri Department of Health **and Senior Services**;

(B) Director means the director of the Missouri Department of Health **and Senior Services**; and

(C) Health professional shortage area (HPSA) means those counties or parts of counties designated by the United States Department of Health and Human Services as having a shortage of *[primary care]* physicians as published in the *Code of Federal Regulations*.

(2) The department is committed to assisting all residents of Missouri to have access to quality, affordable health care. Therefore, under certain conditions, the department is prepared to consider recommending a waiver of the foreign residence requirement on behalf of physicians holding J-1 visas.

(A) A waiver request must come from a Missouri health care facility on behalf of a J-1 physician and not directly from a J-1 physician. All of the required information and documentation must be submitted in a single package with the documents presented in the order in paragraphs (2)(A)1.–14. Waiver requests that do not comply with these requirements will not be considered. The required documents include:

1. A letter from the head of the facility at which the physician will be employed that—

A. Requests that the department act as an interested government agency and recommend a waiver for the J-1 physician;

B. Summarizes how the health care facility has attempted to locate qualified United States physicians;

C. Describes the physician's qualifications, proposed responsibilities and how his/her employment will satisfy important unmet health care needs of a medically underserved rural community; and

D. States unequivocally that the facility is offering the physician at least three (3) years of employment in a job consistent with the department's mission;

2. A detailed description of the health care facility will be provided, including the nature and extent of the facility's medical services;

3. Valid contract of employment with the health care organization for not less than three (3) years;

4. List of HPSAs or documentation from state and local health care officials stating need for services of the physician;

5. Recruitment and retention efforts including copies of advertisements, agreements with placements services or other like documentation, and if these are not available, a detailed statement describing recruitment efforts. A statement should be submitted detailing the plans for retaining the physician during and beyond the three (3)-year obligation;

6. Effect on area of waiver denial;

7. Qualifications, including proof of Missouri medical licensure eligibility;

8. Physician's curriculum vitae and letters of recommendation;

9. Copies of all IAP-66s of physician, copies of I-94s of physician and family members, and proof of passage of examinations required by the United States Immigration and Naturalization Service;

[10. Completed physician data sheet (attached as Appendix A);

11. Completed J-1 visa waiver policy affidavit and agreement (attached as Appendix B);]

*[12.]***10.** Valid offer of employment with health care organization for at least three (3) years;

*[13.]***11.** A copy of the notice from the department that the facility has been predetermined eligible for participation in the program; and

*[14.]***12.** An original and one (1) unbound copy of the entire package should be included.

(5) The department's J-1 Visa Waiver Program in Missouri will give priority to those physicians who are board-eligible or board-certified in one (1) of the following specialties: Family Practice, General Practice, General Pediatrics, Obstetrics/Gynecology, *[General Internal Medicine]* or Psychiatry and providing services in a primary care clinical setting. *[Physicians with other subspecialties or fellowship experience are not considered to be primary care physicians for the purpose of the J-1 Visa Waiver Program in Missouri.]* The credentials of the J-1 physician must be confirmed by the Missouri Board of Healing Arts. The physician must be eligible for licensure in Missouri.

(6) In addition to the eligible physicians set forth in section (5), waivers may be recommended for other specialties and subspecialties.

(B) *[Only four (4) slots will be allocated to specialty placements in any given program year.]* **The number of specialty placements in any given program year will be determined by the**

quantifiable need for health care services in the state as a whole and the identified placement community.

(14) In order to assist and facilitate the placement of *[primary care]* practitioners in designated HPSAs in Missouri, the department will provide, upon request, the following information:

*AUTHORITY: section 191.411.1, RSMo [1994] **Supp 2001**. This rule was previously filed as 19 CSR 50-4.020. Emergency rule filed April 17, 1995, effective April 27, 1995, expired Aug. 24, 1995. Original rule filed April 17, 1995, effective Oct. 30, 1995. Changed to 19 CSR 10-4.020 July 30, 1998. Emergency amendment filed Sept. 19, 2000, effective Sept. 29, 2000, expired March 27, 2001. Amended: Filed Sept. 19, 2000, effective Feb. 28, 2001. Emergency amendment filed Dec. 16, 2002, effective Dec. 26, 2002, expires June 23, 2003. Amended: Filed Dec. 16, 2002.*

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 Harold Kirbey, Chief, Health Systems Development Unit, 920 Wildwood, Jefferson City, MO 65109. 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 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 20—Division of Environmental Health and Communicable Disease Prevention
Chapter 20—Communicable Diseases

PROPOSED AMENDMENT

19 CSR 20-20.020 Reporting Communicable, Environmental and Occupational Diseases. The Department of Health and Senior Services proposes to amend the Purpose, sections (1)–(4) and (6)–(8), subsections (1)(A), (1)(B) and to add a new subsection (1)(C).

PURPOSE: This amendment: adds the requirement to report infections and adverse reactions due to smallpox inoculation; specifies those diseases included in the current category of "Encephalitis, arthropod-borne," adds "West Nile virus fever," adds human "animal bite wounds," adds three (3) diseases that are nationally notifiable, corrects a misprint regarding human immunodeficiency virus (HIV) viral load measurement, and updates the department's name.

*PURPOSE: This rule designates the diseases, disabilities, conditions and findings that must be reported to the local health authority or the Department of Health **and Senior Services**. It also establishes when they must be reported.*

(1) Category I diseases or findings shall be reported to the local health authority or to the Department of Health **and Senior Services** within twenty-four (24) hours of first knowledge *or suspicion* by telephone, facsimile or other rapid communication. Category I diseases or findings are—

(A) Diseases, findings or agents that occur naturally or from accidental exposure:

Animal (mammal) bite wound, humans
Diphtheria
Haemophilus influenzae, invasive disease
Hantavirus pulmonary syndrome
Hepatitis A
Hyperthermia
Hypothermia
Influenza, suspected—nosocomial outbreaks and public or private school closures
Lead (blood) level greater than or equal to forty-five micrograms per deciliter (45 μg/dl) in any person equal to or less than seventy-two (≤72) months of age
Measles (rubeola)
Meningococcal disease, invasive
Outbreaks or epidemics of any illness, disease or condition that may be of public health concern
Pertussis
Poliomyelitis
Rabies, animal or human
Rubella**,** including congenital syndrome
Staphylococcus aureus, vancomycin resistant
***Streptococcus pneumoniae*, invasive in children less than five (5) years**
Syphilis, including congenital syphilis
Tuberculosis disease
Typhoid fever

(B) Diseases, findings or agents that occur naturally or that might result from a terrorist attack involving biological, radiological, or chemical weapons:

Adult respiratory distress syndrome (ARDS) in patients under fifty (50) years of age (without a contributing medical history)
Anthrax
Botulism
Brucellosis
Cholera
Encephalitis/**meningitis**, Venezuelan equine
Glanders
Hemorrhagic fever (e.g., dengue, yellow fever)
Plague
Q fever
Ricin
Smallpox (variola)
Staphylococcal enterotoxin B
T-2 mycotoxins
Tularemia

(C) Diseases, findings or adverse reactions that occur as a result of inoculation to prevent smallpox, including but not limited to the following:
Accidental administration
Accidental implantation (inadvertent autoinoculation)
Bacterial infection of site of inoculation
Congenital vaccinia
Contact vaccinia (i.e., vaccinia virus infection in a contact of a smallpox vaccinee)
Eczema vaccinatum
Erythema multiforme
Generalized vaccinia
Post-vaccinial encephalitis
Progressive vaccinia (vaccinia necrosum, vaccinia gangrenosa, disseminated vaccinia)
Vaccinia keratitis

(2) Category II diseases or findings shall be reported to the local health authority or the Department of Health **and Senior Services** within three (3) days of first knowledge *or suspicion*. Category II diseases or findings are—

Acquired immunodeficiency syndrome (AIDS)
Arsenic poisoning
Blastomycosis
California serogroup viral encephalitis/meningitis
Campylobacter infections

Carbon monoxide poisoning
CD4+ T cell count
Chancroid
Chemical poisoning, acute, as defined in the most current ATSDR CERCLA Priority List of Hazardous Substances; if terrorism is suspected, refer to **sub**section (1)(B)
Chlamydia trachomatis, infections
Coccidioidomycosis
Creutzfeldt-Jakob disease
Cryptosporidiosis
Cyclosporidiosis
Eastern equine viral encephalitis/meningitis
Ehrlichiosis, human granulocytic**,** *[or]* monocytic**, or other/unspecified agent**
[Encephalitis, arthropod-borne [except VEE, see section (1)(B)]]
Escherichia coli O157:H7
***Escherichia coli*, shiga toxin positive, serogroup non-O157:H7**
Giardiasis
Gonorrhea
Hansen disease (leprosy)
Heavy metal poisoning including, but not limited to, cadmium and mercury
Hemolytic uremic syndrome (HUS), post-diarrheal
Hepatitis B, acute
Hepatitis B surface antigen (prenatal HBsAg) in pregnant women
Hepatitis C
Hepatitis non-A, non-B, non-C
Human immunodeficiency virus (HIV)-exposed newborn infant (i.e., newborn infant whose mother is infected with HIV)
Human immunodeficiency virus (HIV) infection, as indicated by HIV antibody testing (reactive screening test followed by a positive confirmatory test), HIV antigen testing (reactive screening test followed by a positive confirmatory test), detection of HIV nucleic acid (RNA or DNA), HIV viral culture, or other testing that indicates HIV infection
Human immunodeficiency virus (HIV) test results (including both positive and negative results) for children less than two (2) years of age whose mothers are infected with HIV *[Human immunode ficiency virus (HIV) viral load measurement (including nondetectable results)]*
Human immunodeficiency virus (HIV) viral load measurement (including non-detectable results)
Influenza, laboratory-confirmed
Lead (blood) level less than forty-five micrograms per deciliter (< 45 μg/dl) in any person equal to or less than seventy-two (≤ 72) months of age and any lead (blood) level in persons older than seventy-two (> 72) months of age
Legionellosis
Leptospirosis
Listeria monocytogenes
Lyme disease
Malaria
Methemoglobinemia
Mumps
Mycobacterial disease other than tuberculosis (MOTT)
Nosocomial outbreaks
Occupational lung diseases including silicosis, asbestosis, byssinosis, farmer's lung and toxic organic dust syndrome
Pesticide poisoning
Powassan viral encephalitis/meningitis
Psittacosis
Respiratory diseases triggered by environmental contaminants including environmentally or occupationally induced asthma and bronchitis
Rocky Mountain spotted fever
Saint Louis viral encephalitis/meningitis
Salmonellosis
Shigellosis
Streptococcal disease, invasive, Group A
Streptococcus pneumoniae, drug resistant invasive disease
Tetanus
Toxic shock syndrome**,** staphylococcal or streptococcal
Trichinosis
Tuberculosis infection
Varicella deaths
West Nile fever
West Nile viral encephalitis/meningitis
Western equine viral encephalitis/meningitis
Yersinia enterocolitica

(3) The occurrence of an outbreak or epidemic of any illness, disease or condition which may be of public health concern, including any illness in a food handler that is potentially transmissible through food. This also includes public health threats that could result from terrorist activities such as clusters of unusual diseases or manifestations of illness and clusters of unexplained deaths. Such incidents shall be reported to the local health authority or the Department of Health **and Senior Services** by telephone, facsimile, or other rapid communication within twenty-four (24) hours of first knowledge or suspicion.

(4) A physician, physician's assistant, nurse, hospital, clinic, or other private or public institution providing diagnostic testing, screening or care to any person with any disease, condition or finding listed in sections (1)–(3) of this rule, or who is suspected of having any of these diseases, conditions or findings shall make a case report to the local health authority or the Department of Health **and Senior Services**, or cause a case report to be made by their designee, within the specified time.

(6) Any person in charge of a public or private school, summer camp or child or adult care facility shall report to the local health authority or the Department of Health **and Senior Services** the presence or suspected presence of any diseases or findings listed in sections (1)–(3) of this rule according to the specified time frames.

(7) All local health authorities shall forward to the Department of Health **and Senior Services** reports of all diseases or findings listed in sections (1)–(3) of this rule. All reports shall be forwarded within twenty-four (24) hours after being received, according to procedures established by the Department of Health **and Senior Services** director. Reports will be forwarded as expeditiously as possible if a terrorist event is suspected or confirmed. The local health authority shall retain from the original report any information necessary to carry out the required duties in 19 CSR 20-20.040(2) and (3).

(8) Information from patient medical records received by local public health agencies or the Department of Health **and Senior Services** in compliance with this rule is to be considered confidential records and not public records.

*AUTHORITY: sections 192.006, [RSMo Supp. 1999 and] 192.020, 192.139, 210.040 and 210.050, RSMo [1994] **2000**. This rule was previously filed as 13 CSR 50-101.020. Original rule filed July 15, 1948, effective Sept. 13, 1948. For intervening history, please consult the **Code of State Regulations**. Emergency amendment filed Dec. 16, 2002, effective Dec. 26, 2002, expires June 23, 2003. Amended: Filed Dec. 16, 2002.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions one thousand three hundred eighty-six dollars ($1,386) annually in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities seven thousand four hundred eighty-three dollars ($7,483) annually in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with Bryant McNally, Director, Division of Environmental Health and Communicable Disease Prevention, PO Box 570, Jefferson City, MO 65102-0570, Phone (573) 751-6080. 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.*

FISCAL NOTE
PUBLIC COST

I. RULE NUMBER

Rule Number and Name:	19 CSR 20-20.020, Reporting Communicable, Environmental and Occupational Diseases
Type of Rulemaking:	Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision:	Estimated Cost of Compliance in the Aggregate:
Note: Reports of communicable, environmental and occupational diseases and conditions come from the following public entities. The percents listed reflect the percent of these reports received by DHSS that come from each of these entities:	
-State Public Health lab, public hospital labs	13% ($720.72)
-County/district health agencies	9% ($498.96)
-Public schools	3% ($166.32)
TOTAL	**25% ($1,386) annually**

III. WORKSHEET - PUBLIC COST ANALYSIS

1. REPORTING SMALLPOX VACCINATION-RELATED CONDITIONS.

Assumption: Implementation of Phase II of the smallpox inoculation plan from the Centers for Disease Control and Prevention (CDC), with approximately 200,000 Missourians inoculated. Estimated rates of secondary transmission and adverse reactions are as follows[1]:

a. Secondary transmission (contact vaccinia): 2-6 cases/100,000; worst-case is **12 cases**.

b. Adverse reactions:

- Inadvertent autoinoculation: 606 cases/1 million inoculations = **121.2 cases.**
- Bacterial infection of site of inoculation: Unknown rate – less common in adults due to less scratching at site and better care of site. **Negligible number of cases.**
- Congenital vaccinia: Defined as infection of the fetus in the last trimester with evidence of disease in the newborn infant. No proven instance of congenital abnormalities has been attributed to vaccination during any stage of pregnancy. Some have postulated that vaccination in the first trimester results in some fetal loss but this has not been substantiated. Congenital vaccinia is a very rare event. Despite large-scale vaccination campaigns in the past that undoubtedly resulted in inadvertent

vaccination of many pregnant women, fewer than 50 cases of congenital disease have been recorded in the literature. **Negligible number of cases.**

- Eczema vaccinatum: 30 cases/1 million inoculations = **6 cases.**
- Erythema multiforme: 30 cases/1 million inoculations = **6 cases.**
- Generalized vaccinia: 212 cases/1 million inoculations = **42.4 cases.**
- Post-vaccinial encephalitis: 4 cases/1 million inoculations = **0.8 case.**
- Progressive vaccinia: 7 cases/1 million inoculations = **1.4 cases.**
- Vaccinia keratitis: Unknown, but not common. **Negligible number of cases.**

c. Accidental administration: Occurs "occasionally." **Negligible number of cases.**

Total number of reportable incidents related to 200,000 smallpox inoculations = 189.8

PUBLIC ENTITY COST TO REPORT SMALLPOX INOCULATION-RELATED INCIDENTS = **$110.18.** It has been calculated that generally about 25% of the communicable disease reports received by the Department of Health and Senior Services (DHSS) come from public sources such as the State Public Health Laboratory, public hospital laboratories, county/district health agencies, and public schools. The remaining 75% of the communicable disease reports come from private sources such as hospitals, hospital laboratories, private laboratories, private providers, and private schools. However, most of the smallpox inoculation-related conditions are diagnosed clinically and a larger proportion of these incidents would probably be reported by private hospitals and physicians. The proportion of public to private reporting of smallpox inoculation-related conditions is therefore estimated to be 15% and 85%, respectively. The public entity cost is then calculated using the following: (a) 15% of the reports received by DHSS come from public sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The public entity cost is:

(1) *No. Cases Per Year*	*(2)* *0.2 X Hourly Rate-$*	*(3)* *Salary Expense-$ (1 X 2)*	*(4)* *Postage Rate*	*(5)* *Postage Total-$ (1 X 4)*	*(6)* *Total (3 + 5)*	*(7)* *0.15(Total) 0.15(6)*
189.8	3.50	664.30	0.37	70.23	734.53	**$110.18**

[1] Sources: (1) CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book)*; (7th Ed.); April 2002. (2) CDC. *Interim Smallpox Response Plan and Guidelines.* (3) ACIP. Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. *MMWR* 2001; 50 (No. RR-10).

(4) http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/.html (figures based on worst case of either CDC's 1968 National Survey or 1968 Ten State Survey for 20+ year age group).

2. SPECIFICATION OF DISEASES CURRENTLY INCLUDED IN CATEGORY OF "ENCEPHALITIS, ARTHROPOD-BORNE." These conditions are: (a) California serogroup viral encephalitis/meningitis, (b) Eastern equine viral encephalitis/meningitis, (c) Powassan viral encephalitis/meningitis, (d) Saint Louis viral encephalitis/meningitis, (e) West Nile viral encephalitis/meningitis, (f) Western equine viral encephalitis/meningitis. These conditions are already reportable, so there is no additional public cost.

3. ADDITION OF "WEST NILE FEVER." National data indicate that about 23% of the human West Nile virus infections result in fever rather than meningoencephalitis. Assuming Missouri has the same number of WNV infections in 2003 as in 2002 (i.e., 169), then statistically, 38.87 (0.23 X 169) of these infections would be classified as WN fever and will represent a new reporting burden.

PUBLIC ENTITY COST TO REPORT WNV FEVER CASES = **$37.61**. The public entity cost is calculated using the following: (a) 25% of the reports received by DHSS come from public sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The public entity cost is:

(1)	*(2)*	*(3)*	*(4)*	*(5)*	*(6)*	*(7)*
No. Cases Per Year	*0.2 X Hourly Rate-$*	*Salary Expense-$ (1 X 2)*	*Postage Rate*	*Postage Total-$ (1 X 4)*	*Total (3 + 5)*	*0.25(Total) 0.25(6)*
38.87	3.50	136.05	0.37	14.38	150.43	**$37.61**

4. ADDITION OF "COCCIDIOIDOMYCOSIS." This disease is endemic in the southwestern U.S. and is on CDC's list of nationally notifiable diseases. Since only an occasional imported case might occur in Missouri, the public costs associated with reporting this disease are negligible.

5. ADDITION OF "ANIMAL (MAMMAL) BITE WOUND, HUMAN." Data gathered using the Sentinel Active Surveillance System (SASS) from 1995 through 2000 indicate that an average (mean) of 1,959 animal bites are reported to local public health agencies across Missouri each year. SASS was replaced with the High Alert Surveillance System following the events of September 11, 2001 and animal bites are not reported under the latter system. "Animal bite wound" is not a laboratory-diagnosed condition and the assumption is again made (as with the smallpox vaccination analysis noted above) that a greater than normal proportion of reports would come from private sources than from public sources, i.e., public sources – 15%, private sources 85%.

PUBLIC ENTITY COST TO REPORT ANIMAL BITE CASES = **$1,137.20**. The public entity cost is calculated using the following: (a) 15% of the reports received by DHSS come from public sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The public entity cost is:

(1) *No. Cases Per Year*	*(2)* *0.2 X Hourly Rate-$*	*(3)* *Salary Expense-$ (1 X 2)*	*(4)* *Postage Rate*	*(5)* *Postage Total-$ (1 X 4)*	*(6)* *Total (3 + 5)*	*(7)* *0.15(Total) 0.15(6)*
1,959	3.50	6,856.50	0.37	724.83	7,581.33	**$1,137.20**

6. ADDITION OF "*STREPTOCOCCUS PNEUMONIAE*, INVASIVE IN CHILDREN LESS THAN 5 YEARS." This disease was recently added to CDC's list of nationally notifiable diseases. Only one to two cases per year occur in Missouri, so additional public reporting costs are negligible.

7. ADDITION OF "*ESCHERICHIA COLI*, SHIGA TOXIN POSITIVE, SEROGROUP NON-O157:H7." Based on information from CDC and existing Missouri data, it is estimated that an average of 104 cases of this condition occur annually in Missouri.

PUBLIC ENTITY COST TO REPORT *E. COLI* NON-O157:H7 CASES = **$100.62**. The public entity cost is calculated using the following: (a) 25% of the reports received by DHSS come from public sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The public entity cost is:

(1) *No. Cases Per Year*	*(2)* *0.2 X Hourly Rate-$*	*(3)* *Salary Expense-$ (1 X 2)*	*(4)* *Postage Rate*	*(5)* *Postage Total-$ (1 X 4)*	*(6)* *Total (3 + 5)*	*(7)* *0.25(Total) 0.25(6)*
104	3.50	364	0.37	38.48	402.48	**$100.62**

8. CORRECTION OF MISPRINT REGARDING HIV VIRAL LOAD MEASUREMENT. No additional public reporting costs.

9. UPDATE OF DEPARTMENT OF HEALTH AND SENIOR SERVICES' NAME. No additional public reporting costs.

10. TOTAL PUBLIC COST: $110.18 + $37.61 + $1,137.20 + $100.62 = $1,385.61 annually

IV. ASSUMPTIONS

A. Missouri will implement Phase II of the Centers for Disease Control and Prevention's smallpox inoculation plan, which will result in inoculation of 200,000 Missourians.

B. Generally, about 25% of the communicable disease reports received by the Department of Health and Senior Services (DHSS) come from public sources such as the State Public Health Laboratory, public hospital laboratories, county/district health agencies, and public schools. The remaining 75% of the communicable disease reports come from private sources such as hospitals, hospital laboratories, private laboratories, private providers, and private schools.

C. The incidence of West Nile virus cases in Missouri in 2003 will be similar to the number during 2002.

FISCAL NOTE
PRIVATE COST

I. RULE NUMBER

Rule Number and Name:	19 CSR 20-20.020, Reporting Communicable, Environmental and Occupational Diseases
Type of Rulemaking:	Amendment

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the proposed rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
	Note: Reports of communicable, environmental and occupational diseases and conditions come from the following private entities. The percents listed reflect the percent of these reports received by DHSS that come from each of these entities:	
153	-Hospitals	26% ($2,594.11)
91	-Hospital laboratories	14% ($1,396.83)
34	-Private laboratories	13% ($1,297.05)
6,328	-Private providers	8% ($798.19)
90	-Private schools	4% ($399.09)
	-Unknown	10% ($997.73)
	TOTAL	**75% ($7,483) annually**

III. WORKSHEET - PRIVATE COST ANALYSIS

1. REPORTING SMALLPOX VACCINATION-RELATED CONDITIONS.

Assumption: Implementation of Phase II of the smallpox inoculation plan from the Centers for Disease Control and Prevention (CDC), with approximately 200,000 Missourians inoculated. Estimated rates of secondary transmission and adverse reactions are as follows[1]:

a. Secondary transmission (contact vaccinia): 2-6 cases/100,000; worst-case is **12 cases.**

b. Adverse reactions:

- Inadvertent autoinoculation: 606 cases/1 million inoculations = **121.2 cases.**
- Bacterial infection of site of inoculation: Unknown rate – less common in adults due to less scratching at site and better care of site. **Negligible number of cases.**

- Congenital vaccinia: Defined as infection of the fetus in the last trimester with evidence of disease in the newborn infant. No proven instance of congenital abnormalities has been attributed to vaccination during any stage of pregnancy. Some have postulated that vaccination in the first trimester results in some fetal loss but this has not been substantiated. Congenital vaccinia is a very rare event. Despite large-scale vaccination campaigns in the past that undoubtedly resulted in inadvertent vaccination of many pregnant women, fewer than 50 cases of congenital disease have been recorded in the literature. **Negligible number of cases.**

- Eczema vaccinatum: 30 cases/1 million inoculations = **6 cases**.

- Erythema multiforme: 30 cases/1 million inoculations = **6 cases**.

- Generalized vaccinia: 212 cases/1 million inoculations = **42.4 cases**.

- Post-vaccinial encephalitis: 4 cases/1 million inoculations = **0.8 case**.

- Progressive vaccinia: 7 cases/1 million inoculations = **1.4 cases**.

- Vaccinia keratitis: Unknown, but not common. **Negligible number of cases.**

c. Accidental administration: Occurs "occasionally." **Negligible number of cases.**

Total number of reportable incidents related to 200,000 smallpox inoculations = 189.8

PRIVATE ENTITY COST TO REPORT SMALLPOX INOCULATION-RELATED INCIDENTS = **$624.35.** It has been calculated that generally about 25% of the communicable disease reports received by the Department of Health and Senior Services (DHSS) come from public sources such as the State Public Health Laboratory, public hospital laboratories, county/district health agencies, and public schools. The remaining 75% of the communicable disease reports come from private sources such as hospitals, hospital laboratories, private laboratories, private providers, and private schools. However, most of the smallpox inoculation-related conditions are diagnosed clinically and a larger proportion of these incidents would probably be reported by private hospitals and physicians. The proportion of public to private reporting of smallpox inoculation-related conditions is therefore estimated to be 15% and 85%, respectively. The private entity cost is calculated using the following: (a) 85% of the reports received by DHSS come from private sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The private entity cost is:

(1) No. Cases Per Year	*(2) 0.2 X Hourly Rate-$*	*(3) Salary Expense-$ (1 X 2)*	*(4) Postage Rate*	*(5) Postage Total-$ (1 X 4)*	*(6) Total (3 + 5)*	*(7) 0.85(Total) 0.85(6)*
189.8	3.50	664.30	0.37	70.23	734.53	**$624.35**

[1] Sources: (1) CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book)*; (7th Ed.); April 2002. (2) CDC. *Interim Smallpox Response Plan and Guidelines.* (3) ACIP. Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. *MMWR* 2001; 50 (No. RR-10). (4) http://www.bt.cdc.gov/training/smallpoxvaccine/reactions/.html (figures based on worst case of either CDC's 1968 National Survey or 1968 Ten State Survey for 20+ year age group).

2. SPECIFICATION OF DISEASES CURRENTLY INCLUDED IN CATEGORY OF "ENCEPHALITIS, ARTHROPOD-BORNE." These conditions are: (a) California serogroup viral encephalitis/meningitis, (b) Eastern equine viral encephalitis/meningitis, (c) Powassan viral encephalitis/meningitis, (d) Saint Louis viral encephalitis/meningitis, (e) West Nile viral encephalitis/meningitis, (f) Western equine viral encephalitis/meningitis. These conditions are already reportable, so there is no additional private cost.

3. ADDITION OF "WEST NILE FEVER." National data indicate that about 23% of the human West Nile virus infections result in fever rather than meningoencephalitis. Assuming Missouri has the same number of WNV infections in 2003 as in 2002 (i.e., 169), then statistically, 38.87 (0.23 X 169) of these infections would be classified as WN fever and will represent a new reporting burden.

PRIVATE ENTITY COST TO REPORT WNV FEVER CASES = **$112.82**. The private entity cost is calculated using the following: (a) 75% of the reports received by DHSS come from private sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The private entity cost is:

(1) No. Cases Per Year	*(2) 0.2 X Hourly Rate-$*	*(3) Salary Expense-$ (1 X 2)*	*(4) Postage Rate*	*(5) Postage Total-$ (1 X 4)*	*(6) Total (3 + 5)*	*(7) 0.75(Total) 0.75(6)*
38.87	3.50	136.05	0.37	14.38	150.43	**$112.82**

4. ADDITION OF "COCCIDIOIDOMYCOSIS." This disease is endemic in the southwestern U.S. and is on CDC's list of nationally notifiable diseases. Since only an occasional imported case might occur in Missouri, the private costs associated with reporting this disease are negligible.

5. ADDITION OF "ANIMAL (MAMMAL) BITE WOUND, HUMAN." Data gathered using the Sentinel Active Surveillance System (SASS) from 1995 through 2000 indicate that an average (mean) of 1,959 animal bites are reported to local public health agencies across Missouri each year. SASS was replaced with the High Alert Surveillance System following the events of September 11, 2001 and animal bites are not reported under the latter system. "Animal bite wound" is not a laboratory-diagnosed condition and the assumption is again made (as with the smallpox vaccination analysis noted above) that a greater than normal proportion of reports would come from private sources than from public sources, i.e., public sources – 15%, private sources 85%.

PRIVATE ENTITY COST TO REPORT ANIMAL BITE CASES = **$6,444.13** The private entity cost is calculated using the following: (a) 85% of the reports received by DHSS and/or local public health agencies come from private sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The private entity cost is:

(1) *No. Cases Per Year*	*(2)* *0.2 X Hourly Rate-$*	*(3)* *Salary Expense-$ (1 X 2)*	*(4)* *Postage Rate*	*(5)* *Postage Total-$ (1 X 4)*	*(6)* *Total (3 + 5)*	*(7)* *0.85(Total) 0.85(6)*
1,959	3.50	6,856.50	0.37	724.83	7,581.33	**$6,444.13**

6. ADDITION OF "*STREPTOCOCCUS PNEUMONIAE*, INVASIVE IN CHILDREN LESS THAN 5 YEARS." This disease was recently added to CDC's list of nationally notifiable diseases. Only one to two cases per year occur in Missouri, so additional private reporting costs are negligible.

7. ADDITION OF "*ESCHERICHIA COLI*, SHIGA TOXIN POSITIVE, SEROGROUP NON-O157:H7." Based on information from CDC and existing Missouri data, it is estimated that an average of 104 cases of this condition occur annually in Missouri.

PRIVATE ENTITY COST TO REPORT *E.*COLI NON-O157:H7 CASES = **$301.86**. The private entity cost is calculated using the following: (a) 75% of the reports received by DHSS come from private sources, (b) It takes about 12 minutes to report each case or 0.2 hourly salary of a Community Health Nurse II with a salary of $36,960/year ($17.50 hour), (c) Postage of $0.37 to mail each report (this overstates the expense since many will be sent electronically). The private entity cost is:

(1) *No. Cases Per Year*	*(2)* *0.2 X Hourly Rate-$*	*(3)* *Salary Expense-$ (1 X 2)*	*(4)* *Postage Rate*	*(5)* *Postage Total-$ (1 X 4)*	*(6)* *Total (3 + 5)*	*(7)* *0.75(Total) 0.75(6)*
104	3.50	364	0.37	38.48	402.48	**$301.86**

8. CORRECTION OF MISPRINT REGARDING HIV VIRAL LOAD MEASUREMENT. No additional private reporting costs.

9. UPDATE OF DEPARTMENT OF HEALTH AND SENIOR SERVICES' NAME. No additional private reporting costs.

10. TOTAL PRIVATE COSTS: $624.35 + $112.82 + $6,444.13 + $301.86 = $7,483.16 annually

IV. ASSUMPTIONS

A. Missouri will implement Phase II of the Centers for Disease Control and Preventions smallpox inoculation plan, which will result in inoculation of 200,000 Missourians.

B. Generally, about 25% of the communicable disease reports received by the Department of Health and Senior Services (DHSS) come from public sources such as the State Public Health Laboratory, public hospital laboratories, county/district health agencies, and public schools. The remaining 75% of the communicable disease reports come from private sources such as hospitals, hospital laboratories, private laboratories, private providers, and private schools.

C. The incidence of West Nile virus cases in Missouri in 2003 will be similar to the number during 2002.