4420.0070 CONTAINMENT FACILITIES.

Subpart 1. **Certification.** To certify a facility as a containment facility, the owner or operator of the facility or the institutional biosafety committee, as defined in the NIH guidelines, for the facility must file with the board a certification stating the level of biosafety maintained at the facility and certifying that the facility complies with the applicable NIH guidelines and that the level of biosafety maintained is appropriate for the genetically engineered organisms being used in the facility. The board shall forward the containment facility certification documents to agencies with a significant environmental permit for review within the agency's authority.

Subp. 2. **Inspection.** The board or an agency with authority to inspect may inspect the containment facility to determine if the facility and its operation comply with the certified level of biosafety and if the level of biosafety is appropriate for the genetically engineered organisms being used. If it is found that the facility does not comply with the certified level of biosafety or that the biosafety level is inappropriate for the genetically engineered organisms being used, the responsible person must be ordered to comply with the guidelines or to cease using the genetically engineered organism or to file an application for a release permit or exemption. Reasonable and appropriate conditions may be placed on the use of the genetically engineered organism while an application for a release permit or exemption is pending.

Subp. 3. **Exemption.**

A. Any person proposing the use of a genetically engineered organism in a facility that does not meet the requirements of a containment facility, but provides adequate containment for the specific organism, may apply for an exemption from the requirement to obtain a release permit.

B. The proposer must file with the board a written request for exemption that includes:

(1) a description of the genetically engineered organism and its use;

(2) a description and location of the facility;

(3) the reasons why the facility provides adequate containment for the genetically engineered organism and its use;

(4) a list of governmental units with approval authority over the use of the facility; and

(5) any relevant submittals to the federal government.

C. Within five days of the filing, the chair must mail notice of the request to the local governmental units within whose jurisdiction the facility is located, governmental

units with approval authority over the use of the facility, and the mailing list identified in part 4420.0060, subpart 1.

D. The board must grant or deny the exemption at its first regularly scheduled meeting after the request for exemption is filed, provided that the request is filed at least 21 calendar days before that meeting.

E. If the board denies an exemption, the board must inform the proposer in writing of its reasons. The proposer may refile a revised request for exemption or may apply for a release permit.

F. The use of the genetically engineered organism allowed in an exemption granted under this subpart is exempt from environmental review for a release under chapter 4410.

Subp. 4. **Facilities existing on August 3, 1992.** On August 3, 1992, any person who is using a genetically engineered organism in a containment facility, or in a facility that is not a containment facility and for which the person will seek an exemption, must file with the board, within 90 days, either the certification required under subpart 1 or the exemption request required under subpart 3.

Statutory Authority: *MS s 116C.94*

History: *17 SR 139*

Published Electronically: *August 21, 2007*