STATE OF MINNESOTA BOARD OF ANIMAL HEALTH

IN THE MATTER OF THE PROPOSED AMENDMENTS
TO RULES OF THE BOARD OF ANIMAL HEALTH
PARTS 1705.1090 THROUGH 1705.1210,
GOVERNING THE CONTROL OF RABIES IN MINNESOTA.

STATEMENT OF NEED AND REASONABLENESS

Minn. Stats. §35.03 (1986) authorizes and requires the Minnesota Board of Animal Health (hereinafter referred to as the "Board") to adopt rules necessary to protect the health of Minnesota's domestic animals. The current rules of the Board provide for the control of rabies in Minnesota and include provision for the quarantine of rabies exposed animals. An early release of a quarantine on dogs or cats may be obtained provided the exposed animals have been vaccinated for rabies at least 21 days prior to exposure and revaccinated immediately after exposure. Minn. Rules Pt. 1705.1175. Such vaccinations must be performed by a licensed veterinarian with a vaccine approved by the Board. Minn. Rules Pt. 1705.1090, subd. 7.

The major change to the existing rules is a new requirement which will require that animal rabies vaccines only be administered by, or under the supervision of, a licensed veterinarian whether or not a quarantine exists. Such a requirement is not novel to the control of rabies but is an existing requirement for many other animal disease control programs. For example, under Minnesota's Brucellosis Disease Control Program, brucella vaccine may only be sold to and administered by veterinarians. Minn. Rules Pt. 1705.0260. Similarly, blood samples drawn to test for pseudorabies in hogs must be drawn only by accredited veterinarians. Minn. Rules Pt. 1705.2410. See also, Minn. Rules Pt. 1705.0920, (Herds Infected with Bovine Tuberculosis may only be tested by a full time regulatory veterinarian). The current rabies rule provides for the quarantine of animals bitten or exposed by a rabid animal. One procedure which may be utilized to release that quarantine when dogs and cats are involved is to assure that the exposed animal has been vaccinated at least 21 days prior to exposure and revaccinated after exposure. These vaccinations, under the rule, must be performed by a veterinarian. The proposed amendment in essence provides that all vaccinations, whether or not they are applied to a quarantined animal, must be performed by a licensed veterinarian.

The United States Department of Agriculture, Animal and Plant Health Inspection Service, has the authority to restrict the use of any biological product to use only by veterinarians or under the supervision of veterinarians. Title 9, CFR Part 102.5. The Department of Agriculture has not placed that restriction upon the labels for rabies vaccination biological products. What it has done, is to require that distribution of such products in each state be limited to authorized recipients designated by proper state officials, under such additional conditions as those authorities may require. See Attachment "A", "Veterinary Services Biologics Notice", dated February 20, 1980. Thus, the Federal Animal Health authorities have recognized and authorized the officials of each state to determine how each of the biological rabies products may be distributed in the state and has recognized that each state has the authority to restrict rabies vaccine use by a veterinarian or under the direction of a veterinarian without conflict under the federal law. See Exhibit A, attached hereto.

The Minnesota Board of Animal Health believes it to be in the best interest for the health and welfare of Minnesota's domestic animals to exercise this authorized authority and require that rabies vaccinations only be administered by or under the supervision of a licensed veterinarian.

Vaccination of animals is a key element in any rabies control program in the United States. The success of such a control program requires that a high percentage of animals be vaccinated; that the vaccines used be safe and effective; that the vaccines be properly stored and administered; and that an adequate system of identification and recordkeeping be maintained to assure that animals are re-vaccinated at the proper intervals to maintain immunity. In the past, national organizations, such as the National Association of State Public Health Veterinarians and the American Veterinary Medical Association Council of Biologics and Therapeutic Agents have gone on record in favor of placing restrictions on the distribution and use of rabies vaccines as a means of strengthening rabies control procedures. Such requests have also been endorsed by the United States Animal Health Association Rabies Committee, the American Veterinary Medical Association Council on Public Health and Regulatory Medicine and the Conference of State and Territorial Epidemiologists.

At the current time, modified live rabies vaccines are restricted to use only by a veterinarian while inactivated rabies vaccines can presently be obtained by pet and animal owners through over-the-counter purchases for use in the vaccination of their own animals. Such use by untrained lay personnel could result in vaccinated animals not being properly immunized because the vaccine used has lost potency from improper handling and storage or because vaccine was not properly administered. Use of rabies vaccines by lay personnel also results in a lack of proper records to assure animals are revaccinated at the appropriate intervals. Also, some rabies vaccines can actually cause rabies if given to the wrong species of animals or if given at the wrong injection site. These problems would be avoided if rabies vaccines were available only to veterinarians who by professional training are knowledgeable in their use. Veterinarians are trained in the correct handling and administering of vaccines. Improper procedures will not give proper immunity. The vaccine must be given at the correct age and must be boostered at the right time; the vaccine must be given at the correct injection site; and the vaccine must be handled properly to prevent deterioration. In addition, vaccination of improper species (skunks, ferrets and other "wild" pets) by the public may lead to a false sense of security. No vaccine is approved to be used in "wild" species. If an owner vaccinated one of these species and is later bitten, he may not seek medical attention because his pet was presumably "vaccinated". Restrictions on the use of vaccines will avoid these concerns.

Another fear expressed by the Minnesota Health Department was that if someone was exposed to rabies they could use these animal vaccines on themselves instead of getting the approved human diploid vaccine from their doctor. The animal vaccine could be purchased for under $25.00 while the M.D. would charge $500 - $1,000 for the proper vaccine.

An additional reason for restriction is the need to complement the provisions of Minn. Stat. §346.51. This section provides:

> An owner or custodian of a dog which does not have an appropriate anti-rabies vaccination and which bites or otherwise exposes a person to rabies virus may be penalized under §346.53.

Section §346.53 provides for petty misdemeanor penalties for violation of §346.51. The term "Appropriate anti-rabies vaccination" is not defined in the statute. Thus, there is presented a great deal of confusion as to what type of vaccination will satisfy the statutory requirements. An "official vaccinate", is defined in the current rule in Pt. 1705.1090, subd. 7, which provides that "vaccinated" means an animal vaccinated for rabies by a licensed veterinarian with a product approved by the Board. The proposed amendment restricting the use of rabies vaccines to use only by veterinarians will assure compliance with §346.51 without creating difficult factual issues for a court to resolve regarding the terms contained therein and whether a particular animal is effectively vaccinated. In addition, proper recordkeeping, identification and certification would be assured.

The remaining changes to the current rule are basically changes in grammar and clarification of terms rather than substantial changes. Primary changes are summarized as follows:

Pt. 1705.1090, Subd. 7:

All biological products which are approved for use in the United States are licensed by the United States Department of Agriculture. Lists of such products which have been approved and licensed by the Department of Agriculture along with indications of the period or duration of the immunity provided by such products is routinely compiled in the "Compendium of Animal Rabies Vaccines, 1986", which is prepared by the National Association of State Public Health Veterinarians, Inc. Thus, the Board felt it would be helpful to assure that the Board maintains a current issue of that Compendium to provide information to veterinarians and the public with respect to what biological products have been approved by the USDA and their period of duration. The Board found it unnecessary to define the "Compendium" as provided by under the current rule but merely to provide a reference to that Compendium advising the public that it is available upon request from them.

Pts. 1705.1140, 1705.1150 and 1705.1160:

These parts are deleted and reinstated in Pts. 1705.1175 and 1705.1180. Thus, the language proposed for Pts. 1705.1175 and 1705.1180 are not new requirements but rather, a recodification of the current rule.

Pt. 1705.1190:

This part provides for the issuance of rabies proclamations and basically repeats the language of Minn. Stat. §35.68. The Board believes the new language provides clarification and guidelines regarding the issuance of such proclamations.

Pt. 1705.1210:

The proposed changes provide clarification of the conditions under which permits for the removal of quarantined dogs will be raised. Such criteria were lacking under the current rule.

In assessing the economic impact of the proposed changes, the Board is aware that the requirement that vaccines be administered only by or under the supervision of licensed veterinarians may increase the cost of such vaccinations to a few animal owners. That cost, however, is felt by the Board to be minimal in view of the

safeguards which will be provided through official, professional vaccinations. The Board has also determined that there will be no additional expenditures of public money by local public bodies because of the rule changes nor will there be any adverse impact on agricultural land in Minnesota. In addition, the Board considered its effect upon small businesses. To the extent Minnesota's livestock enterprises are considered "small businesses" for purposes of Minn. Stat. §14.115, the proposed rule change may have a slight cost factor in the event a livestock owner desires to vaccinate animals. The cost, however, is minimal and the establishment of less stringent compliance standards for such businesses would be contrary and inconsistent with the purposes of the rabies disease control program.

Date: March 12, 1987

T. J. Hagerty, DVM
Executive Secretary
Board of Animal Health

United States Department of Agriculture
Animal and Plant Health Inspection Service
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Hyattsville, MD 20782

February 20, 1980

VETERINARY SERVICES BIOLOGICS NOTICE

Subject: Distribution of Rabies Vaccine, Brucella Abortus Vaccine, Brucella Abortus Antigen, and Tuberculin-PPD Bovis

EXHIBIT "A"

To : Biologics Licensees
State Veterinarians
Regional Directors
Regional Biologics Specialists
Area Veterinarians in Charge
National Veterinary Services Laboratories
Staff Veterinarians
State Public Health Veterinarians

On September 21, 1979, a notice was published in the Federal Register at 44 FR 54737 requesting comments on proposed actions that would provide additional controls on the distribution of certain products under the provisions of Title 9, CFR Part 102.5(e).

Comments on this notice have been considered and all U.S. Veterinary Biological Product Licenses for Rabies Vaccine, Brucella Abortus Vaccine, Brucella Abortus Antigen, and Tuberculin-PPD Bovis have been amended by addition of the following condition:

"Distribution in each State shall be limited to authorized recipients designated by proper State officials--under such additional conditions as these authorities may require."

This action will require licensees for these products to contact the proper officials of each State to determine how each of these products may be distributed. Each State has the authority to restrict the distribution of these products in accordance with local needs, including the authority to restrict Rabies Vaccine to use by a veterinarian only or to use by or under the direction of a veterinarian only, if desired.

The above condition has been added to U.S. Veterinary Biological Product Licenses for the following products:

Code	Product and Form	License Numbers of Producers
1251.00	Brucella Abortus Vaccine, Strain 19, Live Culture	52, 107, 188
1251.01	Brucella Abortus Vaccine, Strain 19, Live Culture	188
1575.80	Feline Panleukopenia-Rabies Vaccine, Killed Virus, Cell Line and Murine Origin	266
1901.03	Rabies Vaccine, Modified Live Virus, Tissue Culture Origin, High Cell Passage, SAD Strain	107, 124, 264
1901.05	Rabies Vaccine, Modified Live Virus, Tissue Culture Origin, High Cell Passage, SAD Strain	124
1901.22	Rabies Vaccine, Modified Live Virus, Cell Line Origin, High Egg Passage, Flury Strain	189
1901.23	Rabies Vaccine, Modified Live Virus, Cell Line Origin, High Cell Passage, SAD Strain	107
1905.00	Rabies Vaccine, Killed Virus, Tissue Culture Origin	107
1905.20	Rabies Vaccine, Killed Virus, Cell Line Origin	225, 227
1905.51	Rabies Vaccine, Killed Virus, Murine Origin	266
1905.55	Rabies Vaccine, Killed Virus, Murine Origin	266
5011.00	Brucella Abortus Antigen, Stained Antigen	107
5302.00	Tuberculin, PPD Bovis, Intradermic	107

M. J. Tillery
Director
National Program Planning Staffs
Veterinary Services