

TITLE 177 NEBRASKA DEPARTMENT OF HEALTH/LABORATORY SERVICES/REGULATIONS

CHAPTER 4 RULES AND REGULATIONS RELATING TO BIOLOGICAL PRODUCTS AND THE DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS

TABLE OF CONTENTS

<u>SUBJECT</u>	<u>STATUTORY AUTHORITY</u>	<u>CODE SECTION</u>
Dating	71-1802	003
Dispensing	71-1802	002
Distribution of Materials Containing Live Micro-Organisms	71-1802	004
Storage	71-1802	001

Title 177 NEBRASKA DEPARTMENT OF HEALTH

Chapter 4 RULES AND REGULATIONS RELATING TO BIOLOGICAL PRODUCTS AND THE DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS

001 STORAGE. Toxins, toxoids, antitoxins, bacterins and bacterial vaccines shall be stored in a refrigerator at not less than 2° C (36° F) nor higher than 10° C (50° F). Freezing shall not be permitted.

Modified smallpox vaccine and rabies vaccine shall be refrigerated at as low a temperature as possible, preferably well below freezing temperature.

Tuberculin in tablet form (P.P.D.) and dried plasma shall be stored in a cool dry place.

002 DISPENSING. Biologicals shall be dispensed only in the unopened original package in which they were placed and sealed by the manufacturer.

003 DATING. Biologicals shall not be dispensed beyond the expiration date which has been indicated on each package by the manufacturer.

004 DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS.

004.01 Application for Permit. Application for permit for the use of aforementioned materials in the prevention or control of diseases of animals shall be made to the State Veterinarian in a manner prescribed by the Department of Agriculture and Inspection. Application for permits for the use of these materials for any other purpose shall be made to the Director of Health, State Department of Health, on forms provided for that purpose. The aforementioned Departments shall keep a record of the date of issuance and other contents of all permits issued.

004.02 Distribution Prohibited Except to Individuals Possessing a Permit. No vaccine, bacterin, immunogen or other material containing live micro-organisms capable of infecting humans and inciting therein any disease or pathological condition shall be transmitted by sale, gift or in any other manner except to an individual possessing a valid permit as provided by these regulations.

004.03 Form of Permits. Permits shall be on forms provided by the respective State Departments. Permits for use of materials referred to herein in veterinary medicine shall be issued by the State Veterinarian; those for all other purposes by the Director of Health, State Department of Health. Permits involving the manufacture or sale of any such product used in veterinary medicine shall bear the endorsement of the State Veterinarian.

Title 177
Chapter 4

004.04 Micro-Organisms Pathogenic to Humans. The following named or described micro-organisms are hereby declared to be pathogenic to humans:

004.04A Bacillus anthracis.

004.04B All varieties of malarial plasmodii including P. vivax, P. malariae and P. falciparum.

004.04C Mycobacterium tuberculosis, human, bovine and avian strains.

004.04D Erysipelathrix rhusiopathiea (swine erysipelas vaccine).

004.04E Salmonellae (all species).

004.04F Newcastle Disease virus.

004.04G Any other species of micro-organism capable of inciting disease in humans, and not listed herein. Exceptions: Virus prepared for the prophylactic treatment of rabies in humans, and smallpox vaccine when manufactured according to the standards of the United States Public Health Service.

004.05 Records of Sale to be Kept. Records of all transfers by sale or otherwise of material containing such pathogens as named herein or supplementally named shall be kept by the individual distributing the pathogen. Such record shall show the date of transfer, the item or items containing pathogenic micro-organisms and the identity of the organisms, the name and address of the person receiving same, and the number of his valid permit, and shall at all times be available for inspection by an authorized representative of the Nebraska State Department of Health or an authorized representative of the state Department of Agriculture and Inspection.

004.06 Renewal of Permits. Permits shall expire on the 31st day of December of the year issued unless revoked prior to that date. Application for renewal must be in writing. In case the information furnished in the application for the original permit is still applicable, the applicant shall so state in his application for renewal. Should changes in the condition under which the original permit was issued have occurred, a new written application shall be submitted and passed on before reissuance of the permit.

004.07 Revocation of Permit. Any permit may be revoked by the Department issuing same when deemed necessary to protect the public health. The individual concerned shall be given an opportunity for a hearing, said hearing to be subject to such rules as may be adopted by the Director of the Department issuing the permit.

SOURCE: Section 71-1802