

Subject: **Licensing and Registration of Producers of Antibodies, Sera and/or Other Animal Parts and Pregnant Mare Urine (PMU)** **Policy #10**

References: 9 CFR, Part 1, Section 1.1
 9 CFR, Part 2, Section 2.6(c)

History: Replaces memos dated August 28, 1990, entitled, “Determination of Need for Licensing or Registration for Antibody Production/Serum Collection” and April 17, 1992, entitled, “License Fees for the Production and Sale of Blood Products.”

Justification: Clarification of the licensing and/or registration of producers of antibodies, sera or other animal parts. Production of PMU is not covered by the Animal Welfare Act.

Policy: A facility that produces antibodies or antisera is “testing” animals for their immune response and selects animals for production based on the results of this testing. Therefore, the facility must be **registered** as a research facility.

A facility which harvests or produces only normal blood or sera for regulated purposes is not testing. The facility is selling parts of the animal which is maintained for this purpose. Therefore, the facility meets the definition of a dealer and must be **licensed** as such.

A research facility selling antibodies, antisera, or other body parts for research, teaching, testing, or experimentation, would require a dealer’s **license** in addition to its registration. This is not intended to apply to legitimate collaboration between researchers and their exchange and/or transfer of body parts, antibodies, and antisera.

The class B dealer’s license fee will be based on the total amount of blood product sales in a year. The cost of the animals will not be deducted from this figure, unless new animals are obtained for every batch of blood products. The table in 9 CFR, Part 2, Section 2.6(c) determines the correct fee.

A license **would not** be required if the research facility only produces antibodies/antisera on a contract basis for particular investigators, not for resale.

Horses used for the production of PMU are not covered by the AWA. This activity is not defined as research, teaching, or testing. People who deal in horses or horse parts are not required to be licensed.

