Subject: **Licensing and Registration Guidelines for Producers of Antibodies, Sera and/or Other Animal Parts, Producers of Genetically Engineered and Cloned Animals, Licensed Exhibitors, and Producers of Pregnant Mare Urine (PMU)** **Policy #10**

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

History: Replaces Policy #10 dated April 14, 1997.

Justification: Clarification of the licensing and/or registration of producers of antibodies, sera or other animal parts, producers of genetically engineered and cloned animals, and licensed exhibitors. Production of PMU is not covered by the Animal Welfare Act (AWA).

Policy: Producers of Antibodies, Sera and/or Other Animal Parts

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.

Producers of Genetically Engineered and Cloned Animals

A facility that produces genetically engineered animals is using such animals in research, tests or experiments to determine the effect of the unconventional introduction of synthetic, species-foreign, or other such genetic material on the phenotype of the animal. Therefore, the facility must be **registered** as a research facility.

A facility which produces cloned animals for regulated purposes utilizing standard veterinary medical practices is considered to be breeding animals, and must be **licensed** as a dealer. Other activities conducted by cloning companies will be reviewed on a case-by-case basis to determine whether they are covered by the AWA.

Activities at Licensed Exhibitors

Licensed exhibitors occasionally collect information on their animals with the intent to improve the nutrition, breeding, management, or care of such animals. These programs may be exempted from the registration requirements of the regulations as long as the collection methods:

- are performed as an adjunct to normal husbandry or veterinary procedures for the benefit of the animal or species (e.g., routine veterinary care, embryo transfer, artificial insemination, electroejaculation); or
- are not invasive (feed studies); or
- do not cause pain or distress to the animal (behavioral observations).

However, if the licensed exhibitor is conducting biomedical research (using the animals as models for human applications), conducting invasive or painful/distressful procedures for nonhusbandry purposes or if the research involves domestic dogs or cats, then the licensee is **not** exempt from the need for registration.

Producers of Pregnant Mare Urine

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.