

Information about Genotyping Laboratory Approval

Approved genotyping laboratories are eligible to conduct privately funded official scrapie genotype testing and compete for National Scrapie Eradication Program (NSEP) funded official genotyping. This approval lasts for 1 year and is subject to review and renewal.

Each laboratory must apply for approval to conduct official genotype tests. This approval process begins by the laboratory sending an application package to the National Veterinary Services Laboratory (NVSL).

The application must contain the following information about the laboratory:

- Name and address of the laboratory.
- Name of the legally responsible official and, if different, the director of the laboratory.
- A description of the laboratory facilities and equipment that will be used in performing genotype tests.
- A list of the types of samples that will be tested.
- The standard operating procedure for each test to be used, including methods, materials, equipment, and other relevant information.
- A list of the names of individuals performing specific tests and a detailed state of each individual's qualifications.
- A detailed description of the procedures to satisfy the recordkeeping requirements of the Scrapie Eradication Program.
- A description of the specific procedures for reporting test results.
- The laboratory quality assurance manual.
- The statement authorizing APHIS to inspect the laboratory without notice during normal business hours. Such an inspection may include, but is not limited to, review and copying of records, observation of tests being conducted, and interviewing of personnel.

Following review of the application package for completeness, each laboratory is required to complete a preliminary test panel of samples to demonstrate basic technical competency for the required tests. NVSL then schedules and conducts a site visit to meet laboratory personnel, observe laboratory operations, inspect facilities and evaluate testing and laboratory protocols. Laboratory that successfully passes the site visit is then sent a second proficiency test panel to demonstrate a statistically high level of accuracy in conducting genotyping tests. Following successful completion of the final proficiency panel the laboratory is given written notification of APHIS approval to conduct official scrapie genotype testing.

If you have any questions or are a representative of a laboratory that would like to be considered for approval to participate in the genotyping of sheep for the Scrapie Eradication Program, please contact Diane.L.Sutton@aphis.usda.gov.