The following is an excerpt (Chapter 1) from the *Surveillance and Data Standards for USDA/APHIS/Veterinary Services, version 1.0 (July 2006)* that was developed by the Centers for Epidemiology and Animal Health in July 2006. This Chapter provides standards and guidelines for planning and evaluation surveillance systems.

Chapter 1   Standards for the Key Components of a Surveillance System

The information in Chapter 1 is intended to assist epidemiologists and surveillance experts who may be developing new surveillance systems or evaluating and improving existing systems. The guidelines provide an overview and generalized framework for details likely to be considered for comprehensive and efficient surveillance. The guide is not intended to be prescriptive or to define mandatory items for inclusion by surveillance architects, but instead to provide a useful tool to expedite development and review processes.

Four categories of information are included in the chapter (see Table 1). First is the introductory information that should lay the foundation for the surveillance system. These standards address components such as purpose, objective, and outcomes of the system, as well as basic considerations about the disease of interest and the people who collect, analyze, or base decisions on the resulting information. The second concept involves standards related to the design of the sampling strategy and data collection. Following this, a group of standards aid the surveillance professional in planning the appropriate analysis and reporting for the data collected. Finally, several guidelines are presented for the implementation and evaluation of the surveillance after a plan is developed.

Table 1. Summary of Standards For Key Components of a Surveillance System

Concept	Standards:
Introductory Information	1.1 Disease Description 1.2 Purpose and Rationale for Surveillance 1.3 Surveillance Objectives: Principal Uses of Data for Decision-Making 1.4 Expected Outcomes: Products, Decisions and Actions 1.5 Stakeholders and Responsible Parties
Population Description and Sampling Methods	1.6 Population Description and Characteristics 1.7 Case Definitions 1.8 Data Sources 1.9 Sampling Methods
Analysis, Reporting, and Presentation	1.10 Data Analysis and Interpretation 1.11 Data Presentation and Reporting
Implementation, Budget, and Evaluation	1.12 Surveillance System Implementation: Priorities, Timelines, and Internal Communications 1.13 Budget 1.14 Surveillance Plan Performance Metrics 1.15 Surveillance System Evaluation

1.1 Disease Description

Standard: The surveillance planning documents include current and relevant supporting information about the disease under surveillance.

   a.   Information included in the disease description is used to develop the case definitions. See standard 1.7.

Supporting Information:

The following classes should be included in the disease description section of the surveillance planning documents, or in documents describing the rationale of the surveillance system.

Class	Guidelines
Etiologic agent	➢ General categories: Virus, bacteria, toxin, external parasite, internal parasite, etc. ➢ Taxonomic classification: Family, genus, species; see <http://www.itis.usda.gov/>. ➢ Common name of the disease or condition. ➢ Pathogen strain or serotype.
Distribution	➢ Available information about location of current cases of disease should be identified. See location guidelines in Chapter 2. ➢ For FAD and diseases affecting trade, distribution throughout the world, at least by continent, should be included. ➢ For endemic diseases, distribution should be defined at the tertiary or lowest available administrative levels when possible, (e.g., National, State, or county.)
Clinical signs	➢ Description is targeted for the general practitioner audience.
Case definitions	➢ Criteria for a positive case, negative case, and others as applicable: Suspect, reactor, laboratory positive, etc. See standard 1.7, case definitions.
Pathological findings	➢ Necropsy results may be necessary for case finding, case definition, or passive reporting of cases. ➢ For lab-based surveillance and reporting, standards should be compatible with laboratory standards. See Chapter 2.
Epidemiology	➢ Considers and discusses the likelihood of disease introduction, outbreak, or change of status. ➢ Includes industry and management factors affecting disease transmission, (e.g., confinement operations, biosecurity practices, or industry awareness.) ➢ Provides measures or estimates of frequency, (e.g., prevalence, incidence, morbidity rate, mortality rate, or case fatality rate.) ➢ Transmission factors such as contagiousness, virulence of

	agent, or infectiousness, may be important components.
	➢ Associated hosts, environmental conditions, and agent factors may influence the surveillance to be conducted.
	➢ Susceptible species, population density, and location of the species are factors for conducting surveillance for many diseases.
Economic impact	➢ Economic impact compares the discounted long-term impact of not controlling the disease or conducting surveillance with the discounted long-term impact of controlling the disease. Includes the impact of disease eradication, assuming surveillance results in eradication, impact of government activities in the affected industry, and consumer and allied industry impacts resulting from the surveillance system.
	➢ Economic indices of disease importance includes the direct and indirect costs of the surveillance system.
Methods for control	Mitigations and methods to control disease at national and herd levels. If conducting an economic impact assessment before initiating the surveillance system, the assessment should consider a number of scenarios about potential surveillance methods.

1.2 Purpose and Rationale for Surveillance

The purpose and rationale describe the need and reasoning for the surveillance system, and provide justification for the type of surveillance planned.

Standard: The purpose and rationale for surveillance are clearly described in the surveillance plan or equivalent program planning documents.
   a. Responsible parties and stakeholders have a clear understanding of the purpose and rationale of the surveillance system.
   b. The purpose and rationale are reiterated in progress and summary reports and presentations.
   c. The purpose and rationale are periodically reviewed to determine relevance.
   d. Changes in the purpose and rationale are documented and shared with stakeholders and all responsible parties.

Supporting Information:

The purpose describes the need and reasoning for the surveillance system and is justified by the rationale for conducting the surveillance.

Some of the purposes of surveillance are to:
   ➢ Estimate the magnitude and baseline status of a problem;
   ➢ Determine the geographic and demographic extent of an outbreak, predict possible spread, and provide data for disease regionalization;
   ➢ Describe the natural history of a pathogen or disease;
   ➢ Detect unusual clusters of disease (spatially or temporally), providing for early detection;

- ➢ Generate hypotheses and stimulate research;
- ➢ Define or assess the health status of a population, providing the foundation for market confidence;
- ➢ Detect changes in health practices, risk factors, or exposure;
- ➢ Facilitate planning of national control and eradication programs and strategies;
- ➢ Evaluate control measures and intervention efforts;
- ➢ Identify factors associated with a disease agent that may be used in conducting surveillance elsewhere and in modeling pathogen spread; and
- ➢ Determine times of year when most cases are observed.

The rationale for a surveillance system may include a description of the severity of the disease and its impact on trade, animal welfare, public health and other key areas. It may also include additional background information about the disease and its impact, and may summarize past surveillance efforts.

The purpose and rationale for the surveillance system may describe requirements for successful surveillance as well as measurement of success. Surveillance plans, supporting documents, and reports should use similar terminology to explicitly declare the purpose and rationale of the surveillance system.

The purpose and rationale of a surveillance system may change or evolve over time, and these changes must be documented and shared with stakeholders and responsible parties.

1.3 Surveillance Objectives: Principal Uses of Data for Decision-Making

Surveillance objectives identify the goals of the surveillance plan that will achieve the purposes described in 1.2 and outline how the resulting data and information will be used for policy actions or decision-making.

Standard: The surveillance objectives are specifically described in a surveillance plan or equivalent documents and explain the principal uses of the data for decision-making. They identify goals that when accomplished, will achieve the purposes of the surveillance system.   Surveillance systems with multiple objectives identify and justify the relative priority of those objectives.

  a. Responsible parties and stakeholders have a clear understanding of surveillance objectives and their relative priority.
  b. Surveillance objectives are addressed in reports and presentations that describe progress in the surveillance system.
  c. The relative priority of the objectives is demonstrated in the implementation of the system. Refer to standard 1.12.
  d. Surveillance objectives and priorities are periodically reviewed to determine the extent of achievement.
  e. Changes in surveillance objectives are documented and shared with responsible parties and stakeholders.

Supporting Information:
When surveillance objectives are achieved, the resulting data are or will be used for action. The following table presents the standard list of 10 surveillance objectives used as a

blueprint for developing swine surveillance systems. [1]	
Foreign Animal Disease	➢ Rapid detection of FAD outbreak on domestic soil
	➢ Detect outbreaks of FAD on foreign soil
	➢ Monitor risk associated with domestic outbreak of FAD
Trade	➢ Document disease-free status
	➢ Describe disease prevalence patterns for regionalization
Disease control	➢ Assess progress in eradication and control campaigns
	➢ Assess progress in education campaigns
	➢ Assess progress in reduction of food-borne pathogens and zoonotic disease
Emerging Animal Disease	➢ Describe trends in hazards, exposures, and health conditions
	➢ Recognition of emerging diseases

Surveillance plans, supporting documents, and reports should use similar terminology to declare the objectives of the surveillance system.

The objectives of a surveillance system and use of its data for decision-making may change over time, and these changes must be documented and shared with stakeholders and responsible parties.

Priorities. Surveillance systems with multiple objectives must identify and justify the priority of those objectives. Criteria prioritization might include impacts on trade and productivity, animal welfare concerns, feasibility of control, cost of surveillance, and public health implications. Implementation of the surveillance system should demonstrate these priorities. See standard 1.12 for priorities in surveillance system implementation.

1.4 Expected Outcomes: Products, Decisions, and Actions

Expected outcomes include the information resulting from the surveillance effort, which is then used for decision-making, policy development, and action—as well as the physical products that are generated, such as databases and reports.

Standard: Surveillance planning documents articulate the expected outcomes of the surveillance system and describe the resulting products, including the decisions and actions resulting from implementation.

Expected outcomes:
  a. Include specific statements for actions to be taken following identification of cases, and methods for ensuring timely response. This may be a reference to a VS response plan, to Uniform Methods and Rules (UM&R), or other actions that surveillance will trigger.
  b. Include specific statements regarding actions to be taken when surveillance demonstrates freedom from the disease at the chosen threshold of detection, such as design prevalence or detection limit.

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[1] Bush E, Lautner E, McKean J, Miller L. Swine Futures Project Final Report. U.S. Department of Agriculture Animal and Plant Health Inspection Service; 1999.

c. Include specific statements regarding how the surveillance system information will affect policy development and agency decision-making.
d. Include metrics allowing for evaluating performance of the surveillance. See standard 1.14 for surveillance plan performance metrics.
e. Are consistent with the objectives of the surveillance system.
f. Are a priority for those responsible for managing the surveillance system to ensure that the outcomes are realized.
g. Are periodically reviewed by stakeholders and responsible parties to compare these outcomes with the surveillance system products as part of internal system review. See document describing Surveillance System Evaluation Protocol; for more information, e-mail national.surveillance.unit@aphis.usda.gov.

Supporting Information:

The expected outcomes are statements that describe, using clear and specific terms, the tangible products that will result from the surveillance system. Expected outcomes include products such as data, reports, and information that will influence policy development or decision-making.

Examples of expected outcomes:

➢ "The surveillance system will produce an annual summary report describing detailed information on the status of DISEASE "X" in the United States…"
➢ "The surveillance system will provide timely and useful information to Federal and State decision-makers that will be used to determine what, if any, additional eradication efforts for DISEASE "X" are needed…"
➢ "The surveillance system will provide annual updates on the effectiveness of educational programs in reducing the incidence of DISEASE "X" in the States of a, b, c, and d…"

Statements of expected outcomes form the foundation for assessment of the surveillance system.

1.5 Stakeholders and Responsible Parties

Standard: The stakeholders and the individuals responsible for designing, implementing, managing, and disseminating information on the surveillance system are clearly identified in the surveillance planning documents.

a. Responsible parties and stakeholders are identified by role, title, group name, or agency rather than by name.
b. Responsible parties and stakeholders are consulted and engaged in surveillance planning and may, in some cases, contribute to the surveillance plan and procedures.
c. Responsible parties have appropriate and adequate training to fulfill their responsibilities. See Chapter 3.
d. An Information Technology (IT) team is identified early in the surveillance planning process; this team is responsible for developing and implementing the database system, including data entry and reporting requirements, for the surveillance program.

Supporting Information:

The documentation of responsible parties need not follow this format, but the individuals or groups responsible for these functions must be identified. The responsible parties should be engaged in the surveillance planning process to provide input regarding their expected role.

Class	Guidelines
Users of surveillance system information (stakeholders)	Are those who are: ➢ Policymakers ➢ Information users ➢ Beneficiaries of the surveillance information ➢ Data providers
Responsible parties for designing, implementing, managing, and disseminating information	Are the groups of individuals responsible for various aspects of the surveillance system, including: ➢ Surveillance system design ➢ Surveillance system implementation and leadership ➢ Data application design, development, and implementation ➢ Data application support and maintenance ➢ Data collection, including field data collection and laboratory data management ➢ Field data collection ➢ Laboratory testing ➢ Who detects cases ➢ Who confirms cases ➢ Who reports cases ➢ Field training of data collectors, data entry personnel, etc. See Chapter 3 ➢ Data analysis and interpretation ➢ Results dissemination and reporting ➢ Actions based on surveillance findings ➢ Review of surveillance system effectiveness

Stakeholders and responsible parties should be provided with appropriate information so they understand the expected outcomes of the surveillance system.

The IT team should be identified early in the surveillance planning process. This team identifies and articulates (1) business processes needed to capture inputs and produce appropriate outputs, (2) business rules for data collection, and (3) the risks, constraints, and assets of the data system.

1.6 Population Description and Characteristics

Standard: The population under surveillance is well defined in system planning documents and in system reports and publications. The population description inherently describes the scope or reach of the system (i.e., National, State, regional, local, and neighborhood.)

Supporting Information:

Depending on the structure of the system, at least two populations need to be described for most surveillance systems. The target population is the universe of eligible units at risk of the condition under surveillance, which gives rise to sampled units or cases. If the target population is sampled, then the study population should be described. The study population is the universe of sampled units that are investigated or counted in the surveillance system. If the target population is not sampled, then the catchment area of the population from which the reported cases come should be described.

The description of the population should include total size, animal type, administrative units, date(s) of surveillance, sampling design, and known risk factors. The following table provides more definition to these classes of a complete population description. See Chapter 2, data standards.

Class	Guidelines
Sampling units	➢ Should be identified and clearly defined. These may be simple units (individuals) or aggregates (herds or flocks). ➢ Geographic or spatial measures should be included, e.g., flocks per sq. km. ➢ Time constraints, if present, are included in description of the sampling unit.
Target population (not to be confused with *targeted* population)	➢ Population about which statistical inference will be made (general population at-risk) should be identified and clearly defined or estimated. ➢ If different from study population, the rationale for inference should be provided. ➢ Size of target population, e.g., number of herds by State, total number of animals by county, or population by Zip Code. (Note: Some NASS data are currently available at the Zip Code level.)
Study population	➢ The population from which the sample is to be drawn should be identified and clearly defined. In most cases, should be same as target population. ➢ Size of study population, (e.g., number of herds by State; total number of animals by county.) ➢ The sample frame (list of units to be sampled) from the study population should be identified.
Targeted population	➢ The population defined by specific disease variables inherent to the disease in question, (e.g., cattle with "high risk" clinical signs compatible with BSE.) ➢ The targeted population is intended to create intentional and predictable bias in the sample frame. ➢ If inference is made to the target (general) population of interest, a detailed explanation of the biological justification for the inference must be included.
Administrative units	➢ Define and include which units are included in the surveillance system , (e.g., States, regions, zones, counties, Zip Code areas, statistical reporting units, sample grid references, neighborhoods, and parcels.)

Size of sample service area	➢ Number of reporting units, (e.g., labs, clinics, slaughter plants.) ➢ Should include geographic area serviced per unit sampled. ➢ Number of eligible units served by reporting unit (per unit of geographic area being serviced).
Animal or group type	➢ The species, breed, and type (if applicable) of animals should be evident; include breeds and crosses. ➢ Define the animal by appropriate production phase concept. ➢ Age categories should include all appropriate categories pertinent to the surveillance objectives.
Date	➢ Population description should include applicable date. ➢ All date entries are as accurate as possible. At the minimum, include the date of sample collection and date of lab diagnosis. ➢ Report results are consistent using the defined date, (i.e., positive scrapie date is NVSL confirmed date.)
Sampling process	➢ Refer to standard 1.9, sampling methods.
Risk and exposure factors	➢ Population risk factors that may influence the outcome of the study. Confounders should be included in the description of the population (e.g., waste feeder hog operations). ➢ Risk factors need to be identified for statistical analysis. Anecdotal descriptions should not be used. ➢ When populations under consideration have unique risk factors or exposure to disease agents, the risk and exposure factors under study (independent variables) should be carefully defined to clearly differentiate the sectors of the population. If the surveillance applies to waste feeder, transitional, and commercial herds, risk/exposure factors must be clearly described prior to sampling.

1.7 Case Definition

Standard: The surveillance system has clear and understandable case definitions that include criteria for diagnosis, laboratory criteria for confirmation, any restriction or application of the case definition to specific geographical or demographic characteristics, and descriptions of case classification categories.

a. The working case definition is clear and understandable by the individuals who use it to identify and report cases.
b. Case definitions are consistent between all documents relating to a surveillance system or program, (e.g., CFR, UM&R, VS policy memos, etc.)
c. Case definitions are specific enough to avoid counting cases in more than one category.
d. Methods used to verify reported cases are clearly described.
e. The process is documented for handling data and information when case definitions change.

Supporting Information:

A surveillance system depends on clear case definitions for animal health-related events under surveillance. The case definition may include clinical manifestations (i.e., clinical signs); laboratory test results; necropsy findings; epidemiologic information such as subject, place, and

time; and/or specified behaviors, as well as levels of certainty including confirmed/definite, probable/presumptive, or possible/suspected).

The use of a standard case definition increases the specificity of reporting and improves the comparability of animal health-related events reported from different sources of data including geographic areas, and minimizes inappropriate regulatory actions, (i.e., movement restrictions, by placing cases in mutually exclusive categories.) Case definitions might exist for a variety of animal health-related events under surveillance, including diseases, injuries, adverse exposures, and risk factor or protective behaviors.

The following table provides guidelines on these classes of a case definition:

Class	Guidelines
Clinical description	➢ Brief one- to two-paragraph synopsis of clinical signs, history, and presentation. ➢ Acute, chronic, and late onset forms of disease should be described. ➢ Consideration should be given to asymptomatic or inapparent carrier reservoirs that could play a role in disease transmission.
Clinical case definition	➢ A clinical case definition can be used to broaden or restrict the sensitivity of a surveillance system by designating the species of animal(s) under surveillance and inclusion or exclusion of clinical signs or lesions for the disease or condition under investigation. Animals meeting a clinical case definition may be used to screen for inclusion of further testing.
Epidemiologic criteria and restrictions	➢ Criteria may restrict case definition to individual animals, herds, flocks, or premises that possess specific epidemiological characteristics. ➢ Criteria and restrictions may relate to the geographic location of an animal, farm, or premises; a particular point in time or season of the year; or a particular behavior associated with disease transmission or risk factor. ➢ Surveillance may be compartmentalized within a segment of a vertically integrated industry, (e.g., genetic grandparent stock, multipliers, commercial production); age group, (e.g., nursery vs. weaners); or commodity type, (e.g., meat type chickens vs. layers.) ➢ Criteria and restrictions should be used to clearly define population of interest under surveillance. See standard 1.6. ➢ May also include variables related to habitat, environmental conditions, seasonality, climate, etc.
Laboratory criteria	➢ May vary depending on the level of certainty required for surveillance. ➢ Screening tests are generally performed rapidly, are usually widely available within a laboratory system, and are relatively inexpensive. They typically trade lower specificity for higher sensitivity, which results in some level of false positive results. False negatives are undesirable but may occur. ➢ Confirmatory tests are typically less rapid and more difficult to perform, are less readily available within a laboratory system because of additional expertise needed to perform the test, and are more expensive than more commonly used screening tests. The ideal confirmatory test should be highly specific. ➢ Laboratory tests may not always serve as the gold standard for

	disease confirmation. Limitations should be identified and addressed. The type of diagnostic test and cutoff point or dilution used to define categories of cases may be included in the case definition. ➢ The type of test (e.g. ELISA, PCR, etc.), and any additional particulars specific to the testing, should be included if applicable.) ➢ The test should adapt to changing technology as new methods are established and are determined superior to older methods.
Case classification (definition categories)	➢ Case classifications usually represent various levels of certainty and include categories such as suspect, probable, and confirmed. ➢ Categories should be clearly defined and mutually exclusive. ➢ Levels of certainty may be defined using clinical signs identified through physical examination of the animal, antemortem or postmortem laboratory diagnostic tests, gross necropsy findings, histopathology, or the opinion of a recognized expert such as a foreign animal disease diagnostician (FADD). ➢ Reporting criteria may vary depending on level of certainty.
Required comments	➢ Surveillance plans may require certain forms of disease to be reported (e.g., fever, encephalitis, or meningitis); documentation of the vaccination status of the animal, herd, or flock; type of vaccine used; or lot number. Environmental exposure history of the animal, flock, or herd; history of arthropod exposure; or history of importation of animals, semen, or embryos from an endemic country or state may also be needed. Other information such as feedstuff or water source, evidence of foreign animal disease exposure or intentional release, or reproductive status could also be included in the case definition.

1.8 Data Sources

Standard: All data sources for the surveillance system are clearly identified.

Supporting Information:

Surveillance efforts typically rely on data from multiple sources. Some examples of data sources include:
➢ Producers
➢ Private practitioners or veterinary teaching hospitals
➢ Veterinary diagnostic laboratories, (e.g., university, State, Federal, or private)
➢ Government agencies, Federal, State, and local (e.g., animal health and agriculture agencies: FSIS, NASS, ERS, CSREES, FSA, RMA, RD, NRCS, etc., U.S. customs or border patrol, EPA, USGS, DHS, DHHS, Census Bureau, and others)
➢ Brand inspectors
➢ Affiliations or professional organizations, (e.g., milk marketing boards, registries)
➢ Businesses, (e.g., abattoirs, packing plants, pharmaceutical companies, zoos)
➢ Livestock markets
➢ Slaughter plants
➢ Renderers
➢ Business reporting services
➢ Surrogate/proxy data
➢ Aerial imagery

The surveillance documents should clearly describe all data sources that the surveillance system is expected to include, as well as associated strengths and limitations.

1.9 Sampling Methods

Standard: Sampling methods are thoroughly detailed in a surveillance plan or equivalent document.

   a. The sampling methods include methods to assure: geographic representation without introducing spatial bias, an appropriate level of sampling, and a measurement method that ensures appropriate denominator information for analysis.
   b. Sample size is determined with appropriate mathematical and epidemiological justification including measures of overall sensitivity such as design prevalence, detection limit, and level of confidence.
   c. Sampling methods include information on modes of data collection, triggers for data collection, frequency of data collection, and transmittal of field or laboratory data to program managers or coordinators.
   d. Sampling strategy should address and avoid unintentional bias, (e.g., sample selection, collection, reporting, and confounders.)
   e. Test sensitivity, specificity, and predictive values are considered in the sample strategy.
   f. Methods of data collection are described for each identified data source.
   g. Sampling methods carefully consider data sensitivity and confidentiality issues. See Chapter 3 for data confidentiality standards. Applicable Federal regulations should be noted.
   h. Changes to sampling methods for the surveillance system are appropriately documented and include a rationale for the change.

Supporting Information:

All sampling procedures and protocols, including field and laboratory data collection techniques, should be documented, including changes to data collection procedures as new procedures are identified to enhance the system. This information may be found in surveillance plans, uniform methods and rules, the code of Federal regulations, or annual or progress reports. See Chapter 3 for additional information on training staff for data collection and data confidentiality standards.

Population parameters are clearly described, including populations involved in the study and surveillance as well as populations for which inferences are being made. See standard 1.6, population characteristics.

Class	Guidelines
Sampling method	➤ Should be clearly defined and may utilize any justifiable epidemiological method, (e.g., simple random, systematic, cluster, stratified, or complex sampling, convenience or probability sampling.) ➤ Includes methods for randomization and stratification. ➤ Includes information on the use of grids and transects where applicable. ➤ Includes discussion, where applicable, of level of detection (threshold), statistical level of confidence, diagnostic (field) sensitivity of the sampling, predictive value, and in some cases comparison to other methods of sampling.
Outcome variables	➤ See standard 1.4, expected outcomes, products, decisions, and actions.
Exposure/risk factor variables	➤ See standard 1.6, population characteristics. Should be clearly identified.
Choice of sampling method	➤ Justification is described including purpose of the sampling strategy (e.g., sampling for detection, census, prevalence determination, or disease trends.)
Geographic extent of the study area under surveillance	➤ Sampling unit should contain a spatial context, (e.g., 2 randomly-selected samples per grid cell from 30 randomly-selected grid cells over a 400-sq.km. area, or 300 slaughter samples from abattoir that services 4 counties.)
Time intervals and frequency of data collection	➤ Sampling rate or frequency and the response rate for survey data. ➤ Time the agent, or the pathological consequences, are first observed. ➤ Information regarding date/times of sample collection, date/times of diagnostics, and date/times of lab reporting.
Methods of data collection and handling	➤ Refers to how raw data are gathered from the field, (e.g., face-to-face interviews, questionnaires, blood samples collected at sale or market, or necropsies of tissues from suspect animals.) ➤ Sample handling protocols, specimen chain-of-custody protocols, and cold chain measures should be available from laboratories. ➤ Sample degradation factors may be critical for some types of surveillance and should be addressed.
Sources of potential bias	➤ Are determined to all possible extent prior to data collection.
Trigger(s) for data collection	➤ Describe the event(s) that initiate data collection, such as the detection of an animal with clinical signs of disease.
Data collection and transmittal	➤ From the field or laboratory may include Web-based data entry forms, e-mail, fax, postal mail, spreadsheets (sent by e-mail or fax), or entry into database software such as Oracle or Microsoft Access.

1.10 Data Analysis and Interpretation

Standard: The methods used in summarizing, analyzing, and interpreting data are described in surveillance planning documents. In addition, the processes for analysis and interpretation are evident in reports and presentations.

      a. The parties responsible for data summarization, analysis, and interpretation are identified.
      b. A scientifically sound and detailed plan of data analysis and interpretation is consistent with the purpose, objectives, and expected products for the surveillance system.
      c. Analytic methods are discussed in terms understood by VS professionals, including decision-makers whose expertise is not in a mathematical or analytical field. See standard 1.11.
      d. The data type collected is appropriate for the method(s) of analysis planned (e.g., categorical data may not be amenable to some methods of quantitative analysis.)
      e. Data analysis methodology is appropriate and supportable given the data sources, sampling methods, and type and quality of data.
      f. Data interpretation provides timely, relevant information that meets surveillance objectives (standard 1.3) and expected outcomes (standard 1.4).
      g. Methods for dealing with inherent biases, confounders, missing records, and unequal sample sizes are addressed.

Supporting Information:

Analysis: Outcomes of interest should have been determined prior to the collection of samples. General information is necessary for most analysis and may include descriptive statistics such as means, medians, modes, and standard deviations, as well as general epidemiological information including prevalence, incidence, and sampling duration. Of particular note to those developing surveillance plans and collecting data is consideration of population denominators. See standard 1.6, population characteristics.

More complex analysis, or analysis for unexpected purposes, may be conducted if the data are adequate; however, without advance planning, these needs may not be met.

Data interpretation is the process by which the analyst translates findings from the data into non-mathematical language useful for decision and policymakers. It should be transparent and describe the methods used to reach the options or conclusions presented. It also should be sensitive to the political environment, but the results not biased by political pressures. Where indicated, the interpretation of the analysis should provide options for decision-makers to consider. For example, if the analysis indicated a need for further surveillance, the analyst might provide parameters for different ways to achieve the goal along with strengths and weaknesses for each of them. Additionally, any assumptions that influenced the interpretation should be clearly articulated along with their ramifications and limitations. Finally, if possible, the sensitivity of any variable with exceptional influence should be discussed. For example, if the data from one area or set of samples have undue influence on the outcome, this influence should be discussed in the interpretation.

1.11 Data Presentation and Reports

Standard: Data presentation and reporting procedures specify the content, frequency, audiences, and methods of data dissemination (e.g., mail, e-mail, fax, private Web site, public Web site) for reporting data obtained through the surveillance system.

  a. The parties responsible for data presentation and reporting are identified.
  b. A plan for information dissemination is developed that assures communication to stakeholders and provides details on reporting format and frequency for distinct audiences so that communications are designed for maximal benefit for the target audiences.
  c. Statistical or mathematic outcomes are explained in terms that an audience of non-specialists is likely to understand, and in technical detail adequate for peer reviewers.
  d. Reports describing progress or conclusions are timely and relevant.
  e. Presentations and reports carefully consider data sensitivity issues. See Chapter 3 for data sensitivity issues and references to Federal regulations regarding confidentiality.
  f. The implementation of data reporting procedures is evident from reports and other presentations and publications.
  g. Data reports and publications are consistent with the expected products for the surveillance system.

Supporting Information:

The dissemination of processed information derived from collected data to users and the linkage of targeted information to specific stakeholders completes the surveillance cycle. No surveillance system is complete unless it provides information that influences actions and decisions. Dissemination of surveillance data to those who need to know is a critical component of a surveillance system. Recipients should include those who prepare (or should prepare) reports, data collectors, and those with administrative or program planning and decision-making authority, as well as those involved with policy development.

A description of the surveillance plan and associated outcomes must include the intended audience and, for each audience, the communication format and frequency of reporting. Audiences include responsible parties within the surveillance system, as well as agency decision-makers and industry groups. In addition, the list of data sources should be considered as a specific audience. Careful planning is needed to target information and reports appropriately for maximal benefit.

The frequency of reports will depend upon the collection system used and the needs of users.

Reports should be timely and relevant. The frequency of reports will depend upon the collection system and the needs of users. Certainly, one must consider the impact and consequences of reporting data in varying stages of analysis and interpretation, but one must also weigh the impact and consequences of delaying reporting.

Chapter 3 provides additional information on data confidentiality standards.

1.12 Surveillance System Implementation: Priorities, Timelines and Internal Communications

Standard: The relative priorities of the surveillance system and timeline for implementing various aspects of the system are described in surveillance and implementation planning documents, and include specific information to facilitate internal communications.

    a. The timeline for implementing the surveillance system is consistent with the stated priorities for the system and there is logical order in implementing the surveillance system.
    b. Surveillance objectives have been prioritized and agreed upon by responsible parties.
    c. Internal communication pathways and documents are clear and understood by all responsible parties.
    d. All responsible persons or groups have received adequate training and have a clear understanding of their role in implementation.

Supporting Information:

The action steps needed to implement the various aspects of the surveillance system, and timelines, are described in the surveillance plan or associated implementation plan.

When surveillance objectives are met, information is provided to help determine actions and decisions. Some decisions and therefore some components of a surveillance system may have higher priority needs than others.
- The political environment and economic impacts associated with the disease may dictate the priority of implementation.
- Resource limitations and time constraints, as well as the need to pilot test various components of the system, may determine which components are addressed first.
- The objectives of the surveillance system should be carefully reviewed to prioritize implementation of various components of the system.
- To lend order to the prioritization process, stakeholders and responsible parties should agree on ranking criteria and their relative importance.
- The priorities of the agency, including those outlined in the VS Strategic Plan and NAHSS Strategic Plan, should be considered when prioritizing the surveillance objectives. See standard 1.3, surveillance objectives.

Responsible parties should develop appropriate documents for internal communications, including disease fact sheets, training manuals for all aspects of the surveillance system, and recording and reporting forms. In addition, internal communication plans and documents should be developed to ensure that all responsible parties understand the surveillance procedures and communication pathways, as well as the implementation action steps and timeline.

Communication with the IT application development team should occur early and often as surveillance moves from the planning stage to implementation. Responsible persons or groups charged with planning, implementation, and IT development should work cooperatively to develop clear data system requirements.

Training for data collection, data entry, sample collection, documentation, shipping of samples, and sample processing should be completed prior to commencement of each

individual's involvement in the surveillance activities. See Chapter 3.

1.13 Resources

Standard: Assessment of necessary resources is prepared to evaluate the human and financial aspects of design, implementation, and maintenance of the surveillance system.

a.   The budget for the surveillance system is consistent with its priorities, purposes, objectives, and expected outcomes.
b.   The budget for the surveillance system sufficiently ensures that the standards for data collection, management, and quality control may be achieved.
c.   Human resources and technical expertise are available to achieve the surveillance priorities, purposes, objectives, and expected outcomes.
d.   Budget information is routinely reviewed to evaluate alignment of the budget, the purpose and objectives of the system, and the system's products to date.

Supporting Information:

The budget includes direct costs.

Direct cost information includes any Federal funds appropriated to support other Federal or State agencies in the surveillance system. Information about use of budgeted funds – labor, rent, capital purchases, testing, indemnity, mail, supplies, vehicles, cleaning and disinfection costs, printing, etc. – must be collected.

Human resources are identified for the surveillance system. These may be new hires or redistributed from other duties.

1.14 Surveillance Plan Performance Metrics

Standard: One or more objective measures of the surveillance system's performance is included in the surveillance plan.

Supporting Information:

Metrics of performance should be part of a surveillance system and provide a means to measure the efficacy of the system.

➢   The performance metrics should be consistent with the objectives and expected outcomes for the surveillance system and, ideally, provide a measure of the extent to which expected outcomes are achieved.
➢   The metrics should be quantifiable and the unit of measure may be addressed for budgeting needs. The population and geographic scope of each metric is identified.
➢   The metrics may be modified or replaced over time as needed to meet the needs of the system or changes in technology.

Note: While quantitative performance metrics are ideal, some subjective metrics may also provide useful information for measuring a system's performance and these may be included as performance metrics.

Examples:

Testing adequate to meet specified prevalence at a given level of confidence. This might be a number of samples or a number of surveillance points from a targeted strategy.

Testing adequate to maintain a predetermined level of confidence. This might be equal to risk of disease introduction + the risk of pre-existing but not yet detectable disease.

Testing adequate to detect disease in a specified number of days/weeks/months.

Testing adequate to meet a specified sensitivity or specificity (i.e., probability of positive surveillance if disease exists or probability of negative surveillance if no disease exists).

Testing adequate to provide a negative predictive value (i.e., a measure of freedom from disease). This is the probability that no disease exists given negative surveillance.

A specified number of samples or observations in a given time, population, or location.

1.15 Surveillance System Evaluation

Surveillance system evaluation is the collection and review of information undertaken to assess how well the surveillance system fulfills its stated objectives and meets accepted standards. The evaluation process identifies system strengths and areas for improvement. The evaluation findings are intended to facilitate the system's role in a coordinated, integrated National Animal Health Surveillance System (NAHSS), consistent with the VS Strategic Plan.

Standard: The surveillance system is periodically evaluated to determine how effectively the system fulfills its stated objectives and meets surveillance system standards. The evaluation is conducted using the methods described in the Protocol for Evaluation of Surveillance Systems. (E-mail national.surveillance.unit@aphis.usda.gov. for more information.)

   a. The purpose and outcome of the evaluation process are articulated and understood by responsible parties, stakeholders, and those involved in conducting the evaluation.
   b. Results of the evaluation are shared with responsible parties and stakeholders.
   c. Evaluation results provide meaningful information for program budgeting and setting program priorities.
   d. Evaluation results provide viable alternatives, improvements, or suggested solutions for components of the surveillance system that are deficient.
   e. The uses of past evaluation results are evident.

Supporting Information:

Surveillance systems should reflect national disease control and eradication priorities and promote the best use of public resources in the development of effective and efficient surveillance. National animal health surveillance systems have been developed in the past without standardized guidelines, designed at different times, and operated by different units within Veterinary Services (VS).   VS field staff have been charged with implementing multiple systems with different objectives using different methods, terminology, and reporting forms and frequency. This may introduce extra costs and inefficiencies into these systems. Thus, there is a pressing need for regular evaluation of current animal health surveillance systems, especially given their complexity and the fact that most animal health data are collected under less than ideal circumstances. Also, in order to remain effective and useful, surveillance systems should adapt to changing situations such as new research findings regarding diagnostics, therapeutics or control procedures, significant changes in prevalence, legislation, global market pressures, or producer/public attitudes.

Surveillance systems should be evaluated regularly to ensure that they remain efficient, useful, and effective in order to meet their objectives. The evaluation process should include an assessment of whether the system's objectives are being achieved and whether it is serving a useful function. The evaluation of surveillance systems should include recommendations for improving quality and efficiency, such as eliminating unnecessary duplication.

The 2001 Animal Health Safeguarding Review recommended that VS promote a more coordinated and integrated approach to the surveillance and control of infectious disease. The proposed evaluation protocol is an important tool to achieve this goal.