

APHIS Evaluation Procedures for Bovine Brucellosis

Classification of Foreign Regions

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Introduction

This document describes the process by which the Animal and Plant Health Inspection Service (APHIS) evaluates and classifies foreign regions for brucellosis (*Brucella abortus*) in bovine animals. The essential considerations for such evaluations are outlined in title 9, Code of Federal Regulations, part 93.441 (9 CFR 93.441), as follows:

1. Region boundaries and composition
2. Veterinary control and oversight (including notification)
3. Prevalence of bovine brucellosis
4. Surveillance
5. Diagnostic testing for bovine brucellosis
6. Epidemiological investigations
7. Affected herd management
8. Control of livestock movement
9. Vaccination

A region seeking APHIS classification and recognition of brucellosis status must demonstrate that it has in place a brucellosis program that meets or exceeds the minimum standards in 9 CFR 93.441. This process starts with the region submitting the *APHIS Bovine Brucellosis Evaluation Questionnaire*, which details the information and data required for APHIS to evaluate each factor. Initial information gathering is typically followed by one or more onsite visits to verify and complement the information provided. APHIS teams conduct the onsite visits using the *APHIS Onsite Bovine Brucellosis Review Template*, which prompts team members to record and analyze critical data and information in a standardized format.

APHIS teams assess both program elements and program implementation. Program elements are the essential building blocks that support program operations, without which the program may be fundamentally flawed (e.g., legal authority, comprehensive program standards,¹ financial and personnel resources, monitoring and oversight systems, etc.). APHIS therefore assesses the existence or absence of a program element as a binary variable: yes or no. APHIS evaluates the quality of a brucellosis program by examining on certain critical actions necessary for program implementation within each factor, using a 5-point scale:

- 1 = Very Poor or Almost Never
- 2 = Poor or Rarely
- 3 = Fair or Sometimes
- 4 = Good or Usually
- 5 = Very Good or Almost Always

APHIS teams record the findings using the *Review Template* and associated checklists as described below. The findings are summarized for each factor in tabular form. A given brucellosis program will optimally have all program elements in place and score above 3 on program execution; however, an apparent deficiency in one area may be balanced by other findings. The brucellosis status of a region that meets or exceeds the minimum

¹ Program standards = regulations, manuals, guidelines, instructions, standard operating procedures, etc.

program standards is determined by the herd prevalence, as described in 9 CFR 93.440. Level I regions have had a herd prevalence less than 0.001 percent for the last 24 consecutive months. Level II regions have had a herd prevalence of less than 0.01 percent over the last 24 consecutive months. APHIS classifies regions that it has not evaluated, as well as those in which prevalence is equal to or greater than 0.01 percent or the brucellosis program does not meet the minimum standards in 9 CFR 93.441, as Level III.

The following sections describes the evaluation process in more detail, focusing on each factor in turn. Key program elements and the procedures by which APHIS assesses both program elements and execution are briefly described in each section, along with the corresponding summary table from the *Review Template*.

Note: in rare instances, APHIS may have initiated a brucellosis evaluation some years before the provisions of 9 CFR 92.441 came into effect and the corresponding evaluation procedures were fully developed. In these cases, APHIS will assess the region against the criteria in 9 CFR 92.441 but the format of the evaluation may differ.

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Evaluation factors

1. Region boundaries and composition

The APHIS team initially examines the geographic extent of the region seeking classification and confirms that the borders are clearly defined along administrative boundaries and/or distinct geographic barriers. The team determines the composition of the region by confirming the administrative units (states, provinces, prefectures, counties, municipalities, etc.) included. If the regional authority has created a higher-risk zone² by “zoning out” certain higher-prevalence administrative units, the borders and composition of this higher-risk zone must be clearly defined as well. If a border of the higher-risk zone bisects an administrative unit, the subunits included within the region seeking classification must be identified and the border mapped using global positioning system (GPS) data points. The border should not bisect individual premises. Ideally, the brucellosis program has developed and is actively implementing a plan to reduce the prevalence in any defined higher-risk zone(s).

The APHIS team identifies the regions adjacent to the region seeking classification and gathers estimates of the brucellosis prevalence of each. The team further assesses the mitigations in place to prevent and/or detect introduction of bovine brucellosis from adjacent higher-risk regions and established higher-risk zones, if present. A buffer zone should be in place along parts of the region border that are not adequately protected by geographic barriers, with annual testing of the herds within the buffer zone to detect brucellosis introduction.

The summary evaluation criteria for region boundaries and composition are listed in Table 1.

Table 1: Evaluation criteria—region boundaries and composition

| |
|--|
| <i>Program elements</i> |
| The geographic extent and boundaries of the region are clearly defined. |
| Buffer zones or other measures to prevent brucellosis introduction are clearly established. |
| Regular (annual) surveillance of herds adjacent to higher-risk zones and regions is required. |
| A comprehensive plan is in place to reduce brucellosis prevalence in higher-risk zones. |
| <i>Program execution</i> |
| Regular (annual) surveillance of herds adjacent to higher-risk zones and regions is conducted. |
| The brucellosis program is actively working to reduce brucellosis prevalence in higher-risk zones. |

2. Veterinary control and oversight

The APHIS team assesses the organizational structure and resources of the bovine brucellosis program at the central, regional, and local levels, as well as the personnel and financial resources available for program activities. The team interacts with regulatory and supervisory officials at all levels to assess overall qualifications and training, as well as the accountabilities and coordination mechanisms in place for brucellosis program

² Higher risk zone: Zone created by national or subnational authorities which is within or adjacent to the region under evaluation and consists of higher prevalence administrative units under the same national and/or subnational authority.

activities, and determine whether the available personnel and financial resources appear to meet the program needs. Specific education and training is assessed in other sections.

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that the disease is compulsorily notifiable. In addition, regulatory officials must have the legal authority to inspect live animals and records; apply diagnostic tests for brucellosis; collect blood samples and selected tissues at slaughter; control animal movement into, within, and out of the region; establish quarantines and restrict animal movement; control the disposition of infected animals and affected herds; require identification of bovine animals and premises with bovine animals; enforce brucellosis program requirements and penalize noncompliance; and require vaccination against *B. abortus* (if applicable). The APHIS team examines all pertinent regulatory acts and assesses the application of these acts to carry out brucellosis program activities, with particularly attention to demonstrated ability or failure to require and enforce compliance with the elements described above. The summary evaluation criteria for veterinary control and oversight are listed in Table 2.

Table 2: Evaluation criteria—veterinary control and oversight

| Program elements |
|--|
| Personnel resources available to the brucellosis program are sufficient to support program activities. |
| Financial resources available to the brucellosis program are sufficient to support program activities. |
| Roles and responsibilities within the brucellosis program are clearly defined. |
| Chains of reporting and communication within the brucellosis program are well established. |
| Brucellosis (<i>B. abortus</i>) is a compulsorily notifiable disease throughout the region. |
| Program officials have sufficient legal authority to carry out an effective brucellosis control program. |
| Violations and associated sanctions are well defined in the legal and regulatory framework. |
| An effective system is in place to track legal cases from the initial report to closure. |

3. Prevalence of bovine brucellosis

3.1 Animal and herd demographics

To calculate the herd prevalence of brucellosis, the APHIS team first gathers data on the number and type of bovine herds in the region. A region seeking classification must have established and maintained an accurate herd census, since this is a critical data point for prevalence calculations. The team notes the date of the last herd census, how it is updated, and progress towards conducting a new herd census (if applicable). The APHIS team also gathers data on production parameters for the various types of cattle operations in the region.

The summary evaluation criteria for animal and herd demographics are listed in Table 3.

Table 3: Evaluation criteria—animal and herd demographics

| |
|---|
| Program elements |
| The region has conducted a census of bovine animals and herds. Systems are in place to update and inform the census over time. |
| Program execution |
| Rate the quality of the census data for the purpose of calculating herd prevalence. |

3.2 Herd prevalence

The APHIS team then assesses the criteria used to classify the brucellosis status of individual animals and herds, and determines the number brucellosis-affected herds during the evaluation period.³ The criteria must be clearly defined and equivalent to APHIS domestic standards, namely: (1) reactor: test results on blood serum indicate that the animal has been exposed to and infected with *Brucella*, other diagnostic tests result in the recovery of field-strain *Brucella* organisms, a significant rise in titer occurs, or other epidemiological evidence of infection is demonstrated; and (2) affected herd: a herd in which any animal has been determined to be infected with field strain *B. abortus* by polymerase chain reaction or culture, or classified as a brucellosis reactor by a designated epidemiologist, and which has not been released from quarantine. The team examines data on laboratory sample submissions and results, quarantine herd lists, and case files to determine whether brucellosis program personnel follow the classification criteria.

APHIS defines prevalence as the number of affected herds occurring during the evaluation period (9 CFR 93.400). Any region seeking APHIS classification must first meet the minimum program standards; classification level is then determined according to herd prevalence (see Table 4).

Table 4: Prevalence criteria for brucellosis status classification (from 9 CFR 93.440)

| Status level | Prevalence criteria |
|------------------|---|
| Level I | Program that meets APHIS requirements for classification and prevalence of less than 0.001 percent over at least the previous 2 years (24 consecutive months). |
| Level II | Program that meets APHIS requirements for classification and prevalence equal to or greater than 0.001 percent but less than 0.01 percent, over the previous 2 years (24 consecutive months). |
| Level III | Program that does not meet APHIS requirements for classification, prevalence equal to or greater than 0.01 percent, or unassessed by APHIS with regard to <i>B. abortus</i> . |

³ Evaluation period = 24 consecutive months, specifically the first 24 months of the previous 26-month period.

3.3 Other sources of infection

Finally, the APHIS team gathers and verifies information on other livestock or wildlife sources of *B. abortus* within the region and reviews surveillance and control measures with responsible regulatory officials, if applicable. The summary evaluation criteria are listed in Table 5.

Table 5: Evaluation criteria—other sources of infection

| |
|---|
| <i>Program elements</i> |
| Surveillance for bovine brucellosis is conducted in susceptible wildlife and non-bovine domestic species. No wildlife reservoirs of bovine brucellosis have been identified within the region. The official bovine brucellosis program includes susceptible non-bovine domestic species if necessary. |
| <i>Program execution</i> |
| Applied mitigations effectively prevent brucellosis transmission to domestic bovines from other species. |

4. Surveillance

The APHIS team examines the official surveillance plan and program standards for the various surveillance components such as slaughter sampling, first point testing, abortions screening, and targeted herd testing. The team evaluates sample submission data for all slaughter plants in the region and visits several plants to assess the facilities and equipment, inspection practices, systems for correlation of animal identification with slaughter samples, preservation and storage of samples, and documentation of samples submitted for laboratory diagnostics, using the checklist in [Appendix A](#). The team also visits several concentration points (auctions, sale barns, gathering centers) to assess sampling practices for first point testing using the checklist in [Table E-1](#) in Appendix E (if applicable). Finally, the team examines policies and data concerning abortion screening conducted during the evaluation period (see also Section 5).

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) comprehensive program standards are in place to guide implementation of each surveillance component; (2) inspection and sampling is conducted by qualified and trained personnel; (3) appropriate minimum standards to validate surveillance are established and met; and (4) effective systems are in place for monitoring performance and addressing deficiencies. Tissue sampling of reactor animals should include representative sampling of the reticuloendothelial system, testes from the male, and udder and uterine tissue from the female.

As a general benchmark, a region should be able to demonstrate that 95 percent of intact bovine animals that are 12 months of age or older are sampled for brucellosis at slaughter or, if moving within trade or marketing channels, at the first point of concentration. Such surveillance may not be necessary if a region can substantiate a claim of biological freedom from bovine brucellosis, although targeted or risk-based surveillance should still be conducted as needed to demonstrate continued freedom. APHIS would evaluate these regions on a case-by-case basis. Summary evaluation criteria for surveillance are listed in Table 6.

Table 6: Evaluation criteria—surveillance

| |
|---|
| Program elements |
| <p>Program standards: (1) Address the critical actions necessary for brucellosis sampling at slaughter.</p> <p>(2) Address the critical actions necessary for brucellosis reactor tissue sampling and submission.</p> <p>(3) Address the critical actions necessary for live-animal testing for bovine brucellosis.</p> <p>Appropriate minimum standards are in place to validate each surveillance component.</p> |
| Program execution |
| <p>Sampling for bovine brucellosis at slaughter occurs in accordance with program standards.</p> <p>Reactor tissue sampling at slaughter occurs in accordance with program standards.</p> <p>First-point sampling for bovine brucellosis occurs in accordance with program standards.</p> <p>Sampling processes promote accurate correlation of animal ID/documents with samples taken.</p> <p>Samples are properly stored and preserved prior to delivery to the laboratory.</p> <p>Individuals collecting brucellosis samples receive adequate instruction and training.</p> <p>Deficiencies in sample collection or storage are rapidly detected and corrected.</p> <p>Each surveillance component meets the minimum validation standards.</p> |

5. Diagnostic testing for bovine brucellosis

The APHIS team typically visits the one or more diagnostic laboratory for bovine brucellosis in the region under evaluation and assesses the diagnostic techniques and quality assurance measures against APHIS National Veterinary Services Laboratories (NVSL) and international standards, using the checklist in [Appendix B](#). The team also evaluates the laboratory procedures for abortion screening and, if vaccination is practiced, the procedures for differentiation of infected and vaccinated animals (DIVA techniques).

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) the tests conducted and testing algorithms to detect and confirm *B. abortus* meet international standards; (2) diagnostic laboratories supporting the brucellosis program are properly equipped; (3) at least one laboratory is proficient in diagnostic techniques to differentiate *B. abortus* from other *Brucella* and cross-reacting species; (4) laboratories are accredited according to international standards; (5) an effective quality control system is in place; and (6) interpretation or classification of results is in accordance with international standards. If vaccination is practiced, at least one laboratory should have DIVA capability, and receive all samples for differentiation. All laboratories should regularly engage in competency or proficiency testing for brucellosis diagnostics. The summary evaluation criteria for laboratory diagnostic testing are listed in Table 7.

Table 7: Evaluation criteria—diagnostic testing

| <i>Program elements</i> |
|---|
| <p>The laboratories supporting the program are accredited to international standards (ISO 17025).</p> <p>The laboratories supporting the brucellosis program are equipped to conduct the required tests.</p> <p>The SOPs for conducting official diagnostic tests for brucellosis reflect international standards.</p> <p>Interpretation/classification of test results is in accordance with international standards.</p> <p>Accredited laboratories regularly engage in competency/proficiency testing for brucellosis diagnostics.</p> |
| <i>Program execution</i> |
| <p>The laboratories report diagnostic results to the brucellosis program in a timely manner.</p> <p>Laboratory personnel conducting diagnostic tests are adequately qualified and trained to do so.</p> <p>Quality control measures rapidly detect and correct deficiencies in diagnostic protocols or techniques.</p> |

6. Epidemiological investigations

The APHIS team reviews the program standards for conducting and documenting epidemiological investigations and assesses them against the checklist in [Appendix C](#), noting any deficiencies that could negatively impact the quality of the investigations. The team also reviews multiple case files to assess implementation of the program standards, evaluate the knowledge and training of the responsible regulatory officials, and determine whether deficiencies in the investigative process are rapidly detected and corrected. The team further correlates the case files with laboratory submission data and quarantine herd lists to ascertain whether the brucellosis program conducts follow-up testing and/or initiates an epidemiological investigation as appropriate.

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) the program standards address the critical actions for effective and thorough epidemiological investigations; (2) designated officials conduct epidemiological investigations in accordance with the program standards; (3) every brucellosis reactor is subject to investigation; (4) investigators quickly and accurately determine the status of non-negative animals and herds; and (5) movement from herds under investigation is promptly and effectively regulated while the brucellosis status is determined. As a general benchmark, the successful traceback rate—i.e. the percentage of slaughter and first-point cases traced to the most probable herd of origin (MPHO) and the MPHO tested—should be at least 95 percent. If the MPHO tests negative, the case file should contain evidence of further traceback investigations based on the sampling order. Investigations must be well-documented with orderly and complete case files.

The summary evaluation criteria for epidemiological investigations are listed in Table 8.

Table 8: Evaluation criteria—epidemiological investigations

| <i>Program elements</i> |
|---|
| <p>Program standards address critical actions for effective traceback of slaughter or other reactors.</p> <p>The successful traceback rate meets or exceeds the minimum standard.</p> <p>Program standards address critical actions for investigation of other brucellosis reactors.</p> <p>Program standards address the critical actions for effective investigation of related/implicated herds.</p> <p>Program standards promote logical, standardized, and well documented case files.</p> |
| <i>Program execution</i> |
| <p>Traceback investigations are conducted in accordance with the program standards.</p> <p>Traceback investigations result in detection of a brucellosis-affected herd.</p> <p>Investigation of other brucellosis reactors are conducted in accordance with the program standards.</p> <p>Investigations of related/implicated herds are conducted in accordance with the program standards.</p> <p>Investigators quickly and accurately determine the status of non-negative animals and herds.</p> <p>Movement from herds under investigation is regulated while the brucellosis status is determined.</p> <p>Investigations are well documented with orderly and complete case files.</p> <p>Program officials conducting epidemiological investigations receive adequate instruction and training.</p> <p>Deficiencies in the investigative process are rapidly detected and corrected.</p> |

7. Affected herd management

The APHIS team reviews and assesses the program standards for managing brucellosis-affected herds by depopulation or test-and-remove against the checklist in [Appendix D](#), and notes any deficiencies. The team notes any deficiencies in the program standards and works through multiple case files to assess implementation of the program standards, evaluate the knowledge and training of the responsible regulatory officials, and determine whether deficiencies in management processes are rapidly detected and corrected.

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) the program standards address the critical actions for effective management of brucellosis-affected herds; (2) designated officials manage affected herds in accordance with the program standards; (3) movement from affected herds is effectively regulated with periodic inventory reconciliation; and (4) management actions are fully documented. The summary evaluation criteria for affected herd management are listed in Table 9.

Table 9: Evaluation criteria—affected herd management

| <i>Program elements</i> |
|---|
| <p>Program standards address the critical actions necessary to manage herds via depopulation.</p> <p>Program standards address the critical actions necessary to manage herds via test-and-removal.</p> <p>Program standards promote logical, standardized, and well documented affected herd case files.</p> |

| <i>Program execution</i> |
|--|
| <p>Program officials and affected herd owners are implementing official herd management plans.</p> <p>Management via depopulation is conducted in accordance with the program standards.</p> <p>Program officials account for all animals in the herd at the time of depopulation.</p> <p>Management via test-and-removal is conducted in accordance with program standards.</p> <p>Program officials regularly monitor the inventory of herds undergoing test and removal.</p> <p>Movement from brucellosis-affected herds is effectively regulated while under quarantine.</p> <p>Herd management actions are well documented with orderly and complete case files.</p> <p>Program officials conducting affected herd management receive adequate instruction and training.</p> <p>Deficiencies in herd management processes are rapidly detected and corrected.</p> |

8. Control of livestock movement

8.1 Animal identification and traceability

The APHIS team assesses the legal and regulatory framework supporting animal and premises identification and movement control within the region, including compliance enforcement. The team evaluates implementation by examining cattle for official identification and reviewing movement control documents, reviewing and assessing procedures at issuing centers for official identification and movement control documents, and challenging the identification and traceability systems using data gathered from case files and the sites visited (see [Table E-1](#) in Appendix E). The team also evaluates enforcement by assessing the systems in place to detect and report noncompliance and reviewing data on the violations reported and the sanctions applied.

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) official identification of bovine animals and herds is mandatory; (2) documentation of bovine animal movements promotes traceability; and (3) effective compliance monitoring and enforcement systems are in place. Ideally, bovine animals should be individually and uniquely identified prior to leaving the premises of origin. Official animal identification should be accurately linked to a specific owner and premises. Bovine animals should be moved with appropriate documentation of origin, destination, date, and identification, and changes in ownership and location should be captured in a central database. Violations and associated sanctions should be adequately defined in the legal framework with effective systems in place to monitor and enforce compliance. The summary evaluation criteria for animal identification and traceability are listed in Table 10.

Table 10: Evaluation criteria—animal identification and traceability

| <i>Program elements</i> |
|--|
| <p>Official identification of bovine animals is required for movement from the premises of origin.</p> <p>Official identification of herds / premises and bovine concentration points is required.</p> <p>Control and distribution of official identification is strictly regulated.</p> <p>Documentation is required for all movements of bovine animals between premises.</p> <p>Violations and associated sanctions are clearly defined in the legal or regulatory framework.</p> |

| |
|---|
| <i>Program execution</i> |
| <p>Bovine animals are officially identified prior to movement.</p> <p>Herds / premises and bovine concentration points are officially identified.</p> <p>Movement of bovine animals between premises is fully documented.</p> <p>Data and documents necessary for tracing bovine animals are readily available to investigators.</p> <p>Noncompliance is reported, prosecuted, and legal sanctions applied.</p> |

8.2 Entry into the region

The APHIS team reviews the requirements for bovine animals to enter into the region and assesses them against APHIS import requirements for brucellosis detailed in 9 CFR 93.440, making note of any deficiencies that could negatively impact control of movement into the region or allow legal importation of brucellosis-infected animals. The team also evaluates any program standards established to guide inspection at the points of entry and assesses the placement of movement control checkpoints in relation to the major access routes into the region. Finally, the team evaluates implementation of entry controls by visiting checkpoints and/or ports, interviewing the inspectors, examining documents, and observing inspection procedures (see [Table E-2](#) in Appendix E).

Table 11: Evaluation criteria—entry into the region

| |
|---|
| <i>Program elements</i> |
| <p>Program standards clearly describe the entry requirements and inspection procedures.</p> <p>Requirements for bovine entry into the region are risk based and equivalent to U.S. standards.</p> <p>Checkpoints are strategically located at the most likely points of entry from higher-risk regions.</p> <p>Checkpoint are in good condition with appropriate signage, lighting, corrals, etc.</p> |
| <i>Program execution</i> |
| <p>All shipments of bovine animals passing through the checkpoint are subject to inspection.</p> <p>Shipments not fully compliant with the entry requirements are denied entry into the region.</p> <p>Shipments of higher-risk animals move to destination or transit the region under seal.</p> <p>Official personnel confirm the arrival of higher-risk animals at destination or point of exit.</p> <p>Inspectors record the details of all shipments of bovine animals into or through the region.</p> <p>Movement control measures are effective in preventing illegal entry into the region.</p> <p>Regulatory officials enforcing movement requirements receive adequate instruction and training.</p> <p>Deficiencies in the movement control system are rapidly detected and corrected.</p> |

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) requirements for bovine entry into the region provide risk mitigation equivalent to APHIS requirements; (2) checkpoints are strategically located; (3) any bovine animals that arrive at a checkpoint without proper identification, testing, and documentation are denied entry; (4) checkpoints records are sufficient to promote traceability; and (5) measures are in place to confirm that higher-risk animals arrive at the stated destination. Checkpoint facilities should be in good physical condition, an authorized inspector present whenever the checkpoint is open, and

entry effectively prevented if the checkpoint is closed. The summary evaluation criteria for entry into the region are listed in Table 11.

8.3 Export to the United States

8.3.1 Export certification

The APHIS team reviews the program standards for export certification, making note of any deficiencies that could negatively impact compliance. The team works through multiple export certificates with the regulatory officials responsible for validating the conditions specified on the certificate, to assess their processes, knowledge, and competency (see [Table E-3](#) in Appendix E). The team also takes into account any previously disclosed issues with cattle from the region presented for export to the United States.

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) export certificates are prepared by well-trained and authorized regulatory officials in accordance with comprehensive program standards; (2) the regulatory officials verify the accuracy of the information provided by exporters prior to certifying; and (3) a robust review process is in place to rapidly detect and correct any deficiencies in the verification or certification processes.

Summary evaluations criteria for export certification are listed in Table 12.

Table 12: Evaluation criteria—export certification

| |
|---|
| <i>Program elements</i> |
| Program standards clearly describe the processes for export certification and review of certificates. Regulatory officials certifying cattle exports and reviewing certificates are qualified and trained. |
| <i>Program execution</i> |
| Export certification is conducted in accordance with the program standards. Shipments are only certified for export if they meet all requirements of the importing country. |

8.3.2 Export gathering centers

Regions seeking classification for bovine brucellosis may have regulated facilities to gather and sort cattle for export to the United States. At a minimum, each such export gathering centers must demonstrate that (1) it is a designated facility which only accepts cattle for export; (2) all animals entering the facility are uniquely identified and accompanied by appropriate documentation; (3) brucellosis testing at the facility is conducted in accordance with APHIS requirements; and (4) biosecurity measures are in place to prevent disease transmission from neighboring herds. Export gathering centers must be approved by the authorized regulatory entity and subject to routine and effective regulatory oversight sufficient to detect and correct noncompliance. If applicable, the export gathering center must maintain a tick immersion bath and conduct tick treatment as required for export to the United States. The APHIS team typically visits several export gathering centers to assess the procedures and practices using the checklist in [Table E-4](#) in Appendix E or similar.

Summary evaluation criteria for export gathering centers are listed in Table 13.

Table 13: Evaluation criteria—export gathering centers

| <i>Program elements</i> |
|--|
| <p>Program standards for export centers: (1) Clearly define approval requirements.</p> <p>(2) Clearly define the requirements for animal entry into the facility.</p> <p>(3) Require unique identification of animals entering the center.</p> <p>(4) Require the center to keep accurate records of entries, exits, and animal inventory.</p> <p>(5) Require the center to keep accurate records of testing conducted on the premises.</p> <p>(6) Require appropriate risk mitigation measures (fencing, biosecurity, etc.).</p> <p>Export gathering centers are subject to regular (monthly) inspection and supervision.</p> |
| <i>Program execution</i> |
| <p>Export centers are approved, operated, and supervised in accordance with the program standards.</p> <p>Regulatory officials responsible for supervision of export centers are qualified and trained to do so.</p> <p>Noncompliance with the program standards is rapidly detected and corrected.</p> |

8.4 Approved feedlots

Brucellosis Level I and Level II regions may have approved (quarantine) feedlots⁴ which accept cattle from higher-risk regions destined for slaughter and national consumption (not export). The APHIS team reviews the program standards for approval and supervision of approved feedlots, making note of any deficiencies that could allow the spread of brucellosis from these entities. The team reviews the approval and supervisory records with the responsible regulatory officials and visits several approved feedlots to assess implementation of the program standards, supervision, and regulatory oversight. The APHIS team visits several approved feedlots to assess the practices and procedures using the checklist in [Table E-5 Appendix E](#) or similar.

At a minimum, a region seeking APHIS classification for brucellosis must demonstrate that (1) entry of animals into an approved feedlot is strictly controlled; (2) all animals entering the feedlot are uniquely and permanently identified; (3) biosecurity measures are in place to prevent disease spread to neighboring herds; (4) animals exit the feedlot only to slaughter; and (5) approved feedlots are subject to routine and effective regulatory oversight sufficient to detect and correct noncompliance.

Summary evaluation criteria for approved feedlots are listed in Table 14.

⁴ Approved (quarantine) feedlot = terminal feedlot authorized to receive animals of higher risk for tuberculosis/brucellosis.

Table 14: Evaluation criteria—approved feedlots

| <i>Program elements</i> |
|--|
| <p>Program standards for approved feedlots: (1) Clearly define approval and supervision requirements.</p> <p>(2) Require unique identification of animals entering approved feedlots.</p> <p>(3) Require all animals exiting an approved feedlot to go directly to slaughter.</p> <p>(4) Require approved feedlots to keep accurate records of entries, exits, and animal inventory.</p> <p>(5) Require approved feedlots to keep accurate records of births and deaths.</p> <p>(6) Contain appropriate risk mitigation measures (fencing, biosecurity, etc.).</p> <p>Approved feedlots are subject to regular (monthly) inspection and supervision.</p> |
| <i>Program execution</i> |
| <p>Approved feedlots are approved, operated, and supervised in accordance with the program standards.</p> <p>Regulatory officials responsible for supervision of approved feedlots are qualified and trained to do so.</p> <p>Noncompliance with the program standards is rapidly detected and corrected.</p> |

8.5 Accreditation of brucellosis-free herds

Level I-III regions may have accredited herds for brucellosis; animals from these herds are generally subject to reduced testing requirements for movement within the region and for export to the United States. The APHIS team reviews the program standards for accreditation of herds for brucellosis against APHIS standards using the checklist in [Table E-6](#) in Appendix E and assesses the impact of any differences in accreditation or reaccreditation processes. The team reviews several accredited herd files with the responsible regulatory official(s).

To be considered an accredited herd for the purpose of exporting bovine animals to the United States, the accreditation and reaccreditation processes must be equivalent to U.S. domestic standards. The brucellosis program should maintain a file on each herd with complete documentation of whole-herd testing, inventory reconciliations, and provenance and/or testing of purchased additions. Regions in which the accreditation and reaccreditation practices are not equivalent to U.S. domestic standards are not eligible to export cattle under the reduced testing requirements that would otherwise apply to bovine animals from accredited herds. Summary evaluation criteria for accreditation of brucellosis-free herds are shown in Table 15.

Table 15: Evaluation criteria—accredited herds

| <i>Program elements</i> |
|---|
| <p>Program standards for accreditation and reaccreditation: (1) meet APHIS standards for export purposes.</p> <p>(2) Require inventory reconciliation at the time of reaccreditation testing.</p> <p>(3) Restrict entry to animals from other accredited herds or with appropriate testing.</p> |
| <i>Program execution</i> |
| <p>Herds are accredited and reaccredited in accordance with APHIS standards for export.</p> <p>Regulatory officials responsible for oversight of herd files receive adequate instruction and training.</p> <p>Annual review of accredited herd files results in detection and correction of any deficiencies.</p> |

9. Vaccination

Many regions vaccinate against brucellosis as part of a control and eradication strategy. If applicable, the APHIS team reviews the program standards for vaccination, including the eligible population, timing of vaccination, vaccine used, identification of vaccinates, and strategies to monitor the extent of vaccination and to differentiate vaccinated animals from those infected with field strain *B. abortus*. At a minimum, a region seeking APHIS classification of brucellosis status must be able to demonstrate that (1) the vaccine(s) used and vaccination strategy are in accordance with international standards; (2) vaccinates are permanently and uniquely identified; (3) persons authorized to apply the vaccine are trained and supervised; and (4) an effective DIVA strategy is utilized. Summary evaluation criteria for vaccination are shown in Table 16.

Table 16: Evaluation criteria—vaccination

| <i>Program elements</i> |
|---|
| <p>Program standards address the critical actions for an effective vaccination campaign.</p> <p>The vaccine(s) used and general vaccination plan are acceptable by international standards.</p> <p>Effective DIVA techniques are available for the vaccine(s) used.</p> <p>Program standards promote standardized documentation and recordkeeping.</p> <p>Program standards require monitoring of vaccine coverage in target population(s).</p> |
| <i>Program execution</i> |
| <p>Vaccine handling and vaccination are conducted in accordance with the program standards.</p> <p>Each animal is uniquely identified at the time of vaccination.</p> <p>Estimated vaccine coverage is sufficient to promote herd immunity in the target population(s).</p> <p>Persons conducting brucellosis vaccination are adequately qualified and trained to do so.</p> <p>Deficiencies in the vaccination program are rapidly detected and corrected.</p> |

Appendices

Appendix A: Checklist for slaughter inspection and sampling

| | | <i>Slaughter plant ID:</i> | | | |
|----------|--|----------------------------|--------------|--------------|--------------|
| A | General | Info | Info | Info | Info |
| 1 | Type of plant (municipal, TIF, other): | | | | |
| 2 | Number of cattle killed per week: | | | | |
| 3 | Number of days per week the plant operates: | | | | |
| 4 | Type of cattle killed (dairy, beef, mixed): | | | | |
| 5 | Age of cattle killed (adult >2 years, young): | | | | |
| 6 | Origin of cattle killed: | | | | |
| 7 | Number of inspectors working at the plant: | | | | |
| B | Facilities (Y/N) | Score | Score | Score | Score |
| 1 | Slaughter plant facilities are in good physical condition: | | | | |
| 2 | The slaughter plant has pens to offload and inspect arriving cattle: | | | | |
| 3 | Equipment is sufficient for quality inspection (head rack, tables, etc.): | | | | |
| 4 | Lighting is sufficient for quality inspection: | | | | |
| C | Access to pertinent program standards (Y/N) | Score | Score | Score | Score |
| 1 | Guidelines for slaughter inspection, sampling, and sample submission: | | | | |
| 2 | A current list of herds under quarantine within the region: | | | | |
| 3 | Copies of pertinent laws and regulations: | | | | |
| D | Entry requirements (5 pt) | Score | Score | Score | Score |
| 1 | All animals are officially identified with a unique ID number. | | | | |
| 2 | All animals are accompanied by an official transit guide. | | | | |
| 3 | All animals are accompanied by a health certificate (if required). | | | | |
| 4 | A designated person records the owner and ID of all animals upon arrival. | | | | |
| 5 | Cattle from lower status regions arrive in sealed conveyances. | | | | |
| a | An authorized official breaks the seals and records the seal numbers. | | | | |
| E | Inspection practices (5 pt) | Score | Score | Score | Score |
| 1 | A veterinarian inspects and verifies the health of the cattle prior to slaughter. | | | | |
| 2 | Postmortem inspection is conducted by trained and authorized inspectors. | | | | |
| 3 | An effective system is in place to correlate animal ID with all carcass parts. | | | | |
| F | Training and supervision (5 pt) | Score | Score | Score | Score |
| 1 | Inspectors are adequately qualified and trained for the job. | | | | |
| 2 | A designated official reviews slaughter inspection and sampling procedures at least monthly. | | | | |
| a | Review findings are documented in a formal report provided to the inspectors. | | | | |
| b | A designated official ensures that reported deficiencies are corrected. | | | | |
| G | Sample submissions | Info | Info | Info | Info |
| 1 | Number of intact cattle \geq 12 months slaughtered during the previous 12 months: | | | | |
| a | Number of blood samples from intact cattle \geq 12 months during the previous 12 months: | | | | |
| b | Number of blood samples that were positive for brucellosis: | | | | |
| 2 | Number of other tissue samples submitted for lab diagnostics during the previous 12 months: | | | | |
| a | Number of other tissue samples that were positive for brucellosis: | | | | |
| H | Sampling practices (5 pt) | Score | Score | Score | Score |
| 1 | Sample submission forms are complete (name, age, sex, brand, ID, reactor/exposed). | | | | |
| 2 | Samples are stored properly and adequately preserved for laboratory diagnostics. | | | | |
| 3 | Samples are shipped properly and received by the lab within 10 days of collection. | | | | |
| 4 | The plant keeps all documents related to a submission (invoices, transit papers, lab results). | | | | |

Appendix B: Checklist for diagnostic testing

| | | <i>Laboratory:</i> | | |
|----------|---|--------------------|-------------------|-------------------|
| A | Facilities (Y/N) | | Info | Info |
| 1 | The laboratory is accredited to national or international standards [by whom and date] (Y/N): | | | |
| 3 | The laboratory has a designated area for bacterial culture (Y/N): | | | |
| 4 | The laboratory has a designated area for serological testing (Y/N): | | | |
| 5 | The laboratory can conduct DIVA testing (if region vaccinates) (Y/N): | | | |
| 6 | All samples are uniquely identified and correlated to the incoming submission (Y/N): | | | |
| 7 | Effective quality monitoring and control systems are in place (Y/N): | | | |
| 8 | From where does the laboratory receive samples? Indicate percentages from each region: | | | |
| B | Serology (5 pt) | | Info/Score | Info/Score |
| 1 | Number of samples received per year: | | | |
| 2 | Diagnostic test(s) conducted: | | | |
| 3 | The laboratory is properly equipped to conduct the above tests (Y/N): | | | |
| 4 | SOPs for conducting the above tests are available to the technicians (Y/N): | | | |
| 5 | Date of last proficiency or competency testing of technicians: | | | |
| 6 | Technicians are adequately qualified and trained to perform the diagnostic test(s). | | | |
| 7 | The technician records all samples and results as they are received. | | | |
| 8 | Effective measures are in place to prevent cross-contamination. | | | |
| 9 | A designated official conducts periodic supervisory reviews (including QC assays and technician proficiency). | | | |
| a | Findings are documented in a formal report provided to the technician. | | | |
| b | The designated official ensures that deficiencies are corrected in a timely manner. | | | |
| C | Bacteriology (5 pt) | | Info/Score | Info/Score |
| 1 | Number of samples received per year: | | | |
| 2 | Diagnostic test(s) conducted: | | | |
| 3 | Culture system and media used: | | | |
| 4 | The laboratory is properly equipped to conduct the above tests (Y/N): | | | |
| 5 | SOPs for conducting the above tests are available to the technicians (Y/N): | | | |
| 6 | Date of last proficiency or competency testing of technicians: | | | |
| 7 | Technicians are adequately qualified and trained to perform the diagnostic test(s). | | | |
| 8 | The technician records all samples and results as they are received. | | | |
| 9 | Effective measures are in place to prevent cross-contamination. | | | |
| 10 | A designated official conducts periodic supervisory reviews (including QC assays and technician proficiency). | | | |
| a | Findings are documented in a formal report provided to the technician. | | | |
| b | The designated official ensures that deficiencies are corrected in a timely manner. | | | |
| B | Other testing (5 pt) | | Info/Score | Info/Score |
| 1 | Number of samples received per year: | | | |
| 2 | Diagnostic test(s) conducted: | | | |
| 3 | The laboratory is properly equipped to conduct the above tests (Y/N): | | | |
| 4 | SOPs for conducting the above tests are available to the technicians (Y/N): | | | |
| 5 | Date of last proficiency or competency testing of technicians: | | | |
| 6 | Technicians are adequately qualified and trained to perform the diagnostic test(s). | | | |
| 7 | The technician records all samples and results as they are received. | | | |
| 8 | Effective measures are in place to prevent cross-contamination. | | | |
| 9 | A designated official conducts periodic supervisory reviews (including QC assays and technician proficiency). | | | |
| a | Findings are documented in a formal report provided to the technician. | | | |
| b | The designated official ensures that deficiencies are corrected in a timely manner. | | | |

Appendix C: Checklist for epidemiological investigations

| | | Brucellosis-affected herds | | | Other investigations | | |
|----------|--|----------------------------|--------------|--------------|----------------------|--------------|--------------|
| | | Herd ID: | | | | | |
| A | Live animal testing investigations (5 pt) | Score | Score | Score | Score | Score | Score |
| 1 | Disclosure of non-negative animals on primary testing resulted in herd movement restrictions / precautionary quarantine. | | | | | | |
| a | Intact animals only left the MPH0 premises to inspected slaughter or necropsy. | | | | | | |
| b | All movements of animals from the MPH0 occurred under seal and/or with official supervision. | | | | | | |
| 2 | All animals non-negative on primary testing were subject to an official secondary test or postmortem examination. | | | | | | |
| a | All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem. | | | | | | |
| b | All animals non-negative on two consecutive secondary tests were examined postmortem with sampling for lab testing. | | | | | | |
| B | Slaughter traceback investigations (5 pt) | Score | Score | Score | Score | Score | Score |
| 1 | An epidemiological investigation was initiated within 15 days of issuance of the lab report. | | | | | | |
| 2 | The MPH0 was placed under movement restrictions / precautionary quarantine while the brucellosis (BR) status was determined. | | | | | | |
| a | Intact animals only left the MPH0 premises to inspected slaughter or necropsy. | | | | | | |
| b | All movements of intact animals from the MPH0 occurred under seal and/or with official supervision. | | | | | | |
| 3 | The MPH0 was subject to a whole-herd test (WHT) of all intact animals ≥ 6 months of age. | | | | | | |
| a | All animals non-negative on primary testing were subject to an official secondary test or postmortem examination. | | | | | | |
| b | All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem. | | | | | | |
| 4 | The MPH0 was subject to a second WHT within 30-90 days and prior to quarantine release if the first test was negative. | | | | | | |
| 5 | Additional traceback investigations were conducted based on the slaughter sample order (3 up and 3 down) if the MPH0 was negative. | | | | | | |
| 6 | The epidemiological investigation was completed within 90 days of issuance of the lab report. | | | | | | |
| C | Investigation of herds related to a BR-affected herd (5 pt) | Score | Score | Score | Score | Score | Score |
| 1 | All adjacent or in contact herds were placed under movement restrictions within 15 days of identifying an affected herd. | | | | | | |
| a | All herds adjacent to or in contact with the affected herd were subject to a WHT of all intact animals ≥ 6 months of age. | | | | | | |
| 2 | All trace-in and trace-out herds were placed under movement restrictions within 30 days of identifying an affected herd. | | | | | | |
| a | All trace-in and trace-out herds were subject to a WHT of all intact animals ≥ 6 months of age. | | | | | | |
| 3 | All animals non-negative on primary testing were subject to an official secondary test or postmortem examination. | | | | | | |
| 4 | All animals non-negative on secondary testing were retested in an appropriate timeframe or examined postmortem. | | | | | | |
| 5 | Intact animals only left herds under movement restrictions to inspected slaughter, necropsy, or approved (quarantine) feedlot. | | | | | | |
| 6 | All movements of animals from herds under movement restrictions occurred under seal and/or with official supervision. | | | | | | |
| D | Documentation in the case file (Y/N) | Score | Score | Score | Score | Score | Score |
| 1 | Up-to-date investigative narrative: | | | | | | |
| 2 | Flow diagram of case investigation: | | | | | | |
| 3 | Map of the area including adjacent herds: | | | | | | |
| 4 | Sample submission form for the case animal: | | | | | | |
| 5 | Laboratory results for sample(s) from the case animal: | | | | | | |
| 6 | Field test charts for all herds tested as part of the investigation (should include ear tag and brand information): | | | | | | |
| 7 | Official test charts for all herds tested as part of the investigation (should include ear tag and brand information): | | | | | | |
| 8 | Pertinent official and field test charts for historical herd tests (prior to the investigation): | | | | | | |
| 9 | Invoices and transit papers used to trace animals involved in the investigation: | | | | | | |
| 10 | Records of quarantines issued and released during the course of the investigation: | | | | | | |
| 11 | Animal inventory records / evidence of inventory reconciliation between herd tests (if applicable): | | | | | | |
| 12 | Permits for animal movement from herd(s) under movement restrictions / quarantine (if applicable): | | | | | | |
| 13 | Documents pertaining to tracing of animals illegally moved while under movement restrictions (if applicable): | | | | | | |
| 14 | Sample submission forms for animals non-negative on BR testing (if applicable): | | | | | | |
| 15 | Laboratory results for samples from animals non-negative to BR testing (if applicable): | | | | | | |

Appendix D: Checklist for affected herd management

| | <i>Herd ID:</i> | | | | |
|----------|---|--------------|--------------|--------------|--------------|
| A | Management via depopulation (5 pt) | Score | Score | Score | Score |
| 1 | Depopulation of the affected herd occurred within 60 days of confirming infection. | | | | |
| 2 | The affected herd remained under continuous movement restrictions / quarantine until depopulated. | | | | |
| a | Intact animals only left the premises to inspected slaughter or necropsy. | | | | |
| b | All movements of animals from the premises occurred under seal and/or with official supervision. | | | | |
| 3 | The affected herd underwent a complete herd inventory at the time of depopulation. | | | | |
| a | All animals present at the time of initial movement restrictions / quarantine were accounted for at depopulation. | | | | |
| 5 | The affected premises was cleaned and disinfected prior to restocking. | | | | |
| B | Management via test and removal (5 pt) | Score | Score | Score | Score |
| 1 | The affected herd remained under continuous movement restrictions / quarantine until depopulated. | | | | |
| a | Intact animals only left the premises to inspected slaughter or necropsy. | | | | |
| b | All movements of animals from the premises occurred under seal and/or with official supervision. | | | | |
| 2 | The affected herd was subject to regular herd inventories with inventory reconciliation. | | | | |
| a | All animals present at the time of initial movement restrictions / quarantine were accounted for on reconciliation. | | | | |
| 3 | Release testing consisted of 3 WHTs that occurred or is occurring on the schedule established in the herd plan.* | | | | |
| a | The initial release test was conducted at least 30-60 days after reactor removal. | | | | |
| b | The second release test was conducted at least 180-210 days after reactor removal. | | | | |
| c | The third test was conducted at least 365 days after reactor removal. | | | | |
| d | At least one release test was conducted within 6 months post-calving. | | | | |
| e | All intact animals ≥ 6 months of age were tested during each WHT. | | | | |
| f | All reactors were necropsied or slaughtered with inspection. | | | | |
| g | The testing protocol was restarted if any postmortem evidence of brucellosis was disclosed. | | | | |
| 4 | The herd underwent a WHT 6-12 months after quarantine release (assurance testing). | | | | |
| 5 | Vaccination was conducted in accordance with program standards and international recommendations. | | | | |
| C | Documentation in the case file (Y/N) | Score | Score | Score | Score |
| 1 | Field test charts for all testing of animals in the affected herd: | | | | |
| 2 | Official test charts for all testing of animals in the affected herd: | | | | |
| 3 | Animal inventory records / evidence of inventory reconciliation between herd tests: | | | | |
| 4 | Investigation of any animals moved illegally from the affected herd: | | | | |
| 5 | A herd plan signed by the herd owner: | | | | |

*Recommended: Testing must occur at intervals of at least 60 days.
 Post-calving test must be at least 75 days after calving.

Appendix E: Checklists for control of livestock movement

Table E-1: Checklist for concentration points (auction markets, gathering centers, feedlots)

| | | <i>Facility ID:</i> | | | | |
|----------|---|---------------------|--------------|--------------|--------------|--------------|
| A | General | | Info | Info | Info | Info |
| 1 | Type of facility: | | | | | |
| 2 | Capacity (no. head): | | | | | |
| 3 | Current inventory (no. head): | | | | | |
| 4 | Type of cattle (beef, dairy, mixed): | | | | | |
| 5 | Cattle origin (source and %): | | | | | |
| 6 | Cattle destination(s): | | | | | |
| 7 | Average length of stay: | | | | | |
| B | Facilities (Y/N) | | Score | Score | Score | Score |
| 1 | Facilities are in good physical condition (particularly fencing): | | | | | |
| 2 | Facility infrastructure is sufficient to monitor animal movements: | | | | | |
| 3 | Facility infrastructure is sufficient to maintain cattle in individual lots if necessary: | | | | | |
| C | Documentation and recordkeeping (5 pt) | | Score | Score | Score | Score |
| 1 | All animals allowed entry have an official ear tag; and | | | | | |
| a | A brand indicating the original owner (if applicable); and | | | | | |
| b | An official transit guide; and | | | | | |
| c | Documentation validating the origin and purchase of the animal; | | | | | |
| d | Proof of required brucellosis (BR) testing (if applicable); and | | | | | |
| e | An animal health certificate (if applicable). | | | | | |
| 2 | The official ID and accompanying documentation of each animal is recorded on entry and exit. | | | | | |
| 3 | The entry and exit records are maintained in a format that allows tracking of individual animals (logbook). | | | | | |
| 4 | Animals transiting through a lower status region arrive in sealed conveyances. | | | | | |
| a | A designated employee confirms that the seal is unbroken and records the seal number on arrival. | | | | | |
| 5 | Animals from BR Level III regions are not permitted entry. | | | | | |
| 6 | Animals from herds under movement restrictions or quarantine are not permitted entry. | | | | | |
| 7 | All births on the premises are recorded and newborns officially identified. | | | | | |
| 8 | All deaths and abortions on the premises are recorded (with ID). | | | | | |
| 9 | All animals leave the facility with an official transit guide. | | | | | |
| G | Sample submissions | | Info | Info | Info | Info |
| 1 | Number of intact cattle ≥ 12 months on the premises during the previous 12 months: | | | | | |
| a | Number of blood samples from intact cattle ≥ 12 months during the previous 12 months: | | | | | |
| b | Number of samples that were positive for BR: | | | | | |
| 2 | Number of other tissue samples submitted for lab diagnostics during the previous 12 months: | | | | | |
| a | Number of other tissue samples that were positive for BR: | | | | | |
| H | Sampling practices (5 pt) | | Score | Score | Score | Score |
| 1 | Sample submission forms are complete (name, age, sex, brand, ID, reactor/exposed). | | | | | |
| 2 | Samples are stored properly and adequately preserved for laboratory diagnostics. | | | | | |
| 3 | Samples are shipped properly and received by the lab within 10 days of collection. | | | | | |
| 4 | The facility keeps all documents related to a submission (invoices, transit papers, lab results). | | | | | |

Table E-2: Checklist for movement control checkpoints

| | <i>Checkpoint ID:</i> | | | | |
|----------|---|--------------|--------------|--------------|--------------|
| A | Staffing levels and hours of operation | Info | Info | Info | Info |
| 1 | Number of inspectors: | | | | |
| 2 | Average number of bovine shipments inspected per month: | | | | |
| 3 | Hours of checkpoint operation: | | | | |
| 4 | An inspector is on duty whenever the checkpoint is open (Y/N): | | | | |
| 5 | Procedures to ensure inspection if the checkpoint is closed (if applicable): | | | | |
| B | Checkpoint facilities (Y/N) | Score | Score | Score | Score |
| 1 | Checkpoint facilities are in good physical condition: | | | | |
| 2 | Signage clearly indicates upcoming checkpoint location: | | | | |
| 3 | Inspectors have access to pens for off-loading bovine animals: | | | | |
| 4 | Lighting is sufficient for inspection at night: | | | | |
| 5 | Computer, radio, and phone are onsite or otherwise accessible: | | | | |
| 6 | Checkpoint has a designated vehicle or access to vehicular support: | | | | |
| C | Access to pertinent program standards (Y/N) | Score | Score | Score | Score |
| 1 | Up-to-date quarantine herd list: | | | | |
| 2 | Movement and testing requirements for entry of bovine animals into the region: | | | | |
| 3 | Manual or SOPs for inspection at checkpoints: | | | | |
| 4 | (M) List of State statuses according to APHIS: | | | | |
| 5 | Copies of pertinent laws and regulations: | | | | |
| D | General (5 pt) | Score | Score | Score | Score |
| 1 | All shipments of bovine animals passing the checkpoint are subject to inspection. | | | | |
| a | Inspectors visually inspect all bovine animals passing the checkpoint. | | | | |
| b | Inspectors correlate ID between animals and documents. | | | | |
| 2 | Inspectors record all shipments of bovine animals through the checkpoint. | | | | |
| E | Personnel resources and supervision (5 pt) | Score | Score | Score | Score |
| 1 | Inspectors are adequately qualified and trained for the job. | | | | |
| 2 | A designated official conducts a supervisory review at least monthly. | | | | |
| a | The review includes exercises or exams for the inspectors. | | | | |
| 3 | Review findings are documented in a formal report provided to the inspectors. | | | | |
| 4 | A designated official ensures that reported deficiencies are corrected. | | | | |
| F | Use of seals (5 pt) | Score | Score | Score | Score |
| 1 | Animals for direct slaughter or approved feedlot move to destination under seal. | | | | |
| 2 | Imported animals requiring quarantine move to the place of quarantine under seal. | | | | |
| 3 | Potentially higher-risk animals transiting the region move under seal. | | | | |
| 4 | Inspectors record the numbers of all seals removed and placed. | | | | |
| G | Tracking of shipments (5 pt) | Score | Score | Score | Score |
| 1 | Authorities confirm arrival of direct slaughter animals at the slaughter plant. | | | | |
| 2 | Authorities confirm arrival of feeder animals at the approved feedlot. | | | | |
| 3 | Authorities confirm exit of higher-risk animals in transit from the region. | | | | |
| H | Animal ID and documentation (5 pt) | Score | Score | Score | Score |
| 1 | All animals are officially identified with a unique ID number. | | | | |
| 2 | Inspectors require an official, valid transit guide with origin, destination, and animal IDs. | | | | |
| 3 | All animals are accompanied by proof of brucellosis testing (if applicable). | | | | |
| 4 | All animals are accompanied by an official health certificate (if required). | | | | |
| 5 | All animals are accompanied by an official entry permit (if required by the region). | | | | |

Table E-3: Checklist for export certification

| | | <i>Certificate number:</i> | | | |
|----------|---|--|--------------|--------------|--------------|
| A | Documentation in the export file (Y/N) | | Score | Score | Score |
| 1 | | Solicitation for export: | | | |
| 2 | | International health certificate: | | | |
| 3 | | Test chart for the lot test with the USDA-approved official tag numbers of all animals exported (if applicable): | | | |
| 4 | | Test charts for herd of origin testing (if applicable): | | | |
| 5 | | Certificate of brucellosis-free herd (if applicable): | | | |
| 6 | | Transit guides from the herd of origin to the export center (if applicable): | | | |
| 7 | | Herd of origin certificate and annex (if applicable): | | | |
| 8 | | Spay certificates for spayed heifers: | | | |
| 9 | | Tick treatment Certificate: | | | |
| B | Verification by certifying official (5 pt) | | Score | Score | Score |
| 1 | | The herd of origin certificate accurately lists all animals presented for export. | | | |
| 2 | | The herd of origin information for all animals presented for export is accurate. | | | |
| 3 | | Animals that are non-negative to the brucellosis test on herd or lot testing are prohibited export. | | | |
| 4 | | Heifers from Level II and III regions are in compliance with the APHIS Spayed Heifer Protocol. | | | |
| a | | Heifers were less than 18 months of age at the time of spaying. | | | |
| 5 | | Tick treatment was by immersion and in accordance with APHIS facility requirements (no vegetation, etc.). | | | |

Table E-4: Checklist for export gathering centers (EGCs)

| | | <i>Center ID:</i> | | | |
|----------|---|-------------------|--------------|--------------|--------------|
| A | Facilities (Y/N) | | Score | Score | Score |
| 1 | EGCs are only approved by the authorized regulatory entity once all requirements are met: | | | | |
| 2 | The entire facility is an EGC (not just pens within the facility): | | | | |
| 3 | All cattle are maintained on dry lot conditions (no pasturing): | | | | |
| 4 | The EGC is surrounded by a perimeter fence with double fencing where there are adjacent herds: | | | | |
| 5 | The EGC has a tick immersion bath, handling chute, drying area, and decantation vat: | | | | |
| 6 | The EGC is clearly divided physically and by biosecurity between clean and dirty areas: | | | | |
| 7 | Clean pens are maintained vegetation-free for a minimum 10m perimeter: | | | | |
| 8 | The EGC has a separate pen for test responders and sick animals (10m separation): | | | | |
| B | Cattle entry and recordkeeping (5 pt) | | Score | Score | Score |
| 1 | All animals allowed entry into the EGC have an official ear tag; and | | | | |
| a | A brand indicating the original owner (if applicable); and | | | | |
| b | An official transit guide; and | | | | |
| c | Documentation validating the origin and purchase of the animal; and | | | | |
| d | An animal health certificate (if applicable). | | | | |
| 2 | All intact animals allowed entry into the EGC have resided since birth in a Level I or II region for brucellosis (BR). | | | | |
| 3 | Intact animals non-negative to any BR test are not allowed to enter the EGC. | | | | |
| 4 | Intact animals from BR Level II regions have proof of a valid negative herd test or originate from a BR-free herd. | | | | |
| a | Proof of a negative secondary test is provided for any animal that was non-negative on the herd test. | | | | |
| 5 | Animals transiting through a lower status region to reach the EGC arrive in sealed conveyances. | | | | |
| a | A designated EGC employee confirms that the seal is unbroken and records the seal number on arrival. | | | | |
| 6 | The EGC ensures that the ID of the animals presented for entry matches that on the accompanying documents. | | | | |
| 7 | The EGC records the official ID and control numbers of the corresponding documents for each animal on entry and exit. | | | | |
| 8 | The EGC maintains entry and exit records in a format that allows tracking of individual animals (logbook). | | | | |
| 9 | The EGC documents all deaths on the premises and records the ID. | | | | |
| a | Regulatory officials are notified of all abortions on the premises and samples sent for laboratory diagnostics. | | | | |
| 10 | All animals leave the EGC within 90 days of entry. | | | | |
| 11 | The EGC maintains strict control over records of cattle entry, exit, and origin. | | | | |
| C | Supervision (5 pt) | | Score | Score | Score |
| 1 | A designated regulatory official is responsible for oversight and supervision of the EGC. | | | | |
| 2 | The designated official conducts a supervisory review at least monthly. | | | | |
| a | Review findings are documented in a formal report provided to the EGC owner / operator. | | | | |
| b | The designated official ensures that reported deficiencies are corrected within 30 days. | | | | |
| D | Brucellosis testing (5 pt) | | Score | Score | Score |
| 1 | All BR tests of intact animals at the EGC are conducted by an authorized, accredited, or official veterinarian. | | | | |
| a | Animals non-negative to the BR test are immediately separated to the designated pen. | | | | |
| b | Non-negative animals are subject to secondary testing at least 30 days after the non-negative test. | | | | |
| c | In-contact, intact animals are only processed for export if the BR reactor animal is confirmed. | | | | |
| E | Tick treatment (5 pt) | | Score | Score | Score |
| 1 | Cattle for export are treated for ticks using the immersion bath (dip vat). | | | | |
| 2 | EGC personnel agitate the bath to mix the solution for at least 30 minutes prior to dipping cattle. | | | | |
| 3 | The EGC keeps a record of quality control parameters (pH, agitation, pollution, level of solution, animals dipped, etc.). | | | | |

Table E-5: Checklist for approved feedlots

| | <i>Feedlot ID:</i> | | | |
|----------|--|--------------|--------------|--------------|
| A | Facilities (Y/N) | Score | Score | Score |
| 1 | The feedlot was approved by the authorized regulatory entity only after verification that all requirements were met: | | | |
| 2 | The feedlot consists of the entire premises (not just certain pens): | | | |
| 3 | The feedlot is surrounded by a perimeter fence with double fencing where there are adjacent herds: | | | |
| 4 | The perimeter fence is at least 2 meters high with a cement base to prevent entry of wildlife: | | | |
| 5 | The feedlot has a separate pen for animals close to delivery: | | | |
| 6 | Animals in the feedlot are confined to dry lot conditions (no pasturing): | | | |
| 7 | Facility infrastructure is sufficient to monitor animal movements: | | | |
| 8 | Any cattle on adjacent premises are tested annually: | | | |
| B | Cattle entry (5 pt) | Score | Score | Score |
| 1 | The origin of all cattle entering the feedlot is recorded with reference to all documentation. | | | |
| 2 | Bovine animals must have a permit from the authorized regulatory entity to enter the feedlot. | | | |
| 3 | Animals from lower brucellosis (BR) status regions arrive to the feedlot under seal. | | | |
| a | A designated feedlot official confirms that the seal is unbroken and records the seal number. | | | |
| 4 | Feedlots in TB Level II regions only accept animals from TB-accredited regions and Level V zones (not regions). | | | |
| a | Animals from TB Level V zones are maintained at least 10 meters from animals originating from TB-accredited regions. | | | |
| 5 | Animals arrive to the feedlot with official identification. | | | |
| a | Identification is verified and recorded at the time of entry. | | | |
| 6 | Each animal in the feedlot is marked as eligible for slaughter only. | | | |
| 7 | All animals entering the facility tested negative for BR w/in 30 days prior to entry. | | | |
| 8 | Feedlots in BR Level I and II regions apply appropriate biosecurity following abortions to prevent BR transmission. | | | |
| a | All abortions tissues are collected in closed containers until properly disposed (incineration or biodigestion). | | | |
| C | Cattle exit (5 pt) | Score | Score | Score |
| 1 | The destination of all cattle leaving the feedlot is recorded with reference to all documentation. | | | |
| 2 | All cattle go directly to another approved feedlot or an approved slaughter facility. | | | |
| a | Cattle leaving the feedlot do so under seal. | | | |
| b | All cattle exits are authorized in writing by an authorized regulatory entity responsible for supervising the feedlot. | | | |
| D | Recordkeeping (5 pt) | Score | Score | Score |
| 1 | The feedlot maintains entry and exit records in a format that allows tracking of individual animals (logbook). | | | |
| 2 | All births on the feedlot are documented and the newborns officially identified. | | | |
| a | Animals born on the feedlot remain there until moved to another approved feedlot or an approved slaughter facility. | | | |
| 3 | The feedlot keeps a record of all animals that die or are euthanized, including identification. | | | |
| 4 | All natural abortions are recorded, samples are collected for laboratory diagnostics, and an investigation is conducted. | | | |
| E | Supervision (5 pt) | Score | Score | Score |
| 1 | A designated regulatory official is responsible for oversight and supervision of the EGC. | | | |
| 2 | The designated official conducts a supervisory review at least monthly. | | | |
| a | Review findings are documented in a formal report provided to the EGC owner / operator. | | | |
| b | The designated official ensures that reported deficiencies are corrected within 30 days. | | | |

Table E-6: Checklist for accredited herds

| | <i>Herd ID:</i> | | | |
|----------|--|--------------|--------------|--------------|
| A | Bulk milk testing (5 pt) | Score | Score | Score |
| 1 | Accreditation: the herd had at least 4 negative milk tests at intervals of approximately 90 days; and | | | |
| a | The herd had a negative blood test of all intact animals \geq 12 months within 90 days of the last milk test. | | | |
| 2 | Reaccreditation: the herd had at least 4 negative milk tests at intervals of approximately 90 days; and | | | |
| a | All bulls and purchased animals received a negative blood test. | | | |
| 3 | Reaccreditation occurs annually with the last milk test and blood tests conducted within 60 days of the anniversary date. | | | |
| a | All natural additions to the herd were recorded at the time of reaccreditation. | | | |
| b | All purchased additions to the herd were recorded at the time of reaccreditation. | | | |
| c | Purchased animals came from an accredited herd or with proof of a negative WHT and individual test. | | | |
| 4 | If reaccreditation occurred within 60 days <u>after</u> the anniversary date, accredited status was suspended pending testing. | | | |
| a | The accreditation period is adjusted to 12 months after the reaccreditation test (not the anniversary date). | | | |
| B | Blood testing (5 pt) | Score | Score | Score |
| 1 | Accreditation: the herd had at least 2 negative tests of all intact animals \geq 12 months conducted 10-14 months apart. | | | |
| 2 | Reaccreditation occurs annually via a negative herd test conducted within 60 days of the anniversary date. | | | |
| a | All natural additions to the herd were recorded at the time of reaccreditation. | | | |
| b | All purchased additions to the herd were recorded at the time of reaccreditation. | | | |
| c | Purchased animals came from an accredited herd or with proof of a negative WHT and individual test. | | | |
| 3 | If reaccreditation occurred within 60 days <u>after</u> the anniversary date, accredited status was suspended pending testing. | | | |
| a | The accreditation period remains 12 months from the anniversary date. | | | |
| B | Documentation in the herd file (Y/N) | Score | Score | Score |
| 1 | Complete field and official test charts for each WHT: | | | |
| 2 | Field and official test charts for any secondary tests conducted: | | | |
| 3 | Summary of the herd inventory and brucellosis test history: | | | |
| | Evidence of inventory reconciliation between herd tests, including missing and additions: | | | |
| 4 | Entry documentation for purchased additions (e.g., certificate of accreditation, transit guide, test charts): | | | |
| 5 | Certificates of accreditation and re-accreditation: | | | |
| 6 | Documentation of suspension of accreditation (if applicable): | | | |